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ROBERT ABRAMS, DAVID MORAN and JOSEPH WOLVERTON, on behalf of themselves and all others similarly situated, Plaintiffs, v. STRYKER HOWMEDICA OSTEONICS; HOWMEDICA OSTEONICS CORPORATION; STRYKER CORP; PFIZER, INC.; ABC CORPS. 1-25; JOHN DOES 1-25, Defendants.	SUPERIOR COURT OF NEW JERSEY OCEAN COUNTY - LAW DIVISION DOCKET NO. L-3040-02 **PLAINTIFFS' OPPOSITION TO DEFENDANT'S MOTION FOR PROTECTIVE ORDER PURSUANT TO R.4:10-3**
HELEN LASORDA-SIVIERI and GINO SIVIERI, Plaintiffs, v. HOWMEDICA OSTEONICS CORP.; STRYKER CORP.; PFIZER, INC; ABC CORPS. 1-25; JOHN DOES 1-25, Defendants.	SUPERIOR COURT OF NEW JERSEY OCEAN COUNTY - LAW DIVISION DOCKET NO. L-2243-02
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I. INTRODUCTION

The Court must deny Defendant Howmedica Osteonics Corporation's ("HOC") Motion for a Protective Order because HOC has both ignored the rules on meeting its burden of proof on confidentiality and has failed to come forward with any specific evidence on the issue of confidentiality. Indeed, despite the fact that the Court clearly instructed HOC to file a motion for protective order for the certain documents which HOC claims are confidential, *see* Kincannon Cert., *Exhibit 1*, Transcript (6/17), p. 31:7-14 ("...there will have to be a motion immediately made before the Court as quickly as possible to declare certain documents privileged and subject to some order by this Court of non-disclosure....I don't think you can say here, you can have these and by the way, tell us which ones you don't agree to."), HOC has chosen instead to discuss the documents generally by category and by yet again proposing a blanket protective order to cover these 6000 documents,[1] as well as future documents. As HOC's only support for its confidentiality claims are two conclusory and unenlightening certifications,[2] HOC has failed to carry its burden.

HOC's broad net of confidentiality goes too far in that it clearly sweeps up wholly unprotected documents that are material to public health and safety. More and more, courts are

[1]HOC states that it has already produced 15,000 responsive documents to Plaintiffs and only maintains confidentiality claims to the remaining 6000 documents which are the subject of this Motion. Plaintiffs in no way concede that these documents constitute all documents responsive to Plaintiffs' discovery requests, and Plaintiffs will pursue proper relief, *i.e.*, motion to compel, for their discovery in the near future. For example, no electronic discovery has been produced. Likewise, no discovery relating to other cases has been produced, despite the fact that the Court has preliminarily indicated Plaintiffs are entitled to such information. Kincannon Cert. *Ex. 2,* Transcript (5/6/03), p.69:17-24. Defendants have also improperly limited discovery responses in the *Abrams* class action to the three products belonging to the named Plaintiffs.

[2]*See Frankl v. Goodyear Tire and Rubber Company*, No. L-003052-99, slip op. at 37 (N.J. Sup. Ct., December 18, 2001)(Sabatino, J.S.C.) ("Documents do not automatically become proprietary or confidential just because a company official proclaims them to be so. Rather, the substance of the documents must determine their legal classification."), attached to Kincannon Cert. as *Ex. 3, p.37-38*.

rejecting blanket protective orders as a result of finding out what was being covered up. *See Frankl v. Goodyear Tire and Rubber Company*, No. L-003052-99, slip op. at 41 (N.J. Sup. Ct., December 18, 2001)(Sabatino, J.S.C.)("In such a setting where the public health and safety may be at peril, the court should not accept a manufacturer's claims of confidentiality without testing those claims rigorously."), Kincannon Cert. *Exhibit 3,* p. 41. We see this in sexual abuse cases, tire cases[3] and drug cases. *See*, Kincannon Cert., *Exhibit 4*.

In addition to improperly seeking protection of documents evidencing consumer fraud or adverse impact on human health and safety, HOC's categories of purportedly confidential documents includes documents which HOC's counsel admitted are not entitled to protection. At the June 17 case management conference, HOC's counsel stated, "[w]ithin these, you know, four or five binders of documents the majority of them are confidential. There are documents within there that are not confidential." Kincannon Cert., *Exhibit 1,* p.33:12-33:15. Moreover, as discussed more fully below, several of the products at issue are no longer manufactured or sold, so there should be no trade secrets attached to documents related to those products. None of Defendants' products are currently sterilized in the same manner as they were when Plaintiffs' products were manufactured and sterilized (gamma irradiation in air), so there should be no trade secrets attached to documents relating to this now abandoned method of sterilization. Equally important, each product design was submitted to the FDA as being "substantially equivalent" to already existing products. Kincannon Cert., *Exhibit 5*. This admission against interest is dispositive, and is never explained away. These products are also subject to reverse engineering, so again, there is no trade secret attached to these

[3] *See, e.g., Frankl v. Goodyear Tire and Rubber Company*, No. L-003052-99 (N.J. Sup. Ct., December 18, 2001)(Sabatino, J.S.C.), attached to Kincannon Cert. as Ex. 3; *Talalai, et al, v. Cooper Tire & Rubber Co.*, No. MID-L-8839-00MT, slip op. at 15 (N.J. Sup. Ct. July 17, 2001)(Corodemus, J.S.C., denying motion for protective order), attached to Kincannon Cert., *Ex. 6*.

documents. For many of these documents, disclosure will not result in any harm to HOC, due to the standardization and FDA regulations for the industry, so again, there is no need to invoke a burdensome protective order. Finally, documents available publically from government agencies such as the FDA, via Freedom of Information laws are not subject to blanket protection. Nevertheless, HOC has lumped all of these documents together in its quest for a protective order.

This briefing process was intended to be the end of Plaintiffs' months of struggling to obtain responses to discovery requests. The documents which are the subject of this Motion were originally to have been produced in early May. After two months of discussions, the parties were set for a resolution on July 25 with the Court's decision on HOC's Motion. Even if one assumed *arguendo* that some of HOC's documents may contain trade secret or proprietary information, HOC's general discussions of broad categories of information do not satisfy its burden of good cause in this case and do not provide sufficient information for the Court to make a determination as to secrecy. *See*, *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3rd Cir. 1994)(a proponent cannot generally fulfill its burden based upon the subject matter at issue, but must satisfy the good cause standard for each and every individual document sought to be concealed). Accordingly, the Court must order the disclosure of all HOC's documents responsive to current discovery and deny its improper request for a blanket protective order.

II. STATEMENT OF FACTS

"Independent of the interests of the parties and their attorneys in the litigation that comes before our courts, there is a profound public interest when matters of health, safety and consumer fraud are involved." *Hammock v. Hoffman-LaRoche, Inc.*,142 N.J. 356, 379 (1995).

This case is about the health and safety of thousands of citizens. This case is also about the clear consumer fraud committed by these Defendants, one of whom now moves to frustrate the open access policy of our courts and cloak their improper and tortious conduct in a veil of secrecy.

This is not mere colorful prose. Although HOC has dragged its feet throughout this discovery process, Plaintiffs can still prove the following right now,[4] which clearly shows that this case involves not only the health and safety of our citizens, but an imminent risk thereto:

1. Defendants were aware for at least the past decade that the sterilization process used on the products involved in these actions, gamma irradiation in air, compromised the integrity of the polyethylene components of the products. This fact should not be covered up with a blanket protective order, and certainly does not give HOC a legitimate competitive edge.

