IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA

CRYOLIFE, INC.,	)	
	)	
Plaintiff,	)	
v.	)	Civil Action No.
	)	
C.R. BARD, INC.; DAVOL, INC.; and MEDAFOR, INC.,	)	
	)	
Defendants.	)	
	)	

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff CryoLife, Inc. ("CryoLife") brings this action against Defendants C.R. Bard, Inc. ("Bard"), Davol, Inc. ("Davol"), and Medafor, Inc. ("Medafor") (collectively, "Defendants") for Declaratory Judgment of Non-Infringement and Invalidity of United States Patent No. 6,060,461.

PARTIES

1. CryoLife is a corporation organized and existing under the laws of the State of Florida with its principal place of business at 1665 Roberts Boulevard, NW, Kennesaw, Georgia 30144.

2. CryoLife is a biomedical company that manufactures, markets, and distributes surgical adhesives, sealants and hemostats, cardiac lasers, and

implantable end-stage renal disease access grafts, and it processes, preserves, and distributes human cardiac and vascular tissues.

3. On information and belief, Bard is a corporation organized and existing under the laws of the State of New Jersey with its principal place of business at 730 Central Avenue, Murray Hill, New Jersey 07974.

4. On information and belief, Bard is a multinational manufacturer and marketer of medical technologies in the fields of vascular, urology, oncology, and surgical specialty products.

5. On information and belief, Davol is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 100 Crossings Boulevard, Warwick, Rhode Island 02886. On information and belief, Davol is a wholly-owned subsidiary of Bard.

6. On information and belief, Davol is a biomedical company specializing in comprehensive soft tissue reconstruction, delivering a line of mesh prosthetics, biologic implants and fixation systems.

7. On information and belief, Medafor is a corporation organized and existing under the laws of the State of Minnesota with its principal place of business at 4001 Lakebreeze Avenue, Minneapolis, Minnesota 55429. On information and belief, Medafor is a wholly-owned subsidiary of Davol.

THE PATENT-IN-SUIT

8. On May 9, 2000, United States Patent No. 6,060,461 B1, entitled "Topically Applied Clotting Material," issued to James Franklin Drake. On September 4, 2012, the United States Patent and Trademark Office issued Reexamination Certificate No. 6,060,461 C1. United States Patent No. 6,060,461 B1 and Reexamination Certificate No. 6,060,461 C1 (collectively, "the '461 patent") is attached as Exhibit A.

9. Medafor is the assignee of record of the '461 patent.

10. On information and belief, Bard (through its wholly-owned subsidiary Davol) owns all right, title and interest in and to, or has valid rights to use, sell, import and license the '461 patent.

JURISDICTION AND VENUE

11. This action arises under the Patent Laws of the United States of America, 35 U.S.C. § 1 *et seq.* This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331 and 1338, based on an actual controversy between CryoLife and Defendants for claims under the Patent Laws of the United States of America, 35 U.S.C. § 1 *et seq.* CryoLife is seeking relief pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

12. This Court has personal jurisdiction over Bard. On information and belief, Bard maintains a division located in Covington, Georgia for the design, manufacture and sale of medical devices and products, and Bard sells its products in various states, including Georgia. On information and belief, Bard maintains a registered agent, Corporation Process Company, in this district at 2180 Satellite Boulevard, Suite 400, Duluth, Georgia 30097. Bard has also availed itself of this Court's jurisdiction by filing suit in this Court (*see C.R. Bard, Inc. v. Transcon Lines*, No. 1:86-cv-01840-GET) and by filing counterclaims in this Court (*see Go Medical Industries Pty, Ltd. v. C.R. Bard, Inc.*, No. 1:95-cv-02307-HTW; *Medical Marketing Group, Inc. v. C.R. Bard, Inc.*, No. 1:93-cv-01539-JOF; *Advance-United v. C.R. Bard, Inc.*, No. 1:89-cv-02149-ODE; *Beraha v. C.R. Bard, Inc.*, No. 1:88-cv-02823-JTC; and *Go Medical Industries Pty, Ltd. v. C.R. Bard, Inc.*, No. 1:93-cv-01538-HTW).

13. This Court has personal jurisdiction over Davol. On information and belief, Davol conducts business in various states, including Georgia. Additionally, Davol has availed itself of this Court's jurisdiction. *See Cofer v. Davol, Inc.*, No. 1:09-cv-00370-WSD.

