UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Edith Ramirez, Chairwoman**
Julie Brill
Maureen K. Ohlhausen
Joshua D. Wright
Terrell McSweeny

In the Matter of	)	
SUBPOENA AD TESTIFICANDUM TO VIROPHARMA, INC. DATED SEPTEMBER 4, 2014	)	**File No. 121-0062** **October 29, 2014**

ORDER DENYING PETITION TO QUASH SUBPOENA AD TESTIFICANDUM

By McSWEENY, Commissioner:

Shire ViroPharma, Inc. ("Shire"), as successor to ViroPharma, Inc. ("ViroPharma"),[1] has petitioned to quash a subpoena ad testificandum issued to ViroPharma on September 4, 2014. For the reasons stated below, the petition to quash ("Petition") is denied.

I. BACKGROUND

On September 4, 2014, the Commission issued a Subpoena Ad Testificandum ("Subpoena") to obtain oral testimony from Shire at an investigational hearing as part of an investigation to determine whether ViroPharma may have unlawfully delayed generic competition with its branded drug, Vancocin, by filing and maintaining multiple meritless petitions to the U.S. Food & Drug Administration ("FDA") and the courts or by filing and maintaining those petitions without regard to the merits. Those petitions include, among other things, a citizen petition, amendments and supplements to that petition, Freedom of Information Act ("FOIA") requests, and lawsuits against the FDA.

Under Section 2.7(h) of the FTC Rules of Practice and Procedure, 16 C.F.R. § 2.7(h), the Commission may obtain the testimony of a corporate entity by describing with "reasonable particularity the matters for examination." The corporate entity then "must designate one or more officers, directors, or managing agents, or designate others persons who consent, to testify

[1] Shire acquired ViroPharma in January 2014. Pet. at 1. We refer to ViroPharma when our discussion relates to events that predated the acquisition.

on its behalf."[2] Rule 2.7(h) was added to the FTC Rules of Practice and Procedure in 2012. This rule provides a process for taking oral testimony from corporate entities that parallels the process in Federal Rule of Civil Procedure 30(b)(6).[3] Accordingly, precedent regarding Rule 30(b)(6) provides us with useful guidance in evaluating Shire's Petition.

The testimony of the designated witness presents the corporation's position on the topics and represents the collective knowledge of the corporation, not merely that of the individual witness.[4] Consistent with Rule 2.7(h)'s requirements, the Subpoena required Shire's designated witness or witnesses to testify on October 3, 2014, regarding 20 specified topics. Those topics include ViroPharma's Vancocin filings with the FDA, including its citizen petition, amended petition, and their supplements; ViroPharma's lawsuits against the FDA; studies and reports about the approval, safety, or use of Vancocin; the sales and marketing of Vancocin; and ViroPharma's analyses of the likelihood and market effect of generic Vancocin entry.

In its Petition, Shire contends that the Commission's request for oral testimony is unduly burdensome because many topics for which the Commission seeks testimony are the subject of ViroPharma's submissions in response to a Civil Investigative Demand ("CID") and its white papers.[5] In addition, Shire contends that because employees involved in ViroPharma's FDA petitioning have left the company, "[p]reparing a company representative with no first-hand knowledge of the topics to attempt to answer" questions on the topics "would require a massive effort disproportionate to any new information that staff could hope to gain."[6]

II. ANALYSIS

Compulsory process is proper if the inquiry "is within the authority of the agency, the demand is not too indefinite and the information sought is reasonably relevant" to the investigation.[7] Here, Shire does not question the relevance of any topic identified in the Subpoena. Nor does Shire argue that the Commission failed to describe with "reasonable particularity" the topics identified in the Subpoena as required by Rule 2.7(h). Instead, Shire contends that it is unduly burdensome because of the need to prepare witnesses who "must testify about information known or reasonably available to the entity[.]"[8]

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[2] 16 C.F.R. §2.7(h).

[3] *See* 77 Fed. Reg. 3191-01 (Jan. 23, 2012).

