UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

In re	§	
	§	**PUBLIC**
Subpoena Ad Testificandum	§	
dated September 4, 2014	§	File No 121-0062, ViroPharma, Inc.
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Petition of Shire ViroPharma, Inc. to Quash Subpoena Ad Testificandum

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INTRODUCTION

Shire ViroPharma, Inc. ("Shire"), as successor to ViroPharma, Inc.,[1] petitions the Federal Trade Commission ("FTC") to quash the Subpoena issued to ViroPharma in this matter, dated September 4, 2014.[2] Specifically, Shire requests that the Commission direct staff to work with Shire to find alternatives to the Subpoena that: 1) not duplicate the responses and documents that ViroPharma and Shire have already provided; and, 2) not require Shire to undertake an investigation that entails preparing a company witness to speak about events that occurred at least eight years ago and about which Shire has no first-hand knowledge. Shire began that process in a meet-and-confer session on September 22, 2014. Before and after that meeting Shire requested that staff extend the due date for filing this petition, but staff declined to do so.[3]

Staff is investigating ViroPharma's petitioning of the FDA in response to a change in policy made by the FDA in 2006. The Subpoena puts Shire in an extremely difficult position because it requires Shire to produce a witness to testify about events that significantly predate Shire's acquisition of ViroPharma. Some topics relate to events that date back to early 2006, and at least one topic concerns events that date far back as 1986. At present, Shire's knowledge of these events is largely based on documents that have been previously produced to FTC. The key ViroPharma employees with potential knowledge of the topics set forth in Subpoena are not current employees of Shire. These employees left Shire shortly after Shire acquired ViroPharma. Interviewing these employees, and other persons these employees might identify as knowledgeable on the topics in the Subpoena, to prepare a "company representative" to speak on the far-reaching topics in the

[1] Shire acquired ViroPharma, Inc. in January 2014. This petition will refer to ViroPharma for all background facts arising before the acquisition.

[2] The Subpoena was served on counsel on September 8, 2014. This petition is therefore timely under Rule 2.10(a).

[3] *See* Statement of Counsel, attached as Exhibit 1.

subpoena requires considerable effort and resources, *i.e.*, more than a reasonable investigation. Hence, preparing a "company representative" to address the subpoena, as distinct from the third-party witnesses that potentially have first-hand knowledge, is challenging — and, unreasonable and unduly burdensome.

In addition, ViroPharma has already provided responses to many of the topics of questions in the Subpoena.[4] ViroPharma previously provided responses to FTC's requests for information in the form of narrative interrogatory answers; identification of responsive documents; two white papers; and by providing FTC with an early interview of a former ViroPharma employee who had first-hand knowledge of the FDA proceedings that are subject of FTC's investigation.

If the purpose of the Subpoena is, as staff stated at the meet and confer, to obtain Shire's formal position on the identified topics, then staff already has the company's position in the form of the answers to the interrogatory-type specifications that ViroPharma provided two years ago. If the purpose is to obtain information not contained in the documents and responses produced to date, then it would be less burdensome — and more efficient — for staff to interview directly the relevant fact witnesses. Accordingly, Shire proposed to staff — and continues to assert — that it would be more productive for the parties to work together to identify specific topics that have not been previously addressed in discovery and develop a plan to address those topics. Such a collaborative effort might result in a narrowing of the scope and number of topics, the identification of specific former employees with relevant knowledge, reliance on previous submissions, or follow-up questions to be answered in writing, among other possibilities.

Shire is not trying to prevent staff from obtaining the information it needs to complete this investigation. In fact, as set forth above, Shire would like to continue its dialogue with the FTC to

[4] *See* Appendix.

attempt to find a path forward that addresses both parties' concerns. However, for the reasons set forth above, Shire is submitting this Petition to Quash the Subpoena because requiring Shire to prepare and produce a witness on October 3, 2014 to testify on the extensive topics in the Subpoena is unreasonable and unduly burdensome.

