Order Granting In Part And Denying In Part Plaintiffs' Request To Remove Confidentiality Designations

10/02/2002

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

IN RE: PHENYLPROPANOLAMINE (PPA) PRODUCTS LIABILITY LITIGATION, _____ This document relates to all actions	MDL NO. 1407 ORDER GRANTING IN PART AND DENYING IN PART PLAINTIFFS' REQUEST TO REMOVE CONFIDENTIALITY DESIGNATIONS

I. INTRODUCTION

Plaintiffs filed a Motion to Dispute Confidentiality of Discovery Material Pursuant to CMO 2 ("Plaintiffs' Motion"), relating to documents designated confidential by defendant Novartis Consumer Health ("NCH"). Having reviewed pleadings filed in support of and in opposition to the motion, along with the remainder of the record, and, being fully advised, the court finds and concludes as follows:

II. BACKGROUND

Case Management Order No. 2 ("CMO 2") limits the disclosure of discovered confidential documents in appropriate circumstances. Specifically, CMO 2 permits the confidentiality designation of discovery material "containing trade secrets, or other confidential or proprietary research, development, manufacturing or commercial or business information." CMO 2, ¶ 3. It also allows a party, following good faith negotiation attempts, to dispute a confidentiality designation by motion to the court "at any time . . . for any reason." Id. at ¶ 10.a. In the event such a challenge is brought, CMO 2 places the burden of proof for establishing the propriety of a confidentiality designation on the designating party. Id.

Plaintiffs deposed Vincent Termini, a NCH employee, in March 2002. Pursuant to CMO 2, NCH designated as confidential the bulk, if not all, of the exhibits to that deposition. Plaintiffs' MDL Discovery Committee thereafter requested the removal of those confidentiality designations. In response, NCH removed the designation from three documents, but also designated as confidential all portions of the

Termini deposition relating to exhibits designated confidential, as well as some thirty additional deposition pages.

Plaintiffs again requested the removal of the remaining confidentiality designations. Negotiations on the issue failed, resulting in the filing of the current motion. In their Opposition to Plaintiffs' Motion ("NCH's Opposition"), NCH removed the confidentiality designation from several additional documents, deposition testimony corresponding with those documents, and much of the thirty some additional pages of testimony previously designated confidential. As such, the parties currently dispute the confidentiality designations of a total of thirteen exhibits and corresponding deposition testimony.[11] But see infra part III (discussing plaintiffs' allegation as to the ongoing nature of this problem).

III. DISCUSSION

Plaintiffs assert that NCH has misused the umbrella protective order encapsulated in CMO 2 by designating documents confidential in an unrestricted fashion. This practice, plaintiffs argue, renders the Termini deposition virtually unusable in a public trial without clearing the courtroom, makes it difficult to discuss facts at issue in briefing to the court and between plaintiffs' counsel, and places a burden on the court and parties to file documents under seal. Plaintiffs distinguish NCH's behavior from the behavior of other defendants, whom they aver have been able to designate confidential documents selectively and appropriately. They note that the alleged over-designation problem has continued to arise in every NCH deposition with virtually every document produced from NCH's files.

NCH describes plaintiffs' motion as an attempt to rob it of its only benefit in stipulating to CMO 2 – the agreement that the sensitive, confidential nature of documents it produced would be maintained. They aver that plaintiffs threaten the efficiency of discovery in this case and prematurely seek a waiver of confidentiality, despite the fact that these documents have not yet been filed with the court in support of or against a substantive motion, or relied upon by the court in rendering a decision.

A. NCH's Burden to Demonstrate Good Cause:

"Generally, the public can gain access to litigation documents and information produced during discovery unless the party opposing disclosure shows 'good cause' why a protective order is necessary." Phillips v. GMC, 289 F.3d 1117, 1121 (9th Cir. 2002). CMO 2 allows

the parties in this MDL to designate discovered documents confidential,[22] However, the confidentiality designations established in the course of discovery do not necessarily reflect the treatment that will be afforded those documents at the time of trial. but maintains this good cause standard in the face of challenges to those designations. CMO 2, ¶ 10.a.[33] The parties devoted considerable attention to the question of whether a presumptive right of public access to these documents exists or would apply in this case. However, because, as discussed below, the court finds good cause lacking for protection of the majority of the documents at issue here, and appropriate for protection of only some discrete information, it does not find it necessary to address this particular issue.

