IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

IN RE: EpiPen (Epinephrine Injection, USP) Marketing, Sales Practices and Antitrust Litigation	**MDL No: 2785**
	Case No. 17-md-2785-DDC-TJJ
(This Document Applies to All Cases)	

MEMORANDUM AND ORDER

This matter is before the Court on the Motion of Mylan Inc. and Mylan Specialty L.P. to Compel Compliance with Subpoena Directed to kaléo, Inc. (ECF No. 492). Mylan Inc. and Mylan Specialty L.P. ("Mylan") seek an order requiring non-party kaléo to produce documents responsive to Mylan's subpoena served on February 1, 2018. Kaléo opposes the motion. As set forth below, the Court will deny Mylan's motion.

I. Relevant Background

On February 1, 2018, Mylan served a subpoena on kaléo pursuant to Fed. R. Civ. P. 45.[1] The following day, through its vice president and general counsel, kaléo served objections to the document requests.[2] The parties held a meet-and-confer on February 14, 2018, during which Mylan agreed to extend the subpoena's return date to March 20, 2018, and kaléo agreed to send more definite objections to the individual requests in the subpoena.[3] On March 20, through

[1] ECF No. 493-2.

[2] ECF No. 493-4.

[3] *See* ECF No. 493-1 at 1.

outside counsel, kaléo sent a letter to Mylan outlining which documents it possessed and intended to produce, which documents it did not possess, and which documents it possessed but would not produce, with further comment on each document request.[4] The March 20 letter also stated that kaléo was not waiving any of the objections made in its letter of February 2.

On March 29, 2018, Mylan and kaléo held their second telephone conference. That day, kaléo electronically produced a significant amount of data, and four days later Mylan received kaléo's production of additional documents in hard copy. Counsel continued to communicate electronically, and on April 26, 2018 they once again met and conferred by telephone. Kaléo agreed to produce a privilege log in addition to its earlier agreement to produce additional responsive documents.[5] As it became evident they were unable to fully resolve their differences, kaléo agreed to Mylan filing a motion to compel in this district.

Mylan's 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. Summary of the Parties' Arguments

Mylan argues that kaléo is improperly withholding documents from the time after kaléo reclaimed its licensing rights from Sanofi, and has begun marketing Auvi-Q itself. This period begins in February 2017 and extends to the present. Mylan also argues that kaléo should be ordered to provide details concerning the search it undertook to respond to the subpoena so Mylan may assess whether it was a reasonable search.

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[4] ECF No. 493-5.

[5] ECF No. 493-1 at 2-4.

Kaléo contends it has produced all relevant documents in its possession responsive to the subpoena other than its confidential and proprietary documents for which Mylan has not shown substantial need and for which disclosure would imperil kaléo's existence. The basis of kaléo's argument is that discovery by Mylan of its proprietary and confidential information would have the disastrous potential to destroy kaléo and eliminate the only existing competitive market check on Mylan in North America.

III. 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."[6] Non-parties responding to Rule 45 subpoenas generally receive heightened protection from discovery abuses.[7]

Federal Rule of Civil Procedure 45 governs both motions to compel compliance with and motions to quash a subpoena served on a non-party.[8] 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

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[6] Fed. R. Civ. P. 45(d)(1).

[7] *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)).

[8] Kaléo agreed to Mylan filing the instant motion in this district and has not filed a motion to quash the subpoena in this or any other federal district court.

applies," and when the subpoena "subjects a person to undue burden."[9] The rule also allows a court discretion to quash or modify a subpoena that requires the disclosure of a "trade secret or other confidential research, development, or commercial information."[10]

"The scope of discovery under a subpoena is the same as party discovery permitted by Fed. R. Civ. P. 26."[11] 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.[12] Information still "need not be admissible in evidence to be discoverable."[13] 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.[14] Conversely, when the relevancy of the discovery request is not readily apparent on its face, the party seeking the discovery has the

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[9] Fed. R. Civ. P. 45(d)(3)(A).

[10] Fed. R. Civ. P. 45(d)(3)(B).

[11] *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)).

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

[13] Fed. R. Civ. P. 26(b)(1).

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

burden to show the relevancy of the request.[15] Relevancy determinations are generally made on a case-by-case basis.[16]

Trade secrets and similar confidential information are not afforded absolute privilege.[17] 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."[18] 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.[19] 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.[20] Finally, the court must balance the need for the trade secrets against the claim of injury resulting from disclosure.[21] If the requesting party demonstrates both relevancy and need, the

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

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

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

[18] Fed. R. Civ. P. 26(c)(1).