BACKGROUND

Shire, and ViroPharma before it, has cooperated with staff throughout this entire investigation — now in its third year. Before receiving compulsory process, ViroPharma voluntarily produced over 100,000 pages and arranged for Tom Doyle, then a top executive and key fact witness, to meet with staff to discuss ViroPharma's petitioning of FDA. After receiving the civil investigative demand (CID), ViroPharma collected documents from forty-four custodians and numerous centralized files. ViroPharma employed a team of twenty-five contract attorneys full time for over seven months to review nearly 700,000 documents. ViroPharma produced over 250,000 documents totaling over three million pages and provided over 75,000 privilege log entries.[5]

Additionally, in September and October 2012, ViroPharma provided twenty written narrative responses to the CID's interrogatory-like specifications. Many of these responses directly address the topics identified in the Subpoena.[6]

Finally, in response to requests from staff, ViroPharma drafted two white papers totaling over eighty pages on the *Noerr-Pennington* doctrine and its application. The white papers discussed ViroPharma's petitioning in great detail, covering many of the topics identified in the Subpoena, and demonstrated that all of ViroPharma's petitioning had an objective basis and was

[5] Later, at staff's request, ViroPharma further employed teams of contract attorneys to create more detailed privilege logs.

[6] *See* Appendix.

protected by *Noerr-Pennington* (notwithstanding any possible pattern exception). Twice ViroPharma counsel met with staff to discuss these papers.

ARGUMENT

While the staff's ability to investigate is broad, it fundamentally must be reasonable. The FTC's "[s]ubpoena enforcement power is not limitless," *FTC v. Ken Roberts Co.*, 276 F.3d 583, 586 (D.C. Cir. 2001). And, as explained in *United States v. Morton Salt Co.*, 338 U.S. 632, 652 (1950), "governmental investigation into corporate matters may be of such a sweeping nature and so unrelated to the matter properly under inquiry as to exceed the investigatory power." Thus, a subpoena may not be "unduly burdensome or unreasonably broad," *FTC v. Texaco*, 555 F.2d 862, 882 (D.C. Cir. 1977). These principles, of course, apply here.

The sixty-eight-part Subpoena is a poor vehicle for staff to obtain the information it seeks and is unreasonable because it is duplicative and unduly burdensome. ViroPharma has already produced 3,250,000 pages of documents and has provided written responses to the original CID. The Subpoena seeks information that can be readily found by staff in these responses to the original CID. Moreover, the Subpoena covers virtually every aspect of ViroPharma's business for over eight years, and due to the passage of time and corporate control changes, the key employees with first-hand knowledge of the topics are no longer employed at Shire. Preparing a company representative with no first-hand knowledge of the topics to attempt to answer each of the sixty-eight parts would require a massive effort disproportionate to any new information that staff could hope to gain.

I. The Subpoena Is Unduly Burdensome Because It Seeks Information ViroPharma Already Provided.

In the two and half years of this investigation, ViroPharma has submitted written narrative responses to many of the *exact* questions sought by the sixty-eight-part Subpoena and has produced

millions of pages of documents — many of which go *directly* to topics in the sixty-eight-part Subpoena. Moreover, ViroPharma has submitted two white papers — totaling over 80 pages and including detailed summaries of its petitioning with footnotes to relevant documents — that precisely answer topics in the sixty-eight-part Subpoena.

As just one of many examples, Specification 13, which actually consists of eight specifications, most vividly illustrates this duplicativeness. It seeks testimony for "[e]ach Vancocin FDA Submission" on:

(a) ViroPharma's reason(s) for filing the Vancocin;

(b) ViroPharma's basis (or bases) for filing the Vancocin FDA Submission;

(c) when ViroPharma learned or discovered the information or data referenced in Spec. 13(b);

(d) who at ViroPharma decided to file the Vancocin FDA Submission;

(e) when ViroPharma decided to file the Vancocin FDA Submission;

(f) when ViroPharma filed the Vancocin FDA Submission;

(g) who drafted or participated in drafting the Vancocin submission; and

(h) ViroPharma's assessment(s) of the Vancocin FDA Submission.

Staff already posed these questions in Specifications 21–23 in the August 2012 CID. And, ViroPharma already responded on September 18 and October 26, 2012:

> 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.

Ex. 3. In addition, given this sort of specification, it is perfectly appropriate for ViroPharma also to respond "Each ViroPharma FDA Submission speaks for itself." Ex. 4.

