United States Court of Appeals for the Federal Circuit

C R BARD INC., BARD PERIPHERAL VASCULAR, INC.,
Plaintiffs-Appellants

v.

ANGIODYNAMICS, INC.,
Defendant-Appellee

2019-1756, 2019-1934

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

Decided: November 10, 2020

DEANNE MAYNARD, Morrison & Foerster LLP, Washington, DC, argued for plaintiffs-appellants. Also represented by SETH W. LLOYD, BRIAN ROBERT MATSUI; VINCENT JOSEPH BELUSKO, DYLAN JAMES RAIFE, Los Angeles, CA.

DANIELLE VINCENTI TULLY, Cadwalader, Wickersham & Taft LLP, New York, NY, argued for defendant-appellee. Also represented by JACLYN HALL, CHRISTOPHER A. HUGHES, JOHN MOEHRINGER, MICHAEL BRIAN POWELL.

Before REYNA, SCHALL, and STOLL, *Circuit Judges*.

REYNA, *Circuit Judge*.

The appellants, manufacturers of implantable medical devices for intravascular injections, sued their competitor for patent infringement. Partway through the jury trial, the district court granted judgment that the asserted claims were not infringed, were not willfully infringed, and were invalid as directed to printed matter. We hold that there was substantial evidence in the record to support a jury finding of infringement and willfulness. We also hold that the asserted claims are not directed solely to printed matter, and thus are patent eligible under 35 U.S.C. § 101, and that a genuine dispute of material fact precludes summary judgment as to anticipation. Thus, we reverse-in-part and vacate-in-part the district court's judgments and remand for further proceedings.

BACKGROUND

A. The Technology, Patents, and Accused Products

The appellants, C. R. Bard Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard"), and the appellee, AngioDynamics, Inc., are manufacturers of vascular access ports, which are devices implanted underneath a patient's skin that allow medical providers to inject fluid into the patient's veins on a regular basis without needing to start an intravenous line each time. Vascular access ports were traditionally used to administer injections at a low pressure and flow rate. However, certain procedures, like computed tomography ("CT") imaging, required injection of fluids into patients at a high pressure and high flow rate. This type of injection is referred to as "power injection." As of 2005, vascular access ports were not specifically approved by the FDA for use with power injection. Nonetheless, certain medical providers were using existing ports for power injection, and in some cases, the pressure of the injection ruptured the port, seriously injuring the patient. In light

of these reported cases, 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. J.A. 31850–51, 32089.

At the time, Bard's commercially marketed vascular port product was already structurally suitable for power injection, although it had not been approved for such use. Around the time of the FDA warnings, Bard confirmed the power injection capability of its product and proceeded to develop identifiable features that would reliably convey that capability to medical providers after the port was implanted. The primary identifying feature Bard developed was a radiographic marker in the form of the letters "CT" etched in titanium foil on the device. This marker could be detected during an x-ray scan such as the "scout scan" typically performed at the start of a CT procedure. Other identifiers incorporated into the device included a triangular shape and small bumps that were palpable through the skin. Bard also included identifiers with its product that were separate from the device itself, such as labeling on the device packaging and small items to be carried by the patient or kept in the patient's medical records (i.e. a keychain, wristband, or sticker). Bard obtained FDA approval for its new product and launched it under the brand name, PowerPort, as the first vascular access port labeled for power injection.

Bard also filed patent applications claiming its strategies for identifying a power injectable port. These applications eventually issued as the patents-in-suit in this case, U.S. Patent Nos. 8,475,417, 8,545,460, and 8,805,478. The patents have substantially similar written descriptions, and each of the claims require the presence of a radiographic marker identifying the claimed port as power injectable.

The '417 and '460 patents claim "assemblies" and "systems" for identifying a vascular access port as suitable for power injection. Bard asserted claims 5, 6, 12, and 13 of the '417 patent, which each depend from either claim 1 or claim 8; and dependent claims 2 and 4 of the '460 patent, which depend from claim 1. Claim 1 of the '417 patent is illustrative of these claims:

> 1. An assembly for identifying a power injectable vascular access port, comprising:
>
> a vascular access port comprising a body defining a cavity, a septum, and an outlet in communication with the cavity;
>
> a first identifiable feature incorporated into the access port perceivable following subcutaneous implantation of the access port, the first feature identifying the access port as suitable for flowing fluid at a fluid flow rate of at least 1 milliliter per second through the access port;
>
> a second identifiable feature incorporated into the access port perceivable following subcutaneous implantation of the access port, the second feature identifying the access port as suitable for accommodating a pressure within the cavity of at least 35 psi, wherein one of the first and second features is a radiographic marker perceivable via x-ray; and
>
> a third identifiable feature separated from the subcutaneously implanted access port, the third feature confirming that the implanted access port is both suitable for flowing fluid at a rate of at least 1 milliliter per second through the access port and for accommodating a pressure within the cavity of at least 35 psi.

'417 patent col. 30 l. 51–col. 31 l. 6. The asserted dependent claims of the '417 and '460 patents further require that the radiographic marker be in the form of radiographic letters

or other symbols, patterns, or characters, and that the extrinsic identifier include one or more of a key chain, a bracelet, a wrist band, a sticker provided on a patient's chart, a patient ID card, or a label provided on the product packaging.

The '478 patent claims methods for performing a power injection procedure that include identifying a vascular access port suitable for power injections and performing the power injection. Bard asserted claims 3, 5, 9, and 11 of the '478 patent, which each depend from either claim 1 or claim 8. Claim 8 is illustrative of the method claims:

> 8. A method of performing a power injection procedure, comprising:
>
> providing an access port including a cannula-impenetrable housing and a radiographic feature indicating that the access port is suitable for flowing fluid at a rate of at least 1 milliliter per second through the access port;
>
> implanting the access port in a subcutaneous pocket formed under a patient's skin;
>
> taking an image of the implanted access port via imaging technology;
>
> identifying the access port as being suitable for flowing fluid at a rate of at least 1 milliliter per second through the access port via the image of the radiographic feature of the access port; and
>
> injecting contrast media fluid through the access port at a rate of at least 1 milliliter per second.

'478 patent col. 31 ll. 41–56. The asserted dependent claims of the '478 patent contain additional limitations concerning the radiographic feature and external features that are analogous to those in the asserted dependent claims of the '417 and '460 patents.

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