Nos. 22-1136; -1186

United States Court of Appeals For the Federal Circuit

C.R. BARD, INC. and 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,
Case No. 2:12-cv-00032-RJS-DAO, Chief District Judge Robert J. Shelby

PRINCIPAL AND RESPONSE BRIEF OF DEFENDANT-CROSS-APPELLANT MEDICAL COMPONENTS, INC.

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Dated: March 18, 2022

PATENT CLAIMS AT ISSUE IN CROSS-APPEAL

Medical Components, Inc.'s cross-appeal concerns claims 1, 19, 20, 26, 39, 40, 41, and 42 of U.S. Patent No. 8,021,324. Claim 1 is exemplary:

> An implantable venous access port assembly, comprising:
>
> > a needle-penetrable septum; and
> >
> > a housing securing the needle-penetrable septum, the housing comprising a housing base having a bottom wall and X-ray discernable indicia embedded in the bottom wall, the X-ray discernable indicia comprising one or more characters that visually indicate, under X-ray examination, a pressure property of the port assembly.

Appx00232 at 4:37-45.

CERTIFICATE OF INTEREST

Counsel for Medical Components, Inc. ("MedComp") hereby certifies the following:

1. The full name of every party or amicus represented by me is: Medical Components, Inc.

2. The name of the Real Party in interest (Please only include any real party in interest NOT identified in Question 3) represented by me is: None.

3. All parent corporations and any publicly held companies that own 10% or more of the stock of the party or amicus curiae represented by me are: None.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court (and who have not or will not enter an appearance in this case) are:

- MONTGOMERY McCRACKEN WALKER & RHOADS LLP: Aaron S. Haleva, Alfred W. Zaher, Brianna Vinci*, John J. Powell, Peter Breslauer, Stephanie K. Benecchi, Joseph C. Monahan, Maryellen Madden, Patrick J. Farley, Joseph E. Samuel, Jr.
- DENTONS DURHAM JONES PINEGAR, PC: J. Mark Gibb, Clinton E. Duke
- HORN WILLIAMSON LLC: Michael B. Hayes
- BLANK ROME LLP: Bruce D. George*, Joel L. Dion*

- BUCHANAN INGERSOLL & ROONEY PC: Ralph G. Fischer*, Samantha L. Southall*
- Jeffrey A. Stephens*

* -- attorney no longer with firm and/or has withdrawn as counsel

5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal: *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.). This civil action previously came before this Court on a petition for writ of mandamus concerning an unrelated issue. *See* Order, *In re Medical Components, Inc.*, Case No. 13-148 (Fed. Cir. Aug. 2, 2013). The panel was comprised of Judges Rader, Bryson, and Wallach.

6. 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: March 18, 2022

/s/ Alfred W. Zaher
Alfred W. Zaher

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STATEMENT OF RELATED CASES

This civil action previously came before this Court on a petition for writ of mandamus concerning an unrelated issue. *See* Order, *In re Medical Components, Inc.*, Case No. 13-148 (Fed. Cir. Aug. 2, 2013). The panel was comprised of Judges Rader, Bryson, and Wallach. No other appeal in or from the same civil action in the lower court was previously before this or any other appellate court. The following cases are known to counsel to be pending in other courts that will be directly affected by this Court's decision in the pending appeal:

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.)

PRELIMINARY STATEMENT

Chief District Judge Shelby's Opinion is not, as Bard contends, an "outlier." Rather, it is a well-reasoned, thorough 40-page decision, which should be affirmed. In it, the District Court correctly found that the patent claims asserted by Bard (the "Bard Port ID claims") are patent ineligible as solely directed to printed matter, consistent with this Court's long-standing precedent that printed matter includes the "matter" itself, and recognizing that the only purported advance of the claims is an informative label not functionally related to the operation of the venous access port substrate. In so finding, the District Court also methodically followed the requirements of a Section 101 analysis and properly concluded that (i) the Bard Port ID claims are patent ineligible at *Alice* step one, and (ii) because at the relevant time it was routine and conventional to place radiopaque information on implantable medical devices and the claims otherwise cover only standard ports, the claims do not recite an invention at *Alice* step two. As to the step two analysis, the District Court relied on a record that contains *undisputed* evidence, outside the patent prior art, that manufacturers of implantable medical devices had routinely applied conventional radiopaque indicia, or particular shapes, to their products to identify either the products themselves or characteristics about them.

Tellingly, Bard's opening brief largely ignores the record in this case, instead relying extensively on records from other cases variously involving

different patents, different facts, different issues, and different parties. For example, Bard—in an attempt to undermine the determinations of the District Court—discusses an unreported 2018 decision in a different case ruling that a different party, AngioDynamics, had not proven certain claims of Bard's asserted patents unpatentable under Sections 102 and 103. No such issues are before this Court and, in any event, MedComp is not bound by any fact-finding in a proceeding to which it was not a party. In another example, with the same inappropriate purpose, Bard relies heavily on *C.R. Bard Inc. v. AngioDynamics, Inc.*, 979 F.3d 1372 (Fed. Cir. 2020) ("*AngioDynamics*"), which involved different patents, different facts, and also did not involve MedComp.

This is diversionary – and wrong. Bard cannot skirt the record *in this case*, which shows that the District Court correctly applied the law to the undisputed facts and correctly held the Bard Port ID claims invalid under Section 101. Specifically, Bard cannot escape the fact that its claims cover *old medical devices* (i.e., conventional implantable venous access ports) and routine and conventional means (i.e., radiopaque labeling and/or device shape) to convey information about the device post-implantation (here, whether the port is "power injectable"). That is, Bard's patents are solely directed to old ports and routine ways for someone to perceive information about them after implantation in a patient.

That is the record here. With those undisputed facts, the District Court properly applied the law *to those facts*. The District Court recognized Bard was trying to do exactly what it is trying to do here: impermissibly attempting to shift the focus away from the asserted patent claims—which are all about port identification—to the purported disclosure in some other patents in some other cases of "new" power injectable ports. Indeed, the District Court saw fit to state unequivocally that it would "not countenance" Bard's tactic. Appx00027. This Court should reject that tactic too.

Importantly, as discussed below, it is undisputed that Bard itself and other port manufacturers had sold ports capable of and used for power injection for years before Bard filed for the Asserted Patents. Those old ports infringe the Bard Port ID claims solely if their manufacturers use routine and conventional means to indicate that the ports have that old capability. The claims, as a result, are directed to an old product that includes routine and conventional means to convey information about it and so are directed solely to ineligible subject matter, just as the District Court found.

Notably, the Bard Port ID claims are not limited to a port with specific technical capabilities, and old ports were capable of power injection. In other words, the claims cover old, standard ports that happened to be capable of power injection. But, for the same reason, because the claims are not limited to a port

with specific technical capabilities, they cover any future port that may be made, the maker of which believes it is "power injectable." As a practical matter, because of the FDA requirements, the claims cover any port that meets those requirements—old or new—and that has any symbols or shape that by then have come to mean that the port has been approved for power injection: it could be a conventional port (since they were capable of power injection) or it could be a port with "better" performance than a conventional port, and it could be any words or symbols that medical practitioners by then understand indicate power injection.

JURISDICTIONAL STATEMENT

The District Court had jurisdiction over this patent case under 28 U.S.C. §§ 1331 and 1338(a). This Court has jurisdiction under 28 U.S.C. § 1295(a)(1). On November 5, 2021, the district court entered partial final judgment pursuant to Fed. R. Civ. P. 54(b). Appx00070-71. MedComp timely filed its notice of cross-appeal on November 17, 2021. Appx04229-4231.

COUNTER-STATEMENT OF THE ISSUES

1. Whether the Bard Port ID claims are solely directed to non-functional printed matter, and thus constitute patent-ineligible subject matter under step one of *Alice*.

2. Whether, because the patent-ineligible subject matter itself may not be used to find an inventive concept, the Bard Port ID claims remain patent-ineligible under step two of *Alice*.

3. Whether the same reasoning this Court applies to the Bard Port ID claims requires affirming the District Court's holding that the asserted claims of MedComp's '324 Patent are invalid.

COUNTER-STATEMENT OF THE CASE

This appeal arises from the District Court's order invalidating the asserted Bard Port ID claims of Bard's U.S. Patent Nos. 7,785,302 (the '302 Patent), 7,947,022 (the '022 Patent), and 7,959,615 (the '615 Patent) (collectively, the "Asserted Patents") as subject matter ineligible under 35 U.S.C. § 101. The Asserted Patents "are directed to systems and methods for identifying a vascular access port as suitable for power injection following implantation of the device in the human body." Appx00001.

The District Court applied the printed matter doctrine and held that "the claims at issue are directed solely to non-functional printed matter and contain no additional inventive concept." Appx00028. Then, after examining the claims "in their entirety" under *Alice* to determine whether, "both individually and as an ordered combination," they "transform the nature of the claim into a patent eligible application," Appx00029, the District Court held that the Bard Port ID claims "are

directed to the abstract idea of communicating information and lack an inventive concept" and, as such, are invalid. Appx00040.

MedComp's cross-appeal arises from the District Court's order invalidating the asserted claims of MedComp's U.S. Patent No. 8,021,324 (the '324 Patent), on the same grounds under the law of the case doctrine. Appx00055. Using the framework of its order invalidating the Bard Port ID claims, the District Court held that the asserted claims in MedComp's '324 Patent are also invalid under Section 101 because the use of radiopaque identifiers on a conventional access port did not constitute an inventive concept. *Id.* In its cross-appeal, MedComp only asserts that if the District Court's judgment against Bard is reversed, its judgment against MedComp on law of the case grounds should be similarly reversed.

I. BACKGROUND

A. Venous Access Ports

Bard and MedComp are medical device manufacturers who develop, produce, and market implantable medical devices, including subcutaneous venous access ports. Appx00001. Long before Bard filed for the Asserted Patents, their venous access port had been a well-known and widely sold implantable medical device used in the care of patients needing long-term, yet intermittent, intravenous access. Appx02347. For a patient requiring chemotherapy or transfusions on a weekly or monthly basis, instead of having to insert a catheter into a vein in the

arm or hand each time, a port can be implanted in the patient's arm or chest. *Id.* Ports have long provided reliable and less disruptive access for taking blood, blood transfusions and administering nutrition, fluid and medication (e.g., chemotherapy agents). And, importantly, since well before Bard filed for the Asserted Patents, medical professionals had used Bard's (and others') ports in imaging procedures, when "power injection" was used to introduce contrast agent into the port. Appx00002.

The Asserted Patents describe the basic structure of those ports. There is nothing in any Asserted Patent describing anything new about ports. Instead, their specifications describe those old ports. Specifically, the specifications state that a port includes a housing or body that defines a reservoir, a septum and an outlet stem. *E.g.*, Appx00109 at 1:20-21. Ports typically are formed from titanium or other biocompatible material. *E.g.*, Appx00110 at 4:61-63. The septum seals the reservoir but allows for repeated needle piercing for injecting fluid into, or withdrawing fluid from, the reservoir. *E.g.*, Appx00109 at 1:27-37. The outlet stem communicates with the reservoir and provides a secure connection point for a catheter that enters the patient's vasculature. Appx02411. There is no evidence that the Asserted Patents require anything other than an old port.

Years before Bard filed the Asserted Patents, medical professionals had used those old ports for power injection, such as for contrast enhanced computed

tomography (CECT) imaging procedures. *See* Appx00002. In those procedures, medical professionals had used power injector machines to inject contrast media into patients at high pressure via the ports. *Id.* It is undisputed that Bard's ports were already "structurally suitable" for power injection long before it filed for any asserted patent. Appx02596 (citing *AngioDynamics*, 979 F.3d at 1375).

However, because these power injection procedures can produce high pressures, the FDA "cautioned medical providers in 2004 and 2005 that they should not use vascular access ports for power injection unless the ports were specifically and identifiably *labeled* for such use." Appx00002. Therefore, port manufacturers, including Bard and MedComp, recognized the need for their *implanted* ports to be labeled for power injection. *Id.*

As shown below, port manufacturers including Bard, MedComp, and AngioDynamics, all recognized the need to ensure that to identify an *implanted* port as labeled for power injection, the label had to be on the port. They all recognized that this could be done using routine and conventional means. Pertinent here, this included placing on the port information that could be viewed by x-ray, or by conveying it by the shape of the port, so it could be perceived through the skin or by x-ray.

Thus, before Bard filed for any of the Asserted Patents, old ports were capable of power injection and had been used to do so, but the need had arisen to label them as such.

B. The Bard Port ID Patents

All three Bard Asserted Patents are directed to systems and methods for venous access port identification. Appx00003. The '022 Patent is a continuation in part of the '302 Patent, and the '615 Patent is a continuation of the '302 Patent. *Id.* Thus, the specifications of the '615 and '302 Patents are essentially identical, and the detailed descriptions of the specifications of the '302 and '022 Patents are substantially similar. *Id*.

The specifications of the Asserted Patents recite the purpose of *conventional* access ports, as the District Court recognized. Appx00025 (citing Appx00109; Appx00215). The background sections of the '302 and '615 Patents assert that "access ports"—but not *power injectable* access ports—"provide a convenient method to repeatedly deliver a substance to remote areas of the body without utilizing surgical procedures." Appx00109 at 1:13-15; Appx00215 at 1:17-19. Similarly, the specifications describe – only – the standard construction of a conventional port: a housing assembly, a septum, a reservoir, and an outlet of the housing that communicates with a catheter which accesses a vein. Appx00109 at 1:20-24; Appx00215 at 1:24-28. In other words, there is no description in the

specifications of any of the Asserted Patents of what is required of a particular port for it to be power injectable beyond the capabilities of conventional ports. Appx00072-221.

Bard asserted several claims. Before turning to the specifics, as shown below, every claim covers a conventional port and a feature that conveys information to a medical professional that the port is "power injectable." Two of the patents claim the feature as characters on the port, the other as its shape. Specifically, each independent and dependent claim of the '302 and '022 Patents requires radiopaque markings that allow someone who sees them to know, somehow, that it is power injectable. *Id*. Similarly, the sole asserted claim of the '615 Patent requires a structural feature that allows someone who feels, or through x-ray sees, the structure to know the port is power injectable. *Id*.

Before turning to more specifics, it is important to understand that the Asserted Patents describe only conventional ports and not some "new" power injectable port different from those that had been used for years to perform power injections. That fact is one of many ways that the patents, specifications, and claims in this case part ways with those in *AngioDynamics*. That appeal involved patents that described and claimed specific and ostensibly "new" ports with specific performance characteristics that are not disclosed in any Asserted Patent.

In contrast, and as shown above, nothing in any Asserted Patent describes anything other than a conventional port.

In addition, the only reference in any asserted claim to "power injectable" is to describe the conclusion that a medical practitioner will reach upon seeing by the port's radiopaque markings or seeing or feeling its shape.

So, a medical professional can understand that a port is "power injectable" only if two things occur: (1) either an X-ray is taken of the port or the person touches it, and (2) the professional has, from some other source, learned that the characters or shape she sees or the shape she feels indicates that the port is "power injectable."

While some specific shapes are described, the claims cover all shapes that ever convey the idea of power injectability. There is no explicit teaching of characters that would mean "power injectability," but the claims cover any perceivable message that will ever do so.

1. The Asserted Claims Of The '302 And '022 Patents

Although Bard asserted numerous claims from these two patents, claim 1 of the '302 Patent is illustrative of the asserted claims of both the '302 and the '022 Patents:[1]

> 1. A venous access port assembly for implantation into a patient, comprising:
>
> [a] a housing having a discharge port, a needle-penetrable septum, and a cap securable to the housing and retaining the septum securely in the assembly, the housing having a housing base defining a bottom wall of at least one reservoir, and an outwardly facing bottom surface,
>
> [b] 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.

The preamble is not limited to a port that is power injectable (unlike the *AngioDynamics* case). The first element [a] recites parts of a standard prior art port, and the second element [b] recites radiopaque characters that are included in the base. Notably, the claim does not recite any structure that makes a port "power injectable." And, as shown above, the specifications do not describe any characteristics, structure – anything – other than of a standard port, or any way that

[1] Bard asserted independent claims 1, 5, 8, and 10, and dependent claims 3, 4, 6, and 7 from the '302 Patent. Appx00003. Bard asserted independent claims 1 and 10, and dependent claims 3, 5, 8, 9, 12 and 14 from the '022 Patent. *Id.*

a standard port should be modified. It only describes a standard port and claims a standard port.

The second element includes the radiopaque markings on the port that will convey to a medical professional, after seeing them on an x-ray, that the port is "power injectable." This is the only mention in the claims of power injectability. It was undisputed that standard ports were power injectable, and as set forth in detail below, the District Court found that it had been routine and conventional at the time Bard filed its applications to use radiopaque markings on implanted devices. Appx00036.

2. The Asserted Claim Of The '615 Patent

Bard asserted independent claim 8 of the '615 Patent. It also recites a standard port but instead of characters, it claims a structural feature that, if perceived by a practitioner, is understood to identify the port as power injectable:

> 8. An access port for providing subcutaneous access to a patient, comprising:
>
> [a] a body defining a cavity accessible by inserting a needle through a septum, the body including a plurality of side surfaces and a bottom surface bounded by a bottom perimeter, the bottom surface on a side of the port opposite the septum, the bottom perimeter including a concave portion, the side surfaces including a first side surface through which an outlet stem extends; and
>
> [b] at least one *structural feature of the access port identifying the access port as being power injectable* subsequent to subcutaneous implantation, the at least one structural feature comprising at least one concave side surface in a second side surface different from the first

side surface, the concave side surface extending to the bottom perimeter concave portion.

Appx00221 at 13:23-14:7.

As with the two other Asserted Patents, there is no disclosure of any "new" port, merely a description of standard ports, which were known to have been "power injectable." The claim preamble again recites a generic "access port for providing subcutaneous access to a patient," and the only reference to "power injectable" is in the *information* that the port's shape conveys: *the structural feature of the access port identifying the access port as being power injectable*. Thus, as with the radiopaque markings, the only function of the shape is to convey to a medical professional that the port is "power injectable."

C. The Record Contains Undisputed Evidence That Manufacturers Of Implanted Medical Devices Had Routinely Applied Conventional Radiopaque Indicia To Their Products To Identify Them Or Characteristics About Them

As shown above, the Bard Port ID claims cover conventional ports; they do not require any port with specific capabilities beyond those of conventional ports. *Id.* Specifically, each asserted claim of the '302 and '022 Patents requires a marker visible under x-ray that when perceived would make the person viewing it understand that the port is "power injectable." Appx00114 at 12:56-14:21; Appx00177 at 15:11-16:44. The asserted claim of the '615 Patent requires a

structural feature that would make the person perceiving it understand that the port is "power injectable." Appx00221 at 13:23-14:9.

So, each asserted claim purports to convey patentability to old, pre-2005 power injectable ports—including ports sold by Bard—so long as they now sport a radiopaque label or structural feature that would ostensibly communicate to a person perceiving it that the port is power injectable. *Id.* As the District Court found, the claims merely "add a subcutaneous identifier to an existing product." *Id.*

An x-ray is, of course, a conventional test to examine inside the human body. Medical product manufacturers had long applied symbols to medical devices that are viewable on an x-ray (radiopaque indicia) to provide information about their devices, and have done so widely, routinely, and since well before Bard filed for the Asserted Patents. Appx00034-36. Indeed, medical journals and other sources scrutinized by the District Court showed the wide use of radiopaque marking on implantable medical devices well before Bard sought patent protection.

For example, a decade before Bard filed for the Asserted Patents, radiopaque indicia had been used on implanted defibrillators. A 1995 article by Drs. Sergio L. Pinski and Richard G. Trohman, which discussed issues presented by patients who have implanted defibrillators, described the need to identify the defibrillator model including by radiography:

> [r]apid identification of the defibrillator model is important when the device must be deactivated or reprogrammed. Patients with defibrillators should carry identification cards that list manufacturer information, the model number, therapy options, the type of lead system, and a 24-hour emergency contact telephone number. However, compliance with this recommendation is not perfect. *In an emergency, an overpenetrated radiograph that shows the generator permits the identification of the device because all manufacturers' pulse generators have a radiopaque identifier*.

Appx02527 (emphasis added).

As the District Court found, in 2001, years before it filed for the Asserted Patents, "Bard was already utilizing the technology on its own implantable stent products." Appx00036; Appx02524. Further evidencing this is the sworn affidavit by a Bard actor, Kenneth Eliasen, made in a related IPR. Appx02567-2568. In his affidavit, Eliasen represents under penalty of perjury:

> There are only a limited number of locations where radiopaque markings can be placed on the venous access port. Accordingly, it would have been obvious to a person of ordinary skill in the art during the 2006 timeframe to modify the device defined by claim 1 to incorporate this additional limitation to allow the convenient placement of the radiopaque markings on a surface of the housing base. Such a modification would have only involved ordinary creativity on behalf of the designer.

