UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF ILLINOIS

IN RE: YASMIN AND YAZ (DROSPIRENONE) MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION

3:09-md-02100-DRH-PMF

MDL No. 2100

This Document Relates to:

Judge David R. Herndon

ALL CASES

CASE MANAGEMENT ORDER 45

Herndon, Chief Judge

Pending before the Court is plaintiff Kaitlyn Dietrick's motion for authority to petition the FDA and its advisory committee by presenting key "protected" documents concerning public health issues regarding drospirenone-containing oral contraceptives (Doc. 2051). Plaintiff, through the Plaintiffs' Steering Committee (PSC), requests the Court, pursuant to the First Amendment, to de-designate documents previously held confidential pursuant to the Protective Order (CMO 7) (Doc. 291).

Defendant Bayer responds contesting not plaintiff's right to petition the government, but the use of confidential documents in her petition (Doc. 2079). Plaintiff seeks de-designation of 58 documents (Doc. 2069) (filed under seal). Defendant agrees to de-designate ten of the subject documents (Doc. 2069, Bayer Addendum Items 8, 10, 12, 14, 31, 44, 48, 52, 54, and 55) (filed under seal).

Thus, 48 documents are at issue. For the following reasons, the Court **DENIES** plaintiff's motion. To consider the subject documents in Doc. 2069, the Court grants the Motion to Supplement found at Doc. 2068.

ARGUMENT AND APPLICATION

1. Plaintiff has no 1st Amendment Right to Disseminate Confidential Information Obtained Through Discovery and not Otherwise Filed With the Court

a. Protective Orders Entered Pursuant to 26(c) are not Subject to Strict Scrutiny

Plaintiff argues the important right bestowed upon every United States citizen to "petition the Government for a redress of grievances," allows her the right to present confidential documents, obtained solely through discovery in these proceedings, to the FDA Advisory Committee (Doc. 2051, pp. 4-8) (citing U.S. Const. amend. I). Defendant contends plaintiff is free to exercise her right to petition the government through presenting documents to the FDA Advisory Committee. However, she may not do so with the subject confidential documents without compromising the integrity of the instant discovery process as well as the controlling German privacy laws. More importantly, defendant argues, the fact the pertinent confidential documents are designated confidential to avoid a German law conflict, does not violate plaintiff's First Amendment rights (Doc. 2079, p. 5). The Court finds defendant's reasoning controlling.

Litigants do not have an unfettered First Amendment right to disseminate documents obtained through the discovery process. *See Seattle Times Co. v.*

Rhinehart, 467 U.S. 20 (1984). In *Seattle Times,* the Supreme Court held in addressing whether the subject protective order, limiting dissemination of information obtained solely through the discovery process, offended the First Amendment required consideration of, "whether the 'practice in question [furthers] an important or substantial government interest unrelated to the suppression of expression' and whether the 'limitation of First Amendment freedom [is] no greater than is necessary or essential to the protection of the particular governmental interest involved.'" *Id.* at 20-21. The Supreme Court further explained, "[a] litigant has no First Amendment right of access to information made available only for purposes of trying his suit. Furthermore, restraints placed on discovered information are not a restriction on a traditionally public source of information." *Id.* at 21. Thus, "Rule 26(c) furthers a substantial governmental interest unrelated to the suppression of expression," as "[l]iberal pretrial discovery" rules have a "significant potential for abuse."*Id.* Thus, the use of protective orders does not violate the First Amendment. *Id.*

Significant to the instant dispute, the Supreme Court based its determination on the privacy and reputational rights of the subject individuals of the underlying documents. Therefore, as the trial court entered the subject protective order upon a showing of "good cause" pursuant to Rule 26(c), the order was limited solely to the context of pretrial civil discovery, and the order did not restrict dissemination of information obtained through other sources, the Supreme Court held it did not violate the First Amendment. *Id.* Thus, *Seattle*

Times demonstrates protective orders are not subject to the same" exacting First Amendment scrutiny" as a "classic prior restraint." *Id.* at 34. As such, they are not subject to strict scrutiny; provided "good cause" pursuant to 26(c) supports the protective order, it is valid under the First Amendment. Notably, as the Seventh Circuit has reiterated, the public's presumptive right of access to discovery materials does not apply when the parties have not filed the subject documents with the court. *Bond v. Utreras*, 585 F.3d 1061, 1073 (7th Cir. 2009).

