

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS**

**KPH HEALTHCARE SERVICES, INC.,
a/k/a KINNEY DRUGS INC.,
FWK HOLDINGS LLC, and
CESAR CASTILLO, LLC, individually
and on behalf of all others similarly
situated,**

Plaintiffs,

v.

**MYLAN N.S., MYLAN SPECIALTY
L.P., MYLAN PHARMACEUTICALS,
INC., PFIZER, INC., KING
PHARMACEUTICALS, INC.,
MERIDIAN MEDICAL
TECHNOLOGIES, INC.,**

Defendants.

Case No. 2:20-cv-2065-DDC-TJJ

MEMORANDUM AND ORDER

This matter is before the Court on the Motion of KPH Healthcare Services, Inc., FWK Holdings, LLC, and Cesar Castillo, LLC (“Plaintiffs”) to compel non-party Kaléo, Inc. (“Kaléo”) to produce documents in compliance with subpoena (ECF No. 203). Plaintiffs seek an order requiring Kaléo to produce documents responsive to Request 16 in Schedule A to Plaintiffs’ subpoena served on March 9, 2022. Kaléo opposes the motion. As set forth below, the Court denies Plaintiffs’ motion.

I. Relevant Background

This case arises out of the manufacture and sale of the Epi-Pen—an epinephrine auto-injection (“EAI”) drug device used to treat anaphylaxis. Plaintiffs bring this lawsuit on behalf of

themselves and a putative class of direct purchasers of the Epi-Pen. Generally, Plaintiffs assert that Defendants engaged in unlawful monopolization of the EAI market, violating Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, and Section 3 of the Clayton Act, 15 U.S.C. § 14. Kaléo is a third-party corporation which sells EAIs in direct competition with the Mylan Defendants.¹ Specifically, Kaléo sells the Auvi-Q, an EAI that competes with EPI, an EAI sold by the Mylan Defendants, and the “generic Epi-Pen,” an EAI sold by Teva Pharmaceuticals USA, Inc.

On March 9, 2022, Plaintiffs served a subpoena on Kaléo pursuant to Fed. R. Civ. P. 45.² On March 25, 2022, Kaléo served objections to the document requests.³ Specifically, Kaléo objected to the production of transaction-level sales data for Auvi-Q. On April 26, 2022, Plaintiffs’ counsel and counsel for Kaléo participated in a meet-and-confer videoconference regarding Kaléo’s responses and objections to the Subpoena. On May 6, 2022, Plaintiffs’ counsel emailed Kaléo’s counsel an excel spreadsheet containing a proposed template for Kaléo’s transaction-level sales data production. On May 20, 2022, Plaintiffs’ counsel and Kaléo’s counsel participated in another videoconference regarding Kaléo’s responses and objections to the Subpoena. During that conference, Kaléo’s counsel informed Plaintiffs’ counsel that the parties’ negotiations concerning Plaintiffs’ document subpoena were at an impasse and that Kaléo would not produce the requested Auvi-Q transaction-level sales data absent a Court order.

¹ The Court notes the Mylan Defendants previously filed a similar motion to compel a subpoena directed to Kaléo in *In re: EpiPen (Epinephrine Injection, USP) Marketing, Sales Practices and Antitrust Litigation*, Case No. 17-md-2785 (D. Kan. August 10, 2018). The Court denied the motion on similar, but distinct grounds as discussed in this Order. *Id.*, see (ECF No. 869).

² ECF No. 204-1.

³ ECF No. 204-2.

Plaintiffs’ and Kaléo’s counsel have communicated at length regarding their clients’ respective positions on the subpoena. The Court finds they have complied with the requirements of D. Kan. R. 37.2.

II. Legal Standard

In issuing a subpoena, a party must “take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena.”⁴ Non-parties responding to Rule 45 subpoenas generally receive heightened protection from discovery abuses.⁵

Federal Rule of Civil Procedure 45 governs both motions to compel compliance with and motions to quash subpoenas served on non-parties.⁶ Under Rule 45(d)(2)(B), if the entity commanded to produce documents serves written objections to the subpoena, the serving party may seek compliance by filing a motion to compel production of the documents. If the non-party wishes to challenge the subpoena, it does so by filing a motion to quash. Rule 45(d)(3) sets forth circumstances under which a court must quash or modify a subpoena, including when the subpoena “requires disclosure of privileged or other protected matter, if no exception or waiver applies,” and when the subpoena “subjects a person to undue burden.”⁷ The rule also allows a court discretion to quash or modify a subpoena that requires the disclosure of a “trade secret or other confidential

⁴ Fed. R. Civ. P. 45(d)(1).