Id. Further, during prosecution of the '302 Patent, Bard filed a Suggestion of an Interference with another MedComp patent application (U.S. 11/725,287). Appx00869. Bard argued that based on the Eliasen affidavit, claims 2-3 of MedComp's '287 application were obvious. Appx00870-871. These claims

recited a conventional port with "radiopaque markings that include indicia that convey information indicative of an attribute of the assembly." Appx00881.

Bard was not alone in using this well-understood, conventional manner of marking implanted medical devices and products. An April 2003 article describes a new medical device—unlike the old ports here—that needed to be imprinted with radiopaque ink. Appx02534. To do so, the manufacturer looked to a vendor that "had extensive experience with these kinds of inks and excelled in solving medical-device-imprinting problems." *Id.* That "extensive experience" was in using radiopaque markings on implanted medical devices, and they had been used to solve problems with imprinting medical devices with information *extensively* before Bard filed its patent applications.

Radiopaque markings had also been used in the medical field to identify objects that were not intended to be implanted, but accidentally were left in a patient during surgery. Again, about a decade before Bard filed its applications, a 1996 article explained that radiopaque markers had been placed on surgical swabs and surgical sponges, so that if one was accidentally left in, it could be identified. Appx02535; Appx02536-2544. So well-known and routine was the use of radiopaque markings that a 2003 article stated that "*[m]ost* sponges are detectable because of an incorporated radiopaque marker." Appx02545-02553 (emphasis added).

None of this was disputed. Medical product and device manufacturers had used radiopaque markings on implanted medical devices and products of all kinds to identify them, or characteristics about them, or both, well before Bard filed for the Asserted Patents. "The use of radiopaque identifiers was," as the District Court found, "well-understood, routine, and conventional at the time of the asserted Bard patents." Appx00036.

The use of shape identifiers was similarly well-known in the medical device field long before Bard filed the Asserted Patents. Appx00039. A 1969 article in the *New England Journal of Medicine* recognized the need to identify the brand and type of an implanted pacemaker in emergency situations and proposed "a method of pacemaker identification using the distinctive shape of each brand of pacemaker." Appx02554. The following year, after recognizing that in the intervening period several new pacemakers had been introduced to market use, a follow-up article updated medical professionals as to new device shapes and other identification information. Appx02556-2557. More recent academic articles confirm that it had been routine and conventional to use shape to identify an implanted pacemaker. Appx02558-2560. As the District Court found, "utilizing a device's shape to convey information is not a new concept." Appx00040.

II. PROCEEDINGS BELOW

Presumably because they all turned to conventional means to mark their ports, Bard sued MedComp and two other port makers on a dozen different patents. In January 2012, Bard sued MedComp for infringement of the Asserted Patents in the United States District Court for the District of Utah. Appx00251. MedComp counterclaimed and asserted that Bard infringed its '324 Patent. *Id.*

After successful venue challenges, the cases against AngioDynamics and Smiths were transferred to the District of Delaware. AngioDynamics sought *inter partes* review of the Asserted Patents, and the cases against MedComp, AngioDynamics, and Smiths were stayed. After the Board found a majority of the claims unpatentable under Sections 102 or 103, this Court in a non-precedential decision affirmed in part, vacated in part, reversed in part, and remanded the case to the Board. *AngioDynamics*, 748 F. App'x at 1021. Shortly thereafter, the District Court lifted the stay in October 2019. Appx00259.

A. The District Court Enters Summary Judgment Against Bard

After nearly a year of discovery, MedComp moved for summary judgment under Section 101, showing that the asserted claims were invalid for lack of eligible subject matter. The District Court granted MedComp's motion and held the asserted claims invalid. Appx00001-40.

The District Court considered Bard's argument that it was bound by the fact findings in this Court's *AngioDynamics* decision, considered Judge Nielson's decision concerning Bard's other patents in *C.R. Bard, Inc. v. Medical Components, Inc.*, No. 2:17-cv-00754 (D. Utah, March 11, 2021) (Appx03726-3728), and had before it a fully-developed record that had been presented by both Bard and MedComp. The District Court addressed all of those issues along with the intricacies of both the printed matter doctrine and Section 101 in a lengthy and carefully reasoned opinion.

First, the District Court considered whether the printed matter doctrine was implicated by each asserted claim. Appx00023. The District Court analyzed what printed matter, if any, was present in each asserted claim. Appx00014-23. The District Court correctly noted that "[s]ince 1931, both the Federal Circuit and its predecessor court 'have consistently limited the printed matter rule to *matter* claimed for its communicative content.'" Appx00015 (quoting *In re Distefano*, 808 F.3d 845, 849 (Fed. Cir. 2015) (emphasis in original)). The District Court relied on a long line of precedential Federal Circuit cases holding that the means by which information was conveyed—in other words, the "matter"—was "found to be printed matter." Appx00015 ("markings on meat"; "FDA label"; "instructions on how to perform a DNA test"; "numbers printed on a wristband"; and "markings on dice") (internal citations omitted). Recognizing that even this was "not an

exhaustive list," the District Court concluded that "it is clear that '[t]he common thread amongst all of these cases is that printed matter must be *matter* claimed for what it communicates.'" *Id.* (quoting *Distefano*, 808 F.3d at 850).

The District Court fully rejected Bard's mischaracterization of this Court's opinion in the *AngioDynamics* case as standing "for the proposition that, when applying the printed matter doctrine, the content of the information conveyed can be divorced from the medium used to convey the information." Appx00017. The District Court recognized that Bard's argument ignored what the *AngioDyanmics* court itself said, writing: "as the Federal Circuit in *AngioDynamics* further explained, the matter claimed for its communicative content is not strictly limited to 'printed' material, but instead encompasses 'the conveyance of information using *any medium*.'" *Id.* (quoting *AngioDynamics*, 979 F.3d at 1381).

The District Court recognized that the long line of cases *and AngioDynamics itself* meant that the asserted claims contained printed matter. "Whether or not the limitations are technological structural features of the access ports," the District Court appreciated that under this Court's line of precedent, what was important was that "their sole function is to convey the information that the port is power injectable." *Id.* Thus, the District Court concluded that both the radiopaque markings claimed in the '302 and '022 Patents and the structural feature claimed in the '615 Patent "are printed matter." *Id.*

The District Court then continued to apply this Court's precedent, which required examining whether the printed matter changed how the claimed port worked or its capabilities. The District Court found that the printed matter (i.e., the radiopaque label or structural feature) "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." Appx00020-21. Further, the District Court found that there was "no functional relationship between the printed matter and the underlying power injectable access port upon which it is printed." *Id.* Therefore, the District Court found that the claim limitations were not entitled to patentable weight. Appx00021.

Having concluded that the claimed radiopaque markings and structural features were printed matter, the District Court turned to consider whether each Asserted Claim was subject matter ineligible under Section 101. Before proceeding to the two-step Section 101 inquiry under *Alice Corp. Pty. v. CLS Bank Int'l,* 573 U.S. 208, 216 (2014), the District Court applied the legal framework required by this Court, including this decision in *AngioDynamics.* The District Court recognized that the *AngioDynamics* panel had "added a preliminary inquiry for claims involving printed matter: 'a claim may be found patent ineligible under § 101 on the grounds that it is [1] directed solely to non-functional printed matter

and [2] the claim contains no additional inventive concept.'" Appx00025 (quoting *AngioDynamics*, 979 F.3d at 1383).

Applying the first step of this "preliminary inquiry," the District Court observed that "[w]hen each claim is read as a whole, the focus of the claimed advance is using the … identifying features, in conjunction with an already known and typically constructed access port, to convey the information that the access port is power injectable." Appx00026. The District Court saw through Bard's argument that the claimed ports described in the Asserted Patents were somehow different from conventional ports as an attempt to divert attention away from the claimed purpose—namely, identifying ports as power injectable. Appx00026-27. The District Court emphatically stated that it would "not countenance" this argument. Appx00027. Rather, the District Court found, Bard's asserted claims "merely describe[] venous access port assemblies," and "[t]here is nothing in the language of any of the asserted claims to specify what about these conventional features makes them capable of power injection." *Id.*

At the second step of this preliminary analysis, the District Court concluded that the asserted claims did not contain any "additional inventive concept beyond the claimed printed matter." Appx00028. The court observed that besides the "printed matter identifier conveying that the port is power injectable," the asserted claims merely "recite only the assembly of a typical venous access port." *Id.*

The District Court then analyzed Bard's asserted claims under *Alice*. In so doing, it adhered to this Court's requirement that, in contrast to an analysis under Sections 102 or 103, when analyzing subject matter ineligibility courts are required to "look to the claim language in its entirety, including the printed matter." Appx00029 (citing *Two-Way Media Ltd. v. Comcast Cable Commc'ns, LLC*, 874 F.3d 1329, 1337 (Fed. Cir. 2017)).

At *Alice* step one, the District Court saw parallels between the asserted claims and those in *Secured Mail Solutions, LLC v. Universal Wilde, Inc.*, 873 F.3d 905 (Fed. Cir. 2017). It recognized that under *Secured Mail*, "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." Appx00032 (citing *Secured Mail Solutions*, 873 F.3d at 910). Applying *Secured Mail*, the District Court concluded that the asserted claims are "directed to an abstract idea" because they require the use of an identifier, whether by radiopaque markings or shape, that does not functionally affect the port or the X-ray technology used to view the identifiers. Appx00032.

Finally, at *Alice* step two, the District Court considered the full record before it and found that the use of radiopaque markers and shape to identify medical products or devices had at the time of filing merely involved "well-understood,

routine, and conventional activities previously known in the industry." Appx00032-40. It made specific findings as to both markers and shapes.

Specifically, with respect to the '302 and '022 Patents, the District Court found the record before it showed it was "clear" that the use of radiopaque identifiers had been "well-understood, routine, and conventional within the implantable medical device industry long before Bard decided to add the identifiers to its power injectable ports." Appx00036. As such, "the use of a radiopaque identifier is not an inventive concept." Appx00037.

With respect to the '615 Patent, the District Court reviewed the record before it and found that it was "clear that utilizing a device's shape to convey information is not a new concept." Appx00040. The District Court again found that "the evidence presented by MedComp establishing the use of shape identifiers in the medical device field is persuasive." Appx00039.

In reaching those detailed findings, the District Court rejected Bard's effort to violate basic principles of judicial decision-making and consider statements made in other cases involving different records, different patents, and sometimes different parties, and further pointed out that the record the District Court was required to review was "considerably different" than what Bard wanted it to rely on (the appellate decision in *AngioDynamics*). The District Court wrote:

> As this court reads it, the Federal Circuit in *AngioDynamics* essentially reviewed and rejected, based on the record there provided, the trial

> court's factual finding that use of radiographic markings was routine and conventional in the art at the relevant time. Both the trial court's ruling and the Federal Circuit's evaluation were undoubtedly constrained by the evidence and arguments presented by the parties. But this court does not have before it the same record AngioDynamics generated in *Port II*. The evidence and arguments submitted here by MedComp are considerably different. This court can only consider in the context of the arguments presented by the parties whether MedComp's evidence is sufficient to show that the use of radiopaque identifiers was well-understood, routine, and conventional at the time of the asserted Bard patents. ***The court concludes the evidence establishes exactly that.***

Appx00036 (emphasis added). Thus, the District Court considered the record before it, and the evidence and arguments here in reaching its findings that Bard's use of radiopaque identifiers had been routine, conventional, and well-understood.

In addition, the District Court found that none of the additional elements of the asserted claims either "individually" or "as an ordered combination" sufficiently "transform the nature of the claim" into patent-eligible subject matter in light of the record that both parties had full opportunity to present. Appx00032; Appx00040.

B. District Court Applies Law Of The Case Doctrine To Enter Summary Judgment That MedComp's Asserted Claims Are Invalid

After the District Court invalidated Bard's asserted claims, Bard argued that under the law of the case doctrine, the District Court's reasoning applied "with equal force" to the validity of MedComp's '324 Patent. Appx03923. Bard had not included a Section 101 argument in its initial motion for summary judgment, but

the District Court invited Bard to file a renewed motion asserting that the '324 Patent was invalid for the same reasons that Bard's Asserted Patents were. *Id.* Bard so moved, but stated that its motion was "made at the Court's invitation" and "based solely on law-of-the-case principles." *Id.*

In its responsive brief, MedComp agreed to "accept the consequences" of the District Court's "correct and well-reasoned [Section 101] analysis," so long as that analysis continued to apply to Bard's Asserted Patents. Appx04213. The District Court recognized that "[l]ike the Bard Patents at issue, the '324 Patent uses radiopaque indicia to identify features of a subcutaneous access port after implantation." Appx00041. After analyzing the '324 Patent under the printed matter doctrine and *Alice*, the District Court held that "using the prior Order's framework, now law of the case, the asserted claims in Patent '324 are invalid under Section 101 because the use of radiopaque identifiers on a typical access port does not constitute an inventive concept." Appx00055.

SUMMARY OF THE ARGUMENT

The District Court's judgment of patent invalidity of the asserted claims of the Bard Port ID Patents should be affirmed.

The District Court correctly held that the claims asserted by Bard are solely directed to printed matter which is patent ineligible under Section 101, and correctly recognized that under this Court's long-standing precedent, printed matter includes the "matter" itself.

Because the only purported advance of the claims asserted by Bard is an informative label, this Court should affirm the District Court's findings that the claims are *solely* directed to printed matter. The District Court correctly held that the printed matter elements recited in Bard's claims are not functionally related to the operation of a port. Given that the claims are directed to non-functional printed matter, the District Court also correctly held that these claims are patent ineligible at *Alice* step one.

Finally, because it had been routine and conventional to place radiopaque (*i.e.*, the quality of being visible under x-ray) information on implanted medical devices, and because the claims otherwise only cover conventional ports, the District Court also correctly held that Bard's asserted claims do not recite an invention at *Alice* step two. The District Court's holdings are well-supported in that the record contains undisputed evidence that manufacturers of implanted

medical devices had routinely applied conventional radiopaque indicia, or particular shapes, to their products to identify either those products or characteristics about them.

In the event that this Court finds Bard's claims eligible under Section 101, it should similarly find MedComp's '324 Patent claims eligible under the law of the case doctrine.

STANDARD OF REVIEW

Patent eligibility under Section 101 is a question of law that may contain underlying questions of fact. *Interval Licensing LLC v. AOL, Inc.*, 896 F.3d 1335, 1342 (Fed. Cir. 2018) (*citing Berkheimer v. HP Inc.*, 881 F.3d 1360, 1365 (Fed. Cir. 2018)). For example, "whether a claim element or combination of elements is well-understood, routine, and conventional to a skilled artisan in the relevant field is a question of fact." *Berkheimer*, 881 F.3d at 1368. A district court's ultimate conclusion on patent eligibility is reviewed *de novo*. *Interval Licensing*, 896 F.3d at 1342. This Court applies regional circuit law when reviewing a district court's grant of summary judgment. *See Convolve, Inc. v. Compaq Comput. Corp.*, 812 F.3d 1313, 1317 (Fed. Cir. 2016). In the Tenth Circuit, orders granting summary judgment are reviewed *de novo*. *Carlile v. Reliance Standard Life Ins. Co.*, 988 F.3d 1217, 1221 (10th Cir. 2021).

However, where, as here, the nonmovant (Bard) fails to dispute or properly address the movant's asserted facts by citing to opposing facts in the record, a district court may properly consider the movant's facts undisputed. Fed. R. Civ. P. 56(c)(1)(A) and (e)(2)-(3). In a related context, this Court has also held that "a district court can properly grant, as a matter of law, a motion for summary judgment on patent invalidity when the factual inquiries into obviousness present no genuine issue of material facts." *Ryko Mfg. Co. v. Nu–Star, Inc.*, 950 F.2d 714, 716 (Fed. Cir. 1991).

ARGUMENT

Here, the District Court correctly applied the printed matter doctrine and Section 101 on undisputed facts. It did so without being distracted by Bard's efforts—repeated in this Court—to rely on different claims in different patents and on different records. Its conclusion that the asserted claims—to old medical devices conveying printed matter using routine and conventional means—are invalid is not only consistent with this Court's precedent, it is demanded by it.

I. BARD'S LACK OF EVIDENTIARY RECORD IN THE DISTRICT COURT

As laid out in detail above, the Asserted Patents do not describe any new way to make a power injectable port.

The District Court noted that whether or not a claim element "is well-understood, routine, and conventional to a skilled artisan in the relevant field is a

question of fact." Appx00036 (citing *AngioDynamics*, 979 F.3d at 1384). It then found, based on non-patent evidence proffered by MedComp and undisputed by Bard, that:

> . . . it is clear that the application of radiopaque identifiers to subcutaneous medical devices was well-understood, routine, and conventional within the implantable medical device industry long before Bard decided to add the identifiers to its power injectable ports. Indeed, Bard was already utilizing the technology on its own implantable stent products.

Id. at 00036, citing to Appx02477. As noted above, one such piece of evidence is the Eliasen affidavit. Appx002567-68. Federal Circuit precedent holds that patent owner admissions regarding the prior art can support a determination of conventionality under *Alice* step two sufficient to justify a summary judgment determination under Section 101. *See, e.g.*, *Berkheimer*, 881 F.3d at 1370.

The District Court also relied on an additional Bard admission in a parallel case, "And by its own admission in the Port III case pending before Judge Nielson in this court, 'Bard did not invent radiopaque markings on subcutaneous medical devices for identification by x-ray or other imaging.'" Appx00036-37. Indeed, the District Court found and relied upon MedComp's cited evidence including the affidavit. Appx00034. Bard acknowledges this evidence, including the sworn admission, *see* Opening Brief ("OpBr.") at 34, but Bard fails to rebut it and other evidence with any counter evidence either in the district court or in its opening brief. Instead, Bard cites *AngioDynamics* and argues that the undisputed evidence

in the record here somehow still "is insufficient to establish lack of inventive concept in *Alice* step two." Again, Bard's legal argument was rejected by the District Court, which found that MedComp's "considerably different" evidence presented in this case required a different result than in *AngioDynamics*. Appx00036.

Similarly, while addressing Bard's '615 Patent, Chief Judge Shelby again pointed to the evidentiary record established in this case:

> [T]he evidence presented by MedComp establishing the use of shape identifiers in the medical device field is persuasive. MedComp provides articles and charts from medical journals dating between 1969 to 2019, describing the use of shape to differentiate between the brand and type of implanted pacemakers.

Appx00039.

While Bard's brief characterizes the radiographic markings as a "technological innovation," not only does the evidence show that the use of radiographic markings on medical devices was well-understood, routine and conventional prior to the filing of the Asserted Patents, but Bard itself admitted that it did not invent such radiographic markings. Appx00034-00036. Moreover, Bard failed to present evidence in the District Court rebutting MedComp's facts, and, as a result, summary judgment was properly entered by Chief Judge Shelby. As a result, Bard has no record to point to before this Court to challenge or negate MedComp's persuasive evidence

Having failed to make an evidentiary record, Bard's conclusory attempts to apply the findings of the *AngioDynamics* case to the present case before this Court are improper. *See Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1039 (Fed. Cir. 2016) (*en banc*) ("We granted Apple's *en banc* petition to affirm appellate function as limited to deciding the issues raised on appeal by the parties, deciding these issues only on the basis of the record made below, and as requiring appropriate deference be applied to the review of fact findings."). This case before the Court is different than *AngioDynamics*, concerns different patents, involves different claims, and has a different record below, precisely as found by the District Court. Appx00036-37.

II. THE DISTRICT COURT CORRECTLY HELD THAT THE BARD PORT ID CLAIMS ARE SOLELY DIRECTED TO PRINTED MATTER

A. The District Court Correctly Recognized That Under This Court's Precedent Printed Matter Includes The "Matter" Itself

1. The Scope Of The Asserted Claims

As stated above, two of the Asserted Patents claim markings to indicate power injectability, and one claims "features." Both are printed matter, as the District Court held. At the outset, however, the breadth of the claims is pertinent to the printed matter inquiry.

First, with respect to the markings (characters, messages and/or identifiers) limitation, it is important to recognize that the claims of the '302 and '022 Patents

(e.g., representative claim 1 of the '302 Patent) preempt *all* markings whatsoever, whenever developed, that are selected to be recognized as indicating power injectability. Such a categoric preemption was specifically the concern behind precluding a patent applicant from patenting an abstract idea. "Preemption is the underlying concern behind the abstract idea exception, but, at the same time, the Supreme Court has made clear that merely appending conventional steps to an abstract idea is not enough for patent eligibility." *In re Marco Guldenaar Holding B.V.*, 911 F.3d 1157, 1161 (Fed. Cir. 2018), *citing Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66, 81 (2012)).

Second, if, as Bard says, no port had characters, for example, indicating that it was power injectable, then there was no known symbology or phrasing to convey that capability. So, for a medical professional to understand that some alphanumeric characters conveyed the intended information, a *mental step* was required to understand the characters, and their intended meaning learned from some other source. The claim not only recites preemptive printed matter but also requires a mental step by the claimed practitioner based on after-acquired knowledge.

