

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
THIRD DIVISION**

<i>In re: Guidant Corp. Implantable</i>	§	
<i>Defibrillators Products Liability Litigation</i>	§	
	§	MDL No. 1708
	§	(DWF/AJB)
<i>This Document Relates to All Actions</i>	§	
	§	
	§	
	§	

**DEFENDANTS' RESPONSE WHY DESIGNATED DOCUMENTS SHOULD REMAIN
CONFIDENTIAL**

Defendants submit this memorandum of law responding Why Designated Documents Should Remain Confidential.

SUMMARY OF MOTION

In their Amended Memorandum In Support of Bloomberg L.P.'s Motion to Intervene and Unseal the Summary Judgment Motion Papers and Associated Materials, and Plaintiffs' Renewed Motion for An Order Compelling Defendants to Show Cause Why Designated Documents Should Remain Confidential, ("Motion") Plaintiffs' mischaracterize Defendants' conduct in designating documents as confidential in an unreasonable attempt to skirt this Court's Protective Order and divert Defendants' resources on the eve of trial. Plaintiffs motion should be denied.

On May 3, 2007, Plaintiffs challenged the confidential designation for 109 documents. *See* 5/3/07 Letter from Zimmerman to Carpenter. (Attached as Exhibit A). Defendants responded to Plaintiffs' request stating that eight of the documents were not initially designated confidential and that Defendants would de-designate 36 documents.

See 5/16/07 Letter from Carpenter to Zimmerman at 1-3 (Attached as Exhibit B). The remaining 65 documents would remain confidential. *Id.* at 3-6. Since that time, Defendants have determined that they will de-designate one more document. Plaintiffs now challenge the confidentiality designation of these 64 documents that Defendants cannot in good faith de-designate. *See* Motion at 4-5.¹ The 64 documents at issue here are attached as Exhibit C.

These 64 documents contain trade-secret information that is a business asset and must be kept confidential to maintain its value. *See* Harrold Aff. at ¶5 (Attached as Exhibit D). Plaintiffs' interest in publicly disseminating these documents does not outweigh Defendants' interest in maintaining their confidentiality. Consequently, neither Plaintiffs nor the general public would be prejudiced by maintaining the confidentiality of these 64 documents, particularly where Defendants have either not designated or de-designated numerous other documents as confidential. Accordingly, these documents should remain confidential.

But in addition to challenging these 64 documents, Plaintiffs' Motion also seeks to have this Court unseal the *Duron* and *Clasby* summary judgment and *Daubert* motions and all attached exhibits. It should be noted, however, that none of the briefs were filed under seal. Thus, the briefs are already publicly available. With regard to the attached exhibits, however, Plaintiffs' request is premature. This Court's Protective Order requires Plaintiffs to "confer in good faith" before asking this Court to intervene

¹ In their Motion, Plaintiffs also mention their November 7, 2006 motion challenging confidentiality of certain documents. That motion is moot. To the extent that documents challenged in their November 7 motion are not among the 64 documents at issue here, those documents must remain confidential.

with confidentiality designations. *See* 6/1/07 Protective Order at ¶11. With respect to the summary judgment and *Daubert* motion exhibits, Plaintiffs have not followed that procedure. Therefore, Plaintiffs’ request that this Court unseal all summary judgment and *Daubert* motion exhibits in *Duron* and *Clasby* should be denied.

Plaintiffs also seek to have this Court order the Defendants to reconsider the confidentiality designations of *all* 14 million pages of documents already produced. As Defendants have designated documents as confidential in good faith, such a request is baseless. Plaintiffs’ request is also unduly burdensome in light of the upcoming trials, and antithetical to this Court’s Protective Order. This Court’s umbrella Protective Order has allowed for a faster and more efficient production, while still protecting Defendants’ trade secrets. Through this request, Plaintiffs are essentially re-litigating the propriety of this Court’s Protective Order. Consequently, Plaintiffs’ motion should be denied in its entirety.

ARGUMENT AND AUTHORITIES.

I. The 64 Challenged Documents Contain Trade Secret or Other Confidential Information and Therefore Cannot be Publicly Distributed.