⁵ *XPO Logistics Freight, Inc. v. YRC, Inc.*, No. 16-mc-224-CM-TJJ, 2016 WL 6996275, at *3 (D. Kan. Nov. 30, 2016) (citing *Speed Trac Techs., Inc. v. Estes Exp. Lines, Inc.*, No. 08-212-KHV, 2008 WL 2309011, at *2 (D. Kan. June 3, 2008)).

⁶ Kaléo agreed to Plaintiffs filing the instant motion.

⁷ Fed. R. Civ. P. 45(d)(3)(A).

research, development, or commercial information.”⁸

“The scope of discovery under a subpoena is the same as party discovery permitted by Fed. R. Civ. P. 26.”⁹ In other words, the relevancy standards set forth in Rule 26 define the permissible scope of a Rule 45 subpoena. Relevancy is to be “construed broadly to encompass any matter that bears on, or that reasonably could lead to other matter that could bear on” any party’s claim or defense.¹⁰ Information still “need not be admissible in evidence to be discoverable.”¹¹ When the discovery sought appears relevant, the party resisting discovery has the burden to establish the lack of relevancy by demonstrating that the requested discovery (1) does not come within the scope of relevancy as defined under Fed. R. Civ. P. 26(b)(1), or (2) is of such marginal relevancy that the potential harm occasioned by discovery would outweigh the ordinary presumption in favor of broad disclosure.¹² Conversely, when the relevancy of the discovery request is not readily apparent on its face, the party seeking the discovery has the burden to show the relevancy of the request.¹³ Relevancy determinations are generally made on a case-by-case basis.¹⁴

⁸ Fed. R. Civ. P. 45(d)(3)(B).

⁹ *In re Syngenta AG MIR 162 Corn Litig.*, MDL No. 2591, No. 14-md-2591-JWL, 2017 WL 1106257, at *16 (D. Kan. Mar. 24, 2017) (citing *Schneider v. CitiMortgage, Inc.*, No. 13-4094, 2014 WL 4749181, at *2 (D. Kan. Sept. 24, 2014)).

¹⁰ *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 351 (1978).

¹¹ Fed. R. Civ. P. 26(b)(1).

¹² *Gen. Elec. Cap. Corp. v. Lear Corp.*, 215 F.R.D. 637, 640 (D. Kan. 2003).

¹³ *McBride v. Medicalodges, Inc.*, 250 F.R.D 581, 586 (D. Kan. 2008).

¹⁴ *Breck & Young Advisors, Inc. v. Lloyds of London Syndicate*, No. 09-cv-2516-JAR, 2011 WL 765882, at *3 (D. Kan. Feb. 25, 2011).

Trade secrets and similar confidential information are not afforded absolute privilege.¹⁵ However, under Federal Rule of Civil Procedure 26, for good cause shown a court may “issue an order 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 revealed or be revealed only in a specified way.”¹⁶ A person seeking to resist disclosure must (1) establish that the information sought is a trade secret or other confidential research, development, or commercial information, and (2) demonstrate that its disclosure might be harmful.¹⁷ If these requirements are met, the burden shifts to the party seeking discovery to establish that the disclosure of trade secrets is relevant and necessary to the action.¹⁸ Finally, the court must balance the need for the trade secrets against the claim of injury resulting from disclosure.¹⁹ If the requesting party demonstrates both relevancy and need, the trade secrets should be disclosed unless they are privileged or the subpoenas are unreasonable, oppressive, annoying, or embarrassing.²⁰

III. Analysis

Plaintiffs argue Kaléo is improperly withholding Auvi-Q transaction-level sales data that is necessary to establish the contours of the relevant product market and Kaléo’s objections to

¹⁵ *MGP Ingredients, Inc. v. Mars, Inc.*, 245 F.R.D. 497, 500 (D. Kan. 2007).

¹⁶ Fed. R. Civ. P. 26(c)(1).

¹⁷ *MGP*, 245 F.R.D. at 500.

¹⁸ *Id.*

¹⁹ *Centurion Indust., Inc. v. Warren Steurer & Assocs.*, 665 F.2d 323, 325 (10th Cir. 1981).

²⁰ *Id.* at 326.

producing the data have no merit. Kaléo argues the requested transaction-level sales data is confidential commercial information that should be protected under Fed. R. Civ. P. 45(d)(3)(B)(i), the requested transaction-level sales data for Auvi-Q did not occur during the relevant time period, and disclosure of 48 separate data points for each direct sale ever made is not necessary to Plaintiffs' action.

A. Whether the transaction-level sales data is confidential information

Plaintiffs argue the requested information is not confidential commercial information because Kaléo's competitors are likely well-aware of who purchases Auvi-Q directly from Kaléo and at approximately what quantities and prices. Kaléo argues it may properly withhold production on the grounds that the requested sales data constitutes confidential commercial information.