The same is true for the "features" limitation in asserted claim 8 of the '615 Patent. Unless there was in place some standard or convention associating a given shape (*e.g.*, a concave side surface opposite the side from which the stem extends)

with this information, a practitioner must somehow learn, from some external source, what the claimed shape means.

For all three patents, an external source of information is required. One example of such an external source is the 1970 article by Lt. Col. William H. Walter, III, MC, USAF, entitled "*Radiological Recognition of Commonly Used Implanted Pulse Generators*" cited to in MedComp's summary judgment motion at Appx02481 (the article is at Appx02556-57). This decoding by a practitioner of a given shape's meaning based on an external source, just as in the case of the '302 and '022 Patents, similarly requires a mental step by the practitioner.

2. The Claims Include Ineligible Printed Matter

The record here shows that each asserted claim covers ports that were power injectable. An old device does not suddenly become patentable by putting a label on it – particularly one that describes characteristics the device already has. That claim is solely directed to printed matter and is patent ineligible.

This Court has generally held printed *matter* to fall outside the scope of Section 101, and therefore not patentable. *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1064 (Fed. Cir. 2010). "While historically 'printed matter' referred to claim elements that literally encompassed *only printed material*, the doctrine has evolved over time to guard against attempts to monopolize the conveyance of information using any medium." *AngioDynamics*, 979 F.3d at 1383 (citing

Praxair Distrib., Inc. v. Mallinckrodt Hosp. Prods. IP Ltd., 890 F.3d 1024, 1032 (Fed. Cir. 2018); *In re Distefano*, 808 F.3d at 849-50).

The District Court applied that principle. It recognized that since 1931, both this Court and its predecessor "have consistently limited the printed matter rule to matter claimed for its communicative content." Appx00015 (citing *Distefano*, 808 F.3d at 849). The District Court provided a partial list of Federal Circuit cases that addressed printed matter, and not one contemplated a distinction between the printed matter itself and the information conveyed by it. Those cases included an FDA label providing dosage instructions for a drug (*AstraZeneca*, 633 F.3d at 1064-65), markings on meat indicating the name of the producer (*In re McKee*, 20 C.C.P.A. 1018, 64 F.2d 379 at 379-380 (1933)), and numbers printed on a wristband (*In re Gulack*, 703 F.2d 1381, 1384-85 (Fed. Cir. 1983)). This is even the case where, as in *Gulack* or in *In re Miller*, 418 F.2d 1392 (C.C.P.A 1969), the printed matter was found to have patentable weight. *Gulack*, 703 F.2d at 1386-87; *Miller*, 418 F.2d at 1395-1396. In fact, prior to the *AngioDynamics* decision, not one case decided by this Court ever drew a distinction between the actual printed matter, and the information that the printed matter conveys in abstract, so as to only apply the printed matter doctrine to the purely semantic "informational content." This is tacit recognition that it is illogical to on the one hand find printed matter ineligible *in any medium* and on the other hand for the medium conveying

the message to be patent eligible. Importantly, an *en banc* decision would be required to overturn previous precedent. Fed. Cir. R. 35(a)(1). The *AngioDynamics* case was decided by a three Judge panel.

As the District Court noted when summarizing the printed matter doctrine, "[t]he common thread amongst all of these cases is that printed matter must be *matter* claimed for what it communicates." Appx00015 (*citing Distefano*, 808 F.3d at 850). Printed matter is not just the information itself, which can only be processed in a human mind; rather, like ink on a page, or a peace sign made of metal, it is a tangible medium ("matter") that *conveys* the information.

In all of the cases applying the printed matter doctrine, there has always been an "element of the claim" that is *matter*, separate and distinct from the information conveyed by that matter; be it a label, a letter, a symbol, an instruction sheet, a shape, a barcode, a radiographic ink or material, or any other means of conveying information. This case is no different.

To state the obvious, Bard's claims violate the fundamental limitations of patentable subject matter. Bard's claims cover any characters or letters that anyone ever uses that come to mean power injectability. These patents claim the concept of choosing symbols or shapes to indicate function. "Preemption is the underlying concern behind the abstract idea exception, but, at the same time, the Supreme Court has made clear that merely appending conventional steps to an abstract idea

is not enough for patent eligibility." *Marco Guldenaar*, 911 F.3d at 1161 (*citing Mayo*, 566 U.S. at 81).

B. Because The Only Claimed Advance Of The Bard Port ID Claims Is That Of An Informative Label, This Court Should Affirm the District Court's Findings that the Claims are Solely Directed To Printed Matter

AngioDynamics is the first opinion of this Court holding that a claim directed to printed matter is also patent-ineligible subject matter under step one of *Alice*. *AngioDynamics*, 979 F.3d at 1383.

The "focus of the claimed advance" standard has long been used in analyzing claims to determine if they are directed to printed matter, both before *Alice* under the printed matter doctrine and after it.

The *AngioDynamics* opinion quoted a 1931 opinion from the Supreme Court of the District of Columbia deciding an appeal from a rejection of patent claims by the Patent Office, which articulated the standard as follows:

> I am of the opinion that in all cases 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.*

Boggs v. Robertson, 13 U.S.P.Q. 214 (D.C. Sup. Ct. 1931), at 31 (emphasis added).

It is this same *Boggs* decision that this Court indirectly cited to in *AngioDynamics*, commenting as follows:

> This is consistent with the post-*Alice* decisions in which we have recognized that the mere conveyance of information that does not

> improve the functioning of the claimed technology is not patent-eligible subject matter under § 101.

AngioDynamics, 979 F.3d at 1383 (quoting *In re McKee*, 22 C.C.P.A. 1072, 75 F.2d 991, 992 (1935), which itself cites *Boggs*).

The *AngioDynamics* court then concluded: "We therefore hold that a claim may be found patent ineligible under § 101 on the grounds that it is directed solely to non-functional printed matter and the claim contains no additional inventive concept." *Id.* The clear meaning of that standard, following all prior Federal Circuit precedent, is that "solely directed to" is semantically equivalent to "is the sole feature of alleged novelty" as first articulated in *Boggs*, which was the *AngioDynamics* court's source, and upon which the *AngioDynamics* court relied.

Similarly, the "focus of the claimed advance" standard for evaluating printed matter claim elements was also affirmed in *In re Lowry*, 32 F.3d 1579, 1583 (Fed. Cir. 1994). There, this Court noted that "[t]he printed matter cases 'dealt with claims defining as the invention certain novel arrangements of printed lines or characters, useful and intelligible only to the human mind.'" *Id.* (quoting *In re Bernhart*, 417 F.2d 1395, 1399 (C.C.P.A. 1969)).

Two related bodies of law take a similar approach to determine if a claim is directed to ineligible subject matter under *Alice* step one, such as an abstract idea or a law of nature. At the *Alice* step one analysis, a court first asks "what the patent asserts to be the focus of the claimed advance over the prior art," *Simio*,

LLC v. Flexsim Software Products, Inc., 983 F.3d 1353, 1359 (Fed. Cir. 2020), so as to determine the claim's "character as a whole." *Id.* This concept has been applied to analyze whether claims are directed to both abstract ideas and laws of nature.

Cases addressing abstract claims are particularly instructive since printed matter has also been characterized as addressing "abstract subject matter." *See, e.g.*, *Boggs*, 13 U.S.P.Q. 214. This makes the *Alice* jurisprudence dealing with an "abstract idea" highly informative. Conceptually, printed matter is a species of the genus "abstract idea."

This Court succinctly reiterated this approach in *Personalweb Technologies, LLC v. Google, LLC*, 8 F.4th 1310 (Fed. Cir. 2021), an *Alice* step one "abstract idea" case:

> Because all inventions embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas, we must decide whether that patent-ineligible concept is what the claim is "directed to." To do so, we evaluate the focus of the claimed advance over the prior art to determine if the claim's character as a whole is directed to excluded subject matter.

Id. at 1315 (citations and quotations omitted).

The approach is the same when analyzing whether a claim is directed to a "law of nature." To determine what a claim is "directed to" at step one, courts "look to the 'focus of the claimed advance.'" *American Axle & Mfg. v. Neapco Holdings*, 967 F.3d 1285, 1292 (Fed. Cir. 2020).

This analysis applies with equal force to determine if a claim is "solely directed to printed matter." Here, the asserted claims recite nothing more than conventional, well-known venous access ports with an added label that conveys some piece of information to a human. The District Court thus correctly found that:

> At 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. The addition of merely novel yet nonfunctional printed matter identifiers does not change the fact that the focus of the claimed advance is solely on the content of the information conveyed. Any novelty in the implementation of this idea, through radiopaque features or concave surfaces, "is a factor to be considered only in the second step of the *Alice* analysis." If the court were to find otherwise, it would undermine the rationale underlying the printed matter doctrine, which "guard[s] against attempts to monopolize the conveyance of information using any medium." Accordingly, the court holds that the claims at issue are directed solely to non-functional printed matter. (footnotes omitted)

Appx00027-00028. This Court should affirm.

C. Because Under *AngioDynamics* A Claim "Solely Directed To Printed Matter" Satisfies The *Alice* Step One Analysis, The Printed Matter Analysis Performed By The District Court Was Both Necessary And Correct

In its opening brief, Bard characterizes the District Court's printed matter analysis as a somehow inappropriate "*innovation*." OpBr. at 19 ("Instead [the District Court] created a redundant four-step test to evaluate patent eligibility in the printed matter context"); *id.* at 29 ("Nor was the District Court empowered to create a new *four-step* framework for § 101 challenges based on printed matter,

rather than adhering to the familiar to-step Alice inquiry that this Court applied to alleged printed matter in *AngioDynamics*.")

Bard uses these erroneous assertions to confuse (1) a structural relationship of a label to the information contained in or indicated by that *very same label*, with (2) a functional relationship between a printed matter claim element and the *actual substrate or device* that is the subject of the rest of the claim. Building on this misdirection, Bard seeks to wholly revise the established jurisprudence as to what a claim is "directed to," and what that legal characterization really means. This is detailed in the following section.

Ironically, *AngioDynamics* recognizes the appropriateness for a threshold printed matter analysis before applying *Alice*. "[A] claim may be found patent ineligible under § 101 on the grounds that it is (1) directed solely to non-functional printed matter and (2) the claim contains no additional inventive concept." *AngioDynamics*, 979 F.3d at 1383. One way to do this is to first determine whether a claim is directed to printed matter, and then determine if the printed matter is non-functional.

III. THE DISTRICT COURT CORRECTLY HELD THAT THE PRINTED MATTER ELEMENTS RECITED IN THE CLAIMS OF THE BARD PORT ID PATENTS ARE NOT FUNCTIONALLY RELATED TO THE OPERATION OF A PORT

A. Each Bard Port ID Claim Recites A Standard Port With A Label; The Label Does Not Affect Or Interoperate With The Port In Any Way

Even if a patent claim has a limitation that comprises printed matter, that, in and of itself, does not mean it is not entitled to patentable weight: the printed matter must also be non-functional. *Distefano*, 808 F.3d at 850 ("Only if the limitation in question is determined to be printed matter does one turn to the question of whether the printed matter nevertheless should be given patentable weight. Printed matter is given such weight if the claimed informational content has a functional or structural relation to the substrate.") As this Court detailed in *Miller*, non-functional printed matter is printed matter that has no functional relationship with the substrate, and is thus orthogonal to whatever "structure" or "structural relationship" may be present:

> It seems to us that what is significant here is not structural but *functional* relationship and that it is of no moment with respect to measuring devices such as the spoons, where the volume is measured by *filling the receptacle to its brim*, which could also be true of a cup, in what position on or relation to the receptacle the indicia and legend are placed. Claims 10-12 call for the indicia being 'on' and the legend being 'attached to' the receptacle. Claim 13 specifies that the indicia and the legend are both 'on' the 'cup-shaped receptacle.' This specifies the required functional relationship to carry out appellant's invention and clearly defines the disclosed invention as required by section 112.

Miller, 418 F.2d at 1396 (emphasis in original).

As next described, the printed matter in the Bard Port ID claims is no different. It does not affect the operation of the claimed ports in any way.

First, the Asserted Patents describe only a standard port, and the claims do not exclude those standard ports, which were power injectable. As the District Court correctly observed:

> There is nothing in the language of any of the asserted claims to specify what about these conventional features makes them capable of power injection. 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.

Appx00027.

The District Court, applying *In re Ngai*, 367 F.3d 1336, 1338-39 (Fed. Cir. 2004), found that the printed matter recited in each of the Bard Port ID claims was non-functional printed matter:

> Here, the court finds there is no functional relationship between the printed matter and the underlying power injectable access port upon which it is printed. 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. In other words, "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 identifier to] an existing product." For this reason, the court finds that the claim limitations in question are printed matter not entitled to patentable weight.

Appx00021-22.

Chief Judge Shelby's finding is corroborated by the fact that Bard did not even argue that the radiopaque markings/identifiers and structural feature were functionally related to the underlying power injection port.

> Bard makes no argument that the radiopaque markers/identifiers and structural feature are functionally related to the underlying power injection port. And MedComp's argument against a functional relationship relies on the Federal Circuit's holding in *AngioDynamics* that "mere identification of a device's own functionality" is not "sufficient to constitute new functionality for purposes of the printed matter doctrine.
>
> Here, the court finds there is no functional relationship between the printed matter and the underlying power injectable access port upon which it is printed. 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. In other words, "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 identifier to] an existing product." For this reason, the court finds that the claim limitations in question are printed matter not entitled to patentable weight.

Appx00020. In so holding, the District Court followed *AngioDynamics*. *See* 979 F.3d at 1382 ("mere identification of a device's own functionality" is not "sufficient to constitute new functionality for purposes of the printed matter doctrine.").

Bard states that its patent claims are directed to "self-identifying access ports." For several reasons, this position is untenable. First, it was rejected in *AngioDynamics*:

> 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.

AngioDynamics, 979 F.3d at 1382 (citations and quotations omitted).

Second, as indicated above, Bard's position clearly contravenes established case law. For example, as developed in *AstraZeneca,* citing *Ngai:*

> This court considered the printed matter exception in *Ngai*, a case similar to the one now before us. In *Ngai*, the Board affirmed the rejection of a claim reciting a kit comprising instructions to amplify ribonucleic acids. The Board found that the only difference between the claimed kit and the prior art was the content of the claimed instructions. Concluding that this content was not functionally related to the kit, the Board found that the claim was anticipated by the prior art. This court affirmed, rejecting the argument that the addition of new printed matter to a known product makes the product patentable. This court reasoned that ''the printed matter in no way depends on the kit, and the kit does not depend on the printed matter. All that the printed matter does is teach a new use for an existing product.'' *Ngai*, 367 F.3d at 1339.

AstraZeneca, 633 F.3d at 1064-65.

AstraZeneca addressed an FDA required label on a drug. Similarly, in its claim construction brief filed in the District Court, Bard argued that its radiopaque markings were responsive to the FDA's labelling requirement for power injectable ports, and that its labels were somehow "more" than mere labels:

> Importantly, Bard recognized that its new ports would need to be identifiable as safe for power injection after implantation. Bard solved this problem by providing radiographic markers and structural features used by medical personnel to identify ports as power injectable, and Bard's asserted patents disclose and claim that subcutaneous port identification technology.

> MedComp contends that Bard's claims cover "mere labeling" such that Bard's patents cover non-power injectable "prior art port[s] with a label on [them]." D.I. 459 at 13, 15. That is untrue. Bard's asserted patent claims cover power injectable ports that are identifiable as such after implantation through radiopaque features or other structural features.

Appx02616-17.

However, Bard's assertions here are simply false. First, the claims do not specifically recite power injectable ports at all, just labels that are intended to be recognized as meaning "power injectable." Moreover, as noted above, the claims read on conventional ports which *were* power injectable. Second, Bard admits that the radiopaque or structural features are, in fact, just "identifiers." Just as was the case in *AstraZeneca*, an FDA requirement to provide a label has nothing to do with the patentability of the label:

> The instructions in no way function with the drug to create a new, unobvious product. Removing the instructions from the claimed kit does not change the ability of the drug to treat respiratory diseases. Although AstraZeneca is correct that FDA regulations require a label containing information needed for the safe and effective use of any drug, *this is a requirement for FDA approval, not patentability.*

AstraZeneca, 633 F.3d at 1064-65 (emphasis added).

As noted above, the standard for *functional* printed matter is whether or not the underlying device would operate the same way, in absence of the printed matter, or, on the other hand, if the presence of the printed matter changes the way the device operates. This Court, in *In re Jie Xiao,* 462 F. App'x 947 (Fed. Cir. 2010), a recent opinion that summarized *Miller* and *Gulack*, and which involved a

combination lock that allowed one of the digits—"position labels"—to be a "wild card," reiterated the Court's long-standing and well settled rule regarding non-functional printed matter*:*

> *Miller* and *Gulack* thus both concerned printed matter interrelated with its substrate to an extent that the overarching invention's function depended on their interaction. Just as a cook would have found *Miller's* measuring cup counterproductive without its matched indicia and legend, *Gulack's* mathematical device relied on combining its physical circularity and cyclical printed matter to achieve its educational utility. In contrast, Appellant's claims demonstrate no such functional relationship between the wild-card position labels and the underlying lock. The claimed lock's function turns solely on the physical alignment among tumbler rings, regardless of what may be printed at each position or how an individual user subjectively perceives any particular position label. *In short, the presence or identity of a given position label has no bearing on the lock's ultimate function, and the claimed device can be used in the same way and for the same purposes with or without wild-card position labels.*

Jie Xiao at 951 (emphasis added).

Thus, for printed matter to have a functional relationship with the substrate, it must actually *interoperate* with the underlying device, and contribute to its function. If it does not contribute to the operation of the device or the apparatus, then it is *non-functional* printed matter, and has no patentable weight.

B. The Interplay Of Printed Matter And Patent Ineligibility Under *Alice*

Given that the District Court found that the asserted claims were solely directed to non-functional printed matter (Appx00028, ("[a]ccordingly, the court holds that the claims at issue are directed solely to non-functional printed

matter")), under *AngioDynamics*, this, in and of itself, is sufficient to conclude that the claims are directed to patent-ineligible subject matter at *Alice* step one. This conclusion then requires the *Alice* step two analysis to be performed, in order to determine if, besides the printed matter elements, there is an inventive concept. "[A] claim may be found patent ineligible under § 101 on the grounds that it is [1] directed solely to non-functional printed matter and [2] the claim contains no additional inventive concept." *Id.* (citing *AngioDynamics*, 979 F.3d at 1383).

Thus, initially, analysis of a claim as to possible printed matter and the functionality of that printed matter is to be performed. If the claim is found to be solely directed to non-functional printed matter, then that factual finding becomes an input to the two step *Alice* analysis. This is precisely the protocol that was followed by the District Court. Appx00028 ("having found that the claims at issue are directed solely to non-functional printed matter and contain no additional inventive concept, the court will proceed to the two-step *Alice* inquiry.").

IV. THE DISTRICT COURT CORRECTLY HELD THAT THE CLAIMS OF THE BARD PORT ID PATENTS ARE PATENT INELIGIBLE AT *ALICE* STEP ONE

Alice established a two-step framework for analyzing subject matter eligibility under Section 101. The Court provided a guide for analyzing patent claims containing abstract ideas and to discern claims that are ineligible from claims that nevertheless are patent eligible. This is known as the *Alice* inquiry,

although it was first articulated in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012). *Alice*, 573 U.S. at 217. In *Alice*, the Court stated:

> [In Mayo] we set forth a framework for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts. First, we determine whether the claims at issue are directed to one of those patent-ineligible concepts. If so, we then ask, "[w]hat else is there in the claims before us?"

Id. (citing *Mayo*, 566 U.S. at 78). As this Court noted in *AngioDynamics*,

> Today, printed matter encompasses any information claimed for its communicative content, and the doctrine prohibits patenting such printed matter unless it is 'functionally related' to its 'substrate,' which encompasses the structural elements of the claimed invention.

AngioDynamics, 979 F.3d at 1381 (citing *Praxair*, 890 F.3d at 1032; *DiStefano*, 808 F.3d at 848-49).

This Court, however, observed that it had never "directly addressed whether a patent claim as a whole can be deemed patent ineligible on the grounds that is directed to printed matter at [*Alice*] step one and contains no additional inventive concept at step two." *AngioDynamics* at 1383. As noted above, the Court concluded that claims could be held ineligible for this very reason if the claims were "solely directed to printed matter." *Id*.

The first step of the *Alice* inquiry is to assess the "focus of the claims, their character as a whole." *Elec. Power Grp., LLC v. Alston S.A.*, 830 F.3d 1350, 1353 (Fed. Cir. 2016) (internal quotations omitted).

In evaluating these claims under step one of the *Alice* analysis, the Bard Port ID claims perhaps present a simpler illustration for this analysis than did the claims in *AngioDynamics.* For example, Claim 1 of the '302 patent reads:

> 1. A venous access port assembly for implantation into a patient, comprising:
>
> a housing having a discharge port, a needle-penetrable septum, and a cap securable to the housing and retaining the septum securely in the assembly, the housing having a housing base defining a bottom wall of at least one reservoir, and an outwardly facing bottom surface, *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.*

Appx00114 at 12:57-67 (emphasis added).