The Federal Rules of Civil Procedure authorize the Court to issue “any order which justice requires to protect a party or person from annoyance, embarrassment, oppression or undue burden or expense...” *See* Fed. R. Civ. P. 26(c). Included in this protection is any “trade secret or other confidential research, development, or commercial information.” Fed. R. Civ. P. 26(c)(7).

A party wanting to maintain the confidential designation of a document must show “good cause” for continued confidentiality. *Id.* Federal courts have used a variety of language as to what satisfies the requirements of good cause. *Culinary Foods, Inc. v. Raychem Corp.*, 151 F.R.D. 297, 300-01 (N.D. Ill. 1993) (collecting cases). Generally speaking, though, to maintain the confidential designation of a document, a party must show something more than “[b]road allegations of harm, unsubstantiated by specific examples or articulated reasoning.” *Cipollone v. Liggett Group, Inc.*, 785 F.2d 1108, 1121 (3d Cir. 1986). Furthermore,

[t]o determine whether good cause exists, courts balance the need for information against the injury that might result if uncontrolled disclosure is compelled. . . . The balance struck should incorporate consideration of the overarching purpose of the discovery process: Discovery involves the use of compulsory process to facilitate orderly preparation for trial, not to educate or titillate the public.

In re Zyprexa Injunction, ___ F. Supp. 2d ___, 2007 WL 460838 at *28 (E.D.N.Y. February 13, 2007) (citations and quotations omitted).

Subsection (7) of Rule 26(c) protects a wide variety of documents from public dissemination, and is not limited to “true” trade secrets. *See* 8 Wright & Miller at §2043. Documents protected from public disclosure under Rule 26(c)(7) include confidential research and development information, marketing plans, revenue and overhead information, pricing information, certain business proposals and contracts, manufacturing specifications, and customer lists. *In re Zyprexa*, 2007 WL at *29 (collecting cases); *see also Cipollone v. Liggett Group, Inc.*, 106 F.R.D. 573, 577 (D.N.J. 1985) rev’d on other grounds, 785 F.2d 1108 (3d Cir. 1986) (“Defendants continue to be

entitled to protection from the disclosure of matters which are truly secret, where disclosure thereof will affect the operation of their business, but not their potential liability. Formulae, marketing strategy and other matters whose disclosure would affect defendants with their respective competitors or in conjunction with the day-to-day operation of their business are entitled to protection.”). All of the 64 documents at issue fall within these categories.

A. Design, Manufacturing, and Quality Assurance Documents Should Remain Confidential.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

In *Culinary Foods*, the court held that information concerning product design modifications were held to be confidential, stating:

Here, we believe that Raychem has met its burden concerning product design modifications and changes. Raychem has spent a great deal of time and money in developing and modifying its products. Furthermore, Raychem has gone through exhaustive efforts to maintain the confidentiality of this information. We believe the injury to Raychem from disclosure of its product design modification and changes is patent.

Culinary Foods, 151 F.R.D. at 305. Similarly here, Defendants have spent a good deal of money in developing and modifying their products, and in maintaining the confidentiality of that information. *See Harrold Aff.* at ¶¶5-27. Accordingly, this information should remain confidential.

Additionally, in *Miles v. Boeing Co.*, 154 F.R.D. 112, 113 (E.D. Penn. 1994) the court found that documents detailing how specific products are manufactured, including an ordered list of the tasks to be performed on each part made by Boeing during the manufacturing process, contained confidential business information. *Id.* The court held that public disclosure of the information in those documents would put Boeing at a competitive disadvantage, and therefore, ordered those documents not be disclosed to anyone but expert witnesses. *Id.* at 115.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Even one of Plaintiffs' experts, Randy Armstrong, recognized that the technology used to produce one of Guidant's devices is cutting edge. *See* Armstrong Dep. 4/3/07 at 13:11-25 (Attached as Exhibit E). Armstrong also recognized that information regarding Guidant's design, manufacturing, and quality-control processes is proprietary and of significant value to the corporation. *Id.* at 18:1-14.

Overall, Defendants' ability to remain competitive would be damaged if its competitors obtained the information described in these 64 documents. *See* Harrold Aff. at ¶50. This information is a critical business asset that must remain confidential. *Id.* at ¶5.

