**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF COLUMBIA**

| | |
|---|---|
| **ALBANY MOLECULAR RESEARCH, INC.,**<br><br>**Plaintiff,**<br><br>**v.**<br><br>**GEORGE C. SCHLOEMER, et al.,**<br><br>**Defendants.** | **Misc. No. 11-0096 (JDB)** |

## MEMORANDUM OPINION

Currently before the Court is a Motion to Quash Non-Party Subpoena filed by PGxHealth, LLC ("PGxHealth") and defendant George C. Schloemer. The motion requests that the Court quash plaintiff Albany Molecular Research, Inc.'s ("AMRI") subpoena to the United States Food and Drug Administration ("FDA") to produce "(1) the application submitted by PGxHealth for Vilazodone; (2) the FDA's application file for Vilazodone, and (3) correspondence or notes, whether in paper or electronic format, of meetings between the FDA and PGxHealth concerning Vilazodone." Pl's Sur-Reply at 2 (referencing Ex. C, Defendant and Counterclaim Plaintiff Albany Molecular Research, Inc.'s First Request for Production of Documents to Plaintiff, May 20, 2009). For the reasons set forth below, the Court will deny the motion to quash.

## BACKGROUND

This discovery matter arises out of a contractual dispute between AMRI and PGxHealth that is currently pending in both the Northern District of New York ("New York action") and

Massachusetts state court ("Massachusetts action"). In March 2007, PGxHealth contracted with AMRI to "develop a viable commercial manufacturing process for the active ingredient in Vilazodone," an anti-depressant drug, with the goal of filing a new drug application ("NDA") with the FDA by late 2009. See PGxHealth and Def. George C. Scholemer's Mot. to Quash Non-Party Subpoena ("Def's Mot.") at 6. Between July 2008 and January 2009, AMRI produced several batches of Vilazodone with "unacceptably-high levels of impurities or the wrong 'polymorph' or crystalline form of Vilazodone." Id. AMRI asserts that "such polymorph problems are not unusual and AMRI was working to solve the problem." Pl's Mem. in Opp'n to Def's Mot. to Quash ("Pl's Opp'n") at 5. In January 2009, PGxHealth notified AMRI that it was terminating the Master Services Agreement ("MSA") for cause and refused to pay the remaining balance on the contract. See Def's Mot. at 6; Pl's Opp'n at 2.

Subsequent to AMRI's termination, PGxHealth entered into an agreement with ScinoPharm Taiwan ("ScinoPharm") to produce the needed samples of Vilazodone. Pl's Opp'n at 2. In April 2009, PGxHealth brought suit against AMRI in Massachusetts state court for breach of contract and for a declaratory judgment stating that PGxHealth was under no contractual obligation to make additional payments to AMRI. See Def's Mot. at 7; Pl's Opp'n at 2. In 2010, AMRI filed suit in the United States District Court for the Northern District of New York against George C. Schloemer, a consultant hired by PGxHealth, for tortious interference with its contractual relations with PGxHealth. Id. AMRI claims that Schloemer was a former board member and consultant for ScinoPharm during the period he was working on the PGxHealth/AMRI contract. See Pl's Opp'n at 2-3.

Roughly a year after terminating the contract, PGxHealth filed its NDA for Vilazodone

with the FDA "using registration batches successfully produced" by ScinoPharm. See Def's Mot. at 7. On January 21, 2011, the FDA approved PGxHealth's NDA for Vilazodone to be marketed as an anti-depressant. See Def's Mot. at 8; Pl's Opp'n at 3. During the course of discovery in the Massachusetts action, AMRI requested from PGxHealth all documents and correspondence related to the FDA approval and announcements regarding Vilazodone. See Def's Mot. at 8-9; Pl's Opp'n at 3. PGxHealth objected to AMRI's request, claiming that the request was "overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence." Def's Mot. at 9; Pl's Opp'n at 3. PGxHealth ultimately did produce correspondence with the FDA from January 2011 regarding Vilazodone approval, but has not complied with AMRI's request in full at this time. Id. On February 4, 2011, AMRI served the FDA with a subpoena seeking the production of documents related to the Vilazodone application and approval. See Pl's Opp'n at 3. PGxHealth and defendant George Schloemer then filed the motion to quash now before this Court on February 28, 2011.[1]

