UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

IN RE VIROPHARMA INCORPORATED SECURITIES LITIGATION	Civil Action No. 12-2714 CLASS ACTION **AMENDED CLASS ACTION COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS** DEMAND FOR JURY TRIAL

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Lead Plaintiff, Carpenters' Local 27 Benefit Trust Funds ("Carpenters" or "Plaintiff"), by its undersigned attorneys, hereby brings this Amended Class Action Complaint ("Complaint") against ViroPharma Incorporated ("ViroPharma" or the "Company"), Vincent J. Milano ("Milano"), Charles A. Rowland ("Rowland"), Thomas F. Doyle ("Doyle"), and John P. Wolf ("Wolf"), collectively ("Defendants"). The allegations herein are based on Plaintiff's personal knowledge as to its own acts and on information and belief as to all other matters, such information and belief having been informed by the investigation conducted by and under the supervision of its counsel. Plaintiff's counsel's investigation included a review and analysis of publicly available information regarding ViroPharma, including United States Securities and Exchange Commission ("SEC") filings by ViroPharma, regulatory filings and reports, securities analysts' reports and research data, investor conference transcripts, press releases and other public statements issued by the Company, media reports about the Company, documents received from the FDA in response to a Freedom of Information Act ("FOIA") request, filings from the following actions filed by ViroPharma against the FDA: *ViroPharma v. Dep't. of Health and Human Servs. and Food and Drug Admin*., 1:08-cv-02189 (D.D.C.); *ViroPharma v. Margaret A. Hamburg, M.D., in her official capacity as Commissioner, Food and Drug Admin., et al*., 1:10-cv-01529 (D.D.C.) ("*Hamburg I*"); and *ViroPharma v. Margaret A. Hamburg, M.D., in her official capacity as Commissioner, Food and Drug Admin., et al*., 1:12-cv-00584 (D.D.C.) ("*Hamburg II*"), consultations with an expert in the biopharmaceutical industry and on FDA regulations, and interviews of former employees of ViroPharma and other persons with knowledge of the matters alleged herein (some of whom have provided information in confidence; those confidential witnesses ("CWs") will be identified herein by number (CW1, CW2, *etc.*) and will be described in the masculine in all cases in order to protect their identities).

Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery. On behalf of itself and the class it seeks to represent, Plaintiff alleges as follows:

I. NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class (the "Class") of all persons other than Defendants and related persons who purchased ViroPharma securities between December 14, 2011 and April 9, 2012, inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the Securities Exchange Act of 1934 (the "Exchange Act").

2. ViroPharma develops, licenses, and markets pharmaceutical products. The Company's most important and valuable product was Vancocin, an antibiotic drug primarily used to treat Clostridium Difficile Associated Diarrhea ("CDAD" or "*c. difficile*"). CDAD is a severe infection of the gastrointestinal tract that, left untreated, can result in death. The incidence of CDAD increased more than ten fold since 1982, and Vancocin was the only drug approved by the FDA to treat the condition.[1] Thus, ViroPharma had a virtual monopoly on the market for treating CDAD, and one that it coveted dearly.

3. Vancocin is very expensive. ViroPharma charges patients approximately $800-$1,000 for a ten day dose and makes an incredible ***97% profit margin*** on those sales. Vancocin was also very important to ViroPharma, accounting for over half of ViroPharma's 2011 revenues. ViroPharma's net sales from Vancocin in 2011 alone were $288.9 million, representing an 11% increase over 2010. ViroPharma admits that it relied on the revenue

[1] Another drug, metronidazole, is also used by some physicians to treat CDAD, but it is not approved by the FDA for that usage and is generally considered less effective than Vancocin. Metronidazole is sometimes prescribed off-label because it is much less expensive than Vancocin, and because there are less expensive generic versions available.

stream from Vancocin to finance its research and development efforts. Thus, maintaining its dominant position over Vancocin sales and preventing less expensive generic competitors to Vancocin from entering the market was vital to ViroPharma's financial success.

4. Because Vancocin was no longer protected by patent,[2] ViroPharma's monopoly had been protected only by a barrier constructed by the FDA that made it cost prohibitive for generic versions of the drug to enter the market. Specifically, before 2006, the FDA required generic versions of Vancocin to be tested using human clinical trials as a condition of approval. Pharmaceutical companies wanting to compete with ViroPharma complained that human trials were far too expensive to conduct. As a result, drug manufacturers did not even bother applying for FDA approval of generic Vancocin.

5. Then in March of 2006, in response to industry pressure to allow generic competition to enter the market and thus bring down the price to consumers, the FDA changed its position and allowed generic versions of Vancocin to be approved on the basis of laboratory tests alone. The FDA's change understandably sent shockwaves throughout both ViroPharma and its investors. On March 16, 2006, when the market learned of the change, ViroPharma's stock experienced a multi-day sell-off that cut ViroPharma's market capitalization by 40% (approximately $500,000,000). The Company also publicly acknowledged that it could lose as much as 60 to 90% of the Vancocin market within months if generic versions of the drug were approved by the FDA.

6. The next day, on March 17, 2006, in a desperate effort to protect its monopoly, ViroPharma filed a formal complaint with the FDA in the form of a Citizen's Petition. ViroPharma's Citizen's Petition requested a stay of the FDA's action, challenged the legal

[2] The patent on Vancocin expired in 1996.

grounds for the change, and argued that the FDA should revert back to its prior position and not approve any applications for generic Vancocin without first requiring human clinical trials.

7. By filing the Citizen's Petition, ViroPharma essentially blocked FDA approval of any application for generic Vancocin until the Citizen's Petition was resolved. Knowing that, ViroPharma amended and supplemented its Citizen Petition ***over twenty times*** between 2006 and 2011. Thus, ViroPharma used its Citizen Petition and subsequent amendments to both attack the FDA's decision, and as a means to stall generic competitors from entering the market. Because of this type of abuse, Congress has since prohibited name-brand drug manufacturers from abusing the Citizen's Petition process in this manner, specifically as a means to block generic competition from entering the market.

8. In 2007, while ViroPharma's Citizen's Petition was pending, three pharmaceutical companies submitted applications to the FDA seeking approval of generic versions of Vancocin based on the new, relaxed FDA standard. ViroPharma knew it was just a matter of time until the FDA approved the applications.

9. In October 2008, ViroPharma saw a glimmer of hope to possibly extend the Vancocin monopoly upon which it so heavily depended. That hope came in the form of a new statute called the QI Program Supplemental Funding Act of 2008 (the "QI Act"), and particularly Section 4 of the QI Act entitled "Incentives for the Development of, and Access to, Certain Antibiotics." The QI Act allowed the FDA to grant an additional three years of marketing exclusivity for certain "Old Antibiotics" that were no longer protected by patent[3] if the company that owned the drug could demonstrate a new "condition of use" for the drug

[3] Vancocin was considered an "Old Antibiotic" subject to this requirement. *See* 21 C.F.R. §§ 355(c) and 355(v).

based on "substantial evidence from [adequate and well-controlled] investigations."[4] With its Citizen Petition still pending, ViroPharma went to work using the new QI Act as an additional weapon to ward off generic competitors to Vancocin.

10. As a first step, in June 2009, ViroPharma licensed a failed clinical trial (the "Genzyme Study" or the "Study") conducted by Genzyme Corporation designed to compare Genzyme's experimental drug tolevamer to Vancocin and metronidazole for the treatment of patients with CDAD. While the Genzyme Study failed for its primary purpose, ViroPharma sought to create opportunity for itself by licensing the data from the Study from Genzyme.

11. As a second step, ViroPharma attempted to use the data from the failed Genzyme Study to create a new label for Vancocin. ViroPharma then presented its proposed "new" label to the FDA for approval in a process called a "Supplemental New Drug Application," or "sNDA," which the FDA approved on December 14, 2011.

12. As a final step, ViroPharma again supplemented its Citizen's Petition on December 22, 2011 (the "Citizen's Petition Supplement") and asked the FDA for three additional years of marketing exclusivity under the QI Act based on the newly approved Vancocin label. The request was based on ViroPharma's assertion that the changes it made to Vancocin's label provided "meaningful" new safety and efficacy data, and thus met the QI Act's requirement of demonstrating a new "condition of use." However, what ViroPharma failed to mention was that the FDA already told the Company that the Genzyme Study was not an adequate and well-controlled trial ***as to Vancocin***, and that Vancocin was not being approved for a new indication or dosing regimen.

[4] 21 U.S.C. §§ 355(d) and (v)(3)(B).

13. Indeed, before ViroPharma applied for exclusivity under the QI Act, the FDA privately told the Company ***at least five times*** that its labeling changes did not meet the criteria the Company knew it had to satisfy to qualify for an additional three years of exclusivity.

14. Specifically, the FDA sent letters to the Company on February 18, 2011 and May 20, 2011, and held a teleconference with representatives of ViroPharma on May 24, 2011 during which the FDA informed the Company that because the Genzyme Study's primary purpose and design was to test tolevamer's effectiveness (and ***not*** Vancocin), the Study would not be considered the type of adequate and well-controlled trial required to support ViroPharma's claim that Vancocin was comparatively more effective than metronidazole.[5] Moreover, as the FDA advised, changing the purpose of the Study after the fact (in a *post hoc* analysis) to show Vancocin's effectiveness was improper because of the potential for statistical bias. Thus, ViroPharma was told repeatedly by the FDA that its attempt to use the Genzyme Study for something other than the Study's primary purpose was unacceptable, and the Study could not provide the substantial evidence needed to support efficacy for a new "condition of use."

15. Then, on December 8, 2011, the FDA conducted a "labeling teleconference," with representatives of ViroPharma during which the FDA told the Company that because the Genzyme Study was not designed to show Vancocin's efficacy, but rather was designed to show that tolevamer was safe and effective for treating CDAD, the FDA would not permit the Company to include data from the Genzyme Study on the new label comparing Vancocin to

[5] The objective of the Genzyme Study was, by design, to compare Genzyme's tolevamer against Vancocin and metronidazole, and not to compare Vancocin to a control group. Any use of a clinical study's data for a purpose other than for what the study was specifically designed renders it an uncontrolled study, and thus inadequate to show efficacy for a new condition of use under FDA regulations. *See*, 21 C.F.R. §§ 201.56(a)(3) and 314.126(e).

tolevamer, and would only allow a "descriptive" summary of the Vancocin results from the Study. The December 8, 2011 letter was the ***fourth time*** the FDA told ViroPharma that the Genzyme Study was not an adequate and "well-controlled" study as it related to Vancocin, and ViroPharma's attempt to use the Genzyme Study for something other than the Study's primary purpose was unacceptable.

16. Finally, on December 14, 2011, in a culmination of what the FDA had been telling the Company all along, the FDA approved Vancocin's label change, but expressly told ViroPharma that Vancocin ***was not being approved for a new indication***, ***or new dosing regimen***, and noted that ViroPharma's sNDA for the new label ***did even not request such approval***. Thus, after nearly a year of the FDA repeatedly telling Defendants that the Genzyme Study was inadequate to support a claim of efficacy for a new condition of use, the FDA directly told ViroPharma that the Vancocin sNDA was not being approved for a new condition of use such as a new indication or new dosing regimen.

17. Despite being told privately by the FDA ***at least five times*** that neither the Genzyme Study nor the new Vancocin label was the type of change that would support an application for marketing exclusivity under the QI Act, ViroPharma nevertheless proceeded to apply for exclusivity anyway, misrepresenting in the Citizen's Petition Supplement (which it made available to the market) that the new label contained numerous new conditions of use, and falsely representing (to the market and the FDA) that the new label was for a new indication and a new dosing regimen. Moreover, ViroPharma publicly announced that three years of marketing exclusivity for Vancocin was a *fait accompli*.

18. Throughout the Class Period, Defendants repeatedly assured investors that the newly approved label for Vancocin entitled the Company to three more years of marketing

exclusivity, when in fact they knew based on what the FDA told them on at least five occasions, that the changes to the label ***would not support*** such approval. For example, on December 14, 2011, ViroPharma issued a press release claiming that as a result of the changes it made to the Vancocin label, "ViroPharma believes [that] ***Vancocin meets the requirements for, and thus has, three years of [marketing] exclusivity***, and that ***generic vancomycin capsules will not be approved during this period***."[6]

19. The market price of ViroPharma common stock jumped significantly following the announcement increasing 17.9%, or $4.21 per share, to close at $27.80 per share on December 14, 2011, on heavy volume of approximately 4.8 million shares traded.

20. Defendants then went a step further and issued a sales forecast for Vancocin on January 5, 2012, based on continued marketing exclusivity, projecting revenues of $260M to $310M in net sales from Vancocin in 2012 alone. The forecast was in line with 2011 sales of $288.9 million, and further reinforced to the market that exclusivity for Vancocin would be maintained for years without competition from generic manufacturers. Securities analysts following the Company issued reports repeating Defendants' representations that ViroPharma had three more years of marketing exclusivity for Vancocin, and many of them upgraded their ratings and increased their price targets for ViroPharma stock.

21. Notwithstanding Defendants' continuous, persistent and bullish comments on maintaining exclusivity, and what that would mean for ViroPharma's revenues going forward, Defendants never disclosed that the FDA repeatedly advised them prior to the start of the Class Period that neither the Genzyme Study nor the new label provided the substantial evidence needed to support efficacy for a new "condition of use," and the new Vancocin label was not

[6] Emphasis throughout the Complaint is added in bold and italics unless otherwise indicated.

being approved for a new indication or new dosing regimen. Thus, Defendants knew prior to the start of the Class Period, or were reckless in not knowing, that Vancocin did not meet the criteria for extended exclusivity.

22. Defendants were ultimately forced to reveal that their previous public statements about market exclusivity were not true. On April 10, 2012, before the market opened, the Company issued a press release announcing the FDA's decision denying ViroPharma's application for an additional three years of marketing exclusivity because Vancocin's new label did not reflect a "significant new use or indication." The press release further disclosed that the FDA simultaneously approved applications for generic versions of Vancocin from three different manufacturers.

23. The market was shocked by the news. On April 10, 2012, the price of ViroPharma's common stock plummeted 22% or $6.17 per share to close at $22.44 per share. Securities analysts cut their price targets and downgraded their ratings of ViroPharma stock as a result of thereof.