In addition to the narrative responses, Specification 13 is duplicative of the white papers. The white papers submitted by ViroPharma include extensive and detailed discussions of the reasons for the submissions, the basis for the submissions, and when ViroPharma learned or discovered the information that formed the basis. The second white paper submission, for instance, notes that a "review of the file shows that each submission had a specific, distinct purpose (either seeking or providing information), reacted to a specific new development or commented on an FDA proposal," and discusses many submissions in great detail. *See* ViroPharma Mar. 1, 2013 White Paper at 5–9.[7] Likewise, the first white paper provides a chronological recounting of ViroPharma's petitioning, directly explaining the reasons and bases for ViroPharma's petitions. *See* ViroPharma Oct. 12, 2012 White Paper at 4–30.

Specification 13 is also duplicative of the documents themselves. Before receiving compulsory process, ViroPharma voluntarily produced the entire FDA Citizen Petition docket. *See* VP_00015815 through VP_00023680. The text and context of any ViroPharma filing will answer

- the reason for the filing;
- the basis of the filing;
- the information relied upon in the filing; and
- when ViroPharma learned or discovered that information.

[7] The second white paper states that "we are happy to discuss in detail any submission that the Commission wishes." This remains true. Shire is willing to engage in a substantive discussion on any filing. This petition seeks only to tailor and narrow staff's inquiry, not to prevent it entirely. Shire requests that staff identify specific questions regarding specific filings, and Shire will endeavor to address those questions.

Take, for instance, ViroPharma's February 27, 2009 submission. VP_00018555–57. Apparent on the face of the document is that

- the reason for the filing was to comment on the FDA's December 16, 2008 draft guidance based on the requirements of good scientific and regulatory practice;
- the basis of the filing was ViroPharma's discovery that FDA had surreptitiously made changes to the draft guidance;
- the information relied upon was ViroPharma's own careful reading and analysis of the FDA's draft guidance(s); and
- ViroPharma discovered the information while preparing comments (the change was made sometime after December 15, 2008, when the original guidance was posted, while ViroPharma was drafting comments in January or February).

All of ViroPharma's petitions are susceptible to this same careful reading. All submissions state upfront the reason that they are being filed, all supply the basis for their filing, all identify an FDA action to which they are responding or demonstrably new information that ViroPharma has learned or discovered, and all were submitted shortly after ViroPharma learned or discovered it.

Many of the specifications in the sixty-eight-part Subpoena are similarly duplicative, including[8]:

- Specification 1 demands testimony on uses of Vancocin, which can be found on the FDA-approved label produced at VP_00017014–20.
- Specification 2 demands testimony on FDA approvals, which can be found at VP_00015929–16003. Shire also understands that staff has obtained relevant information from [redacted]
- Specification 5 demands testimony on periodic safety reports, which can be found, among other places, at VP_00106553–732, VP_02563714–47, and VP_03244628–5362.
- Specification 6 demands testimony on communications between ViroPharma and Lilly, which can be found, among other places, at VP_00687417–7378386 and VP_001051943–2041.

[8] *See also* the Appendix.

- Specification 8 demands testimony on ViroPharma's acquisition of Vancocin, which can be found in ViroPharma's narrative responses to Specification 13 (Ex. 2) and 4(c) documents-related to the transaction produced at VP_00025769–939.

- Specification 9 demands testimony on ViroPharma's marketing and sales of Vancocin, which were addressed in ViroPharma's narrative responses to Specification 32 (Ex. 2) and produced, among other places, at VP_00108627–787 and VP_00109084 –236293.

- Specification 14 demands testimony on ViroPharma's acquisition of Genzyme data, which were addressed in ViroPharma's narrative responses to Specification 25 (Ex. 4) and produced at VP_00026291–106314.

- Specification 15 demands testimony on ViroPharma's communications with FDA, which were addressed in ViroPharma's narrative responses to Specification 24 (Ex. 4) and documents produced, among other places, at VP_00408070–156, VP_00997909–13, VP-00998039–41, VP_03226280–81.

- Specification 17 demands testimony on ViroPharma's use of third-party consultants in petitioning, which were addressed in ViroPharma's narrative responses at Specification 20 (Ex. 3), numerous exchanges with staff, and documents produced, among other places, at VP_00650648–777994 and VP_00792436– 819133. Shire also understands that staff has obtained relevant information from [redacted]

- Specification 18 demands testimony on ViroPharma's FDA-related litigation, which were addressed in ViroPharma's narrative responses to Specification 6 (Ex. 2), Specification 28 (Ex. 3), and Specification 27 (Ex. 4), the Oct. 12, 2012 White Paper at 4–30, the Mar. 1, 2013 White Paper at 5–9, and documents produced at VP_00000024–3510.