Following the preamble reciting a conventional port assembly, the claim recites well known, routine and conventional structural elements of an access port. *Id.* at 12:59-63 ("a housing having a discharge port, a needle-penetrable septum, and a cap securable to the housing and retaining the septum securely in the assembly, the housing having a housing base defining a bottom wall of at least one reservoir, and an outwardly facing bottom surface"). The claim does not recite that any feature of the port is structured to make it power injectable, and the specification contains no description of how to make a port such that it is capable

of withstanding the flow rates and pressures developed in power injection. The claim then recites that the housing base includes "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." *Id.* at 12:64-67 (emphasis added). The purpose of the radiopaque (*i.e.*, visible in X-ray images) alphanumeric characters is to convey information by the very language of the claim itself. Viewing the claim as a whole under *Alice* step one, the claim cannot be directed to the conventional structural features of the port recited, but to the radiopaque alphanumeric characters that convey that the port is power injectable.

Claim 1 of the '022 patent is very similar:

> 1. An access port for providing subcutaneous access to a patient, comprising: a body defining a fluid cavity accessible by inserting a needle through a septum; and ***at least one radiopaque identification feature*** of the access port observable via imaging technology subsequent to subcutaneous implantation of the access port, ***the at least one radiopaque identification feature including one or more alphanumeric characters identifying the access port as a power injectable port***.

Appx00177 at 15:12-21 (emphasis added).

As in Claim 1 of the '302 patent, claim 1 of the '022 patent recites conventional port structures (not in any way designed or specified as "power injectable") and a radiopaque identification feature containing alphanumeric characters that *identify* the port as power injectable. Again, the alleged inventive

focus is the radiopaque identifier that conveys a message to a user that the port is power injectable.

Claim 8 of the '615 patent is also similar. *See* Appx00221 at 13:23-14:7. Here, too, the claim recites conventional port structures with a focus on the alleged inventive aspect of a structural feature of at least one concave side surface to identify the port as power injectable. In each case, the same message is conveyed by either a radiopaque message or a shape.

Following Supreme Court precedent in *Alice* and *Mayo*, the claims should be evaluated by asking if the claims are directed to a patent ineligible concept (*i.e.*, a natural phenomenon, law of nature, abstract idea, *etc.*) under *Alice* step one, and then analyze under *Alice* step two whether anything else in the claim was sufficient, individually and as an ordered combination, to transform the nature of the claim into a patent-eligible application of the ineligible concept. *See Alice*, 573 U.S. at 217.

In this case, the claims of each of the '302, '022 and '615 patents are directed to communicating to a person that a port is power injectable (although nothing about the structure of the recited elements provides that the port is, in fact, power injectable). The structural elements of the ports in the respective claims are conventional port bodies, stems, needle-penetrable septa, etc., without any description as to what makes them "power injectable." In short, they are

recitations of conventional features. The thrust of the claims are to the radiopaque markings or having at least one concave side that communicates that the port is power injectable.

The Supreme Court did not use the phrase "'*solely*' directed to" as one of the patent-ineligible categories, as was articulated by this Court in *AngioDynamics*. It is indisputable that if a claim was "solely" directed to a patent ineligible concept, it would be unpatentable under Section 101 without the necessity of any analysis at all under *Alice*. Instead, the Supreme Court recognized that claims may contain—and be directed to—patent ineligible subject matter and nevertheless contain additional elements.

As Chief Judge Shelby noted, the Bard Port ID patents are similar to claims before this Court in *Secured Mail,* involving "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 . . . before the mail object is sent." *Secured Mail*, 873 F.3d at 909. *In Secured Mail*, this Court found, *inter alia*, that the claims were "not directed to an improvement in computer functionality," or "a new barcode format," or "an improved method of generating or scanning barcodes." Appx00030 (citing *Secured Mail*, 873 F.3d at 910). Similarly, as Chief Judge Shelby noted, in this case the claims are not directed to an improvement in port function, the claim language does not describe how the identifiers are generated,

and are devoid of any language of the x-ray technology used to view the identifiers. Appx00031.

In the District Court, Bard attempted to shift the argument from the claimed purpose (*i.e.*, providing an identifier) to the unclaimed but "purported novelty of power injectable ports," to which the Court emphatically stated "[t]he court will not countenance this argument." Appx00027. Thus, the District Court found that just as in *Secured Mail*, each of the asserted claims in this case is directed to "communicating information using a marking or identifier that does not functionally improve any aspect of the underlying object or identification process" and therefore "is an abstract idea not directed to patent eligible subject matter." Appx00032 (citing *Secured Mail*, 873 F.3d at 910-11).

V. THE DISTRICT COURT CORRECTLY HELD THAT BECAUSE IT HAD BEEN ROUTINE AND CONVENTIONAL TO PLACE RADIOPAQUE INFORMATION ON MEDICAL DEVICES, AND BECAUSE THE CLAIMS OTHERWISE ONLY COVER CONVENTIONAL PORTS, THE CLAIMS OF THE BARD PORT ID PATENTS DO NOT RECITE AN INVENTION AT *ALICE* STEP TWO

In the second step of the *Alice* analysis, a court searches for "an 'inventive concept'—*i.e.*, an element or combination of elements that is 'sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible] concept itself.'" *Alice*, 573 U.S. at 218 (citing *Mayo*, 566 U.S. at 72-73) (alteration in original). The *Alice c*ourt stated that it considers "the elements of

each claim both individually and 'as an ordered combination' to determine whether the *additional elements* 'transform the nature of the claim' into a patent-eligible application. *Id.* at 217 (citing *Mayo*, 566 U.S. at 78) (emphasis added). As Chief Judge Shelby noted: "[t]he second step of the Alice inquiry 'is satisfied when the claim limitations involve more than performance of well-understood, routine, and conventional activities previously known in the industry.'" Appx00032 (quoting *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1367 (Fed. Cir. 2018) (internal quotation marks, internal alteration, and citations omitted); and "whether a claim recites patent eligible subject matter is a question of law which may contain underlying facts." *Berkheimer*, 881 F.3d at 1368.

In *AngioDynamics*, this Court stated that the sole focus of the claimed advance was not "on the content of the information conveyed, but also on the means by which that information is conveyed." *AngioDynamics*, 979 F.3d at 1384.

However, *all markings on medical devices* make the claimed device particularly useful for its purpose because the marker allows the implanted device to be readily and reliably identified via x-ray. Merely claiming that the device includes a radiopaque marker does not mean that the marker or label is an "inventive feature" or some sort of "technological advance." The evidentiary record developed in the District Court shows that MedComp provided persuasive

evidence on this point. As Chief Judge Shelby noted when analyzing the *AngioDynamics* decision:

> [T]he Federal Circuit in *AngioDynamics* essentially reviewed and rejected, based on the record there provided, the trial court's factual finding that use of radiographic markings was routine and conventional in the art at the relevant time….The evidence and arguments submitted here by MedComp are considerably different. This court can only consider in the context of the arguments presented by the parties whether MedComp's evidence is sufficient to show that the use of radiopaque identifiers was well-understood, routine, and conventional at the time of the asserted Bard patents. The court concludes the evidence establishes exactly that.

Appx00036.

In particular, the District Court found:

> In reviewing MedComp's evidence, it is clear that the application of radiopaque identifiers to subcutaneous medical devices was well-understood, routine, and conventional within the implantable medical device industry long before Bard decided to add the identifiers to its power injectable ports. Indeed, Bard was already utilizing the technology on its own implantable stent products. And by its own admission in the Port III case pending before Judge Nielson in this court, "Bard did not invent radiopaque markings on subcutaneous medical devices for identification by x-ray or other imaging."

Appx00036-37 (citing Appx002489).

Based on all of the evidence presented, Chief Judge Shelby correctly found that as to the '302 and '022 Patents, there was no inventive concept at *Alice* step two:

> When analyzing the asserted claims individually, the use of a radiopaque identifier to convey information is not an inventive concept. Based on the evidence provided by MedComp, radiopaque identifiers

> were routinely used as information conveyors throughout the implantable medical device industry at the time of Bard's asserted patents. And when scrutinizing the asserted claims as an "ordered combination," the court still cannot find an inventive concept that transforms the claims into a patent-eligible application. Each of the claims begins with a typical access port made up of conventional features and then incorporates a radiopaque identifier into the port for the purpose of conveying its suitability for power injection. The addition of a non-functional radiopaque identifier to a known product is not an inventive concept. If the court were to hold otherwise, any medical device manufacturer would be able to add a radiopaque identifier to any commonly produced implantable medical product and—so long as they are the first to the patent office—claim a monopoly over an established product. Accordingly, the court finds that none of the asserted claims in the '302 and '022 Patents contain an inventive concept under *Alice* step two.

Appx00037.

Before the District Court, Bard did not present any of its own evidence to negate or rebut MedComp's substantial evidentiary submissions. *See* Appx00035; Appx00038.

Similarly, as regards the '615 Patent, Chief Judge Shelby also found that MedComp presented persuasive evidence that the use of shape as an identifier for implanted medical devices was well-understood routine and conventional in the medical device field. Appx00038. Importantly, Chief Judge Shelby also noted that "Bard does not respond to this argument." *Id*.

Based on all of the evidence presented, Chief Judge Shelby correctly found that as to the '615 Patent, there was no inventive concept at *Alice* step two:

> . . . the evidence presented by MedComp establishing the use of shape identifiers in the medical device field is persuasive. MedComp provides articles and charts from medical journals dating between 1969 to 2019, describing the use of shape to differentiate between the brand and type of implanted pacemakers. While the articles do not address the innovation of using palpation in conjunction with the shape of the medical devices, it is clear that utilizing a device's shape to convey information is not a new concept. Consequently, in analyzing the asserted claim language under Alice step two, the court finds that claim 8 of the '615 Patent does not contain an inventive concept.

Appx00039-40.

As noted by Chief Judge Shelby, Bard did not produce any evidence to the District Court to negate or rebut that of MedComp, instead relying solely on *AngioDynamics*. Appx00035. Now, however, in its opening brief, Bard attempts to discount compelling evidence presented by MedComp as to what was routine and conventional by first mischaracterizing the evidence as patent prior art, and second by falsely stating that the evidence fails some manufactured "commercialization requirement." OpBr. at 45. There is no requirement of "commercialization" when demonstrating what was "routine and conventional" in an *Alice* step two analysis, and Bard cites no authority whatsoever to support this innovative addition to *Alice* jurisprudence. Further, MedComp did not rely on any "unidentified patents." Instead, MedComp's persuasive evidence that (1) the application of radiographic identifiers to subcutaneous medical devices, and (2) the use of shape in the medical device field, was well-understood, routine and

conventional, as noted by Chief Judge Shelby was not "unidentified patents." Appx00034-35.

On the contrary, the evidence included several known and used devices such as pacemakers, Bard's own commercially available nitinol biliary stents, Bard's own representations during prosecution of the '302 Patent, implantable defibrillators, as well as stray surgical swabs and sponges. Appx00034-35. Bard's feeble attempt to somehow gainsay all of the evidence presented by MedComp, and relied upon by Chief Judge Shelby, amounts to little more than "a generalized assertion that disputed issues of material fact precluded summary judgment," *McKinzy v. I.R.S.*, 367 F. App'x 896, 897 (10th Cir. 2010). Indeed, having not fully developed these arguments in the District Court, Bard waived them for purposes of this appeal. *McDonald v. Kinder-Morgan, Inc.*, 287 F.3d 992, 999 (10th Cir. 2002).

Thus, when viewed individually, each element recited from the conventional port parts (*i.e.*, stem, septum housing *etc.*) and a radiopaque identifier are not inventive concepts. This remains the case even when the claim elements are evaluated in an "ordered combination," as in *BASCOM Global Internet Servs., Inc. v. AT&T Mobility LLC*, 827 F.3d 1341, 1347 (Fed. Cir. 2016), where the Court analyzed the individual elements to see if "an inventive concept can be found in the non-conventional and non-generic arrangement of known, conventional

pieces." *BASCOM*, 827 F.3d at 1350. Here, the Bard Port ID claims fail as it was conventional to label implanted medical devices with radiopaque labels or to provide a particular shape that, when viewed on X-ray, provided the medical practitioner with information regarding the device's properties. Thus, whether viewed individually or as an "ordered combination," the use of well-known, routine and conventional methods of marking an implantable product or providing a particular external shape in order to convey a message that can be viewed by X-ray after implantation is not an inventive concept under *Alice* step two. Failing *Alice*, which shows that radiopaque identifiers and shape are not inventive, but instead are routine and conventional, the analysis reveals that the claims are indeed solely directed to non-functional printed matter, claimed for its communicative content and in insufficient to transform the claimed subject matter into a patent-eligible application of the abstract idea. As the Court described in *Marco Guldenaar*:

> Because *the only arguably unconventional aspect* of the recited method of playing a dice game is printed matter, which falls outside the scope of § 101, the rejected claims do not recite an "inventive concept" sufficient to "transform" the claimed subject matter into a patent-eligible application of the abstract idea.

911 F.3d at 1161 (emphasis added).

Finally, Bard's argument that the radiopaque indica is not routine and conventional because it was not used before on a port is of no moment. What is well-understood, routine and conventional is determined by the relevant audience:

> [T]he claims inform a relevant audience about certain laws of nature; ***any additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific community***; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately.

Mayo, 566 U.S. at 79-80 (emphasis added).

Here, the relevant audience is the medical practitioners who would find radiopaque makings on medical devices well-known, routine and conventional, irrespective of whether it was on a port or some other device. Moreover, as noted by this Court, radiopaque markings had been used on a vascular port which contained "an x-ray tag that identified the port's flow rate." *AngioDynamics*, 979 F.3d at 1384.

Thus, when the Bard Port ID claims are evaluated in light of the well-developed evidentiary record, the District Court correctly held these claims to be drawn to ineligible subject matter under *Alice* and invalid under Section 101.

VI. IN THE EVENT THIS COURT FINDS BARD'S PORT ID CLAIMS ELIGIBLE UNDER SECTION 101, IT SHOULD SIMILARLY FIND ELIGIBLE THE CLAIMS OF MEDCOMP'S '324 PATENT

MedComp cross-appeals the judgment of the District Court only if this Court finds that Bard's Port ID patents are not patent ineligible under Section 101. The

asserted claims of MedComp's '324 Patent are somewhat different than the Bard Port ID claims. Nevertheless, MedComp did not press the distinction in claim language as MedComp believed that the claims should rise or fall with the District Court's well-reasoned analysis applied to Bard's claims with respect to printed matter and *Alice*. *See* Appx04211-4216. The District Court only held that the '324 Patent was ineligible under Section 101 because its "prior Order" was "now law of the case." Appx00055. Accordingly, if this Court were to reverse that order, the law of the case doctrine dictates that the judgment against MedComp be similarly reversed. Should this Court disagree with Chief District Judge Shelby's analysis, MedComp respectfully requests that this Court apply the same reasoning to MedComp's '324 Patent claims.

CONCLUSION

For the above reasons, the District Court's judgment of invalidity of the Bard Port ID claims should be affirmed. The same reasoning that this Court applies to the Bard Port ID claims should be applied to the asserted claims of MedComp's '324 Patent.

Respectfully submitted,

Dated: March 18, 2022

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ADDENDUM

Memorandum Decision And Order Granting Motion For Summary Judgment (Dkt. 750) And Denying Motion For Summary Judgment (Dkt. 460) As Moot, dated November 3, 2021

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH

C.R. BARD, INC., a New Jersey corporation, and BARD PERIPHERAL VASCULAR, INC., an Arizona corporation, Plaintiffs, v. MEDICAL COMPONENTS, INC., a Pennsylvania corporation, Defendant.	**MEMORANDUM DECISION AND ORDER GRANTING MOTION FOR SUMMARY JUDGMENT (DKT. 750) AND DENYING MOTION FOR SUMMARY JUDGMENT (DKT. 460) AS MOOT** 2:12-cv-00032-RJS-DAO Chief District Judge Robert J. Shelby Magistrate Judge Daphne A. Oberg

Before the court are Plaintiff C.R. Bard, Inc. and Plaintiff Bard Peripheral Vascular, Inc.'s (Bard's) two Motions for Summary Judgment of Invalidity of Medical Components, Inc.'s (MedComp's) U.S. Patent No. 8,021,324.[1] For the reasons explained below, the court GRANTS the second Motion[2] and DENIES the first Motion[3] as moot.

FACTS

Bard and MedComp develop, produce, and market various vascular access devices, including subcutaneous access ports. Access ports provide a convenient method of delivering infusions of medicine, blood products, or other fluids without requiring surgical procedures.[4] Power injection machines employing high pressure are sometimes used to deliver fluids through

[1] Dkt. 460; Dkt. 750.

[2] Dkt. 750.

[3] Dkt. 460.

[4] *See* Dkt. 585-2 (Bard's Redacted Tutorial Exhibit) at 4.

access ports.[5] Unlike regular access ports that can fracture and cause significant bodily injury if subjected to power injection, special power-injectable ports are designed to withstand high pressures.[6] Generally, access ports offered by different manufacturers and different models exhibit similar geometries, making it difficult to differentiate between power injectable ports and regular access ports once they have been implanted in the body of a patient.[7] Access port manufacturers thus seek methods of adding identifiers to their ports to enable identification of power-injectability following implantation.[8] The various iterations of port identification methods comprise the heart of the patent disputes between Bard and MedComp.

Bard asserts three patents in this case—U.S. Patent Nos. 7,785,302 (the '302 Patent); 7,947,022 (the '022 Patent), and 7,959,615 (the '615 Patent)—relating to the radiopaque identification of subcutaneous access ports.[9] MedComp's counterclaim asserts U.S. Patent No. 8,021,324 (the '324 Patent).[10] Like the Bard Patents at issue, the '324 Patent uses radiopaque indicia to identify features of a subcutaneous access port after implantation.[11]

PROCEDURAL HISTORY

On January 11, 2012, Bard filed the instant action against MedComp, alleging infringement of the '022, '302, and '615 Patents.[12] On March 14, 2012, MedComp answered

[5] *See id.* at 15–18.

[6] *See id.* at 20, 23–24.

[7] *See id.* at 26–27.

[8] *See id.* at 29–33; *see also* Dkt. 579 (Disk with MedComp's Technology Tutorial) at 26–30 (on file with Clerk's Office).

[9] Dkt. 69 (Amended Complaint) ¶¶ 7–10.

[10] *See* Dkt. 640 (Second Amended Answer and Amended Counterclaims) at 27–28.

[11] Dkt. 19-1 (U.S. Patent No. 8,021,324) at 1.

[12] Dkt. 2 ¶¶ 11–20.

and counterclaimed, alleging Bard infringed its '324 Patent.[13] On December 17, 2012, the case was stayed and administratively closed while the patents-in-suit underwent *inter partes* reexamination before the United States Patent and Trademark Office.[14] On October 4, 2019, the stay was lifted.[15] Fact discovery closed on February 8, 2021. The parties completed claim construction briefing on April 2, 2021, and conducted a technology tutorial for the court on April 28, 2021.[16]

Bard filed its first Motion for Summary Judgment on March 5, 2021,[17] and MedComp filed its own Motion for Summary Judgment on the same day.[18] Bard argued the '324 Patent must be invalidated because Bard's PowerPort MRI was prior art.[19] MedComp argued, *inter alia*, that it was entitled to summary judgment on the invalidity of Bard's asserted patents under 35 U.S.C. § 101.[20] On July 22, 2021, this court issued a Memorandum Decision and Order (the Order) partially granting MedComp's Motion for Summary Judgment.[21] The court found that Bard's three asserted patents were invalid under 35 U.S.C. § 101 because the claims at issue were directed solely to non-functional printed matter and contained no additional inventive concept.[22]

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[13] Dkt. 19 ¶¶ 33–35.

[14] Dkt. 93 (Memorandum Decision and Order Administratively Closing Case).

[15] *See* Dkt. 161 (Order Reopening Case).

[16] *See* Dkt. 539 (Bard's Memorandum in Opposition to MedComp's Motion to Consolidate) at 2–3 (summarizing procedural history).

[17] Dkt. 460.

[18] Dkt. 463.

[19] *See* Dkt. 460 at 17–29.

[20] Dkt. 463 at 10–22.

[21] Dkt. 715-1 (Memorandum Decision and Order).

[22] *See id.* While the court granted MedComp's request for summary judgment on the issue of patent invalidity, it deferred consideration of MedComp's request for summary judgment on Bard's alleged infringement of MedComp's asserted patent.

At the court's invitation, Bard filed a new Motion for Summary Judgment (the Motion) challenging MedComp's '324 Patent based on the framework set forth in the court's Order.[23] The court now turns to Bard's Motion.