Plaintiff gained access to the disputed documents solely through the discovery process. The documents are not filed with the Court. Further, plaintiff is not restricted from disseminating the subject information if obtained through other means. Therefore, based on the holdings of *Seattle Times* and *Bond*, the Court finds preservation of CMO 7 will not violate plaintiff's First Amendment right to petition the government provided defendant makes the requisite showing of "good cause" pursuant to 26(c).

b. Relevance of German Law Does not Change Applicable First Amendment Level of Scrutiny

Plaintiff further argues application of the German privacy laws at issue violates her First Amendment rights as preservation of the documents' confidential status acts as a prior restraint on speech (*See* Doc. 2068). As previously explained, Rule 26(c) protective orders are not prior restraints on First Amendment rights. *See Seattle Times*, 467 U.S. at 34. Further, the principle of comity requires the Court to recognize the relevant German privacy laws at issue.

See Societe Nationale Industrielle Aerospatiale v. U.S. Dist. Ct. for the So. Dist. of Iowa, 482 U.S. 522, 546 (1987). Moreover, despite application of German privacy law to the instant dispute, provided defendant demonstrates "good cause" for confidentiality of the subject documents under Rule 26(c), whether based on privacy rights, trade secrets, or intellectual property, the protective order is valid and does not violate the First Amendment. *See Seattle Times*, 467 U.S. at 21.

2. Defendant has Made Required Showing of "Good Cause" Under Rule 26(c) Requiring Preservation of Documents' Confidential Status

FEDERAL RULE OF CIVIL PROCEDURE 26(c) provides, "[t]he court may, for good cause, issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense." Rule 26(c) specifically holds a court may issue an order "requiring that a trade secret or other confidential research, development, or commercial information not be revealed or be revealed only in a specified way." FED.R.CIV.P. 26(c)(1)(G). Moreover, "although Rule 26(c) contains no specific reference to privacy or other rights or interests that may be implicated, such matters are implicit in the broad purpose and language of the Rule." *Seattle Times*, 467 U.S. at 38 n. 21. The Court finds defendant has met its burden of proving "good cause" exists to preserve the confidential status of the documents at issue.

a. Documents Require Confidential Status Pursuant to German Privacy Laws

The Court finds application of the German Federal Data Protection Act (BDSG) demonstrates "good cause" under Rule 26(c) as to twenty-eight of the subject documents. The BDSG applies as the processing of the personal data at issue took place in Germany. Thus, the participants expected, rightfully so, that German law would dictate the use of their personal data. CMO 7 § II.B dictates German entities may designate as confidential documents containing "personal data" pursuant to the BDSG (Doc. 291, p. 3). The Court finds defendant has made a particularized showing that twenty-eight of the confidential documents at issue contain "personal data" pursuant to the BDSG.

As defendant explains, the BDSB presumptively prohibits the "collection, processing and use of personal data . . . to achieve a maximum degree of protection" (Doc. 2079, p. 14) (citing Doc. 2079, Ex. 2, ¶ 11). Further, the BDSG broadly defines "personal data" as "any information concerning the personal or material circumstances of an identified or identifiable individual." *Id.* at ¶ 13. Moreover, defendant states, "[t]he BDSG applies to personal data processed in Germany regardless of the nationality, citizenship, or domicile of the individual to whom the information pertains" (Doc. 2079, p. 14) (citing Doc. 2079, Ex. 2, ¶ 8).

After consulting with Dr. Henning Moelle, German attorney-at-law, defendant contends twenty-eight of the confidential documents contain "personal data" as defined under the BDSG as they "include names, job titles, phone numbers, email addresses, or other personal data for literally hundreds of individuals, and thus concern the 'personal or material circumstances of an

identified or identifiable individual'" (Doc. 2079, p. 16) (citing Doc. 2079, Ex. 2, ¶ 19).