- Attached to Kincannon Certification as *Exhibit 7* is the letter from Howmedica Inc. to the FDA, dated December 14, 1993, which states:

> Irradiation of ultra-high molecular weight polyethylene (UHMWPE) induces molecular changes in the polymer. This irradiation causes chain scission, cross-linking of the molecular chains, and generation of free radicals. Free radicals can react with oxygen to cause oxidation. The changes produced by the irradiation and oxidation may lead to some change in material properties of the polyethylene. Packaging the polyethylene in an inert environment and subsequent sterilization and heat treatment has been shown to reduce the effect of oxidation on the material.

- Additionally, Dr. Dumbleton, one of Defendant's experts, co-authored an article to be presented at the Fifth World Biomaterials Congress meeting. The first line of this article, attached to Kincannon Cert. as *Exhibit 8*, states,

[4]The documents discussed herein were obtained by Plaintiffs either via FOIA requests to the FDA or in similar litigation against some of these Defendants relating to the Duracon Uni-knee device in which undersigned counsel was involved. Notably, while many of these documents are stamped confidential, no protective order was entered or agreed to by undersigned counsel; thus underscoring Plaintiffs' argument that Defendant's proposed confidentiality order is too broad and encompasses many documents which are not in fact confidential. *See* Kincannon Cert., para 2. Moreover, these documents are responsive to Plaintiffs' discovery requests in these cases, but have not yet been produced by Defendants.

"[o]xidation-induced material property changes have been reported in the literature." *Exhibit 8.* That sentence cites to a textbook written in 1981.

- A Howmedica Technical Report, dated April 27, 1993, compared conventional gamma irradiation to gamma irradiation in a nitrogen (instead of air) environment. The conclusion reads, "The UHMWPE [using nitrogen] irradiated sample showed a smaller oxidation peak and a lower oxidation index, both indicating reduced oxidation compared to the UHMWPE/air irradiated sample." Kincannon Cert, *Exhibit 9.*

- An Osteonics report, entitled "R&D Internal Tech Report", dated February 16, 1994, states clearly, "Sterilization by gamma-irradiation induces surface oxidation on UHMWPE. The oxidation induced is influenced by the dose of radiation as well as gas environment. Of the three gas environments investigated in this study, oxidation was least prevalent in specimens packaged and sterilized under argon and most prevalent in those packaged in air. Finally, since neither argon nor nitrogen is incorporated into the surface of UHMWPE, it is reasonable to expect that it measures could be taken to completely exclude oxygen, the potential for oxidation could be avoided." Kincannon Cert, *Exhibit 10*.

- A Howmedica Technical Report, dated March 9, 1995, tested UHMWPE hip inserts that had been sterilized using gamma in air versus gamma in nitrogen, and concluded, "up to 5 million cycles on the hip joint simulator, Method B (N2/heat) reduces the wear rate of UHMWPE by approximately 40% over Method A (Air/irradiated)." Kincannon Cert, *Exhibit 11*. A similar test was done regarding knees, resulting in a Technical Report dated October 20, 1995. That report concluded that, "[t]he present results from the reciprocating pin-on-disk wear test indicate that Method B (N2/Heat) reduces the wear rate of UHMWPE by approximately 68% over Method A (Air/Irradiated). Kincannon Cert, *Exhibit 35*.

2. Defendants not only knew that their Polyethylene was defective, they knew the consequence of that defect.

- FDA inspection report, for an October 26, 2000, FDA inspection of Defendant's plant discusses, *inter alia*, the recall of the Duracon Total Knee Posterior Stabilized "(PS)" Tibial Insert, which was recalled because the gamma in air irradiated polyethylene was fracturing, as Plaintiffs have alleged it will. Defendant had a Health Risk Assessment done by a doctor Anthony Hedley, M.D., which is referenced therein. It sets out the effects of the fracturing, and callously states, "[i]n the long term, the patients undergo a revision procedure where the tibial insert is removed and replaced by a new [differently sterilized] Duration packaged PS tibial insert component.

Patients remain ambulatory, allowing the capability of returning for an office visit, and eventually to the hospital for revision procedure." Kincannon Cert, *Exhibit 12*.

- The above cited inspection report states with regard to the failure of only the Duracon Total Knee (PS) Tibial Insert, "[t]here were approximately 44 MDR's [FDA requires reports] filed between 1999 and 2001 associated with fractured post necessitating revision surgery and hence serious injury." Kincannon Cert, *Exhibit 12*. Again, this report involves only one device, and for only a limited period of time.

3. Defendants are well aware that the premature wear of the polyethylene components causes little particles of polyethylene to collect and trigger an autoimmune response by the body, known as osteolysis, wherein the body, thinking it has been infected, actually attacks and erodes healthy bone. This leads to the need for a more complex revision and may require bone grafting in order to compensate for lost bone stock.

- A Technical Report, dated, November 2, 2000, analyzed HOC's new polyethylene, Duration Polyethylene. The conclusion section states in relevant part, "The incidence of wear debris induced osteolysis is expected to be lower for Duration IV tibial inserts than control Duration tibial inserts due to wear rates." Kincannon Cert, *Exhibit 13*.

As discussed more fully below, these documents and others demonstrate that Defendants were aware that gamma irradiation in air compromised the integrity of the polyethylene components of their implants, causing them to wear prematurely. They were aware that this premature wear could lead to device failure and serious injuries, including the need for revision surgeries, and the onset of osteolysis. Although these Defendants were aware of these defects, they continued to manufacture, market, and sell these devices.

Thus it is readily apparent that HOC has not overcome the compelling interest of our courts in protecting our citizens with an open court policy and has failed to show good cause for the entry of a blanket protective order which seeks to protect admittedly non-confidential documents

(including future discovery documents) and which fails to distinguish what type of protection it claims is warranted. A Court simply cannot order such a sweeping mandate based upon such a dearth of evidence submitted in an effort to carry such a heavy burden.

III. LEGAL ARGUMENT

A. Legal Standard and Defendant's Burden of Proof

The discussion begins with the recognition that New Jersey has a policy of open discovery.[5] Moreover, since these cases involve the health, safety and consumer fraud of New Jersey's citizens, the public interest is amplified.[6]

Furthermore, there is no absolute privilege for trade secrets and similar confidential information. *Federal Open Market Committee v. Merrill*, 443 U.S. 340 (1979); Wright, Miller & Marcus, FEDERAL PRACTICE AND PROCEDURE, § 2043 (1994) at 554-555 ("It is well settled that there is no absolute privilege for trade secrets and similar confidential information; the protection afforded is that if the information sought is shown to be relevant and necessary, proper safeguards will attend disclosure.").

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[5] *See*, *Jenkins v. Rainner*, 69 N.J. 50, 56, 350 A.2d 476, 476 (N.J. 1976) ("Our court system has long been committed to the view that essential justice is better achieved when there has been full disclosure so that the parties are conversant with all the available facts."); *Shanley & Fisher v. Sisselman*, 215 N.J.Super. 200, 215-16 (App.Div. 1987); *See also Medford v. Duggan*, 323 N.J.S.127 (App. Div 1999) ("[o]ur rules of discovery are designed to eliminate, as far as possible, concealment and surprise at trial so that cases are decided upon their merits rather than the skill and maneuvering of counsel.")(*citing Abtrax Pharmaceuticals, Inc. v. Elkins-Sinn, Inc.*, 139 N.J. 499, 512, 655 A.2d 1368 (1995)); *Frankl v. Goodyear*, *supra.,* slip op. at 23 (citing *Hammock* as signifying that "confidentiality orders in pretrial litigation ought not to be approached routinely or casually. Indeed, there are significant public policies that weigh against such casual treatment. New Jersey has a long tradition of openness in judicial proceedings."), Kincannon Cert., *Ex. 3*.

[6] *See Hammock v. Hoffmann-LaRoche*, 142 N.J. 356, 378 (1995) ("in litigation that comes before our courts, there is a profound public interest when matters of health, safety, and consumer fraud are involved").