14. This Court has personal jurisdiction over Medafor. Medafor has availed itself of this Court's jurisdiction by filing a counterclaim in this Court. *Cryolife, Inc. v. Medafor, Inc.*, No. 1:09-cv-01150-AT.

15. This Court may also exercise personal jurisdiction over Medafor by virtue of Bard and Davol's acquisition of Medafor. Bard (through its wholly-owned subsidiary Davol) acquired Medafor and its Arista hemostat product. (Exhibit B at I-3.) In an August 19, 2013 letter to shareholders, Medafor Chief Executive Officer Gary J. Shope wrote, "I am thrilled to share with you that the Medafor Board of Directors has approved a definitive agreement for our company to be acquired by Davol Inc., a division of C. R. Bard, Inc[.]" (Exhibit C.) Bard also announced the acquisition of Medafor via a press release on August 19, 2013, noting that "[t]his acquisition is expected to expand the business opportunities for Bard surgical specialties in its Davol subsidiary." (Exhibit D.)

16. The August 19, 2013 Bard press release further stated that "the Arista® hemostat provides a great alternative to other commercially available hemostats while providing strong synergy with our Progel® Sealant technology and sales channel. This technology platform represents an important building block for our surgical specialty product offering and provides a global footprint for continued expansion." (Exhibit D.)

17. Bard closed on its acquisition of Medafor on October 1, 2013. (Exhibit E.) On information and belief, by April 1, 2014, Bard (through its wholly-owned subsidiary Davol) owns, controls, and directs all operations formerly controlled by Medafor including marketing, sales, and distribution of the Arista product.

18. On information and belief, Bard (through its wholly-owned subsidiary Davol) owns all right, title and interest in and to, or has valid rights to use, sell, import and license the ’461 patent.

19. On information and belief, Arista is a commercial embodiment of the ’461 patent.

20. On information and belief, Arista is sold exclusively by Bard through its wholly-owned subsidiary Davol. Medafor’s website no longer exists; instead, a web user who types in http://www.medafor.com is automatically directed to http://www.davol.com/products/biosurgery/arista/, a Davol webpage on “Arista™ AH Absorbable Hemostatic Powder with MPH Technology.” On that webpage, Arista is described as “The Latest Generation in Hemostasis from Bard®.” Bard (through its wholly owned subsidiary Davol) represents that “Bard, Davol and Arista are trademarks and/or registered trademarks of C. R. Bard, Inc.” (Exhibit F, accessed by http://www.davol.com/default/assets/File/Arista%20Product%20Information.pdf.)

21. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b). Bard, Davol, and Medafor are each subject to personal jurisdiction in this District, and thus reside in this District under 28 U.S.C. § 1391(b)(1).

BACKGROUND

CryoLife's Perclot® Products

22. CryoLife has developed and sought to commercialize two PerClot Polysaccaride Hemostatic System products for the United States market, namely one for use to control bleeding during surgical procedures ("PerClot IDE"), and another for use in topical applications such as topical ENT surgical wounds and nosebleeds, for the control of bleeding from the skin at percutaneous needle access, vascular access, and percutaneous catheter access sites ("PerClot Topical") (collectively, "PerClot").

23. PerClot is a medical device composed of absorbable polysaccharide granules and delivery applicators. PerClot granules have a molecular structure that rapidly absorbs water, forming a gelled adhesive matrix that provides a mechanical barrier to further bleeding. The gelled adhesive matrix thus promotes the normal, physiological clotting cascade.

24. PerClot has CE mark designation, indicating it complies with applicable European laws and regulations, and CryoLife began distributing PerClot in several international markets in the fourth quarter of 2010.

25. On April 4, 2011, CryoLife issued a press release publicly announcing that it had filed an Investigational Drug Exemption ("IDE") application with the United States Food and Drug Administration ("FDA") to begin a pivotal clinical trial to gain FDA approval to commercialize PerClot in the United States (*i.e.*, PerClot IDE). (Exhibit G.)

26. The PerClot IDE is a prospective, multicenter, multidisciplinary, controlled clinical investigation. The study is designed to include 324 patients across cardiac, general and urological surgical specialties. The primary objective of the investigation will be to collect clinical data concerning the safety and efficacy of PerClot versus Arista in multiple surgical disciplines when used as an adjunct to conventional means of achieving hemostasis such as pressure or ligature.

27. On April 2, 2014, CryoLife announced that it received FDA approval of its PerClot IDE. CryoLife plans to begin enrollment in the trial in the second quarter of 2014 and could receive pre-market approval from the FDA by the end of 2015. (Exhibit H.)