**DISCUSSION**

Defendant George Scholemer and PGxHealth filed their motion to quash pursuant to Fed. R. Civ. P. 45(c)(3)(B)(i), which permits a court to quash or modify a subpoena if it requires "disclosing a trade secret or other confidential research, development, or commercial

[1] On March 15, 2011, the Massachusetts Superior Court issued two relevant orders: (1) denying AMRI's motion to compel production of documents and (2) deferring judgment on PGxHealth's cross-motion for a protective order "until the documents issue is resolved." Pl's Response to Order for Clarification ("Pl's Resp.") at 1; Def's Response to Order for Clarification ("Def's Resp.") at 1-2; see Def's Ex. 1 (Copy of AMRI's Motion to Compel Production of Documents Containing Written Order from Massachusetts Superior Court, March 15, 2011); Def's Ex. 2 (Copy of PGxHealth's Opp'n to AMRI's Motion to Compel Production of Documents and Cross-Motion for a Protective Order Containing Written Order from Massachusetts Superior Court, March 15, 2011). The Court appreciates the additional filings prepared by the parties and ultimately concludes that the recent Massachusetts orders do not impact the Court's decision nor require a stay in the proceedings as requested by defendant Schloemer and PGxHealth.

information." In determining whether information is protected under Rule 45, courts must evaluate whether the information being sought is the type of commercial information that should not be disclosed to the public. Courts typically consider two factors in analyzing Rule 45 cases, beginning with whether the release of the information would unfairly harm the disclosing party's ability to compete in the marketplace. Falicia v. Advanced Tenant Serv., Inc., 235 F.R.D. 5, 7 (D.D.C. 2006) (referencing Manning Mills, Inc. v. Armstrong World Indus., Inc., 206 F.R.D. 525, 528-29 (D. Del. 2002)). If the disclosed information would unfairly harm the disclosing party's financial health, then the information should be protected from disclosure because "commercial information can be used to directly compete with the disclosing party or, alternatively, might be disclosed by a competitor to decrease the competitive advantage of the commercial information." Id. (citing Echostar Commc'ns Corp. v. News Corp., Ltd., 180 F.R.D. 391, 395 (D. Colo. 1998).

Courts also consider who could potentially receive the disclosed information, assuming "'that disclosure to a competitor is more harmful than disclosure to a non-competitor.'" Id. (quoting Am. Standard Inc. v. Pfizer Inc., 828 F.2d 734, 741 (Fed. Cir. 1987)). Thus, if the court determines that the subpoena requests commercial information, "the burden shifts to the party seeking the information to show that obtaining the information is both relevant and necessary." Id. (referencing Am. Standard, 828 F.2d at 740-41). Ultimately, "[i]f this burden is satisfied, then the court must balance the two competing interests and determine what aspect of the subpoena, if any, will be enforced." Id. (citing Am. Standard., 828 F.2d at 742).

AMRI initially argues that neither PGxHealth nor Schloemer have standing to quash the subpoena because "the only party that has standing to quash a Rule 45 subpoena in the issuing

court is the party subpoenaed." Pl's Opp'n at 3 (citing 2 Wright & Miller, Federal Practice & Procedure, § 2463.1 (2010)). However, a party to the underlying action may move to quash the subpoena where the subpoena directly implicates the party's privilege or rights. See Chiperas v. Rubin, 1998 U.S. Dist. LEXIS 23578, *4-5 (D.D.C. 1998); Doe v. Verizon Online, 2010 U.S. Dist. LEXIS 50594, *4-5 (D.D.C. 2010). Although AMRI tries to assert that neither PGxHealth nor Schloemer has any special privilege or right implicated by the documents in question, the Court finds that they have a real and defined interest in the business records requested in the subpoena so as to satisfy the standing requirements. Hence, the Court will consider whether PGxHealth and Schloemer have satisfied the standard under Rule 45 to quash AMRI's subpoena.

