

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

PROVIDENCE, SC.

Filed 7-21-09

SUPERIOR COURT

BARBARA BROKAW, RAYMOND :  
MUTZ, TAMMY OAKLEY, and :  
DELZA YOUNG :  
 :  
v. :  
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 :  
 :  
DAVOL INC. and C.R. BARD, INC. :

C.A. No. 07-5058

C.A. No. 07-4048

C.A. No. 07-1706

C.A. No. 07-3666

DECISION

GIBNEY, J. Before this Court is the motion of Plaintiffs—Barbara Brokaw, Raymond Mutz, Tammy Oakley, and Delza Young, (“Plaintiffs”)—to Require Compliance with the Court’s Protective and Confidentiality Order (Protective Order). Defendants C.R. Bard, Inc. and Davol Inc. (collectively “Defendants”) object to said motion. At issue is whether Defendants violated the terms of the Protective Order by designating the substantial majority of the documents thus far produced during discovery as “confidential.”

**I**

**Factual Background**

This litigation involves products liability cases related to alleged defects in the Compositx Kugel Mesh Patch, a device designed, manufactured and distributed by Defendants for use in the repair of hernias. There are currently over 1000 such cases pending before this Court.

On August 22, 2007, by agreement of the parties, this Court entered a Protective Order, pursuant to Super. R. Civ. P. 26(c).<sup>1</sup> The Protective Order governs “confidential, proprietary and other protected information” that may be disclosed during the course of these actions. (Protective Order, ¶ 1.) The Protective Order provides that “any Party may designate as ‘Confidential Material’ any information reasonably and in good faith believed to be suitable for protection under applicable law . . . .” Id. at ¶ 2. The Order limits use of the “confidential” designation to information subject to a legal privilege under the law of this state:

‘Confidential’ material will at all times only apply to information that is subject to a legal privilege under Rhode Island Law. In the event that material is not subject to a legal privilege under Rhode Island Law, the designation of ‘Confidential’ . . . and the terms of this Protective Order will have no application. Id. at ¶ 1.

Materials designated as “confidential” may not be released to the public or used in other legal actions as defined by the Protective Order. Id. at ¶¶ 10, 15.

Should a party object to a designation of material as proprietary, confidential, or otherwise protected, the Protective Order requires “a good faith effort to resolve the dispute informally with the disclosing Party.” Id. at ¶ 13. If the parties are still unable to resolve the dispute, the objecting party may apply to the Court “within a reasonable time” for a ruling that the contested information should not be entitled to protection under the Protective Order. Id. The Party designating the material as confidential has the burden of proving that the material is subject to protection. Id.

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<sup>1</sup> The parties stipulated to a substantially similar Protective Order in related litigation in the United States District Court for the District of Rhode Island.

In a letter to Defendants, dated January 29, 2008, Plaintiffs first raised the issue that is the subject of this motion; namely, that Defendants were allegedly designating documents as “confidential” essentially as a matter of course. Specifically, Plaintiffs complained that Defendants had given a confidential designation “to each and every document produced in the course of discovery in the Rhode Island State cases.” The Plaintiffs requested that Defendants withdraw the confidential designation given to every document produced and re-designate only those documents that Defendants “reasonably believe[d] in good faith” are suitable for protection under Rhode Island Law. On February 4, 2008, Defendants responded to Plaintiffs’ request by re-designating a small percentage of the documents identified in Plaintiffs’ letter, while insisting that the vast majority of their confidential designations were appropriate.

On October 14, 2008, Plaintiffs filed the instant motion alleging that Defendants continued to violate the “good faith” requirements of the Protective Order by designating virtually every document produced as confidential.<sup>2</sup> The “blanket” use of the

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<sup>2</sup> Prior to filing this motion, the issue was raised orally during a May 1, 2008 hearing in the related federal court cases. Following the hearing, the federal court issued a Practice and Procedure Order Number 10, which provides:

**Confidential designations.** Defendants shall not use “blanket” confidential designations for all documents produced to Plaintiffs. For each and every document produced, the producing party shall make [a] reasonable and good faith determination regarding whether the document should be marked as confidential prior to the initial production.

