

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

In Re: COOK MEDICAL, INC., IVC FILTERS
MARKETING, SALES PRACTICES AND
PRODUCTS LIABILITY LITIGATION

Case No. 1:14-ml-2570-RLY-TAB
MDL No. 2570

This Document Relates to:

David McDermitt
1:18-cv-00946

THE COOK DEFENDANTS' BRIEF
IN SUPPORT OF PLAINTIFF'S MOTION TO
MAINTAIN DOCUMENTS UNDER SEAL [DKT. NO. 13065]

I. INTRODUCTION

Plaintiff has filed Plaintiff's Memorandum of Law in Support of Motion to Exclude or Limit the Expert Testimony of Antonios P. Gasparis, M.D. [Dkt. No. 13063] (the "Memorandum"). Plaintiff has submitted as supporting **Exhibit A [Dkt. No. 13064-1]** the Expert Report of Antonios P. Gasparis, M.D. (dated January 13, 2020) and as supporting **Exhibit B [Dkt. No. 13064-2]** the Expert Report of Todd A. Lee, Ph.D. (dated January 13, 2020). **Exhibit A [Dkt. No. 13064-1]** and **Exhibit B [Dkt. No. 13064-2]** include and rely on confidential and proprietary Cook commercial and business information produced by Cook and designated as "Company Confidential" or "Confidential – Subject to Protective Order" by the Cook Defendants¹, pursuant to Case Management Order #8 (Stipulated Protective Order on Confidential Information). In accordance with Local Rules 5-11(d)(1) and 5-11(d)(2)(A)(ii), Plaintiff filed **Exhibit A [Dkt. No. 13064-1]** and **Exhibit B [Dkt. No. 13064-2]** to the

¹ The Cook Defendants in this matter are Cook Incorporated, Cook Medical LLC (f/k/a Cook Medical Incorporated), and William Cook Europe ApS (collectively, the "Cook Defendants" or "Cook").

Memorandum *under seal*. Further, Plaintiff has filed Plaintiff's Motion to Maintain Documents Under Seal [Dkt. No. 13065].

As the parties designating the documents and information as confidential, the Cook Defendants submit this Brief in Support of Plaintiff's Motion to Maintain Documents Under Seal and respectfully request that the Clerk of this Court maintain **Exhibit A [Dkt. No. 13064-1]** and **Exhibit B [Dkt. No. 13064-2]** *under seal*.

The Clerk should maintain **Exhibit A [Dkt. No. 13064-1]** and **Exhibit B [Dkt. No. 13064-2]** *under seal* because there is good cause for sealing the documents. The documents contain Cook confidential and proprietary trade secrets, product research and development, post-market product analysis, sales, marketing, and public relations, regulatory affairs, or complaint handling documents and information. **Exhibit A [Dkt. No. 13064-1]** and **Exhibit B [Dkt. No. 13064-2]** contain confidential business and commercial information entitled to be protected from disclosure. There is good cause to maintain the documents *under seal* in order to protect the Cook Defendants' interests in their confidential and proprietary information and to protect the Cook Defendants from competitive harm.

Further, **Exhibit A [Dkt. No. 13064-1]** contains and discusses private, sensitive medical information regarding Plaintiff David McDermitt. There is good cause to maintain **Exhibit A [Dkt. No. 13064-1]** *under seal* out of an abundance of caution to protect Plaintiff's interest in his medical privacy.

II. THE APPLICABLE LEGAL STANDARD

1. Under Federal Rule of Civil Procedure 26(c)(1)(G), the court may, "for good cause," enter an order "requiring that a trade secret or other confidential research, development, or commercial information not be revealed or be revealed only in a specified way." *See also*

Baxter International, Inc. v. Abbott Laboratories, 297 F.3d 544, 546 (7th Cir. 2002) (documents that “meet the definition of trade secret or other categories of bona fide long-term confidentiality” may be sealed). Likewise, private health information should be maintained under seal at least until consent by the patient is obtained. *See generally Cole v. Janssen Pharmaceuticals, Inc.*, 2017 WL 2929523, at *3 (E.D. Wis. July 10, 2017).