Rule 4:10-3 allows the Court discretion to grant a protective order, but only after the party seeking the protective order has demonstrated good cause for the order. *See Pansy*, 23 F.3d 772. In other words, the Court may not exercise its discretion or balance competing interests until HOC has met the threshold showing of good cause.

In New Jersey, the search for good cause has been aided by the following list of illustrative factors:

> (1) The nature of the lawsuit and the issues raised by the pleadings.
> (2) The substantive law likely to be applied in the resolution of the issues raised by the pleadings.
> (3) The kind of evidence which could be introduced at the trial, and the likelihood of it being discovered by the pretrial discovery procedure which is the subject of the application for a protective order.
> (4) Whether trade secrets, confidential research, or commercial information are sought in the discovery procedure employed, whether they are material and relevant to the lawsuit, and whether a protective order will insure appropriate confidentiality.
> (5) Whether the pretrial discovery seeks confidential information about persons who are not parties to the lawsuit.
> (6) Whether the pretrial discovery sought involves privileged material.
> (7) Whether the pretrial discovery sought relates to matters which are or are not in dispute.
> (8) Whether the party seeking discovery already has the materials sought.
> (9) The burden or expense to the party seeking the protective order.

Catalpa Investment Group, Inc. v. Franklin Township Zoning Bd. of Adjustment, 254 N.J. Super. 270, 273-274 (N.J. Super. 1991)(citations and footnotes omitted).

The discovery at issue involves matters of public health and safety which would be of interest to other litigants. For example, although Defendants were clearly aware of the problems associated with their sterilization technique, the Duracon Total Knee (PS) Tibial Insert (which at all relevant times was gamma irradiated in air) was shipped by the Defendants from April 13, 1995, until September 19, 2001. Kincannon Cert, *Exhibit 12*. Worst of all, Defendants have made clear that their top priority is not the health and safety of their customers, but sales. This attitude is clear in an inter-company correspondence from an Eddie Slater, attached to Kincannon Cert, as *Exhibit 14*,

which reads in relevant part, "[s]ales of the existing Duracon Uni will continue until adequate inventories of the Mark II version are available to permit the swap out of inventories *without interruption to the programme*." (Emphasis added). HOC's Vice President of Sales, Greg Rainey, concurred with this view when asked about having his sales people in the field versus reporting issues regarding products back to HOC:

> "Q. Do you get any kind of regular reporting from them or from a branch manager-
>
> A. No.
>
> Q. - other than sales data?
>
> A. I don't. The commission sales force - you mentioned earlier about putting the people, salespeople, in front of the customer for selling time, filling out reports doesn't do that for us."

Kincannon Cert., *Exhibit 15*, p. 107.

Further, there remain a great number of devices still implanted in unsuspecting patients. For example, a May 20, 2003 correspondence to the FDA from Defendant again regarding the Duracon Total (PS) tibial insert, states that there are 8,956 units estimated implanted. Kincannon Cert, *Exhibit 16.* This is for just one of the devices that falls within the class definition of *Abrams*; yet, it clearly shows that there are literally thousands of defective devices still implanted in patients who have no idea that the device implanted into them may be failing and eroding healthy bone in the process.

Moreover, the information contained in the documents at issue are directly related to the resolution of the merits of Plaintiffs' claims. These factors weigh against a protective order.

Good cause requires more than mere conclusory allegations; it requires specific examples of harm that could reasonably result from disclosure. *See* Wright, Miller & Marcus, FEDERAL

PRACTICE AND PROCEDURE, § 2043 (1994), p. 559; *Glenmede Trust Co. v. Thompson*, 56 F.3d 476, 483-85 (3rd Cir. 1995) (explaining that party seeking protective order may not rely upon broad allegations of harm, but must show specific examples); *Cipollone v. Liggett Group, Inc.*, 785 F.2d 1108, 1121 (3rd Cir. 1986) (stating that harm must be significant and not merely trifling). Design drawings, given reverse engineering, for example, simply do not meet the requisite test. The need for specificity rests upon the well-founded public policy that:

> protective orders which would remove portions of the judicial process from public scrutiny cannot be granted with reckless abandon. The public airing of grievances is the fundamental means by which the integrity of the judicial process is preserved. Without a showing of good cause, this principle simply cannot be ignored.

Andrew Corp. v. Rossi, 180 F.R.D. 338, 343 (N.D. Ill. 1998); *see also Hammock*, 142 N.J. at 381 ("the person who seeks to overcome the strong presumption of access must establish by a preponderance of the evidence that the interest in secrecy outweighs the presumption"). New Jersey courts, recognizing that because all parties to litigation have a duty to engage in proper discovery, *see* R. 4:10-1 and -2, have likewise indicated that issuance of protective orders should be used sparingly. *See*, *Hammock*, 142 N.J. at 369.[7]

As discussed fully below, HOC has attempted to meet its burden of good cause based on general categories of documents.[8] Generally, a party seeking a protective order must justify the

[7]Notably, HOC cannot meet its burden of showing good cause by arguing that Plaintiffs are not prejudiced since its proposed protective order will not restrict discovery to Plaintiffs in the instant cases. *Nestle Foods Corp. v. Aetna Casualty and Surety Co.*, 129 F.R.D. 483, 486 and n.4 (D. N.J. 1990)("Litigants are seeking protective orders with increasing regularity.... However, when as here, consent is unavailing the movant seems unwilling or unable to make the required showing – appearing that a protective order should be available for the asking. The law is to the contrary. Parties should not assume that the court will accede to a protective order because no substantial harm to the party opposing the application can be shown.").

[8]The categories used by HOC simply are not useful. In addition, the use of categories makes no sense. Here, where Defendants have been sued hundreds or thousands of times, internal indices of documents would likely have been produced simply for the purposes of sound and efficient case management. Since HOC unilaterally refused to answer discovery on these other cases, deeming it "irrelevant", this information is not before the Court. *See*, Kincannon Cert., *Ex. 17*.

confidentiality of each and every document for which a protective order is sought. *Pansy*, 23 F.3d at 786-787; *see also Frankl v. Goodyear,* Kincannon Cert., *Exhibit 3*, p. 40-41 ("Even if, as B.R. contends, each of the subject documents contains matters that should not be disclosed, it is not clear whether at least some parts of the documents nevertheless should be made available....[I]t may be feasible to redact the documents in some fashion that accommodates both the interests of Goodyear and those of the intervenors and the public at large."). Absent this required specificity, any protective order based on general categories, without a review of each document, will certainly encompass documents that do not contain trade secret or confidential information and will therefore be too broad. It is ultimately the Court, not the Defendant who must decide whether a particular document is entitled to judicial protection. If the Defendant were allowed to identify groups of documents rather than specific documents, it would become a "self-appointed censor." *See United States v. IBM Corp.*, 82 F.R.D. 405, 409 (N.D. N.Y. 1973).

It is also important to note that even if HOC establishes "good cause" for some documents, no decision warrants expanding that result to all documents on HOC's statements that its trade secrets are inescapably "co-mingled" with non-privileged documents. *See*, *Pansy*, 23 F.3d at 786 (a proponent cannot generally fulfill its burden based upon the subject matter at issue, but must satisfy the good cause standard for each and every individual document sought to be concealed). This is a clear flaw in HOC's argument, as HOC's counsel has acknowledged in open court that some of the documents that are the subject of this motion are not confidential. Kincannon Cert, *Exhibit 1,* Transcript (6/17/03), p.33:5-34:1. Indeed, such co-mingling could be considered as evidence that HOC does not treat its own trade secrets internally with the degree of care the law requires.