LEGAL STANDARD

Summary judgment is appropriate when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law."[24] A dispute is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party."[25] A fact is material if, under the governing substantive law, it could "affect the outcome of the suit."[26] When applying this standard, the court "view[s] the evidence and make[s] all reasonable inferences in the light most favorable to the nonmoving party."[27]

ANALYSIS

The court first summarizes the framework from its earlier Order, in which it found that Bard's three asserted patents were invalid under 35 U.S.C. § 101 because the asserted claims were directed only to abstract ideas. Next, the court analyzes MedComp's asserted patent using the same framework, first ascertaining the undisputed facts and then applying the law of the case to MedComp's '324 Patent.

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[23] *See* Dkt. 721 (Docket Text Order); Dkt. 750 (Bard's new Motion for Summary Judgment).

[24] Fed. R. Civ. P. 56(a).

[25] *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

[26] *Id.*; *see also United States v. Simons*, 129 F.3d 1386, 1388 (10th Cir. 1997) ("The substantive law of the case determines which facts are material.").

[27] *N. Natural Gas Co. v. Nash Oil & Gas, Inc.*, 526 F.3d 626, 629 (10th Cir. 2008).

a. The *AngioDynamics* and *Alice* Frameworks

Under 35 U.S.C. § 101, patentable subject matter includes "any new or useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."[28] The Federal Circuit "has generally found printed matter to fall outside the scope of § 101."[29] "While historically 'printed matter' referred to claim elements that literally encompassed 'printed' material, the doctrine has evolved over time to guard against attempts to monopolize the conveyance of information using any medium."[30] Accordingly, under the printed matter doctrine, printed matter cannot be patented "unless it is functionally related to . . . the structural elements of the claimed invention."[31] In the *AngioDynamics* decision, the Federal Circuit set out a two-step inquiry to determine if a claim limitation is directed solely to printed matter.[32] The Federal Circuit then applied what is known as the *Alice* framework to determine if claimed printed matter was patent eligible.[33]

In its prior Order, the court applied the *AngioDynamics* inquiry and *Alice* framework to the Bard Patents and found they were invalid under § 101. Specifically, the court first found under *AngioDynamics*, Bard's asserted claim limitations were directed solely to printed matter with no additional inventive concept.[34] Next, the court determined the Bard Patents were invalid

[28] 35 U.S.C. § 101.

[29] *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1064 (Fed. Cir. 2010).

[30] *C R Bard, Inc. v. AngioDynamics, Inc.*, 979 F.3d 1372, 1381 (Fed. Cir. 2015)

[31] *Id.* (internal citations and quotations omitted).

[32] *Id.* at 1381–82; *see also* Dkt. 715-1 at 25 (summarizing the *AngioDynamics* inquiry).

[33] *AngioDynamics*, 979 F.3d at 1382–84.

[34] *See* Dkt. 715-1 at 25–29 (applying *AngioDynamics*, 979 F.3d at 1381–82).

under the *Alice* framework, which determines whether a patent is invalid for being directed toward a patent ineligible concept, such as an abstract idea.[35]

Under the *AngioDynamics* inquiry, "a claim may be patent ineligible under § 101 on the grounds that it is: (1) directed solely to non-functional printed matter and (2) the claim contains no additional inventive concept."[36] The claims at issue in Bard's '302 and '022 Patents required a radiopaque identifier conveying to a medical practitioner that the implanted port is power injectable, and the claim at issue in the '615 Patent required a structural feature with at least one concave side, also conveying that the implanted port is suitable for power injection.[37] The court found at step one of the inquiry these asserted claims were directed solely to non-functional printed matter: in the case of '302 and '022 Patents, by using radiopaque identifiers to communicate that subcutaneous access ports were suitable for power injection, and in the case of the '615 Patent, by using a concave surface to communicate the same idea.[38] At step two of the *AngioDynamics* inquiry, the court found the Bard Patents contained no additional inventive concept because the focus of each claimed advance was using the radiopaque or concave identifying features in conjunction with a typically-constructed access port to convey the information that the access port is power injectable.[39]

The court then moved to the two-step *Alice* inquiry, under which it determines whether a claim is patent-eligible under 35 U.S.C. § 101 by distinguishing patent-ineligible claims for abstract ideas from patent-eligible applications of abstract ideas.[40] At step one, the court asked

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[35] *See id.* at 29–40 (applying *Alice Corp. Pty. Ltd. v. CLS Bank Intern.*, 573 U.S. 208, 217–18 (2014)).

[36] Dkt. 715-1 at 25 (citing *AngioDynamics*, 979 F.3d at 1383).

[37] *See* Dkt. 715-1 at 25–26 (discussing the Bard Patents).

[38] Dkt. 715-1 at 25–28.

[39] *Id.* at 28.

[40] *Id.* at 23–25 (discussing patent eligibility under 35 U.S.C. § 101 and citing *Alice*, 573 U.S. at 216–18).

whether the claims at issue, in their entirety, were directed to ineligible subject matter.[41] The court found all the asserted claims were directed to using a specific identifier—either a radiopaque identifier or a structural element including at least one concave side—to communicate information to a medical practitioner that the access port in question is power injectable subsequent to implantation.[42] The court further noted the claims were not directed to an improvement in port technology, there was no description in the claim language describing how the radiopaque identifiers or concave side surfaces are generated, and the claims contained no discussion of the X-ray technology used to view the radiopaque identifiers after implantation—in other words, the claims provided no functional improvement to the port itself or the X-ray technology used to view radiopaque identifiers.[43] Thus, because each asserted claim centered only on the use of an identifier to communicate information about the power injectability of the underlying port, the court found the claims were directed to an abstract idea.[44]

At *Alice* step two, the court analyzed the claims to determine whether they contained an inventive concept sufficient to transform the nature of the claim into a patent-eligible application,[45] and found the claims in the '302 and '022 Patents did not contain an inventive concept because the use of a radiopaque identifier to convey information was not inventive.[46] The court noted that MedComp had provided "numerous pieces of evidence supporting its argument that radiopaque identifiers were well-understood, routine, and conventional to those

[41] *Id.* at 30.

[42] *Id.* at 31–32.

[43] *Id.* at 31.

[44] *Id.* at 32.

[45] *Id.* (citing *Alice*, 573 U.S. at 217).

[46] *Id.* at 33–37.

skilled in the art of implantable medical devices."[47] The court further found the '615 Patent did not contain an inventive concept because the asserted claim about the required structural feature of one concave side was also routine and conventional in the medical device field.[48]

Having found the claims at issue were directed to the ineligible abstract idea of communicating information and lacked an inventive concept, the court accordingly held the asserted claims of the '302, '022, and '615 Patents were invalid under § 101, and granted MedComp's Motion for Summary Judgment on the Bard Patents' invalidity.[49]

The Order, and its interpretation of *AngioDynamics* and *Alice*, is now law of the case.[50] Accordingly, the court will evaluate the '324 Patent under the same framework.

b. MedComp's '324 Patent

Bard argues that given the court's Order finding the '302, '022, and '615 Patents invalid under 35 U.S.C. § 101, the '324 Patent must also be found invalid.[51] MedComp does not contest Bard's argument.[52] The court agrees that the '324 Patent is invalid under law of the case.

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[47] *Id.* at 34.

[48] *Id.* at 37–40.

[49] *Id.* at 40.

[50] *See, e.g.*, *Grigsby v. Barnhart*, 294 F.3d 1215, 1219 (10th Cir. 2002) ("Generally, once a court decides an issue, the same issue may not be relitigated in subsequent proceedings in the same case.") (internal citations and quotation omitted). There are only three "exceptionally narrow" reasons to depart from law of the case, none of which are implicated here: "(1) when the evidence in a subsequent trial is substantially different; (2) when controlling authority has subsequently made a contrary decision of the law applicable to such issues; or (3) when the decision was clearly erroneous and would work a manifest injustice." *Id.* n.4 (citing *Huffman v. Saul Holdings Ltd. P'ship*, 262 F.3d 1128, 1133 (10th Cir. 2001)).

[51] *See* Dkt. 750 at 1–2 (summarizing argument). In asserting this argument, Bard maintains it disagrees with the court's Order and reserves the right to challenge it once it becomes final. *See id.* at 1 n.1.

[52] Dkt. 759 (Opposition) at 1 ("MedComp . . . does not find fault with the Court's Summary Judgment Order. MedComp will accept the consequences of the Court's application of the same . . . analysis with respect to MedComp's asserted '324 Patent claims.").

i. The Material Facts are Undisputed

In its Motion for Summary Judgment, Bard provides a Statement of Undisputed Material Facts concerning the '324 Patent's independent and dependent claims.[53] MedComp only disputes one of these facts: it correctly notes the title of the '324 Patent is "Venous Access Port Assembly With X-Ray Discernable Indicia," not "Venous Access Port With X-Ray Discernable Indicia," as indicated in Bard's Motion.[54] With no other material facts disputed, the court adopts the rest of the undisputed facts set forth in Bard's Motion.[55]

MedComp, however, does dispute some of Bard's characterizations of the record.[56] The court briefly discusses each disputed characterization, but finds none of these disagreements ultimately material to the Motion.

First, MedComp argues Bard mischaracterizes its Provisional Application disclosure of "a metal disk in the bottom of plastic port" as an invalidating prior invention and maintains that this does not constitute prior art under pre-AIA 35 U.S.C. § 102, and further that this is "an attempt by Bard to perpetuate the misconception that the conception date of the inventions claimed in the '324 Patent is later than the date of Bard's Provisional Application."[57] Second, MedComp argues Bard mischaracterizes the Provisional Application disclosure as evidence of what is routine and conventional, and argues "the mere fact that a patent description teaches or suggests a claimed element does not make the element 'routine' or 'conventional' for purposes

[53] Dkt. 750 at 3–5.

[54] *Compare id.* at 3 *with* Dkt. 759 at 1.

[55] *See* Dkt. 750 at 3–5.

[56] Dkt. 759 at 1–3.

[57] *See* Dkt. 759 at 1–2. MedComp also notes that the Provisional Application in question here is the one Bard allegedly deceived the USPTO about to "obtain an illegitimate priority date for its asserted patents."

of the *Alice* patent eligibility test."[58] But MedComp does not dispute there is other prior art that incorporates radiopaque markers in the object to be identified. In fact, MedComp identified this prior art at some length in its own Motion for Summary Judgment.[59] Whether Bard's Provisional Application is considered prior art or not is irrelevant for the purposes of determining the instant Motion given the body of prior art MedComp has already identified.

Third, MedComp notes that Bard asserts similarity in embodiments of the access port described in the '324 Patent, and "disputes Bard's inference that this somehow establishes non-inventiveness."[60] MedComp further argues "Bard's conclusion that 'MedComp's claims do not provide for any functional improvement in the X-ray technology' is entirely divorced from that comparison."[61] Bard notes in its Reply, however, the conclusion is not divorced from the comparison because it did list an example of how MedComp's claims do not provide improvement.[62] Regardless of the level of similarity between the ports, the central point is that the embodiment of the access port itself is not inventive, as the court discussed in its prior Order discussing the Bard Patents.[63] Therefore, this characterization is also not relevant to the ultimate disposition of the Motion.

Fourth and finally, MedComp disputes that the '324 Patent has only two embodiments: cut-outs and stamped discrete elements bearing the letters "CT."[64] Rather, MedComp asserts that each embodiment represents "a genus of two species," "one where the indicia is fully

[58] *Id.* (citing *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 79–80 (2012)).

[59] *See* Dkt. 463 at 16–22.

[60] Dkt. 759 at 2.

[61] *Id.*

[62] Dkt. 762 (Reply) at 4 (citing Dkt. 750 at 10).

[63] *See* Dkt. 715-1 at 30–40.

[64] Dkt. 759 at 2.

embedded in the port body such that it is not visible from below, and another where it is only partially embedded such that it is visible from below."[65] MedComp further asserts the indicia can be any character, including alphabetical letters and numbers, and argues that this "raises an important point of distinction between the Bard claims and the claims of the '324 Patent for the Court's consideration."[66] Bard rejoins that MedComp's claims potentially incorporating "a larger set of characters including letters and/or numbers" does not "weigh in favor of patentability . . . under § 101."[67] Indeed, no matter which characters are used, the claimed innovation of the '324 Patent—like the Bard Patents—is using radiopaque indicia to communicate information about the access port to medical professionals. The court agrees with Bard that the precise characters used to communicate that information are immaterial for purposes of evaluating the instant Motion.

Having found none of the disputes concerning Bard's characterizations of the facts are material to the Summary Judgment Motion, the court will apply the law of the case to the undisputed facts surrounding MedComp's '324 Patent.

ii. The '324 Patent is Invalid Under the Law of the Case

The '324 Patent's asserted independent claim 1 consists of:

> An implantable venous access port assembly, comprising: a needle-penetrable septum; and a housing securing the needle-penetrable septum, the housing comprising a housing base having a bottom wall and X-ray discernable indicia comprising one or more characters that visually indicate, under X-ray examination, a pressure property of the port assembly.[68]

Similarly, independent claim 19 consists of:

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[65] *Id.*

[66] *Id.* at 3.

[67] Dkt. 762 at 5.

[68] Dkt. 19-1 at 11 (Claim 1).

> An implantable venous access port assembly, comprising: a housing comprising a housing base comprising a bottom wall and radiopaque indicia embedded in the bottom wall of the housing base, the radiopaque indicia comprising one or more characters indicating a pressure property of the port assembly under X-ray examination; a needle-penetrable septum; and a cap securing the needle-penetrable septum to the housing.[69]

Like the three Bard Patents, the asserted claims of the '324 Patent consist of an access port with radiopaque indicia to indicate a pressure property of the port. The issue is whether these asserted claims are patent ineligible under § 101 and the printed matter doctrine.

First, to determine whether the claims may be patent ineligible, the court turns to the *AngioDynamics* inquiry, under which "a claim may be patent ineligible under § 101 on the grounds that it is (1) directed solely to non-functional printed matter and (2) the claim contains no additional inventive concept."[70]

Under the first step of the *AngioDynamics* inquiry, the '324 Patent's independent claims are directed solely to non-functional printed matter. The '324 Patent's independent claims describe venous access port assemblies and the radiopaque identification feature directed to conveying information about the port. Though the radiopaque indicia are embedded into the bottom wall of the housing base, rather than included on the housing base as in Bard's '302 and '022 Patents, the '324 Patent's sole function—like the Bard Patents—is to convey the information that the port is power-injectable. The '324 Patent's Summary of the Invention specifically highlights the X-ray identifiable feature: "The invention is the incorporation of X-ray discernible indicia onto a venous access port that is discernible under X-ray examination to provide information concerning the nature or key attribute of the venous access port, so that the

[69] *Id.* at 12 (Claim 19).

[70] *See* Dkt. 715-1 at 25 (citing *AngioDynamics*, 979 F.3d at 1383).

practitioner . . . can determine that nature or key attribute under X-ray examination."[71] Specifically, using the letters CT "would be understood in medical practice to indicate the port is suitable for the high pressure injection."[72] Because the claimed invention is the particular identifying features of the radiopaque indicia, the claims in the '324 Patent are directed solely to non-functional printed matter.

Under the second step of the *AngioDynamics* inquiry, the '324 Patent contains no additional inventive concept. Like the invalidated Bard Patents, the '324 Patent recites the assembly of a typical venous access port with the additional feature of the printed matter conveying the information that the port is power-injectable.[73] As this court stated in its prior Order concerning the Bard Patents, "[b]eyond the printed matter, there are no other elements that could be considered 'inventive.'"[74] Moreover, as discussed above, the fact that the '324 Patent may encompass a larger range of letters and numbers as part of its radiopaque indicia, or embed those characters differently on the port, does not change this result. If the focus of the claimed advance is on making the port identifiable via X-ray technology to medical practitioners—in other words, to communicate information—it has no additional inventive concept, regardless of the particular characters used. Therefore, under the *AngioDynamics* framework, the '324 Patent is directed solely to printed matter.

Having determined the claims are directed solely to printed matter under the *AngioDynamics* inquiry, the court moves on to the two-step *Alice* framework to determine if the claims comprise only patent-ineligible subject matter.

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[71] Dkt. 19-1 at 10.

[72] *Id.*

[73] *See id.* at 1 (Abstract), 10 (Summary of the Invention).

[74] Dkt. 715-1 at 28.

At *Alice* step one, the court asks whether the claims at issue, in their entirety, are directed to ineligible subject matter.[75] The independent claims asserted are directed to the access port, specifically the "X-ray discernable indicia embedded in the bottom wall . . . comprising one or more characters that visually indicate . . . a pressure property of the port assembly."[76] In other words, the claims are directed to communicating information about the characteristics of the access ports. Because the radiopaque identifiers provide no functional improvement to the port itself or to the X-ray technology used to view the identifiers, and the rest of the claimed invention pertains to a typical access port, the claims are directed to an abstract idea. This is patent ineligible subject matter.

At *Alice* step two, the court analyzes the claims to determine whether they include an inventive concept sufficient to make them a patent-eligible application.[77] As discussed in the prior Order, "the addition of a non-functional radiopaque identifier to a known product is not an inventive concept."[78] Here, the '324 Patent's specification describes the invention as the "incorporation of X-ray discernable indicia . . . to provide information concerning the nature or key attribute of the venous access port."[79] As discussed, the two embodiments therein are described as a "genus of two species – one where the indicia is fully embedded in the port body such that it is not visible from below and another where it is only partially embedded such that it is visible from below,"[80] which can include any character.[81] While the parties dispute the extent

[75] *See* Dkt. 715-1 at 29 (citing *Alice*, 573 U.S. at 217–18).

[76] Dkt. 19-1 at 11 (Claim 1); *see also id.* at 12 (Claim 19) ("radiopaque indicia embedded in the bottom wall . . . comprising one or more characters indicating a pressure property of the port.").

[77] Dkt. 715-1 at 29 (citing *Alice*, 573 U.S. at 217–18).

[78] Dkt. 715-1 at 37.

[79] Dkt. 19-1 at 10 (Summary of the Invention).

[80] Dkt. 759 at 2.

[81] *See id.*

to which these particular embodiments differentiate the claims in the '324 Patent from the Bard Patents, the claimed inventive concept, at bottom, is an access port with radiopaque indicia used for the purpose of informing medical practitioners of the pressure capacity of the port. As with the Bard Patents, there is no additional inventive concept because radiopaque identifiers are not new within the medical device field.[82] Because the radiopaque identifiers only communicate an abstract idea, the claims in the '324 Patent do not contain an inventive concept sufficient to render them a patent-eligible application.

In summary, using the prior Order's framework, now law of the case, the asserted claims in Patent '324 are invalid under 35 U.S.C. § 101 because the use of radiopaque identifiers on a typical access port does not constitute an inventive concept. Therefore, Bard's Motion for Summary Judgment on MedComp's asserted Patent is GRANTED.[83]

CONCLUSION

For the foregoing reasons, Bard's Motion for Summary Judgment of Invalidity of the '324 Patent is GRANTED.[84] Additionally, Bard's first Motion for Summary Judgment is DENIED as moot.[85]

SO ORDERED this 3rd day of November, 2021.

BY THE COURT:

ROBERT W. SHELBY
United States Chief District Judge

[82] *See* Dkt. 715-1 at 33–37 (explaining that the use of radiopaque identifiers is not inventive).

[83] Dkt. 750.

[84] Dkt. 750.

[85] Dkt. 460.

Memorandum Decision And Order Certifying Claims Under Rule 54(b), dated November 4, 2021

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH

C.R. BARD, INC., a New Jersey corporation, and BARD PERIPHERAL VASCULAR, INC., an Arizona corporation, Plaintiffs, v. MEDICAL COMPONENTS, INC., a Pennsylvania corporation, Defendant.	**MEMORANDUM DECISION AND ORDER CERTIFYING CLAIMS UNDER RULE 54(b)** 2:12-cv-00032-RJS-DAO Chief District Judge Robert J. Shelby Magistrate Judge Daphne A. Oberg

Before the court are the parties' respective case management briefs concerning the most efficient way to proceed in this aged case.[1] Plaintiffs C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, Bard) contend the most efficient route is to certify for immediate appeal under Federal Rule of Civil Procedure 54(b) the court's recent Summary Judgment Orders,[2] which found all asserted patents in this case invalid.[3] Defendant Medical Components, Inc. (MedComp) argues conducting a bench trial on the issue of Bard's alleged inequitable conduct prior to appeal would be more efficient because the bench trial will resolve a potentially dispositive issue, and resolving the inequitable conduct issue first would allow all issues in the case to be appealed to the Federal Circuit together.[4] For the reasons explained below, the court

[1] Dkt. 743 (Bard's Opening Case Management Brief); Dkt. 744 (MedComp's Opening Case Management Brief).

[2] *See* Bard's Case Management Brief at 3.

[3] Dkt. 715-1 (Memorandum Decision and Order Partially Granting MedComp's Motion for Summary Judgment) (hereinafter Summary Judgment Order I); Dkt. 765 (Memorandum Decision and Order Granting Motion for Summary Judgment) (hereinafter Summary Judgment Order II).

[4] *See* MedComp's Case Management Brief at 1–2.

finds Bard's proposed course preferable, and certifies its Summary Judgment Orders for immediate appeal under Rule 54(b).