2. **Trade Secrets** – Indiana has generally adopted the definition of trade secret found in the Uniform Trade Secret Act.² *See, e.g., Star Scientific, Inc. v. Carter*, 204 F.R.D. 410, 414 (S.D. Ind. 2001).³ Under this standard, a protectable trade secret has four characteristics: (1) information; (2) that possesses independent economic value; (3) that is not generally known or readily ascertainable by proper means by other persons who can obtain economic value from its disclosure or use; and (4) is the subject of efforts to maintain its secrecy that are reasonable under the circumstances. *See, e.g., Hamilton v. State Farm Mut. Auto Ins. Co.*, 204 F.R.D. 420, 423 (S.D. Ind. 2001); *Zemco Mfg., Inc. v. Navistar Intern. Transp. Corp.*, 759 N.E.2d 239, 245-46 (Ind. Ct. App. 2001); *Burk v. Heritage Food Serv. Equip., Inc.*, 737 N.E.2d 803, 813 (Ind. Ct. App. 2000).

3. Other confidential business or commercial information that does not technically fit the definition of trade secret is similarly entitled to the same level of protection as trade secrets if its disclosure would be harmful physically or economically. *See Chaib v. GEO Grp., Inc.*, 2014 WL 4794194, at *1–3 (S.D. Ind. Sept. 24, 2014); *Ellis v. CCA of Tenn., LLC*, 2009

² The presence of Cook’s headquarters in Indiana justifies the application of Indiana trade secret law to the issues here, because Indiana is the state where Cook would feel any injury or harm. *See, e.g., Micro Data Base Sys., Inc. v. Dharma Sys., Inc.*, 148 F.3d 649 (7th Cir. 1998) (applying Indiana choice-of-law principles in a trade-secret case and holding that New Hampshire substantive law governed because the entity holding the trade secrets was headquartered there).

³ The Indiana Uniform Trade Secret Act is identical to the Uniform Trade Secrets Act, 1(4), 14 U.L.A. 438 (1985).

WL 234514, at *1 (S.D. Ind. Feb. 2, 2009) (finding that protection is required where disclosure of certain proprietary information would “provide a blueprint for competitors”).

4. **Research and Development** – Federal courts, including this court, have consistently held that product development, research, and testing documents and information are entitled to protection from disclosure as confidential and proprietary business information. Such information constitutes confidential business information because “a competitor’s access to [a company’s] research and development . . . present[s] potential dangers and may lead to a windfall to the discovering party.” *Star Scientific*, 204 F.R.D. at 416 (S.D. Ind. 2001) (Baker, J.); *see also United States ex rel. Long v. GSD&M Idea City LLC*, 2014 WL 12648520, at *2 (N.D. Tex. Jan. 3, 2014) (“[I]nformation in which the producing party has a commercial interest, such as . . . research data, . . . has been found to constitute confidential commercial information.”); *Kowalsky v. Hewlett-Packard Co.*, 2012 WL 892427, at *2 (N.D. Cal. Mar. 14, 2012) (exhibits were “sealable in their entirety because they contain[ed] HP’s confidential product testing and evaluation process”); *cf. Andrx Pharm., LLC v. GlaxoSmithKline, PLC*, 236 F.R.D. 583, 586 (S.D. Fla. 2006) (“Courts dress technical information with a heavy cloak of judicial protection because of the threat of serious economic injury to the discloser of scientific information.” (citation omitted)), *affirmed*, 2006 WL 2403942 (S.D. Fla. 2006).

5. **Post-Market Product Analysis** – Similarly, post-market product analysis is also entitled to protection from disclosure as confidential and proprietary business information. Disclosure of such proprietary post-market analysis information is harmful because it would “provide a blueprint for competitors.” *Ellis v. CCA of Tenn., LLC*, 2009 WL 234514, at *1 (S.D. Ind. Feb. 2, 2009); *see also Star Scientific*, 204 F.R.D. at 415 (research and data, such as sales

techniques, constitute protectable trade secrets because “the information is created to enhance their business and give them a competitive edge”).