24. Plaintiff and other Class members have suffered significant losses and damages as a result of Defendants' materially false and misleading statements and omissions, and the precipitous decline in the market value of ViroPharma's securities when the truth was ultimately revealed.

25. At the same time, certain of the Defendants greatly profited from their deception ***selling nearly $8 million in stock*** at artificially inflated prices during the short four-month Class Period.

II. JURISDICTION AND VENUE

26. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5.

27. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1337, and Section 27 of the Exchange Act, 15 U.S.C. § 78aa.

28. Venue is proper in this District pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa, and 28 U.S.C. § 1391(b), because ViroPharma's principal place of business is located in this District and the acts charged herein, including the dissemination of materially false and misleading information, occurred in this District.

29. In connection with the challenged conduct, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the United States mails, interstate telephone communications and the facilities of the national securities markets.

III. PARTIES

30. Lead Plaintiff, Carpenters' Local 27 Defined Benefit Fund, purchased ViroPharma securities at artificially inflated prices during the Class Period and was damaged thereby as set forth in the certification filed at Docket No. 20-3, incorporated by reference herein. Carpenters is an institutional investor that manages more than $433 million in assets on behalf of more than 9,000 beneficiaries.

31. Defendant ViroPharma is a corporation organized under the laws of the state of Delaware, maintaining its principal place of business in this District at 730 Stockton Drive, Exton, PA 19341. ViroPharma describes itself as a global biotechnology company dedicated to the development and commercialization of products that address serious diseases, with a focus

on products used by physician specialists or in hospital settings. ViroPharma's common stock trades on the NASDAQ market under the symbol "VPHM."

32. Defendant Vincent J. Milano has served as the President and Chief Executive Officer ("CEO"), and Chairman of the Board of Directors of ViroPharma since March 2008. Milano joined the Company in 1996 and was Vice President, Chief Financial Officer ("CFO"), and Treasurer from 1997 to 2006. In 2006, he assumed the role of Chief Operating Officer ("COO") in addition to maintaining his role as CFO. Prior to joining ViroPharma, Milano was a Senior Manager with KPMG LLP, independent certified public accountants.

33. Defendant Charles A. Rowland, Jr. has served as ViroPharma's Vice President and CFO since he joined the Company in October 2008. Prior to joining ViroPharma, Rowland served as Executive Vice President and CFO of Endo Pharmaceuticals from December 2006 to September 2008. Prior thereto, Rowland was Senior Vice President and CFO of Biovail Pharmaceuticals, Inc. from 2004 to 2006.

34. Defendant Thomas F. Doyle has served as ViroPharma's Vice President, Strategic Initiatives since January 2008. Doyle previously served as Vice President and General Counsel of ViroPharma from November 1997 to January 2008, as Secretary from February 1997 to January 2008, and as Executive Director and Counsel from November 1996 to February 1997.

35. Defendant J. Peter Wolf has served as ViroPharma's Vice President, General Counsel, and Secretary since January 2008. Wolf previously served as Associate General Counsel of ViroPharma beginning in 2004.

36. Defendants Milano, Rowland, Doyle and Wolf are collectively referred to herein as the "Individual Defendants."

IV. RELEVANT BACKGROUND AND FACTS

A. Overview of the Company

37. Founded in 1994, ViroPharma is a global biotechnology company that markets and sells Vancocin HCl capsules in the U.S. and its territories. Vancocin is the oral capsule formulation of vancomycin hydrochloride, and is indicated for the treatment of CDAD, a severe and deadly gastrointestinal infection. ViroPharma acquired Vancocin from Lilly Research Laboratories ("Lilly") in 2004. Lilly had owned the rights to Vancocin which the FDA first approved in 1986. The patent protection on Vancocin expired in 1996.

B. The Importance of Vancocin to ViroPharma

38. Vancocin has been tremendously important to ViroPharma's business. Prior to acquiring Vancocin in 2004, ViroPharma had limited sales revenue and posted annual operating losses. From 2005 through 2008, Vancocin sales accounted for nearly 100% of the Company's revenues. Vancocin was very profitable to ViroPharma during that time and accounted for hundreds of millions of dollars in sales. As reflected in the chart below, by 2008, Vancocin sales accounted for over $230 million a year in net sales for ViroPharma:

Year Ended December 31,	Vancocin Net Sales (thousands)	Total Net Sales (thousands)
2008	$232,284	$232,307
2007	$203,770	$203,770
2006	$166,617	$167,181
2005	$125,853	$132,417

39. ViroPharma admittedly relied on the revenue stream from Vancocin to finance its research and development efforts.[7] Vancocin's success allowed the Company to expand and acquire other drugs to add to its portfolio. For example, in October of 2008, ViroPharma

[7] *Hamburg I*, Case No. 1:10-cv-01529 (D.D.C. filed Sept. 10, 2010) Complaint ¶26.

acquired Lev Pharmaceuticals and its drug Cinryze for $453.1 million. Vancocin's profits also allowed ViroPharma to acquire two other drugs, Buccolam and Diamorphine, and increase the overall sales of its products to nearly $550 million in 2011. This growth and expansion would have been impossible without Vancocin. From 2009 through 2011, Vancocin continued to account for a substantial portion of the Company's business, and accounted for more than 50% of the Company's sales in 2011.

Year Ended December 31,	Vancocin Net Sales (thousands)	Total Net Sales (thousands)
2011	$288,893	$544,374
2010	$259,567	$439,012
2009	$213,138	$310,449

40. Vancocin was also extremely valuable to ViroPharma because, unlike its other drugs, Vancocin was self-sustaining. The Company needed to spend millions of dollars marketing its other drugs, but because of its dominant market position, the Company hardly needed to spend any money marketing Vancocin.

41. According to CW1,[8] ViroPharma did virtually no marketing for Vancocin because of its dominant market position. CW2[9] confirmed this stating that Vancocin was the Company's "cash cow" because it "didn't have to do anything" to sustain or promote Vancocin.

[8] CW1 was the former Manager of Sales Operations at ViroPharma. CW1 worked at the Company from December 2007 through February 2012. CW1 reported to Peter Galiano, Vice President of Sales until February 2012 and then briefly reported to Ron Dullinger when Dullinger assumed the role of Vice President of Sales. CW1 was responsible for performing analytics and providing the sales team with the tools necessary to do their jobs.

[9] CW2 was the Associate Director of Medical Affairs from June 2007 through November 2010 and later the Associate Director of Clinical Development from November 2010 through May 2011. As Associate Director of Medical Affairs, CW2 was responsible for educational work and training sales personnel. He reported to Steve Gelone, the Vice President of Clinical Development, who reported to Colin Broome. As Associate Director of Clinical Development, he handled the global clinical trials of Cinryze and worked on orphan drug applications. In this role he also reported to Steve Gelone.

CW3[10] also confirmed that the Company did very little marketing for the drug. According to CW3, Vancocin had "a life of its own" and was profitable without a lot of expense because of its exclusivity in the market. According to CW4[11], Vancocin had an ***enormous 97% profit margin***.

42. From 2004 through the end of the Class Period, ViroPharma enjoyed an extremely lucrative monopoly selling Vancocin. Although Vancocin's patent had long since expired, generic drugs had been kept from the market because (as explained below), the FDA approval process for generic competition to Vancocin was long, difficult and expensive requiring generic manufacturers to conduct costly clinical trials. Even after the FDA relaxed the standard for generic approval, ViroPharma was able to delay the entry of generic competitors by filing and continuously supplementing a Citizen's Petition challenge to the FDA's decision to make approval of generic competition easier for generic manufacturers. Thus, throughout the Class Period, Vancocin enjoyed exclusivity as the only drug approved by the FDA for treating CDAD. Indeed, Vancocin was referred to as "the gold standard" treatment in the industry.

43. Any loss of profits from Vancocin would have been a devastating blow to the Company, impacting its research and development efforts and slashing the Company's revenues. The Company has publically acknowledged that it expected to potentially lose as much as ***60 to 90%*** of the Vancocin market within months if generic competition were

[10] CW3 was former Senior Area Director for Eastern U.S. at ViroPharma from March 2009 through June 2012. CW3 was responsible for marketing ViroPharma's drug Cinryze. CW3 reported to Peter Galiano, Vice President of Sales.

[11] CW4 was a sales representative at ViroPharma. From February 2008 to January 2010 he was a hospital account manager and reported to Peter Galiano, Vice President of Sales. From January 2010 until he left the Company in August 2011 he was a Hereditary Angiodema specialist, marketing Cinryze, and reported to CW3.

approved by the FDA.[12] Therefore, ViroPharma had a strong motivation to keep generics from threatening the Company's Vancocin exclusivity.

C. Statutory and Regulatory Framework For Prescription Drug Approval

1. "Pioneer" or "Innovator" Drugs

44. Pharmaceutical companies seeking to market prescription drug products are regulated by the Federal Food, Drug and Cosmetic Act ("FDCA").[13] If a pharmaceutical company seeks to market a "pioneer" or "innovator" drug, it must first obtain FDA approval by filing a New Drug Application ("NDA") with the FDA.[14] The NDA must contain extensive clinical and scientific data and other information, including investigative reports demonstrating the drug's safety and effectiveness, a statement of the drug's components, and specimens of proposed labeling for the drug.[15] Approval of an NDA, or a supplement to an NDA under an sNDA, requires "substantial evidence [from adequate and well-controlled investigations] that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof."[16]

2. Generic Drug Alternatives

45. Pharmaceutical companies can seek to market generic competitors to drugs whose patents have expired by submitting an application to the FDA (an Abbreviated New Drug Application or "ANDA") under The Drug Price Competition and Patent Term Restoration Act of 1984 (commonly referred to as the "Hatch-Waxman Amendments" or "Hatch-

[12] Decl. of Charles Rowland at ¶ 27, *Hamburg II,* 1:12-cv-00584-ESH (D.D.C. Apr. 13, 2012).
[13] 21 U.S.C. § 301 *et seq.*
[14] 21 U.S.C. § 355(a), (b).
[15] 21 U.S.C. § 355(b)(1).
[16] 21 U.S.C. § 355(d)(5) *et seq.*

Waxman").[17] The Hatch-Waxman Amendments permit the submission of ANDAs for generic versions of previously approved drug products,[18] and were intended to balance encouraging innovation in drug development with accelerating the availability of lower cost generic alternatives to existing drugs.

3. Requirements for Generic Drug Approval

46. To obtain FDA approval of a generic drug, an ANDA references an approved pioneer drug, and relies on the FDA's previous finding that the approved drug is safe and effective. The ANDA applicant, however, must provide sufficient information to show that the proposed generic drug has the same active ingredients, dosage form, route of administration, and strength as the approved, pioneer drug, and that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have previously been approved for the pioneer drug.[19]

47. The ANDA applicant must also demonstrate that the generic product is "bioequivalent" to the previously approved pioneer drug and has (with certain permitted differences), the same labeling.[20] "[B]ioequivalence may be demonstrated by several *in vivo* [through human testing] and *in vitro* [laboratory testing] methods. *The FDA may require in vivo or in vitro testing, or both,* to . . . establish the bioequivalence of specific drug products."[21]

48. The FDCA does not prescribe a required method for establishing bioequivalence, and it gives the FDA broad discretion to determine the appropriate method for a given drug product. "The selection of the method used to meet an *in vivo* or *in vitro* testing

[17] 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271 and 282
[18] 21 U.S.C. § 355(j).
[19] 21 U.S.C. § 355(j)(2)(A)(i), (ii), (iii).
[20] *Id.,* 21 U.S.C. § 355(j)(2)(A)(iv), (v).
[21] 21 C.F.R. § 320.24(a).

requirement depends on the purpose of the study, the analytical methods available, and the nature of the drug product."[22] When the FDA requires *in vivo* testing, generic drug manufacturers must sponsor lengthy and costly laboratory studies and human tests. The great expense of these *in vivo* studies often makes them cost prohibitive.

D. *The Generics Are Coming;* ViroPharma's Multi-Year Battle to Ward Off Generic Competition for Vancocin

49. In 1996, the FDA issued its initial recommendation that a clinical human *in vivo* study was the only way for an ANDA sponsor to demonstrate the bioequivalence of a generic version of Vancocin. Companies hoping to market generic vancomycin were stymied by the cost of such a study. As a March 17, 2006 internal FDA email confirmed, the FDA was told by "the industry" that, with regard to generic vancomycin, such a trial "was nearly impossible to do and this was confirmed by the fact that there were no ANDAs submitted for this product."

1. The FDA Changes its Requirements for Vancocin Bioequivalence

50. For nine years after the FDA recommended that generic manufacturers conduct *in vivo* studies to demonstrate bioequivalence, not a single manufacturer submitted an ANDA to market generic vancomycin. In 2005, in response to industry pressure, the FDA embarked on a research project to determine whether a less onerous process for confirming Vancocin's bioequivalence could be developed. As a result, in 2006 the FDA declared Vancocin eligible for a waiver of *in vivo* testing. The FDA then developed criteria for determining bioequivalence of Vancocin that consisted of simple lab testing.

51. On March 16, 2006, a Canadian analyst at Infinium Capital Corp. published a report announcing that the FDA had adopted a more easily satisfied *in vitro* test for establishing bioequivalence for approval of generic versions of Vancocin. The report further noted that its

[22] 21 C.F.R. § 320.24(a).

"recent communications with the FDA regarding the approval process . . . [led it] to believe a generic [version of Vancocin] could enter the market 1-2 years sooner than current expectations." The release of the Infinium report triggered a multi-day stock sell-off that cut ViroPharma's market capitalization by 40% (approximately $500,000,000).[23]

52. The next day, on March 17, 2006, ViroPharma filed a Citizen's Petition with the FDA requesting a stay of any FDA action that would result in the approval of generic vancomycin without *in vivo* testing, and challenging the legality of the FDA's actions. ViroPharma supplemented and/or amended its Citizen's Petition ***twenty times*** from 2006 to 2011 allowing ViroPharma to maintain its monopoly.

53. A Citizen's Petition allows an interested person to petition the FDA to "issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action."[24] The FDA was required to consider and respond to every Citizen Petition, and an ANDA could not be approved until after the FDA responded to all pending Citizen Petitions. For that reason, the filing of a Citizen's Petition necessarily delayed the approval of any pending ANDA.

