No. 23-2056

United States Court of Appeals For the Federal Circuit

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

Plaintiffs-Appellants

v.

ANGIODYNAMICS, INC.,

Defendant-Appellee.

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

CORRECTED BRIEF OF AMICUS CURIAE MEDICAL COMPONENTS, INC. IN SUPPORT OF AFFIRMANCE FOR DEFENDANT-APPELLEE ANGIODYNAMICS, INC.

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Dated: March 14, 2024

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT
CERTIFICATE OF INTEREST

Case Number 23-2056

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

Filing Party/Entity Medical Components, Inc.

Instructions:

1. Complete each section of the form and select none or N/A if appropriate.
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I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: March 14, 2024 Signature: */s/ Alfred W. Zaher*

Name: Alfred W. Zaher

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

☐ Additional pages attached

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

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

☑ Yes (file separate notice; see ☐ No ☐ N/A

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

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

☑ None/Not Applicable ☐ Additional pages attached

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INTEREST OF THE AMICUS CURIAE AND LEAVE TO FILE

Medical Components, Inc. ("MedComp"), a corporation incorporated under the laws of the Commonwealth of Pennsylvania with a principal place of business at 1499 Delp Dr., Harleysville, Pennsylvania, 19438, has an interest in this appeal because it is defending against charges of patent infringement by Bard on highly similar patents and asserted claims in actions pending in Utah District Court. Specifically, MedComp is the Defendant in *C.R. Bard, Inc. et al. v. Medical Components, Inc.*, No. 2:12-cv-00032 (D. Utah), and in *C.R. Bard, Inc. et al. v. Medical Components, Inc.*, No. 2:17-cv-00754 (D. Utah), where Bard has asserted U.S. Patent Nos. 7,785,302; 7,947,022; 7,959,615; 8,382,723; 8,585,663; 8,603,052; and 9,682,186, which all claim vascular access ports identifiable as power-injectable variously by a radiographic feature or by shape.

Pursuant to Federal Circuit Rule 29, this amicus brief is filed with the consent of all parties.

STATEMENT REGARDING AUTHORSHIP AND FUNDING

This brief was authored in whole by the undersigned counsel representing amicus curiae MedComp. No portion of this brief was authored by counsel for either party to this appeal. No party or party's counsel contributed any money intended to fund preparation or submission of this brief. Funds used for preparation and submission of this brief came entirely from amicus curiae MedComp.

SUMMARY OF THE ARGUMENT

The patents and asserted claims at issue in this appeal are to vascular access ports that are: (1) power-injectable, and (2) identifiable as power-injectable after implantation. Following trial on remand, the District Court granted, among other things, judgment as a matter of law ("JMOL") that Bard's asserted patents are invalid as anticipated under 35 U.S.C. § 102. The District Court's grant of JMOL was correct and should be affirmed.

Bard swore under oath to the Patent Office when seeking the asserted claims that its invention was a new access port for power injection that can be identified subcutaneously. *See, e.g.*, 35 U.S.C. § 115(b)(2); Bard's Opening Brief at 7 ("Bard's new port structure"). At the same time, it swore the opposite under oath to the Food and Drug Administration when seeking approval to sell access ports to the public. Appx24402, Appx24440, Appx4692-4693. In fact, Bard used its decades old conventional port, the Bard Adult Titanium Port ("ATP") as a predicate device to prove to the FDA that it already made and sold a safe power injectable port. *Id.* Based on this representation to the FDA Bard obtained certification for its old device to be sold as a power injectable port.

None of this was ever disclosed by Bard to the Patent Office as required under 37 CFR 1.56, not even to this day.

The only difference between Bard's decades old prior art ATP and Bard's "PowerPort" is its shape, color, and the addition of a label which is visible with the naked eye but also can be seen via X-ray after implantation. This Court has already determined that this label is printed matter and entitled to no patentable weight. *C R Bard, Inc. v. AngioDynamics, Inc.* 979 F.3d 1372, 1381-82 (Fed. Cir. 2020).

The District Court held that the asserted claims require power injectable ports with radiographic attributes that recite printed matter. Accordingly, once the printed matter is afforded no patentable weight, the asserted claims are anticipated under 35 U.S.C. § 102 by at least Bard's own ATP, which itself was power injectable and had radiographic attributes.

The District Court should be affirmed on this ground and this Court need not even reach the other issues raised by this appeal.

ARGUMENT

I. THE DISTRICT COURT'S JMOL FOR ANTICIPATION SHOULD BE AFFIRMED

A. The Undisputed Evidence Showed Bard's Power Port is Identical to its Prior Art ATP

Congress, the FDA, and the Patent and Trademark Office ("PTO") have been concerned that in some instances, the makers of drugs, medical devices, biosimilars, etc., are making significantly different statements in submissions to the FDA, that are in direct conflict to statements made to the PTO:

> For example, inconsistent statements submitted to the Food and Drug Administration (FDA) to secure approval of a product — asserting that the product is the same as a prior product that is already on the market— can then be directly contradicted by statements made to the PTO to secure a patent on the product. When a certain piece of prior art is already being applied by the examiner, and the patent applicant has made statements about that prior art to another federal agency that establish that the invention claimed is not novel, making conflicting statements to the PTO should be cause for rejecting the application and, when made knowingly and with bad intent, potentially other sanctions.

