IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

C R BARD INC. ET AL,

PLAINTIFF,

V.

ANGIODYNAMICS INC.,

DEFENDANT.

1:15CV218

MEMORANDUM AND ORDER

This matter is before the Court following plaintiff's presentation of its case at trial. At the end of plaintiff's case, the Court listened to motions and arguments from the parties. The Court determined that plaintiff C.R. Bard Inc. (hereinafter "Bard") had not presented sufficient evidence regarding its claims and, therefore, issued a judgment as a matter of law pursuant to Fed. R. Civ. P. 50(a) at the close of plaintiff's case. The Court made some findings on the record but also told counsel it would follow up with a written memorandum and order and a judgment. Prior to the filing of this Court's memorandum and order, the plaintiff filed an appeal of the rulings this Court made at the close of the plaintiff's case in chief for infringement. With this memorandum and order, the Court enters judgment, and any deadline for appeal of the Court's rulings shall be calculated from this date.

I. BACKGROUND

Bard filed its original application on April 25, 2006; it's '417 patent on July 2, 2013; it's '460 patent on October 1, 2013; and its '478 patent, the method patent, on August 12,

2014.[1] D.I. 192, See Exs. 1-3[2]. The United States Patent Office permitted Bard to patent its "means of identification" concept, and it also issued Bard's method patent. At issue in this infringement action is a port which is a power injection port, with an identifiable feature by x-ray, and an identifiable feature that is separate for the device.

AngioDynamics, Inc. (hereinafter "Angio") filed with the Food and Drug Administration (hereinafter "FDA") in August of 2006 and used Bard as a predicate device. Angio received approval from the FDA. First approval included a round port with a sticker and a hospital wrist band, and there were no indicators that the port was power injectable. However, there was a problem identifying the type of port after insertion. Thereafter, Angio developed the scalloped shape device and it is radiographic.[3]

This case has lingered in the district court since 2015. The parties have hotly disputed discovery, legal issues, two claims construction orders and multiple motions for summary judgment. In the interim, administrative hearings and appeals were taken including a decision in the Federal Circuit. Bard contends the infringing products include a scallop shape and/or a radiopaque CT marking and extraneous identification materials.

[1] Two of them are apparatus patents, the '460 and the '417, and one is a method patent, the '478.
[2] Bard is the owner of the three patents at issue, which are identified as U.S. Patent No. 8,475,417, U.S. Patent No. 8,545,460, and U.S. Patent No. 8,805,478. The Court will use the shortened version of the patent numbers throughout this Memorandum and Order.
[3] "The parties have stipulated and agreed to the following facts. Angio first sold the Smart Port CT between March and May 2007. Angio first sold the Smart Port CT low profile between June and August 2010. Angio first sold the Smart Port CT Mini between June and August 2010. Angio first sold the BioFlo ports between September and November 2013. Angio first sold the Xcela Plus ports without PASV, PASV, all capitals, between September and November 2013. Angio first sold the Xcela Plus ports with PASV, again capital PASV, between March and May 2013. And last, Angio first sold the Xcela ports without PASV, again, PASV, all capitals, between December and February 2009." PASV is a valve technology. D.I. 446, Transcript, 206:24-207:11.

II. LAW

Judgment as a matter of law is appropriate if "the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for [a] party" on an issue. Fed. R. Civ. P. 50(a)(1).[4] "Entry of judgment as a matter of law is a 'sparingly' invoked remedy, granted only if, viewing the evidence in the light most favorable to the nonmovant and giving it the advantage of every fair and reasonable inference, there is insufficient evidence from which a jury reasonably could find liability." Marra v. Phila. Hous. Auth., 497 F.3d 286, 300 (3d Cir. 2007) (citation omitted).

