IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY
CAMDEN DIVISION

IN RE: Valsartan N-Nitrosodimethylamine (NDMA), and Irbesartan Products Liability Litigation This Document Relates to All Actions	**MDL No. 2875** **Civil No. 19-02875 (RBK/JS)**

SPECIAL MASTER REPORT AND ORDER NO. 56

Plaintiffs in this multidistrict litigation arising out of the alleged contamination of blood pressure medication have moved for sanctions, asserting that the ZHP Defendants, through their counsel and witnesses, "have systematically obstructed Plaintiffs' efforts to obtain responsive deposition testimony." (Brief in Supp. of Mot. for Sanctions (ECF No. 1276) at 1.) The relief sought by Plaintiffs includes "striking and sanctioning the improper objections presented," "deeming the questions that were not responsively answered to be admitted," and awarding "attorneys fees and costs for time and expense incurred in connection with [the] motion, and the obstructed depositions." (Reply Brief in Supp. of Mot. for Sanctions (ECF No.1443) at 20.) For the reasons that follow, Plaintiffs' Motion will be granted in part.

I. BACKGROUND

In the summer of 2018, the U.S. Food and Drug Administration ("FDA") and several of its European and Canadian counterparts learned of contamination of prescription generic blood pressure drugs containing valsartan ("VCDs") with nitrosamines, a known carcinogen. Government agencies ordered recalls of VCDs made with active pharmaceutical ingredients ("APIs") manufactured by pharmaceutical companies located in India and China, including

Defendant Zhejiang Huahei Pharmaceuticals Ltd. ("ZHP"). Litigation throughout the United States to seek redress for the contamination ensued, with the Judicial Panel on Multidistrict Litigation ("JPML") consolidating the individual cases into MDL 2875 in February of 2019. Discovery has been intense and extensive. Commencing in early 2021, depositions of a host of ZHP corporate representatives were taken pursuant to Fed. R. Civ. P. 30(b)(6).[1]

"Rule 30(b)(6) . . . is an additional, supplementary and complimentary deposition process designed to aid in the efficient discovery of facts." *Mitsui & Co. (U.S.A.), Inc. v. Puerto Rico Water Res. Auth.*, 93 F.R.D. 62, 65 (D.P.R. 1981). The rule is intended "to avoid the possibility that several officers and managing agents might be deposed in turn, with each disclaiming personal knowledge of facts that are clearly known to persons within the organization and thus to the organization itself." *Tellis v. LeBlanc*, 18-CV-541, 2020 WL 5732628, at *3 (W.D. La. Sept. 24, 2020), *aff'd*, 18-CV-0541, 2020 WL 6828026 (W.D. La. Nov. 19, 2020) (citations and internal quotation marks omitted). "It places the burden of identifying responsive witnesses for a corporation on the corporation." *Black Horse Lane Assoc., L.P. v. Dow Chem. Corp.*, 228 F.3d 275, 303 (3d Cir. 2000). As explained in *Harris v. New Jersey*, 259 F.R.D. 89, 92 (D.N.J. 2007):

> The testimony of a Rule 30(b)(6) witness is binding on the entity *and goes beyond the individual's personal knowledge.* A corporation has an affirmative duty to produce a representative who can answer questions that are within the scope of the matters described in the notice. . . . A 30(b)(6) deposition more

[1] Rule 30(b)(6) provides in pertinent part as follows:

> (6) Notice or Subpoena Directed to an Organization. In its notice or subpoena, a party may name as the deponent a public or private corporation, a partnership, an association, a governmental agency, or other entity and must describe with reasonable particularity the matters for examination. The named organization must designate one or more officers, directors, or managing agents, or designate other persons who consent to testify on its behalf; and it may set out the matters on which each person designated will testify. Before or promptly after the notice or subpoena is served, the serving party and the organization must confer in good faith about the matters for examination….

> efficiently produces the most appropriate party for questioning, curbs the elusive behavior of corporate agents who, one after another, know nothing about facts clearly available within the organization and suggest someone else has the requested knowledge, and reduces the number of depositions for which an organization's counsel must prepare agents and employees. [Emphasis added; citations and internal quotation marks omitted.]

To date, more than 15 ZHP corporate designees have been deposed. Due to Chinese law, a number of the ZHP Party witnesses traveled outside China (to Hong Kong or Macau) to be deposed. Due to the pandemic, the depositions have been conducted remotely, with counsel located in the United States and the witness generally located in a hotel room on the other side of the world. Due to differences in language, interpreters have generally been required, increasing the duration of the depositions. According to the ZHP Parties, more than 160 hours of deposition time (exclusive of time for translations) have been produced on 59 corporate designee topics.

The deposition process has been far from smooth. In March of 2021, counsel sought the intercession of the Special Master in the middle of a deposition of a ZHP corporate designee, Peng Dong ("Mr. Peng"). Intending to facilitate the completion of depositions, several rulings were articulated. Relevant here are the following rulings: First, counsel was instructed to inform the witnesses to give direct answers to questions that called for a "yes or no" answer, or to explain why the question could not be answered with a simple yes or no. (Ex. "B" to the ZHP opposition to Plaintiffs' Motion for Sanctions at 11.) Second, Plaintiffs' counsel was told that it was not necessary to move to strike an answer to preserve the ability to later seek to have the answer stricken as non-responsive. (Ex. 2 to Plaintiffs' Motion for Sanctions at 2.) And third, counsel were instructed to refrain from asking the same question over and over again when it became apparent that the witness was not going to provide a direct answer. In this regard, counsel were told that they could pursue a motion to deem a matter admitted in response to a witness who refused to answer. (Ex. 2 at 4.)

On May 27, 2021, Plaintiffs filed a comprehensive "Motion for Sanctions for Defendant ZHP's Obstruction and Failure to Provide Responsive Deposition Testimony." (ECF No. 1276.) An opposition brief and exhibits were filed on July 2, 2021. (ECF No. 1367.) With the submission of Plaintiffs' Reply Brief on July 30, 2021 (ECF No. 1443), briefing on the motion was completed. The parties presented oral argument on the motion on September 8, 2021.