Finally, in addition to failing to particularize its "good cause" arguments, HOC has also failed to distinguish between the categories of information, uniformly characterizing all the alleged secret

information as "trade secret, confidential or proprietary." Yet, this is an important and necessary distinction recognized by the New Jersey courts, as our caselaw provides less protection for confidential or proprietary information than trade secret information and requires a compelling reason to keep them sealed. *See Hammock*, 142 N.J. at 383-384 ("Confidential information and proprietary information are not entitled to the same level of protection from disclosure as trade secret information...While a justification for sealing trade secrets may be more readily established, it is more difficult to seal proprietary information.").

B. HOC Has Failed to Establish Good Cause for a Protective Order for Its Categories of Documents

As an initial matter, it is easy to see the failure of HOC's argument by what is missing from its submittal. The rules regarding the protection of trade secret or other proprietary competitive information only apply if the circumstances indicate (1) a competitive market, (2) the documents are relevant to a basis of competition, and (3) the information has never been shared; otherwise, there is no competitive harm to the disclosure of the information. *See generally, Smith v. BIC Corp.,* 869 F.2d 194, 200 (3rd Cir. 1989).[9]

[9]Factors for consideration as to whether information is a trade secret include: (1) the extent to which the information is known outside of the owner's business; (2) the extent to which it is known by employees and others involved in the owner's business; (3) the extent of measures taken by the owner to guard the secrecy of the information; (4) the value of the information to the owner and to his competitors; (5) the amount of effort or money expended by the owner in developing the information; and (6) the ease or difficulty with which the information could be properly acquired or duplicated by others. *Smith v. BIC Corp.,* 869 F.2d 194, 200 (3rd Cir. 1989). As will be discussed in further detail, much of the information in these documents is known outside HOC's business, as the industry is relatively standardized and regulated by the FDA and/or is of little value to competitors.

A failure of HOC's argument is that much about the medical device manufacturing industry is standard and common knowledge. This is necessarily true because the FDA has promulgated stringent guidelines associated with the manufacture of these products, including material composition, sterilization procedures, evaluations, testing and project management. *See, e.g.,* FDA's Design Control Guidance for Medical Device Manufacturers, attached to Kincannon Cert. as *Exhibit 18*. Much of the innovative research is done by universities or other public entities and that information is shared throughout the industry in meetings such as Orthopedic Research Society meeting or the Bio-materials meetings, and then manufacturers take that information and use it in their own products. The manufacturing process is routine and it has limitations with respect to how a manufacturer can deviate from the standard procedure.

Even product development is governed by regulations, which do not put the emphasis on innovative technology. A leading trade publication has noted:

> New products in orthopedics are generated routinely by simply rearranging the sizes, shapes, and materials of the old components, generally not a very expensive process.

Kincannon Cert., *Exhibit 19*, p.2.

There is no evidence showing that HOC is competing based on break through products. Indeed, Since the late 1970s, there have been very few technological innovations by Stryker Howmedica or its predecessors in the development of total knee or total hip arthroplasty:

> The mid-1970s signaled the start of the modern era of total knee arthroplasty. Although the Total Condylar and kinematic prosthesis were effective in the long term, the few failures that did occur led to evolutionary designs that are still in use today; only a few minor changes were made to the original design.

Kincannon Cert, *Exhibit 20*. Rather, all of the evidence suggests that orthopedic implants compete based on relations between sales people and the doctors who buy their products. The July 2002

addition of Orthopedic Network News, confirms this with research establishing that a sales force is generally the biggest expense of a company, which dwarfs that spent on R&D. Kincannon Cert., *Exhibit 19*, p.2. Mr. Rainey, HOC's Vice President of Sales, highlighted the importance of sales at a recent deposition, stating that if HOC lost a salesmen, "[y]ou will lose 30 to 40 percent of the business almost immediately. In some cases I've seen it where we've lost 100 percent of the business in a day." Kincannon Cert, *Exhibit 15*, p. 58:5-8. When asked why HOC was slightly below its national average with respect to sales of knee devices in New Jersey, Mr. Rainey responded that HOC was being outsold in New Jersey. Kincannon Cert. *Exhibit 15*, p. 80:6.

As further evidence of lack of competitive market and standardized industry, HOC has alleged the affirmative defense of state of the art; thereby planning to justify its problems by claiming everyone was doing it.

Even if there is real competition in the industry, in order for documents to be trade secret or otherwise protected, the information must form a basis of the competition. Products that are no longer manufactured, were designed poorly and were irradiated in air do not qualify.

Plaintiffs maintain that the PCA Hip System is no longer manufactured and sold; however, HOC claims in its brief that documents associated with the PCA Hip System should be confidential because the PCA Hip System is manufactured on a case-by-case basis or as needed. Motion, p.4. What does that mean? Is it enough to meet the threshold requirement of a competitive interest? Presumably, this statement could be made for any device to keep from having to admit it is obsolete, as long as the manufacturer retained the designs and materials necessary to create one. HOC contradicts this statement, or at least neglects to qualify their statement about the PCA Hip System later in its brief, when it refers to the PCA Hip System as a product no longer manufactured. Motion, p.17. For confirmation that this product is no longer manufactured, Plaintiffs obtained a copy of the

April, 2003 Orthopedics Today magazine, which contains a listing of hip systems offered for sale this year. Kincannon Cert., *Exhibit 21*. The PCA Hip System is not among the products listed, not even in the section on products for revisions.

HOC has failed to cull out subsets of documents or documents dealing with products or designs that are no longer being used and for which HOC therefore has no proprietary interest. For example, the first category of documents contains Engineering Change Notices ("ECN"), depicting changes or modifications in the design of a product. Certainly, if a design is changed to remediate a device failure, HOC would have no proprietary interest in the original flawed design. However, HOC's proposed order would cover these documents as well. In effect, evidence of knowledge of a known defect in products sold or being sold would be covered up, even for products that are no longer manufactured by HOC.

Another example is HOC's sterilization specifications/sterility records category. Plaintiffs are aware that each of the personal injury Plaintiffs' products was sterilized by a technique called gamma irradiation in air, and its effects on the UHMWPE component of these devices is one of the causes of premature failure of Plaintiffs' devices. The class action is limited to devices manufactured, sterilized and implanted between 1992 and 1996 using the gamma irradiation in air technique. This is significant because that sterilization technique is no longer used by Defendants or any other manufacturer to sterilize their products, a fact HOC fails to acknowledge in its brief. Accordingly, relevant documents relating to the sterilization of Plaintiffs' products would not be trade secret, as they relate to an obsolete method of sterilization. HOC claims its unique sterilization standard distinguishes its products from products of its competitors, giving it a competitive advantage. Motion, p.9. It is unclear if HOC is referring to its current sterilization standard or the standard no longer used. Regardless, as noted above, there is no harm in disclosure

of a method no longer used and that was in fact admittedly bad for certain products. Kincannon Cert, *Exhibit 22; Exhibit 7.* Further, the current sterilization process is not relevant to Plaintiffs' products.[10]

In submitting the certification of Paul Serekian, vice president of Advanced Technologies, HOC has not connected discovery about old and discarded technologies with new or advanced technologies, assuming there are any. HOC never explains what advanced technologies does in terms of new research and how that relates to their products and Plaintiffs' discovery requests. Without this explanation, Mr. Serekian's certification is irrelevant to the issues at hand.

Finally, much of this information HOC seeks to capture in its broad confidentiality net includes information submitted to the FDA or which has otherwise been shared with third parties.