6. **Sales, Marketing, and Public Relations** – Confidential marketing plans or sales strategies have been held to constitute protectable trade secrets or protected confidential business information. *See, e.g., PepsiCo, Inc. v. Redmond*, 54 F.3d 1262, 1270 (7th Cir. 1995) (trade secret material for sports drink includes information regarding the pricing, distribution and marketing of the drink and not just the drink formula); *Star Scientific*, 204 F.R.D. at 415 (research and data, such as sales techniques, constitute protectable trade secrets because “the information is created to enhance their business and give them a competitive edge”); *Burk v. Heritage Serv. Equip.*, 737 N.E.2d 803, 814 (Ind. Ct. App. 2000) (finding that employee unfairly used marketing information and sales strategies in breach of the Indiana trade secrets clause); *see also Brunswick Corp. v. Jones*, 784 F.2d 271 (7th Cir. 1986) (confidential marketing strategies held protectable); *AGS Capital Corp., Inc. v. Prod. Action Intern., LLC*, 884 N.E.2d 294, 311 (Ind. Ct. App. 2008) (stolen information related to marketing strategy would “put [a company’s competitors] at a severe disadvantage”). Good cause exists to maintain the confidentiality of such strategic plans and analysis when disclosure of that information would reveal the company’s “response to changing market situations and competitive threats within the marketplace, and could therefore give a competitor insight into “[the company’s] internal thinking” and when publicizing this material “would allow [the company]’s competitors the benefit of this information without incurring the effort or expense.” *Bradburn Parent/Teacher Store, Inc. v. 3M*, 2004 WL 1146665, at *4 (E.D. Pa. May 19, 2004) (citation omitted).

7. **Regulatory Affairs** – Courts have held that information related to regulatory compliance and/or submission efforts and strategies constitutes confidential business

information. *See, e.g., Bayer Healthcare, LLC v. Norbrook Labs., Ltd.*, 2009 WL 3444938, at *1 (E.D. Wisc. Oct. 23, 2009) (good cause existed to seal deposition testimony and internal company emails containing proprietary commercial information and strategy related to an FDA filing). Such proprietary information, like confidential information regarding pricing and sales, is confidential because “the information is created to enhance [companies’] business and give them a competitive edge”. *Star Scientific*, 204 F.R.D. at 415.

8. **Complaint Handling** – Internal complaint handling procedures and materials constitute trade secrets in Indiana if they contain (1) information; (2) that derives independent economic value; (3) is not generally known or readily ascertainable by proper means by other persons who can obtain economic value from its disclosure or use; and (4) is the subject of efforts reasonable under the circumstances to maintain its secrecy. *Zemco Mfg., Inc. v. Navistar Intern. Transp. Corp.*, 759 N.E.2d 239, 245-46 (Ind. Ct. App. 2001); *see also, e.g., Hamilton v. State Farm Mut. Auto. Ins. Co.*, 204 F.R.D. 420, 423-24 (S.D. Ind. 2001); *Rep. Servs. Inc. v. Liberty Mut. Ins. Cos.*, 2006 WL 1635655, at *5 (E.D. Ken. June 9, 2006) (concluding that claims handling and training materials “had economic value to [defendant] due to (1) their confidential nature, (2) the time, effort, and expense [defendant] invested in creating these materials, (3) the evolutionary process surrounding the development of these materials, (4) the competitive nature of the [industry’s] business, and (5) the fact that competitors in [that] industry do not disclose information about their claims handling policies and procedures to one another.”).

9. **Internal Information on Corporate Structure and Business Operations** – Courts also have determined that information about a corporation’s internal business operations and corporate structure is confidential and proprietary and, therefore, entitled to protection from

public disclosure. *E.g., True Health Chiropractic, Inc. v. McKesson Corporation*, 2015 WL 3409721 (USDC N.D. Cal.) (May 27, 2015) at *4 (granting motion to seal confidential and proprietary information about the defendant’s internal business operations and corporate structure).

10. **Confidential Financial Information** – Similarly, Courts have determined that highly-sensitive and confidential information including financial records, production records, manufacturing records, sales records, customer information, and vendor information is entitled to protection from public disclosure. *See e.g., ABRO Indus., Inc. v. 1 New Trade, Inc.*, 2015 WL 13655677 (USDC N.D. Ind.) (Sept. 16, 2015) at *3 (granting plaintiff’s motion for a protective order with respect to confidential information about its financial records, sales, customers, and pricing).

11. **Communications with Consulting Experts** – Federal Rule of Civil Procedure 26(b)(4)(D) protects against an opposing party’s discovery of facts and/or opinions of “consulting experts” who are retained in anticipation of litigation and not expected to testify at trial. Furthermore, Federal Rule of Civil Procedure 26(b)(3) protects from discovery documents and tangible things that are prepared in anticipation of litigation by a party’s consultant.