54. The Citizen Petition process was frequently abused by pharmaceutical companies attempting to prolong monopolies for brand named drugs. In 2007, citing the rampant abuse of the process, Congress passed FDCA § 505(q) which prevented the FDA from delaying the approval of any ANDA unless a delay was necessary to protect the public health. However, the statute did not apply retroactively to any Citizen Petition filed before the enactment of the statute. Accordingly, ViroPharma's 2006 Citizen Petition and its numerous

[23] *Hamburg I,* 1:12-cv-00584-ESH, at 24.
[24] 21 C.F.R. § 10.25.

supplements continued to block generics from entering the market until the FDA issued a formal response thereto.

55. Despite ViroPharma's pending Citizen's Petition, several pharmaceutical companies were ready and eager to enter the market with generic versions of Vancocin. In 2007, following the FDA's decision to no longer require *in vivo* clinical testing, and with the expectation that the FDA would eventually deny ViroPharma's requested relief, three pharmaceutical companies submitted ANDAs seeking FDA approval for generic vancomycin.

56. Meanwhile, as the Company admitted, the FDA's changed standard for showing bioequivalence materially and adversely affected ViroPharma's entire business. With the specter of generic competition looming over its head, ViroPharma was forced to reject a number of clinical development initiatives that were under consideration and to eliminate medical education efforts for Vancocin. In addition, the significant loss of market capitalization resulting from the FDA's decision to eliminate the *in vivo* requirement to show bioequivalence dramatically impacted ViroPharma's ability to fund the acquisition of additional products and product candidates.

2. A New Statute Opens the Door to the Possibility of Three Additional Years of Marketing Exclusivity for "Old Antibiotics" Like Vancocin

57. In October 2008, ViroPharma was seemingly granted a new lifeline for Vancocin. Specifically, Congress passed a law that allows pharmaceutical companies to request three additional years of marketing exclusivity for "Old Antibiotics" like Vancocin if certain conditions were met.

58. Prior to that time, the Food and Drug Administration Modernization Act of 1997 ("FDAMA") considered "Old Antibiotics" like Vancocin ineligible for Hatch-Waxman's exclusivity provisions. The FDAMA called those antibiotics "Old Antibiotics" because they

were approved before the effective date of the statute; November 21, 1997.[25] The FDA expressly cited Vancocin as an "Old Antibiotic."[26]

59. On October 8, 2008, everything changed for ViroPharma. On that date, the FDCA was amended through the QI Act,[27] which incorporated "Old Antibiotics" into the Hatch-Waxman regulatory scheme for the first time, and created a limited opportunity for a company with an Old Antibiotic to obtain Hatch-Waxman marketing exclusivity.[28]

60. However, the QI Act limited the circumstance in which an Old Antibiotic could obtain exclusivity. Congress stated that the additional three-year marketing exclusivity period was not available for "Old Antibiotics" unless the Old Antibiotic was administered for a new "condition of use." Specifically, the section of the statute entitled "Limitations" provides that the provisions entitling "Old Antibiotics" to three year exclusivity do not apply to ***"any condition of use for which the [Old Antibiotic] . . . was approved before [the date of the enactment of the QI Act]***."[29] Therefore, in order for an Old Antibiotic like Vancocin to be granted three additional years of marketing exclusivity, the condition of use must be a new one; one which had not previously been approved. In other words, the condition of use could not be the same as the use for which the drug was ***currently*** being prescribed.

61. As the legislative history of the QI Act reveals, the intent of the provision providing for additional marketing exclusivity was to encourage development of truly novel antibiotics and ***novel uses*** of "Old Antibiotics". Congress also explained that a "new condition

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[25] *See* Pub. L. No. 105-115, Title I, § 125(d)(2)(A).

[26] *Marketing Exclusivity and Patent Provisions for Certain Antibiotic Drugs; Proposed Rule*, 65 Fed. Reg. 3623, 3627 (Jan. 24, 2000).

[27] *QI Program Supplemental Funding Act of 2008*, Pub. L. No. 110-379, 122 Stat. 4075, § 4, entitled "Incentives for the Development of, and Access to, Certain Antibiotics."

[28] 21 U.S.C. § 355(v)(1)(A).

[29] 21 U.S.C. § 355(v)(3)(B).

of use" means a "new indication."[30] As Senator Edward Kennedy stated in the context of making additional marketing exclusivity available to "Old Antibiotics" under certain circumstances, "the [Old Antibiotic] amendment would make certain molecules that are part of old active ingredients eligible for recognition as new active ingredients, provided they will be used for ***a new indication.*** This provision includes limits that would prevent pharmaceutical manufacturers from abusing the process to extend the life of old active ingredient drugs."[31]

62. Other members of Congress echoed these thoughts making clear that the intent of the law was to incentivize novel or new uses of antibiotics. Senator Orrin B. Hatch, when originally proposing the bill in 2007, stated: "[t]he Hatch amendment is intended to be an initial step in the fight against the resistant strains of bacteria by increasing incentives and innovation."[32]

63. Representative Frank Pallone, who also supported the law, reiterated the purpose of the QI Act was to provide an incentive to encourage pharmaceutical companies to develop new innovative antibiotic therapies:

> [T]his legislation also contains a provision that would encourage and incentivize drug manufacturers to research and develop antibiotics. Presently, there's too little research being done to develop ***new and innovative antibiotics therapies***…This is an important provision that I believe will help reverse that trend and lead to ***new breakthroughs*** and help protect the public health.[33]

64. Defendants were well aware that marketing exclusivity for "Old Antibiotics", such as Vancocin, would be granted only in limited circumstances where the drug would treat a

[30] An "indication" for a drug refers to the use of the drug for treating a particular disease. For example, diabetes is an indication for insulin. Put the other way, insulin is indicated for the treatment of diabetes.

[31] 153 Cong. Rec. S 5759-58234 (May 9, 2007).

[32] 153 Cong. Rec. S 5624 (May 7, 2007).

[33] 154 Cong. Rec. H10170-02 (Sept. 27, 2008).

new "condition of use." Defendants' knowledge is demonstrated by their statements to the FDA in ViroPharma's December 22, 2011 Citizen's Petition Supplement described in ¶¶107-112 below and in Appendix A, in which Defendants claimed repeatedly that the new label for Vancocin contained numerous "new conditions of use" and that the label contained a "new indication." Defendants were also well aware of and understood the QI Act's legislative history, as they cited to it extensively in their Citizen's Petition Supplement.

3. ViroPharma's Hopes of Blocking Generics on the Bioequivalence Front Are Dealt A Significant Blow

65. In December 2008, after conducting further testing and considering information such as submissions by ViroPharma, the FDA issued draft guidance revising the bioequivalence requirements slightly for Vancocin. The draft guidance continued to recommend *in vitro* testing as the bioequivalence standard for an ANDA.

66. ViroPharma submitted comments objecting to the FDA's draft guidance in March 2009 and in two additional submissions, but those submissions proved futile. In August 2009, an FDA advisory committee voted unanimously in favor of endorsing the bioequivalence recommendations set forth in the draft guidance. Thus, ViroPharma knew that its efforts to keep generics off the market premised on the cost to generic manufacturers of showing bioequivalence had virtually no chance of success. Now, ViroPharma was faced with the almost surety of losing exclusivity of its prized drug unless it could somehow use the QI Act to its own ends.

4. ViroPharma Purchases Clinical Studies From Genzyme Corporation's Failed Drug tolevamer in a Desperate Attempt to Maintain Exclusivity

67. After the FDA's 2009 decision on bioequivalence, the QI Act represented ViroPharma's best and likely only chance of extending exclusivity for Vancocin. However,

under the Limitations provision of the Act, the Company still had to demonstrate that the proposed exclusivity was based on a new "condition of use." Defendants therefore came up with a plan to license a failed clinical study conducted by Genzyme, to use that study to support an sNDA for a new Vancocin label, and then use the new label as a platform to request an additional three years of marketing exclusivity for Vancocin under the QI Act.

68. In the failed Genzyme Study, Genzyme was testing its own unapproved drug, tolevamer, on patients diagnosed with CDAD. Genzyme conducted two clinical trials comparing tolevamer to Vancocin and metronidazole. The Genzyme Study was specifically designed to test the primary hypothesis of the effectiveness of tolevamer compared with that of Vancocin and metronidazole in treating CDAD (the same indication that Vancocin was currently approved for treating). Importantly (as explained below), a placebo was not used in the Genzyme Study. In the words of CW6[34] the Study was designed to test "non-inferiority," meaning whether tolevamer was "as good as or better than" Vancocin. But, it was not meant to test whether Vancocin was as effective, or more effective than a placebo (*i.e.*, better than receiving no drug at all). The Genzyme Study was a failure and Genzyme could not use the results of the study as a basis to support FDA approval of tolevamer.

69. In June 2009, ViroPharma entered into an Exclusive Clinical Study and Data License Agreement with Genzyme whereby ViroPharma acquired exclusive use of the Genzyme Study in return for payments of 10%, 10% and 16% of Vancocin's sales per year in each of the three years following any approval of an sNDA for Vancocin.

[34] CW6 was a Principal Scientist at Genzyme from 1997 through 2008. CW6 was responsible for the invention and development of tolevamer, the main drug in the failed Genzyme Study. CW6 reported to Randy Holmes-Farley, Distinguished Scientific Fellow and Vice President at Genzyme.

5. ViroPharma's sNDA

70. ViroPharma submitted an sNDA to the FDA for new Vancocin labeling on April 23, 2010, based on the *post hoc* analysis of the data obtained from the Genzyme Study, even though it knew, based on FDA policy statements, that the FDA would not accept such an analysis as evidence of effectiveness for any use. According to CW 1, defendant Milano was involved in the sNDA process. Additionally, CW4 stated that defendants Doyle, Milano, Wolf and Rowland all worked closely on the sNDA. CW5[35] confirmed Wolf and Doyle's involvement in the sNDA process, adding that that Colin Broome, ViroPharma's Vice President and Chief Scientific Officer, and Robert Pietrusko, Vice President Global Regulatory Affairs and Quality**,** were also involved. While the sNDA included some clinical data from the Genzyme Study, it did not include CMC (chemistry, manufacturing, and controls), pharmacology/toxicity, clinical pharmacology, clinical microbiology, or any studies on a pediatric population.

71. The FDA rejected the sNDA on February 18, 2011 for the reasons set forth in ¶¶74-76. ViroPharma had a meeting with the FDA on May 24, 2011 (described below), after which the Company amended and resubmitted the sNDA in June 2011.

6. The sNDA Approval

72. On December 14, 2011, the first day of the Class Period, the FDA advised ViroPharma that the sNDA for Vancocin's new label was approved (the "December 14, 2011

[35] CW5 was the Head of Medical Affairs at ViroPharma from June 2008 until February 2011. CW5 reported to Colin Broome – Vice President and Chief Scientific Officer. Broome reported directly to Milano. CW5's responsibilities included establishing and running a team of scientists both in the field and HQ based, to provide scientific education and guidance to all healthcare providers on *c. difficile*, among other diseases. CW5 also worked on Vancocin's sNDA.

Letter").[36] On that same date, ViroPharma issued a press release (the "December 14, 2011 Press Release") announcing the approval, and also announcing that "[a]s a result of today's sNDA approval, ViroPharma believes Vancocin meets the requirements for, and thus has, three years of [marketing] exclusivity, and that generic vancomycin capsules will not be approved during this period."

73. According to ViroPharma, the changes to ViroPharma's label included:

- Clinical safety and efficacy data of Vancocin capsules;
- An instruction to monitor renal function in all patients;
- An instruction that elderly patients should not be prematurely discontinued from treatment, or switched to other therapies; and
- A specific dosing regimen for CDAD.

E. The FDA Privately Advised ViroPharma That While It Approved the New Label, It Did Not Meet The Criteria For Three More Years of Exclusivity

74. Despite their Class Period statements to the contrary Defendants had been told by the FDA ***at least five times*** prior to the start of the Class Period, that their sNDA did not meet the criteria that would support an application for an additional three years of marketing exclusivity for Vancocin under the QI Act.

1. The February 18, 2011 Letter

75. On February 18, 2011, Katherine Laessig, MD, Deputy Director of the Division of Anti-Infective and Ophthalmology Products, Office of Antimicrobial Products at the Center for Drug Evaluation and Research sent a letter to Colleen Matkowski, MS, Associate Director, U.S. Regulatory Affairs, at ViroPharma. The letter, entitled "Complete Response," informed ViroPharma that the FDA was not approving ViroPharma's sNDA in its present form, and pointed to the following defects in ViroPharma's submission. First, it noted that ViroPharma's

[36] The December 14, 2011 Letter was a two-page letter addressed to Colleen Matkowski, MS, ViroPharma's Associate Director of U.S. Regulatory Affairs. It was not publicly available until after the Class Period.

pooling of the results of the two trials involved in the Genzyme Study was "problematic because the trials were conducted in different patient populations with different profiles of CDAD severity." Next, it noted that the pooled trials were inadequate to support any claim of comparative effectiveness, because comparative effectiveness claims must be supported by multiple trials, and "at best," the pooled trials represented only a single trial.[37]

76. Most significantly, however, the letter informed ViroPharma that the Genzyme Study could not be used to compare Vancocin to metronidazole because "the comparisons of vancomycin with metronidazole were secondary analyses…" In other words, ViroPharma could not use the Genzyme Study to draw any conclusions from a comparison between Vancocin and metronidazole because that was not a primary purpose of the Study.

77. In addition, the FDA advised ViroPharma that it could not impose a *post-hoc* interpretation of the Genzyme Study to suit its own ends calling this "the multiplicity of comparisons." This was highly significant because any new efficacy claim must be supported by an adequate and well-controlled trial conducted in conformance with 21 C.F.R. § 314.126, which requires a study with "a clear statement of the objectives of the investigation" designed to permit a valid comparison with a control, such as a placebo, to provide a quantitative assessment of a drug's effect.[38] Uncontrolled studies or partially controlled studies are not acceptable as the sole basis for approval for claims of effectiveness.[39] The FDA's message was clear. Because the primary purpose of the Genzyme Study was to test tolevamer and ***not*** to test

[37] "Per 21 C.F.R. § 201.56(a)(3), comparative effectiveness claims must be supported by substantial evidence from adequate and well-controlled trials. At best, the pooled studies only represent a single trial." FDA letter to ViroPharma dated February 18, 2011.