In sum, the sixty-eight-part Subpoena is duplicative of ViroPharma's written responses already provided, white papers already submitted, and documents already produced.

II. The Broad Scope of the Subpoena Is Unduly Burdensome.

The Subpoena covers virtually all of ViroPharma's business activities from 2004 to 2012. From 2004 to 2008, Vancocin was ViroPharma's only product approved for sale by the FDA, and the Subpoena covers the entire spectrum of activities related to Vancocin. As a few examples:

- Specification 5 seeks testimony on routine FDA regulatory filings, requiring a ViroPharma regulatory affairs employee with knowledge spanning from 2004–12.

- Specification 7 seeks testimony on quality assurance and manufacturing related documents, requiring a ViroPharma quality assurance or manufacturing employee with knowledge spanning from 2004–12.

- Specification 8 seeks testimony on ViroPharma's original decision to acquire Vancocin, requiring a ViroPharma senior manager from 2004.

- Specification 9 seeks testimony on marketing issues, requiring a ViroPharma marketing employee with knowledge spanning from 2004–12.

- Specification 11 seeks testimony concerning manufacturing forecasting, requiring a ViroPharma commercial employee with knowledge spanning from 2004–12.

- Specification 14 seeks testimony on ViroPharma's acquisition of Genzyme data, requiring a ViroPharma scientist.

- Specification 18 seeks testimony on ViroPharma's litigation matters, requiring a ViroPharma in-house counsel.

- Specification 20 seeks testimony on communications between ViroPharma and any member of the United States Congress or staff, requiring a ViroPharma lobbyist with knowledge spanning from 2004–12.

Such specifications are unduly burdensome because they require expertise from completely disparate areas of ViroPharma, covering the entire depth and breadth of the company. Adequately preparing a corporate representative by October 3, 2014 to give binding testimony on each of these areas is unduly burdensome.

The Subpoena not only includes the entire span of daily business activity, but also extends outside the scope of ViroPharma's business. Parts of the Subpoena seek testimony on knowledge outside of any conceivable ViroPharma employee:

- Specification 2 seeks testimony on the FDA approval of Vancocin, which occurred in 1986, eighteen years before ViroPharma acquired Vancocin.

- Specification 3 seeks testimony on clinical studies of Vancocin, which again would have occurred well before ViroPharma acquired Vancocin.

There simply is no legitimate reason for such specifications. We understand that staff has already obtained information [redacted]

III. Time and Change in Circumstance Magnifies the Subpoena's Unreasonableness.

The sixty-eight-part Subpoena is poor vehicle for staff to obtain either Shire's official position or any new information. Nine years have elapsed from the FDA's original change in

policy, which prompted ViroPharma to petition. ViroPharma, as constituted during the petitioning, no longer exists. Shire acquired it — including, of course, its liabilities — in January 2014. By that time, Vancocin was no longer ViroPharma's major product. Many ViroPharma-legacy employees have now left Shire. The ViroPharma-legacy employees involved in the FDA petitioning have left. This impairs Shire's ability to prepare a company representative to respond to the Subpoena in a manner useful to the investigation.

Requiring Shire to provide and prepare a company representative to respond to the sixty-eight-topic Subpoena will result in an exceedingly long and fruitless investigational hearing. Without any personal knowledge, the Shire representative will likely be forced to answer questions simply by referring to and reading from the particular document. Moreover, many of these answers will simply duplicate what ViroPharma already stated in the answers to the interrogatory-like specifications. The result of producing such a representative requires great time and expense on Shire's part and fails to provide staff with any information that is not already in the documents ViroPharma produced or narrative responses that it supplied to the FTC. Even if Shire tracked down all the relevant former ViroPharma employees in order to prepare Shire's representative, FTC staff would not discover anything related to the subjective motivations of ViroPharma for filing any petition or lawsuit[9] for the simple reason that the subjective minds that thought those thoughts are gone.

[9] Shire maintains, consistent with both white papers, that so long as there was an objective basis for ViroPharma's petitioning, *Noerr* protection applies and subjective intent is irrelevant. Although we are not trying to pre-empt an investigation simply because we believe it is meritless, it is relevant for the Commission to consider whether the burdens being imposed on the petitioner are proportionately justified given the multiple reasons the investigation should be closed. After ViroPharma counsel submitted two separate white papers on *Noerr-Pennington*, and had two meetings with staff to discuss *Noerr*, staff has failed to articulate a theory to Shire counsel that would overcome *Noerr*.