Plaintiffs raised the issue a second time at a similar hearing in federal court on September 8, 2008. The Court advised Defendants’ counsel of “the need to be very careful about documents that are so marked [“confidential”] and for them to make an assessment as to whether or not it truly falls within the protective order . . . .” (Tr., Sept. 8, 2008 Chambers Conference, 13.)

confidential label, Plaintiffs argue, is a significant burden because the Protective Order places numerous restrictions on how confidential documents may be used.<sup>3</sup>

In its motion, Plaintiffs have identified and provided examples of ten categories of documents labeled confidential by Defendants that they believe typify the abuse of the confidential designation. The Plaintiffs request this Court to order Defendants to “review, reconsider, and re-designate where appropriate, each and every document produced thus far and provide the Plaintiffs with logs showing which of the already produced pages should be deemed ‘Confidential’ under the Protective Order,” and which should not.

The Defendants counter that Plaintiffs’ motion should be denied as untimely and contrary to the agreed procedure for settling disputes as set forth in the Protective Order. Specifically, Defendants argue that Plaintiffs waited eight months after its only proper confidentiality challenge in January 2008, to file the instant motion. In the interim, Defendants point out that 224,709 documents (totaling 1,843,931 pages) have been produced. The Defendants insist that Plaintiffs should have identified for Defendants the specific documents challenged and, if still unsatisfied, they should have made a motion “within a reasonable time.” Furthermore, Defendants argue that the Protective Order and Super. R. Civ. P. 26(c)(7) bestow broad protections on confidential commercial information, including the documents at issue. The wholesale review of all documents

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<sup>3</sup> Pursuant to the Protective Order, all pages bearing the confidential designation must be treated as “confidential and private.” (Protective Order, ¶ 9.) The disclosure of material marked confidential is permissible only insofar as it is reasonably necessary to prosecute Plaintiffs’ claims and defenses. Id. Confidential material may also only be disclosed to those directly involved in the litigation, such as the parties, counsel of record, and the experts and contractors retained by them. Id. at ¶ 10. In addition, Plaintiffs’ counsel must maintain a list of all persons to whom confidential disclosures have been made, advise each person of the Protective Order, and require each one to sign an agreement to be bound by its terms. Id. Plaintiffs must seek leave of court to file a document under seal if that filing includes any exhibits which have been designated “confidential.” Id. at ¶ 16.

produced to date, Defendants protest, would be “an astronomic burden and a staggering remedy,” one likely to set the litigation back months.

## II Standard of Review

The Superior Court has broad discretion to regulate how and when discovery occurs. Martin v. Howard, 784 A.2d 291, 296 (R.I. 2001) (citing Colvin v. Lekas, 731 A.2d 718 (R.I. 1999); Bashforth v. Zampini, 576 A.2d 1197 (R.I. 1990)). Rule 26(c) of the Superior Court Rules of Civil Procedure permits the Court to issue “any order which justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense . . . .” As with all our Rules of Civil Procedure, Rule 26(c) should always be “construed and administered to secure the just, speedy, and inexpensive determination of every action.” Super. R. Civ. P. 1; Martin v. Howard, 784 A.2d 291, 296 (R.I. 2001).

Protective orders are commonly obtained by agreement of the parties, particularly with respect to confidential information and in litigation involving a large volume of documents. Wright, Miller & Marcus, Federal Practice and Procedure: Civil 2d § 2035 at 476 (1994). “Frequently these take the form of ‘umbrella’ protective orders that authorize any person producing information to designate that which is confidential as protected under the order.” Id. “When the volume of potentially protected materials is large, an umbrella order will expedite production, reduce costs, and avoid the burden on the court of document-by-document adjudication.” David F. Herr, Annotated Manual for Complex Litigation (Fourth), § 11.432, at 94 (2008). However, some courts have found that these types of protective orders “simply postpone, rather than eliminate, the need for

close scrutiny of discovery material to determine whether protection is justified, thereby delaying rather than expediting the litigation.” Id.

### **III Analysis**

#### **Rule 26(c)(7)’s “Good Cause” Requirement**

By the language of the Protective Order, the designation of “confidential” is appropriate only when Defendants “reasonably and in good faith” believe that the material is subject to “a legal privilege under Rhode Island Law.” (Protective Order, ¶¶ 1, 2.) Rhode Island law recognizes at least forty-two evidentiary privileges. See Advisory Committee’s Note to R.I. R. Evid. 501; Robert B. Kent et al., Rhode Island Civil and Appellate Procedure, § 26:7 (2006). In addition to the privileges grounded in the law of evidence, Super. R. Civ. P. 26(c)(7) permits the Court to provide qualified protection for “a trade secret or other confidential research, development, or commercial information.” See Kent, § 26:7. In order to obtain such protection, however, the party seeking it must show “good cause.”