II. DISCUSSION

Plaintiffs' sanctions motion concerns depositions of corporate representatives undertaken pursuant to Fed. R. Civ. P. 30(b)(6). When it became evident that the deposition process was being impeded by refusals to provide straightforward answers to some questions, Plaintiffs were instructed to complete depositions and then file an appropriate motion, as opposed to adjourning the depositions to obtain a ruling. (Ex. 2 to Plaintiffs' Sanctions Motion, excerpts from March 29, 2021 Hearing.)

As explained in *Security National Bank of Sioux City, IA v. Day*, 800 F.3d 936, 942 (8th Cir. 2015):

> Discovery abuse has been a topic of widespread concern in the legal community. *See Shelton v. Am. Motors Corp.*, 805 F.2d 1323, 1330 (8th Cir.1986); *see also Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 559 (2007). Preventing such abuse depends in part on reducing the reluctance of attorneys to seek sanctions and of judges to impose them. *See Matter of Yagman*, 796 F.2d 1165, 1182 (9th Cir.1986); *see also* Fed.R.Civ.P. 26, advisory committee notes (1983 amendments). The purpose of sanctions is to "penalize those whose conduct may be deemed to warrant" them and "deter those who might be tempted to such conduct in the absence of such a deterrent." *Nat'l Hockey League v. Metro. Hockey Club*, 427 U.S. 639, 643 (1976).

Notably, the topics to be covered by the corporate designees were approved by the Court, and the ZHP Parties did not pursue a motion for a protective order on any of the topics. "[A] corporation has 'a duty to make a conscientious, good-faith effort to designate knowledgeable

persons for Rule 30(b)(6) depositions *and to prepare them to fully and unevasively answer questions about the designated subject matter*." *Great Am. Ins. Co. of New York v. Vegas Const. Co., Inc.*, 251 F.R.D. 534, 539 (D. Nev. 2008) (citations omitted; emphasis added). "The duty of preparation goes beyond matters personally known to the designee or to matters in which the designee was personally involved, and if necessary the deponent must use documents, past employees or other resources to obtain responsive information." *Harris*, 259 F.R.D. at 92. "[W]hen a witness is designated by a corporate party to speak on its behalf pursuant to Rule 30(b)(6), '[p]roducing an unprepared witness is tantamount to a failure to appear' that is sanctionable under Rule 37(d)." *Black Horse Lane Assoc.*, 228 F.3d at 304.

Plaintiffs' motion is based upon 44 excerpts from the depositions of the following five ZHP Rule 30(b)(6) witnesses: Peng Dong, Min Li, Eric Gu, Hai Wang, and Lihong (Linda) Lin. Plaintiffs argue that the excerpts illustrate obstructive and baseless objections, evasive and non-responsive testimony, and repeated resort to "talking points" as opposed to replying directly to straightforward questions. Each witness will be addressed in turn. Following an assessment of Plaintiffs' claims for each witness, the question of appropriate sanctions for that witness, if any, will be addressed.

A. Peng Dong

Peng Dong, ZHP's Deputy Director of Technology, was designated to testify on behalf of ZHP on the following topics:

> 11. ZHP's evaluation of the potential risks to the purity or contents of ZHP's valsartan API posed or caused by solvents used during the manufacturing process (regardless of intended sale location) manufactured in any facility that manufactured ZHP's valsartan API for sale in the United States.
>
> 33. The "primary process validation of Process II (Zn cl2) completed in April 2012" referenced on ZHP00004372.

> 34. The modifications with regard to the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for ZHP's valsartan API, including: (1) the reasons for the modifications, (2) the testing and evaluation in connection with the modification, and (3) the relationship between the modifications and the nitrosamine contamination of ZHP's valsartan API (regardless of intended sale location) in any facility that manufactured ZHP's valsartan API for sale in the United States.
>
> 35. Any evaluation conducted by or on behalf of ZHP with regard to health or safety issues arising from the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for ZHP's valsartan API (regardless of intended sale location) in any facility that manufactured ZHP's valsartan API for sale in the United States.
>
> 37. The process changes referenced in section 3.4.1 on ZHP00004371.

(Brief in Supp. of Plaintiffs' Mot. for Sanctions at 6-7.) Seven excerpts from Peng Dong's testimony have been provided by Plaintiffs, and the ZHP Defendants have provided an excerpt-by-excerpt response in Exhibit A to their Brief in Opposition to the Motion for Sanctions.

The first excerpt at issue concerned a statement in a document titled "Change Request Form," and pertained to ZHP's decision to use a zinc chloride process in making Valsartan, a change that Plaintiffs claim caused the nitrosamine contamination. Mr. Peng was asked whether the "Explanation Section" of the "Change Request Form" provided the reasons for the change to the zinc chloride process. ZHP objected to the form of the question, which was "Looking now at the Explanation Section, this provides the explanation for why this was being done, correct?" Mr. Peng replied to this question by stating, "On the screen in the Explanation Section, there is a paragraph written in Chinese." When pressed for a direct response to the question, Mr. Peng said, "I will tell the truth." Plaintiffs argue that Mr. Peng's answers are inappropriate. ZHP's written rebuttal is that the document "speaks for itself, the question lacked a proper foundation, and defense counsel's objections to form and harassment were appropriate."

Mr. Peng was designated to testify on behalf of ZHP concerning the reasons for the change to the zinc chloride process. He failed to respond to a question that directly addressed that topic, providing instead an evasive reply. "An 'evasive or incomplete' answer must be treated as a failure to answer." *Doe I v. Exxon Mobil Corporation*, --- F.Supp.3d ---- (2021), 2021 WL 1840649, at *4 (D.D.C., May 7, 2021) (citing Fed.R.Civ.P. 37(a)(4)).

Appropriate relief is thus warranted. Because this deposition took place pursuant to a court-sanctioned deposition protocol on topics approved by the Court, Mr. Peng's failure to answer questions within the court-approved topics can be regarded as a failure to obey an order of court to permit discovery, and sanctions may be imposed for the failure to provide discovery. *See id.* at *7; *State Farm Mut. Auto. Ins. Co. v. New Horizont, Inc.*, 250 F.R.D. 203, 217 (E.D. Pa. 2008).