[4] *See, e.g., QBE Ins. Corp. v. Jorda Enters., Inc.*, No. 10-21107, 2012 WL 266431, at *9 (S.D. Fla., Jan. 30, 2012).

[5] Pet. at 4-5.

[6] Pet. at 4.

[7] *United States v. Morton Salt Co.*, 338 U.S. 632, 652 (1950). *See also FTC v. Invention Submission Corp.*, 965 F.2d 1086, 1088 (D.C. Cir. 1992); *FTC v. Texaco, Inc.*, 555 F.2d 862, 874 (D.C. Cir. 1977).

[8] 16 C.F.R. §2.7(h).

While identifying and preparing the appropriate witnesses to testify on behalf of a corporation might require substantial effort, that does not excuse a corporation from the obligation to provide relevant testimony. Courts have acknowledged that "[p]reparing a . . . designee [to provide a corporation's testimony] may be an onerous and burdensome task, but this consequence is merely an obligation that flows from the privilege of using the corporate form to do business."[9] Despite the burden, the corporation must make a conscientious, good-faith effort to prepare its designated witnesses so that they can answer fully the questions posed.[10] "[A] corporation with no current knowledgeable employees must prepare its designees by having them review available materials, such as fact witness deposition testimony, exhibits to depositions, documents produced in discovery, materials in former employees' files and, if necessary, interviews of former employees or others with knowledge."[11] Such an approach is necessary to ensure that those who are entrusted to carry out a law enforcement inquiry are not shifted from one corporate representative to another in a blind search for a witness who is willing and able to testify on behalf of the corporation.[12] Thus, the obligation to identify and prepare corporate designees to testify ordinarily provides no basis to excuse the testimony.

We next turn to the specific issues identified in Shire's Petition.

A. Oral Testimony is Appropriate Even Though Written Narrative Responses, Documents, or Other Parties Have Addressed the Same Topics

We reject Shire's principal contention that the Subpoena is unreasonable and unduly burdensome because staff has information available from other sources that cover the designated topics. Specifically, Shire argues that previously produced company documents address the topics enumerated in the Subpoena.[13] Shire also argues that it has previously submitted material addressing the designated topics in its white papers and responses to interrogatories.[14] Finally, Shire claims that other parties are better positioned to address certain topics covered by the Subpoena and that consequently, Shire's testimony would not be particularly beneficial.[15]

[9] *QBE*, 2012 WL 266431, at *11.

[10] *Sprint Commc'ns Co., L.P. v. Theglobe.com, Inc.*, 236 F.R.D. 524, 528 (D. Kan. 2006).

[11] *QBE*, 2012 WL 266431, at *11.

[12] *See Great Am. Ins. Co. of NY v. Vegas Const. Co., Inc.*, 251 F.R.D. 534, 538 (D. Nev. 2008).

[13] Pet. at 5-7.

[14] Pet. at 4-7, 13-16.

[15] Pet. at 9-10.

Testimony elicited at an investigational hearing is qualitatively different from documentary evidence and written discovery.[16] An investigational hearing is iterative and live. It can elicit a more spontaneous response than written discovery. Moreover, even when a witness offers a conclusory or prepared response, an investigational hearing allows staff to probe the underlying facts, circumstances, and motivations. Consequently, "[b]y its very nature, the discovery process entails asking witnesses questions about matters that have been the subject of other discovery . . . Thus, the fact that information has been provided . . . concerning a particular category does not, in itself, make that category an impermissible subject of a 30(b)(6) deposition."[17]

Furthermore, even when a corporation has responded to document requests, oral testimony can provide a "roadmap" through the documents[18] and shed light on how the corporation has construed them.[19] For these reasons, courts consistently reject the proposition that a corporation need not provide testimony in response to a Rule 30(b)(6) subpoena on the ground that its documents are a viable substitute.[20] In fact, oral testimony conventionally follows written submissions because it enables FTC staff to probe the details, explanations, and limitations of prior written responses. "[A] party who has received written production is entitled to explanations of the information produced, including how the information was gathered, by whom, whether or not the party adopts that information, where the information came from, [and]

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[16] *See, e.g., In re Vitamins Antitrust Litig.*, 216 F.R.D. 168, 174 (D.D.C. 2003) (rejecting argument that a Rule 30(b)(6) deposition is unnecessary or duplicative by distinguishing between depositions and document production and stating that "the two forms of discovery are not equivalent."); *Marker v. Union Fidelity Life Ins. Co.*, 125 F.R.D. 121, 126 (M.D.N.C. 1989) ("Because of its nature, the deposition process provides a means to obtain more complete information [than a written response to an interrogatory] and is, therefore, favored.").