BACKGROUND AND PROCEDURAL HISTORY

The court will not recite at length the facts underlying this longstanding patent litigation. Briefly, Bard asserts three patents: U.S. Patent Nos. 7,785,302 (the '302 Patent); 7,947,022 (the '022 Patent), and 7,959,615 (the '615 Patent).[5] MedComp's counterclaim asserts U.S. Patent No. 8,021,324 (the '324 Patent).[6] The patents all relate to the radiopaque identification of subcutaneous access ports.[7]

On January 11, 2012, Bard filed the instant action against MedComp, alleging infringement of the '022, '302, and '615 Patents.[8] MedComp counterclaimed, alleging Bard infringed its '324 Patent.[9] On December 17, 2012, the case was stayed and administratively closed while the patents-in-suit underwent *inter partes* reexamination before the United States Patent and Trademark Office.[10] On October 4, 2019, the stay was lifted.[11] Since that time, the case has progressed as follows: (1) fact discovery commenced on March 30, 2020 and closed on February 8, 2021; (2) the parties completed claim construction briefing on April 2, 2021; and (3) the parties conducted a technology tutorial for the court on April 28, 2021.[12]

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[5] Dkt. 69 (Amended Complaint) ¶¶ 7–10.

[6] Dkt. 640 (Second Amended Answer and Amended Counterclaims) at 27–28.

[7] *See* Dkt. 2-1 (U.S. Patent No. 7,785,302); 2-2 (U.S. Patent No. 7,947,022); Dkt. 2-3 (U.S. Patent No. 7, 959,615); Dkt. 19-1 (U.S. Patent No. 8,021,324).

[8] Dkt. 2 (Complaint) ¶¶ 11–20.

[9] Dkt. 19 (Answer and Counterclaim) ¶¶ 33–35.

[10] *See* Dkt. 93 (Memorandum Decision and Order Administratively Closing Case).

[11] *See* Dkt. 161 (Order Reopening Case).

[12] *See* Dkt. 539 (Bard's Memorandum in Opposition to MedComp's Motion to Consolidate Cases) at 2–3 (summarizing procedural history).

On March 5, 2021, the parties filed Cross-Motions for Summary Judgment.[13] Bard argued in its Motion the '324 Patent must be invalidated because its PowerPort MRI was prior art.[14] MedComp argued in its Motion, *inter alia*, that it was entitled to summary judgment on the invalidity of Bard's asserted patents under the printed matter doctrine.[15]

On July 22, 2021, this court issued a Memorandum Decision and Order (Summary Judgment Order I) partially granting MedComp's Motion for Summary Judgment, specifically finding Bard's three asserted patents were invalid under the printed matter doctrine.[16] The court declined to consider MedComp's request for summary judgment on the grounds Bard had infringed MedComp's patent.[17]

On July 25, 2021, Bard moved to certify Summary Judgment Order I under Rule 54(b), arguing that immediate appeal of the patents' invalidity would be efficient given that Bard is asserting the same patents in concurrent litigation pending in other districts.[18] The court denied the 54(b) Motion without prejudice[19] in light of the discussion at a July 27, 2021 hearing, in which Bard was invited to move for summary judgment against MedComp's '324 Patent under the law of the case adopted in Summary Judgment Order I.[20] Bard took up that invitation, filing a second Motion for Summary Judgment on August 27, 2021.[21] The court granted that motion

[13] Dkt. 460 (Bard's First Motion for Summary Judgment); Dkt. 463 (MedComp's Motion for Summary Judgment).

[14] *See* Bard's First Motion for Summary Judgment at 17–29.

[15] See MedComp's Motion for Summary Judgment at 10–22.

[16] *See* Summary Judgment Order I.

[17] *See id.* at 1 n.1.

[18] Dkt. 718 (Bard's Motion to Certify Under Rule 54(b)) at 5–8.

[19] Dkt. 721 (Docket Text Order).

[20] *See* Dkt. 727 (Hearing Transcript) at 3:18–5:14.

[21] Dkt. 750 (Bard's Second Motion for Summary Judgment).

on November 3, 2021, finding the '324 Patent invalid in its Memorandum Decision and Order Granting Bard's Motion for Summary Judgment (Summary Judgment Order II).[22]

In the July 27 hearing, the parties were directed to submit case management briefs proposing the most efficient way to proceed.[23] Those briefs have now been filed. Bard contends that the court's Orders finding all of the asserted patents in this case invalid should be certified under Rule 54(b) for immediate appeal.[24] MedComp argues that the court should first hold a bench trial on its inequitable conduct claim, enabling appeal of all the issues in the case together after that trial is completed.[25]

Having considered these arguments, for the reasons explained below, the court concludes that the most efficient course will be to immediately certify for appeal under Rule 54(b) its Summary Judgment Orders finding invalidity, and to stay the case while the appeal is pending.

LEGAL STANDARD

Under 28 U.S.C. § 1295, the United States Court of Appeals for the Federal Circuit has exclusive jurisdiction over "an appeal from a final decision of a district court of the United States . . . in any civil action arising under . . . any act of Congress relating to patents."[26] Because 28 U.S.C. § 1291 also limits the jurisdiction of the courts of appeals (other than the United States Court of Appeals for the Federal Circuit) to "final decisions of the district courts,"[27] the Federal Circuit applies principles of finality promulgated under § 1291 to determine whether a judgment

[22] Dkt. 765 (Summary Judgment Order II).

[23] See Dkt. 721 (Docket Text Order).

[24] Bard's Case Management Brief at 2–3.

[25] MedComp's Case Management Brief at 1.

[26] 28 U.S.C. § 1295(a)(1).

[27] 28 U.S.C. § 1291.

is final under § 1295.[28] A "final" decision is one that "ends litigation on the merits and leaves nothing for the court to do but execute the judgment."[29]

"[F]or a district court judgment to be appealable to [the Federal Circuit] under 28 U.S.C. § 1295(a)(1), the judgement must resolve all claims and counterclaims or make an express determination under Rule 54(b) . . . that there is no just reason for delay."[30] Rule 54(b) provides, in relevant part, that "[w]hen an action presents more than one claim for relief—whether as a claim, counterclaim, cross-claim, or third-party claim—or when multiple parties are involved, the court may direct entry of a final judgment as to one or more, but fewer than all, claims or parties only if the court expressly determines there is no just reason for delay."[31]

"Rule 54(b) was implemented to specifically 'avoid the possible injustice of delay[ing] judgment on a distinctly separate claim [pending] adjudication of the entire case.'"[32] In deciding whether to certify a claim under Rule 54(b), the district court "act[s] as a dispatcher," weighing the "historic" policy of preventing piecemeal appeals against the "equities involved."[33] "It is left to the sound discretion of the district court to determine the appropriate time when each final

[28] *See, e.g.*, *Alfred E. Mann Foundation for Scientific Research v. Cochlear Corp.*, 841 F.3d 1334, 1347 (Fed. Cir. 2016); *W.L. Gore & Assocs., Inc. v. Int'l Med. Prosthetics Research Assocs., Inc.*, 975 F.2d 858, 862 n.3 (Fed. Cir. 1992).

[29] *Gelboim v. Bank of America Corp.*, 574 U.S. 405, 409 (2015) (quoting *Catlin v. United States*, 324 U.S. 229, 233 (1945)); *see also W.L. Gore*, 975 F.2d at 863–64 (Fed. Cir. 1992) (holding district court's order finding patent invalid was final, appealable decision under § 1295).

[30] *Synchronoss Technologies, Inc. v. Dropbox, Inc.*, 987 F.3d 1358, 1365 (Fed. Cir. 2021).

[31] Fed. R. Civ. P. 54(b); *see also, e.g.*, *Int'l Elec. Tech. Corp. v. Hughes Aircraft Co.*, 476 F.3d 1329, 1331 (Fed. Cir. 2007) (cautioning that parties may only appeal to the Federal Circuit when a judgment is final or with a Rule 54(b) certification).

[32] *Alfred E. Mann Foundation*, 841 F.3d at 1347 (citing *Gelboim*, 574 U.S. at 409); *see also W.L. Gore*, 975 F.2d at 861 ("Rule 54(b) acknowledges the policy that in multiple claim actions 'some final decisions, on less than all of the claims, should be appealable without waiting for a final decision on all of the claims.'") (citing *Sears, Roebuck & Co. v. Mackey*, 351 U.S. 427, 432 (1956)).

[33] *Curtiss-Wright Corp. v. General Elec. Co.*, 446 U.S. 1, 8 (1980) (citing *Sears*, 351 U.S. at 435, 438).

decision in a multiple claims action is ready for appeal."[34] Rule 54(b) certifications should not "be granted routinely."[35] Accordingly, "[t]here are three prerequisites for invoking Rule 54(b): (1) multiple claims for relief or multiple parties must be involved; (2) at least one claim or the rights and liabilities of at least one party must be finally decided; and (3) the district court must find that there is no just reason for delaying an appeal."[36] The court will consider each prerequisite in turn.

ANALYSIS

I. The Summary Judgment Orders are Certified Under Rule 54(b)

Having found MedComp's '324 Patent invalid,[37] and having previously found Bard's '302, '022, and '615 Patents invalid,[38] the court has disposed of all claims relating to the validity of the asserted patents, leaving only MedComp's inequitable conduct claim. Rule 54(b) certification of the invalidity rulings is warranted because: (1) this case involves multiple claims and parties, (2) the summary judgment orders finding invalidity represent final decisions, and (3) there is no just reason for delaying appeal.[39]

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[34] *Id.*

[35] *Id.* at 10.

[36] *Alfred E. Mann Foundation*, 841 F.3d at 1347 (citing 10 Charles Alan Wright et al., Federal Practice and Procedure § 2656 (3d ed. 2016)).

[37] Summary Judgment Order II.

[38] Summary Judgment Order I.

[39] While the court will discuss all three necessary prerequisites for Rule 54(b) certification, it bears noting that the parties' case management briefing does not dispute the first and second prerequisites. Bard writes in its Opening Case Management Brief that "[t]here is no dispute that the Court's invalidity Summary Judgment Order disposed of/mooted all of Bard's claims against MedComp, leaving nothing left to do but to enter judgment on those claims." Dkt. 743 at 1. MedComp does not contest this. *See* Dkt. 744; Dkt. 758 (MedComp's Responsive Case Management Brief). The parties' Rule 54(b) arguments and counterarguments largely focus on the third prerequisite—that is, whether there is "no just reason for delaying appeal." The court assumes therefore the parties agree that the first and second prerequisites for Rule 54(b) certification are met in this case and will focus its analysis on the third prerequisite.

a. This Lawsuit Involves Multiple Claims

For Rule 54(b) certification to be appropriate, a case must involve multiple claims for relief or multiple parties.[40] A claim or counterclaim may be viewed as "a separable unit" suitable for certification under the rule.[41] The instant lawsuit involves multiple claims and counterclaims, each concerning the various patents at issue, and the parties seek relief under different theories involving distinct facts.[42] Specifically, Bard brings claims for infringement of the '302, '022, and '615 Patents.[43] MedComp brings counterclaims alleging the invalidity of the Bard Patents, infringement of the '324 Patent, and inequitable conduct.[44] The parties each seek damages based on the alleged patent infringement and attorneys' fees and costs.[45] Therefore, the first element for Rule 54(b) certification is satisfied.

b. The Summary Judgment Orders Represent a Final Decision

For Rule 54(b) certification to be appropriate, the decision resolving the claim or claims at issue must be final.[46] Additionally, "[c]ourts analyzing whether Rule 54(b) applies must focus on both the finality of the judgment and the separateness of the claims for relief."[47]

[40] *Alfred E. Mann Foundation*, 841 F.3d at 1347.

[41] 10 Charles Alan Wright et al., Federal Practice and Procedure § 2657 (4th ed.).

[42] *See Sears*, 351 U.S. at 436, 437, n.9 (discussing different theories of relief in multiple claims in the context of affirming a district court's Rule 54(b) certification).

[43] Dkt. 69 (Amended Complaint).

[44] Dkt. 640 (Second Amended Answer to Amended Complaint).

[45] *See* Amended Complaint at 12–13; Second Amended Answer at 50–51.

[46] *Alfred E. Mann Foundation*, 841 F.3d at 1347.

[47] *W. L. Gore*, 975 F.2d at 861–62 (citing *Sears*, 351 U.S. at 436).

Finality is a "statutory mandate and not a matter of discretion." [48] A district court may only certify judgments that are final under § 1291.[49] For purposes of Rule 54(b), an order is final if it is "an ultimate disposition of an individual claim entered in the course of a multiple claims action."[50] Here, the Summary Judgment Orders finding the Bard Patents and the '324 Patent invalid under 35 U.S.C. § 101 represented final judgments on Bard's claims for infringement and MedComp's counterclaim for infringement because a finding that a patent is invalid represents a final decision in a patent enforcement action under § 1295.[51] Accordingly, the claims to be certified under Rule 54(b) are final.

In addition, a claim certified under Rule 54(b) must be separate from others in the same action.[52] Determining whether a claim is sufficiently separate falls within the district court's discretion and turns on factors such as: (1) "whether the claims under review were separable from the others remaining to be adjudicated" and (2) "whether the nature of the claims already determined was such that no appellate court would have to decide the same issues more than once even if there were subsequent appeals."[53]

Here, the claims are sufficiently separable from the remaining claims in the case. The Summary Judgment Orders left intact MedComp's claim alleging Bard engaged in inequitable conduct.[54] This claim is sufficiently separate and distinct from the Summary Judgment Orders,

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[48] *W.L. Gore*, 975 F.2d at 862 (citing *Sears*, 351 U.S. at 437) (applying § 1291 finality analysis to Federal Circuit jurisdiction under § 1295).

[49] *Id.*

[50] *Curtiss-Wright Corp.*, 446 U.S. at 7 (citing *Sears*, 351 U.S. at 436).

[51] *W.L. Gore*, 975 F.2d at 864 ("Because the infringement claim and several dipositive defenses were ruled upon [by the decision that the patent-in-suit was invalid] the district court's judgment was final.").

[52] *Id.* at 861–62.

[53] *W.L. Gore*, 975 F.2d at 862 (citing *Curtiss-Wright Corp.*, 446 U.S. at 8).

[54] *See* Dkt. 727 (July 27, 2021 Hearing Transcript) at 9:2–11:19 (discussing the outstanding inequitable conduct claim).

as it concerns Bard's conduct before the PTO and relies on a distinct set of facts and legal arguments.[55] Were there separate appeals of the Summary Judgment Orders and the inequitable conduct claim, the Federal Circuit would not need to decide the same issues more than once, as the appeal based on the '324 and Bard Patents' invalidity takes up the patents' relationship to the printed matter doctrine, unlike a hypothetical future appeal of the inequitable conduct claim, which concerns Bard's conduct before the PTO. These inquiries turn on different factual questions, legal questions, and would provide for separate recovery.

The Summary Judgment Orders finding invalidity of the patents represent final decisions that are sufficiently separable from the remaining claim in the case, meeting the second prerequisite for Rule 54(b) certification.

c. There is No Just Reason for Delaying Appeal

A district court must make a finding there is "no just reason for delay" and "explain why judicial economy supports its . . . determination" in certifying a claim for immediate appeal under Rule 54(b).[56] In this evaluation, "a district court must take into account judicial administrative interests as well as the equities involved."[57] Both interests—intertwined in this case—are served by permitting immediate appeal of the Summary Judgment Orders finding the patents are invalid.

Bard argues there is no just reason to delay appeal because immediate appeal of the patents' invalidity would allow resolution of the "tension" between the Summary Judgment Orders and Federal Circuit case law, and conserve judicial resources by obtaining the Federal

[55] *See* Second Amended Answer at 30–50 (detailing factual allegations concerning Bard's alleged inequitable conduct that are distinct from the facts surrounding the specifications of the patents-in-suit for purposes of the infringement claims and counterclaims).

[56] *Intellectual Ventures I LLC v. Capital One Financial Corp.*, 850 F.3d 1332, 1336 (Fed. Cir. 2017).

[57] *Curtiss-Wright*, 446 U.S. at 8.

Circuit's guidance on the validity of the Bard Patents in this and other cases.[58] MedComp responds that Rule 54(b) certification prior to a bench trial on inequitable conduct is inefficient and will lead to piecemeal appeals.[59] The court agrees with Bard.

As an initial matter, the validity of the asserted patents is at the heart of this case. Having found that none of the asserted patents in this case are valid, there is nothing left to decide on the merits of Bard's infringement claims, MedComp's infringement counterclaim, nor any of MedComp's defenses to infringement. Waiting for conclusion of a bench trial on the inequitable conduct issue would cause significant delay in resolving an issue central to most of the claims in this case. That delay will also have ripple effects considering pending litigation in other districts and the need to clarify an important doctrinal question.

And Rule 54(b) certification will also give the Federal Circuit an opportunity to further address the application of its patent eligibility case law as it relates to 35 U.S.C. § 101 and the printed matter doctrine.[60] As the court acknowledged in a hearing following Summary Judgment Order I, the finding that the Bard Patents are invalid is in "some tension" with how Judge Howard Nielsen interpreted the Federal Circuit's recent holding in another case Bard is litigating in this district.[61] As this doctrine affects a number of patents, and the law in this area has continued to evolve,[62] immediate appeal would enable litigants and courts to more quickly receive guidance from controlling authority that will assist with resolving disputes.

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[58] Bard's Opening Case Management Brief at 3–4.

[59] MedComp's Opening Case Management Brief at 1–2.

[60] Bard's Opening Case Management Brief at 3–4 ("There is much uncertainty here that requires appellate resolution.").

[61] Dkt. 727 (July 27, 2021 Hearing Transcript) at 15:13; *see C.R. Bard, Inc. v. Medical Components, Inc.*, No. 2:17-CV-00754, 2020 WL 6902367, at *20–21 (D. Utah Nov. 24, 2020) (finding Bard's asserted patents valid under the printed matter doctrine).

[62] *See, e.g.*, *Alice Corp. Pty. Ltd. v. CLS Bank Intern.*, 573 U.S. 208, 217–18, 221 (2014) (refining two-step test for patent eligibility when a patent concerns abstract ideas); *C R Bard, Inc. v. AngioDynamics, Inc.*, 979 F.3d 1372,

Further, Rule 54(b) certification will avoid duplicative and potentially conflicting judgments in pending litigation in other districts.[63] Bard has asserted the same patents against two other companies.[64] Typically, this court's invalidity ruling would be issue preclusive in these cases,[65] but issue preclusion will not apply until the Summary Judgment Order becomes final.[66] Absent Rule 54(b) certification, the parties to the pending cases may have to relitigate the issue of the Bard Patents' validity, creating the possibility of conflicting judgments and additional appeals.

MedComp's primary argument against Rule 54(b) certification is that holding a bench trial on the issue of inequitable conduct before any appeal would allow all issues in this case to be appealed "in a single package," thereby preventing piecemeal appeals.[67] MedComp also asserts that "[a]n inequitable conduct bench trial is short and efficient and will not result in unreasonable delay."[68] MedComp further argues that if the '302 Patent is held unenforceable on the basis of inequitable conduct, "the continuations and continuations-in-part of the '302 Patent here and in the 2017 Litigation, will be rendered unenforceable in accordance with the doctrine of infectious unenforceability."[69] For that reason, MedComp asserts, "both invalidity and

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1381–82 (Fed. Cir. 2015) (using two-step inquiry to determine whether a claimed invention is directed toward printed matter).

[63] Bard's Opening Case Management Brief at 4.

[64] *See C.R. Bard, Inc. v. Smiths Medical ASD, Inc.*, No. 1:20-cv-01543-CFC (D. Del.); *C.R. Bard, Inc. v. AngioDynamics, Inc.*, No. 1:20-CV-01544-CFC (D. Del.).

[65] *See, e.g., Blonder-Tongue Labs, Inc. v. Univ. of Illinois Found.*, 402 U.S. 313, 334 (1971).

[66] *See, e.g., Vardon Golf Co. v. Karsten Mfg. Corp.*, 294 F.3d 1330, 1334 (Fed. Cir. 2002) (a "partial summary judgment was not an appealable final judgment" when it was not certified as "final under Rule 54(b)").

[67] MedComp's Responsive Case Management Brief (Dkt. 758) at 5.

[68] MedComp's Case Management Brief at 1.