Plaintiffs ask that the answer to the question, "[l]ooking now at the Explanation Section, this provides the explanation for why this was being done, correct," be deemed admitted. In *Estate of Spear v. C.I.R.*, 41 F.3d 103, 111 (3d Cir. 1994), the Third Circuit directed that in considering whether to deem facts admitted as a sanction for litigation misconduct the following factors should be weighed: "1) culpability (including willfulness and bad faith, and whether the client was responsible or solely the attorney); 2) prejudice; and 3) whether lesser sanctions would have been effective." Where, however, "the sanction of deeming facts to be true is not the equivalent of dismissal, willfulness and bad faith are not prerequisites for imposing that sanction." *Id.* at 112.

Given the language and cultural differences at play in this matter, it is difficult to determine whether the witness was acting in bad faith. The prejudice to Plaintiffs, however, seems minimal and can be remedied by affording ZHP the following choice: either produce at

ZHP's expense a knowledgeable corporate designee to answer this question in a non-evasive manner, *see Tellis*, 2020 WL 5732628, at *3 ("[i]f it becomes obvious that the deposition representative designated by the corporation is deficient, the corporation is obligated to provide a substitute"),[2] or admit that the Change Request Form presented to Mr. Peng at his deposition provides the explanation for the change to the zinc chloride process.[3]

The second excerpt dealt with the following question: "One of the reasons for this quality review is to identify any impurities due to the new process, correct?" Following an objection to the form of the question, Mr. Peng testified that "[t]he QC department will, based on its departmental responsibility as well as the content of the change application . . . conduct an assessment." Once again, the question fairly calls for a direct "yes or no" answer, and Mr. Peng failed to provide a comprehensible answer. Appropriate relief here is to either produce a knowledgeable witness to provide a direct answer to the question or admit that one of the reasons for the quality review was to identify any impurities due to the new process.

The third excerpt involved whether the change in process was consistent with current Good Manufacturing Processes ("cGMP"). The question at issue is as follows: "If this change was against cGMP code, it says it was supposed to be rejected. That is what it says, correct?"

[2] The designee could be Mr. Peng, but he must answer provide a direct, non-evasive answer to the question. The cost of any new deposition, including Plaintiffs' counsel fees, will be imposed upon ZHP.

[3] The sanctions awarded here are intended to be proportional to the degree of the sanctionable conduct. "A sanction is proportional if it accounts for prejudice to the opposing party and to the justice system and if it meets the need to deter similar misconduct in the future." *Doe I v. Exxon Mobil Corporation*, 2021 WL 1840649, at *10. Here, the sanctions being ordered will enable Plaintiffs to obtain answers to relevant question and compensate Plaintiffs for the expense of having to take additional deposition testimony.

ZHP's rebuttal is that the document shown to the witness speaks for itself and the question lacked a proper foundation.

"Objection on the basis that a document 'speaks for itself' is improper." *Fed. Trade Comm'n v. Vylah Tec LLC*, 217CV228FTM99MRM, 2018 WL 7364589, at *8 (M.D. Fla. Nov. 26, 2018). As noted in *Reed v. Duree*, 16-CV-07041-VC, 2018 WL 582442, at *1 (N.D. Cal. Jan. 26, 2018), "stating that the 'document speaks for itself' . . . is neither an answer to the deposing party's question nor a legitimate reason to not answer a question." *Accord, Holloway v. County of Orange*, SACV1901514DOCDFMX, 2020 WL 7906691, at *3 (C.D. Cal. July 23, 2020) ("repeated objections of . . . 'the document speaks for itself' were not well-taken"); *Cullen v. Nissan N.A., Inc.*, 3-09-0180, 2010 WL 11579750, at *6 (M.D. Tenn. Feb. 2, 2010) ("The Court agrees with the defendant that the plaintiff has not provided the Court with any authority supporting the propriety of objections based on a document 'speaking for itself.'").

Nor is the foundation objection well taken in the context of a Rule 30(b)(6) deposition. Here, Mr. Peng was speaking, not for himself, but as ZHP itself. In that capacity he was required to answer questions that fell within the topics for which he had been designated by ZHP as its corporate spokesperson. The burden was on ZHP "to designate the persons having knowledge of the matters sought . . . and to prepare those persons in order that they can answer fully, completely, [and] unevasively, the questions posed . . . as to the relevant subject matters." *Costa v. Cty. of Burlington*, 254 F.R.D. 187, 189 (D.N.J. 2008) (citations omitted). ZHP does not contend that the question at issue is outside the scope of the topics for which it designated Mr. Peng as its corporate representative. Accordingly, Mr. Peng should have been prepared to state whether the change in process should have been rejected if it was inconsistent with cGMP. Appropriate relief is either to produce at ZHP's own expense a knowledgeable ZHP corporate

designee to reply to this question directly or to admit that a change that conflicted with cGMP code should be rejected.

Excerpt 4 involved what appears to be a straightforward question: "Was your company required to perform a risk assessment in connection with the process change to the zinc chloride process?" Mr. Peng did not provide a direct answer to the question, instead stating that "[i]n 2011 for the process change using zinc chloride for valsartan, we conducted corresponding work based on the requirements of ICH and SOP at that time."[4] Mr. Peng was designated to testify on behalf of ZHP about its "evaluation of the potential risks to the purity or contents of ZHP's valsartan API posed or caused by solvents used during the manufacturing process." The question at issue falls within that topic, and a direct answer should have been provided by him. Appropriate relief is either to produce at ZHP's own expense a knowledgeable ZHP corporate designee to reply to this question directly or to admit that ZHP was required to perform a risk assessment in connection with the change to the zinc chloride process.

The fifth excerpt involved an exchange concerning whether the phrase, "impact to product quality," as used in a certain ZHP "Standard Management Procedure," included formation of NDMA as a result of the process change. Mr. Peng replied by the stating that ZHP undertook its analysis based on the requirements of ICH and SOP. Following a colloquy between counsel, Mr. Peng replied, "[t]he product quality was formulated based on the ICH requirement for the API's quality specifications, which was then approved by FDA." (Ex. E to ZHP's Opp. Brief, Peng Dep. Tr. at 139.) In Exhibit A to its opposition brief, ZHP asserts that at the time the process change was implemented, neither ICH nor its own SOP required evaluation

[4] ICH refers to the "International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use." *See* ICH Official Website, ICH, https://www.ich.org/ (last visited Dec. 8, 2021) It appears that "SOP" means Standard Operating Procedures.

for NDMA contamination. Under these circumstances, Mr. Peng's testimony is sufficiently responsive so as to not require court intervention.