B. Documents Filed with the FDA Remain Confidential.

Several of the challenged documents, including PMA supplements, were filed with the FDA. *See* Harrold Aff. at ¶¶31-34. These documents contain detailed design and manufacturing information that constitute trade secrets. *See Miles*, 154 F.R.D. at 113; *Culinary Foods*, 151 F.R.D. at 305. These documents do not lose their confidentiality simply because the information has been filed confidentially with a third party. *Culinary Foods*, 151 F.R.D. at 302. In *Culinary Foods*, documents containing trade secret information were disclosed to the Underwriters Laboratories for testing and a UL listing. *Id.* at 302. The court held that the defendant did not waive any right to

protect the trade secrets merely because the information was filed confidentially with a third party. *Id.*

The same should be true here, particularly where federal law prevents FDA disclosure of trade secrets and other confidential commercial or financial information. *See* 21 C.F.R. § 20.61(c) (“Data and information submitted or divulged to the Food and Drug Administration which fall within the definitions of a trade secret or confidential commercial or financial information are not available for public disclosure.”). By designating documents filed with the FDA confidential, these documents are exempt from disclosure under the Freedom of Information Act. *See, e.g., Judicial Watch, Inc. v. FDA*, 449 F.3d 141, 148 (D.C. Cir. 2006) (acknowledging that the FDA often declines to release information submitted with new drug applications in response to FOIA requests pursuant to FOIA’s exemptions for “documents containing trade secrets and privileged commercial or financial information”); *see also* Harrold Aff. at ¶32. Consequently, the documents filed with the FDA should maintain their confidential designation. *See* Harrold Aff. at ¶¶31-34.

C. Marketing Documents Should Remain Confidential.

Cipollone v. Liggett states “Formulae, marketing strategy and other matters whose disclosure would affect defendants with their respective competitors or in conjunction with the day-to-day operation of their business are entitled to protection.” *Cipollone*, 106 F.R.D. at 577. [REDACTED]

[REDACTED]

[REDACTED]

██████████ *Id.* As a result, this sensitive information should also remain confidential.

II. Plaintiffs’ Interest in Releasing these 64 Documents Does not Outweigh Guidant’s Need to Maintain Confidentiality.

To determine whether to maintain the confidential designation of the 64 challenged documents, this Court must balance Plaintiffs’ interest in publicly disseminating them against Defendants’ interests in keeping the information confidential. *See Webster Groves Sch. Dist. v. Pulitzer Publishing Co.*, 898 F.2d 1371, 1376 (8th Cir. 1990) (finding that the newspaper’s interest in access to court records was outweighed by the defendant’s privacy interest and the state’s interest in protecting minors from the public dissemination of hurtful information); *see also* Fed. R. Civ. P. 26(c) Advisory Committee Notes (recognizing that court has in each case weighed litigants’ claim to privacy against the need for disclosure). Here, Defendants’ interest in keeping the information confidential is significant.

Defendants are engaged in an extremely competitive industry. *See Harrold Aff.* at ¶4. The 64 documents at issue contain detailed information about Defendants’ design, manufacturing, marketing and quality assurance processes. This information is a business asset that must remain secret, or else its value is lost. *Id.* at ¶5. If Defendants’ competitors had access to this information, Defendants’ competitive position would be significantly affected. *See Harrold Aff.* at ¶¶5, 50; *see also Cardiac Pacemakers, Inc. v. Aspen II Holding Co., Inc.*, No. 04-4048, 2006 WL 3043180, at *5 n.5 (D. Minn. Oct. 4, 2006) (“the Court finds that [intervenor’s] interest in access to the records is generally

outweighed by Guidant's interest in keeping trade secrets and proprietary business information confidential").

Judge Weinstein of the United States District Court for the Eastern District of New York recently enjoined several individuals and media sources from distributing documents produced in a product liability MDL, recognizing the potential for irreparable harm to the Lilly, the manufacturer of Zyprexa:

Disclosure of confidential proprietary material and trade secrets poses a significant risk of harm to Lilly, a pharmaceutical company operating in a competitive marketplace. Both Lilly's competitors' and detractors' use of the materials has the potential to inflict severe commercial harm on the company. See Dec'l of Gerald Hoffman, ¶ 18 ("If Lilly's internal documents were to be publicly disseminated, every pharmaceutical company in the world, including competitors to all of Lilly's marketed medications, including Zyprexa, would have access to a treasure trove of competitive intelligence, in an organized and assembled manner."). The disclosure of its trade secrets can be considered tantamount to appropriation of the company's property.