Rhode Island case law interpreting Rule 26(c)(7)’s “good cause” requirement is sparse. Since the language of Rhode Island Rule 26(c)(7) is substantially the same as the comparable federal rule, this Court will look to federal court interpretations for guidance in this matter. See Hall v. Insurance Co. of North America, 727 A.2d 667, 669 (R.I. 1999) (“[F]ederal-court interpretations of a procedural rule that is substantially similar to one of our own state rules of civil procedure should serve as a guide to the construction of our own rule.”); see also Committee Note to Super. R. Civ. P. 26 (Subdivision (c) . . . “generally tracks the federal rule.”).

Federal courts have interpreted “good cause” in this context as a two-prong requirement. The party seeking the protective order must first establish that the material sought to be protected constitutes a trade secret or confidential information. See Wright, Miller & Marcus, Federal Practice and Procedure, § 2043, at 555. Courts tend to define the term “trade secret” narrowly, and most look to the definition provided by the Restatement of Torts.<sup>4</sup> Id. at 556.

Aside from trade secrets, the rule also encompasses “other confidential research, development, or commercial information.” Fed. R. Civ. P. 26(c)(1)(g). This latter category has been held to include “a wide variety of business information,” including, but not limited to, patent agreements, financial records and statements, license fees and oral contracts with customers, customer and supplier lists, and profit and gross income data. See Zenith Radio Corp. v. Matsushita Elec. Indus. Co., Ltd., 529 F.Supp. 866, 890, n.42 (D.C. Pa. 1981). However, in order to obtain a protective order for confidential material a party must show that the material has actually been treated confidentially. See Brittain v. Stroh Brewery Co., 136 F.R.D. 408, 415 (M.D.N.C. 1991).

Once the party seeking protection has established that the material is either a trade secret or confidential information within the meaning of the rule, the party must then demonstrate that disclosure will work “a clearly defined and serious injury” and the resisting party “will indeed be harmed by disclosure.” Zenith Radio Corp., 529 F.Supp. at 891. Conclusory statements, unsubstantiated by specific examples are generally

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<sup>4</sup> The six factors to ascertain whether information is a trade secret are (1) the extent to which the information is known outside the business; (2) the extent to which it is known by employees and others involved in the business; (3) measures taken to guard the secrecy of the information; (4) the value of the information to the holder and his competitors; (5) the amount of effort or money to develop the information; and (6) the ease or difficulty with which the information could be properly acquired or duplicated by others. DDS, Inc. v. Lucas Aerospace Power Transmission Corp., 182 F.R.D. 1, 5 (N.D. N.Y. 1998).

insufficient. Id.; see also Anderson v. Cryovac, Inc., 805 F.2d 1, 7 (1<sup>st</sup> Cir. 1986) (finding of good cause must be based on “a particular factual demonstration of potential harm”). However, “hard and fast rules in this area are inappropriate,” and “the court’s common sense is a helpful guide.” Zenith Radio Corp., 529 F.Supp. at 891.

Where a broad umbrella protective order is in place, as is the case here, a party need not make a particularized showing to initially designate a document as “confidential,” but should have a “good faith” belief that the documents are entitled to protection. See Manual for Complex Litigation § 11.432, n.134; see also Cipollone v. Liggett Group, Inc. et al., 785 F.2d 1108, 1122 (3d. Cir.1986) (stating that the umbrella order initially protects “all documents that the producing party designated in good faith as confidential”). The opposing party must then “indicate precisely which documents it believed to not be confidential,” and the party asserting confidentiality has the burden of proof in justifying the protective order with respect to those documents. Cipollone, 785 F.2d at 1122. The burden of proof is at all times on the party asserting confidentiality; “only the burden of raising the issue with respect to certain documents would shift to the other party.” Id.