The District Court in DiSalvio stated:

> JMOL, pursuant to Federal Rule of Civil Procedure 50, is appropriate only where, as a matter of law, there is not by sufficient evidence to allow a reasonable juror to arrive at a contrary verdict. See Link v. Mercedes-Benz, 788 F.2d 918, 921 (3d Cir.1986). In making the determination to grant JMOL, the court must find that as a matter of law, "the record is critically deficient of the minimum quantity of evidence from which the jury might reasonably afford relief." Simone v. Golden Nugget Hotel & Casino, 844 F.2d 1031, 1034 (3d Cir.1988). The party opposing JMOL is entitled to the benefit of all reasonable inferences that can be drawn from the evidence in order to determine whether there is any rational basis for the verdict. See Bhaya v. Westinghouse Elec. Co., 832 F.2d 258, 259 (3d Cir.1987). JMOL is only appropriate when there is no evidence or reasonable inference that can be drawn supporting the verdict. See SCNO Barge Lines, Inc. v. Anderson Clayton & Co., 745 F.2d 1188, 1192-93 (8th Cir.1984).

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[4] Fed. R. Civ. P. 50(a) states:

a) Judgment as a Matter of Law.
(1) In General. If a party has been fully heard on an issue during a jury trial and the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue, the court may:
(A) resolve the issue against the party; and
(B) grant a motion for judgment as a matter of law against the party on a claim or defense that, under the controlling law, can be maintained or defeated only with a favorable finding on that issue.
(2) Motion. A motion for judgment as a matter of law may be made at any time before the case is submitted to the jury. The motion must specify the judgment sought and the law and facts that entitle the movant to the judgment.

DiSalvio v. Lower Merion Sch. Dist., CIV.A. 00-5463, 2002 WL 734343, at *1 (E.D. Pa. Apr. 25, 2002). JMOL is appropriate when "a party has been fully heard on an issue and there is no legally sufficient evidentiary basis for a reasonable jury to find for that party on that issue." Fed.R.Civ.P. 50(a)(1) (2002). Hence, a grant of JMOL on an issue is improper if a reasonable jury could find for the nonmoving party on that issue. Doyle v. Crain Indus., Inc., 49 Fed. Appx. 920, 922 (Fed. Cir. 2002).

III. DISCUSSION

At the close of plaintiff's case, Angio moved for judgment as a matter of law of non-infringement on three separate grounds pursuant to Fed. R. Civ. P 50(a).[5] For the purpose of its ruling, the Court considers the evidence presented during the plaintiff's case in chief and the evidence produced in the context of the multiple motions for summary judgment filed by both parties.[6] Throughout the exhausting motion practice for this case, the Court gave the plaintiff the benefit of the doubt, relying on the weight of evidence that may be provided by the plaintiff's expert witness. After the plaintiff presented its evidence about its alleged invention and infringement, the Court finds the defendant's position is correct as a matter of law. Fundamentally, after listening to the evidence presented to the jury and considering the evidence for the previous motions for summary judgment, the Court finds this patent is about labeling, not invention and not

[5] The third ground argued by Angio is that Bard failed to produce evidence of willful infringement. The Court finds herein that there is no infringement, so it follows there is no evidence of willful infringement. Further, Angio received a written opinion of counsel upon which Angio relied regarding both invalidity and infringement. Bard put on no testimony that this opinion by counsel was drafted by a bad law firm, nor did Bard put on any other evidence of willfulness. Bard has failed to sustain its burden t of proof. The JMOL is granted as to willfulness and will not be further discussed herein.

[6] See D.I. 356 at 1-21, addressing summary judgment motions 248, 249, 250, 253, 254, 255, and 256. See also Claims Construction Memorandum and Order, D.I. 416, wherein the Court determined that Judge Robinson did not specifically decide the printed matter issue regarding construction of printed matter, as the Praxair case was not decided until a year later. Id. at 3. Praxair Distrib., Inc. v. Mallinckrodt Hosp. Prods. JP Ltd., 890 F.3d 1024, 1033 (Fed. Cir. 2018).

technology. Praxair Distrib., Inc. v. Mallinckrodt Hosp. Prod. IP Ltd., 890 F.3d 1024, 1032 (Fed. Cir. 2018) ("Claim limitations directed to the content of information and lacking a requisite functional relationship are not entitled to patentable weight because such information is not patent eligible subject matter under 35 U.S.C. § 101"). It is clear from the evidence, or lack of evidence, that the labeling does not change the port and labeling is old technology.