[38] Approval of an NDA or an efficacy supplement to an NDA (sNDA) requires "substantial evidence [from adequate and well-controlled investigations] that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof." 21 U.S.C. § 355(d)(5) *et seq.*

[39] 21 C.F.R. § 314.126(e).

Vancocin against a control group, ViroPharma could not use the Genzyme Study to support a comparative effectiveness claim for Vancocin, the Genzyme Study was not "adequate and well controlled" as to Vancocin, and the Genzyme Study data could not be used to demonstrate Vancocin's efficacy for a new condition of use. Indeed, the FDA stated that "the results [from the Genzyme Study] are not interpretable" due to these significant issues.

2. The May 20, 2011 Letter

78. On May 20, 2011, J. Christopher Davi, MS, Senior Regulatory Project Manager at the Division of Anti-Infective Products ("DAIP"), sent another letter to Colleen Matkowski at ViroPharma in anticipation of a May 24, 2011 teleconference between representatives of ViroPharma on one hand, and the FDA on the other. The FDA's letter was in response to certain questions posed in a "briefing document" ViroPharma submitted to the FDA on April 27, 2011. The DAIP letter repeated and amplified the message in the FDA's February 18, 2011 "Complete Response" letter specifically noting the following about the Genzyme Study:

> *In retrospect, the two studies are independent and were never prospectively designed to be combined into one study. Comparative effectiveness claims must be supported by substantial evidence from adequate and well-controlled trials (21 C.F.R. 201.56(a)(3)). The comparisons of vancomycin with metronidazole were secondary analyses. However,* ***these studies failed for its primary hypothesis and any subsequent testing could seriously inflate the type-I error.*** *Any clinical trial may be subject to unanticipated, undetected, systemic biases and these biases are amplified in a post hoc analysis of the data.*
>
> *In general,* ***demonstrating superiority requires more than one adequate and well-controlled investigation which reflects the need for independent substantiation of experimental results, if the hypothesis is pre-specified****.*

(Italics in original).

79. Thus, the FDA told ViroPharma again on May 20, 2011, that because the purpose of the Genzyme Study was ***not*** to test Vancocin against a control, ViroPharma's

attempt to use the Genzyme Study to demonstrate Vancocin's superiority to another drug ***after*** the Genzyme Study's completion was unacceptable and represented a *post hoc* change in the Study's hypothesis, which introduces the potential for statistical bias. Moreover, if ViroPharma's intent was to demonstrate Vancocin's superiority, such a claim needed to be supported by more than one adequate and well-controlled trial where the objective of the study was pre-specified. In other words, because the Genzyme Study was not initially designed to test Vancocin's efficacy, the Genzyme Study could not support a claim of Vancocin's superiority to another drug, let alone that Vancocin could be used for a new indication or new use. Because of these significant failings, the Genzyme Study was not an "adequate and well-controlled" trial for Vancocin, which would be required to demonstrate efficacy for a new condition of use.

3. The May 24, 2011 Teleconference

80. On May 24, 2011, representatives of the FDA held a teleconference with representatives of ViroPharma to discuss the sNDA, ViroPharma's April 27, 2011 submission, and the FDA's May 20, 2011 letter responding thereto. ViroPharma's representatives on the teleconference were: 1) Defendant Doyle, 2) Colin Broom, MD, VP and Chief Scientific Officer, 3) Steven Gelone, PharmD, VP Clinical Development, 4) David Fitts, PhD, MPH, Senior Director, Biometrics, 5) Robert Pietrusko, PharmD, VP, Global Regulatory Affairs and Quality, 6) Roy Baranello, MS, Senior Director, Regulatory Affairs, 7) Colleen Matkowski, and 8) Kenneth Wilmarth, PhD, MSPH, Regulatory Consultant. The FDA's May 20, 2011 response was discussed in more detail at the meeting among the attendees.[40] The FDA minutes from

[40] While the meeting minutes from the May 24, 2011 meeting, as produced by the FDA pursuant to a FOIA request were redacted in large measure, it is reasonable to infer that ViroPharma was advised of,

(continued . . .)

the May 24, 2011 meeting specifically noted that the purpose of the sNDA was for "***updating safety information*** in the label and converting the label to the Physician's Labeling Rule Format." Based on the application the Company submitted, ViroPharma was applying to update its label, and ***not*** applying for a new indication or new condition of use. These meeting minutes were sent to the Company on July 13, 2011 in a letter addressed to Colleen Matkowski.

4. The December 8, 2011 Labeling Teleconference

81. On December 8, 2011, six days before the Class Period begins, the FDA held a "labeling teleconference" with ViroPharma to discuss the sNDA. During that teleconference, the FDA told ViroPharma ***again*** that because the Genzyme Study was not designed to test the safety and efficacy of Vancocin, the Company ***could not include*** any comparative efficacy information based on the Genzyme Study on the new Vancocin label.[41] Again, this was highly significant because any claim of efficacy for a new condition of use must be supported by an adequate and well-controlled trial conducted in conformance with 21 C.F.R. § 314.126, which requires a study designed to permit a valid comparison with a control, such as a placebo, to provide a quantitative assessment of a drug's effect.[42] Uncontrolled studies or partially controlled studies are not acceptable as the sole basis for approval for claims of effectiveness.[43]

(. . . continued)
and thus, aware of the FDA's position on the shortcomings of the Genzyme Study as it applied to Vancocin, especially because the purpose of the meeting was to discuss the May 20, 2011 letter.

[41] The substance of the labeling teleconference was discussed and revealed in an internal memo to the FDA's Vancocin file dated April 9, 2012 authored by the FDA's Center for Drug Evaluation and Research (the "CDER Memo"), opining on Vancocin's application for exclusivity.

[42] Approval of a NDA or an efficacy supplement to an NDA (sNDA) requires "substantial evidence [from adequate and well-controlled investigations] that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof." 21 U.S.C. § 355(d)(5) *et seq.*

[43] 21 C.F.R. § 314.126(e).

82. As the FDA stated yet again, the Genzyme Study was designed to test Genzyme's drug tolevamer for the treatment of CDAD, not to test Vancocin. Moreover, any comparison of Vancocin with another drug (this time tolevamer) was a secondary analysis. Thus, Defendants were made well-aware that such a secondary analysis made the Study as it related to Vancocin an "uncontrolled study" and inadequate to support efficacy for a new condition of use.[44]

83. Because of the Genzyme Study's shortcomings as it related to Vancocin, the FDA advised ViroPharma on the December 8, 2011 teleconference that "only descriptive" information from the Genzyme Study about the Vancocin results was permitted to be included on the new label, and the label could not compare Vancocin to tolevamer as a "putative placebo." Specifically, the FDA concluded:

> Although ViroPharma asserts that the Genzyme studies demonstrate the drug's comparative efficacy against a "putative placebo," ***the new labeling is only descriptive in nature*** with no mention of the "putative placebo." It should be noted that the Genzyme studies were originally designed to test the primary hypothesis of efficacy for tolevamer in comparison to vancomycin and metronidazole, with the comparison of vancomycin and metronidazole serving only as a secondary analysis. Thus, any comparison of vancomycin with tolevamer (the "putative placebo") would have been considered a secondary analysis…
>
> In light of these limitations, and in keeping with the conclusions drawn from the review of the submission for the first cycle, the Division determined that only descriptive [redacted] efficacy analyses were appropriate to be included in the labeling. ***The Division notified ViroPharma of this conclusion at a final labeling teleconference with the company on December 8, 2011.***[45]

[44] *See*, 21 C.F.R. § 314.126(e) and the QI Act, 21 U.S.C. § 355(d)(5).

[45] CDER Memo at page 10 (regarding its analysis and recommendations regarding ViroPharma's request for Vancocin exclusivity and describing the FDA's December 8, 2011 teleconference with ViroPharma).

84. The FDA's December 8, 2011 letter again sent the clear message that ViroPharma's attempt to use the Genzyme Study for something other than the Study's primary purpose was unacceptable. Based on what ViroPharma was told by the FDA, it submitted a revised proposal of the Clinical Studies section of the label to the FDA that contained only a descriptive "summary" of Vancocin's results from the Genzyme Study without any comparator data.

85. The absence of any comparative data in the Clinical Studies section of the new label prevents any conclusions from being drawn regarding Vancocin's effectiveness.[46]

86. A memo from the FDA's Office of Chief Counsel (OCC) and Office of Regulatory Policy (ORP) sent to the FDA's Office of Antimicrobial Products and Division of Anti-Infectious Products on December 12, 2011 (the "December 12, 2011 ORP Memo"), further documented the FDA's position that the information ViroPharma proposed in its new Vancocin label could only include merely descriptive and not meaningful comparative data. The December 12, 2011 ORP Memo states: "[t]he new information provided by this study, for the purpose of this label, ***are limited to the contents of its results***…" If the label could not speak to Vancocin's effectiveness, it could not support efficacy for a new condition of use. Defendants thus knew or were reckless in not knowing that the new Vancocin label did not meet the criteria for three more years of exclusivity under the QI Act.

5. The sNDA Approval Letter

87. On December 14, 2011, the FDA notified ViroPharma in the December 14, 2011 Letter that its sNDA was approved. The December 14, 2011 Letter clearly stated that while ViroPharma was receiving approval for "updates to the prescribing information for

[46] *See generally* 21 C.F.R. § 314.126.

VANCOCIN. . .” as well the conversion of the current label into Physicians Labeling Rule (PLR) format, it was ***not being approved for***: 1) a new active ingredient; 2) a new indication; 3) a new dosage form; 4) a new dosage regimen, or 5) a new route of administration.

88. Specifically, under the heading “REQUIRED PEDIATRIC ASESSMENTS,” the December 14, 2011 Letter stated:

> Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), ***all applications*** for new active ingredients, ***new indications***, new dosage forms, ***new dosage regimens***, or new routes of administration ***are required to contain*** an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.
>
> ***Because none of these criteria apply to your application***, you are exempt from this requirement.

89. By indicating that none of the criteria applied to the Company’s sNDA, the FDA was clearly stating that ViroPharma’s new label did not support a new active ingredient, a new indication, a new dosing regime, or a new route of administration. Indeed, the Company was well aware that it needed to conduct pediatric studies as a condition of any such approval. CW2 and CW5 both confirmed that ViroPharma contemplated conducting pediatric studies from 2007 through 2010, but the Company could not afford to conduct these trials. CW5 recalled attending a meeting held in late 2010 with Broome, Wolf, Doyle, Gelone, and Pietrusko, among others, where they discussed trying to find available data on Vancocin use on pediatric patients, but they were ultimately unable to find any relevant pediatric information. CW2 stated that the goal of conducting the pediatric studies was to get a new indication and an additional three years of exclusivity.

90. The December 14, 2011 Letter’s clear statement that the sNDA was not being approved for: 1) new active ingredients; 2) a new indication; 3) a new dosage form; 4) a new

dosage regimen, or 5) a new route of administration, further demonstrates that Defendants knew or were reckless in not knowing that the new Vancocin label did not meet the criteria for three more years of exclusivity under the QI Act.

F. Despite the FDA's Pronouncements, ViroPharma Amended its Citizen's Petition on December 22, 2011 Requesting Three More Years of Marketing Exclusivity Based on the New Label

91. Notwithstanding what ViroPharma was clearly and directly told by the FDA in 1) the February 18, 2011 Complete Response letter, 2) the May 20, 2011 letter in anticipation of the May 24, 2011 teleconference, 3) the May 24, 2011 teleconference, 4) the December 8, 2011 teleconference and 5) the December 14, 2011 Letter, ViroPharma's December 22, 2011 Citizen's Petition Supplement (described more fully herein at ¶¶107-112, and Appendix A) boldly and misleadingly asserted multiple times that Vancocin's new label contained both new indications and a new dosing regimen, described numerous alleged new "conditions of use," and proffered those changes as a basis for three additional years of marketing exclusivity under the QI Act.

G. The FDA Officially Denies ViroPharma's Exclusivity Application and Approves Three Applications for Generic Versions of Vancocin

92. On April 9, 2012, the FDA formally denied ViroPharma's Citizen's Petition. In a letter addressed to defendant Doyle and the Company, the FDA rejected ViroPharma's bid for exclusivity and confirmed what Defendants had known all along but withheld from investors; that ViroPharma's application did not support three more years of marketing exclusivity because, as Defendants were repeatedly told by the FDA, the Study on which the sNDA was based was not adequate to demonstrate efficacy for a new condition of use, and the sNDA was not approved for a new indication or dosing regimen. Therefore, the new Vancocin label did not qualify for an additional three years of exclusivity under the QI Act.

93. In the FDA's April 9, 2012 response to ViroPharma's Citizen's Petition, the FDA specifically told Defendants the following:

> Notably, ViroPharma's position that [the Genzyme] studies were essential to the approval of a new indication and new dosing regimen ***are inconsistent with the contents of the sNDA that contained those studies***, and the ***letter detailing the approval of the sNDA.*** As indicated in the approval letter, the Agency determined that the supplement supported "updates to the prescribing information" and "conversion of the current label into the [PLR] format." In addition, ***had you intended to seek approval for a new indication or a new dosing regimen (or a new active ingredient, new dosage form, or new route of administration), you would have been required by statute to have conducted an assessment of the safety and effectiveness of the product for the claimed indication in the pediatric patients under the Pediatric Research Equity Act (PREA). You did not submit any such assessments in your sNDA or otherwise reference PREA's requirements by seeking a deferral or waiver of this requirement.*** Moreover, your approval letter to which you did not object, confirmed that PREA was not triggered by your sNDA. ***This confirms that you, like the Agency, did not believe your labeling changes constituted a new indication, new dosing regimen, or other PREA-triggered change.***

94. In addition, on that day, the FDA approved three applications for generic versions of Vancocin. Once the market learned the truth, ViroPharma shares declined over 21**%**, or $6.17 per share on April 10, 2012, to close at $22.44 per share on extraordinarily high volume. As analysts assimilated and conveyed this information and its impact for ViroPharma going forward, ViroPharma's stock price continued to decline on April 11, 2012 to $21.86 on heavy volume.