PGxHealth and Schloemer argue that the subpoena should be quashed because details regarding how a drug is manufactured, "including a description 'of the drug substance and the final drug product, the general method of preparation and formulation, the analytical methods employed to assure quality and consistency, and the results of stability testing' are 'paradigmatic example[s] of trade secret and confidential information.'" Def's Mot. at 10 (citing Sokolow v. FDA, 1998 U.S. Dist. LEXIS 23672, *10 (E.D. Tex. 1998)). PGxHealth and Schloemer are correct in noting the precarious nature of the requested documents, but the analysis does not end simply because the documents at issue involve confidential information surrounding FDA approval. Because documents that contain confidential material often fall under the broad definition of relevance, the court must strike a balance between the need for the information being sought and the risk to the financial health of the business from production. See Falicia, 235 F.R.D. at 5.

The Court recognizes that some of the requested documents undoubtably contain sensitive material concerning the FDA application and subsequent approval of Vilazodone. However, neither Schloemer nor PGxHealth have demonstrated that AMRI is a direct competitor and that disclosing the redacted material would represent a threat to the financial health of the company. See Falicia, 235 F.R.D. at 10. PGxHealth asserts that AMRI is a "direct competitor" because it is "entitled to receive royalties on worldwide sales of commercialized compounds designed to treat depression." Def's Mot. at 10. PGxHealth and Schloemer attempt to argue that they only learned during discovery in the Massachusetts action that AMRI is a competitor of PGxHealth because AMRI had developed its own pharmaceutical compound designed to treat depression and had "entered into an agreement with Bristol-Myers Squibb ("BMS") for the further development of this compound, and . . . received substantial milestone payments since that time." Def's Mot. at 8.

However, it is quite clear that AMRI's relationship with BMS was publicly disclosed in 2005, two years before PGxHealth and AMRI entered into a contract for the production of Vilazodone. See Pl's Opp'n at 8-9. Furthermore, the fact that AMRI was developing a separate compound for anti-depressant drugs does not make the two companies direct competitors such that the requested information represents the "'lifeblood of [the company's] well being'" and is "critical to the financial health of the non-party's business." Falicia, 235 F.R.D. at 10 (citing In re Vitamins Antitrust Litig., 267 F. Supp. 2d 738, 741-42 (S.D. Ohio 2003)); see also Pl's Ex. B (Affidavit of Roy Swarigen, Jr, Independent Pharmaceutical Consultant, February 24, 2011) (explaining that "simply because two compounds are slated for use as the same class of drug, like

an anti-depressant, does not mean that they are 'potential competitors' or similar compounds . . . It is not be [sic] unusual for a large chemical development company to work on dozens, if not hundreds, of drugs that are destined for the same class of use, i.e., as an anti-depressant"). Thus, the Court does not find that AMRI and PGxHealth are direct competitors such that releasing the redacted documents would jeopardize the financial well-being of PGxHealth.

As noted, the parties are currently entangled in litigation in two separate jurisdictions. Although the Court is able to reach the merits of defendant's motion to quash without detailed descriptions of the pending matters in New York and Massachusetts, certain factors are relevant under a proper Rule 45 analysis. There is a protective order in place in the Massachusetts action. It is well settled that a court has broad discretion under Fed. R. Civ. P. 26(c)(7) to determine both whether a protective order is warranted and the necessary restrictions, if any, to be imposed. Aluminum Co. of Am. v. U.S. Dep't of Justice, Antitrust Div., 444 F. Supp. 1342, 1346-47 (D.D.C. 1978) (citing C. Wright and A. Miller, 8 Federal Practice and Procedure, § 2043 at 305 (1970)). Specifically, "the court . . . may make any order which justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense, including . . . that a trade secret or other confidential research, development, or commercial information not be disclosed or be disclosed only in a designated way." Fed. R. Civ. P. 26(c)(7).