[17] *Tri-State Hospital Supply Corp. v. United State*s, 226 F.R.D. 118, 126 (D.D.C. 2005). *Accord New Jersey v. Sprint Corp.*, No. 03-2071, 2010 WL 610671, at *2 (D. Kan. Feb. 19, 2010) (a party "should not be prevented from questioning a live witness in a deposition setting just because the topics proposed are similar to written requests[.] . . Such a result would essentially limit a [party] to the first form of discovery served, since the topics are bound to overlap."); *Mitsui & Co. (U.S.A.), Inc. v. Puerto Rico Water Res. Auth.*, 93 F.R.D. 62, 65 (D.P.R. 1981) (explaining 30(b)(6) deposition is "supplementary and complementary" to other discovery, including depositions of individual employees); *Ierardi v. Lorillard, Inc.*, No. 90-7049, 1991 WL 158911, at *2 (E.D. Pa. Aug. 13, 1991) (rejecting argument that other discovery procedures would cause Rule 30(b)(6) testimony to be fruitless). *See also, e.g.*, *Great Am. Ins.*, 251 F.R.D. at 541 (adequately preparing 30(b)(6) designee may require educating witness with witness testimony, exhibits, and prior submissions).

[18] *See State Farm Mut. Auto. Ins. Co. v. New Horizont, Inc.*, 250 F.R.D 203, 208 (E.D. Pa. 2008) (noting a 30(b)(6) deposition can provide a "roadmap" in navigating large amounts of written discovery by allowing a deponent to answer questions or directing counsel to the relevant documents or interrogatory responses).

[19] *United States v. Taylor*, 166 F.R.D. 356, 361 (M.D.N.C. 1996).

[20] *See, e.g., QBE*, 2012 WL 266431, at *11 (citing *Great Am. Ins.*, 251 F.R.D. at 540); *Ierardi*, 1991 WL 158911, at *2 (explaining that documents can be interpreted in various ways and 30(b)(6) witness can provide the corporation's interpretation); *Twentieth Century Fox Film Corp. v. Marvel Enters., Inc.*, Case No. 01-CIV-3016, 2002 WL 1835439, at *3 (S.D.N.Y. Aug. 8, 2002) (requiring a 30(b)(6) designee to provide the corporation's interpretation of documents and events); *In re Vitamins Antitrust Litig.*, 216 F.R.D. at 174 (rejecting argument that underlying documents provide all relevant information).

whether there is some additional information."[21] Where responses include ambiguities and qualifications, those "ambiguities and qualifications mean that [the party's] responses are subject to interpretation. In this situation, the . . . [investigator] should be permitted to depose [the party] regarding these qualifications and attempt to clarify these ambiguities."[22]

Many of Shire's CID submissions raise questions that are best explored only through questions propounded to a live witness in an investigational hearing. In its Petition, Shire focuses in particular on Topic 13 of the Subpoena, which seeks testimony on "[e]ach Vancocin FDA Submission."[23] Shire asserts that parts of Topic 13 seek information that Shire already provided in its responses to CID Specifications 21 through 23.[24] Yet those responses were incomplete and lacking in detail,[25] or invited the Commission to request additional information.[26] Shire identifies other topics that were also the subject of the earlier CID.[27] When there are "explanations or interpretations that [the subpoena recipient] has regarding the submissions, [the investigator is] entitled to them[.]"[28] As such, Shire's earlier submissions on

[21] *United States v. Educ. Mgmt. LLC*, No. 2:07-CV-00461, 2014 WL 1391105, at *4 (W.D. Pa. Feb. 24, 2014) (quoting *State Farm*, 250 F.R.D. at 207).