Excerpt 6 concerned this question: "The chemists who were evaluating DMF were responsible to know if DMF could decompose during this process, correct?"[5] Plaintiffs have explained that DMF was converted to Dimethylamine in the zinc chloride process which then reacted with nitrous acid in the quenching process to form NDMA. Mr. Peng testified that '[i]n 2011 for the zinc chloride process change for valsartan, ZHP conducted corresponding evaluation for their work based on the requirements of ICH, SOP, as well as their knowledge then." Although Mr. Peng's answer is not the "yes or no" reply Plaintiffs were seeking, it is responsive to the inquiry when considered in the context of his testimony following a colloquy between counsel. He explained that in 2011, neither the industry nor ZHP had knowledge that DMF, an otherwise stable solvent, would decompose, but that ZHP "added testing of DMF in the . . . finished product testing." (Ex. E to ZHP's Opp. Brief, Peng Dep. Tr., at 158-59.) He also explained that individuals at ZHP responsible for evaluating the potential decomposition of DMF no longer worked for ZHP. Given this fact, his testimony on this point is sufficiently responsive so as to not require sanctions.

The final excerpt from Mr. Peng's deposition is as follows:

Q: ZHP had the ability to obtain published scientific literature in 2011, correct?

[5] DMF is the common abbreviation for dimethylformamide. As explained by one chemical manufacturer, DMF is "widely used in applications that require high solvency power, low volatility, large liquid state range, aprotic nature, and high dielectric constant." *Belle Chemical DMF*, CHEMPOINT, https://www.chempoint.com/products/belle-chemical-company/belle-chemical-methylamine-based-solvents/dmf-dimethylformamide-solvent/belle-chemical-dmf?_bt=537343114748&_bk=dmf%20chemical&_bm=e&_bn=g&_bg=102049293592&gclid=Cj0KCQiAkZKNBhDiARIsAPsk0Wix13XSnyXkeThkWEVk3cBiZH1JV-J_ZhHwOoGLMElsRmwPe5FYAUEaArn7EALw_wcB (last visited Dec. 8, 2021).

> A: I cannot provide an accurate answer to your question. I hope you can make your question more clear or more specific. For example, when you talk about the ability to obtain published scientific literature in 2011, what types of scientific literature are you referring to? Are they in Chinese or English? What type of database are they from?
>
> Q: ZHP had the ability to obtain scientific literature regarding the chemicals and the solvents it was going to use in the zinc chloride process and in the sodium nitrite quenching process in 2011 in order to evaluate the risks, correct?
>
> A: In 2011, ZHP's main direction of our work at that time was to formulate quality specifications that were in compliance with the ICH requirement and manufactured products such as valsartan in compliance with such quality specifications. Therefore, ZHP conducted related patent search for their product synthetic process, including Chinese patents as well as worldwide patents that would start with the patent number WO.

Plaintiffs ask that the answers be stricken and the questions deemed admitted.

The requested relief will not be granted. Mr. Peng's request for clarification as to the first question was appropriate. His answer to the second question was not direct, but he did state what ZHP actually did in developing the zinc chloride process: it undertook a related patent search. Furthermore, deeming as admitted the fact that ZHP had the ability to obtain scientific literature regarding the products used in the zinc chloride process seems unnecessary. Such ability would appear to be axiomatic given ZHP's position in the pharmaceutical industry.

B. Min Li

Min Li, who has a PhD in organic chemistry from Johns Hopkins University and is Vice President of Analytical Operations at ZHP, was designated to testify on the following topics:

> 1. The cause of the contamination of ZHP's valsartan API with nitrosamines including NDMA.
>
> 2. The root cause investigation for the nitrosamine impurities, including NDMA and NDEA in the ZHP API.
>
> 7. The chromatogram and mass spectrometry results for all testing by ZHP or its agents of ZHP's valsartan API (regardless of intended sale location)

> manufactured in any facility that manufactured ZHP's valsartan API for sale in the United States.
>
> 36. ZHP's evaluation and knowledge of the health risks of nitrosamines including NDMA and NDEA, including but not limited to as a contaminant of ZHP's valsartan API, and ZHP's valsartan finished dose.

(Brief in Supp. of Plaintiffs' Mot. for Sanctions at 12.)

Sixteen excerpts from Dr. Li's deposition have been identified by Plaintiffs as problematic. Attachment A to the ZHP Opposition Brief provides ZHP's excerpt-by-excerpt rebuttal.

Excerpt 1 is offered by Plaintiffs as "an example of the incessant, improper objections interposed throughout the course of the deposition." (Brief in Supp. of Mot. for Sanctions at 13.) Dr. Li was asked whether a third party toxicologist retained by ZHP, Dr. Charles Wang, provided a biography as part of a draft report. ZHP counsel objected for lack of foundation and mischaracterization of testimony. There then ensued a colloquy between counsel concerning the foundation objection. Plaintiffs' counsel asserted that it had already been established that the document in question had been identified as a draft report dated June 15, 2018, and ZHP counsel rejoined that Plaintiffs' counsel had not established anything about the document other than it was a draft report dated June 15, 2018, and had been produced by Dr. Wang.

The Fact Witness Deposition Protocol, adopted as Case Management Order No. 20 (ECF No. 632), provides:

> Counsel shall comply with Fed. R. Civ. P. 30(c)(2) concerning objections at a deposition. Counsel shall not engage in colloquy in objecting to a question or an answer, or responding to an objection. Any objections to an examiner's questions or to the deponent's answer, shall be made in a concise manner and counsel shall not suggest an answer to the witness or instruct the witness on how to answer a question, unless the witness must be instructed to not answer the question on the basis that it seeks privileged information. The phrases "objection as to form", "objection as to foundation", or similar language are sufficient and shall preserve all objections as to form and foundation until a

> party seeks to use a deposition. However, to determine whether there is a need to cure a defect in a question, the examiner may ask the attorney lodging the objection to identify the specific defect in the question. In the absence of such a request, the basis for the objection shall not be explained further.