28. CryoLife has already secured FDA clearance to market PerClot Topical. Under Section 510(k) of the Federal Food, Drug, and Cosmetic Act, a device manufacturer who intends to introduce a device into commercial distribution is required to submit a premarket notification, or 510(k), to the FDA at least 90 days before commercial distribution is to begin. The Act provides that the FDA grant clearance for marketing and commercial distribution for a device deemed safe and effective.

29. On July 5, 2013, CryoLife submitted a 510(k) notification to the FDA for PerClot Topical. PerClot Topical is the same as PerClot (the medical device that is the subject of the pending PerClot IDE application) but is intended for other uses, namely "as a topical dressing for the temporary treatment of mildly bleeding wounds such as surgical wounds (post-operative, donor sites, dermatological), cuts and laceration and for the treatment of mild bleeding from topical ENT surgical wounds and nosebleeds. It is also indicated for control of bleeding from the skin at percutaneous needle access, vascular access, and percutaneous catheter access sites." (Exhibit I.)

30. On April 3, 2014, CryoLife received a 510(k) clearance letter from the FDA regarding PerClot Topical. The letter states that CryoLife may market PerClot Topical subject to the general control provisions of the Act. (Exhibit I.)

31. CryoLife plans to begin marketing and selling PerClot Topical in the United States by summer 2014.

The Presence Of An Actual Case Or Controversy

32. Medafor has expressed an intent to enforce the '461 patent against CryoLife. On September 18, 2012, five months after CryoLife publicly announced that it had filed the PerClot IDE and fourteen days after the reexamination certificate for the '461 patent issued, outside counsel for Medafor sent a cease and desist letter to Steve Anderson, Chairman, President and Chief Executive Officer of CryoLife, stating:

> You have advised the public that you hope to introduce a product in the United States that will, when used in accordance with the method you have published in your literature and with the instructions for use, infringe Medafor's '461 patent. Specifically PerClot and PerClot Laparoscopic, if made or sold in the United States in conjunction with the instructions for use, will infringe the '461 patent and therefore CryoLife, Inc. will be inducing infringement of Medafor's '461 patent rights.
>
> It is our understanding that you do not currently have approval for and therefore currently cannot make or sell PerClot and PerClot Laparoscopic or any other hemostat particle in the United States. On behalf of Medafor, we request that you refrain from making or selling PerClot and PerClot Laparoscopic in the United States and immediately cease any plans to make or sell PerClot and PerClot Laparoscopic or any other product that will induce infringement of Medafor's patent rights in the United States.

(Exhibit J.)

33. On information and belief, Medafor's September 18, 2012 communication to CryoLife demonstrates Medafor's belief that CryoLife has been infringing or would infringe the '461 patent following the FDA's approval of PerClot.

34. On September 18, 2012, the same day that Medafor sent the cease and desist letter to CryoLife, Medafor and HemArrest, Inc. filed a patent infringement lawsuit against Hemostasis LLC ("Hemostasis") in the District of Minnesota alleging that Hemostasis "has been and is making, using, selling, offering for sale, and/or importing, without license or authority from [Medafor and HemArrest, Inc.], in [the District of Minnesota] and elsewhere in the United States, certain hemostat powders, including, without limitation, BleedArrest Powder OTC and NexStat Topical Hemostat Powder (collectively, the "Hemostasis Accused Products") and have induced the sale and/or use in [the District of Minnesota] and elsewhere in the United Sates of those Hemostasis Accused Products which results in direct infringement one or more of the claims of the '461 Patent." (*Medafor, Inc. v. Hemostasis, LLC*, No. 12-2407 (D. Minn.), D.I. 1.)

35. CryoLife has obtained 510(k) clearance from the FDA for PerClot Topical, and it expects to begin selling PerClot Topical by summer 2014.

36. The FDA posted on its website that PerClot Topical received 510(k) clearance. (Exhibit K.)

37. On information and belief, Defendants became aware of CryoLife's 510(k) for PerClot Topical in April 2014.

38. On information and belief, Defendants have monitored and continue to monitor CryoLife's activities with the FDA as they pertain to the PerClot IDE.