V. MATERIALLY FALSE AND MISLEADING STATEMENTS MADE DURING THE CLASS PERIOD

A. December 14, 2011 Press Release and Form 8-K

95. The Class Period begins on December 14, 2011. On that date, ViroPharma issued a press release and filed it with the SEC on Form 8-K, signed by defendant Wolf,

announcing that the FDA approved its sNDA for proposed changes to the label for Vancocin. The press release made the following statements regarding the impact of the sNDA approval and the Company's ability to obtain an additional three years of marketing exclusivity for Vancocin:

> Vancocin Labeling Changes
>
> Through the sNDA approval, ***Vancocin's label for the first time includes clinical safety and efficacy data for Vancocin in treating*** currently circulating strains of Clostridium difficile, including ***the BI/NAP1 strain***. Vancocin's labeling now includes important safety and efficacy data from 260 patients with C. difficile associated diarrhea (CDAD) treated with Vancocin in two pivotal studies of Genzyme Corporation's investigational drug, tolevamer. The Vancocin arm of the trials provides important information to help ensure appropriate use of Vancocin. ViroPharma purchased exclusive rights to the two studies from Genzyme for which it will pay Genzyme royalties of 10**%**, 10**%** and 16**%** on net sales of Vancocin for the three year period following the approval of the sNDA.
>
> "This new label provides physicians a better understanding about how to treat and monitor patients suffering from the serious and often life threatening infections that require oral Vancocin therapy," said Vincent Milano, ViroPharma's president and chief executive officer.
>
> Exclusivity Incentives for Antibiotic Treatments
>
> As a result of today's sNDA approval, ***ViroPharma believes Vancocin meets the requirements for, and thus has, three years of exclusivity, and that generic vancomycin capsules will not be approved during this period. Under FDA's regulations, labeling changes based on new clinical investigations that are essential to approval of the sNDA and to which the applicant has exclusive rights may be entitled to three years of exclusivity, and generic drug labeling cannot include information protected by such three-year exclusivity.*** A generic may seek approval by omitting labeling protected by three-year exclusivity; however, if such omissions render the generic drug less safe or effective, it cannot be approved until the three-year exclusivity expires.
>
> In keeping with FDA efforts to facilitate antibiotic approvals as well as preserve the safety and efficacy of current treatments,

> *today's sNDA approval* following ViroPharma's investment in the Genzyme data ***accomplishes an objective of the law to incent private industry to address a serious public health need—modernizing old antibiotic labeling.*** The modernized label approved by the FDA contains important new information for prescribers and patients, including:
>
> - Clinical safety and efficacy data of Vancocin capsules, ***including efficacy data for the more lethal, epidemic BI/NAP1 strain;***
> - An instruction to monitor renal function in all patients;
> - An instruction that elderly patients should not be prematurely discontinued from treatment, or switched to other therapies; and
> - ***A specific dosing regimen for CDAD***.
>
> ViroPharma believes that attempting to omit Vancocin labeling changes protected by exclusivity would render generic versions of Vancocin less safe and effective.

96. The above-statements were false and misleading when made. Specifically, it was misleading to state that "[a]s a result of today's sNDA approval, ViroPharma believes Vancocin meets the requirements for, and thus has, three years of exclusivity" while omitting the following material information:

(a) While ViroPharma's sNDA sought to update the Vancocin label, ViroPharma ***did not*** seek approval of a new indication, new dosing regimen, or other such change which would be necessary to qualify Vancocin for an additional three years of exclusivity;

(b) the FDA specifically told ViroPharma in the February 18, 2011 and May 20, 2011 letters, and at the May 24, 2011 teleconference that the *post-hoc* analysis of the Genzyme Study did not constitute an adequate and well-controlled study with respect to Vancocin's efficacy, and was therefore inadequate to demonstrate efficacy of Vancocin for a new condition of use;

(c) the FDA told Defendants during the December 8, 2011 labeling teleconference that because the Genzyme Study was not an adequate and well-controlled study designed to test Vancocin against a control group, the new Vancocin label could only contain "descriptive" information describing only Vancocin's performance in the Genzyme Study without including any comparator data. This merely "descriptive" information could not support a claim of efficacy for a new condition of use necessary to support exclusivity under the QI Act;

(d) the FDA specifically told ViroPharma in the December 14, 2011 Letter, that it was not approving the new Vancocin label for a new ingredient, ***new indication***, new dosage form, ***new dosage regimen***, or new route of administration. If ViroPharma had intended on requesting a new indication or dosing regimen, ViroPharma would have to complete and submit an assessment of the safety and effectiveness of the product in pediatric patients under PREA. ViroPharma did not do so, despite knowing about the PREA requirement; and

(e) Defendants thus knew or were reckless in not knowing that the new label did not meet the criteria for three more years of exclusivity under the QI Act, and Defendants had a duty to disclose this information in order to make their statements to the market not misleading.

97. The statement "today's sNDA approval. . . accomplishes an objective of the law to incent private industry to address a serious public health need—modernizing old antibiotic labeling" was also misleading, as the objective of the law was to develop new uses for "Old Antibiotics" as described in the legislative history of the FDCA and set forth in ¶¶61-63 herein.

98. The statement "[t]hrough the sNDA approval, Vancocin's label for the first time includes clinical safety and efficacy data for Vancocin in treating currently circulating strains of Clostridium difficile, including the BI/NAP1 strain" was false and misleading because a new

efficacy claim regarding the BI/NAP1 strain would need to be supported by an adequate and well-controlled clinical trial designed to test that claim. Defendants knew, from the repeated statements from the FDA, that the Genzyme Study was not considered by the FDA to be such an adequate and well-controlled trial designed to show Vancocin's efficacy for a new condition of use, making Defendants' statements regarding new information regarding efficacy for the BI/NAPI strain false.

99. Finally, it was misleading to describe the Vancocin labeling changes as being "protected by exclusivity," and to state that "[u]nder FDA's regulations, labeling changes based on new clinical investigations that are essential to approval of the sNDA and to which the applicant has exclusive rights may be entitled to three years of exclusivity, and generic drug labeling cannot include information protected by such three-year exclusivity" without 1) stating that, as applied to "Old Antibiotics", the change had to reflect a new condition of use to qualify for exclusivity, 2) omitting to state the information set forth in ¶96 above, and 3) failing to state as the FDA told ViroPharma in its Citizen's Petition response, that the Genzyme data was not essential to the sNDA approval.

100. ViroPharma's stock price reacted extremely positively to this news. Trading on unusually high volume, the Company's stock price jumped 17.85% on the day of the announcement to close at $27.80 on December 14, 2011, up from a closing price of $23.59 on December 13, 2011.

101. The market accepted Defendants' statements and believed that the additional three years of marketing exclusivity for Vancocin was a *fait accompli* as reflected in reports by stock market analysts who followed ViroPharma. For example, a December 14, 2011 J.P.

Morgan analyst report adopted ViroPharma's representations regarding extended exclusivity for Vancocin:

> **Vancocin Label Update Would Add 3 Years' Exclusivity – ALERT**
>
> This afternoon, Viropharma announced an update to the Vancocin label. Specifically, the updated label now includes data for treating currently circulating strains of *Clostridium difficile (BI/NAP1)* that will help physicians better understand how to treat patients with this potentially fatal infection. More important, Viropharma believes the sNDA meets the criteria for three years of exclusivity, blocking a potential generic entrant. Recall, a generic Vancocin has been anticipated for some time, and delaying a generic for three years would conservatively add $4-5/share based on an NPV analysis. However, the decision on exclusivity will ultimately lie with the FDA (confirmation expected within the next few months). In our view, the argument for exclusivity is compelling, considering a generic that excludes these labeling changes would likely be considered less safe. Overall, we view this as a positive development that raises the bar for a potential generic Vancocin and likely provides 3 years of exclusivity. Therefore, we reiterate our Overweight rating.
>
> • . . . **would add exclusivity to franchise.** Importantly, this would add 3 years of exclusivity for Vancocin. Our model currently assumes a generic Vancocin enters the market in 2012, and we forecast 2012-2014 revenues of $60M, $30M and $15M, respectively. Therefore, our estimates could prove conservative. Assuming flat Vancocin sales of ~$300M for the next 3 years would conservatively add ~$4-5/share in valuation.
>
> • **Reiterate Overweight rating**. We believe today's news is an upside surprise, given the Street was expecting a generic Vancocin in the relative near term.

102. According to a December 15, 2011 Caris & Company report, ViroPharma's announcement meant that Vancocin exclusivity was all but assured. The report entitled "3 Years Worth of Vanco A Nice Stocking Stuffer; Worth $4+ in DCF", states:

> VPHM late yesterday announced a surprise sNDA label update for Vancocin which triggers 3 years of exclusivity, pushing our generic assumption from Q1:12 to Q1:15, unless overturned by generic efforts in the coming months/years. We calculate the

> additional Vanco revenue at $200MM+/year in 2012-15, which raises EPS by $1.00- 1.30/year. Our price target stands $5 higher at $29 including the $300MM+ in vanco cash flow....

103. A December 15, 2011 JMP Securities analyst report entitled "ViroPharma Incorporated: Nine Lives…Vancocin Lives On; Raising PT to $35" likewise confirmed the market's understanding that ViroPharma had effectively extended exclusivity for Vancocin until mid-December 2014:

> • **Nine lives …Vancocin lives on; reiterate Market Outperform rating on ViroPharma and increase price target to $35 from $23**. Yesterday, the FDA expanded the label for Vancocin to include clinical data for the hypervirulent strain of *c. difficile,* NAP1, amassed during the clinical development of a failed therapy for CDI, tolevamer, effectively extending the market exclusivity for this compound until mid-December 2014. We are therefore increasing our revenue estimate for Vancocin in 2012 to $306M from $113M and assuming generic entry in early 2015 we estimate 2015 revenue at $85M, significantly higher than our previous estimate of $7M. Given this, we are increasing our 2015 EPS estimate to $1.66 from $0.98 and our price target to $35 from $23.
>
> • **Vancocin's nine lives**. The clinical data that forms the basis of the sNDA regarding efficacy in *c. difficile* infection (CDI) is based on the clinical trial data regarding utility in the hypervirulent NAP1 strain, obtained from the development of Genzyme's tolevamer (which did not meet the endpoint of non-inferiority to Vancocin in a Phase 3 study). ViroPharma purchased these data from Genzyme, and as a result, owes Genzyme royalties for the net sales of Vancocin for the next three years of 10%, 10% and 16% respectively. The sNDA may allow for three years of exclusivity under FDA incentives for antibiotic treatments and therefore we believe a generic competitor will not enter the market until 2015 at the earliest.

104. Other analyst reports, including Piper Jaffray reports published on December 14 and 15, 2011, and reports by Oppenheimer, AURIGA, and Maxim Group on December 15, 2011 also trumpeted Defendants' representations of the implications of ViroPharma's announcement.

105. On December 22, 2011, another analyst, Brean Murray Carret & Company initiated coverage on ViroPharma with a "buy" rating and a price target of $37 per share. The report stated, "***We believe the extension of the Vancocin monopoly until at least 2014 will provide ViroPharma with considerable cash flow over the next few years***. The report went on to add:

> **Vancocin, the 'Gift that Keeps Giving.'** Vancocin has long been the source of ViroPharma's revenue, generating more that $250 million per year. Without patent protection, ViroPharma has had to rely on legal and administrative-delaying measures to keep generics out of the market. ***We believe the recent sNDA approval provides ViroPharma with at least three more years of exclusivity and annual revenue of over 280 million, translating to over $7 per share in value.***
>
> …
>
> Based on clinical data collected by Genzyme, ViroPharma added safety and efficacy data to the label which included, efficacy against the virulent B1/NAP1 strain, instruction to monitor renal function of patients, a specific dosing regimen for CDAD, and instructions to not discontinue elderly patients. ***ViroPharma has the exclusive right to modified content for 3 years and no other oral vancomycin producer can place these statements on its label.*** The companies awaiting ANDA approval for generic vancomycin can try omitting the statements from their label, but if this omission makes the product less safe or less efficacious the FDA must reject the application. ***ViroPharma believes the modifications it made to its label are vital to safe and efficacious use of Vancocin and will protect the product from generic competition through year-end 2014.***

106. None of the analysts (like the market), were privy to the correspondence or the oral communications from the FDA from February 2011 through December 2011 during which Defendants were specifically told that the sNDA was not approving a new ingredient, new indication, new dosage form, new dosage regimen, or new route of administration, and that Vancocin's approved label change was based on a inadequate trial, was merely descriptive, and did not support a new condition of use.

B. January 4, 2012 8-K

107. On January 4, 2012, ViroPharma filed a report on Form 8-K with the SEC signed by defendant Wolf. The Form 8-K attached ViroPharma's December 22, 2011 Citizen's Petition Supplement submitted to the FDA and requesting exclusivity for Vancocin. The Citizen's Petition Supplement was signed by defendant Doyle and requested that the FDA not approve any generic applications for Vancocin for a three year period based on the recently approved sNDA.

108. The Citizen's Petition Supplement was deceptively drafted, highlighting portions of the FDCA while ignoring key elements of the QI Act which applied when exclusivity is sought for "Old Antibiotics" such as Vancocin. The Citizen's Petition Supplement focused on and referenced the parts of the FDCA that provide for a three year period of exclusivity for an sNDA approved after September 24, 1984, and attempted to demonstrate that the new Vancocin label satisfied the statute because it "contain[s] reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement. . ." However, it did not cite or reference the QI Act's clearly applicable limitations on exclusivity for "Old Antibiotics", *i.e.,* that the provisions entitling "Old Antibiotics" to three-year exclusivity do not apply to "any condition of use for which the [Old Antibiotic] . . . was approved before the date of enactment [of the QI Act]," nor did it attempt to demonstrate how the limitation did not apply to Vancocin. Instead, the Citizen's Petition Supplement simply referred to each of the label changes as "new conditions of use" without referencing the statute or how it applied.