Even absent the change in control, Shire's ability to comply is hampered by the passage of time. The petitioning in question began nearly nine years ago. ViroPharma acquired Vancocin ten years ago. For example, preparing a witness for Specification 8 — ViroPharma's acquisition from Eli Lilly & Co. of rights to Vancocin, including business factors considered in ViroPharma's decision to acquire the rights — would require not just a ViroPharma senior manager, but a ViroPharma senior manager *from 2004*. Likewise, Specifications 2 and 3 demand testimony concerning the FDA approval of Vancocin. Vancocin Capsules were approved *in 1986*. Vancocin Oral Solution was approved *in 1958*.

Percipient witnesses to ViroPharma's petitioning exist, and should this case ever go to trial, both Shire and staff will undoubtedly call those witnesses to testify. Nothing prevents staff from questioning those witnesses directly before subpoenaing Shire. Those investigational hearings would be more productive for staff and almost certainly provide staff with a path to narrowing any outstanding questions it has for Shire.

IV. Conclusion

Shire acknowledges staff's right to control its own investigation. Shire acknowledges staff's right to have investigational hearings. Shire acknowledges staff's right to ask Shire's position on particular issues. But, for the reasons stated above, this sixty-eight-part Subpoena is unreasonable — it is duplicative and unduly burdensome. If staff wants Shire's official position on specific topics that have not already been addressed, then Shire will work with staff to attempt to address those topics. If staff wants to obtain new information, then at present, the best place to start looking for that information is relevant witnesses with first-hand knowledge of the activity.

Shire, and ViroPharma, have been cooperative throughout this two and half year investigation. Shire has offered to engage with staff in a more focused process that accommodates the unique circumstances of this investigation in a reasonable way. Shire asks that the Commission

quash the Subpoena and direct staff to tailor any new subpoena to information not already available to it or more readily attainable from third parties. Alternatively, Shire asks the Commission to lift the return date on this Subpoena and allow Shire and staff to for at least sixty days to allow Shire and staff to continue negotiations. If this petition is denied, Shire anticipates that it will need at least sixty days to prepare adequately a company representative.

Dated: Washington, DC
September 29, 2014

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Appendix: Subpoena specifications compared to CID specifications to which ViroPharma supplied written narrative responses.

2014 Subpoena	2012 CID
Specification 2: FDA approval(s) of Vancocin and application(s) by Eli Lilly or ViroPharma for FDA approval of Vancocin.	**Specification 14:** Identify the following and submit all documents supporting your response: A. what type of data ViroPharma believes was the basis for the FDA's approval of the Vancocin NDA; and B. when and how ViroPharma arrived at that belief.
Specification 8: ViroPharma's acquisition from Eli Lilly & Co. of rights to Vancocin, including: a. the business factors considered in ViroPharma's decision to acquire the rights to Vancocin; and b. ViroPharma's due diligence of Vancocin, including, but not limited to: i. FDA approval(s) of Vancocin; and ii. the likelihood of Generic Vancocin approval or entry.	**Specification 13:** Identify, in ViroPharma's acquisition from Eli Lilly & Co. of rights to Vancocin: A. the date ViroPharma first entered discussions with Eli Lilly & Co.; B. the date ViroPharma entered into agreement with Eli Lilly & Co.; and C. the purchase price, including any royalties.
Specification 9: ViroPharma's marketing and sale of Vancocin Capsule, including: a. the pricing of Vancocin Capsule, including how it was determined and by whom; b. any reduction, elimination, or increase in promotional support for Vancocin Capsule; and c. any forecasts, projections, or analyses of other products on Vancocin Capsule dollar sales, unit sales, and net income.	**Specification 32:** Identify how the pricing for Vancocin is determined, including but not limited to any promotions, rebates, or discounts offered, and competitive responses to any product identified in response to Specification 30 [all products that competed with Vancocin].