The burden rests on NCH to show good cause as to why the documents are entitled to confidentiality designations. See CMO 2, ¶ 10.a; accord Fed. R. Civ. P. 26(c); Beckman Indus. v. International Ins. Co., 966 F.2d 470, 475-76 (9th Cir. 1992).[44] Given that CMO 2 affords a party the right to dispute a confidentiality designation at any time and for any reason, the court rejects NCH's suggestion as to the prematurity of the current motion. "For good cause to exist, the party seeking protection bears the burden of showing specific prejudice or harm[.]" Phillips, 289 F.3d at 1121. See also San Jose Mercury News, Inc. v. U.S. Dist. Court, 187 F.3d 1096, 1102-03 (9th Cir. 1999). "'Broad allegations of harm, unsubstantiated by specific examples or articulated reasoning, do not satisfy the Rule 26(c) test.'" Beckman Indus., 966 F.2d at 476 (9th Cir. 1992) (quoting Cipollone v. Liggett Group, Inc., 785 F.2d 1108, 1121 (3d Cir. 1986)).

NCH argues that good cause exists to maintain the confidentiality of the Termini deposition exhibits given that the designations were asserted to protect NCH's trade secrets and other proprietary information. See CMO 2, ¶ 3; accord Fed. R. Civ. P. 26(c)(7) (allowing court to issue a protective order indicating "that a trade secret or other confidential research, development, or commercial information not be revealed or be revealed only in a designated way[.]") A trade secret is generally defined to include:

> information, including a formula, pattern, compilation, program, device, method, technique, of process that: (i) derives independent economic value, actual or potential, from not being generally known to, and not being readily

> ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use; and (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

Unif. Trade Secrets Act § 1(4) (1985) (adopted in approximately 44 states, including Washington).

NCH provides justification for the confidentiality designation asserted for each document. Generally, NCH argues that all of these documents remain commercially valuable to NCH because they reveal current and confidential business practices, including formulation, testing, marketing, and sales decisions, from which NCH derives value by denying its competitors access. See Encyclopedia Brown Prods. v. Home Box Office, 26 F. Supp. 2d 606, 613 (S.D.N.Y. 1998) ("[T]he principal considerations [in determining whether the documents contain trade secrets] are whether the information is confidential and whether it is commercially valuable to the holder.") NCH asserts that it takes an innovative approach towards all of its products, and argues that disclosure of these documents will provide its competitors insight into its internal processes, resulting in clearly defined and serious competitive harm. See, e.g., Joint Stock Soc'y v. UDV N. Am., Inc., 104 F. Supp. 2d 390, 405 (D. Del. 2000) (recognizing serious competitive injury if media, advertising, marketing, and promotional strategies released); Encyclopedia Brown Prods., 26 F. Supp. 2d at 613-14 (finding documents relating to defendant's operations confidential; "It suffices here to note that defendants' competitive position would be affected at most, if not at all, economic levels, vis-a-vis their direct and indirect competitors, upstream suppliers and downstream customers.")

Plaintiffs refute NCH's ability to show good cause. Generally, they argue that the documents at issue here, dating from 1980 to 1990, are stale and do not reveal confidential information, let alone information that could be effectively used by a competitor today. See, e.g., In re "Agent Orange" Prod. Liab. Litig., 104 F.R.D. 559, 575 (E.D.N.Y. 1985) ("An important factor in determining whether disclosure will cause competitive harm is whether the information that the party seeks to protect is current or stale.") If anything, plaintiffs aver, the NCH documents reflect fairly common business practices, such as market research, product strategies, and decision making, typical within the pharmaceutical industry. They

describe the conclusions offered by NCH as to each of the documents as insufficient in being stereotypical and conclusory, rather than particular and specific. See Cipollone, 785 F.2d at 1121.

B. Confidentiality Designations in Dispute:

The court must determine whether good cause exists to prevent the disclosure of the documents at issue. See Phillips, 289 F.3d at 1123. As such, the court will examine the documents themselves and the arguments proffered by NCH in support of the confidentiality designations.