[69] *Id.* at 3. The doctrine of infectious unenforceability applies when a patent rendered unenforceable by inequitable conduct causes other related patents in the same technology family to also be rendered unenforceable. *See id.* at 4 (citing *Therasense v. Becton, Dickinson and Co.*, 649 F.3d 1276, 1288–89 (Fed. Cir. 2011)).

inequitable conduct are potentially dispositive issues . . . [which] would benefit from a unified appeal."[70] Bard counters that holding a bench trial first would require claim construction, causing delay and violating Bard's Seventh Amendment right to have factual questions decided first by a jury.[71] Bard additionally disputes that finding the '302 Patent unenforceable would lead to others in its line being affected by the doctrine of infectious unenforceability.[72]

MedComp is correct that the inequitable conduct claim could provide an independent reason the Federal Circuit affirms the Bard Patents' invalidity. However, the Federal Circuit will have to consider the invalidity issues decided in Summary Judgment Order I and II in any of the following scenarios: (1) the Federal Circuit does not affirm a hypothetical finding of inequitable conduct following a bench trial, (2) a bench trial finds no inequitable conduct, or (3) either this court or the Federal Circuit finds that the doctrine of infectious unenforceability does not apply to the '022 and '615 Patents. Regardless of the outcome of the inequitable conduct bench trial, these possible scenarios suggest the Federal Circuit will likely take up the invalidity issue and, as previously discussed, the Federal Circuit's guidance on the invalidity issue is strongly desirable not just in this case but in other pending litigation.[73] Therefore, both the equities and judicial efficiencies counsel finding "no just reason for delay."

[70] MedComp's Responsive Case Management Brief at 5.

[71] Bard's Opening Case Management Brief at 6–13.

[72] Bard's Responsive Case Management Brief at 11–13.

[73] Similarly, MedComp is also correct that a holding the '302 Patent is unenforceable would have ripple effects across other litigation in which Bard asserts the '302 Patent (though again, the parties dispute whether a finding the ''302 Patent is unenforceable would cause other related Bard patents to be found unenforceable through the doctrine of infectious unenforceability). Regardless of the extent of this hypothetical unenforceability, this court's Orders finding all the asserted patents unenforceable under § 101 will certainly have ripple effects across any litigation asserting similar patents, and therefore, receiving the Federal Circuit's guidance on the validity of the patents-in-suit is critical.

More practically, even assuming *arguendo* that the court need not construe patent claims prior to a bench trial on inequitable conduct, and that the trial could be completed in only two to three days, the issue likely could not be resolved before next summer. Both the court's calendar and the ongoing pandemic would adversely impact the time to resolution. The court has confirmed first-place jury trial settings for cases in November, December, and January. The latter two are multiweek trials. This is in addition to the court's other work, including numerous fully briefed motions already set for hearing or awaiting a hearing date. Given its current docket, it is likely the court would need at least a couple months to provide its findings and conclusions even after a not-yet-scheduled bench trial could be completed.[74] And the concerning state of the pandemic in the District of Utah continues to present significant health risks (especially with evidentiary hearings) and impair the court's efficiency in many ways. Under these circumstances, withholding a Rule 54(b) certification likely would result in a ten-to-twelve-month delay in resolving patent validity issues important in several pending cases in multiple district courts. In light of these judicial administrative interests, certifying the Summary Judgment Orders for immediate appeal is the more efficient course.[75]

Thus, having considered the equities involved as well as the judicial administrative interests, the court finds there is "no just reason for delay" and that Rule 54(b) certification of the Summary Judgment Orders is appropriate.[76]

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[74] As Bard notes, expert discovery and pre- and post-trial motion practice could also take significant time, further delaying appeal. *See* Bard's Opening Case Management Brief at 9.

[75] *See* Dkt. 743-1 (Exhibit A to Bard's Opening Case Management Brief) (demonstrating that the median time from docketing date to decision in Federal Circuit cases decided on the merits is about thirteen months).

[76] Having certified the patent invalidity issue under Rule 54(b), the court does not reach the issue of whether holding the inequitable conduct bench trial prior to a jury trial on the infringement claims violates Bard's Seventh Amendment rights, nor does it decide whether claim construction would be necessary prior to an inequitable conduct trial.

II. The Case is Stayed Pending Appeal

Having certified the Summary Judgment Orders for immediate appeal under Rule 54(b), the proceedings in this action are stayed, and the case is administratively closed while the appeal is pending.[77] The parties are directed to submit status reports to the court every six (6) months concerning the progress of the appeal.

Finally, all currently-pending motions in the case are DENIED without prejudice. Should the case be remanded following consideration by the Federal Circuit, the parties may refile any motions remaining relevant to the litigation.

CONCLUSION

For the foregoing reasons, the court's prior summary judgment orders[78] in this case are certified for appeal under Rule 54(b), the case is STAYED and ADMINISTRATIVELY CLOSED pending appeal, and all pending motions are DENIED without prejudice.

SO ORDERED this 4th day of November, 2021.

BY THE COURT:

ROBERT J. SHELBY
United States Chief District Judge

[77] *See Landis v. N. Am.* Co., 299 U.S. 248, 254 (1936) (the district court has the power to stay proceedings pending before it as part of its inherent power to control its docket); *accord Cherokee Nation of Oklahoma v. United States*, 124 F.3d 1413, 1416 (Fed. Cir. 1997). The court recognizes MedComp's argument that a stay would be inefficient, *see* MedComp's Responsive Case Management Brief at 5, but notes the argument is the same as MedComp's opposition to Rule 54(b), namely, that waiting to try all issues in this case in one appeal would be most efficient. Having decided to certify the Summary Judgment Orders for immediate appeal, the court has determined staying the case will be most efficient to avoid the possibility of redoing work following a ruling from the Federal Circuit.

[78] Dkt. 715-1; Dkt. 765.

Rule 54(b) Judgment On Claims For Patent Infringement, dated November 5, 2021

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH

C.R. BARD, INC., a New Jersey corporation, and BARD PERIPHERAL VASCULAR, INC., an Arizona corporation, Plaintiffs, v. MEDICAL COMPONENTS, INC., a Pennsylvania corporation, Defendant.	**RULE 54(b) JUDGMENT ON CLAIMS FOR PATENT INFRINGEMENT** 2:12-cv-00032-RJS-DAO Chief District Judge Robert J. Shelby Magistrate Judge Daphne A. Oberg

On July 22, 2021, the court granted in part Defendant Medical Components, Inc.'s (MedComp) Motion for Summary Judgment,[1] finding all asserted claims of Plaintiff C.R. Bard, Inc. and Plaintiff Bard Peripheral Vascular, Inc.'s (collectively, Bard) three asserted patents invalid.[2] On November 3, 2021, the court granted Bard's Motion for Summary Judgment,[3] finding all asserted claims of MedComp's asserted patent invalid.[4]

The court subsequently issued a Memorandum Decision and Order expressly determining under Rule 54(b) of the Federal Rules of Civil Procedure that there is "no just reason for delay" and certifying the patent infringement claims and counterclaim for immediate appeal.[5]

[1] Dkt. 463.

[2] Dkt. 715-1 (Memorandum Decision and Order Granting in Part Motion for Summary Judgment) (finding claims 1, 3, 4, 5, 6, 7, 8, and 10 of the '302 Patent, 1, 3, 5, 8, 9, 10, 12, and 14 of the '022 Patent, and claim 8 of the '615 Patent invalid under 35 U.S.C. § 101).

[3] Dkt. 750.

[4] Dkt. 765 (Memorandum Decision and Order Granting Motion for Summary Judgment) (finding claims 1, 19, 20, 26, 39, 40, 41, and 42 of the '324 Patent invalid under 35 U.S.C. § 101).

[5] Dkt. 766 (Memorandum Decision and Order Certifying Claims Under Rule 54(b)).

Accordingly, the court hereby enters Judgment pursuant to Rule 54(b) as to Bard's claims for patent infringement[6] and MedComp's counterclaim for patent infringement.[7]

SO ORDERED this 5th day of November, 2021.

BY THE COURT:

ROBERT J. SHELBY
United States Chief District Judge

[6] Dkt. 69 (Amended Complaint) ¶¶ 11–51 (Bard's First, Second, and Third Causes of Action).

[7] Dkt. 640 (Second Amended Answer, Affirmative Defenses, and Amended Counterclaims) ¶¶ 63–74 (MedComp's Seventh Counterclaim).

U.S. Pat. No. 8,021,324

US008021324B2

(12) **United States Patent**
Bizup et al.

(10) **Patent No.: US 8,021,324 B2**
(45) **Date of Patent: Sep. 20, 2011**

(54) **VENOUS ACCESS PORT ASSEMBLY WITH X-RAY DISCERNABLE INDICIA**

(75) Inventors: **Raymond Bizup**, Feasterville, PA (US); **Kevin Sanford**, Chalfont, PA (US); **Christopher Linden**, Allentown, PA (US)

(73) Assignee: **Medical Components, Inc.**, Harleysville, PA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **12/175,182**

(22) Filed: **Jul. 17, 2008**

(65) **Prior Publication Data**

US 2009/0024098 A1 Jan. 22, 2009

Related U.S. Application Data

(60) Provisional application No. 60/961,133, filed on Jul. 19, 2007.

(51) **Int. Cl.**
A61M 37/00 (2006.01)

(52) **U.S. Cl.** **604/88**; 604/175; 604/288.04

(58) **Field of Classification Search** 604/288.01–288.04, 86, 88, 116, 604/167.02

See application file for complete search history.

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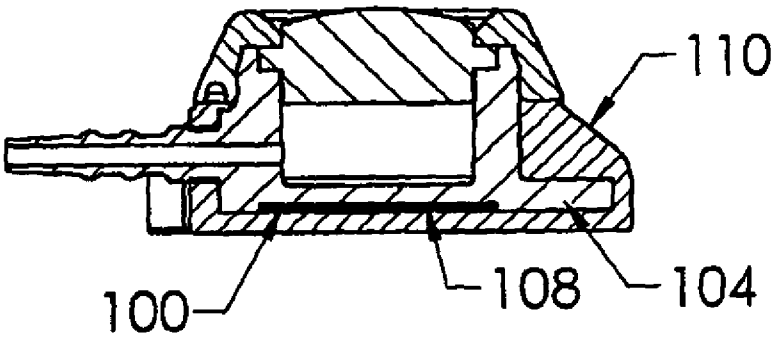
(57) **ABSTRACT**

A venous access port assembly (**10**) having a housing base (**28**) with a discharge port (**16**), a septum (**14**) and a cap (**48**), with an interior reservoir (**22**). The housing base (**28**) is provided with X-ray discernable indicia (**100**,**200**) to identify an attribute of the assembly (**10**) after its implantation and clearly appear on an X-ray of the patient in a manner informing the radiologist or technologist and the medical practitioner of that particular attribute. Such indicia can be depicted as cutouts (**102**) through a disc of radiopaque material (**100**) where the cutouts are in the form of alphabetical letters such as "CT", or can be a set (**200**) of discrete elements (**202**) of radiopaque material, that are affixed along the bottom surface of the housing base or embedded within the thickness of the bottom housing wall.

44 Claims, 4 Drawing Sheets



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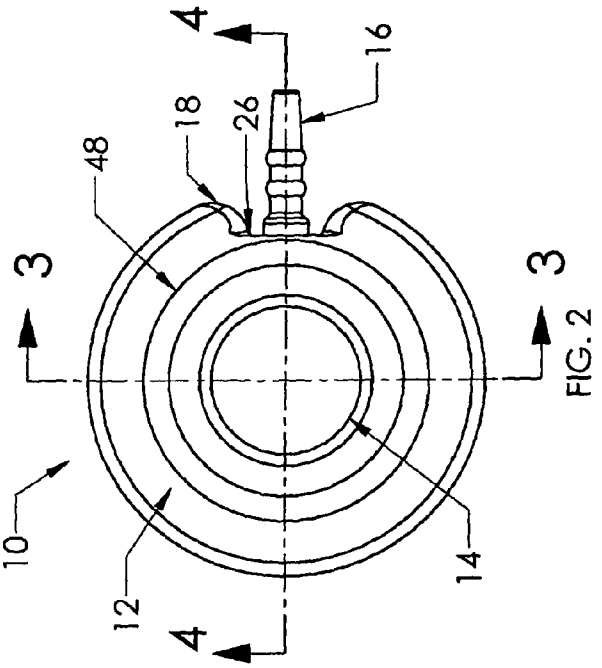

FIG. 2

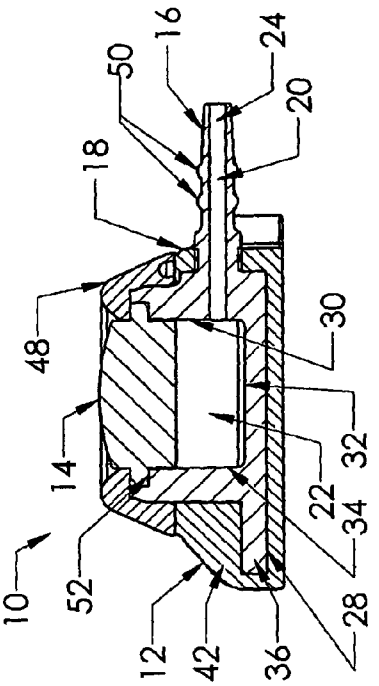

FIG. 4

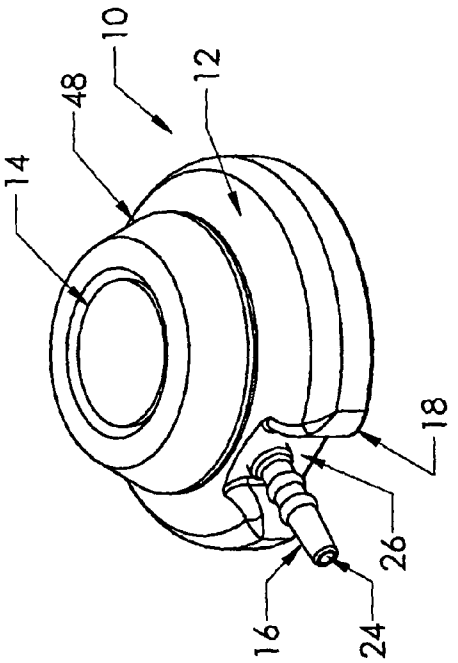

FIG. 1

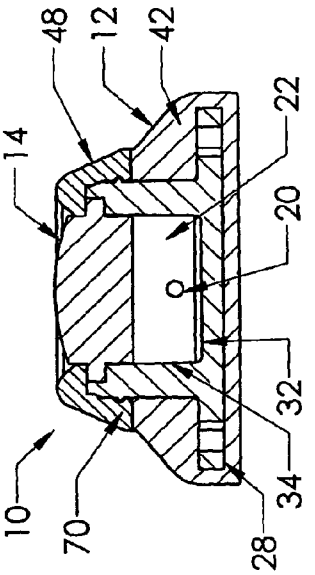

FIG. 3

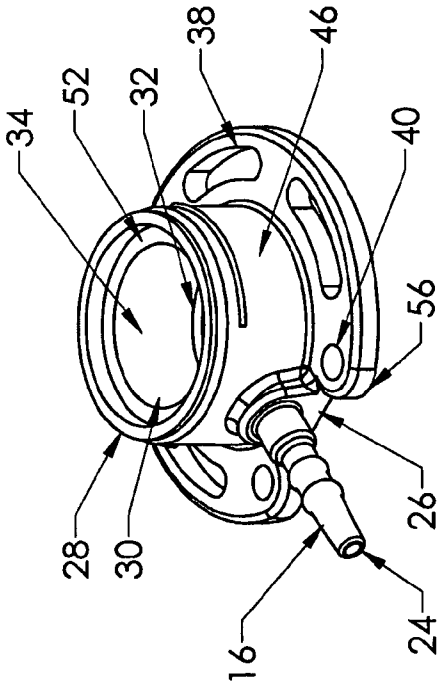

FIG. 5

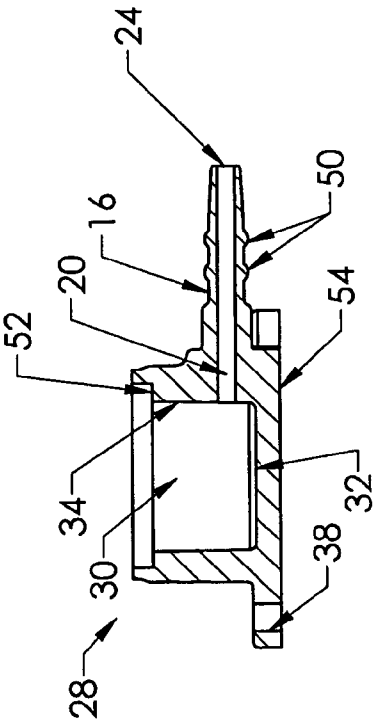

FIG. 7

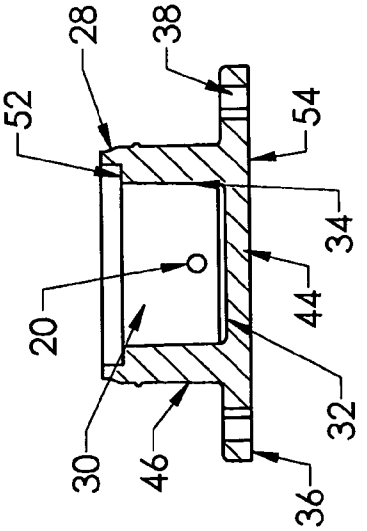

FIG. 6

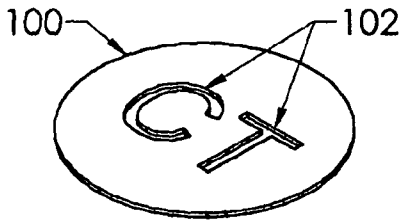

FIG. 8

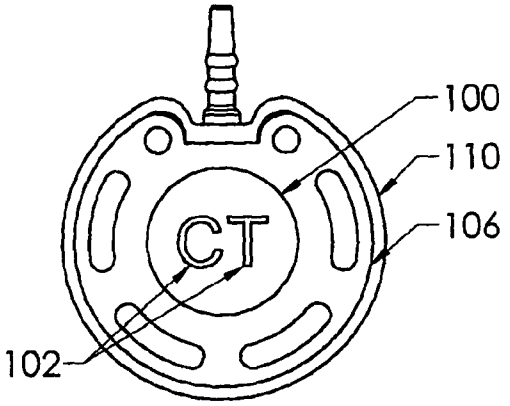

FIG. 9

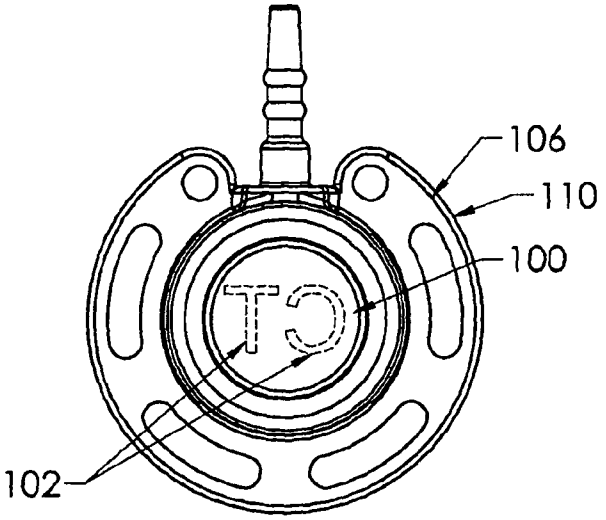

FIG. 11

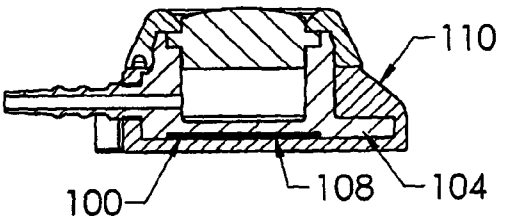

FIG.10

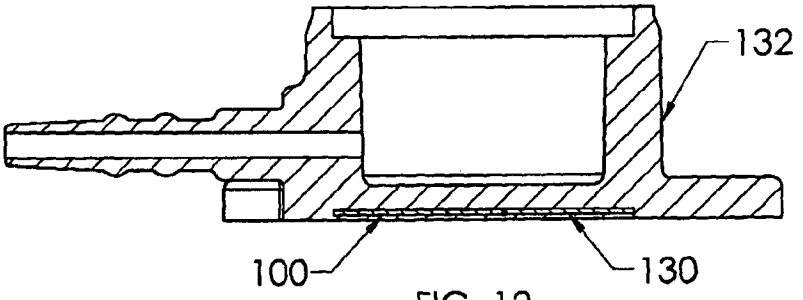

FIG. 12

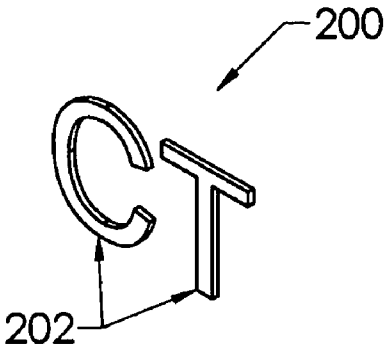

FIG. 13

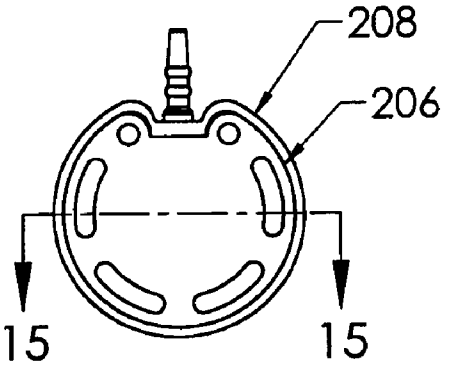

FIG. 14

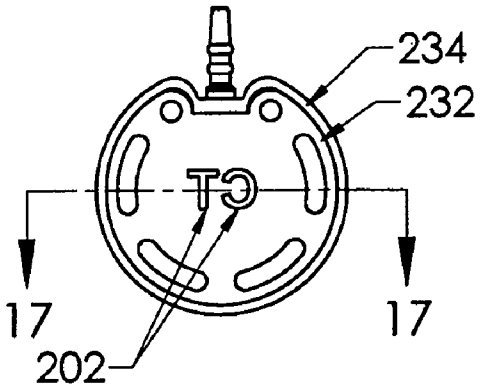

FIG. 16

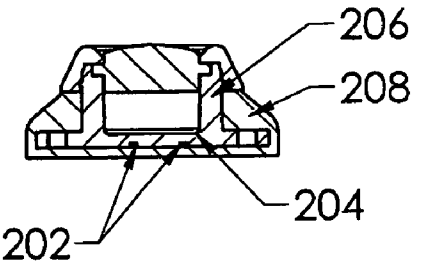

FIG. 15

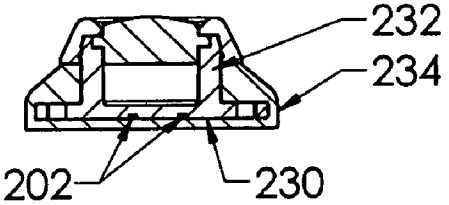

FIG. 17

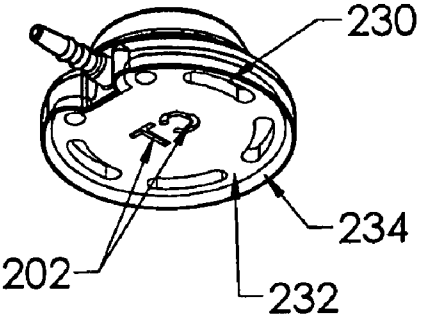

FIG. 18

VENOUS ACCESS PORT ASSEMBLY WITH X-RAY DISCERNABLE INDICIA

CROSS-REFERENCE TO RELATED APPLICATION

This claims the benefit of U.S. Provisional Patent Application Ser. No. 60/961,133 filed Jul. 19, 2007.

