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 the *Sanofi* Case)	

MEMORANDUM AND ORDER

This matter is before the Court on The Mylan Defendants' Motion to Compel Sanofi to Produce Documents and Amended Request for Admission Responses (ECF No. 1324).[1] Pursuant to Fed. R. Civ. P. 36 and 37, Mylan seeks an order requiring Plaintiff Sanofi-Aventis U.S., LLC to (1) produce all documents in its possession responsive to Request No. 7 of Mylan's Seventh Requests for Production, and (2) produce amended responses to several of Mylan's Requests for Admission to remove allegedly extraneous, non-responsive, and argumentative commentary and clearly admit or deny the requests at issue.[2] As set forth below, the Court denies Mylan's motion.

[1] The Mylan Defendants include Defendant Mylan Inc. and Defendant/Counterclaim Plaintiff Mylan Specialty L.P. As in its earlier orders, the Court will refer to them collectively as Mylan.

[2] Mylan's motion also asks the Court to order Sanofi to abide by agreements it reached with Mylan regarding other discovery requests. In its response, Sanofi takes umbrage with Mylan's suggestion and states that it fulfilled all such commitments before Mylan filed the instant motion. Mylan's reply does not dispute Sanofi's assertion. Accordingly, the Court finds the issue moot.

I. Relevant Background

On September 28, 2018, Mylan issued 145 Requests for Admission to Sanofi, along with both its Seventh Set of Document Requests and its Third Set of Interrogatories. Three days later, Mylan served its Eighth Set of Document Requests on Sanofi. Sanofi timely responded to the discovery, and on November 14, 2018, Mylan sent a letter to Sanofi describing deficiencies it perceived in Sanofi's responses and modifying certain of its requests. The parties continued to engage in written and oral communication in an attempt to resolve their differences. Based on the parties' efforts, the Court finds they have complied with the requirements of D. Kan. R. 37.2.

II. Summary of the Parties' Arguments

Sanofi has refused to produce documents responsive to RFP No. 7 of Mylan's Seventh Set of Document Requests, which seeks documents related to the Lovenox litigation. Sanofi bases its refusal on the grounds that the request violates an earlier discovery order and belatedly seeks reconsideration of that order, the request is not a genuine discovery demand and Mylan would not be prejudiced without the discovery, and responding to the request would be unduly burdensome to Sanofi and disproportionate. Mylan argues the documents are highly relevant, whereas Sanofi's objections are boilerplate and unsupported by evidence demonstrating that producing responsive documents would be unduly burdensome.

Mylan contends Sanofi's responses to 88 of its Requests for Admission are evasive, fail to answer the request, or contain extraneous statements that should be stricken. Sanofi argues that Mylan's generalized criticism of the majority of the RFAs it addresses does not warrant relief under Federal Rule of Civil Procedure 36, that its responses comply with Rule 36, and that Mylan's RFAs are improper attempts to have the court prematurely adjudicate merits disputes.

III. Legal Standards

Federal Rule of Civil Procedure 26(b)(1) sets out the general scope of discovery and provides as follows:

> Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit. Information within this scope of discovery need not be admissible in evidence to be discoverable.[3]

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.[4] Information still "need not be admissible in evidence to be discoverable."[5] 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.[6] Conversely, when the relevancy of the discovery request is not readily

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

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

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

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

apparent on its face, the party seeking the discovery has the burden to show the relevancy of the request.[7] Relevancy determinations are generally made on a case-by-case basis.[8]

Federal Rule of Civil Procedure 36 governs requests for admission. It allows a party to serve on any other party a written request to admit "the truth of any matters within the scope of Rule 26(b)(1) relating to: (A) facts, the application of law to fact, or opinions about either; and (B) the genuineness of any described documents.[9] Requests for admission serve "two vital purposes, both of which are designed to reduce trial time. Admissions are sought, first to facilitate proof with respect to issues that cannot be eliminated from the case, and secondly, to narrow the issues by eliminating those that can be [eliminated]."[10] The purpose of a request for admission generally is "not to discover additional information concerning the subject of the request, but to force the opposing party to formally admit the truth of certain facts, thus allowing the requesting party to avoid potential problems of proof."[11]

IV. Analysis

A. RFP No. 7 of Seventh Set of Document Requests

RFP No. 7 seeks the following: "All documents filed under seal, all transcripts from court proceedings, and all transcripts and exhibits from depositions taken in *Eisai, Inc. v. Sanofi*

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

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

[9] Fed. R. Civ. P. 36(a)(1).