1. Position Paper and Attached Memorandum:

Exhibit 3-B is a 1989 memorandum transmitting a position paper comparing PPA and pseudoephedrine ("PSE"), the substance which ultimately replaced PPA, summarizing the conclusions of the paper, and then suggesting that a "follow-up study of physician perceptions . . . might be the most useful next step." See Declaration of Lance E. Palmer in Support of Plaintiffs' Motion ("Palmer Decl."), Ex. 3-B. The paper itself summarizes studies and literature on the subject, and reaches a conclusion as to the relative safety of PPA and PSE. Id. at Ex. 3-C. NCH describes these documents as discussing its internal evaluation of published literature relating to different ingredients used in its products. See Affidavit of Michal Holzman ("Holzman Aff."), ¶ 5. NCH maintains that, although based on publicly available medical literature, the evaluation reflects the company's current internal thought processes and analyses. Id.

However, the court finds it highly unlikely that NCH's review of studies and literature pertaining to one of its drugs and a potential replacement product constitutes an innovative practice within the pharmaceutical industry. Neither does the fact that NCH anticipated looking into physician perceptions appear likely to reveal a strategy unique to NCH. As such, it is entirely unclear how disclosure of either document now, over thirteen years after the fact and two years after all of the defendants replaced PPA with PSE, could possibly provide NCH's competitors with a competitive advantage. The court, thus, concludes that NCH lacks good cause to maintain a confidentiality designation for either of these documents.

2. Reformulation Efforts:

A number of the exhibits relate to "reformulation" efforts for products containing PPA and, thus, the conversion from PPA to PSE. NCH describes exhibit 3-D, a 1980 memorandum, as reflecting the use

of a three phase reformulation process and giving the precise formulations of both former and current NCH products. Holzman Aff., ¶ 6; Palmer Decl., Ex. 3-D. Exhibits 3-E, 3-F, 3-K, 3-L, 3-N, and 3-R, documents with dates ranging from 1983 to 1989, all relate to NCH's decision-making with regard to replacing PPA with PSE, and include status reports, discussions of cost issues and projections, and recommendations. Holzman Aff., ¶¶ 5, 7, and 10; Palmer Decl., Exs. 3-E, 3-F, 3-K, 3-L, 3-N, and 3-R. NCH argues that, although maintaining back-up formulations on stability is an industry-wide practice, the NCH reformulation process, concerns, and strategies described in these documents are confidential, unique, still employed by NCH, and relate to currently marketed brands. See Holzman Aff., ¶¶ 5, 7, 9-10.

If any of the product formulations contained in Exhibit 3-D remain current and confidential, the court agrees that good cause exists to maintain the confidentiality of at least those portions of the document. See Citizens First Nat'l Bank of Princeton v. Cincinnati Ins. Co., 178 F.3d 943, 945 (7th Cir. 1999) (finding that for documents containing trade secrets as well as material not falling within the definition of a trade secret "all that would be required to protect a party's interest in trade secrecy would be redaction of portions of the document.") However, the court questions the purported confidential status of the three phase process itself. The phases referred to include reformula-tions of products first without PPA and pyrilamine, then without PPA alone, and finally without guaifenesin alone. See Palmer Decl., Ex. 3-D. This process appears to reveal nothing more than the fact that NCH conducted thorough reformulations based on the "possibility of governmental action against several of the ingredients in [its] cough and cold products." Id. Given that NCH was not alone in facing the possibility of this governmental action, the court does not find that disclosure of this "three phase process," in this case utilized over twenty years ago, would result in any prejudice or harm to NCH.

Similarly, the court does not find the factors considered and the reformulation efforts undertaken by NCH, as reflected in the other reformulation documents, at all unusual for a pharmaceutical company. In Exhibit 3-E, a 1983 memorandum, NCH discusses the status of the FDA review of PPA and recommends that the company continue to pursue reformulation efforts for some products, while declining to do so for other products due to "costs, product contribution and long-range strategies." Id., Ex. 3-E. Exhibit 3-F

provides a status report on the various reformulation efforts and a cost estimate for conversion to PSE as of 1983. Id. at Ex. 3-F. Exhibits 3-K, 3-L, and 3-R also discuss the projected cost of conversion, and related contracting issues, as of 1988 and 1990. Id. at Exs. 3-K, 3-L, and 3-R. Exhibit 3-N recommends that the company refrain from converting to PSE, while taking various actions to support this position, including conducting follow up research with physicians and taking action against any "competitive 'anti-PPA' campaign." Id. at Ex. 3-N. This document also provides a rationale for the continued use of PPA, based on factors such as costs, sales, and market research. Id.