### **Defendants’ Procedural Argument**

Utilizing this standard, the Court will proceed to evaluate whether Defendants have met their burden for attaching confidential designations to each of the categories of documents identified by Plaintiffs. Before proceeding, however, the Court will briefly address Defendants’ procedural argument; namely, that that Plaintiffs’ motion should be dismissed because they identified the challenged documents by category, rather than by

specific document, and that they failed to file this motion within a reasonable time, as provided in paragraph 13 of the Protective Order.

As to timeliness, while the Court agrees that Plaintiffs could, and probably should, have made a motion earlier than they did to head off this problem before document production accumulated to the extent that it has, this Court will not dismiss Plaintiffs' motion on account of delay. The Protective Order itself does not require such a remedy, and the record indicates that this issue was brought to the attention of the federal court multiple times before the motion was filed. The Defendants were clearly on notice that this was a contested issue and would continue to be so as discovery proceeded. The Court, therefore, rejects the argument that Plaintiffs "sat on their hands" as Defendants relied to their detriment on the status quo.

Nor does the Court fault Plaintiffs for contesting Defendants' designations by category, rather than by specific document. While it is true that the Plaintiffs have the burden under the Protective Order of raising the issue with respect to certain documents, see Cipollone, 785 F.2d at 1122, the Court finds that they satisfied that burden by organizing challenged documents into categories and providing examples. Given the extent of the disagreement between the parties, which involves thousands upon thousands of documents, addressing this issue through representative samples of various categories of documents is the only practical way in which to proceed. See id. at 1123, n.18 ("the time it would take a judicial officer to rule on the protectability of thousands of documents could cripple the court[]"); see also Zenith Radio Corp., 529 F.Supp. 866 (declassifying by discrete category a large quantity of documents marked confidential pursuant to a protective order).

### **Analysis of Document by Discrete Category**

The Court will now address each category of documents in the order in which Plaintiffs challenged them. The Defendants maintain that their liberal use of confidentiality designations with respect to the following categories of documents is in keeping with their companies' protection of their business information from the general public and specific competitors. The Defendants point out that they "operate in the competitive field of hernia patches against seven other major competitors . . . in which scientific and technical advantages are the source of continued success of each company," and they "keep their information in highly secure headquarters with security systems for the entire building." In addition, Defendants argue that they "operate under strictly enforced federal regulations that the FDA and HHS promulgate, such as HIPAA . . . ." In sum, Defendants maintain that "as two highly regulated businesses whose business models are predicated on intellectual property and which receive private medical information from patients and their medical providers," they have good cause to support their confidentiality designations.

#### **1**

#### **DVDs and Hard Drives**

The Plaintiffs first challenge Defendants' practice of labeling data storage devices, such as DVDs, hard drives, and discs as "confidential." The Plaintiffs insist that "[a]s the entire drive is designated as "confidential," we [Plaintiffs] must treat every page printed from that hard drive (hundreds of thousands of pages) as if it is subject to the Protective Order. The Court disagrees. Paragraph 6 of the Protective Order provides that

[i]f responses to interrogatories, requests for admission, or other written responses to discovery . . . contain Confidential Material, the Parties may designate them as

Confidential Material by marking the face of any such response . . . and indicating the page and line references of the material that is subject to this Protective Order.

The confidential designation on storage devices merely serves as a warning that some of its contents are subject to the Protective Order. In order to be deemed confidential, the documents within the storage device must also bear a confidential label. Defendants, themselves, advanced this interpretation of the Protective Order in their memorandum. Accordingly, Plaintiffs need only treat documents contained in storage devices as confidential if the individual documents therein are labeled as such.

## 2

### **Blank Pages and Corporate Logos**

The Court need not waste time determining whether blank pages, corporate logos, file placeholder sheets, and the like, are confidential. They are not. Neither party contends that they are. The Plaintiffs brought these documents to the Court's attention as evidence that Defendants are "rubberstamping" documents as confidential. The Defendants, however, maintain that most blank pages and corporate logos marked confidential are, in fact, "an artifact of the production process" that occurs when an email containing an image file cannot be produced on the same page as the text. These items get marked confidential because "the instructions to the production vendor were to code every document as confidential unless a reviewer had marked it non-confidential."

Therein lies the problem. Defendants should have given their product vendor the opposite instruction; namely, the vendor should have coded every document as nonconfidential unless the attorney reviewers marked it confidential. This would have

been more consistent with the terms of the Protective Order and would have insured more careful review of individual documents.

