IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

| | | |
|---|---|---|
| CRYOLIFE, INC., | ) | |
| | ) | |
| Plaintiff, | ) | |
| | ) | |
| v. | ) | Civ. No. 14-559-SLR |
| | ) | |
| C.R. BARD, INC., DAVOL, INC. AND MEDAFOR, INC., | ) | |
| | ) | |
| Defendants, | ) | |
| | ) | |

**ORDER**

At Wilmington this 10th day of March 2015, consistent with the memorandum issued this same date;

IT IS ORDERED that defendants' motion to dismiss (D.I. 19) is granted in part and denied in part.

United States District Judge

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

| | | |
|---|---|---|
| CRYOLIFE, INC., | ) | |
| | ) | |
| Plaintiff, | ) | |
| | ) | |
| v. | ) | Civ. No. 14-559-SLR |
| | ) | |
| C.R. BARD, INC., DAVOL, INC. AND MEDAFOR, INC., | ) | |
| | ) | |
| | ) | |
| Defendants, | ) | |
| | ) | |

**MEMORANDUM ORDER**

At Wilmington this 10th day of March, 2015, having heard argument on, and reviewed the papers[1] filed in connection with, defendant Medafor, Inc.'s ("Medafor") motion for a preliminary injunction;

IT IS ORDERED that said motion (D.I. 40) is granted, for the reasons that follow:

1. **Background.** On April 28, 2014, plaintiff CryoLife, Inc. ("CryoLife") filed this declaratory judgment action against defendants C.R. Bard, Inc. ("Bard"), Davol, Inc. ("Davol"), and Medafor (collectively, "defendants") seeking a declaration that U.S. Patent No. 6,060,461 ("the '461 patent") is invalid and not infringed. (D.I. 1) On June 19, 2014, defendants moved to dismiss for lack of subject matter jurisdiction and failure to state a claim (D.I. 10), and on June 26, 2014, CryoLife filed an amended complaint

[1] The parties' citations throughout the briefing to abbreviations (D.I. 79 at iv; D.I. 103 at iv), rather than D.I. # s is inconsistent with D. Del. LR 7.1.3(a)(6) and this judge's preferences and added to the court's burden in processing the papers filed in connection with the motion practice.

(D.I. 17). On July 14, 2014, defendants again moved for partial dismissal.[2] (D.I. 19) On August 25, 2014, Medafor filed a counterclaim for infringement. (D.I. 37) On September 19, 2014, Medafor filed a motion for preliminary injunction. (D.I. 40) The court has jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

2. CryoLife is a corporation organized and existing under the laws of the State of Florida with its principal place of business in Kennesaw, Georgia. (D.I. 17 at ¶¶ 1-2) Medafor is a corporation organized and existing under the laws of the State of Minnesota with its principal place of business in Minneapolis, Minnesota. (D.I. 37 at ¶ 1) Bard is a corporation organized and existing under the laws of the State of New Jersey with its principal place of business in Murray Hill, New Jersey. (D.I. 17 at ¶¶ 3-4) Davol is a corporation organized and existing under the laws of the State of Delaware with its principal place of business in Warwick, Rhode Island. Davol is a wholly-owned subsidiary of Bard. (D.I. 17 at ¶¶ 5-6) The parties are each biomedical companies.

3. The '461 patent, titled "Topically Applied Clotting Material," was filed on February 8, 1999 and issued May 9, 2000. Representative independent claim 32 recites:

> A method for enhancing the formation of clots in a wound of an animal where blood is present, the method comprising the steps of: applying porous particles having average diameter dimensions of from about 0.5 to 1000 micrometers to at least a portion of said wound where blood is present in said wound; applying pressure to said porous particles in said wound; and allowing said porous particles to remain in contact with said blood in said wound while clotting initiates in said wound.

[2] Defendants' motion to transfer (D.I. 14) was withdrawn in court during oral argument on January 23, 2015.

Medafor received FDA approval in 2006 for ARISTA® AH ("Arista"), an innovative hemostatic powder that is used to control bleeding when conventional methods are ineffective. (D.I. 22, ex. 2 at 1) In April 2014, CryoLife received FDA clearance to market PerClot Topical ("PerClot"), its powdered hemostat product for topical use. (D.I. 79 at 5) CryoLife is seeking FDA approval to market PerClot for surgical indications ("PerClot Surgical") and received FDA approval of its Investigational Drug Exemption application on March 27, 2014. (*Id.* at 5-6)

4. **Standard**. "The decision to grant or deny ... injunctive relief is an act of equitable discretion by the district court." *eBay, Inc. v. MercExchange, LLC*, 547 U.S. 388, 391 (2006). The grant of such relief is considered an "extraordinary remedy" that should be granted only in "limited circumstances." *See Kos Pharma., Inc. v. Andrx Corp.*, 369 F.3d 700, 708 (3d Cir. 2004) (citation omitted). A party seeking preliminary injunction relief must demonstrate: (1) a reasonable likelihood of success on the merits; (2) the prospect of irreparable harm in the absence of an injunction; (3) that this harm would exceed harm to the opposing party; and (4) the public interest favors such relief. *See, e.g., Sciele Pharma Inc. v. Lupin Ltd.*, 684 F.3d 1253, 1259 (Fed.Cir.2012); *Antares Pharma., Inc. v. Medac Pharma., Inc.*, Civ. No. 14–270, —— F.Supp.3d ——, ——, 2014 WL 3374614, at *2 (D. Del. July 10, 2014). The burden lies with the movant to establish every element in its favor or the grant of a preliminary injunction is inappropriate. *See P.C. Yonkers, Inc. v. Celebrations, the Party and Seasonal Superstore, LLC*, 428 F.3d 504, 508 (3d Cir. 2005). If either or both of the fundamental requirements—likelihood of success on the merits and probability of irreparable harm if

relief is not granted—are absent, an injunction cannot issue. *See McKeesport Hosp. v. Accreditation Council for Graduate Med. Educ.*, 24 F.3d 519, 523 (3d Cir. 1994).