Considered in isolation, this exchange appears to be consistent with the Fact Witness Deposition Protocol. Defending counsel objected in a concise manner, and the inquiring attorney requested a brief explication of the basis for the foundation objection. The problem, however, is that the objection itself is not well-taken. A proper foundation for this inquiry of the 30(b)(6) witness had been established. The document in question had been produced by ZHP and it was a document received by the 30(b)(6) witness as part of ZHP's assessment of the toxicological implications of the NDMA contamination.

Plaintiffs represent that this objection is an example of a pattern of disruptive conduct. The interposition of a foundation objection to practically every question asked is certainly disruptive and may provide a basis for sanctions. In this regard, the 1993 Advisory Committee Notes to Federal Rule of Civil Procedure 30(d) provide that sanctions may be awarded "when an attorney engages in . . . practices that improperly frustrate the fair examination of the deponent, such as making improper objections," and warn that "an excessive number of unnecessary objections may itself constitute sanctionable conduct."

While the example provided in Excerpt No. 1 of Dr. Li's deposition is troublesome, Plaintiffs have not provided a sufficient record to warrant the imposition of sanctions on the basis of opposing counsel's objections during Dr. Li's deposition. For instance, Plaintiffs have not provided the number of times a foundation objection was interposed. Plaintiffs' reliance on isolated deposition excerpts is insufficient.

Excerpts 2 through 11, 15, and 16 involve questioning about "ZHP's evaluation and knowledge of the health risks of nitrosamines including NDMA and NDEA," a topic approved

by the Court and for which Dr. Li was ZHP's designated witness. ZHP counsel objected to the questions in these excerpts as calling for expert testimony, and Dr. Li declined to answer many of the questions on that basis. Excerpt 6 illustrates the issue. Dr. Li was asked whether ZHP knew that "the potential risk to patients of taking [nitrosamine-contaminated Valsartan] was an unacceptable health risk." (Ex. 5 to Plaintiffs' Motion at 9.) ZHP objected, asserting, *inter alia*, that the question "calls for expert testimony." (*Id.*) Dr. Li then responded by stating that "the best answer would be by a toxicologist in terms of what level . . . is acceptable. . . ." (*Id.* at 10.)

Neither the objection nor Dr. Li's deferring to a toxicologist is appropriate given that he was designated to testify *as the corporation* on the health risks of nitrosamine contamination of Valsartan. As pointed out by Plaintiffs, ZHP, through its affiliated entities (Prinston and Solco), had issued statements concerning the health risks of NDMA and NDEA, and ZHP had submitted Deviation Inspection Reports ("DIRs") that included discussions of the health risks of the contamination. Having staked out positions on the health risks posed by the contamination, ZHP was obligated to designate a corporate representative to testify as the corporation about those risks. It is not sufficient to answer the questions by stating that they could be better answered by a toxicologist.

As explained recently in *Power Home Solar, LLC v. Sigora Solar, LLC*, 339 F.R.D. 64, 76 (W.D. Va. 2021):

> Unlike a Rule 30(b)(1) deponent who testifies in his or her personal capacity, a Rule 30(b)(6) designee "speak[s] for the corporation." . . . A corporate designee is "not expected to be a corporate encyclopedia," able to answer anything and everything about the company. . . . But she is required to be "reasonably and adequately prepared to answer questions about the relevant deposition topics." . . . She must therefore prepare to testify beyond her own personal knowledge to matters known to the corporation as a whole. *Doing so may require extensive preparation, document review, interviews, and other forms of investigation to reasonably identify the corporation's relevant knowledge and positions and educate the corporate designee on the same. . . .*

> Indeed, "a corporation is expected to create an appropriate witness or witnesses from information reasonably available to it if necessary." . . . And although "preparing for a Rule 30(b)(6) deposition can be burdensome," that is "merely the result of the concomitant obligation from the privilege of being able to use the corporate form in order to conduct business."

(Citations omitted; emphasis added.) "When a corporation produces an employee pursuant to a Rule 30(b)(6) notice, it represents that the employee has the authority to speak on behalf of the corporation with respect to the areas within the notice of deposition. This extends not only to facts, *but also to subjective beliefs and opinions*." *Tellis*, 2020 WL 5732628, at *3 (emphasis in original). *See also MP NexLevel, LLC v. Codale Elec. Supply, Inc.*, 2:08-CV-727-CW-PMW, 2012 WL 2368138, at *2 (D. Utah June 21, 2012) ("failure to provide a prepared Rule 30(b)(6) witness is not excused by provision of an expert witness, because expert testimony is not a sufficient substitute for the testimony of a corporate representative"); *Harris*, 259 F.R.D. at 92–93.

Thus, the objections that the questions called for expert testimony were not proper, and Dr. Li was not entitled to decline to answer the queries on the risks posed by contaminated valsartan. On the contrary, ZHP was obligated to produce an adequately prepared witness to testify about "ZHP's evaluation and knowledge of the health risks of nitrosamines including NDMA and NDEA." Dr. Li, evidently, was not prepared to testify on this topic. As noted above, "when a witness is designated by a corporate party to speak on its behalf pursuant to Rule 30(b)(6), '[p]roducing an unprepared witness is tantamount to a failure to appear' that is sanctionable under Rule 37(d)." *Black Horse Lane Assoc., L.P.*, 228 F.3d at 304. Appropriate relief here is to have ZHP produce Dr. Li again or produce another knowledgeable witness on the matters covered in excerpts 2 through 11, 15, and 16 of Dr. Li's deposition, and to pay Plaintiffs'

reasonable costs and attorneys' fees to depose again Dr. Li or to depose another 30(b)(6) designee.