See Patrick Leahy & Thom Tillis, Letter to USPTO (Sep. 9, 2021), at 1-2.

That is precisely what occurred here. It is undisputed that years before Bard filed for the asserted patents, some vascular access ports were sold in the United States that were capable of power injection – including Bard's own ATP. *AngioDynamics*, 979 F.3d at 1375. Indeed, this Court noted in *AngioDynamics* that "Bard's commercially marketed vascular access port product was already structurally suitable for power injection, although it had not been approved for such use." *Id*.

After the FDA announced that ports should be labeled to indicate power injection capability, Bard sought FDA approval by submitting test data for its own prior art ATPs. *See* Response Brief of Defendant-Appellee at 30. That is, Bard did not provide the FDA with data for some newly made "PowerPort," but instead provided data using the prior art ATPs and thereby demonstrated that these decades-old, prior art ports were capable of power injection. *Id.* (citing Appx38, Appx 4704-4706, Appx24452, Appx24484-24485). With this data, and with "Bard's swearing

to the FDA that the ATP and PowerPort were 'identical in all aspects that would affect test results,'" Bard persuaded the FDA to allow Bard to market its later-made "PowerPorts" as being rated for power injection. *Id.* (citing Appx24452).

As the District Court held, the asserted patents do not disclose or claim any new structure that makes a port "suitable" for power injection, nor do they disclose or claim any modifications to enable "reliable" or "safe" power injection. *See* Appx27-28. Rather, the claims are directed to ports that are *identifiable* as being capable of power injection. Thus, the only claimed advancement over the prior art is a means to convey to medical practitioners that a port is power injectable. *See* Appx30-31.

The printed matter includes any marking or indicia visible on X-ray (*i.e.*, "radiopaque," "radiographically identifiable," "visible on X-ray," *etc.*), port shape, or textured indicia. Bard merely took its old, prior art port and put an x-ray visible "label" on it and/or shaped it so a person could read the label or associate the shape with *identifying* it as power-injectable; and Bard now claims a patent monopoly over power injectable ports with *any* indicia that ever serves to convey power injectability.

This Court and its predecessor have consistently rejected the notion that "the addition of new printed matter to a known product makes the product patentable." *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1064-65 (Fed. Cir. 2010); *see also*

In re McKee, 64 F.2d 379, 379-80 (C.C.P.A. 1933) (markings on meat "arranged in a certain manner for the purpose of identifying the meat" is printed matter claimed for only what it communicates). The fact that the indicia inform a medical professional that a port is power injectable in no way changes the functioning of the port, just as "informing a patient about the benefits of a drug in no way transforms the process of taking the drug with food." *King Pharms., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 1279 (Fed. Cir. 2010) (a label instructing a patient to take a drug with food); *see also In re Ngai*, 367 F.3d 1336, 1338–39 (Fed. Cir. 2004) (instructions on how to perform a DNA test); *In re Gulack*, 703 F.2d 1381, at 1384-85 (Fed. Cir. 1983) (numbers printed on a wristband); *In re Marco Guldenaar Holding B.V.*, 911 F.3d 1157, 1161 (Fed. Cir. 2018) (markings on dice communicating whether a player has won or lost a wager); *Praxair Distribution, Inc. v. Mallinckrodt Hosp. Prod. IP Ltd.*, 890 F.3d 1024, 1033-34 (Fed. Cir. 2018) (the mental step requiring a medical provider to weigh the benefit of treating neonatal patients with inhaled nitric oxide).

"The common thread amongst all of these cases is that printed matter must be *matter* claimed for what *it* communicates." *In re Distefano*, 808 F.3d 845, 850 (Fed. Cir. 2015) (emphasis added). Only if the printed matter communicates information that is structurally or functionally related to the substrate may it be given patentable weight. *Id.* (citing *In re Gulack* at 1385). Here, the radiographic markings are not structurally or functionally related to the substrate and this Court has already

determined that the radiographic markings are printed matter and not entitled to patentable weight. *AngioDynamics* at 1381, 1383-84.

Here, the District Court correctly followed the developed jurisprudence. The District Court properly recognized that printed matter cannot distinguish a claim from the prior art. *In re Distefano*, 808 F.3d at 848. Therefore, Bard's asserted claims merely read on its own prior art ATP, and the printed matter—radiographic markings and letters—cannot save the claims from anticipation under 35 U.S.C. § 102.

CONCLUSION

Because it was undisputed that Bard's own ATP – and other prior art ports – had been capable of power injection, and the only difference between the asserted patent claims and those prior art ports is mere printed matter, the asserted claims are anticipated under § 102, and no reasonable jury could have found otherwise. The District Court's grant of JMOL for anticipation should be affirmed.

Respectfully submitted,

DATED: March 14, 2024

By: /s/ *Alfred W. Zaher*

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATIONS

Case Number: 23-2056

Short Case Caption: C.R. Bard Inc. *et al.* v. AngioDynamics, Inc.

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