[10] Fed. R. Civ. P. advisory committee's note to 1970 amendment.

[11] *Solis v. La Familia Corp.*, No. 10-2400-EFM-GLR, 2012 WL 1906508, at *2 (D. Kan. May 25, 2012).

Aventis U.S., LLC, No. 3:08-cv-4168 (D.N.J.) and No. 14-2017 (3d Cir.)."[12] In *Eisai*, Sanofi was accused of antitrust violations in connection with its anticoagulant drug Lovenox. Mylan later narrowed the request to those portions of depositions of Sanofi witnesses or sealed filings "in which Sanofi or its witnesses discuss Sanofi's contracting for the products at issue in [*Eisai*,], Sanofi's knowledge and characterization of the industry practice of contracting for pharmaceutical products in general, the reasons for and effects of Sanofi's and the industry's contracting practices, and Sanofi's market share for the products at issue in [*Eisai*,]."[13] In response, Sanofi objected (1) on the basis of relevancy, proportionality, and that the request falls outside the scope of the Court's earlier "other products" ruling;[14] (2) the request is untimely and seeks information available from other sources; and (3) the request is unduly burdensome to the extent it would require Sanofi to review and redact documents that contain other parties' confidential information that may be subject to a protective order in *Eisai*.

Mylan contends the requested materials are highly relevant to its defense because in *Eisai*, "Sanofi was alleged to have engaged in conduct analogous to the conduct it challenges in its complaint against Mylan here and have engaged in such conduct with respect to a Sanofi product—Lovenox—that had a dominant market share."[15] Mylan asserts it is entitled to conduct discovery on what position Sanofi took in defending its conduct, given that Sanofi now alleges Mylan's similar conduct is illegal.

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[12] ECF No. 1325-2.

[13] ECF No. 1325 at 5 (quoting Mylan email to Sanofi, ECF No. 1327-5 at 5).

[14] *See* ECF No. 435 at 6-10.

[15] ECF No. 1325 at 6.

Ruling on this issue requires the Court to assess Mylan's relevancy argument in the context of what the parties refer to as the Court's earlier "other products" ruling. In its First Set of Requests for Production to Sanofi, Mylan propounded requests seeking information about rebates Sanofi had offered to PBMs or Third-Party Payors. In RFP 24, Mylan sought documents "relating to any contract, agreement, bid or offer" under which Sanofi offered rebates to any PBM or Payor for any of its products. Sanofi objected to producing the information and Mylan modified the RFP to limit the requested information to twelve Sanofi products in the U.S. over a five-year period from 2012 to 2016.[16] When the parties were still unable to reach agreement, Mylan filed a motion to compel Sanofi's responses to this and other discovery requests.[17]

In its Memorandum and Order ruling on Mylan's motion to compel, the Court found that in general, information pertaining to rebates Sanofi paid is relevant on its face, at least with respect to the exclusive dealing claim Sanofi asserts against Mylan.[18] Although the Court found Mylan's original request overbroad,[19] the Court went on to assess the narrowed version of RFP 24 Mylan had proposed. Mylan asserted its proposal would provide "relevant information concerning the structure and circumstances of the industry," as well as "discovery of the rebate agreements Sanofi itself has claimed constitute 'lawful, procompetitive price competition.'"[20]

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[16] ECF No. 371-6 at 2-3.

[17] ECF No. 285.

[18] ECF No. 435 at 5-6.

[19] *Id*. at 9.

[20] ECF No. 371-6 at 3 (quoting Sanofi's Memorandum in Support of its Motion to Dismiss the complaint in *Eisai*).