Excerpt 12 involved a question based upon a July 27, 2017 email sent to Dr. Li and others indicating that a cause of NDMA in valsartan was sodium nitrate used in the quenching process. The question at issue was that "as of July 27, 2017, you and others in your company knew that when valsartan was quenched with sodium nitrate, it was formed in NDMA, correct?" (Ex. 5 to Plaintiffs' Sanctions Mot. at 2.) Following an objection that the question was vague and mischaracterized the document in question, Dr. Li testified that the author of the email "didn't specifically follow up with me or brought that . . . specifically to my attention." (*Id.*)

This answer is not responsive to the question. In Attachment A to its opposition to the sanctions motion, ZHP contends that "Dr. Li cannot be expected to speak on behalf of others in the company as to their knowledge of this improperly stated, highly technical question about an email written by someone else." (Att. A at 15.) But Dr. Li was required to be prepared to testify about the "cause of the contamination of ZHP's valsartan API with nitrosamines including NDMA." The question fell well within this Court approved 30(b)(6) topic, and it was incumbent upon him to testify about the corporation's knowledge of this fact. His evasive reply is sanctionable. Dr. Li or another knowledgeable person should be made available at ZHP's expense to provide a direct response to the matters covered in Excerpt 12, or ZHP should admit that as of July 27, 2017, employees of ZHP knew that when valsartan was quenched with sodium nitrate, NDMA was formed,

Excerpts 13 and 14 concerned the genotoxic propensity of NDMA. (Ex. 5 at 11-12, 13.) Dr. Li's answers included his explanation that the conclusion that NDMA has genotoxic propensities is based upon animal studies involving high dosages. His answers were not

improper. He gave an explanation on behalf of ZHP for the observation of genotoxic propensities in NDMA, *i.e.*, high dosage. There is nothing sanctionable in Excerpts 13 and 14 from Dr. Li's deposition.

C. Eric Gu

Mr. Gu, President of Shanghai Syncores Technologies, Inc., a subsidiary of ZHP, was designated to testify on the following topics:

> 35. Any evaluation conducted by or on behalf of ZHP with regard to health or safety issues arising from the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for ZHP's valsartan API for sale in the United States.
>
> 35A. ZHP's evaluation and knowledge of the risk of the creation of nitrosamines including NDMA and NDEA as a result of the manufacturing process for ZHP's valsartan API (regardless of intended sale location) in any facility that manufactured ZHP's valsartan API for sale in the United States.

(Brief in Supp. of Plaintiffs' Mot. for Sanctions at 24.)

Eight excerpts from Mr. Gu's two days of deposition testimony, compiled as Exhibit 6 to Plaintiffs' sanctions motion, have been cited by Plaintiffs as warranting sanctions. The first and last excerpts do not warrant relief, but the other excerpts do.

The first excerpt is as follows:

> Q. When SynCores was helping to develop the zinc chloride process, did it identify NDMA as a potential impurity that had to be tested for?
>
> A: As I said, okay, at 2011, we did the process development based on the ICH guidelines. And at that time, okay, we follow the GMP protocols. And we didn't know the NDMA was the potential impurity in the process. And the industry didn't know. The FDA doesn't know. And nobody knows at that time. [Ex. 6 at 2-3.]

While this answer may not have been as direct as Plaintiffs desired, it is responsive and plainly indicates that NDMA had not been identified as a potential impurity. No relief is warranted based upon this exchange.

The final excerpt from Mr. Gu's deposition challenged by Plaintiffs concerned whether there were alternatives to valsartan on the market. (Ex. 6 at 16.) ZHP appropriately notes that this question was outside the topics for which Mr. Gu had been designated to testify. Consequently, no relief on the basis of his failure to answer this question is warranted.

Excerpts two through seven do, however, involve evasive responses to inquiries falling squarely within the topic of ZHP's evaluation of the risk of creating nitrosamines as a result of the manufacturing process for ZHP's valsartan. For example, Mr. Gu was asked whether there was "any document from SynCores or ZHP that documents that potential degradation of DMF as part of the zinc chloride process was evaluated and that somebody determined, because of the boiling point, it wasn't a concern?" (*Id.* at 4.) No objection as to form with respect to this compound question was asserted,[6] and Mr. Gu replied that "[i]f the boiling point was a concern, boiling point was the indication of how stable the solvent is." (*Id.*) Plaintiffs' counsel followed up by asking whether there was "any document that has that information in it, that that was actually considered back when zinc chloride process was being developed?" (*Id.* at 5.) Mr. Gu replied, "I don't know how to answer these questions. Okay. Let me state it again, okay. The DMF was distilled . . . off to make the DMF. It must be stable at that temperature, right?" (*Id.*) These responses, however, are evasive. Mr. Gu does not directly answer the question of whether there are documents indicating that ZHP evaluated the potential degradation of DMF as part of the zinc chloride process.

[6] The fact witness deposition protocol specifies that "[a]ll objections are reserved until trial or other use of the deposition, *except those objections regarding the form of the question* or the existence of a privilege." (ECF No. 632 at 10.) Thus, it may be that the compound question objection noted in ZHP's reply to the sanctions motion has been waived.

Nor does Mr. Gu reply directly to this question: "Because ZHP never identified the nitrosamine impurities, it never was able to get to the second, third, or any other steps of the risk assessment process, correct?" (*Id.* at 6-7.) ZHP objected to the question as vague, but this question was posed after Mr. Gu had described the steps in the risk assessment process. Considered in context, this question was not vague. And Mr. Gu's response, ("at this time, okay the entire industry, the FDA, the EDQM, nobody knows that was the risk that existed in the valsartan. So putting this into content, okay, no one knows at that time back before existed in valsartan back in 2011" (*id.*)), is plainly defensive and evasive. Plaintiffs' counsel followed up by specifying that "I'm only asking about ZHP," to which Mr. Gu provided an equally defensive and evasive answer ("You are asking ZHP, but I don't thinks ZHP was the only one making valsartan and sold in the U.S. market." (*Id.*).)

Mr. Gu similarly failed to answer questions about (a) whether the presence of NDMA in valsartan was "acceptable," (Ex. 6 at 8-9); and (b) whether ZHP had assessed the potential for DMF to decompose as part of the zinc chloride process (*id.* at 10-15.) He was asked fairly direct questions, and his evasive responses concerning ZHP's assessment of the risks from the zinc chloride process, such as his statement, "[r]emember in the old days, we think the earth is square," (i*d.* at 11), are sanctionable. Mr. Gu or another knowledgeable person should be made available to provide a direct response to the matters covered in excerpts 2 through 7. Alternatively, if ZHP fails to produce a knowledgeable witness who gives direct answers to straightforward questions, then it can choose to admit facts covered by excerpts 2 through 7.[7]

[7] Should ZHP fail to produce a knowledgeable and responsive witness on these matter, Plaintiffs will be afforded an opportunity to provide in numbered paragraph format the facts that they believe should be deemed admitted. ZHP will be given an opportunity to respond, and to the extent there is disagreement about what should be deemed admitted, a conference call will be conducted to resolve the matter.