That NCH continually monitored the status of its reformulation efforts, took actions such as conducting research and acting against any adverse campaigns, and made decisions based on issues such as the cost of conversion, sales, and market research, is unlikely to come as a surprise to any of its competitors. That these documents are not only outdated, but relate to products which have already been converted – by NCH and its competitors alike – also works against the asserted need for confidentiality. Cf. In re Adobe Systems, Inc. Sec. Litig., 141 F.R.D. 155, 162-63 (N.D. Cal. 1992) (finding "forward-looking" documents created in the two years preceding the court's decision to remain sensitive and confidential). As such, except to the extent that the reformulation documents may contain current formulas and technological information properly redacted as confidential, the court does not find good cause to exist for these confidentiality designations.[5] However, defendants could maintain the confidentiality of documents providing cost of conversion figures, see Palmer Decl., Exs. 3-F, 3-K, 3-L, and 3-R, if those documents would reveal current and confidential cost and profit margin information.

3. Corporate Objectives:

Exhibit 3-G contains NCH's 1984 "Strategic Corporate Review," which NCH asserts continues to reflect highly sensitive and confidential corporate objectives. See Holzman Aff., ¶ 7; Palmer Decl., Ex. 3-G. Yet, the apparent objectives identified (including the defense of NCH's continued use of PPA through scientific forums, political activity, corporate and regulatory channels, and the public, as well as continued reformulation efforts) again appear unlikely to be novel approaches in the pharmaceutical industry. Palmer Decl., Ex. 3-G. Likewise, the court finds implausible the suggestion that exhibit 3-H, another 1984 document, would reveal a practice unique to NCH in disclosing NCH's "continued marketing focus on

pediatricians and general practitioners." Holzman Aff., ¶ 8. See id. at Ex. 3-H. As such, the court also finds good cause lacking for these two confidentiality designations.

4. New Product Lines/Product Line Extensions:

Finally, NCH asserts that exhibits 3-I and 3-S, documents from 1987 and 1990 respectively, reflect internal decisions made with respect to potential new product lines or product line extensions. Palmer Decl., Exs. 3-I and 3-S. NCH argues that disclosure of this information would reveal insight into its decision-making processes. Holzman Aff., ¶ 9.

Exhibit 3-I essentially reveals consumer research into the viability of a product line targeting a certain group of consumers, and the decision to not pursue such a line given that the market would be too small, an essential ingredient would be eliminated, and there would be a lack of promotional efficiencies. Palmer Decl., Ex. 3-I. To the extent disclosure of this document would reveal information relating to a line of products currently under consideration for development, or constituting a realistic potential line of future products, the court agrees that a confidentiality designation may be appropriate. See, e.g., Joint Stock Soc'y, 104 F. Supp.2d at 409 (upholding protection of old vodka formulas given their "potential to confer independent economic value.")

Exhibit 3-S appears to contain updates on a variety of different products, and references the unchanged status of PSE reformulations. Palmer Decl., Ex. 3-S. The court does not find any information within this document reflecting a potential new product line or product line extension. As such, unless NCH can demonstrate that this document truly does contain information of this kind, this document would not qualify for a confidentiality designation.

C. Reviewing and Removing Confidentiality Designations:

In sum, the court finds that, with the discrete exceptions discussed above, NCH has failed to demonstrate good cause for the confidentiality designations attached to these exhibits and, consequently, the corresponding deposition testimony. Given the perceived continuing nature of this problem, plaintiffs request that the court order the protections of CMO 2 lifted at the expiration of sixty days as to all documents subject to plaintiffs' requests to admit, except as to those documents specifically identified by NCH within that sixty day period in a motion for a protective order.

Although the court denies plaintiffs' request to lift the protection of CMO 2 as applied to NCH, the court orders NCH to review all of the documents it has thus far designated confidential. NCH should complete this review within the thirty (30) days following the issuance of this order and remove designations where appropriate in accordance with this order by the conclusion of that time period. Any future confidentiality designations should also be applied in accordance with this order.

IV. CONCLUSION

For the reasons discussed above, the court hereby GRANTS in part and DENIES in part plaintiffs' motion to dispute confidentiality designations pursuant to CMO 2. NCH shall comply with this order in removing confidentiality designations from and redacting specific documents as discussed within this order, and reviewing and removing other confidentiality designations as may be appropriate in accordance with this order and the schedule outlined above.

DATED at Seattle, Washington this 30th day of September, 2002.

/s/
BARBARA JACOBS ROTHSTEIN
UNITED STATES DISTRICT JUDGE