Some of the information as described by HOC[11] can be found in documents already produced by HOC. For example, the package inserts, previously produced, contain the materials included in the products. Kincannon Cert, *Exhibit 23*. In response to Form (C)(4) Interrogatories for Plaintiff Bisirri, HOC produced a document entitled "Scorpio Total Stabilizer Revision Knee System Surgical Protocol", bates numbered HOC/BISIRRI 000101-000118. Bates stamped pages HOC/BISIRRI 000117-000118 provide drawings of various components of this device, as well as charts with various measurements for the components. Kincannon Cert, *Exhibit 24*. The package insert for Plaintiff Bisirri's device, HOC/BISIRRI 000120 contains a listing of the materials used in

[10]Interestingly, despite HOC's claims of a unique sterilization technique allegedly giving it a competitive edge over its competition, HOC still loses 30%-40% and possibly 100% of its business when it loses a salesman. Kincannon Cert., Ex. 15 p.58:5-8. Additionally, no brochure or talking point document for doctors has been produced that references this claim on a unique procedure, and such a document would be responsive to Plaintiffs' discovery requests.

[11]Given the general manner in which HOC discusses these categories and lack of detail provided by HOC, Plaintiffs have a serious problem understanding what these categories mean and how a document allegedly ends up in one or another category. Thus, Plaintiffs are unable to discuss the specific categories of documents. It seems that if this was an honest assessment, more information would have been made available.

the various components. Kincannon Cert, *Exhibit 23*. Documents produced in response to class discovery also provide some of this information. *See* Kincannon Cert, *Exhibit* 25, *Exhibit 26*. Brochures and other advertisements and references also provide information regarding the sizes, coatings, materials and finishes. Kincannon Cert, *Exhibit 27*. Moreover, templates of the devices are available to customers to insure proper fit of the device in the patient. *See* Kincannon Cert, *Exhibit 28*. Finally, documents incorporate technical research such as the geometric placement of the implant in the body would not be confidential, as it is provided in the surgical technique brochures already provided in discovery, *see, e.g.,* Kincannon Cert, *Exhibit 29*, and is information that must necessarily be communicated to doctors who are actually implanting the device into a patient. Motion, p.11. *See Subcarrier Communications, Inc. v. Day*, 299 N.J. Super. 634, 646 (App. Div. 1997)("A lease form or template which a company distributes to its customers is not a trade secret.").

HOC has produced technical reports in prior litigation without a protective order, which it now claims is necessary. In an effort to mitigate this problem, HOC claims that the reports previously produced are not the subject of this motion and will be produced herein. Motion, p.11. However, HOC fails to disclose why some technical reports are confidential and some are not. Plaintiffs' counsel was the recipient of some of these previously produced technical reports in a prior case and many of these reports were not specific to products, but to general research, *e.g.*, Kincannon Cert, *Exhibits 9-11, 35,* and were clearly responsive to Plaintiffs current discovery requests. Accordingly, HOC's attempts to argue that certain other non-descript technical reports are confidential and should be the subject of a protective order are suspect, particularly with no basis given to distinguish them from previously produced reports.

Further, documents submitted to the FDA contain specifics regarding the manufacturing and sterilization process, as well as material composition. *See*, Kincannon Cert, *Exhibit 30*. To the extent HOC continues to claim it has a unique material specification above the required standards, this information would surely not remain a secret, as it would be used as a marketing tool to distinguish HOC's products from competitors'.

In addition, given HOC's description of these documents, much of the information contained therein could be obtained by reverse engineering. For example, it would be easy for a competitor to get a device and physically measure it to obtain angle, width, height, depth, diameters and cross-section, which (according to HOC) is what some of these documents entail, and forms the basis of HOC's argument that they are entitled to protection. Further, the package inserts accompanying the products, (already provided by Defendants in discovery) also provide some of this information. Kincannon Cert, *Exhibit 23.*

Notably, HOC claims it utilizes unique material specifications for its products and thereby admits that it deviates from the mandated material standards required by the FDA. Therefore, in order to get approval to use such materials, HOC would have been required to demonstrate to the FDA that its unique materials were substantially similar to the approved, standard material, which is a substantial burden and would likely require considerable testing and possibly even animal testing. Plaintiffs' discovery requests included information about any deviations from applicable standards, so this testing material would be responsive, but such information has not been produced and does not appear in the descriptions of any of the documents that are the subject of this Motion. Accordingly, HOC's claim of using materials that deviate from those required by the FDA is dubious, and this negates HOC's good cause arguments. The same is true of HOC's claim of a unique sterilization method. The FDA has promulgated sterilization standards, which must be

followed, absent substantial testing to establish that the deviations are substantially similar to the approved methods. Kincannon Cert, *Exhibit 31*. Thus, the claim of a unique process itself is further suspect.

1. HOC speaks in general terms, but specificity is required

HOC's submittal is lacking in other respects as well. Assuming *arguendo* that HOC's 6000 document haystack contains certain documents that contain trade secret or confidential information, based upon the information provided by HOC, neither Plaintiffs nor the Court are able to ascertain which documents deserve protection, if any. It is not Plaintiffs' burden to locate the needle. HOC bears the burden of proof and it cannot shift this burden to Plaintiffs and require Plaintiffs to determine which documents should not be protected. Kincannon Cert, *Exhibit 1*, p.31:11-14 ([The Court] "And you can't shift the burden. I don't think you can say here, you can have these and by the way, tell us which ones you don't agree to."). Indeed, the argument that all 6000 documents should be protected is incredible and is even more unbelievable given that HOC's counsel has admitted that some of the 6000 documents are not confidential. Kincannon Cert, *Exhibit 1*, p.33:5-34:1.

Nevertheless, HOC has attempted to satisfy its burden of good cause by grouping the 6000 documents relative to the products at issue in these 14 cases into seven categories of documents.[12]

[12]HOC's grouping of documents relating to all products into seven categories is telling. Previously, HOC has claimed that Plaintiffs have failed to properly identify the products involved in the litigation. This has been HOC's position as late as July 2, in its discovery responses to Form (C)(4) Interrogatories, when HOC objected based on lack of proper product identification. Kincannon Cert., *Ex. 32*. Similarly, HOC has claimed that Plaintiffs' discovery requests are burdensome due to the large number of products at issue, which resulted in late responses. Now, however, HOC's attorneys have succinctly grouped all of Plaintiffs' products into six systems – the Duracon Total Knee System, Osteonics Series 7000 Knee System, Scorpio Knee System, PCA Hip System, Osteonics Omni-fit Hip System and Meridian Hip System. Motion, p.4.

Regardless of HOC's claims, and although Plaintiffs are still not familiar with HOC's products and have not

There is no distinction based on product lines or components. There is no time limitation associated with any of the documents. In fact, there is no specific information as to any of the documents. HOC speaks generally and conclusory about the documents and the alleged harm. This is not sufficient for good cause. *See Pansy*, 23 F.3d at 786 (a proponent cannot generally fulfill its burden based upon the subject matter at issue, but must satisfy the good cause standard for each and every individual document sought to be concealed). On this basis alone, HOC has failed to meet its burden.

Furthermore, HOC makes no delineation as to which documents are alleged to be trade secrets versus confidential or proprietary information. As noted above, trade secrets are afforded more protection, but there are also applicable factors to be used to determine if information is in fact a trade secret. This lack of specificity leaves a large hole in HOC's good cause argument, as the Court cannot guess which standards to factors to apply in its analysis. It is HOC's burden, and this lack of specificity demonstrates HOC's inability to satisfy its burden.

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yet received information responsive to their discovery request regarding which of Defendants' products are no longer manufactured, Plaintiffs know that all relevant products are not covered by this list of six systems. For example, the class definition includes Defendants' knee and hip devices implanted and sterilized from 1992 until 1996 using gamma irradiation in air and containing component(s) made of ultra high molecular weight polyethylene ("UHMWPE"). Clearly, Defendants have manufactured more products than these six systems during the class period. Further, some of the personal injury Plaintiffs' products are not on this list, such as Mr. Gipson's Secur-Fit HA Hip Stem, Ms. Pillow's Secur-Fit HA PSL Screwless Acetabular Shell and Mr. Abrams' Precision Osteolock components.