With respect to four of the twelve Sanofi products included in Mylan's proposal, the Court was able to discern from other submissions the likely reason Mylan included them was that each was the subject of one or more government investigations relating to pricing and trade practices.[21] However, Mylan did not explain why it included the other eight products or how they may have been relevant to the rebate issue in the motion to compel, and the Court denied Mylan's motion to compel insofar as it sought information related to Lovenox and seven other products.[22]

Now that Mylan is once again seeking discovery related to Lovenox, it addresses the Court's "other products" ruling, describing it as neither compelling nor prohibiting such discovery, but simply holding that Mylan had not explained how Lovenox might be relevant. Mylan contrasts its current briefing in which it "provides an explanation of the Lovenox litigation."[23] The Court has quoted that explanation in part, but now sets it forth in full:

> The requested materials are highly relevant to Mylan's defense. In *Eisai, Inc. v. Sanofi-Aventis U.S., LLC,* Sanofi was alleged to have engaged in conduct analogous to the conduct it challenges in its complaint against Mylan here and to have engaged in such conduct with respect to a Sanofi product—Lovenox—that had a dominant market share. Indeed, there, a Sanofi competitor alleged Sanofi provided increased discounts to purchasers when Sanofi had an overall market share in the drug class of 81% to 92%. *Eisai, Inc. v. Sanofi-Aventis U.S., LLC*, 821 F.3d 394, 399-400 (3d Cir. 2016). Mylan is entitled to discovery into what position Sanofi took in defending its

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[21] The four products are Apidra, Lantus, Soliqua, and Toujeo. In addition, Mylan represents that Sanofi is defending a class action alleging it pays unlawful rebates on Apidra, Lantus, and Toujeo. *See* ECF. No. 371 at 7.

[22] ECF No. 435 at 10. The Court did order Sanofi to produce documents relating to rebates it offered for Apidra, Lantus, Soliqua, and Toujeo from 2012 to 2016. Months later, Mylan requested post-2016 final rebate agreements and documents sufficient to show formulary coverage, rebates, and Sanofi's market share in 2017 for those four drugs. *See* ECF No. 1031 at 4. Sanofi moved for a protective order. The Court found Mylan had not demonstrated the relevancy of the post-2016 documents and granted the motion. *Id.*

[23] ECF No. 1325 at 9 n.1.

> conduct, given that Sanofi now alleges Mylan engaged in similar conduct and that that conduct is illegal.[24]

Mylan's explanation contains nothing new. Sanofi's allegations are the same now as they were when Mylan filed its earlier motion to compel. Accordingly, the Court is not persuaded that discovery into Lovenox has become relevant. The Court denies Mylan's motion insofar as it seeks to compel Sanofi to produce all documents in its possession responsive to Request No. 7 of Mylan's Seventh Requests for Production.

B. Requests for Admission

Mylan asks the Court to review and find insufficient dozens of Sanofi's responses to Mylan's Requests for Admission.[25] Mylan claims some of Sanofi's responses are evasive and fail to answer the request, while others contain extraneous, non-responsive statements. Although Mylan seeks to challenge 88 of Sanofi's responses, its briefing discusses only sixteen RFAs, ten of which share a common response. The Court limits its sufficiency review to those responses Mylan actually examines and provides a basis for review.

1. Whether certain responses are evasive and fail to answer

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[24] *Id.* at 6.

[25] A motion to compel under Rule 37 is not available for challenging responses to requests for admission. Instead, Rule 36 authorizes the requesting party to move to determine the sufficiency of an answer or objection. If the court does not sustain an objection, it must order that an answer be served. And if the court determines an answer does not comply with the rule, the court may (1) order that the matter is admitted; (2) order that an amended answer be served; or (3) defer its final decision until a pretrial conference or a specified time before trial. Fed. R. Civ. P. 36(a)(6). Here, Mylan asks that Sanofi be ordered to produce amended responses that "remove all extraneous, non-responsive, and argumentative commentary and admit or deny the various requests at issue in a clear manner." ECF No. 1324 at 2.

Mylan complains that in response to RFA Nos. 110 and 138 respectively, Sanofi did not state whether it had performed a study to establish Auvi-Q as therapeutically equivalent to EpiPen, nor did Sanofi confirm it had conducted no study to support the claim that Auvi-Q can withstand higher temperatures than EpiPen. Instead, Mylan alleges, Sanofi responded with a discussion of whether the devices are bioequivalent (No. 110) and with its recommended temperature for storing Auvi-Q devices (ECF No. 138). Mylan contends these responses fail to directly answer the RFAs presented. And with respect to RFA No. 103, Mylan describes Sanofi's response as evasive because Sanofi objects that the phrase "Sanofi sales representative" is vague and ambiguous, but then adds a number of other statements including a claim that Sanofi has hundreds of sales representatives.[26]