This Court will not, however, grant Plaintiffs' request to require Defendants to identify and re-designate blank pages and the like as nonconfidential. To do so would only waste time and do nothing to further Super. Ct. R. Civ. P. 1's objective of providing for a "just, speedy, and inexpensive determination of every action." Moreover, the Protective Order provides that "[i]n the event any material is not subject to a legal privilege under Rhode Island Law, the designation of "Confidential" . . . will have no application. (Protective Order, ¶1.) Therefore, the parties may henceforth treat these obviously nonconfidential items as common sense would dictate.

### 3

#### **Product Inserts, Technique Guides, Instructions for Use, and Labeling.**

The Plaintiffs challenge Defendants' confidential designations of the above-named items, claiming that "[a]ll documents have been released to non-parties, including healthcare providers and the general public without restriction on dissemination." The Defendants claim that these are in fact "draft" materials that have not been released to the public and therefore have been properly designated confidential.

The Court cannot discern from the examples provided whether these documents are, or are not, "draft" materials. On their face, however, they do not appear to be drafts, and none are marked as such. Therefore, to the extent that Defendants have marked as "confidential" documents that have been made available to healthcare providers or the general public, without restriction on dissemination, the Court directs Defendants to identify these documents and re-designate them as nonconfidential. There is obviously

no good faith basis for asserting confidentiality over documents that have been disseminated to the public. See U.S. Dept. of Justice v. Landano, 508 U.S. 165, 173, 113 S.Ct. 2014, 2020 (U.S. 1993) (in common usage, “confidential” means “communicated, conveyed, [or] acted on . . . in confidence: known only to a limited few: *not publicly disseminated*”) (quoting Webster's Third New International Dictionary 476 (1986) (emphasis added)).

Assuming, alternatively, that the documents are indeed draft versions and have been kept confidential, the Court is satisfied that Defendants have a reasonable basis for asserting confidentiality over them. It is sensible that draft product inserts, technique guides, instructions for use, and labeling, if not disclosed to the public, would fall within the broad category of “confidential research, development, or commercial information.” See Royal Indem. Co. v. Pepper Hamilton LLP, 2006 WL 3827452, 2 (D.Del. 2006) (finding draft accountant report not distributed to client or the public to be confidential within the meaning of Fed. R. Civ. P. 26(c)). Accordingly, the Court orders Defendants to identify which documents within this category that have released into the public domain and re-designate them as non-confidential.

#### 4

### **Marketing Documents and Advertisements**

The Plaintiffs next challenge Defendants’ “confidential” designations of marketing documents and advertisements, including symposium ads and surgeon training biographies. The Plaintiffs argue that all of these documents have been released to nonparties and purposefully disseminated by the Defendants for the purpose of advancing their products. The Defendants counter that pricing and marketing documents are often

held to be confidential business information and that the category contains highly sensitive business information and draft advertisements. The Defendants agree to tag publicly available advertisements as non-confidential.

The Court agrees with Defendants that marketing and advertising material, to the extent that it has not been publicly disseminated, is commonly viewed as confidential. See Uniroyal Chemical Co. Inc. v. Syngenta Crop Protection, 224 F.R.D. 53, 57 (D.Conn. 2004) (recognizing that “pricing and marketing information are widely held to be confidential business information”) (citing Vesta Corset Co. v. Carmen Foundations, Inc., 1999 WL 13257, at \*2 (S.D.N.Y. 1999); Sullivan Marketing Inc. v. Valassis Commc’ns, Inc., 1994 WL 177795, at \*1 (S.D.N.Y. 1994)).

However, as with the prior category, the documents within this category do not appear on their face to be “draft” versions. Indeed, all of the documents appear to be designed, as Plaintiffs suggest, for public dissemination. As with the prior category, documents that have been released to the public are clearly not confidential and must be identified and re-designated as such.

## 5

### **Published Content and Internet Content**

The Plaintiffs next challenge Defendants’ “confidential” designations of published articles and information that have appeared on the internet. The Defendants maintain that their attorney reviewers have tagged both published articles and printed pages from the internet as non-confidential. However, it appears from a review of the samples provided that a large amount of published content, including photocopies of articles published in medical journals and quite a bit of information seemingly taken

directly from Davol's own website, has been marked as confidential. The Court can discern no valid reason why Defendants would believe these publicly available documents to be confidential. Therefore, as Defendants have not met their threshold burden of having a "reasonable and good faith" belief in the confidentiality of the documents in question, they must re-designate all published documents as non-confidential. This includes anything contained in Defendants' document production publicly disseminated via the internet.