Also, in its brief, HOC's attorneys claim that all of the products are different or "unique" rendering each device distinct from another device. Motion, p.11. Similar to the discussion in the previous paragraph, HOC has taken the position that because the products are so different, much more time is necessary to respond to discovery, as each unique product will have many responsive documents associated with it. However, HOC states that in the event one of Plaintiffs' products is no longer being manufactured, the technology, design, etc., upon which that product was predicated is still being used in current products. Motion, p.23. Moreover, each of Plaintiffs' products were submitted to the FDA for approval via the 510K process as being substantially similar to other products, both manufactured by HOC or a competitor. *See, e.g.*, Kincannon Cert., *Ex. 5*, (Howmedica, Inc.'s 510K application for Duracon Stabilizer Femoral Component and Insert, alleged to be substantially similar to, among others, a J&J product and an Osteonics product). These statements clearly conflict and make no sense, as the products cannot be unique and at the same time, substantially similar or part of current products.

2. The generalized categories of documents claimed to be confidential include documents affecting the public health and safety, which cannot be treated as confidential

Another major problem with HOC's argument and over broad proposed protective order is that it will include non-confidential material showing imminent and substantial endangerment to public health or safety or showing ongoing consumer fraud. Plaintiffs have obtained documents in other litigation or by Freedom of Information Act requests which demonstrate Defendant's knowledge of the problems with its products; yet Defendant continued to manufacture aggressively market and sell them, thereby endangering the public.

In addition to the documents discussed on pages 5-7, Plaintiffs have obtained other documents evidencing Defendants' knowledge of the alleged defects and failure to disclose information relating to the same.

In 1995, Dr. Dumbleton authored a report for Howmedica entitled "The Properties of UHMWPE as a Function of Time Post-Irradiation." This report begins, "Gamma sterilization of medical polymers including ultra high molecular weight polyethylene (UHMWPE) was widely adopted in the United States during the 1970's due to its advantages of high penetration and reliability. *At that time* it was appreciated that gamma irradiation could cause structural changes in the polymers." (Emphasis added) Kincannon Cert, *Exhibit 33.* This report further cites in its footnotes to articles regarding the effect of gamma irradiation in air on UHMWPE that were written in 1991. *Id.*

A Howmedica Technical Report, dated April 27, 1993, compared conventional gamma irradiation to gamma irradiation in a nitrogen (instead of air) environment. The conclusion reads,

"The UHMWPE [using nitrogen] irradiated sample showed a smaller oxidation peak and a lower oxidation index, both indicating reduced oxidation compared to the UHMWPE/air irradiated sample." Kincannon Cert, *Exhibit 9*.

An Osteonics report, entitled "R&D Internal Tech Report", dated February 16, 1994, states clearly, "Sterilization by gamma-irradiation induces surface oxidation on UHMWPE. The oxidation induced is influenced by the dose of radiation as well as gas environment. Of the three gas environments investigated in this study, oxidation was least prevalent in specimens packaged and sterilized under argon and most prevalent in those packaged in air. Finally, since neither argon nor nitrogen is incorporated into the surface of UHMWPE, it is reasonable to expect that it measures could be taken to completely exclude oxygen, the potential for oxidation could be avoided." Kincannon Cert, *Exhibit 10*.

Howmedica Technical Report, dated March 9, 1995, tested UHMWPE hips inserts that had been sterilized using gamma in air versus gamma in nitrogen, and concluded, "up to 5 million cycles on the hip joint simulator, Method B (N2/heat) reduces the wear rate of UHMWPE by approximately 40% over Method A (Air/irradiated)." Kincannon Cert, *Exhibit 11*. A similar test was done regarding knees, resulting in a Technical Report dated October 20, 1995. That report concluded that, "[t]he present results from the reciprocating pin-on-disk wear test indicate that Method B (N2/Heat) reduces the wear rate of UHMWPE by approximately 68% over Method A (Air/Irradiated). Kincannon Cert, *Exhibit 35.*

Another technical report, also issued on April 27 ,1993, compared the effect of the sterilization process on the density of UHMWPE, stating in conclusion, "the density increase in the [Nitrogen sterilized] sample is less than that in the UHMWPE/air irradiated sample, indicating a lower degree of chain scission." Kincannon Cert, *Exhibit 34*.

That HOC was aware, at least as early as the early nineties, that gamma irradiation in air compromised the integrity of the polyethylene components of their implants is absolutely above dispute.

The examples of these devices failing are also abundant. Since December 13, 1984, the FDA's Medical Device Reporting (MDR) regulations have required firms who have received complaints of device malfunctions, serious injuries or deaths associated with medical devices to notify FDA of the incident. These notifications are called MDR's, and users are specifically obligated, pursuant to regulation 519(a) of the Federal Food Drug and Cosmetic Act (as amended by the Safe Medical Devices Act (SMDA) of 1990), to report any and all (1) device-related deaths to the FDA and the device manufacturer; (2) device-related serious injuries to the manufacturer, or to FDA if the manufacturer is not known; and submit to FDA on an annual basis a summary of all reports submitted during that period. The afore cited FDA inspection report, attached to Kincannon Cert, as *Exhibit 12*, states with regard to the failure of only the Duracon Total Knee (PS) Tibial Insert, "[t]here were approximately 44 MDR's filed between 1999 and 2001 associated with fractured post necessitating revision surgery and hence serious injury." Again, this report involves only one device, and for only a limited period of time.

Notably, the documents discussed above have not been produced in these cases, but are clearly relevant and responsive to Plaintiffs' discovery requests.

3. HOC failed to allege specific and actual competitive harm

HOC is unable to specifically articulate how disclosure of this type of information which is routinely known in the industry would be used by a competitor and thereby injure HOC. The truth

is that competitors would have no use for much of the information contained in HOC's seven categories for the reasons generally set forth above.

In the instances in which HOC attempts to allege harm as a result of disclosure of the various categories of information, HOC's allegations are conclusory statements relating to competitive harm. *See* Motion, p.16 ("Any unwarranted or uncontrolled disclosure of such confidential information could cause significant monetary and competitive harm to HOC."); Motion, p.17 ("Even on a product line that is no longer manufactured, such as the PCS Hip System, unrestricted disclosure of trade secret, proprietary and confidential information would cause significant monetary and competitive harm to HOC."); Motion, p.8 (if a competitor could access this information, "it [HOC] would be substantially harmed."). These summary allegations are insufficient, as specific examples of actual harm are required to meet the good cause requirement. *Glenmede Trust Co.*, 56 F.3d at 483-485.

Additionally, HOC's allegations fail to account for the actual practice in the industry and its own practice regarding the development of new products. According to HOC, its research and development documents, its processes and manufacturing sequences are confidential and/or trade secret because they relate to unique devices unlike any other device of its own or of a competitor, and if disclosed, would undercut its market share in the industry. However, it is clear that sales is the driving force of market share, not research and development. *See* Kincannon Cert, *Exhibit 15*, p. 80:6. More money is being spent on sales than R&D, and one study indicated that the development of new products consisted of merely tweaking existing products. Kincannon Cert., *Exhibit 19,* p. 2. This is confirmed by HOC's own 510K approval applications submitted to the FDA claiming new products are substantially similar to prior products, including products by other manufacturers. Kincannon Cert., *Exhibit 5*. This is also confirmed by HOC in its brief, when it states

that technology, manufacturing and/or processing of devices that are no longer being sold is used by HOC in current products. Motion, p.23.