Generally, the BDSG prohibits transfer of personal data to any jurisdiction that does not provide data protection rules functionally equivalent to the E.U. According to German and E.U. lawmakers, this includes the U.S. (Doc. 2079, p. 17) (citing Doc. 2079, Ex. 2, ¶ 21). Defendant concedes an exception exists as the BDSG allows transfer of "personal data" outside the E.U. for purposes of litigation (Doc. 2079, p. 17) (citing Doc. 2079, Ex. 2, ¶ 22 (citing BDSG § 4c(1)(4))). Plaintiff cites this exception as allowing unfettered transfer of the confidential documents (Doc. 2068, p. 10). However, defendant explains in detail that this limited exception does not abrogate the need for either 1) consent of the data subject, or 2) some other provision of the BDSG permitting such transfer, processing, or use(Doc. 2079, p. 17) (citing Doc. 2079, Ex. 2, ¶ 24).

Defendant contends the confidentiality allowed under CMO 7 facilitated defendant's production of over twenty-two million pages of documents containing personal data from many thousands of subjects (Doc. 291). Obviously, obtaining the consent of all the participants is out of the question. Further, defendant contends obtaining consent of the subjects connected to the twenty-eight documents currently at issue would require contact with hundreds of employees, former employees, and individuals generally unknown to defendant (Doc. 2079, p. 18) (citing Doc. 2079, Ex. 2, ¶ 27). Moreover, defendant admits other provisions of the BDSG do permit transfer. However, these provisions require the

documents maintain their confidential status (Doc. 2079, pp. 18-19) (citing Doc. 2079, Ex. 2, ¶¶ 28-33).

The Court finds the BDSG dictates the relevant expectations of privacy of the confidential documents' underlying subjects. Defendant has demonstrated the BDSG does not allow for dissemination of the subjects' "personal data" without consent or pursuant to some other provision of the BDSG. Defendant has further demonstrated it is not practicable, or perhaps possible, to obtain the subjects' consent. Moreover, defendant has adequately shown that no other provision of the BDSG allows for relief from the CMO 7. As stated previously, privacy interests are implicitly encompassed within the "good cause" showing under Rule 26(c).*See Seattle Times*, 467 U.S. at 38 n. 21. Defendant has adequately shown CMO 7 is the only means available to uphold the privacy interests of the confidential documents' subjects. Thus, the Court finds defendant has demonstrated "good cause" for upholding CMO 7 based on the relevant privacy interests of the documents' subjects.

b. The Remaining Documents Constitute Trade Secrets and Intellectual Property Requiring Confidential Status

i. Trade Secrets

Under Rule 26(c), a showing that particular information amounts to a trade secret such that a disclosure may place the holder at a completive advantage constitutes "good cause." *Jamsport Entm't, LLC v. Paradama Prods., Inc.*, No. 02-2298, 2005 WL 14917, at *2 (N.D. Ill. Jan. 3, 2005). The Illinois Trade Secret Act provides relevant guidance to the Court. It defines a trade secret as:

> [I]nformation, including but not limited to, technical or non-technical data, a formula, pattern, compilation, program, device, method, technique, drawing, process, financial data, or list of actual or potential customers or suppliers, that:
>
> > (1) is sufficiently secret to derive economic value, actual or potential, from not being generally known to other persons who can obtain economic value from its disclosure or use; and
> >
> > (2) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy or confidentiality.