12. **Medical Privacy** – With respect to medical information, courts in the Seventh Circuit have routinely recognized that, while parties’ medical information may be made public where it is relevant to the claims at issue and/or necessary to the disposition of the case, other information may be kept under seal with good cause. *See Westedt v. Franklin*, 2016 WL 2997504, at *1 (E.D. Wis. May 23, 2016); *Gibson v. Milwaukee Cnty.*, 2015 WL 12964665, at *1 (E.D. Wis. Mar. 26, 2015); *Noe v. Carlos*, 2008 WL 5070463, at *3 (N.D. Ind. Nov. 26, 2008). The good cause inquiry thus requires balancing a party’s acknowledged interest in

medical privacy, *see Whalen v. Roe*, 429 U.S. 589, 599–600 (1977), against the Court’s (and parties’) interest in the accurate resolution of the conflict and the public interest in transparency. *Cole v. Janssen Pharmaceuticals, Inc.*, 2017 WL 2929523, at *3 (E.D. Wis. July 10, 2017). Private health information should be maintained under seal at least until consent by the patient is obtained. *See generally id.* at *3.

13. The “good cause” standard under Rule 26(c) “requires a balancing of the potential harm to the litigants’ interests against the public’s right to obtain information concerning judicial proceedings.” *Star Scientific, Inc. v. Carter*, 204 F.R.D. 410, 415-16 (S.D. Ind. 2001) (Baker, J.); *see also Felling v. Knight*, 211 F.R.D. 552, 554 (S.D. Ind. 2003) (“The rule essentially operates to balance the public’s interest in open proceedings against an individual’s private interest in avoiding annoyance, embarrassment, oppression, or undue burden or expense.”) (Baker, J.). Consistent with the doctrine discussed earlier, however, “the presumption of public access ‘applies only to the materials that formed the basis of the parties’ dispute and the district court’s resolution; other materials that may have crept into the record are not subject to the presumption.” *Goesel v. Boley Int’l (H.K.) Ltd.*, 738 F.3d 831, 833 (7th Cir. 2013) (citing *Baxter Int’l*, 297 F.3d at 548)).

III. THE CONFIDENTIAL DOCUMENTS AT ISSUE THAT SHOULD BE MAINTAINED UNDER SEAL

Exhibit A [Dkt. No. 13064-1] is the Expert Report of Antonios P. Gasparis, M.D. (dated January 13, 2020). Dr. Gasparis’ report includes information related to Cook’s post-market product analysis and complaint handling for IVC filters from documents produced by Cook marked “Company Confidential” or “Confidential – Subject to Protective Order.” Dr. Gasparis’ report should be maintained under seal for good cause to protect Cook’s confidential business and commercial information. Further, Dr. Gasparis’ report references and discusses in detail

Mr. McDermitt's medical history, conditions, and treatment. Dr. Gasparis' report should be maintained under seal out of an abundance of caution to protect Mr. McDermitt's medical privacy.

Exhibit B [Dkt. No.13064-2] is the Expert Report of Todd A. Lee, Ph.D. (dated January 13, 2020). Dr. Lee's report includes information related to Cook's post-market product analysis and complaint handling for IVC filters from documents produced by Cook marked "Company Confidential" or "Confidential – Subject to Protective Order." Dr. Lee's report states, "This report contains confidential material and is subject to the order governing the production, exchange and filing of confidential material in this matter." Dr. Lee's report should be maintained under seal for good cause to protect Cook's confidential business and commercial information.

IV. THERE IS GOOD CAUSE TO MAINTAIN THE DOCUMENTS UNDER SEAL

Good cause exists to maintain **Exhibit A [Dkt. No. 13064-1]** and **Exhibit B [Dkt. No. 13064-2]** to the Memorandum *under seal*. **Exhibit A [Dkt. No. 13064-1]** and **Exhibit B [Dkt. No. 13064-2]** contain confidential business and commercial information, and the Cook Defendants would face competitive and economic harm if such materials were made publicly available. **Exhibit A [Dkt. No. 13064-1]** and **Exhibit B [Dkt. No. 13064-2]** contain and constitute confidential, proprietary, and sensitive internal company information on trade secrets, product research and development, post-market product analysis, sales, marketing, and public relations, regulatory affairs, complaint handling, internal corporate structure and business operations, or confidential financial information. **Exhibit A [Dkt. No. 13064-1]** and **Exhibit B [Dkt. No. 13064-2]** should not be disclosed to the public.