HOC likewise fails to explain how/if its manufacturing, design, product planning, evaluation, sterilization, testing, etc., differ from the requirements of all manufacturers in the industry. If HOC cannot say it is doing something different (yet still approved by the FDA as substantially similar to the FDA's standardized requirements) from other manufacturers, than it has failed to show any harm resulting from the disclosure of its documents. Likewise, original concepts, preliminary plans, changes, etc., would be of no help to a competitor if it wanted to copy HOC's product. It is well settled that a protective order cannot issue simply because it may be detrimental to the movant in other lawsuits. *Nestle*, 129 F.R.D. at 486 ("Using fruits of discovery from one lawsuit in another litigation, even in collaboration among various plaintiffs's attorneys, comes squarely within the purpose of the Federal Rules of Civil Procedure. The harm possibly emanating therefrom does not form a basis for a protective order.")(citations omitted). Clearly, the competitive harm summarily alleged by HOC is exaggerated for purposes of this motion, which explains why the allegations lack the required specificity.

C. The cases cited by HOC are distinguishable

HOC relies heavily upon *American Standard Inc. v. Pfizer, Inc.* 828 F.2d 734 (Fed Cir. 1987) in support of its motion. That case is distinguishable from the case at bar in several respects. First, *American Standard* was a patent infringement case filed against numerous medical device implant manufacturers, in which Biomet was issued subpoenas for testimony and documents. However, Biomet was not even a party to that litigation, a factor which the court considered and which is not

applicable to the instant case. *Id.* at 738 ("Also weighing against disclosure was Biomet's nonparty status.").

The district court, construing Indiana's Uniform Trade Secrets Act, found that Biomet could suffer from disclosure of some of the discovery sought in the subpoenas, "because disclosure would effectively include most of Biomet's competitors, all parties to the pending lawsuits." *Id.* at 738. Obviously the instant case involves no other medical device manufacturers. More importantly, the focus of the district court's analysis was more specific than the instant case, as Biomet was much more specific in describing the documents at issue and its need for confidentiality. The rationale for the decision of the district court is inapplicable to the present facts. The opinion states, "[t]he [district] court focused specifically on American Standard's requests for Biomet's confidential sales data and certain clinical data." *Id.* Although the court did find that the sales data at issue did not need to be disclosed, there is no such request for any similar documents in the instant case. Further, the court did not compel the disclosure of sales data because, "Biomet's confidential sales data were not relevant to the commercial-success issue in the Delaware and Indiana actions...[T]he court also found that American Standard had not shown need for Biomet's confidential sales data because similar information was available from the actual defendants in the pending litigation." *Id.* Finally, the district court held, and the Federal Circuit agreed, that certain clinical data at issue was relevant to an issue in the case and compelled its disclosure. *Id.* at 744. Accordingly, HOC's strong reliance on this case is misplaced, as the portion of the decision which favors their position is limited and distinguishable on the facts of that particular case.

Similarly misplaced is HOC's reliance on *Coca-Cola Bottling Company of Shreveport, Inc. v. Coca-Cola Company* 107 F.R.D. 288 (D. Del. 1985). The first line of this opinion sets the stage for what is a very different claim of confidentiality than what has been raised by HOC in the instant

case, "[t]he complete formula for Coca-Cola is one of the best kept secrets in the world." *Coca-Cola*, 107 F.R.D. at 289. The court continues, "[T]he formula for Merchandise 7X [secret ingredients of Coke] has been tightly guarded since Coca-Cola was first invented and is known by only two persons with The Coca-Cola Company. The only written record of the secret formula is kept in a security vault at the Trust Company Bank in Atlanta, Georgia, which can only be opened upon a resolution from the Company's Board of Directors." *Id.* Plaintiffs argue that the collection of 6000 purportedly confidential documents at issue herein, regarding, *inter alia*, products that are no longer manufactured by the Defendants and documents which Defendants themselves acknowledge are not confidential, simply does not rise to the level of singular importance that the formula for Coke has for its respective company. The opinion is rife with examples of the extreme measures the Coca-Cola company has gone to in order to protect their formula, examples which are clearly wanting in the instant case, to wit:

> [after statement that formula is kept in vault in Atlanta, *supra*], it is the Company's policy that only two persons in the Company shall know the formula at any one time, and that only those persons may oversee the actual preparation of [the secret formula]. The Company refuses to allow the identity of those persons to be disclosed or to allow those persons to fly on the same airplane at the same time....
> As an indication of the value the Company places on its secret formulae, [the affiant] avers that the Company elected to forego producing Coca-Cola in India, a potential market of 550 million persons, because the Indian government required the Company to disclose the secret formula for Coca-Cola as a condition of doing business there.

Id. at 294.

HOC has simply failed to demonstrate any security measures even remotely on par with those taken by the defendant in *Coca-Cola*. Yet even with those strict and onerous security measures in place, demonstrating clearly that the formula for Coke was desperately protected by that company, the court in that case compelled the production of the secret formula to the plaintiffs. *Id.* at 300. This case actually favors Plaintiffs' position, and shows the search for the truth will not be hampered

by a defendant who seeks to cloak in secrecy that which much necessarily be disclosed in the interests of justice.

HOC cites to *In re Eli Lilly & Company, Prozac Products Liability Litigation*, 142 F.R.D. 454 (S.D. Ind. 1992) for the premise that "a manufacturer 'would undoubtedly suffer economic harm if the manufacturing process it has expended time and money developing became known by its competitors.'" Motion p. 23, *quoting Eli Lilly*, 142 F.R.D. at 460 (incorrectly cited in Defendant's brief as appearing on p. 459). The convenience of using a quote without describing the nature of the case, its relevant or analogous facts, or its disposition is evident here, as is the propriety of using such quotes. Although a protective order was issued in that case, it was not the protective order that the defendant in that case proposed, which was rejected. *Id.* at 460. The protective order the court did approve was limited, in that the court compelled the production of all documents, but allowed the defendant to redact some material. *Id.* The court further required the defendant to indicate the category of redaction (*i.e.*, patient name, doctor name, etc.) for each and every redacted item. *Id.* Defendant HOC has not ever suggested or offered a complete production that merely redacted certain information, Defendant instead seeks a blanket confidentiality order, yet cite to this case for support.

Plaintiffs will not belabor this issue by analyzing each of the numerous cases cited by HOC in which protective orders of some fashion were used. Plaintiffs note that the legal issues dealt with in the instant and cited cases, and the analysis thereon, is a very fact specific inquiry, and accordingly, naked citations to a case (*e.g.,* "*Ecolaire Inc. v. Crissman*, 52 F.Supp. 196, 206 (E.D.Pa. 1982) (holding that drawings and blueprints constitute trade secrets"), Motion p. 22) cannot by themselves stand in support of Defendant's position.

HOC also contends that parties in complex product liability cases often recognize the sensitivity of a company's information and consent to protective orders, citing two cases involving

the Duracon Uni-Knee device. Motion, p.20, n8. Another attorney's decision to consent to a protective order is completely irrelevant, as such consent could be based on any number of reasons, other than believing the documents are in fact confidential.[13] Notably, undersigned counsel also had a Duracon Uni-Knee case against Defendants and undersigned counsel refused to sign a protective order in that case and were still provided discovery, including discovery not yet produced in the cases *sub judice*. *See* Kincannon Cert., para 2.

Moreover, Plaintiffs served a discovery request on HOC asking for pleadings, orders, discovery and other documentation from prior cases arising from its design, manufacture, sterilization, distribution and/or sale of its products. Plaintiffs' First Request for Production of Documents, No. 42. HOC responded that such information is "neither relevant nor reasonably calculated to lead to the discovery of admissible evidence." Kincannon Cert., *Exhibit 17*. Yet, HOC now attempts to cherry pick from this irrelevant prior litigation to support its confidentiality argument. These statements by HOC relating to prior litigation should be recognized for the gamesmanship they are and should be stricken from HOC's papers.