D. Hai Wang

Hai Wang, a top executive of two U.S. subsidiaries of ZHP (Solco and Prinston Pharmaceuticals), was designated to testify as a corporate representative on a host of topics. (*See* (Brief in Supp. of Plaintiffs' Mot. for Sanctions at 28-31.) Plaintiffs take issue with four excerpts from his two days of testimony, which are compiled as Exhibit 7 to Plaintiffs' sanctions motion.

The first excerpt deals with whether valsartan met the compendial requirements of the United States Pharmacopeia ("USP"). The question asked by Plaintiffs' counsel was whether "at all times" the witness's company had represented "to all customers that the valsartan products met the USP standards." (Ex. 7 at 2.) Mr. Wang replied in the affirmative, but then provided an explanation that, because the standards are occasionally revised, "we revise the requirement." Plaintiffs have moved to strike the additional information provided by Mr. Wang after his affirmative response, but he did give a direct answer to the question and was entitled to provide the ensuing explanation. No relief is warranted with respect to the first excerpt.

Part of the second excerpt concerns the absence of any reference on product labeling to the "potential contamination [of valsartan] with NDMA or any nitrosamines." (*Id.* at 4.) Following an objection to form, Mr. Wang stated, "[t]his patient insert is highly regulated by the FDA," and that the "FDA does not allow you to put extra words or cautions." (*Id.*) Plaintiffs want the answers stricken and that ZHP be deemed to have admitted that the presence of NDMA was never indicated on the patient labeling. This relief is not warranted. The answer provided by Mr. Wang supports a fair inference that the product labeling did not include any reference to potential nitrosamine contamination as well as an explanation for the absence of such a reference.

The other part of Excerpt 2 involved questioning as to whether the ZHP parties had disclosed the potential contamination of valsartan with NDMA or any nitrosamines before June of 2018. (*Id.* at 7-11.) Plaintiffs repeatedly insisted on a "yes or no" answer to this question, and the witness equally stubbornly refused to answer in that manner, instead providing an explanation that ZHP was the first company to find the contamination, reported it, and suspended distribution of the product. His answers support a fair inference that the ZHP parties did not disclose the nitrosamine contamination before June of 2018, and there is no need to deem this matter admitted based upon how the witness chose to answer the inquiry.

The third excerpt involves the following exchange:

> Q: Would you agree with me that all of the customers listed here would have been told by your company that they were being sold valsartan that was compliant with the current USP and Orange Book standards?
> MR. GOLDBERG: Objection to form.
>
> A: Yeah, the product is approved by the FDA. It meets all the FDA's requirement and specifications.
> MR. SLATER: Move to strike after "yeah."

Mr. Wang gave a responsive answer, and his additional explanatory comment is not improper. Plaintiffs are not entitled to relief on the basis of this exchange.

The fourth and final excerpt from Mr. Wang's deposition deals with the zinc chloride process change and the potential impurities resulting from that change. Plaintiffs' counsel pressed for an answer to question of whether there was any reference in a change notification form "to a risk assessment evaluation and the potential output of NDMA or nitrosamines as an impurity as a result." (*Id.* at 15-16.) Mr. Wang's response was that "[i]f no one expected NDMA would be formed in the process, it's not possible for someone to say you need to evaluate the NDMA risk assessment." Although not the simple direct answer sought by Plaintiffs, Mr. Wang's testimony is responsive to the question and supports a fair inference that

no consideration was given to the potential output of NDMA or nitrosamines as a result of the process change. Sanctions based upon Mr. Wang's testimony are not warranted.

E. Lihong (Linda) Lin

Lihong (Linda) Lin, ZHP's Director of Regulatory Affairs, was designated to testify on the following 30(b)(6) topics:

> 38. The communications with any regulatory authority, including but not limited to the FDA, with regard to the modifications with regard to the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for ZHP's valsartan API.
>
> 39. The communications with any regulatory authority, including but not limited to the FDA, with regard to the modifications with regard to the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for ZHP's finished dose.
>
> 40. ZHP's disclosures to regulatory authorities, including the FDA, with regard to the actual or potential contamination of ZHP's valsartan API with nitrosamines including NDMA and NDEA.
>
> 41. ZHP's filings with regulatory authorities, including the FDA, regarding manufacturing process changes for ZHP's Valsartan API Drug Master Filings.

(Brief in Supp. of Plaintiffs' Mot. for Sanctions at 37.)

Nine excerpts from her four days of testimony have been provided by Plaintiffs as supporting their sanctions motion. The first four excerpts concern the Drug Master File for valsartan and whether a list of impurities, which did not include NDMA, was complete. Each excerpt includes an objection that the document at issue "speaks for itself."

Plaintiffs assert that during Ms. Lin's deposition ZHP counsel objected at least 68 times on the ground that a document at issue "speaks for itself." As noted above, such an objection during a deposition is inappropriate. Rule 30(d)(2) permits the imposition of "sanctions—including the reasonable expenses and attorney's fees incurred by any party—on a person who impedes, delays, or frustrates the fair examination of the deponent." Fed.R.Civ.P. 30(d)(2). The

repeated assertion of "the document speaks for itself" objection had the effect of impeding the fair examination of Ms. Lin, and a monetary award is warranted under the circumstances. *See In re Neurontin Antitrust Litig.*, CIV.A. 02-1390 FSH, 2011 WL 253434, at *13 (D.N.J. Jan. 25, 2011), *aff'd*, 02-1390, 2011 WL 2357793 (D.N.J. June 9, 2011). Plaintiffs will be given an opportunity to suggest an appropriate monetary sanction for the repeated assertion of the "speaks for itself" objection, and ZHP will be given an opportunity to respond.