Specification 13: Each Vancocin FDA Submission, including: a. ViroPharma's reason(s) for filing the Vancocin; b. ViroPharma's basis (or bases) for filing the Vancocin FDA Submission; c. when ViroPharma learned or discovered the information or data referenced in Spec. 13(b); d. who at ViroPharma decided to file the Vancocin FDA Submission; e. when ViroPharma decided to file the Vancocin FDA Submission; f. when ViroPharma filed the Vancocin FDA Submission; g. who drafted or participated in drafting the Vancocin submission; and h. ViroPharma's assessment(s) of the Vancocin FDA Submission.	**Specification 21**: Identify ViroPharma's reason(s) for filing the Vancocin FDA Submissions and submit all documents relating to your response. **Specification 22**: For each amendment or supplement ViroPharma filed to the Vancocin FDA Submissions, identify the following and submit all documents relating to your response: A. the date of the filing; B. whether the filing was an amendment or a supplement; C. the reason(s) for the filing; D. any new information provided; and E. the date ViroPharma became aware of the new information identified in 22(D) above. **Specification 23**: Identify and describe any assessment ViroPharma made related to the merits of its Vancocin FDA Submissions, including the names of individuals responsible for such assessments, and submit all documents relating to your response.
Specification 14: ViroPharma's acquisition and analysis of Genzyme's data comparing tolevamer to Vancocin in patients with Clostridium difficile-associated diarrhea.	**Specification 25:** Identify the following and submit all documents supporting your response: A. the date ViroPharma first became aware of Genzyme clinical data; B. the date ViroPharma first communicated with Genzyme about purchasing Genzyme clinical data; C. the date ViroPharma entered into agreement with Genzyme about the purchase of Genzyme's clinical data; and D. the reason(s) why the Company purchased the data.

Specification 15: In addition to the Vancocin FDA Submissions, the communications between ViroPharma and the FDA concerning Vancocin or Generic Vancocin.	**Specification 24:** For each instance of communication, including correspondence and meetings, between ViroPharma and the FDA relating to Vancomycin Products, identify: A. the date of the communication; B. the type of communication; C. where applicable, the Persons who sent the communication, including title and affiliation; D. where applicable, the Person to whom the communication was addressed, including title and affiliation; E. where applicable, the Persons attending the meeting or teleconference, including title and affiliation; and a summary of the communication.
Specification 17: Each third party ViroPharma used or hired in considering, preparing, and/or drafting any Vancocin FDA Submission; including: a. dates of work; b. purpose and scope of work; and c. each individual at the third party who was involved in the work and his/her role	**Specification 20**: Identify each ViroPharma employee, representative, agent and consultant involved in the Vancocin FDA Submissions, and for each individual identify: A. his/her role; B. his/her current position with ViroPharma or current employer; and his/her position and/or employer at the time of his/her involvement. **Specification 26:** Identify by name and contact information all Persons outside the Company with whom ViroPharma or its agents have communicated regarding the Vancocin FDA Submissions.
Specification 18: ViroPharma's (i) FDA Litigation, (ii) FOIA Litigation, and (iii) Precose Litigation, including for each Litigation: a. ViroPharma's reason(s) for filing and maintaining the Litigation; b. ViroPharma's basis (or bases) for filing and maintaining the Litigation; c. ViroPharma's assessment(s) of the Litigation.	**Specification 6:** Submit unredacted versions of all documents, except for purely procedural matters, produced or generated in the FDA Litigation, FOIA Litigation, Precose Litigation, and Shareholder Litigation, including but not limited to: A. court rulings and orders, except for purely procedural orders (such as orders granting admission pro hac vice); B. pleadings, motions, and all accompanying briefs, including exhibits, declarations, and other papers,

	except for purely procedural motions; C. expert reports, including any attachments or exhibits; D. deposition transcripts and exhibits to such transcripts; E. interrogatories and interrogatory responses; F. requests for admission, and responses to requests for admissions; G. documents requests and all documents produced by each party and any non-party, including all privilege logs; and H. documents relating to actual or potential settlement of the litigation, including but not limited to negotiations of any settlement; internal or external discussions, communications, analyses, evaluations, and notes relating to any settlement; documents relating to the projected or anticipating impact on the revenues, costs, or profitability of Vancocin; and drafts of any settlement agreement or term sheet (whether or not incorporated in the executed agreement). **Specification 27:** Identify ViroPharma's reason(s) for filing the following litigations and submit all documents relating to your response. A. FDA Litigation; B. FOIA Litigation; C. Precose Litigation. **Specification 28:** Identify and describe any assessment ViroPharma made related to the merits of its (1) FDA Litigation; (2) FOIA Litigation; and (3) Precose Litigation. Include the names of the individuals responsible for such assessments, and submit all documents relating to your response.