[19] *MGP*, 245 F.R.D. at 500.

[20] *Id*.

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

trade secrets should be disclosed unless they are privileged or the subpoenas are unreasonable, oppressive, annoying, or embarrassing.[22]

IV. Analysis

This motion presents very different issues than those decided in motions seeking to enforce other non-party subpoenas the parties have served in this case. In those instances, the subpoenaed entities have nearly all been pharmacy benefit managers. But here we have a party seeking to obtain information from its competitor for the sale of the medical device at the heart of the case, a competitor it acknowledges is "uniquely situated in this litigation."[23] In addition, the subpoenaed competitor, kaléo, has produced responsive documents for the time periods (1) from the inception of the Auvi-Q product to the beginning of the sale of Auvi-Q under license by Sanofi, and (2) during which Auvi-Q was sold under license by Sanofi. It is only the time period after kaléo reclaimed its licensing rights from Sanofi and has begun marketing Auvi-Q itself (i.e., while it has directly competed with Mylan) to which kaléo objects to producing documents.[24] In its objection to producing documents from Time Period Three, kaléo contends its marketing, production, and business-development efforts go to the very heart of its competitive position in the marketplace and the highly-sensitive competitive nature of the documents .[25]

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[22] *Id.* at 326.

[23] ECF No. 559 at 5, 7.

[24] Kaléo and Mylan both refer to these as "Time Periods" One, Two, and Three. Kaléo asserts that documents from Time Periods One and Two are not at issue in this motion, and Mylan does not dispute the assertion.

[25] ECF No. 493-5 at 2.

A. Whether the documents are trade secrets or other confidential information

Kaléo does not object to producing documents from Time Period Three on the grounds of relevancy. Not making a relevancy objection is consistent with kaléo's agreement to produce the requested documents from Time Periods One and Two. Instead, kaléo focuses its objection on whether it may properly withhold production on the grounds that the requested items constitute trade secrets or other confidential 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."[26] To establish such injury, the person seeking protection must make "a particular and specific demonstration of fact, as distinguished from stereotyped and conclusory statements."[27]

Kaléo asserts that the Auvi-Q product resulted from the research and development efforts of brothers Evan and Eric Edwards, who formed the company now known as kaléo. Beginning in 2009, the company entered into a series of licensing agreements with Sanofi to grant Sanofi exclusive manufacturing, sales, and distribution rights to Auvi-Q in North America. The U.S. Food and Drug Administration approved Auvi-Q in 2012.[28] The following year, Sanofi

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[26] *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)).

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

[28] Time Period One begins with the inception of Auvi-Q and ends when Sanofi began selling the product under license.

began selling Auvi-Q under license from kaléo, and continued to do so through October 2015.[29] During this time, Sanofi alleges that "Mylan engaged in illegal conduct to squelch this nascent competition, harming both Sanofi and U.S. consumers . . . [and costing Sanofi] hundreds of millions of dollars in lost sales of Auvi-Q due to Mylan's unlawful conduct. . . ."[30] Kaléo further asserts that Sanofi voluntarily recalled its Auvi-Q devices in October 2015 due to reports of manufacturing difficulties within Sanofi's supply chain, leaving Mylan with an estimated market share of 95% or higher.

In a Termination Agreement effective as of February 24, 2016 (which kaléo has produced in response to Mylan's subpoena), Sanofi returned all of its rights under its license to kaléo. Kaléo then continued to develop the Auvi-Q system and began marketing it in February 2017. Since that time, kaléo and Mylan have been competing in the EAI drug device market, and kaléo reports its market share has risen from zero to approximately 18 percent.

Kaléo argues the documents at issue are proprietary, confidential, and trade secret materials that cover almost every aspect of kaléo's current Auvi-Q business, production of which would cause it to "lay bare to its only competitor, in exquisite detail, the very essence of its current strategic business operations."[31] The subpoena seeks Time Period Three documents relating to kaléo's own marketing plans, strategic plans, market research and analysis, competition in the market, communications relating to any market or market condition, research, planning, analysis, potential costs, revenues, pricing, sales, rebates, incentives, budgets, revenue

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[29] This is Time Period Two.

[30] Sanofi Complaint ¶1 (docketed in Case No. 17-cv-2452-DDC-TJJ at ECF No. 1).