765 ILCS 1065/2(d); *see also Hal Wagner Studios, Inc. v. Elliott*, No. 09-0031, 2009 WL 854676, at *3-5 (S.D. Ill. Mar. 30, 2009).

a. Nonpublic Corporate Product Research

Defendant contends documents for which plaintiff seeks de-designation constitute "non-public research reports related to Yaz or other Bayer products" (Doc. 2079, p. 22-23). Specifically, defendant contends these documents contain "confidential trade secrets as they include technical and non-technical data and/or compilation data" (Doc. 2079, p. 23). Defendant explains at length the need to maintain the confidential status of these documents as they "contain highly sensitive information" of great value to defendant's research and development (Doc. 2079, p. 23-24). Defendant states this information could prove highly valuable to its competitors if made public. These reports are not published nor disseminated outside of defendant's business. Defendant asserts to the extent it has provided these documents to outside entities, such as the FDA, these regulators have agreed to their continuing confidentiality (Doc. 2079, pp. 24-25). The information contained in these documents has cost defendant "hundreds of

thousands, if not millions, of dollars" to produce(Doc. 2079, p. 35). Thus, the Court finds defendant has made the requisite showing of "good cause" to demonstrate these documents constitute trade secrets such that their dissemination would prove economically advantageous to defendant's competitors. Thus, the Court preserves the confidentiality CMO 7 provides these documents.

b. Marketing Related Materials

Plaintiff seeks de-designation of documents defendant claims generally constitute marketing materials. The documents at issue contain "observations and guidance from external healthcare providers," "minutes of the Global Brand Team discussing marketing strategy and planning," "discussions of factors relating to marketing development and growth," and "a report on trends in the development and marketing of oral contraceptives" (Doc. 2079, p. 26) (citing Doc. 2079, Ex. C ¶ 12; Ex. D ¶ 11).

The Seventh Circuit has held customer lists and customer information constitute trade secrets. *Am. Family Mut. Ins. Co. v. Roth*, 485 F.3d 930, 933 (7th Cir. 2007). Moreover, non-public marketing plans are confidential information, properly subjected to protective orders. *See Kimberly-Clark Corp. v. Tyco Healthcare Retail Group, Inc.* No. 05-0985, 2006 WL 6652868, at *1-2 (E.D. Wis. Apr. 6, 2006). The Court finds the documents at issue represent substantial investments of defendant. Investments defendant does not make publicly available. Further, these documents represent "list[s] of actual or

potential customer or suppliers," "compilation[s]," and "process[es]" subject to a proper protective order. *See* 765 ILCS 1065/2(d). As these documents would prove highly valuable to defendant's competitors, represent a large monetary investment of defendant, and are otherwise non-public, the Court finds defendant has demonstrated "good cause" for preservation of CMO 7 as to these documents.

c. Documents Revealing Intellectual Property are Subject to Confidentiality Protection

Plaintiff seeks de-designation of documents defendant contends are "unpublished intellectual property of third parties, and therefore must be maintained as confidential" (Doc. 2079, p. 28). On many of the relevant documents, defendant contends the authors have designated their confidential status through a stamp or other marker (Doc. 2079, p. 28).

Intellectual property is a proper basis for a protective order. *See Sanimax AGS v. Gulf Hydrocarbon, Inc.*, No. 09-37, 2010 WL 2560032, at *1-2 (S.D. Ind. June 23, 2010); *McManaway v. KBR, Inc.*, No. 08-186, 2009 WL 807641, at *1 (S.D. Ind. Mar. 25, 2009). Defendant has sufficiently demonstrated the documents constitute intellectual property. Thus, the Court finds defendant has demonstrated "good cause" for preservation of CMO 7 as to the subject documents.

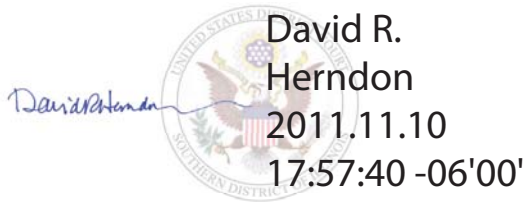
Conclusion

For the foregoing reasons, the Court **DENIES** plaintiff's motion (Doc. 2051). The plaintiff's motion at Doc. 2068 was granted in order to consider the subject documents in 2069, which was inappropriately tagged as a motion. Therefore, to the extent defendant has not otherwise stipulated, the subject documents' status as confidential under CMO 7 is preserved.

IT IS HEREBY ORDERED that plaintiff is not granted relief from CMO 7 except to the extent defendant stipulates.

IT IS SO ORDERED.

Signed this 10th day of November, 2011.



Chief Judge
United States District Court