## 6

### **Correspondence and Communication to Non-Parties**

The next category of documents challenged by Plaintiffs includes the "confidential designations" of correspondence and communication with non-parties, including letters sent to healthcare providers and purchase orders to outside vendors. The Plaintiffs assert that communications to "non-parties" cannot be subject to the Protective Order. The Defendants disagree and point to Zenith Radio Corp., 529 F.Supp. at 890, which held that confidential commercial information under Rule 27(c)(7) is broad enough to include a wide variety of business information, such as "contracts with customers," "contract terms" in otherwise private contracts, and non-publicly disclosed "financial statements."

Upon review of the sample documents, the Court concludes that the Defendants have met their initial burden of having a "reasonable and good faith" belief that the documents in question are "confidential." The documents consist of a variety of correspondence to individual non-parties, including purchase orders, emails to customers, contracts, and pricing information. Unlike the prior categories, these documents are

directed to private individuals and do not appear intended for public consumption. Documents of this nature fall within the broad category of confidential commercial information as described in Zenith Radio Corp., 529 F.Supp. at 890. Consequently, the Court will not require Defendants to do a wholesale review of this category.

7

**Correspondence, Communications, and Presentation to Government Agencies**

The Plaintiffs challenge Defendants’ “confidential” designations of communications to governmental regulatory agencies, particularly the Food and Drug Administration (“FDA”). The Plaintiffs argue that there is no good faith argument why these communications, which can be obtained by any individual through Freedom of Information Act (“FOIA”) request, should be entitled to judicial protection. The Defendants counter that the FDA keeps communications with manufacturers in confidence due to patient privacy concerns, trade secrets, and other proprietary information, which is why when the FDA responds to a FOIA request, “it redacts these materials heavily for public consumption.”

Consistent with FOIA policy of full public disclosure of nonexempt records, see 5 U.S.C.A. § 552(b), the applicable provision of the FDA regulations provides in pertinent part:

The Food and Drug Administration will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade secrets and confidential commercial or financial information, and the need for the agency to promote frank internal policy deliberations and to pursue its regulatory activities without disruption. 21 C.F.R. § 20.20.

Confidential commercial information, in turn, is defined by the FDA under § 20.61 as “valuable data or information which is used in one’s business and is of a type customarily held in strict confidence or regarded as privileged and not disclosed to any member of the public by the person to whom it belongs.” If a requested record contains both confidential and non-confidential information, the confidential portions will be redacted prior to disclosure. 21 C.F.R. § 20.22.

In light of the FDA’s own policies regarding disclosure, it stands to reason that Defendants may only designate as “confidential” those documents submitted to the FDA that are exempt from disclosure under the Freedom of Information Act. See Janice Toran, Information Disclosure in Civil Actions: The Freedom of Information Act and the Federal Discovery Rules, 49 Geo. Wash. L. Rev. 843, 849 (1981) (stating that when information is disclosable under the FOIA, it cannot be considered privileged for discovery purposes).

With respect to documents that contain both disclosable and nondisclosable information, the matter is more complicated. See 21 C.F.R. § 20.22. One court faced with this situation has ruled that in such a case, the document may maintain its confidential status. See Mirak v. McGhan Medical Corp., 142 F.R.D. 34, 37, n.9 (D.Mass. 1992) (finding that an intervenor public interest group was not entitled to obtain from the court reports submitted to the FDA when it could not obtain them in unredacted form under a FOIA request). The Court finds this to be a reasonable conclusion. Otherwise, confidential information contained in reports and correspondence to federal agencies would lose their protection simply because some of their content may be disclosable under FOIA. Therefore, this Court concludes that Defendants may

reasonably assert confidentiality over communications to governmental entities that contain FOIA exempt information, even though the public may gain access to redacted versions of those communications.