[31] ECF No. 521 at 5.

projections, cost projections, and profits associated with Auvi-Q, all for a period beginning fifteen months after Sanofi exited the EAI market.

Documents that comprise trade secrets or other confidential research, development, or 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."[32] The Court has no difficulty in concluding that the Time Period Three documents are trade secrets or other confidential research, development, or commercial information.

B. Whether production would harm kaléo

Kaléo's President and CEO has submitted a declaration containing many details of its operations and explanation of its manner of doing business.[33] He describes the efforts kaléo undertakes to keep its proprietary competitive information confidential and secret, particularly from its competitors and most particularly from Mylan. For instance, every kaléo employee is required to execute a written Loyalty Agreement which forbids disclosure of confidential information and restricts the ability of former kaléo employees to work in a competitive position for Mylan. Kaléo employs tight physical security measures as well, both for its offices and its information technology systems.

Kaléo also considers the composition of its supply chain confidential, disclosure of which would permit Mylan to interfere with and potentially damage the chain, which in turn would have the catastrophic effect of causing a shortage in the product that would threaten kaléo's

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[32] *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)).

[33] ECF No. 521-1.

emerging place in the EAI market. Similarly, kaléo keeps confidential the manner in which it distributes its product and considers its distribution network a significant factor in its rise in sales. The declaration goes on to detail the harm kaléo would suffer if it had to compromise the confidentiality of its proprietary analytical tools, formulation coverage information, marketing plans, product complaints and adverse event reports, and pricing information. With each, the potential harm is heightened by the fact that the entity seeking the confidential information is kaléo's only competitor and the biggest market player. Also relevant is kaléo's size relative to Mylan; kaléo sells only two products, Auvi-Q and Evzio, a medicine used in opioid emergencies and produced in a similar auto-injector format. As courts have noted, disclosure to a competitor is more harmful than disclosure to a non-competitor.[34]

The Court concludes that kaléo would suffer real and substantial harm if it were to disclose the Time Period Three documents.

C. Whether the documents are relevant and necessary to Mylan and balance

Mylan contends the documents are highly relevant to its defense against the antitrust claims in this action. As Mylan points out, both Sanofi and the Class Plaintiffs allege the timing, size, and nature of Mylan's rebates were unprecedented, causing Sanofi to lose out on favorable formulary positions or be excluded altogether, and that Mylan's conduct caused Sanofi to incur significantly higher costs. Mylan characterizes these allegations as an accusation that it deviated from standard industry practices that Sanofi adhered to. From there, Mylan argues that kaléo's conduct also speaks to industry practice because it is a participant in the industry. While the

[34] *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).

Court understands the logic behind Mylan's argument, it (1) presumes that "industry practices" were the same while Sanofi was in the industry as they are now, and (2) further presumes that had Sanofi employed kaléo's business methods, Sanofi's losses to Mylan would have been mitigated. The Court does not find Mylan's argument persuasive.

Moreover, Mylan's argument highlights the lack of proportionality in its request for Time Period Three documents. The breadth of Mylan's request – which encompasses kaléo's marketing and strategic sales plans, a host of information concerning its market, revenue data, and so much more – compels the conclusion that the potential harm to kaléo substantially outweighs the relevancy of this discovery.

Finally, the Court concludes that even if Mylan had shown a need for these documents, the potential harm to kaléo would outweigh Mylan's need. The Court finds that kaléo would indeed be harmed by the disclosure of these documents to its only competitor in the EAI market. The requested documents contain information material and critical to kaléo's business. Disclosing the documents to Mylan would create a competitive disadvantage and potentially devastate the company. While the Court is well aware of the strength 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. Accordingly, the Court will deny the motion insofar as it seeks to compel kaléo to produce documents from Time Period Three.

V. Search Parameters

Mylan argues the Court should compel kaléo to provide the details of the search it conducted so that Mylan can determine whether kaléo and its counsel discharged their discovery obligations competently, diligently, and ethically. Mylan does not suggest any reason to suspect

kaléo and its counsel have failed in their obligations. Absent such, the Court declines to act on Mylan's suggestion. The Court will deny the motion in toto.

IT IS HEREBY ORDERED that Motion of Mylan Inc. and Mylan Specialty L.P. to Compel Compliance with Subpoena Directed to kaléo, Inc. (ECF No. 492) is denied.

Dated this 10th day of August, 2018 in Kansas City, Kansas.

Teresa J. James
U. S. Magistrate Judge