FIELD OF THE INVENTION

This relates to the field of medical devices and more particularly to venous access ports for the infusion of fluids into the patient and/or withdrawal of fluids from the patient.

BACKGROUND OF THE INVENTION

Venous access ports for the infusion and/or withdrawal of fluids from a patient are well-known, secured to the proximal end of an implanted catheter. These ports are typically used for drug infusion or for withdrawal of small amounts of blood, where large flows of fluid are not required. The ports are assemblies of a needle-impenetrable housing with a discharge port in fluid communication with the catheter and the reservoir within the port housing, and provide a subcutaneous self-sealing septum that defines an access site for multiple needle sticks through the covering skin tissue of the patient, through the septum and into the reservoir, without the need to continuously search for new access sites. Examples of such ports are disclosed, for example, in U.S. Pat. Nos. 4,704,103; 4,762,517; 4,778,452; 5,185,003; 5,213,574 and 5,637,102.

It is desired to provide a venous access port assembly that provides for a radiologist, radiology technologist, nurse and ultimately a medical practitioner to be able to discern an important property of the port assembly after the port assembly has been implanted into a patient.

BRIEF SUMMARY OF THE INVENTION

The present invention is related to a venous access port having a housing and a septum, providing an interior reservoir and a passageway extending from the reservoir through a stem of a discharge port to establish fluid communication with a proximal end of a catheter lumen to which the port assembly is secured prior to placement of the assembly into a patient. The port may optionally have more than one reservoir and associated septum. The invention is the incorporation of X-ray discernable indicia onto a venous access port that is discernible under X-ray examination to provide information concerning the nature or key attribute of the venous access port, so that the practitioner, subsequent to the date of implantation thereof, can determine that nature or key attribute under X-ray examination. One such key attribute in particular would be for example that the venous access port is rated to be used for power injection such as of contrast fluid, wherein for example the letters "CT" (for "computed tomography", or "contrast enhanced computed tomography") would be provided that are of radiopaque material, or are cutouts through radiopaque material. The attribute in this example is the property of the port's being adapted to withstand high pressures that are used for injection of contrast fluid into a patient, and the letters "CT" would be understood in medical practice to indicate that the port is suitable for the high pressure injection of contrast fluid.

In one embodiment, a disc of radiopaque material includes cutouts therethrough of letters "CT" (although other indicia may be utilized) through the body of the disc. In another

embodiment, discrete letters "CT" (although other indicia may be utilized) are provided of radiopaque material. With either embodiment, the disc or letters may be insert molded within the housing base bottom wall, or they may be affixed to the bottom surface of the housing base, preferably within complementary recesses thereinto, in such a manner that the letters "CT" are readable from above the port assembly in an X-ray.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings, which are incorporated herein and constitute part of this specification, illustrate the presently preferred embodiments of the invention, and, together with the general description given above and the detailed description given below, serve to explain the features of the invention. In the drawings:

FIGS. **1** and **2** are an isometric view and a plan view of the venous access port of the present invention;

FIGS. **3** and **4** are cross-section views of the port of FIGS. **1** and **2** taken along lines **3-3** and lines **4-4** of FIG. **1**, respectively;

FIG. **5** is an isometric view of the needle-impenetrable housing base of the venous access port of FIG. **1**;

FIGS. **6** and **7** are transverse cross-sectional and longitudinal cross-sectional views of the housing base of FIG. **5**;

FIG. **8** is an isometric view of a first embodiment of X-ray discernable indicia, being a disc of radiopaque material having letters cut out thereof;

FIGS. **9** to **11** are bottom, cross-sectional and top views of the port assembly of FIGS. **1** to **7** having the disc of FIG. **8** affixed to the housing base of FIGS. **6** and **7** and within a shallow recess into its bottom surface, with silicone covering molded thereover, and the indicia being shown in dashed lines in FIGS. **9** and **11**;

FIG. **12** is a cross-sectional view of an alternate embodiment of housing base having the disc of FIG. **8** insert molded embedded within the bottom wall of the base;

FIG. **13** is an isometric view of a second embodiment of radiopaque indicia, comprising a set of discrete letters of radiopaque material;

FIGS. **14** and **15** are a bottom view and a cross-sectional view of a port assembly of FIGS. **1** to **7** having the discrete letters of FIG. **13** insert molded into the bottom wall of the housing base, with FIG. **15** taken along lines **15-15** of FIG. **13**; and

FIGS. **16** to **18** are a bottom view, cross-sectional view and an isometric bottom view of a port assembly of FIGS. **1** to **7** having the discrete letters of FIG. **13** affixed to the bottom surface of the housing base, shown within respective recesses thereinto, with a silicone covering molded thereover, with FIG. **17** taken along lines **17-17** of FIG. **16**.

DETAILED DESCRIPTION OF THE INVENTION

Certain terminology is used herein for convenience only and is not to be taken as a limitation on the present invention. The terms "distal" and "proximal" refer, respectively, to directions closer to and away from the insertion tip of a catheter in an implantable catheter assembly. The terminology includes the words specifically mentioned, derivatives thereof and words of similar import. The embodiments illustrated below are not intended to be exhaustive or to limit the invention to the precise form disclosed. These embodiments are chosen and described to best explain the principle of the invention and its application and practical use and to enable others skilled in the art to best utilize the invention.

Venous access port assembly **10** of FIGS. **1** to **4** includes a housing **12** and a septum **14**, with a discharge port **16** extending from a distal end **18** of the port assembly **10** to be attached securely and sealingly to the proximal end of a catheter (not shown). A passageway **20** extends from the interior reservoir **22** to the distal tip opening **24** of discharge port **16**. A recess **26** is seen to be provided along both sides of discharge port **16**, facilitating insertion of the discharge port **16** into the catheter lumen and providing a clearance for a locking sleeve or clamp (not shown) utilized to compress the catheter lumen wall against the exterior surface of the discharge port **16** for assured sealed connection of the catheter with the port assembly **10**.

With reference now to FIGS. **3** to **7**, the interior of the port assembly **10** is shown to provide an interior reservoir **22**. Housing **12** is shown to include a housing base **28** of needle-impenetrable material that includes a well **30** having a bottom floor **32** and side walls **34** that define the interior reservoir **22** beneath septum **14**. Bottom floor **32** may be convex or elevated (not shown) toward the center of the reservoir, if desired. Housing base **28** includes a base flange **36** extending radially outwardly from the bottom of well **30**, and base flange **36** includes openings **38**,**40** that serve to enable suturing to the patient upon placement of the venous access port and the attached catheter into the patient.

As shown in FIGS. **3** and **4**, a skirt **42** is overmolded about housing base **28** and may be of silicone elastomer. It is seen that skirt **42** encapsulates the outer surfaces of the bottom wall **44** and the bottom portion of the side walls **46** of housing base **28**, and is shown to fill in the suture holes **38**,**40**; but since the material is silicone elastomer, suturing is possible since the suturing needle can easily be inserted through the material of skirt **42** and through the suture holes, and thereafter the filled openings provide minimal opportunity for ingrowth of patient tissue into the openings.

Also seen in FIGS. **1** to **4** is cap **48**, which secures to housing base **28** to in turn secure septum **14** in position in the port assembly **10**. Preferably, skirt **42** is insert molded onto base flange **36** of housing base **28** before cap **48** is secured to the upper portion of housing base **28** to secure the septum in position. It is seen in FIGS. **4** and **7** that discharge port **16** is integral with housing base **28** as is preferable. Discharge port **16** is shown to have a pair of annular ridges **50** that facilitate with the mechanical connection of the catheter proximal end with the port assembly **10**. Housing base **28** includes a septum seat **52** extending into the top of well **30**, into which a flange of the septum will be seated, preferably under radially inward compression. Housing base **28** has a bottom outer surface **54**.

FIG. **8** shows a first embodiment of a component of radiopaque material of the present invention in the form of a disc **100**, such as of titanium. Cutouts **102** are formed through the disc body, shown in FIG. **8** as the alphabetical letters "CT". Disc **100** is affixed to the bottom surface **104** of housing base **106** in FIGS. **9** and **10**, preferably within a complementary shallow recess **108** thereinto. A skirt **110** of silicone material is molded over the housing base, and is transparent so that the letters "CT" are visible from below but in a mirror-image orientation on the bottom outer surface of the housing base (FIG. **9**) so that the indicia would appear as "CT" when the X-ray is viewed (FIG. **11**), easily discerned by the radiologist or technologist. Centering of the indicia within the region directly beneath the reservoir and septum minimizes any obscuring by the structure of the venous access port assembly, and the indicia may also be easily discernable should the port assembly be at an angle from the horizontal plane of the X-ray.

In FIG. **12**, an alternate embodiment of the present invention is shown, in which the disc **100** of FIG. **8** is embedded within the thickness of the bottom wall **130** of the housing base **132**, and the X-ray would appear very similar to that shown in FIG. **11** but the indicia would not be visible from below the housing base or the port assembly.

A second embodiment of X-ray discernable indicia is shown in FIG. **13**, and is utilized in the port assemblies of FIGS. **14** to **18**. In FIG. **13**, the indicia comprise a set of discrete indicia elements of radiopaque material, such as being stamped from a sheet of titanium. Again, as is preferred, the indicia comprise the alphabetical letters "C" and "T" and are utilized together as a set. In FIGS. **14** and **15**, the discrete elements are embedded into the thickness of the bottom wall **204** of housing base **206**, so that they would not be visible from below (see FIG. **14**) even though the silicone overmolded skirt **208** is transparent. However, the discrete letters **202** would clearly be visible on an X-ray very similarly to the port assembly shown in FIG. **11**. Another manner of using discrete letters **202** is depicted in FIGS. **16** to **18**, in which the letters **202** are insert molded along the bottom surface **230** of housing base **232** and recessed thereinto, preferably. With this variant, the radiopaque material may be titanium or may be, for example, silicone material having barium sulfate filler. In this case the mirror-image of "CT" would be visible from below as depicted in FIG. **18** after the silicone overmolding of skirt **234** about the exterior of housing base **232**.

It will be appreciated by those skilled in the art that changes could be made to the embodiments described above without departing from the broad inventive concept thereof. It is understood, therefore, that this invention is not limited to the particular embodiments disclosed, but it is intended to cover modifications within the spirit and scope of the present invention as defined by the appended claims.

What is claimed is:

1. An implantable venous access port assembly, comprising:

a needle-penetrable septum; and

a housing securing the needle-penetrable septum, the housing comprising a housing base having a bottom wall and X-ray discernable indicia embedded in the bottom wall, the X-ray discernable indicia comprising one or more characters that visually indicate, under X-ray examination, a pressure property of the port assembly.

2. The assembly of claim **1**, wherein the X-ray discernable indicia are a set of discrete elements.

3. The assembly of claim **2**, wherein the discrete elements are of titanium.

4. The assembly of claim **2**, wherein the discrete elements are of silicone with barium sulfate filler.

5. The assembly of claim **2**, wherein the discrete elements are alphabetical letters.

6. The assembly of claim **2**, wherein the bottom wall comprises an outwardly facing bottom surface comprising one or more shallow recesses, and wherein the discrete elements are affixed in the one or more shallow recesses of the bottom surface so that the discrete elements are visible to an unaided eye prior to implantation of the assembly.

7. The assembly of claim **2**, wherein the discrete elements embedded in the bottom wall are embedded within a thickness of the bottom wall so that the discrete elements are not visible to an unaided eye prior to implantation of the assembly.

8. The assembly of claim **6**, wherein the discrete elements are arranged in a first orientation visible under visual inspection of the port assembly, which first orientation is a mirror

image of a second orientation of an image of the discrete elements perceived during X-ray examination.

9. The assembly of claim **6**, wherein the housing comprises a skirt formed from radiotransparent material and molded around at least a portion of the housing base.

10. The assembly of claim **1**, wherein the X-ray discernable indicia comprise a disc of radiopaque material, the disc comprising cutouts that indicate the pressure property of the port assembly.

11. The assembly of claim **10**, wherein the cutouts are alphabetical letters.

12. The assembly of claim **10**, wherein the disc is titanium.

13. The assembly of claim **10**, wherein the bottom wall comprises an outwardly facing bottom surface comprising at least one shallow recess, and wherein the disc is affixed in the at least one shallow recess of the bottom surface so that the disc is visible to an unaided eye prior to implantation of the assembly.

14. The assembly of claim **10**, wherein the disc embedded in the bottom wall is embedded within a thickness of the bottom wall so that the disc is not visible to an unaided eye prior to implantation of the assembly.

15. The assembly of claim **13**, wherein the cutouts in the disc are arranged in a first orientation visible under visual inspection of the port assembly, which first orientation is a mirror image of a second orientation of an image of the cutouts perceived during X-ray examination.

16. The assembly of claim **13**, wherein the housing comprises a skirt formed from radiotransparent material and molded around at least a portion of the housing base.

17. The assembly of claim **1**, wherein the X-ray discernable indicia visually indicate, under X-ray examination, that the port assembly is rated to be used for power injection.

18. The assembly of claim **17**, wherein the X-ray discernable indicia further visually indicate, under X-ray examination, that the port assembly is adapted to withstand high pressures used for injection of contrast fluid.

19. An implantable venous access port assembly, comprising:

a housing comprising a housing base comprising a bottom wall and radiopaque indicia embedded in the bottom wall of the housing base, the radiopaque indicia comprising one or more characters indicating a pressure property of the port assembly under X-ray examination;

a needle-penetrable septum; and

a cap securing the needle-penetrable septum to the housing.

20. The port assembly of claim **19**, wherein:

the bottom wall of the housing base comprises a bottom surface comprising one or more shallow recesses, and

the radiopaque indicia are affixed in the one or more shallow recesses of the bottom surface of the bottom wall, whereby the radiopaque indicia are visible by an unaided eye prior to implantation of the port assembly.

21. The port assembly of claim **20**, wherein the radiopaque indicia comprise a metal disc affixed in the one or more shallow recesses of the bottom surface of the bottom wall, the metal disc comprising one or more cutouts indicating the pressure property of the port assembly.

22. The port assembly of claim **20**, wherein the radiopaque indicia comprise one or more discrete metal elements separately affixed in the one or more shallow recesses of the bottom surface of the bottom wall.

23. The port assembly of claim **19**, wherein the radiopaque indicia are embedded into a thickness of the bottom wall of the housing base, whereby the radiopaque indicia are not visible by an unaided eye prior to implantation of the port assembly.

24. The port assembly of claim **23**, wherein the radiopaque indicia comprise a metal disc embedded into the thickness of the bottom wall of the housing base, the metal disc comprising one or more cutouts indicating the pressure property of the port assembly.

25. The port assembly of claim **23**, wherein the radiopaque indicia comprise one or more discrete metal elements separately embedded into the thickness of the bottom wall of the housing base.

26. The port assembly of claim **19**, wherein the radiopaque indicia indicate that the port assembly is rated to be used for power injection.

27. The port assembly of claim **26**, wherein the radiopaque indicia indicate that the port assembly is adapted to withstand high pressures used for injection of contrast fluid.

28. An implantable venous access port assembly, comprising:

a housing comprising a housing base and a skirt overmolded around at least a portion of the housing base, the housing base comprising a bottom wall and radiopaque indicia embedded in the bottom wall of the housing base, the radiopaque indicia comprising one or more characters indicating a pressure property of the port assembly under X-ray examination;

a needle-penetrable septum; and

a cap securing the needle-penetrable septum to the housing.

29. The port assembly of claim **28**, wherein:

the bottom wall of the housing base comprises a bottom surface comprising one or more shallow recesses, and

the radiopaque indicia are affixed in the one or more shallow recesses of the bottom surface of the bottom wall.

30. The port assembly of claim **29**, wherein the radiopaque indicia comprise a metal disc affixed in the one or more shallow recesses of the bottom surface of the bottom wall, the metal disc comprising one or more cutouts indicating the pressure property of the port assembly.

31. The port assembly of claim **30**, wherein the overmolded skirt comprises a transparent material, whereby the metal disc comprising one or more cutouts is visible by an unaided eye prior to implantation of the port assembly.

32. The port assembly of claim **29**, wherein the radiopaque indicia comprise one or more discrete metal elements separately affixed in the one or more shallow recesses of the bottom surface of the bottom wall.

33. The port assembly of claim **32**, wherein the overmolded skirt comprises a transparent material, whereby the discrete metal elements are visible by an unaided eye prior to implantation of the port assembly.

34. The port assembly of claim **28**, wherein the radiopaque indicia are embedded into a thickness of the bottom wall of the housing base, whereby the radiopaque indicia are not visible by an unaided eye prior to implantation of the port assembly.

35. The port assembly of claim **34**, wherein the radiopaque indicia comprise a metal disc embedded into the thickness of the bottom wall of the housing base, the metal disc comprising one or more cutouts indicating the pressure property of the port assembly.

36. The port assembly of claim **34**, wherein the radiopaque indicia comprise one or more discrete metal elements separately embedded into the thickness of the bottom wall of the housing base.

37. The port assembly of claim **28**, wherein the radiopaque indicia indicate that the port assembly is rated to be used for power injection.

38. The port assembly of claim **37**, wherein the radiopaque indicia indicate that the port assembly is adapted to withstand high pressures used for injection of contrast fluid.

39. The assembly of claim **1**, wherein the one or more characters comprise one or more alphabetical letters.

40. The assembly of claim **39**, wherein the one or more alphabetical letters comprise the letters "CT."

41. The port assembly of claim **19**, wherein the one or more characters comprise one or more alphabetical letters.

42. The port assembly of claim **41**, wherein the one or more alphabetical letters comprise the letters "CT."

43. The port assembly of claim **28**, wherein the one or more characters comprise one or more alphabetical letters.

44. The port assembly of claim **43**, wherein the one or more alphabetical letters comprise the letters "CT."

* * * * *

CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Federal Circuit Rule 28.1(b)(2)(A). This brief contains 14,863 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). This Brief has been prepared in a proportionally spaced typeface using Microsoft Word 2010 in 14-point font New Times Roman.

Respectfully submitted,

Dated: March 18, 2022

/s/ Alfred W. Zaher
Alfred W. Zaher

Counsel for Medical Components, Inc.

CERTIFICATE OF SERVICE

I, Alfred W. Zaher, hereby certify that on this 18th day of March, 2022, a true and correct copy of the foregoing Principal and Response Brief of Defendant-Cross-Appellant Medical Components, Inc. has been filed electronically and is available for viewing and downloading from the ECF system. I further certify that I caused a true and correct copy of same to be served on all counsel of record via ECF filing.

Respectfully submitted,

Dated: March 18, 2022

/s/ Alfred W. Zaher
Alfred W. Zaher

Counsel for Medical Components, Inc.