The Cook Defendants' May 1, 2017 letter to Magistrate Baker and the Declaration of Mark Breedlove (attached here for reference as **Exhibit 1**) are instructive and demonstrate good

cause to maintain **Exhibit A [Dkt. No. 13064-1]** and **Exhibit B [Dkt. No. 13064-2]** to the Memorandum *under seal*. Cook invests substantial resources into product research, development, and testing, including with regard to Cook's IVC filter technology. Breedlove Decl. ¶ 6. Cook maintains strict confidentiality over its research and development ideas, efforts, and results, and considers such information to be proprietary to the company. *Id.* And disclosure of such information would therefore result in competitive harm to Cook and could "lead to a windfall to the discovering party." *Star Scientific*, 204 F.R.D. at 416; Breedlove Decl. ¶¶ 6-7. Likewise, Cook invests considerable resources in, derives commercial advantage from, and maintains strict confidentiality over, its post-market product analysis, its sales, marketing, and public relations information, its regulatory affairs strategies and information, and its complaint handling procedures. *Id.* at ¶¶ 8-15. Disclosure of Cook's non-public post-market product analysis, its sales, marketing, and public relations information, its regulatory affairs efforts and strategies, and its complaint handling procedures and information would likewise cause competitive harm to Cook. Breedlove Decl. ¶¶ 8-15; *see EEOC v. Abbott Labs., Inc.*, 2012 WL 3842460, at *2-3 (E.D. Wis. Sept. 5, 2012).

In sum, good cause exists to maintain **Exhibit A [Dkt. No. 13064-1]** and **Exhibit B [Dkt. No. 13064-2]** *under seal*. Cook's trade secrets, product research and development, post-market product analysis, sales, marketing, and public relations, regulatory affairs, complaint handling, internal corporate structure and business operations, and financial documents and information are confidential and proprietary. The disclosure of such information and documents would result in competitive harm to Cook. **Exhibit A [Dkt. No. 13064-1]** and **Exhibit B [Dkt. No. 13064-2]** should be sealed and maintained under seal to protect Cook's interest in its post-market product analysis and complaint handling information for IVC filters.

Further, good cause exists to maintain **Exhibit A [Dkt. No. 13064-1]** under seal because the document contains private, sensitive, and confidential medical information regarding Plaintiff Mr. McDermitt. As set forth above, courts in the Seventh Circuit have routinely recognized that, while parties' medical information may be made public where it is relevant to the claims at issue and/or necessary to the disposition of the case, other information may be kept under seal with good cause. *See Westedt*, 2016 WL 2997504, at *1; *Gibson*, 2015 WL 12964665, at *1; *Noe*, 2008 WL 5070463, at *3. The good cause inquiry thus requires balancing a party's acknowledged interest in medical privacy, *see Whalen*, 429 U.S. at 599–600, against the Court's (and parties') interest in the accurate resolution of the conflict and the public interest in transparency. *Cole*, 2017 WL 2929523, at *3. Private health information should be maintained under seal at least until consent by the patient is obtained. *See generally id.* at *3.

Exhibit A [Dkt. No. 13064-1] contains private, sensitive, and confidential medical information regarding Mr. McDermitt. Plaintiff's medical history, conditions, and treatment are highly relevant to the issues in this case. However, out of an abundance of caution, the Court should permit this document to be filed and maintained under seal until Plaintiff consents to what should be disclosed.

V. CONCLUSION

For all the foregoing reasons, the Cook Defendants respectfully request that the Court issue an Order directing the Clerk to maintain **Exhibit A [Dkt. No. 13064-1]** and **Exhibit B [Dkt. No. 13064-2]** *under seal*. The documents contain Cook confidential, proprietary, and sensitive internal company information on post-market product analysis and complaint handling. There is good cause to seal these documents to prevent public disclosure and competitive harm to the Cook Defendants. Further, **Exhibit A [Dkt. No. 13064-1]** also contains private, sensitive

and confidential medical information regarding Plaintiff Mr. McDermitt. There is good cause to seal the document out of an abundance of caution to protect Plaintiff's interest in his medical privacy.

In accordance with Local Rule 5-11(e)(4), the Cook Defendants have submitted a proposed order maintaining the documents under seal.

Respectfully submitted,

Dated: May 26, 2020

/s/ Andrea Roberts Pierson
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CERTIFICATE OF SERVICE

I hereby certify that on May 26, 2020, a copy of the foregoing **THE COOK DEFENDANTS' BRIEF IN SUPPORT OF PLAINTIFF'S MOTION TO MAINTAIN DOCUMENTS UNDER SEAL [DKT. NO. 13065]** was filed electronically, and notice of the filing of this document will be sent to all parties by operation of the Court's electronic filing system to CM/ECF participants registered to receive service in this matter. Parties may access this filing through the Court's system.

/s/ Andrea Roberts Pierson