Under the applicable standard, Kaléo must first establish that the information sought is indeed a trade secret or other confidential research, development, or commercial information, and that disclosure of the information could be harmful. The latter requires demonstration that disclosure "would 'result in a clearly defined and very serious injury,' such as showing the competitive harm that would befall it by virtue of the disclosure."²¹ To establish such injury, the person seeking protection must make "a particular and specific demonstration of fact, as distinguished from stereotyped and conclusory statements."²²

²¹ *In re Syngenta AG MIR 162 Corn Litig.*, 2017 WL 1106257, at *12 (D. Kan. Mar. 24, 2017) (quoting *Layne Christensen Co. v. Purolite Co.*, 271 F.R.D. 240, 249 (D. Kan. 2010)).

²² *Syngenta*, 2017 WL 1106257, at *12 (quoting *Gulf Oil v. Bernard*, 452 U.S. 89, 102 n.16 (1981)).

Plaintiffs requested transaction-level sales data, from the date Kaléo first sold Auvi-Q to the present, including:

All direct sales/invoice transactions (as well as any discounts or any other price adjustments or offsets contained in the transaction data) including the following fields: (i) price or dollar amount, (ii) source of the transaction price, (iii) number of units sold, returned, or otherwise affected by the transaction, (iv) unit of measure, (v) date of transaction, (vi) information sufficient to identify the type of transaction (e.g., a sale, a return, a discount, etc.), (vii) NDC, (viii) UPC, (ix) SKU, (x) product description, (xi) product form, (xii) product strength, (xiii) package size in extended units per package, (xiv) customer name, (xv) customer number, (xvi) customer address, (xvii) customer class of trade code and the description of that code (all such customer information being provided for both the bill-to customer and the ship-to customer), and (xviii) the customer's parent company (if the data identify a subsidiary, corporate affiliate, division, satellite office, distribution center, warehouse or the like).²³

Plaintiffs requested other transaction-level sales data, such as “All data relating to chargebacks, rebates, discounts, and other consideration given or accrued” and “All administrative fee transactions.”²⁴

Kaléo argues the information at issue is proprietary and confidential commercial information. Kaléo's President and CEO has submitted a declaration describing the efforts Kaléo undertakes to keep its proprietary competitive information confidential and secret, particularly from its competitors and most particularly from Mylan and Teva.²⁵ For instance, every Kaléo employee is required to execute a written Loyalty Agreement which forbids disclosure of confidential information such as “trade secrets or know-how including, but not limited to, any non-public research, product or service plans, products, services, customer lists, . . . pricing, costs,

²³ ECF No. 204-1.

²⁴ *Id.*

²⁵ ECF No. 243-1.

markets, summaries, investment strategies, marketing strategies and other strategies, software, developments, inventions, processes, . . . marketing, [or] financial information or other business information.”²⁶ Kaléo employs tight physical security measures as well, both for its offices and its information technology systems.²⁷

Plaintiffs’ argument that Defendants are likely well-aware of who purchases Auvi-Q and at approximately what quantities and price is not persuasive. Even if Mylan Defendants, Kaléo’s main competitors, had a general idea about who purchases Auvi-Q and at what quantity and price, they do not have a detailed spreadsheet with 48 separate data points for each and every direct sale ever made by the company. Documents that comprise confidential commercial information include “information, which if disclosed would cause substantial economic harm to the competitive position of the entity from whom the information was obtained.”²⁸ The Court concludes that the transaction-level sales data Plaintiffs request is confidential Kaléo commercial information.

B. Whether production would harm Kaléo

Kaléo argues the disclosure of transaction-level sales data will allow Mylan Defendants to undermine the various programs it has instituted to help consumers afford its product, which is Kaléo’s main competitive advantage over Mylan Defendants. Plaintiffs argue the disclosure would not harm Kaléo because Plaintiffs are not Kaléo’s main competitor, and the Protective Order

²⁶ *Id.*

²⁷ *Id.*

²⁸ *Nostrum Pharmaceuticals, LLC v. Dixit*, No. 15-mc-218-JWL-GLR, 2015 WL 6828182, at *2 (D. Kan. Nov. 6, 2015) (quoting *In re S3 LTD*, 242 B.R. 872, 876 (Bank. E.D. Va. 1999)).

entered in this case can be used to protect Kaléo from disclosure of confidential information to Mylan Defendants.