Sanofi disagrees that its responses were anything less than fully compliant with Rule 36. In its response to RFA No. 110, Sanofi contends it fairly responded to the substance of the matter by explaining what studies were completed and admitting what data the studies did not provide. In response to RFA No. 138, Sanofi points out that information relating to EpiPen's manufacture is not within its knowledge or available after reasonable inquiry, thus making it impossible to admit or deny statements concerning EpiPen's ability to withstand high temperatures. Sanofi states that it responded to the portion of the RFA to which it had knowledge by citing the specific storage temperatures for Auvi-Q. And Sanofi argues it attempted in good faith to respond accurately to RFA No. 103 by qualifying its answer with a narrow denial and an affirmative explanation thereof. [27]

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[26] ECF No. 1325 at 10-11.

[27] ECF No. 1367 at 16-17.

"When passing on a motion to determine the sufficiency of answers or objections, the court obviously must consider the phraseology of the requests as carefully as that of the answers or objections."[28] The party making the request bears the burden of succinctly stating the matter to which it seeks an admission, while the responding party is "merely required to agree or disagree, . . . with an occasionally warranted qualification or explanation, for purposes of clarification, if desired."[29]

> Requests are not appropriate for argument. They should not put forward the requester's legal or factual contentions on the premise that, in the requester's view, they ought to be admitted. Requests for admissions should be made only if the requesting party has a reasonable expectation that the opponent should in good faith admit them. . . . With respect to factual matters, a request is appropriate when the evidence at hand indicates that the matter is not reasonably disputable and that proof at trial may thereby be limited or facilitated.[30]

Considering RFA Nos. 110, 138, and 103 as written, the Court finds Sanofi has complied with Rule 36 in responding to each request. In asking Sanofi to admit to comparisons between Auvi-Q and EpiPen in the manner stated in RFA Nos. 110 and 138, it seems unlikely Mylan had a reasonable expectation that Sanofi would admit them. For its part, Sanofi had a duty to make a reasonable inquiry to determine its ability to admit or deny and upon determining neither was possible, to provide a detailed explanation to describe its inability with a response that fairly

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[28] *Audiotext Commc'ns Network, Inc. v. US Telecom, Inc.*, No. 94-2395-GTV, 1995 WL 625744, at *2 (D. Kan. Oct. 5, 1995) (quoting *Thalheim v. Eberheim*, 124 F.R.D. 34, 35 9D. Conn. 1988)).

[29] *Audiotext*, 1995 WL 625744, at *2.

[30] *Id.*

meets the substance of the requested admission.[31] The Court finds Sanofi's responses to RFA Nos. 110 and 138 fairly meet the substance of each request. Similarly, asking Sanofi to admit in RFA No. 103 that a sales representative paid money to "incentivize" a physician may seem to Mylan like a request that ought to be admitted. But the statement is an overly broad minefield of undefined terms that a party should expect would draw a qualified response that explains why it cannot admit or deny. "A request for admission is meant to be answered with a simple admission or denial."[32] RFA No. 103 does not call for a simple admission or denial, and Sanofi's response complies with Rule 36.

The Court denies Mylan's motion insofar as it challenges the sufficiency of Sanofi's responses to RFA Nos. 110, 138, and 103.

2. Whether language should be stricken as non-responsive

Mylan asserts that Sanofi has answered certain requests with extraneous language that does not appropriately qualify as a denial and should be stricken as non-responsive. Mylan points to Sanofi's responses to RFA Nos. 25 and 83, both of which contain an admission but also additional language Mylan refers to as "padding" and "bloated." In RFA No. 25, Mylan asks Sanofi to admit that it offered rebates of 60% or more to a PBM or third-party payor for Auvi-Q. In RFA No. 83, Mylan seeks an admission that a patient experiencing anaphylaxis who did not receive the intended dose of epinephrine could suffer death. Sanofi insists its qualifying and

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[31] *Ash Grove Cement v. Emp'rs Ins. of Wausau*, No. 05-2339-JWL, 2007 WL 2333350, at *2 (D. Kan. Aug. 16, 2007).

[32] *Heartland Surgical Specialty Hosp., LLC v. Midwest Div., Inc.*, 05-2164-MLB-DWB, 2007 WL 3171768, at *6 (D. Kan. Oct. 29, 2007) (citing Fed. R. Civ. P. 36(a)).

explanatory language, offered in addition to its stated admissions and denials, is permissible to fairly respond to each request.