[22] *Educ. Mgmt.*, 2014 WL 1391105, at *5.

[23] Pet. at 5.

[24] *Id*.

[25] Specification 22 asks for information regarding amendments and supplements to ViroPharma's citizen petition. ViroPharma's response states, in part, "If the FTC has any particular topics that it can identify for which it would like additional details, ViroPharma will review to see what additional response it can provide." Pet. at Exh. 4. Specification 23 asks about assessments ViroPharma made to the merits of its Vancocin FDA Submissions. Shire's response to this specification states that ViroPharma "will identify any further specific non-privileged assessments as it continues its review of documents." Pet. at Exh. 3.

[26] For example, ViroPharma's response to Specification 21 states:

> ViroPharma petitioned the FDA in order to raise significant scientific, legal, and regulatory issues that arose in connection with the FDA's consideration and adoption of new bioequivalence standards for approving generic versions of Vancocin. The Vancocin FDA Submissions were generally reactive to shifting FDA positions on bioequivalence standards for generic versions of Vancocin, specific FDA administrative actions (e.g., the convening of advisory committee meetings, the publication of draft guidance), and new information made available to ViroPharma by FDA (in pieces and over time) as a result of a court order following FOIA litigation, from tests performed by ViroPharma, and from the scientific community generally. With regard to the documents relating to this Specification 21, please refer to VP_00000034-23655, VP0025337-730 for the scientific, legal and regulatory issues raised by the FDA Submissions.

Pet. at 5. This response raises several questions that need to be explored through oral testimony because the response is laden with vague and nonspecific terms such as "generally." In addition, the investigation is entitled to specific answers about specific situations, such as the tests ViroPharma performed and the information ViroPharma learned from particular sources.

[27] Pet. at 7-8, 13-16.

[28] *In re Vitamins Antitrust Litig.*, 216 F.R.D. at 174 (citing Fed. R. Civ. P. 30(b)(6)).

these issues do not excuse Shire's testimony on these topics. The investigators are "entitled to test the answers that they were provided."[29]

We also find no merit in Shire's argument that some topics identified in the Subpoena are best addressed by other parties.[30] Even if other parties do possess relevant information, that does not dispense with the Commission's need to take testimony from Shire to understand Shire's position on these issues. As for Shire's claim that it has no more helpful or relevant information, that contention is inconsistent with objections elsewhere in its Petition that Shire has produced documents on these particular topics.[31]

B. The Breadth of the Topics Identified in the Subpoena Does Not Impose Undue Burden

Although Shire does not challenge the relevance of any of the 20 designated topics or argue that the topics were described in insufficient detail, it does claim that the designated topics are overly broad. Even if we were to accept Shire's description, "broadness alone is not sufficient justification to refuse enforcement of a subpoena."[32]

Although we recognize that considerable effort will be required to prepare a witness or witnesses to testify, the alternative – for the Commission to identify the appropriate Shire employees and agents and take their testimonies – would require a far greater expenditure of both Shire and Commission resources. For example, Shire identifies 42 "employees and agents who made important decisions or significant contributions regarding the FDA Submissions."[33] Shire is far better equipped to locate these individuals and designate its witness or witnesses than FTC staff.[34] Moreover, Shire is not limited to designating a current employee and may designate any witness or witnesses to testify on its behalf, including a former employee or employees with personal knowledge of the events covered by the Subpoena. Shire also may designate more than one witness to testify on its behalf.

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[29] *State Farm*, 250 F.R.D. at 208. *See also Marker*, 125 F.R.D. at 126 ("Nothing in the Federal Rules of Civil Procedure gives a party the right to not respond or inadequately respond to a Rule 30(b)(6) deposition notice or subpoena request and elect to supply the answers in a written response to an interrogatory."); *Educ. Mgmt.*, 2014 WL 1391105, at *4 ("Asking . . . 30(b)(6) deponent questions regarding the interrogatory responses appears to provide an efficient means" to identify and narrow issues).

[30] Pet. at 9 (discussing topics such as FDA approval and clinical studies of Vancocin that occurred before ViroPharma acquired the product).