109. The most egregiously false and misleading points, however, were the Citizen's Petition Supplement's repeated statements describing the label changes as a ***"new indication and dosing regimen,"*** despite the fact that ViroPharma was specifically told by the FDA in the

December 14, 2011 Letter that the sNDA ***was not*** being approved for ***a new indication,*** or a ***new dosage regimen.***

110. The Citizen's Petition Supplement contained the following statements:

> On December 14, 2011, FDA approved a supplemental new drug application (sNDA)that fundamentally changed the labeling for Vancocin… Entirely new sections on Clinical Studies, Adverse Reactions: Clinical Trials, Nephrotoxicity, and Geriatric Use were added to Vancocin's labeling based on the new data. ***The new Vancocin labeling also modified Vancocin's indication and for the first time specifies a recommended dosing regimen.***
>
> …
>
> Indeed, ***[Vancocin's] indication itself was changed based on the new data***, and now includes ***a new recommended dose*** of 125 mg q.i.d., the dose demonstrated to be safe and effective in the new studies.
>
> In sum, ***Vancocin's labeling was fundamentally and extensively changed in the new sNDA with numerous new conditions of use***.
> …
>
> • INDICATIONS AND USAGE. ***Vancocin's previous C. difficile indication was changed based on the new studies****, such that Vancocin is now* ***"indicated for the treatment of C. difficile -associated diarrhea."*** Vancocin's new Clinical Studies section explains what is meant by "C. difficile -associated diarrhea" in the new studies that led ***to this changed indication***, as well as the efficacy endpoint by which resolution of CDAD was measured, and ***the new recommended Vancocin dose*** based on these studies is recited in the Dosage and Administration section. In light of the two new CDAD studies, the Indications and Usage section was also modified to reflect the relative absence of data for S. aureus enterocolitis, which is no longer referred to as an indication.
>
> • DOSAGE AND ADMINISTRATION. ***The new Vancocin studies led to the significant modification of Vancocin's previously labeled "usual" 500 mg to 2 g CDAD daily dosing range. For the first time Vancocin is now labeled with a "recommended" CDAD dose:*** 125 mg four times daily for ten days, based on the dose used in the two new studies submitted in the Vancocin sNDA, which also removed the word "usual" from the S. aureus dosing range due to data insufficiency concerns.

…

The new Vancocin studies also modified Vancocin's indication and for the first time included a recommended dose…

…

IV. Generic Products that Omit Vancocin's New Labeling Would Not Be Approvable

…

Vancocin's new exclusivity-protected labeling is extensive**,** and fundamental to the safe and effective use of Vancocin. Excising the protected labeling would remove key required labeling sections – e.g., Clinical Studies, Adverse Reactions: Clinical Trial Experience, Nephrotoxicity, Geriatric Use – in their entirety and thus violate FDA's labeling regulations. ***Generics also would have no indication, or recommended dosing regimen***. The result would be an incoherent patchwork which certainly would not constitute a modern drug label, or even be equivalent to Vancocin's old labeling. Lacking extensive and critical aspects of Vancocin's labeling, generic vancomycin capsule products would be less safe or effective than Vancocin, and thus not approvable.

…

Like Colcrys, ***the protected Vancocin labeling information derives from new controlled clinical data demonstrating the safety and efficacy of an old drug, as well as recommended dose for the drug…***

…

E. Generics that Omit Vancocin's CDAD Indication Would Have No Indication and Therefore Be Unapprovable

…

Vancocin's CDAD indication, however, was one of the new changes to the Vancocin labeling approved in the recent sNDA, such that it is protected by Vancocin's new 3 year exclusivity. Therefore, to comply with the indication regulation and become approvable, ***generic vancomycin drug products must wait until Vancocin's 3 year exclusivity expires.***

…

> ***F. Generics That Include Vancocin's CDAD Indication Would Not Be Approvable***
>
> As an initial matter, ***Vancocin's CDAD indication is protected by Vancocin's new 3 year exclusivity, as explained above.***
>
> However, even assuming arguendo that Vancocin's CDAD indication were not protected by Vancocin's new 3 year exclusivity, generic products which include the CDAD indication would nonetheless fail to meet the standards for approval. ***Even if ANDA labeling could carry Vancocin's new indication and dosing regimen, it could not include the new exclusivity-protected Vancocin conditions of use discussed above***. . .[47]

111. The statements highlighted above and in Appendix A from the Citizen's Petition Supplement were false and misleading. Specifically, the Supplement falsely stated ***eight times*** that the approved labeling change was for a "new indication" and falsely stated ***seven times*** that it included a new "dosing regimen." These statements were false and misleading in that they failed to advise the market that:

(a) the FDA specifically told ViroPharma in the December 14, 2011 Letter, that it was not approving the new Vancocin label for a new ingredient, ***new indication***, new dosage form, ***new dosage regimen***, or new route of administration. If ViroPharma had intended on requesting a new indication or dosing regimen, ViroPharma would have to complete and submit an assessment of the safety and effectiveness of the product in pediatric patients under PREA. ViroPharma did not do so, despite knowing about the PREA requirement;

(b) While ViroPharma's sNDA sought to update the Vancocin label, ViroPharma ***did not*** seek approval of a new indication, new dosing regimen, or other such change which would be necessary to qualify Vancocin for an extra three years of exclusivity;

[47] A chart of the false and misleading statements contained in the 26 page, single-space Supplemental Citizen's Petition, is attached hereto as Appendix A.

(c) the FDA specifically told ViroPharma in the February 18, 2011 and May 20, 2011 letters, and at the May 24, 2011 teleconference that the Genzyme Study was not a properly designed and well-controlled study as it related to Vancocin, and was therefore inadequate to demonstrate efficacy for a new condition of use;

(d) the FDA told Defendants during the December 8, 2011 labeling teleconference that because the Genzyme Study was not an adequate and well-controlled study designed to test Vancocin against a control group, the new Vancocin label could only contain "descriptive" information describing Vancocin's performance in the Genzyme Study without any comparator data. This merely "descriptive" information could not support a claim of efficacy for a new condition of use necessary to support exclusivity under the QI Act; and

(e) Defendants thus knew or were reckless in not knowing that the new label did not meet the criteria for three more years of exclusivity under the QI Act, and Defendants had a duty to disclose this information in order to make their statements to the market not misleading.

112. Moreover, it was false and misleading to state that "Vancocin's CDAD indication. . . was one of the new changes to the Vancocin labeling approved in the recent sNDA," "Vancocin's CDAD indication is protected by Vancocin's new 3 year exclusivity, as explained above," and to describe "Vancocin's new indication and dosing regimen" in light of the fact that Defendants were expressly told by the FDA on December 14, 2011 that the label ***did not*** qualify for a new indication as recently as eight days before the Supplement was filed.

C. January 5, 2012 8-K

113. On January 5, 2012, ViroPharma issued a press release announcing financial guidance for 2012. The press release was attached to a Form 8-K filed with the SEC and signed by defendant Wolf, and quoted defendant Milano who said:

> ***"We believe that 2012 will not only be yet another year of strong growth…, as a result of our sNDA approval, we believe Vancocin (vancomycin hydrochloride, USP) Capsules meets the requirements for, and thus has, three years of exclusivity and that generic vancomycin capsules will not be approved during this period…*** These investments in our clinical pipeline are designed to ultimately bring us closer to delivering solutions for patients as well as provide additional future growth for our shareholders."
>
> Looking ahead in 2012
>
> ViroPharma is providing guidance for the year 2012 as a convenience to investors…
>
> ***For the year 2012, ViroPharma expects the following:***
>
> - ***Worldwide net product sales are expected to be $600 to $660 million***
> - ***Net Vancocin sales are expected to be $260 to $310 million***

114. The above-statements were false and misleading when made. Specifically, the statement "we believe Vancocin (vancomycin hydrochloride, USP) Capsules meets the requirements for, and thus has, three years of exclusivity and that generic vancomycin capsules will not be approved during this period" was false and misleading because it failed to disclose that:

(a) While ViroPharma's sNDA sought to update the Vancocin label, ViroPharma ***did not*** seek approval of a new indication, new dosing regimen, or other such change which would be necessary to qualify Vancocin for an extra three years of exclusivity;

(b) the FDA specifically told ViroPharma in the February 18, 2011 and May 20, 2011 letters, and at the May 24, 2011 teleconference that the *post hoc* analysis of the Genzyme Study did not constitute an adequate and well-controlled study with respect to showing Vancocin's efficacy, and was therefore inadequate to demonstrate efficacy for a new condition of use;

(c) the FDA told Defendants during the December 8, 2011 labeling teleconference that because the Genzyme Study was not an adequate and well-controlled study designed to test Vancocin against a control group, the new Vancocin label could only contain "descriptive" information describing Vancocin's performance in the Genzyme Study. This merely "descriptive" information could not support a claim of efficacy for a new condition of use necessary to support exclusivity under the QI Act;

(d) the FDA specifically told ViroPharma in the December 14, 2011 Letter, that it was not approving the new Vancocin label for a new ingredient, ***new indication***, new dosage form, ***new dosage regimen***, or new route of administration. If ViroPharma had intended on requesting a new indication or dosing regimen, ViroPharma would have to complete and submit an assessment of the safety and effectiveness of the product in pediatric patients under PREA. ViroPharma did not do so, despite knowing about the PREA requirement; and

(e) Defendants thus knew or were reckless in not knowing that the new label did not meet the criteria for three more years of exclusivity under the QI Act, and Defendants had a duty to disclose this information in order to make their statements to the market not misleading.

115. In addition, the expected sales numbers Defendants projected for Vancocin for 2012 were false and misleading and lacked a reasonable basis when made in that they were dependant upon ViroPharma obtaining three years of exclusivity for Vancocin. However, Defendants had actual knowledge at the time the press release was issued that the Vancocin sNDA was not approved for a new indication or new dosing regimen, that the FDA did not view the Genzyme Study as an adequate and well-controlled trial designed to test Vancocin against a control group, and that ViroPharma would only be permitted to include descriptive

information about Vancocin on the new label and could not include comparative data. Accordingly, Defendants had actual knowledge that because the Genzyme Study was deemed by the FDA to be woefully lacking, and could not support efficacy for a new condition of use, Vancocin did not meet the criteria for and would not obtain three more years of exclusivity. *See also* ¶96.

116. Following ViroPharma's January 5, 2012 Press Release, J.P. Morgan issued an analyst report reiterating the Company's confidence in Vancocin exclusivity and the future revenues expected to flow from it. The report adopted the revenue numbers projected by Defendants for 2012 Vancocin sales:

> After the close, ViroPharma provided encouraging 2012 guidance, ahead of the J.P. Morgan Healthcare Conference next week. Specifically, the company guided to 2012 net product sales of $600-660M (consensus for total revenues: $605M). US Cinryze sales guidance of $310-330M bracketed consensus of $318M. ***Importantly, 2012 guidance for Vancocin was provided ($260-310M; cons: $263M), which we believe reflects management's confidence that the recent sNDA approval provides 3 years of exclusivity.*** Overall, we are encouraged by 2012 guidance, which sets a positive tone for the year, in addition to multiple clinical (data from SC dosing of Cinryze) and regulatory (Cinryze manufacturing) catalysts that should be fundamental long-term positives. We are reiterating our Overweight rating, and raising estimates and our Dec 2012 PT to $35 from $23.

117. An Auriga analyst report responded to ViroPharma's guidance by stating: "With the approval of the new label on Vancocin, we think there is room for further revenue growth for the product. Our previous estimate of $260 now appears too conservative." An Oppenheimer report also confirmed the market's acceptance of Defendants' statements regarding Vancocin exclusivity by stating "Importantly, we believe the FDA will issue confirmation during this quarter for Vancocin exclusivity through late-2014."

D. January 11, 2012 J.P. Morgan Global Healthcare Conference

118. On January 11, 2012, ViroPharma made a presentation at the J.P. Morgan Global Healthcare Conference. At that conference, defendant Milano made the following comments:

> **Vincent Milano** – ViroPharma – Chairman, President and CEO
>
> And of course, we ended the year with a little news about a product that some of you might remember, ***Vancocin, where we created an exclusivity proposition*** that we've been longing for, for the better part of 5.5 years.
>
> …
>
> So, on the last product on the product side, the commercial side, is Vancocin. So I think the last few years that I've stood up here, I've had a slide that would show you what the impact of a generic Vancocin would mean. And I'm proud to say today that ***we believe we've gotten three years of exclusivity by taking advantage of the legislation that provides all the antibiotics three years of exclusivity, if you can update the label with meaningful safety and efficacy data, which we did through the licensing of data from a study that Genzyme had done with tolevamer, comparing their drug to Vancocin back in 2008.***
>
> All that being said, we're not done our fight on the bioequivalence front. We still continue to want to ensure that there are no end-arounds that could be played against us. So you can imagine that we'll continue to do the things that you've heard us talk about for the last 5.5 years.
>
> ***But we're in a position now for the first time since March of 2006, frankly, to feel confident that we have exclusivity into the future with Vancocin. And as a result of that, it's the first time since 2009 that we're actually providing guidance for Vancocin of between $260 million and $310 million in sales.***

119. The above-statements were false and misleading when made. Specifically, the statement "we created an exclusivity proposition" was false considering that:

(a) While ViroPharma's sNDA sought to update the Vancocin label, ViroPharma ***did not*** seek approval of a new indication, new dosing regimen, or other such

change which would be necessary to qualify Vancocin for an additional three years of exclusivity;

(b) the FDA specifically told ViroPharma in the February 18, 2011 and May 20, 2011 letters, and at the May 24, 2011 teleconference that the Genzyme Study was not an adequate and well-controlled study as it related to Vancocin, and was therefore inadequate to demonstrate efficacy for a new condition of use;

(c) the FDA told Defendants during the December 8, 2011 labeling teleconference that because the Genzyme Study was not an adequate and well-controlled study designed to test Vancocin against a control group, the new Vancocin label could only contain "descriptive" information describing Vancocin's performance in the Genzyme Study. This merely "descriptive" information could not support a claim of efficacy for a new condition of use necessary to support exclusivity under the QI Act;

(d) the FDA specifically told ViroPharma in the December 14, 2011 Letter, that it was not approving the new Vancocin label for a new ingredient, ***new indication***, new dosage form, ***new dosage regimen***, or new route of administration. If ViroPharma had intended on requesting a new indication or dosing regimen, ViroPharma would have to complete and submit an assessment of the safety and effectiveness of the product in pediatric patients under PREA. ViroPharma did not do so, despite knowing about the PREA requirement;

(e) thus, Defendants were expressly told by the FDA that the new Vancocin label would not meet the criteria for exclusivity, making the statement, "we created an exclusivity proposition" a false statement; and

(f) Defendants thus knew or were reckless in not knowing that the new label did not meet the criteria for three more years of exclusivity under the QI Act, and Defendants

had a duty to disclose that information in order to make their statements to the market not misleading.