In Re Zyprexa, 2007 WL 460838 at *40.

In contrast, Plaintiffs' interest in releasing these documents to the public is not only insignificant, but also suspect. While Plaintiffs do not state their reasons for wanting to publish these documents, their motive is clearly to disparage Defendants in the media. *See* Motion at 7-9. In light of the impending bellwether trials, any attempt to try the case in the media or taint the jury pool should be discouraged.

Conspicuously absent from Plaintiffs' alleged motive for distributing the documents is any reference to public health and welfare. Indeed, there should be no question that the public is fully apprised of the risks and benefits of Defendants'

defibrillators and pacemakers. Taking documents out of context in an effort to embarrass Defendants, in fact, likely does a disservice to the public. And although the documents at issue contain nothing particularly salacious or embarrassing to Defendants, they could be misrepresented if published out of context. *See In Re Zyprexa*, 2007 WL 460838 at *40 (“The harm faced by Lilly is amplified by the fact that the protected documents which respondents seek to disseminate are segments of a large body of information, whose selective and out-of-context disclosure may lead to confusion in the patient community and undeserved reputational harm - - what appears damning may, in context after difficult proof, be shown to be neutral or even favorable to the defendant.”) (citations and quotations omitted). Such out-of-context mischaracterizations in the New York Times have already damaged Defendants’ reputations, as well as caused confusion in the patient community.

Plaintiffs’ efforts to publicize “historical” documents poses the real danger of using the media as a litigation weapon. In 1984, the United States Supreme Court emphasized the importance of protective orders:

Because of the liberality of the pretrial discovery permitted by Rule 26(b)(1), it is necessary for the trial court to have the authority to issue protective orders conferred by Rule 26(c). It is clear from experience that pretrial discovery by depositions and interrogatories has a significant potential for abuse. This abuse is not limited to matters of delay and expense; discovery also may seriously implicate privacy interests of litigants and third parties. The Rules do not distinguish between public and private information.... There is an opportunity, therefore, for litigants to obtain—incidentally or purposefully—information that not only is irrelevant but if publicly released could be damaging to reputation and privacy. The government clearly has a

substantial interest in preventing this sort of abuse of its process.

Seattle Times Co. v. Rhinehart, 467 U.S. 20, 35 (1984) (citations omitted).

Moreover, neither Plaintiffs, nor the public in general would be prejudiced if these documents remained confidential. The information contained in the documents at issue adds little to a story that has already been well publicized, but could severely damage Defendants' position among their competitors. *See Harrold Aff.* at ¶¶5, 50. Consequently, this Court should deny Plaintiffs' Motion.

III. Plaintiffs' Request to Unseal All Summary Judgment and *Daubert* Exhibits Is Premature and Must be Denied.

In their Motion, Plaintiffs not only challenge the confidentiality of these 64 documents that the parties previously discussed, they also request this Court to unseal the *Duron* and *Clasby* summary judgment briefing, *Daubert* briefing, and all related exhibits. *See* Plaintiffs' Motion at 2-3. Initially, it must be noted that the summary judgment and *Daubert* briefing were not filed under seal and are publicly accessible. Additionally, however, Plaintiff's request for this Court's intervention is premature, and therefore must be denied.

This Court's January 6, 2006 Protective Order requires the parties to "first confer in good faith in an attempt to resolve the question of whether or on what terms the document or information is entitled to Confidential treatment," before the parties seek this Court's intervention. *See* 1/6/07 Protective Order at ¶11. Plaintiffs have not conferred with Defendants regarding which summary judgment and *Daubert* motion exhibits should be unsealed. The only relevant documents about which the parties have

conferred are the 64 documents addressed in this response and Mr. Harrold's affidavit. Therefore, with respect to any other documents, Plaintiffs should not yet have requested this Court's intervention.