Given its track record for inconsistent positions, Plaintiffs certainly doubt that all 6000 documents yet to be produced contain trade secret, confidential or proprietary information. Rather than taking a defensible position of claiming certain specific documents or portions of documents for certain specific products or product lines contain proprietary information and are deserving of protection, HOC has overreached and alleged this wide variety of documents, including those which defense counsel already informed the Court are not confidential, relating to many different products,

[13] *See Frankl v. Goodyear*, Kincannon Cert., *Ex.3*, discussing stipulations of confidentiality as a "quid pro quo for the demanding party's prompt and cooperative compliance with its discovery obligations." Kincannon Cert. *Ex. 3,* p. 24. "Litigants needing key information from their adversaries' files, especially those who lack the time and resources to become embroiled in discovery feuds, may all-to-readily capitulate to such demands. They may also tolerate over broad self-designations of confidentiality by their adversaries, even for materials that do not deserve such protection, in order to avoid costly and time-consuming collateral disputes." *Id.* at 24-25.

the designs of which have changed over time and in some cases become obsolete, in an industry with considerable standardization and similar products across manufacturers, are all proprietary and should be the subject of a protective order.

Moreover, as discussed, HOC has failed to articulate specific examples of harm to its competitive position, relying instead on general, unsupported statements of risk to its competitive position.[14] HOC bears the burden in this matter and the law is clear as to what HOC must prove. The need for specificity with respect to documents and actual harm is completely consistent with New Jersey's policy of open, liberal discovery and with New Jersey's disfavor of protective orders. If a company cannot demonstrate how it will be harmed or how a competitor will benefit by the disclosure of its documents, then there is no need to invoke the onerous provisions of a protective order.

D. HOC's Proposed Blanket Protective Order is Improper, Over Broad and Should Be Denied

HOC proposes an blanket protective order, wherein HOC produces its documents and Plaintiffs must come forward to contest documents that Plaintiffs believe do not belong under the order. This is the procedure that HOC has proposed for the last several months and was rejected by Plaintiffs, maintaining that such an order is overly broad, burdensome to the Court and to the parties, shifts the burden to Plaintiffs, and is contrary to New Jersey's policy of open discovery.

Blanket protective orders are not favored, as such blanket orders do not give any indication as to which document(s) warrant protection. This specificity is important because the party seeking

[14]HOC submitted several certifications in support of its confidentiality arguments. However, not only have these certifications not been subjected to cross-examination, *see Conforti v. Guliadis*, 245 N.J. Super. 561, 566 (App. Div. 1991)(self-serving certifications not subject to cross-examination carry little weight); *Lyon v. Glaser*, 60 N.J. 259, 281 (1972)(same), these certifications contain the same conclusory statements at set forth in HOC's brief. Indeed, the certifications merely repeat what is stated in HOC's brief, word for word. This suggests lawyer-written certifications, which do not aid in the demonstration of good cause for secrecy.

the protection carries the heavy burden of showing a positive reason justifying entry of a restrictive order. *E.g.*, FRCP Rule 26(c)[15]; *United States v. United Fruit Co.*, 410 F.2d 553, 557 (5th Cir.), *cert. denied*, 396 U.S. 820 (1969); *Public Citizen v. Liggett Group, Inc.*, 858 F.2d 775, 789 (1st Cir. 1988), *cert. denied*, 488 U.S. 1030 (1989); *In re "Agent Orange" Prod. Liab. Litig.*, 821 F2d 139, 145-46 9 (2d Cir.), *cert. denied*, 484 U.S. 953 (1987); *Krazewski v. State Farm Gen. Ins. Co.*, 139 F.R.D. 156, 159 (N.D. Cal. 1991).

The *Frankl* court correctly recognized that blanket protective orders, "drafted by imaginative counsel on boilerplate forms with sweeping terminology, have the capacity to envelop virtually every bit of information that turns up in a case with a veil of secrecy." Kincannon Cert., *Exhibit 3*, p.24. The same can be said in this case. HOC's proposed order is clearly over broad, as it include documents related to a sterilization process no longer manufactured, designs that have since been modified and are no longer used, products that are no longer manufactured and documents that are admittedly not confidential, but are organized in binders with confidential documents and it would be too much trouble for HOC to separate them. This was certainly not the purpose of this procedure, and Plaintiffs are yet again prejudiced by more delay in discovery.

More surprising, HOC seeks to have this protective order apply to future documents, which are not yet at issue. Many months ago, Plaintiffs sought to establish a procedure for confidentiality claims of future documents that would be produced in discovery, only to be met with a claim that such confidentiality claims were "hypothetical." Now, HOC's position is that product liability cases

[15]New Jersey rules of discovery are similar to the federal rules: "The purpose and scope of our discovery rules, Rule 4:10-1 and Rule 4:10-2, are substantially the same as Federal Rule of Civil Procedure 26. Similarly, Rule 4:10-3 follows the text of Federal Rule of Civil Procedure 26(c). Because of the dearth of decisional law in this State interpreting the right of public access to documents, information and materials submitted to the court in civil matters, we will also examine applicable federal decisions and rules." *Hammock v. Hoffmann-LaRoche*, 142 N.J. 356, 378 (1995). Thus, federal decisions may be useful in determining how the Court will decide the discovery issues in this case.

routinely involve trade secret or confidential documents and protective orders are appropriate for those cases. This is yet another example of HOC's ever-changing and inconsistent positions taken in these cases.

Additionally, by including non-confidential documents affecting the health and safety of the public in its protective order, Plaintiffs' counsel and the Court are forced to become co-conspirators in this illegal coverup. Under HOC's grossly over broad form of order, at the end of the case, all documents must be returned to HOC, so that the public never knows the dangers associated with these products. Proposed Order, Para.C, p.8. [16]

Indeed, HOC's proposed order even requires Plaintiffs to ignore a valid grand jury subpoena or a valid order from another court. Proposed Order, Para.E, p.9.

Another reason to reject blanket protective orders is that they raise the cost of justice for plaintiffs and, in hard fought litigation such as the instant case, they threaten to generate expensive collateral litigation, or a case within a case. For example, according to HOC's grossly over broad proposed form of order, all that is required to initial a dispute "is a good faith belief [without a showing or judicial finding] by counsel for the producing party that there has been a violation of this Order." Proposed Order, Para. A(3), p.7. Accordingly, the rule that defendant show injury to competitive interests is erased. HOC instead substitutes the injury requirement for mere "violation of the order" which may or may not harm them. Subjective good faith in a highly adversarial context is not the rule of law regarding confidentiality. Ironically, HOC agrees, contemporaneously referring to Plaintiffs' complaint as "a lawyer's unsubstantiated allegations." Motion, p.3. Moreover, it is

[16]HOC also seems to suggest that its burden changes with the quality of plaintiffs' cases. HOC complains that it deserves special, favorable treatment because we are only at the complaint stage of the litigation. Motion, p.2. Yet, under the terms of HOC's proposed order, even if Plaintiffs win on the merits, everything remains sealed.

never enough to warrant allowing defendants to get access to plaintiffs non-testifying experts and consultants. *See, e.g.,* Proposed Order, Paras.A(2)(c), (d) and A(3), pp.6-7.

The threat of disclosure and/or "contempt or other proceedings" will deter non-testifying experts from assisting in the litigation. It is a small field, and many doctors with valuable information do not want to be pulled into Court. HOC's order will also have a chilling effect on their participation.

For all the foregoing reasons, Plaintiffs strongly object to the entry of a protective order, especially one in the form submitted by HOC. As Plaintiffs have stated numerous times, Defendants should be required to abide by the Rules of Court, setting forth good cause for the documents it claims are confidential.

IV. CONCLUSION

For the reasons set forth above, this Court should deny HOC's Motion for a Protective Order.[17]

Respectfully submitted by:

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[17]Although Plaintiffs believe the Court should deny HOC's motion outright, alternatively, Plaintiffs seek the opportunity to depose the affiants and any other knowledgeable persons regarding the issues set forth in HOC's submittal on an expedited basis.