Here, the parties stipulate that the protective order issued by Magistrate Judge David Homer in the Massachusetts action applies to the subpoena and redacted documents at issue in this case. See Pl's Opp'n at 8. That protective order permits the parties "to designate documents as confidential or even as attorneys' eyes only." See id. The existence of a protective order

weighs against quashing the subpoena on commercial information grounds because the protective order is designed to protect and prevent public disclosure of confidential and sensitive business information, like that potentially at issue here. See Hillenrich & Bradsby Co. v. MacKay, 26 F. Supp. 2d 124, 127-28 (D.D.C. 1998) (finding the protective order would safeguard the confidentiality of the information at issue and denying the motion to quash the subpoena *duces tecum*). Hence, there is little or no threat that PGxHealth's financial health will be impacted by the document disclosures or that their direct competitors would gain unfair access to the confidential information and use it against the company, since the requested information will be fully protected from disclosure or use outside the ongoing litigation.

Although the balance weighs against granting the motion to quash when considering to whom the documents would be released and the relationship between the parties, AMRI still must show that the documents at issue are relevant and necessary to their discovery efforts. In general, the scope of discovery includes "any non-privileged matter that is relevant to any party's claim or defense - - including the existence, description, nature, custody, condition, and location of any documents or other tangible things and the identity and location of persons who know of any discoverable matter." Fed. R. Civ. P. 26(b)(1). Moreover, "the term relevance at the discovery stage is broadly construed to include information which is not admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence." DL v. Dist. of Columbia, 251 F.R.D. 38, 42 (D.D.C. 2008). Here, Schloemer and PGxHealth claim that the requested documents are not relevant because PGxHealth has already produced documents related to its FDA submission and AMRI is not able to demonstrate that it needs any

additional FDA-related information. See Def's Mot. at 11.

First, the fact that PGxHealth has already disclosed several documents related to the FDA approval of Vilazodone does not impact AMRI's current request to the FDA. It is not surprising that PGxHealth has released documents during the course of discovery in the Massachusetts action and that some of those documents are related to the FDA process and approval of Vilazodone. Hence, it appears that AMRI has received materials relating to the FDA process and approval of Vilazodone from both PGxHealth and the FDA. But AMRI's request to the FDA must be assessed separately from the documents PGxHealth has already disclosed. And the FDA has not produced a significant amount of material. Although PGxHealth argues that the redacted documents at issue are duplicative and thus not necessary, there appear to be hundreds of pages of redacted information at issue. See Pl's Ex. A (Chemistry Review Report from the Center for Drug Evaluation and Research, Application Number: 022567Orig1s000). And there is no contention that AMRI has already received that information from any source.

Secondly, PGxHealth and Schloemer argue that the documents at issue are not relevant because "PGxHealth's NDA for Vilazodone does not discuss Mr. Schloemer's advice to PGxHealth, nor does it discuss Mr. Schloemer's interactions with AMRI." Def's Mot. at 12. But relevancy at the discovery stage is broadly defined, and the Court finds the requested documents to be well within the scope of relevant materials. See Harris v. Koenig, 271 F.R.D. 356, 363 (D.D.C. 2010) (finding that relevancy for discovery purposes is broadly construed). Because the litigation between AMRI and Schloemer focuses on whether Schloemer was influenced by his relationship with ScinoPharm and whether such influence impacted AMRI's contract with

PGxHealth, the documents that discuss ScinoPharm's solution to the impurity and stability issues found in AMRI's work product are relevant and hence discoverable.

## CONCLUSION

Ultimately, PGxHealth and Schloemer have not demonstrated that the relevant and necessary documents at issue will significantly affect the financial health and well-being of the company if disclosed. Moreover, the protective order issued by Magistrate Judge David Homer in the Massachusetts action affords additional protection against misuse. Therefore, the Court will deny PGxHealth and Schloemer's motion to quash the subpoena to the FDA. A separate order has been issued on this date.

/s/
JOHN D. BATES
United States District Judge

Dated: April 14, 2011