## 8

### **Internal Communications and Documents of a Non-Confidential Matter**

The next category of challenged documents consists of various communications between employees of the Defendants. The Plaintiffs argue that even though these documents are internal, their content is not protected by any privilege or subject to special protection under the Protective Order. As an example that Defendants themselves do not consider some of these documents to be confidential, Plaintiffs point to numerous instances wherein “confidential” disclaimers have been intentionally removed by Defendants. The Defendants counter that these internal documents include corporate policy statements, marketing strategies, and internal deliberations that “were made confidentially, were maintained as such by the company, and represent competitive techniques and procedures.” As to the confidential labels deleted in track-changes mode, the Defendants argue that there are different standards for claiming confidentiality in a business context versus a litigation context and that the labels may have been removed for any number of reasons.

While Plaintiffs are correct that internal documents are not per se confidential, after reviewing the sample documents in this category, the Court is satisfied that the Defendants have a reasonable and good faith basis for their assertions of confidentiality. The documents consist of internal memoranda regarding reports of complications, marketing information, and a sensitive email, all of which might cause competitive harm

to Defendants if released to the public. Zenith Radio Corp., 529 F.Supp. at 891 (stating that “[f]requently the injury that would flow from disclosure is patent, either from consideration of the documents alone or against the court’s understanding of the background facts”). Therefore, as Defendants have a reasonable and good faith basis for asserting confidentiality over these documents, the Court will not require a wholesale reconsideration of this category.

**9**

**“Reports of Complications” or Medical Device Reports**

The sample documents in this category consist of reports and charts that summarize, describe, or otherwise catalogue complications involving the medical device at issue in this litigation. The Plaintiffs argue that there is no good cause for withholding this information from the public and that the Defendants were required to disclose information of this nature to various regulatory bodies. The Defendants contend that these documents are, in fact, Medical Device Reports that contain confidential information. As evidence, Defendants point to the heavy redaction seen on such reports received from FOIA requests.

The FDA regulation applicable to medical device reports, 21 C.F.R. § 803.9, provides in pertinent part that:

(a) We may disclose to the public any report, including any FDA record of a telephone report, submitted under this part. Our disclosures are governed by part 20 of this chapter.

(b) Before we disclose a report to the public, we will delete the following:

(1) Any information that constitutes trade secret or confidential commercial or financial information under § 20.61 of this chapter . . . . 21 C.F.R. § 803.9

The situation presented by Defendants' assertion of confidentiality over Medical Device Reports is no different than that for the documents composing category 7. Communication of a report, or other document, to the FDA does not defeat confidentiality because the agency itself protects confidential information contained therein from public disclosure. Therefore, the Court accepts Defendants' assertions of confidentiality over Medical Device Reports, despite the fact that the documents are available in redacted form under the FOIA.

## **10**

### **Recall Information**

The final category of documents consists of communications designed to alert healthcare providers and the public of recalls. The Court sees no valid reason why recall notices, which appear to have been publicly disseminated, should be labeled "confidential." As with prior categories, Defendants should review this category to assure that no documents that have been made available to the public or to health care providers, without restriction on dissemination, have been given a confidential designation.

### **Conclusion**

The Court finds substantial evidence that Defendants have violated the Protective Order's requirement of having a "reasonable and good faith belief" for their confidentiality designations in various categories, particularly 3, 4, 5, and 10, wherein large quantities of documents that appear to have been disseminated to the public, have nonetheless been marked "confidential." While undisclosed business and proprietary

information deserves protection, information already in the public domain, via marketing documents, advertisements, publication, sales literature, the internet, and in other forums, constitutes a waiver of confidentiality. See Sherwin-Williams Co. v. Spitzer, 2005 WL 2128938, 18 (N.D.N.Y. 2005). The Court therefore orders Defendants to review their document production and re-designate as non-confidential all documents already in the public domain. Furthermore, Defendants should provide Plaintiffs with an updated log.

With respect to the remaining categories, the Court is satisfied that Defendants have met the requirement of having a reasonable and good faith belief in the confidentiality of the documents. This ruling, however, does not prevent Plaintiffs from challenging individual documents in the future. They may do so pursuant to ¶ 13 of the Protective Order, i.e., by specifically identifying the contested documents and attempting to confer with Defendants prior to bringing a motion to compel. The Defendants should bear in mind that they have the burden of showing that disclosure of a disputed document would cause “a clearly defined and serious injury” to their competitive position. See Zenith Radio Corp., 529 F.Supp. at 891. Accordingly, Plaintiffs’ Motion To Require Compliance with the Protective Order is granted in part and denied in part. Counsel shall submit an appropriate order for entry.