As addressed more thoroughly in Defendants' Response to Bloomberg L.P.'s Motion to Intervene and Unseal the Summary Judgment Motion Papers and Associated Materials ("Defendants' Response"), Defendants will likely consent to having a large number of the summary judgment exhibits for the *Duron* case unsealed. *See* Defendants' Response at 5. In accordance with this Court's Protective Order, Defendants will provide Plaintiffs with a list that identifies which documents used in the *Duron* and *Clasby* motions Defendants will agree to unseal and which documents should remain confidential. Plaintiffs can then renew their motion as to the specific documents they continue to challenge.

IV. Plaintiffs' Request for Wholesale Reconsideration of All Confidentiality Designations is Antithetical to this Court's Protective Order and Must Be Denied.

Plaintiffs further assert that Defendants have over-designated documents as confidential and request that this Court order Defendants to review all prior confidentiality decisions. Plaintiffs request is baseless and inconsistent with this Court's Protective Order.

Defendants have produced over 14 million pages of documents to date. Defendants have—in good faith—designated documents as confidential to the extent necessary to protect Defendants from losing their competitiveness in the marketplace. Defendants made a good faith determination at the time of production of the

confidentiality of those documents. To expedite production, Defendants erred on the side of not waiving their rightful confidentiality protections. Upon challenge from Plaintiffs, Defendants have de-designated documents where appropriate. In light of Defendants' continued cooperation when the confidentiality designation is challenged, Plaintiffs' lack any reasonable basis to suggest a wholesale reconsideration of all 14 million pages of documents. With or without being designated confidential, Plaintiffs are able to use all 14 million pages for litigation purposes. Wholesale reconsideration of the confidentiality designation for all 14 million pages would be a tremendous waste of time and resources, particularly in light of the impending bellwether trials. Plaintiffs' request is simply one more example of their attempt to deflect resources and attention from the true issues in this litigation.

Additionally, by asking this Court to order Defendants to reconsider all confidentiality designations, Plaintiffs are attempting to re-litigate this Court's Protective Order. This Court's Protective Order has been an indispensable tool for facilitating discovery in this complex MDL. Umbrella protective orders, such as the one entered in this case, are common in such complex litigation. *See In re Zyprexa*, 2007 WL 460838, at *29. Umbrella orders permit parties to designate large volumes of discovery as confidential in advance, and upon challenge, the party seeking protection must then justify the confidential designation. *Id.* The advantages of umbrella orders are so well documented that the Manual for Complex Litigation recommends umbrella orders be issued in complex cases. *Id.* Umbrella orders expedite production, reduce costs, and avoid the burden to the court of document-by-document determinations. *Id.*

This Court's Protective Order has been similarly advantageous. Defendants have been able to produce over 14 million pages of documents and this Court has been asked to intervene in confidentiality determinations only two or three times in two years. Thus, as a result of this Court's Protective Order, the parties and the Court have saved time, money, and judicial resources.

The scarcity of occasions requiring this Court's intervention also demonstrates that Defendants are already acting in good faith in designating documents as confidential. Consequently, Plaintiffs' requests for reconsideration of all confidentiality determinations and for an order instructing Defendants to limit confidentiality designations to those based on a "good faith belief" that the documents are actually confidential, should be denied. In accordance with this Court's Protective Order, Defendants have consistently made designations based on good faith belief of confidentiality, and acted reasonably in de-designating challenged documents when appropriate. For Plaintiffs to suggest otherwise is baseless and harassing.

CONCLUSION

For these reasons, Defendants respectfully request that Plaintiffs' Motion be Denied.

Respectfully submitted,

SHOOK, HARDY & BACON L.L.P.

By: /s/ Timothy A. Pratt

Timothy A. Pratt

Missouri Bar No. 47454

2555 Grand Blvd

Kansas City, Missouri 64108-2613

Telephone: 816.474.6450

Facsimile: 816.421.5547

Joseph M. Price

FAEGRE & BENSON

2200 Wells Fargo Center

90 South Seventh Street

Minneapolis, Minnesota 55402-3901

Telephone: 612-766-7000

Facsimile: 612-766-1600

Attorneys for Defendants