39. CryoLife has made substantial preparations to make, sell, and offer to sell its PerClot products in the United States. CryoLife has expended substantial resources related to its PerClot products, with respect to both development and regulatory (*i.e.*, FDA) approvals. CryoLife continues to expend substantial resources in securing FDA approval of the PerClot IDE, including enrolling 324 patients in clinical trials. CryoLife will continue expending substantial resources throughout the approval process, as well as through launching and marketing its PerClot products.

40. The facts alleged herein show that a substantial controversy exists between CryoLife and the Defendants, parties having adverse legal interests, regarding the validity and alleged infringement of the '461 patent, and that this controversy is of sufficient immediacy and reality to warrant the issuance of a

declaratory judgment. CryoLife has the right to manufacture, use, offer to sell, sell, and/or import PerClot without a license to the '461 patent.

41. On information and belief, if this action is dismissed for lack of subject matter jurisdiction, one or more of the Defendants will sue CryoLife for infringement of the '461 patent in this Court or another court promptly upon commencement of the sale of CryoLife's PerClot products.

42. This Court may and should exercise its broad discretion to adjudicate this action under the Declaratory Judgment Act. There is no better or more effective remedy or forum for resolving the present controversies between the parties regarding the '461 patent and CryoLife's PerClot products. Such adjudication will serve the underlying purpose of the Declaratory Judgment Act by resolving legal disputes between CryoLife and Defendants as it relates to the availability of CryoLife's PerClot products. These disputes should be resolved efficiently and economically in this action, deciding the controversies between the parties with certainty, completeness, and finality.

COUNT I

(Declaratory Judgment Of Non-Infringement Of The '461 Patent)

43. Paragraphs 1 to 40 are incorporated herein as set forth above.

44. An actual and justiciable case or controversy exists between CryoLife and Defendants regarding the alleged infringement of the ’461 patent by CryoLife’s PerClot products.

45. The manufacture, use, offer for sale, and/or sale of CryoLife’s PerClot products has not infringed, does not infringe, and would not, when marketed and sold, directly or indirectly infringe any valid claim of the ’461 patent, either literally or under the doctrine of equivalents.

46. CryoLife is entitled to a judgment declaring that the manufacture, use, offer for sale, and/or sale of CryoLife’s PerClot products before expiration of the ’461 patent does not and will not constitute infringement of the ’461 patent.

COUNT II

(Declaratory Judgment Of Invalidity Of The ’461 Patent)

47. Paragraphs 1 to 44 are incorporated herein as set forth above.

48. An actual and justiciable case or controversy exists between CryoLife and Defendants regarding the invalidity of the ’461 patent.

49. The claims of the ’461 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and 112.

50. CryoLife is entitled to judgment declaring that the claims of the ’461 patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, CryoLife respectfully requests that this Court enter the following relief pursuant to 28 U.S.C. §§ 2201 and 2202:

a. That a declaration be issued under 28 U.S.C. § 2201 that the manufacture, use, offer for sale, and/or sale of CryoLife’s PerClot before expiration of the ’461 patent do not and will not infringe, literally or under the doctrine of equivalents, any valid claim of the ’461 patent;

b. That a declaration be issued under 28 U.S.C. § 2201 that the claims of the ’461 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and 112;

c. That an injunction be issued enjoining Defendants and their agents, representatives, attorneys, employees, and those persons in active concert or participation with them who receive actual notice herefrom from threatening or initiating infringement litigation against CryoLife or its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors or customers of

CryoLife, or charging them either orally or in writing with infringement of the '461 patent;

d. That this case be adjudged an exceptional case under 35 U.S.C. § 285, and awarding CryoLife its attorneys' fees and costs; and

e. That the Court award all other and further relief as it deems just and proper.

Dated: April 29, 2014

Respectfully submitted,

WOMBLE CARLYLE SANDRIDGE & RICE, LLP

/s/ Chittam U. Thakore
Chittam U. Thakore
Georgia Bar No. 890965
John W. Cox
Georgia Bar No. 134059
WOMBLE CARLYLE SANDRIDGE & RICE, LLP
Atlantic Station
271 17th Street, NW, Suite 2400
Atlanta, GA 30363
jwcox@wcsr.com
cthakore@wcsr.com
(404) 872-7000
(404) 888-7490 (fax)

Attorneys for Plaintiff CryoLife, Inc.

Of Counsel:

Mary W. Bourke
Dana K. Severance
222 Delaware Avenue, Suite 1501
Wilmington, DE 19801
(302) 252-4320
(302) 252-4330 (Fax)
mbourke@wcsr.com
dseverance@wcsr.com