In RFA Nos. 61-70, Mylan poses a series of requests relating to Sanofi's rebate practices with respect to Lantus. Mylan argues that one of Sanofi's objections to each request is a non-responsive legal argument. Mylan makes no mention of the balance of Sanofi's responses to each request, all of which contain partial admissions, partial denials, and explanations. Sanofi disputes that the objection in question—that the basal insulin class does not represent Sanofi's share of any appropriate relevant product market under U.S. antitrust law—is a legal argument. Furthermore, Sanofi asserts it is entitled to both object to and answer an RFA, as it did in response to RFA Nos. 61-70.

Finally, Mylan asserts that in response to RFA No. 1, Sanofi has inappropriately regurgitated the allegations in its complaint in a way that obscures what the response admits and denies. The request asks Sanofi to admit that rebate payments from drug manufacturers to PBMs and third-party payors are common in the pharmaceutical industry in the United States. In its response, Sanofi admits the practice is common (as alleged in its complaint), but also notes circumstances in which that is not the case. The fact that Sanofi's explanation is also contained in the allegations of its complaint does not make the response a regurgitation.

The Court finds that in each of these instances, Sanofi's response fairly meets the substance of the requested admissions and no portion of any response need be stricken. The Court is cognizant of cases Mylan cites in which courts have stricken non-responsive and extraneous language in responses to requests for admission,[33] but the situation here does not call

[33] *See* ECF No. 1325 at 14-15.

for that result. The Court finds it helpful to focus on the unique character of a Rule 36 request for admission, described in part as follows:

> In form and substance a Rule 36 admission is comparable to an admission in pleadings or a stipulation drafted by counsel for use at trial, rather than to an evidentiary admission of a party. Unless the party securing an admission can depend on its binding effect, he cannot safely avoid the expense of preparing to prove the very matters on which he has secured the admission, and the purpose of the rule is defeated.
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> Provision is made for withdrawal or amendment of an admission. This provision emphasizes the importance of having the action resolved on the merits, while at the same time assuring each party that justified reliance on an admission in preparation for trial will not operate to his prejudice.[34]

The subject matter of the requests discussed herein can fairly be characterized as pertaining to issues in dispute. As such, they are not well-suited for requests for admission. "The purpose of a request for admissions generally is not to discover additional information concerning the subject of the request."[35] And RFA Nos. 61-70 each contain compound requests, thereby giving rise to extensive responses containing objections, admissions, denials, and qualifying and explanatory language. "The requesting party drafts complex requests at his peril."[36]

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[34] Fed. R. Civ. P. 36 advisory committee's note to 1970 amendment (internal citations omitted).

[35] *Ash Grove Cement*, 2007 WL 2333350, at *1 (quoting *Audiotext*, 1995 WL 625744, at *1). This statement is not inconsistent with the two "vital purposes" requests for admissions serve: to facilitate proof with respect to issues that cannot be eliminated from the case, and to narrow the issues by eliminating those that can be. *See* Fed. R. Civ. P. 36 advisory committee's note to 1970 amendment. Requests for admission only serve their purpose if they are phrased simply and directly, limited to a single point, and stated clearly, unambiguously, and without argument. *Audiotext*, 1995 WL 625744, at *3.

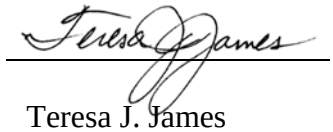
[36] *Audiotext*, 1995 WL 625744, at *5 (quoting *Diederich v. Dep't of the Army*, 132 F.R.D. 614, 621 (S.D.N.Y. 1990)).

Sanofi is entitled to deny requests without explanation, and its denial has no preclusive effect on the issue. If Mylan later proves the truth of any statement Sanofi has denied in its responses, Mylan may seek relief under Federal Rule of Civil Procedure 37(c)(2).

The Court denies Mylan's motion insofar as it seeks amended responses to RFA Nos. 25, 83, 61-70, and 1.

IT IS HEREBY ORDERED that The Mylan Defendants' Motion to Compel Sanofi to Produce Documents and Amended Request for Admission Responses (ECF No. 1324) is denied.

Dated this 24th day of January, 2019 in Kansas City, Kansas.



Teresa J. James
U. S. Magistrate Judge