

# EXHIBIT 4

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October 26, 2012

**VIA COURIER**

June Im, Esq.  
Federal Trade Commission  
Bureau of Competition  
601 New Jersey Avenue, N.W.  
Washington, DC 20001

Re: File No. 121-0062: ViroPharma

Dear June:

Enclosed is a ViroPharma document production in response to the Federal Trade Commission's civil investigative demand. Also enclosed are responses to Specifications 14, 22, 24, 25, 26, 27, 31, and 34.

As you will see, the document production includes (after an initial privilege screen) all responsive, non-privileged documents from Robert Chernitzky, Michel de Boer, and

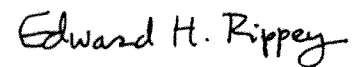
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Production Volume: VPFTC\_012\_2012  
Bates Range: VP\_00236293 - VP\_00246849  
Documents: 2,121  
Images: 10,557  
Natives: 0

Please let me know, of course, if you have any questions.

Sincerely,

A handwritten signature in black ink that reads "Edward H. Rippey". The signature is written in a cursive style with a prominent initial "E".

Edward H. Rippey

Enclosures

**ViroPharma's Responses to Specifications 14, 22, 24, 25, 26, 27, 31, and 34**

With respect to every response set forth below, ViroPharma hereby incorporates by reference each and every objection stated in the General Objections.

**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.

**Response:**

A. ViroPharma believes that the FDA approved the NDA for Vancocin capsules based on drug levels in blood, urine, and feces. ViroPharma believes that dissolution data in the Vancocin NDA was a quality assurance measure in drug manufacture, not a bioequivalence measure.

B. ViroPharma arrived at this belief when it analyzed what it objectively believed were FDA misstatements about the basis for Vancocin approval in June and July 2009, immediately prior to the August 2009 advisory committee meeting. Regarding comparisons between the oral solution and oral capsule formulations of Vancocin, while reviewing proposed labeling for the capsules the FDA stated: "The following sentence in the Clinical Pharmacology section should be deleted since there is insufficient evidence to support it: 'In a comparative bioavailability study of the Pulvule dosage form and the oral solution dosage form, there were no significant differences in serum or fecal concentrations.'" See VP\_00015959.

**SPECIFICATION 22:** For each amendment or supplement ViroPharma filed to the Vancocin FDA Submissions, identify the following and submit all documents relating to our response:

- A. the date of the filing;
- B. whether the filing was an amendment or 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.

**Response:**

Each ViroPharma FDA Submission speaks for itself. 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.

**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
- F. a summary of the communication.

**Response:**

Each ViroPharma communication or meeting with the FDA is reflected in the non-privileged, responsive documents that ViroPharma has already produced or will produce. Each communication speaks for itself and identifies the date and type of communication, the person who sent the communication (including affiliation), the person to whom the communication is addressed (including affiliation), and, to the extent recorded and applicable, the persons attending any meeting or teleconference (including affiliation).

**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.

**Response:**

**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.

**Response:**

Per our agreed upon limitation to this specification, each applicable person with whom ViroPharma or its agents (as defined in ViroPharma's response to Specification 20 on September 18, 2012) have communicated regarding the Vancocin FDA Submissions is reflected in either the non-privileged, responsive documents that ViroPharma has already produced or will produce or in the privilege logs that ViroPharma is in the process of creating.

**SPECIFICATION 27:** Identify ViroPharma's reason(s) for filing the following litigations and submit all documents relating to your responses:

- A. FDA Litigation;
- B. FOIA Litigation; and
- C. Precese Litigation.

**Response:**

A. FDA Litigation

ViroPharma filed the FDA Litigation because there was an objective basis to challenge the scientific, legal, and regulatory basis for FDA's approval of Vancocin ANDAs. First, the

### C. Precose Litigation

ViroPharma filed the Precose Litigation because it had an objective basis to challenge the FDA's failure to follow the Administrative Procedure Act. In June 2010, the FDA published a new Guidance where the FDA pointed to a specific regulation (21 C.F.R. § 320.24) for the broad authority to permit *in vitro* bioequivalence testing for locally acting drugs. See Office of Generic Drugs, Food and Drug Administration, Guidance for Industry: Bioequivalence Recommendations for Specific Products (June 2010), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072872.pdf> (accessed October 4, 2012). ViroPharma believed that invoking this broad authority enabled the FDA to bypass the *in vivo* correlation requirement set out elsewhere in the FDA's regulations. The FDA had earlier referenced this broad authority in connection with its response to a citizen petition filed with respect to a product called Precose, a locally acting GI drug. See FDA Response to Rackoczy Molino Mazzochi Siwik, LLP Citizen Petition, Dkt. No. FDA-2007-P-0418 (May 7, 2008) (the "FDA Precose Response"). The reference to this broad authority in the 2010 guidance document, coupled with its earlier legal analysis in the FDA Precose Response, in ViroPharma's objectively based belief, confirmed to ViroPharma that the FDA had adopted a newly articulated legal position regarding bioequivalence methods for locally acting drugs. As a result, ViroPharma filed suit in September 2010, arguing that the FDA Precose Response represented an effective amendment of the FDA's bioequivalence regulations, such change was done without notice-and-comment rulemaking, and thus was in violation of the Administrative Procedure Act.

**SPECIFICATION 31:** State, on a monthly basis, in dollars and units and separately for each dosage strength of Vancocin:

- A. gross sales;
- B. net sales;
- C. discounts, rebates, and promotions;
- D. costs of goods sold; and
- E. promotional expenses, including, but not limited to detailing, physician and pharmacist marketing, and medical and other journal advertising.

**Response:**

Please see the attached spreadsheet

**Confidential**

**Response:**

Since January 2005, when ViroPharma assumed full responsibility for Vancocin after acquiring it in late 2004, there have been no such supply disruptions of Vancocin.