120. In addition, the statement "we believe we've gotten three years of exclusivity by taking advantage of the legislation that provides all the antibiotics three years of exclusivity, if you can update the label with meaningful safety and efficacy data, which we did" was false in light of the FDA telling Defendants on December 8, 2011 that the new label could only include a descriptive summary of Vancocin's results from the Genzyme Study. The label did not have "meaningful" safety and efficacy data because the label could not include any comparative data that would be necessary to support a new efficacy claim. Moreover, the statement was misleading because it described only one part of the FDCA that provides for exclusivity for labels updated with "meaningful safety and efficacy data", yet omitted to state that, as an Old Antibiotic, Vancocin would only qualify for such exclusivity under the QI Act if it could demonstrate to the FDA that the approval was for a new "condition of use." Defendants already knew that the new Vancocin label did not support a finding of efficacy for a new "condition of use."

121. The statement "we're in a position now . . . to feel confident that we have exclusivity into the future with Vancocin" is misleading in light of the information contained in the February 18, 2011 and May 20, 2011 letters, the May 24, 2011 teleconference, the December 14, 2011 Letter and the information told to Defendants orally by the FDA on December 8, 2011 specifically informing Defendants that the new Vancocin label did not meet the criteria for exclusivity.

122. Finally, the revenue "guidance" Defendants provided for Vancocin's 2012 sales of $260 to $310 million was false and misleading when made and lacked a reasonable basis for the reasons described in ¶¶96 and 115.

123. Moreover, these statements, to the extent they may be considered forward looking, are not protected by the safe harbor because Defendant Milano failed to (1) identify the statements as forward looking, and (2) failed to include an oral warning that "actual results could differ materially from those projected," as is required by the statutory safe harbor for oral statements.

124. A J.P. Morgan analyst report published after the conference ended on January 11, 2012 reiterated ViroPharma's confidence that the Company would receive exclusivity:

> This afternoon, ViroPharma CEO Vincent Milano presented at the J.P. Morgan Healthcare conference. The focus of the presentation was on approved products, including Cinryze and Vancocin, as well as other pipeline opportunities. Overall, the presentation was positive with ***management confident in. . . Vancocin exclusivity.***
>
> · **Vancocin expanded exclusivity highlighted**. ***Management highlighted the recent sNDA approval for Vancocin, which provides for 3 years exclusivity***. This prompted the company to give 2012 Vancocin sales guidance of $260- 310M (JPMe: $285M; cons: $263M) last week. Despite the extension of exclusivity, Viropharma will continue the fight on the bioequivalence front to raise the bar for a potential generic.

E. February 28, 2012 Form 8-K

125. On February 28, 2012, ViroPharma issued a press release announcing 2011 year-end results. The press release was also attached to a Form 8-K filed with the SEC and signed by defendant Wolf. In that press release, the Defendants made the following statements:

> As evidenced by our financial and operational performance throughout the year, 2011 was clearly the most successful period in the history of our company," stated Vincent Milano, ViroPharma's chief executive officer. "***Among the highlights were … the***

> ***approval of our Vancocin sNDA leading to modernized labeling and, we believe, three years of exclusivity….***
>
> …
>
> ***Looking ahead in 2012***
> ViroPharma is reiterating its guidance for the year 2012 as a convenience to investors…
>
> For the year 2012, ViroPharma expects the following:
>
> - Worldwide net product sales are expected to be $600 to $660 million;
> - ***Net Vancocin sales are expected to be $260 to $310 million***

126. The above-statements were false and misleading when made. Specifically, it was misleading to describe "the approval of our Vancocin sNDA leading to modernized labeling and, we believe, three years of exclusivity" while omitting to state what the FDA specifically told ViroPharma in the February 18, 2011, May 20, 2011, and December 14, 2011 letters and verbally on May 24, 2011 and December 8, 2011 which Defendants clearly should have understood to mean that the new label did not meet the criteria for three years of exclusivity. *See infra* ¶96.

127. Moreover, the revenue "guidance" Defendants provided for Vancocin's 2012 sales of $260 to $310 million was false and misleading when made, and lacked a reasonable basis for the reasons described in ¶¶96 and 115.

F. February 28, 2012 Earnings Call

128. On February 28, 2012, ViroPharma held a conference call to discuss its year-end results. Defendants Milano, Wolf, Rowland, Doyle and COO Soland were participants on the call and made the following statements about Vancocin:

> **Vin Milano - ViroPharma - Chairman, President, CEO**
> Thanks, Pete. As many of you saw from our press release we issued this morning, 2011 was unquestionably the most successful period in ViroPharma's history. We continue to demonstrate

strong product growth, achieve two EU product approval, executed four separate business development deals, advanced our pipeline, improved our capital structure through not only our record top and bottom line performance, but also our share repurchase program, and, of course, ***in December received the sNDA approval for Vancocin, which we believe merits three years of additional exclusivity.***

…

Philip Nadeau - Cowen and Company - Analyst

Second question, on Vancocin, I know you guys have been saying the orange book listing for exclusivity could happen sometime over the next few months. Could you give us an update on the time lines? When do you expect to see that and also some clarity on what will be in that designation? Could the FDA designate parts of the label for exclusivity while excluding other parts and would that be clear from the initial indication from the FDA?

Tom Doyle - ViroPharma - VP Strategic Initiatives

As the time line, we really have nothing to add to that. ***We remain confident that our SNDA warrants a three arc [year] exclusivity for the rates [reasons] that we've described.…***

…

Rachel McMinn - BofA Merrill Lynch - Analyst

Okay, that's specific enough for me. (laughter) In terms of the orange book, I just wanted to clarify your comments. I apologize if you said this already, **or** ***but are you saying that you know that you have feedback from the FDA that it will take a few months, or*** that's your speculation because you haven't heard anything at this point?

Dan Soland - ViroPharma - VP, COO

It's probably the latter. We haven't heard back from them yet, and we just think it will take a couple months to get through it.

Vin Milano - ViroPharma - Chairman, President, CEO

To be clear, ***this was our expectation when we received the approval.*** It's not because we haven't heard from them two in months that we're seeing this… **Our expectation was** ***it would take some time for the agency to comprehend this and put it into the context of their orange book***. The message from our point of view is that their behavior to date is consistent with what we had expected, and ***we look forward to seeing them adjudicate this in favor of the exclusivity code in the orange book***.

129. The above-statements were false and misleading when made and omitted to state material information Defendants were required to disclose. Specifically, it was misleading to state "in December[we] received the sNDA approval for Vancocin, which we believe merits three years of additional exclusivity," and "[w]e remain confident that our SNDA warrants a three arc [year] exclusivity for the rates [reasons] that we've described," while omitting to state what the FDA specifically told ViroPharma in the February 18, 2011, May 20, 2011, and December 14, 2011 letters, and verbally on May 24, 2011, and December 8, 2011, as described herein, which Defendants clearly should have understood to mean that the new label did not meet the criteria for three years of exclusivity, and that ViroPharma's Citizen's Petition Supplement requesting exclusivity was based on numerous false and misleading statements to the FDA, and thus was destined to be rejected. *See also* ¶¶96, 107-112 and Appendix A.

130. In addition, when asked by the BofA Merrill Lynch analyst about FDA feedback regarding their request, Defendant Milano and Daniel Soland, ViroPharma's Vice President and Chief Operating Officer, had a golden opportunity to tell the truth about the feedback Defendants already received from the FDA on February 18, 2011, May 20, 2011, May 24, 2011, December 8, 2011 and December 14, 2011, as described herein, indicating that the sNDA was not approved for a new indication or new dosing regimen, and that the FDA would only permit ViroPharma to include descriptive information regarding Vancocin's performance in the Genzyme Study on the label. Defendants failed to take this opportunity to tell the market what they knew and continued to mislead the market. Soland simply responded "[w]e haven't heard back from them yet, and we just think it will take a couple months to get through it." Further, defendant Milano added, ***"this was our expectation when we received the approval,"*** and ***"[o]ur expectation was it would take some time for the agency to comprehend this and put it***

into the context of their orange book. . . their behavior to date is consistent with what we had expected and we look forward to seeing them adjudicate this in favor of the exclusivity code in the orange book." These statements were misleading because they omitted the information set forth in ¶96, *supra*.

G. February 28, 2012 Form 10-K

131. On February 28, 2012, ViroPharma filed its Annual Report on Form 10-K with the SEC. The Form 10-K was signed by defendants Milano and Rowland. As CEO and CFO, defendants Milano and Rowland each certified pursuant to § 302 of the Sarbanes Oxley Act of 2002, that they: 1) reviewed the Annual Report; 2) based on their knowledge, the Report "does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by [the Report];" and 3) each has "disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors: . . [a]ny fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting." Milano and Rowland further certified, pursuant to § 906 of the Sarbanes Oxley Act, that "[t]he information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company."

132. In the Form 10-K, Defendants made the following statements about Vancocin:

> ***We expect future growth to be driven by sales of Vancocin*****,** sales of Cinryze, both domestically and internationally, sales of Buccolam and Plenadren in Europe, and by our primary development programs, including C1 esterase inhibitor and a non-toxigenic strain of C. difficile (VP20621).
>
> …

> Through the sNDA approval, Vancocin's label for the first time includes clinical safety and efficacy data for the use of Vancocin capsules in treating Clostridium difficile. Vancocin's labeling now reflects safety and efficacy data from 260 patients with CDAD treated with Vancocin in two pivotal studies of Genzyme Corporation's investigational drug, tolevamer. We purchased exclusive rights to the two studies from Genzyme for which we will pay Genzyme royalties of 10**%**, 10**%** and 16**%** on net sales of Vancocin for the three year period following the approval of the sNDA.
>
> ***As a result of the sNDA approval, we believe Vancocin meets the requirements for three years of exclusivity, and that generic vancomycin capsules will not be approved during this period. Under FDA's regulations, labeling changes based on new clinical investigations that are essential to approval of the sNDA and to which the applicant has exclusive rights may be entitled to three years of exclusivity,*** and generic drug labeling cannot include information protected by such three-year exclusivity. A generic may seek approval by omitting labeling protected by three-year exclusivity; however, if such omissions render the generic drug less safe or effective, it cannot be approved until the three-year exclusivity expires.
>
> ***We believe that attempting to omit Vancocin labeling changes protected by exclusivity would render generic versions of Vancocin less safe and effective.***

133. The above-statements were repeated numerous times in the Form 10-K. The statements "[a]s a result of the sNDA approval, we believe Vancocin meets the requirements for three years of exclusivity, and that generic vancomycin capsules will not be approved during this period," and "[w]e believe that attempting to omit Vancocin labeling changes protected by exclusivity would render generic versions of Vancocin less safe and effective" and "we expect future growth the be driven by sales of Vancocin" were false and misleading when made for the reasons set forth in ¶96 *supra*. Defendants were also well aware that their Citizen's Petition Supplement requesting exclusivity was based on numerous false and misleading statements regarding the contents of the new label and the conditions of approval of the sNDA. *See* ¶¶107-112.

VI. THE TRUTH IS REVEALED

134. On April 9, 2012, after the market closed, the FDA responded to Defendants' Citizen's Petition formally denying ViroPharma's request for exclusivity (the "FDA Denial Letter"). The FDA Denial Letter was published on www.regulations.gov. after the market closed. The FDA's denial of exclusivity was based on § 505(v)(3)(B) of the FDCA, the limitation on "Old Antibiotics" seeking three years of additional marketing exclusivity, and noted that the "3-year exclusivity period is not available for 'any condition of use for which the [Old Antibiotic]…was approved before the date of the enactment" of the statute. FDA Denial Letter at 69. Because ViroPharma's application was not for a new "condition of use," ViroPharma was not entitled to an additional period of exclusivity.

135. Most significant, however, was the revelation to the market that ViroPharma had been informed directly by the FDA in the December 14, 2011 Letter that Vancocin's new label was not being approved for a "new indication" or "dosing regimen," and the fact that Defendants had never submitted PREA tests in connection with the sNDA confirmed that understanding. As stated in the FDA Denial Letter:

> Notably, ViroPharma's position that these studies were essential to the approval of a new indication and new dosing regimen ***are inconsistent with the contents of the sNDA that contained those studies, and the letter detailing the approval of the sNDA***. As indicated in the approval letter, the Agency determined that the supplement supported "updates to the prescribing information" and "conversion of the current label into [PLR] format." In addition, ***had [ViroPharma] intended to seek approval for a new indication or a new dosing regimen…you would have been required by statute to have conducted an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients under the Pediatric Research Equity Act (PREA).*** You did not submit any such assessment in you sNDA or otherwise reference PREA's requirement by seeking a deferral or waiver of this requirement. ***Moreover, the approval letter to which you did not object, confirmed that PREA was not triggered by your sNDA. This confirms that you like the Agency, did not***

> ***believe your labeling changes constituted a new indication, new dosing regimen, or other PREA-triggering change.***

136. In addition, the FDA reprimanded the Company for their monopolistic delay tactics and excessive submissions to the FDA stating: "FDA notes that you have petitioned FDA in a fashion analogous to interrogatories in civil discovery, demanding answers to more than 170 individual factual questions…this is an improper use of the Citizen's Petition process."[48]

137. Before the market opened on April 10, 2012, ViroPharma filed a Form 8-K with the SEC signed by defendant Wolf, attaching a press release that stated in relevant part that:

> [T]he U.S. Food and Drug Administration (FDA) denied the citizen petition (Docket # FDA-2006-P-0007) filed by ViroPharma on March 17, 2006 related to the FDA's proposed *in vitro* method for determining bioequivalence of abbreviated new drug applications (ANDAs) referencing Vancocin® (vancomycin hydrochloride, USP) Capsules**.** In the FDA's response to the citizen petition, the agency denied ViroPharma's citizen petition and also informed the company that a final guidance for vancomycin bioequivalence consistent with the FDA's citizen petition response is forthcoming.
>
> The FDA also informed ViroPharma in the same correspondence that the recent supplemental new drug application (sNDA) for Vancocin approved December 14, 2011 would not qualify for three additional years of exclusivity based on the agency's assertion that in order for an sNDA for an old antibiotic such as Vancocin to be eligible for a grant of exclusivity, it must be a significant new use or indication**.** FDA also indicated that it is approving three ANDA's for generic vancomycin capsules.
>
> In addition, the company has received a notification that the Federal Trade Commission is conducting an investigation into whether the company has engaged in unfair methods of competition with respect to Vancocin.

[48] FDA Denial Letter at 74.