Kaléo argues the disclosure of its client list with every sale ever made to every client ever serviced, identifying price points, discounts, and what actions led it to win and lose clients would be detrimental to the company. Kaléo sells a single, privately held product and argues Defendants could use the detailed sales data to calculate its revenues, map its sales, determine the areas of the nation in which it concentrates its sales force and marketing strategies, and work back from the data to reverse-engineer Kaléo's proprietary, expensively developed, sales analytical tool. Kaléo asserts its use of innovative pricing strategies allows it to create the Auvi-Q system and make it available to commercially insured customers at little to no out-of-pocket cost, while maintaining a pricing structure adequate to support production, research, and development activities. Kaléo contends this is the crux of its competitive advantage over the Mylan Defendants, and its disclosure would irreparably harm its position as a viable competitor to Mylan Defendants.

Plaintiffs contend they are not Kaléo's competitor, and the risks associated with disclosing the data to Mylan can be eliminated by the Protective Order. As courts have noted, disclosure to a non-competitor is less harmful than disclosure to a competitor.²⁹ However, here, Kaléo's direct competitors, the Mylan Defendants, are entitled to receive responses from third party subpoenas within two days of receipt by the issuing party. Kaléo does, therefore, have legitimate concerns that, if it is required to provide the requested information, its direct competitors will gain access to its confidential transaction-level sales data.

²⁹ *E.g., Am. Standard, Inc. v. Pfizer, Inc.*, 828 F.2d 734, 741 (Fed. Cir. 1987); *Coca-Cola Bottling Co. of Shreveport v. Coca-Cola Co.*, 107 F.R.D. 288, 293 (D. Del. 1985).

The Plaintiffs argue the sales data can be labelled “Highly Confidential,” so only the parties’ outside counsel, two designated in-house counsel from each party under confidentiality guidelines, outside experts or consultants, and others specifically allowed under the Protective Order would have access to Kaléo’s data production. While the Court is aware of the strength of the “Highly Confidential” provision of the protective order in this case, and without casting aspersions on the good faith of any party’s adherence to its terms, the Court does not find the protective order provides adequate protection to Kaléo.

The Court concludes Kaléo could suffer real and substantial harm if it were to disclose the requested transaction-level sales data, and the existence of a protective order is not sufficient to eliminate the risk of irreparable harm to Kaléo.

C. Whether the sales data is relevant and necessary to Plaintiffs

Plaintiffs contend the transaction-level sales data subpoenaed from non-party Kaléo is highly relevant to the claims at issue in the litigation because Auvi-Q was one of the few EAIs on the market during the relevant time period, and the requested transaction-level sales data is necessary to establish Defendants’ monopoly power and the contours of the EAI market. The Court does not find Plaintiffs’ argument persuasive.

First, Plaintiffs allege the Defendants entered into an unlawful reverse payment settlement with Teva on April 26, 2012, the purpose of which was to delay the entry of a generic Epi-Pen into the market from March of 2014 to June of 2015. As a result, Plaintiffs allege direct purchasers such as they had to pay more for Epi-Pens during that period. However, Kaléo did not sell Auvi-Q during this period. Kaléo did not enter the EAI market until February of 2017. Plaintiffs maintain they need to establish Defendants’ monopoly power in the market through the entire class period, which the Fourth Amended Complaint defines as “November 1, 2013 until the


anticompetitive effects of Defendants' conduct cease."³⁰ Even so, the relevance of the transaction level data from 2017 until the present, two years after the delayed entry of a generic Epi-Pen, is questionable and of minimal relevance, if at all.

Further, Plaintiffs fail to explain why the extensive, 48-point inquiry into each sale Kaléo has ever made is necessary to establish Defendants' monopoly power or why pharmacy sales or pharmaceutical products data available for a fee from a public or private data base is insufficient to demonstrate the parameters of the market. In their reply, Plaintiffs merely state "This less granular data is insufficient for Plaintiffs to properly demonstrate the parameters of the relevant market." The significant breadth of Plaintiffs' request compels the conclusion that the potential harm to Kaléo substantially outweighs the relevancy of this discovery.

Finally, the Court concludes that even if Plaintiffs had shown a need for the transaction-level data, the potential harm to Kaléo would outweigh their need. The Court finds that Kaléo would be harmed by the disclosure of the transaction-level sales data to Plaintiffs and Defendants, particularly the Mylan Defendants, Kaléo's main competitors in the EAI market. The requested data contains information critical to Kaléo's alleged competitive advantage over Defendants. Disclosing the data could create a competitive disadvantage in Kaléo's only product. Accordingly, the Court will deny the motion to compel Kaléo to produce Auvi-Q transaction-level sales data.

IT IS HEREBY ORDERED that Plaintiffs' Motion To Compel Non-Party Kaleo, Inc. To Produce Documents In Compliance with Subpoena (ECF No. 203) is denied.

Dated this 7th day of February, 2023 in Kansas City, Kansas.



Teresa J. James
U. S. Magistrate Judge

³⁰ ECF No. 128.