[31] *See* Pet. at 7.

[32] *Adams v. FTC*, 296 F.2d 861, 867 (8th Cir. 1961).

[33] Pet. at Exh. 3.

[34] *See Bracco Diagnostics Inc. v. Amersham Health Inc.*, No. 03-6025, 2005 WL 6714281, at *3-4 (D.N.J. Nov. 7, 2005) (noting a 30(b)(6) deposition puts an end to "endless buck-passing").

Shire contends that its ability to prepare a company representative has been impaired by the departure of employees who were involved in many of the events covered by the Subpoena. That is not a valid basis for excusing Shire from its obligation to provide relevant testimony.[35] Courts recognize that it is not uncommon for a corporation to find that individuals who have first-hand knowledge of a distant event have departed its employ. "These problems do not relieve a corporation from preparing its Rule 30(b)(6) designee to the extent matters are reasonably available, whether from documents, past employees, or other sources."[36] Courts routinely reject the assertion that such testimony imposes undue burden or is unnecessary because the witness, without first-hand knowledge, could only testify about the documents that will be used to prepare the witness.[37] We live in an economic environment where corporate ownership often changes and employees are mobile. Such changes cannot be cited as a basis to frustrate a law enforcement investigation.

Finally, Shire argues that preparation of a corporate designee within 30 days, as required by the Subpoena as issued, is unduly burdensome. During the required meet and confer,[38] Shire was obligated to raise all of its objections with FTC staff. Yet Shire never sought additional time to prepare its witness or witnesses.[39] Now, however, Shire indicates it will need at least 60 days to adequately prepare a company representative if the Commission denies its Petition. While we find the request for 60 additional days excessive, in the exercise of our discretion, we grant Shire an additional 30 days from the date of this Order to prepare its designated witness or witnesses.

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[35] *See QBE*, 2012 WL 266431, at *11.

[36] *Taylor*, 166 F.R.D. at 361. *See also QBE*, 2012 WL 266431, at *11 ("The mere fact that an organization no longer employs a person with knowledge on the specified topics does not relieve the organization of the duty to prepare and produce an appropriate designee.").

[37] *In re Vitamins Antitrust Litig.*, 216 F.R.D. at 173-74. *See also Bd. of Trs. of Leland Stanford Junior Univ. v. Tyco Int'l Ltd.*, 253 F.R.D. 524, 526 (C.D. Cal. 2008) ("Even if the documents are voluminous and the review of those documents would be burdensome, the [Rule 30(b)(6)] deponents are still required to review them in order to prepare themselves to be deposed."); *Great Am. Ins.*, 251 F.R.D. at 541 ("Producing documents and responding to written discovery is not a substitute for providing a thoroughly educated Rule 30(b)(6) deponent."); *SEC v. Morelli*, 143 F.R.D. 42, 45 (S.D.N.Y. 1992) (explaining adequate preparation of Rule 30(b)(6) witness undermines need for designee's first-hand knowledge); *Sprint Commc'ns*, 236 F.R.D. at 528 (explaining that despite burden, corporation must prepare designees so that they may give complete knowledgeable answers); *Ierardi*, 1991 WL 158911, at *2 (refusing to excuse Rule 30(b)(6) testimony even though retired employee was deposed as fact witness).

[38] *See* 16 C.F.R. § 2.7(k).

[39] In support of its Petition, Shire states only that it discussed alternative ways for FTC staff to obtain the information they were seeking and an extension of time to file a petition to quash. Pet. at Exh. 1, ¶ 3.

III. CONCLUSION

For the foregoing reasons, **IT IS HEREBY ORDERED THAT** the Petition of Shire ViroPharma to quash the Subpoena be, and it hereby is, **DENIED**; and

IT IS FURTHER ORDERED THAT Shire ViroPharma shall appear to testify on the topics in the Subpoena on November 28, 2014, or at such mutually agreeable later date as FTC staff and Shire may designate.

By the Commission.

Donald S. Clark
Secretary

SEAL:
ISSUED: October 29, 2014