5. **Analysis**. CryoLife submits that the issue of infringement turns on the construction of two limitations. (D.I. 79 at 6) CryoLife proposes that the limitation "porous particles" should be construed as "substantially spherical materials, e.g., beads, comprising voids or channels open to the surface that are sufficient to act as a molecular sieve by allowing blood liquid and low molecular weight blood components to be adsorbed onto the surface and/or absorbed into the surface of the particles." (D.I. 83 at ¶¶ 21-30) Medafor proposes construing this limitation according to the plain and ordinary meaning, that is, "particles containing pores." (D.I. 41 at 9-10; D.I. 43 at ¶ 19) The specification explains that "[t]he terms particles and beads are not intended to denote any substantive difference in size, shape or performance of materials . . . , but are merely alternative terms." (6:15-19) The specification does not use the term "sphere" or "spherical." CryoLife's proposed construction also improperly imports additional limitations "open to the surface" and "molecular sieve" into the claim. (*See e.g.*, '461 patent, claims 1, 24, 44)

6. CryoLife proposes that the limitation, "allowing said porous particles to remain in contact with blood while clotting initiates," be construed as, "upon contact with blood, the particles must remain intact and remain in contact with blood while clotting initiates." (D.I. 79 at 8; D.I. 83 at ¶ 31) Medafor proposes using the plain and ordinary meaning, that "the particles physically touch the blood while clotting begins in the wound." (D.I. 41 at 11; D.I. 42 at ¶ 56) The specification explains that "[t]he particle application should enable direct contact of the particles with the flow of blood, preferably without

any non-clotting intermediate film or material between the blood at the site of the wound and the clotting particles." (4:9-13) The specification does not use the term "intact" to describe the particles.

7. For both of these limitations, the court concludes that Medafor's constructions are consistent with the specification. CryoLife has offered no non-infringement arguments using Medafor's constructions. The court concludes that Medafor has shown a likelihood of success on infringement.

8. As to invalidity, CryoLife argues, without expert testimony or declarations, that certain prior art anticipates[3] or, in combination,[4] renders the asserted claims obvious. CryoLife supports its anticipation and obviousness arguments with reference to a table of invalidity contentions and the barest of attorney argument. *Mytee Prods., Inc. v. Harris Research, Inc.*, 439 Fed. App'x 882, 886 (Fed. Cir. 2011) (concluding that summary judgment of nonobviousness was proper when defendant relied on "nothing more than 'conclusory assertions, gross generalities, and unsupported assumptions made by counsel'" to provide a "reason why a person of ordinary skill would have been motivated to combine the references."); *Schumer v. Laboratory Computer Systems,*

---

[3] U.S. Patent No. 4,225,580 (D.I. 86, ex. 12); U.S. Patent No. 4,002,173 (*id.* at ex. 15); or U.S. Patent No. 5,606,972 (*id.* at ex. 18). Each of these references was considered by the PTO during reexamination.

[4] U.S. Patent No. 4,225,580 (D.I. 86, ex. 12), U.S. Patent No. 5,149,435 (*id.* at ex. 13) and/or Brandenberg, G., et al., *Chitosan: A New Topical Hemostatic Agent For Diffuse Capillary Bleeding In Brain Tissue*, 15(1) Neurosurgery, 9-13 (1994) (*id.* at ex. 14); U.S. Patent No. 4,002,173 (*id.* at ex. 15), U.S. Patent No. 2,914,444 (*id.* at ex. 16) and/or U.S. Patent No. 2,772,999 (*id.* at ex. 17); U.S. Patent No. 5,606,972 (*id.* at ex. 18), Gelotte, B., *Separation of Pancreatic Enzymes by Gel Filtration*, 18 Acta Chemica Scandinavica, 1283-91 (1964) ("Gelotte") (*id.* at ex. 22) and/or U.S. Patent No. 4,624,868 ("the '868 patent") (*id.* at ex. 19). Gelotte and the '868 patent were also considered by the PTO during reexamination.

*Inc.*, 308 F.3d 1304, 1315 (2002) ("Typically, testimony concerning anticipation must be testimony from one skilled in the art and must identify each claim element, state the witnesses' interpretation of the claim element, and explain in detail how each claim element is disclosed in the prior art reference.") CryoLife also briefly argues (with one citation to Medafor's expert testimony) that the '461 patent fails to provide adequate written description support for Medafor's proposed construction of "porous particle," therefore, such construction is indefinite and renders the asserted claims invalid. Attorney argument is not evidence. Medafor has shown a likelihood of success of arguing against CryoLife's invalidity arguments.

9. Medafor[5] has also carried its burden to demonstrate the remaining prerequisites for preliminary injunction relief. There is sufficient record evidence that CryoLife's PerClot product is in direct competition with Medafor's Arista product and that these products are targeted to the same customers and hospitals. (D.I. 41 at 14-15) Medafor has made persuasive arguments for the loss of its customer base and damage to its goodwill. (*Id.* at 15-19) For these reasons, the balance of the hardships and the public interest weigh in Medafor's favor.

10. **Conclusion**. For the foregoing reasons, Medafor's motion for a preliminary injunction is granted.

United States District Judge

[5] Medafor is the owner of the '461 patent and all the intellectual property associated with Arista, therefore, CryoLife's contentions that Medafor cannot suffer harm are without merit. (D.I. 21 at 2; D.I. 106 at ¶ 20)