Prior to Bard's disclosure of its power injectable port and indicators, the FDA had issued warnings and reported patient complications with vascular ports being used for power injections. After the FDA warning the standard of medical care required practitioners to identify ports capable of power injection before beginning such procedures. The plaintiff understood this news as an opportunity to create a new market – the power injectable vascular port authorized as a new medical device by the FDA. It tested its vascular ports to determine whether they could withstand the pressure and flow rate necessary for power injection. Bard's port, along with others in the industry, were able to qualify for power injection use without essential modification. Bard's marketing team was also astute enough to understand that labeling its vascular ports would give it a competitive advantage. To that end, it decided to further enhance its market share by obtaining a patent for its labeling. It identified three means of labeling: radiographic, extraneous, and otherwise. It also pursued a method patent that outlined a procedure for identifying its patented power injectable ports.

After consideration of the evidence, the Court finds that the "means of identification" patent claims were no more than features that identified a power injectable

port device, externally and/or subcutaneously. The method claim was no more than a recitation of the standards of medical care required following the FDA warning.

The accused devices use the same letters Bard uses to identify its power injectable vascular ports, CT.[7] The letters CT are recognizable by the medical profession because most power injection procedures are used to inject contrast material in preparation for Computer Tomography Scans (commonly referred to as CT Scans). The accused products etch the letters in titanium ports and use radiopaque foil in plastic valves. Both practices took Bard and the defendant, Angio, a matter of months to test, manufacture and market.

Angio, in its initial attempt to identify its power injectable port, created a scalloped shape. The testimony demonstrated that the significance of this shape was not sufficiently clear to users while the CT marking was unmistakably clear. After seeking a legal opinion, Angio marketed a series of power injectable ports that were marked with the letters CT. Thereafter, Bard sued for infringement.

First, Angio contends that Dr. Timothy Clark's opinions relied on incorrect law. Dr. Clark addressed the claim limitations, but according to Angio, Dr. Clark did not address the Court's claim construction. On cross-examination, Dr. Clark admitted he did not rely on Judge Robinson's claim construction regarding the term vascular access port or

[7] The accused products include:

Smart Port CT
Uses radiographic letters, has a scalloped shape, uses external identification and product use literature
Smart Port LP
Uses radiographic letters, uses external identification, and product use literature.
Smart Port mini
Uses radiographic letters, uses external identification, and product use literature.
Xcela, Xcela Plus, BioFlo
Uses radiographic letters, uses external identification, and product use literature.

access port. See Transcript, D.I. 445, 913:2-914:20. When an expert fails to apply the correct claim construction, the testimony does not create triable issues of fact. Weiner v. NEC Electronics, Inc., 102 F3rd 534, 542 (Fed. Cir. 1996) and Quest Licensing Corp v. Bloomberg, 2017 Westlaw 239345 *3 (D. Del. 2017), aff'd 726 Fed. Appx. 819 (D. Del. 2018). The Court agrees that Dr. Clark did not clearly articulate that he followed the claims constructions issued by the Court.

Second, Angio moved for infringement of the '478 method patent contending that Bard failed to offer sufficient evidence that a single person or entity had performed all steps of the claimed method. The Court agrees Bard did not show that Angio took actions with respect to all steps of the claimed methods. Bard failed to do so, and thus this claim fails. Bard also contends that the reference should be "entity" and not separate out physicians, and hospital, and hospital staff, as they all constitute one entity when determining if all the steps are made in compliance with the law. Limelight Networks, Inc. v. Akamai Tech, 572 U.S. 915, 921-23 (2014) (all the steps claimed in the patent must be performed or attributable to one person, or by a person who exercises all the control, and all steps must be carried out). See Akamai Tech., Inc. v. Limelight Networks, Inc., 797 F.3d 1020, 1022 (Fed. Cir. 2015) ("Where more than one actor is involved in practicing the steps, a court must determine whether the acts of one are attributable to the other such that a single entity is responsible for the infringement. We will hold an entity responsible for others' performance of method steps in two sets of circumstances: (1) where that entity directs or controls others' performance, and (2) where the actors form a joint enterprise"). Dr. Clark, argues Angio, did not introduce any evidence of