Ms. Lin, however, did respond to the questions that were asked. For example, in response to repeated questions as to whether NDMA was listed as a potential genotoxic impurity in the DMF, Ms. Lin testified:

> it was not until June of 2018 that NDMA was identified. So at the time we submitted this document in 2013, based on our knowledge of genotoxicity at that time and through our evaluation, we had identified no potentially genotoxic impurities. So here in this document, what's listed are these two [other] potentially genotoxic impurities that have been identified and detected at the time.

(Ex. 8 at 9.) From the answers provided, it is clear that NDMA was not identified in the valsartan DMF. Ms. Lin did not contend otherwise, but maintained that it could not be disclosed until it was discovered. That the witness did not give a direct answer to the questions in excerpts one through four is not a basis for sanctions.

Excerpt 5 shows the conflation of a 30(b)(6) witness with a fact witness. Ms. Lin was designated to testify on the topics identified above. This excerpt, however, concerned information disclosed in scientific literature concerning the potential for DMF to decompose. Ms. Lin testified in part that she "did not read this document before." (*Id.* at 13.) Because this topic does not appear to fall within the subjects for which Ms. Lin was designated to provide testimony, her answer affords no basis for sanctions.

The sixth and seventh excerpts are representative of the improper assertion of the "speaks for itself objection." For instance, Ms. Lin was asked the date of a certain customer notification, and before she could respond counsel objected, "the document speaks for itself." (Ex. 8 at 23-24.) And in one instance, the "speaks for itself" objection was asserted before a question was even asked. (*Id.* at 22.) Such repetitive objections are disruptive and worthy of some monetary sanction.

The eighth excerpt is not within the topics for which Ms. Lin was the corporate designee. It concerned the occurrence of NDMA during the sodium nitrite quenching process. Plaintiffs are not entitled to relief based upon Ms. Lin's responses in Excerpt 8.

The ninth and final excerpt concerned Ms. Lin's understanding of the term "adulterated" as used in the FDA "Warning Letter" issued to ZHP in connection with the nitrosamine contamination of the valsartan API. The specific question that initiated a five page exchange involving Plaintiffs' counsel, ZHP's counsel, and Ms. Lin was the following:

> The third paragraph [of the FDA Warning Letter] states, "Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your API are adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act, 21 USC 351(a)(2)(B)." Do you understand what "adulterated" means?

(Ex. 8 at 16-17.) The question was met with ZHP's counsel's assertion of "[o]objection to form. The document speaks for itself. Lack of foundation." (*Id.* at 17.) Ms. Lin then provided the following response: "Based on my personal understanding, this is a boilerplate sentence that appears in all warning letters from the FDA. All of our manufacturing conforms to GMP." (*Id.*) There then ensued several additional pages of Plaintiffs' counsel seeking Ms. Lin's understanding of the term, "adulterated," and her assiduous adherence to a response that ZHP was in compliance with GMP.

Plaintiffs' counsel was entitled to ascertain ZHP's understanding of the meaning of the term "adulterated" as used in the FDA Warning Letter. Ms. Lin, as Director of Regulatory Affairs at ZHP, should have had some understanding of what that term meant. The objections to this line of inquiry were not meritorious, and Plaintiffs are entitled to relief. Either Ms. Lin should be made available to answer this question in a direct way or ZHP should produce a knowledgeable witness to answer this line of questioning, with the costs of the renewed deposition, including Plaintiffs' counsel fees, borne by ZHP.

III. CONCLUSION

Of the 44 deposition excerpts provided by Plaintiffs as supposedly meriting sanctions, approximately 25 excerpts involving 4 of the 5 deponents warrant some form of relief. This is not the kind of showing that supports a conclusion that there was a systematic effort to obstruct the deposition process. It is also notable that all of the instances that warrant some relief involved the same counsel for Plaintiffs, although depositions of ZHP 30(b)(6) witnesses were taken by a number of lawyers representing the Plaintiffs. This fact also undermines the assertion of a systematic and concerted effort to disrupt the deposition process. Nevertheless, relief is warranted to compensate Plaintiffs for the additional time required where meritless objections were asserted and where witnesses repeatedly failed to give non-evasive responses to appropriate questions. Plaintiffs are also entitled to receive responsive, non-evasive deposition testimony on the matters covered in this decision.

In addition to the relief per deponent set forth above, Plaintiffs are entitled to recover the reasonable fees and costs allocable to the successful parts of this sanctions motion. *See Doe I v. Exxon Mobil Corporation*, 2021 WL 1840649 at *5 ("A party that prevails on a motion to compel is entitled to reimbursement for its reasonable expenses in making the motion, unless it

failed to attempt in good faith to obtain the information on its own, the opposing party's failure to respond was 'substantially justified,' or an award of expenses would otherwise be unjust."); *In re Neurontin Antitrust Litig.*, 2011 WL 253434 at *13. Plaintiffs will be afforded an opportunity to submit its request for fees and expenses incurred in presenting its motion and the ZHP Parties will be given an opportunity to reply. An appropriate Order follows.

NOW, THEREFORE, this 8th DAY OF DECEMBER, 2021, for the reasons set forth above, **IT IS HEREBY ORDERED THAT:**

1. Plaintiffs' Motion for Sanctions (ECF No. 1276) is **GRANTED IN PART.**
2. Plaintiffs and the ZHP Parties shall meet and confer for the purpose of implementing those parts of the decision that require the ZHP Parties to either make available at their expense witnesses to provide testimony on those specific matters set forth above or to admit certain facts, and shall report in writing the results of those discussions no later than **December 21, 2021**.
3. Plaintiffs shall submit their request for a monetary award based upon the repeated assertion of the "speaks for itself" objection during the Min Li deposition no later than **December 21, 2021,** and ZHP shall respond no later than **December 28, 2021.**
4. Plaintiffs shall submit their request for fees and expenses incurred in pursuing their motion along with a statement setting forth their position with respect to the amount of fees properly allocable to the parts of the motion on which Plaintiffs prevailed no later than **December 28, 2021.** The ZHP Parties shall respond no later than **January 11, 2022.**

5. Objections to this Order shall be submitted no later than **December 29, 2021.**

s/ Thomas I. Vanaskie
Hon. Thomas I. Vanaskie (Ret.)
Special Master