infringement by directing the actions of multiple actors. The Court agrees and will also grant the JMOL motion of non-infringement of the '478 Patent on this basis.

In addition, the Court finds there is a failure of proof on the method issue. Bard introduced some evidence regarding a patient at University of Pennsylvania having issues related to the ports. However, the evidence presented that a Smart Port was implanted in that hospital and that the additional required steps taken there is pure speculation. The Court finds there is insufficient evidence, lack of relevant evidence and lack of foundation for this testimony.

Likewise, there is a failure of proof regarding Xcela's being a vascular access for the structured power injection. No one testified in that regard. The only mention is the FDA's indication for power injection, but even Dr. Clark admitted the decision by the FDA was irrelevant to infringement. D.I. 445, Transcript, 828:20-25. Bard provided no testing results on Xcela. The Court will likewise grant JMOL on this issue.

The law is clear, one cannot obtain a patent that simply labels a product, especially if the label is no more than alphabetic letters. Each of the patent claims in this lawsuit rely on the identification of alphabetic letters or words to identify a device. Furthermore, the defendant cannot infringe a patent by simply marking a product with letters that identify its use, nor with a unique shape. This product is not covered by a copyright or trademark protection for the letters "CT", nor a design patent covering the product's shape. The defendant did not infringe the Bard's patent because the patent does not prohibit either.

In addition, the Court notes the following. There is no contention that any of Angio's vascular ports structurally infringe Bard's ports. Bard believes it can prevent

Angio from designing the shape of a port and advertise it as unique for power injection. Bard does not have a design patent. Furthermore, Angio cannot infringe a patent by simply providing instructions for the use of its non-infringing devices.

The Court concludes that the '478 method Patent recites claims that are routine well understood and conventional standards of care present before the claimed invention. "Claim limitations directed to the content of information and lacking a requisite functional relationship are not entitled to patentable weight because such information is not patent eligible subject matter under 35 U.S.C. § 101." Praxair Distrib., 890 F.3d at 1032. The Federal Circuit has generally found printed matter falls outside the scope of § 101. See AstraZeneca LP v. Apotex, Inc., 633 F.3d 1042, 1064 (Fed. Cir. 2010); In re Marco Guldenaar Holding B.V., 911 F.3d 1157, 1161 (Fed. Cir. 2018). See Visual Memory LLC v. NVIDIA Corp., 867 F.3d 1253, 1258 (Fed. Cir. 2017) ("[W]e must ... ask whether the claims are directed to an improvement to computer functionality versus being directed to an abstract idea" (internal quotations omitted)). The shape of the power injectable ports is only protected by a design patent or trademark. Bard has no claim. The extraneous identification materials (I.D. bracelet, I.D. cards, key chain tags, etc.) are not an intrinsic part of the vascular access port and provide no structural function.[8] Any claims under the

[8] Powers, on cross-examination, stated:
Q. Okay. So, identification features. That's the marker, the CT?
A. There are various identification features that are in suit, but CT is one of them, yes.
Q. Okay. So, let's just -- are you alleging we copied the bracelet?
A. I don't think you copied the bracelet, but I don't recall.
Q. Okay. Do we copy the color?
A. I don't think you copied the color, but that was not an important identification feature.
Q. Did we copy the key chain?
A. I don't think so.
Q. Did we copy the sticker?
A. I don't know.
Q. So what are you alleging we copied beyond the marker, the CT marker?
A. The palpable shape, the combination of identification means with the port structured for power injection.
Q. Okay. So, I'll go back to my original question, then. Are you alleging that we copied the port itself?

patent that rely on this claim are unenforceable.[9] The evidence supports that identifying ports capable of power injection by means of the medical record, patient history, product materials or radiograph was routine, conventional and required by the standard of medical

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A. I am not alleging that you copied the port itself. There are aspects that we included that we consider important identification features that were copied and they are radiopaque, and they say the same thing.
Q. What do they say?
A. They suggest to the user that it's a power injectable port with a radiopaque alphanumeric feature.
Q. What is the radiopaque alphanumeric feature that you believe we copied?
A. It says CT.
Q. Does our accused product name have the CT in it?
A. There are more than one accused products, are there not?
Q. Yes. Does the SmartPort CT product have the letters CT in it?
A. I don't remember the correlation with all of those that contain CT.
Q. Does your product have the letters CT in the name?
A. In the name of the product?
Q. Yes.
A. No.
Q. I think you mentioned that we copied the palpable shape. What palpable shape did we copy?
A. They copied a shape that can be identified by palpation. It means to palpate it as an identification means. At least one of the products.

D.I. 444, Depo. Powers, 564:1 – 565:22.

[9] All the claims rely on letters or printed material:

The independent claim for all the patents:
a. power injectable port
b. first identifiable feature
c. second identifiable feature (radiographic marker)
d. third feature – external identification means (wrist bands, etc.)

417 Patent
Claim 5 – identifying letters
Claim 6 – identify external IDs (wrist bands, cards, etc.)
Claim 12 – identify letters
Claim 13 – identify external Ids (wrist bands)

460 Patent
Claim 2 – identify external Ids (wrist bands, etc.)
Claim 4 – identify radiographic marker (letters)

478 Patent (Method)
Claim 3 – identify letters
Claim 5 – identifications not part of the product (ID bracelet, etc.)
Claim 9 – identify letters
Claim 11 – identify letters
(essentially this is a formulation of the standards of care after the FDA notified doctors that the vascular port must be capable of power injection before use as such)

care existing at the time of the alleged invention. The Court agrees that this is ineligible patent subject matter. The Court determines, as it stated on the record that it has no "evidence in the record at all that this is not an abstract idea or that all limitations that were outlined in my order with respect to letters and instructions are even – are even addressed. In fact, everything that you've done has supported the problem that you have with the letters. All you've done is identified your product. I just don't see any evidence in the record that shows me that this patent is eligible under any circumstance." D.I. 446, Transcript, 1229:4-8.

First, the Court agrees that Bard has power ports, but several companies, likewise, have structurally non-infringing power ports. Second, Bard has shown it has radiographic properties suitable for power injection. Bard contends that the scallop shape is an indicator of these claims. The Court disagrees. The evidence demonstrates that doctors did not sufficiently recognize scalloped shape as a power injectable port.

The second alleged infringing feature under the '460 patent are extrinsic indicators identifying the port as power injectable. The evidence is clear that these extrinsic indicators are merely printed material which includes a bracelet and a key tab identifying the product as power injectable. The Court finds these extrinsic indicators are in fact printed material and unpatentable.

As to the '417 patent Bard contends the infringed extrinsic indicators are the scallop shape, the radiopaque letters CT and the device can be identified by palpation. The Court finds the letters and shape are not eligible for patenting as discussed herein. As to whether the shape gives rise to the additional means of identification by palpation, Bard's expert, Powers, admitted that Bard did not invent palpation, as it was well known.

D.I. 444, Transcript – Powers, 579:9-22. Essentially, the expert admitted that none of the alleged infringing means of identification were new or original. On redirect, Mr. Kelly Powers[10] testified:

> Q. Mr. Powers, did you invent radiographic letters?
>
> A. I invented a radiographic identifier that was used in combination with a port structure for power injection to identify that is what it was.
>
> Q. You didn't --
>
> A. Letters being among a broad category that does that in alphanumeric indicia.
>
> Q. But you didn't invent radiographic letters; is that correct?
>
> A. Well, I -- I don't know. I guess I'm not claiming that I invented it. If there are other examples, then I didn't invent it.

D.I. 444, 156:16-157:3. Likewise on cross examination, Dr. Clark testified:

> Q. Okay. So, we agree that there were no changes necessary to the Vaxcel product, then, in order for it to be structured for power injection?
>
> A. Yes.
>
> Q. Okay. Same with Vortex, there were no changes necessary to be made to the Vortex structure in order for it to be structured for power injection?
>
> A. Yes, the same Vortex port that remains on the market, although without the FDA clearance to be marketed as power injectable.
>
> Q. And we also agree that both Vortex and Vaxcel were publicly available and sold and used more than one year before the filing date of these patents?
>
> A. Yes, though not as ports identified as being power injectable.
>
> Q. You're aware that the Vortex ports were sold with labeling, correct?
>
> A. Yes.

[10] During the time in question, Mr. Powers was the head of Research and Development and is alleged inventor of these patents.

Q. And that labeling would have identified the port as a Vortex port?

A. Yes.

Q. You're aware that Vaxcel would also have been sold with labeling?

A. Yes.

Q. And that labeling would have identified the Vaxcel port?

A. Yes.

Q. And both of those ports are structured for power injection?

A. Subsequently shown to be so, yes.

Q. But that doesn't change the fact that they were before. They were structured for power injection more than a year before the filing date of the patents?

A. Right. But I mean as I've said from my own experience just a couple weeks ago we had a patient came into our facility with, I think it was a Vortex port, called the 1-800 number that the patient provided with the ID card and we were instructed not to inject the port.

Q. You didn't provide any evidence of that, right, in your report?

A. Are you implying that that's not so?

Q. I'm just asking, Doctor.

A. It occurred two weeks ago. My report goes back to December of 2017 during your deposition and that deposition occurred following the issuance of my report. So, I don't know how I could have included it in my report after the issuance of my report.

Q. There were no instances -- there were no other instances of that, that issue in your reports, correct?

A. Not in my reports, but it certainly happened multiple times.

Q. But you haven't provided any evidence of that, correct?

A. Other than my 22 years of experience practicing as an interventional radiologist implanting ports.

> Q. Okay. And we saw before, with respect to, put back up 3.68 again. So, with respect to Smart Port, we agree that the separated features is not what makes Smart Port power injectable?
>
> A. Correct.
>
> Q. And the same would be true of Vortex? Correct.

Transcript, D.I. 445, 909:15-912:1.

The Court finds this case is nothing but a labeling issue.[11] Bard used a bracelet, identification card and a key ring. These items are external to the device. They used these to show how to use the Power Port. But the power injectable ports had been in existence for quite some time. Likewise, Bard did not invent CT (computed tomography), nor did it sell CT machines. Bard did not invent the power injection machines or power injection procedures. Bard does not sell the power injection machines. There were power injections as early as 1992; there were titanium ports as early as 1992; the Vortex/Smart Port product belonged to Angio and it existed in 2002. The radiographic markers were not new either. Prior art included a breast implant subcutaneously with a radiographic marker. The Isomed, likewise, had a radiographic label. The Court finds that it does not matter how the information is conveyed, whether it is by CT, color, the bracelet, shape or a separated feature, it is all information. Accordingly, the Court will grant Angio's motion and dismiss this case.

THEREFORE, IT IS ORDERED THAT:

AngioDynamic's oral motion for judgment as a matter of law at the close of

[11] It appears to be true that Bard received FDA approval first. However, the FDA looks at uses for the marketing claims. The FDA then determines whether such uses would be safe. The PTO, on the other hand, decides whether the claims are new and if they have existed before on the market.

plaintiff's case is granted in its entirety, and this case is dismissed.

Dated this 25th day of April 2019.

BY THE COURT:

s/ Joseph F. Bataillon
Senior United States District Judge