138. On April 10, 2012, at 9:30am EST, the Company held a conference call with stock market analysts to discuss the FDA's decision. Milano, Doyle, and Wolf participated on the call. ViroPharma emphasized it intended to continue to fight the FDA's decision, and in the Q & A session that followed Milano's opening remarks Defendant Milano tried to soften the FDA's blow by stating that ViroPharma would be launching its own generic version of Vancocin.

> And even though we are taking action legally, we're moving forward to deploy our own authorized generic.

139. Later in the Q & A, Milano essentially admitted that ViroPharma never expected its Citizen's Petition challenge to the FDA panel's 2009 bioequivalence standard to succeed.

> Q: Hi, good morning. Just a quick question I guess, if, to the extent that Vancocin sales do go away here, would the company look to implement any kind of cost cutting at all, I guess on the periphery? Now there is no really Vancocin-related costs that are kind of embedded in the model at this point, but just with respect to I think some of the European infrastructure buildout and some of the other things you're doing on the R&D front?
>
> A: So, the answer today is that, no, we don't intend on making any cost-cutting moves. As you pointed out, appropriately, there is a limited number of expenses in the Vancocin business. ***And remember that until December of '11 we have spent our entire lives assuming Vancocin was going go away and we've been building the company expecting it someday to go away.***

140. When asked about the chance of success, defendant Doyle admitted that "the hurdle [was] high" but "I also think we have some strong arguments." The call concluded with Milano reassuring analysts that revenue from Vancocin would not disappear:

> And we still have Vancocin cash flow, right, it doesn't go to zero. And again give us some time to analyze the situation, hopefully to provide an update on what that looks like in the near term when we do our earnings call.

141. Analysts were shocked at the revelations. Phil Nadeau, Ph.D. from Cowen and Company stated in a report dated April 10, 2012:

> This morning, the FDA approved three manufacturers' generic versions of ViroPharma's Vancocin capsules, and at least two (Akorn and Watson) indicate that shipments are beginning immediately. The FDA also posted a response to ViroPharma's long-standing Citizen's Petition and indicated that the December 2011 label revision does not entitle Vancocin to the three years of exclusivity. ***We believe investors had largely taken VPHM's word that the additional exclusivity would be granted, that Vancocin would be free from generic competition for three years (if not longer)*** and therefore we expect the stock to be down sharply today. Moreover, without branded Vancocin sales, ViroPharma's earnings will decline through 2013.

142. Cowen further commented on the FDA's denial letter noting that "the FDA chastised [ViroPharma] for 'improper use' of the Citizen Petition process, citing the Company's more than 170 individual factual questions 'analogous to interrogatories in civil discovery' and 20 supplements to the original petition."

143. In an analyst report published on April 10, 2012, Geoff Meachum from J.P. Morgan stated: "We expect VPHM shares to come under pressure today, as ***we believe many had assumed a generic Vancocin was likely to be delayed for at least 3 years***." J.P. Morgan also confirmed the devastating effect that the loss of Vancocin exclusivity would cause ViroPharma: "We had assumed 3 years exclusivity for Vancocin. As such, we are decreasing our 2012-2015 Vancocin sales to $110M, $30M, $20M and $10M from $285M, $295M, $300M and $150M, respectively. Our 2012-2015 EPS decrease to $.0.63, $0.43, $0.63 and $0.91 from $1.62, $1.85, $2.10 and $1.63, respectively." He further noted that the FTC investigation also adds risk to the story.

144. On April 10, 2012, Brean Murray Garret & Co. issued a research report noting that generic approval will result in a significant loss of earnings power over the next few years,

and gross profit will decline 18% in 2012 and 26% in 2013. Brean Murray noted that further efforts to retain the Vancocin franchise will be unsuccessful, and the FDA decision is likely to be final. Further, the Brean Murray analyst noted that the high price of Vancocin gives generics an opportunity to rapidly capture market share. The Brean Murray analyst also noted that the FTC investigation "throws additional fuel into the fire" and is indicative of a federal government that favors generic Vancocin.

145. On April 10, 2012, Piper Jaffray issued a "Hot Comment" noting that ViroPharma "surprised the [s]treet" in December 2011 with the sNDA announcement, and stated "[w]e believed at the time that the label changes would qualify for 3 years of exclusivity." The Piper Jaffrey report also "slashed" Vancocin sales forecasts on the news.

146. On April 11, 2012, Auriga issued a report noting it does not expect ViroPharma's request for a preliminary injunction to be granted and thus it expected "full blown generic erosion to the Vancocin business immediately."

147. As a result of the news, at the close of trading on April 10, 2012, ViroPharma shares had declined $6.17 per share or 22**%**, to close at $22.44 per share on extraordinarily high trading volume. The stock price continued to drop through April 11, 2012 as the full impact of the news was absorbed by the market to close at $21.86 on continued high volume.

VII. ADDITIONAL SCIENTER ALLEGATIONS

148. As alleged herein, Defendants acted with scienter in that each Defendant knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading and/or omitted material information that was needed to make the statements made not misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary

violations of the federal securities laws. As set forth herein in detail, Defendants, by virtue of their receipt of information reflecting the true facts regarding ViroPharma, their control over, and/or receipt and/or modification of ViroPharma's allegedly materially misleading misstatements and omissions and/or their associations with the Company which made them privy to non-public information concerning ViroPharma, participated in the wrongful scheme alleged herein.

149. Defendants were motivated to materially misrepresent to the SEC and investors the true financial condition of the Company because their scheme and illegal course of conduct: (i) deceived the investing public regarding ViroPharma's business, operations, and management and the intrinsic value of ViroPharma securities; (ii) enabled Defendants to artificially inflate the price of ViroPharma securities; and (iii) caused Plaintiff and other members of the Class to purchase ViroPharma securities at artificially inflated prices.

150. Defendants' Doyle, Wolf and the Company's scienter is also demonstrated by Doyle, Wolf, and other senior level executive's attendance at a meeting in 2010 during which pediatric testing Vancocin was discussed, thus demonstrating that they knew the implications of testing Vancocin on pediatric patients. Without pediatric testing, Defendants' label could not qualify for a new indication or new dosing regimen.

151. Indeed, Doyle was very involved in the process, and CW5 said that "very little went on" at the Company that Doyle was not involved in and that Doyle became very familiar with pharmacokinetics, bioequivalence and clinical perspectives. Defendant Doyle signed many of the amendments to the Citizen's Petition submitted by ViroPharma to the FDA starting in 2007, including the December 22, 2011 Citizen's Petition Supplement requesting exclusivity that contains many of the false and misleading statements complained of herein. CW4 stated

that Doyle always spoke at Company meetings about the fear of generics coming onto the market and what the Company was doing to block them.

152. The other defendants were also involved in the sNDA process. CW1 stated that Milano was involved in the sNDA process. This is corroborated by CW4 who stated that Doyle, Milano, Wolf and Rowland all worked closely on the sNDA. CW5 stated that Doyle, Wolf, along with Pietrusko, Gelone and Broome were all intimately involved with the filing of the sNDA. CW2 stated that Doyle, Pietrusko, Broome, Wolf, Gelone and Clayton Fetcher, VP of Business Development and Project Management were all involved in Vancocin's sNDA process and application. Moreover, Doyle, along with other senior executives of the Company, attended and participated in the May 24, 2011 meeting with the FDA. *See* ¶80.

153. CW1 stated that Milano was a very "hands on" type of executive who knew "what was going on" and "when it was going on." CW4 corroborated this adding that Milano, Doyle, Wolf and Rowland were all very hands on. Because of their leadership roles in the Company and the importance of Vancocin sales, CW4 stated that the sNDA approval letter would have "absolutely" been shared with Milano, Doyle, Wolf, and Rowland. CW5 confirmed that when important correspondence from the FDA, such as the sNDA approval, was sent to the Company, senior management would have been made aware of it.

154. Defendants' scienter is further evidenced by their abusive use of the Citizen's Petition process to block generic Vancocin from entering the market. By filing the Citizen's Petition Supplement in December 2011, Defendants assured themselves of at least a few more months of Vancocin monopoly while they waited for the FDA to review its petition and make its final decision. Indeed, from December 31, 2011 through March 31, 2011, Vancocin net sales totaled $66 million, representing nearly ***half*** of the Company's quarterly net product sales.

155. Defendants were well aware that marketing exclusivity for "Old Antibiotics", such as Vancocin, would be granted only in limited circumstances where the drug would treat a new "condition of use." Defendants' knowledge is demonstrated by their statements to the FDA in ViroPharma's Citizen's Petition Supplement in which they claimed repeatedly that the new label for Vancocin contained numerous "new conditions of use" and that the label contained a "new indication." ¶¶107-112 and Appendix A. Defendants were also well-aware of and understood the QI Act's legislative history showed that exclusivity for "Old Antibiotics" was intended only for a "new indication." ¶61.

156. Vancocin accounted for over 50 % of the Company's revenue, with an enormous 97 % profit margin. It was a core drug and revenue driver for the Company. Securing exclusivity for this important drug was extremely important to the Company. It would be incredible to suggest that Defendants were not aware of details surrounding the sNDA application and approval as well as the Company's bid for exclusivity, including the information provided by the FDA in the February 18, 2011 letter, the May 20, 2011 letter, the May 24, 2011 teleconference with the FDA, the December 8, 2011 teleconference and in the December 14, 2011 letter.

A. Correspondence and Meetings With the FDA

157. Defendants were told by the FDA on February 18, 2011, May 20, 2011 and May 24, 2011 that 1) the Genzyme Study was not designed to show Vancocin's efficacy, 2) the data from the Genzyme Study could not be legitimately manipulated *post hoc* to show efficacy information about Vancocin because of the potential for introduction for statistical bias, 3) the Genzyme Study did not constitute an adequate and well-controlled study as it pertained to Vancocin, and 4) because of the deficiencies in using a *post hoc* analysis of the Genzyme Study, the data were inadequate to demonstrate efficacy for a new condition of use.

158. Defendants were told on December 8, 2011 that the FDA would not permit ViroPharma to include comparative data in the new Vancocin label, and ViroPharma would only be permitted to include a "descriptive" summary of Vancocin's results from the Genzyme Study. Comparative data, however, is necessary to support any efficacy claim for a new condition of use, and without it, ViroPharma would not satisfy the criteria for exclusivity.

159. The FDA reinforced this on December 14, 2011 when it confirmed that the Company's label was not approved for a new indication or dosing regimen. Thus, the new label did not meet the criteria for a new indication or new condition of use.

B. Suspicious Insider Selling in Amounts Dramatically Out of Line with Prior Trading History Also Creates a Strong Inference of Scienter

160. During the Class Period, defendants Doyle and Rowland had the opportunity and were motivated to engage in the course of conduct described herein to enrich themselves with insider trading proceeds. These defendants sold their personal shares of ViroPharma stock for an aggregate total of *over $8 million in profit* over a short four-month period. Both Doyle and Rowland exercised options at a fraction of the cost of the inflated ViroPharma shares, and then immediately sold the shares obtained by the exercise for a huge profit, at prices near the Class Period high of $33.17. Rowland sold nearly half of his total holdings during the Class Period.

161. These trades also took place at a suspicious time. The FDA has up to 180 days to respond to a Citizen's Petition.[49] Defendants filed the Citizen's Petition Supplement requesting exclusivity in December 2011. A negative response from the FDA was imminent in March 2012 when defendants Doyle and Rowland made all of their sales. Indeed, the FDA responded just one month after these suspicious sales and the stock dropped to $22.44 once

[49] *See* 505(q)(1)(F) of the FD&C Act.

Defendants' fraud was revealed. This stock drop represented a 30% decline in value compared to defendants Doyle and Rowland's average sale price of $32.23.

162. The following charts sets forth these Individual Defendants' insider trading:

Class Period Insider Trading Activity
(From December 14, 2011 through April 9, 2012)

DEFENDANT DOYLE

Exercised Options

Date	Transaction	Amount	Price	Cost of Options
3/5/2012	Exercised Option	60,000	$3.14	$188,400
3/5/2012	Exercised Option	20,000	$3.93	$78,600
3/5/2012	Exercised Option	30,000	$2.09	$62,700
3/5/2012	Exercised Option	100,000	$3.55	$355,000
Total Cost to Doyle of 210,000 Exercised Options				**$684,700**

Sales

Date	Transaction	Amount	Price	Proceeds
3/5/2012	Sale	210,000	$32.48	$6,200,800
Total Profit to Doyle for Sale of 210,000 Shares (Proceeds – Cost of Options)				**$6,136,100**

DEFENDANT ROWLAND[50]

Exercised Options

Date	Transaction	Amount	Price	Cost of Options
3/1/2012	Exercised Option	35,000	$11.96	$418,600
3/1/2012	Exercised Option	10,000	$5.91	$59,100
3/1/2012	Exercised Option	25,000	$8.86	$221,500
Total Cost to Rowland of 70,000 Exercised Options				**$699,200**

Sales

Date	Transaction	Amount	Price	Proceeds
3/1/2012	Sale	70,000	$32.12	$2,248,400.00
3/1/2012	Sale	12,750	$32.11	$409,402.50
Total Profit to Rowland for Sale of 82,750 Shares (Proceeds – Cost of Options)				**$ 1,958,602.50**

163. Moreover, this trading was not in line with trading activity for the year prior to the Class Period. For the entire year prior to the Class Period, Doyle and Rowland stock sales totaled a meager $405,400 compared to nearly $8 million during the Class Period. Remarkably, Doyle's profit in the twelve months prior to the Class Period was $36,000 compared to profits of over $6 million during the four-month Class Period. Rowland profits in the twelve months prior to the Class Period were $369,000 compared to nearly $2 million in profits during the four-month Class Period.

[50] On March 7, 2012 Rowland exercised 30,638 options which vested on that date for a total cost of $374,985. On that same date, he sold 12,715 shares for proceeds of $374,965 in order to pay an exercise tax nearly equal to the total amount of the March 7, 2012 exercised options. *See* Rowland Form 4 dated Mar. 9, 2012. This transaction is not included in the above analysis because the difference in purchase price and sale price is negligible, and the purpose of exercising the options and selling the shares was to pay taxes, not to gain profit.

164. The following charts sets forth these Individual Defendants' pre-Class Period trades:

Pre-Class Period Insider Trading Activity
(From December 13, 2010 through December 13, 2011)

DEFENDANT DOYLE

Exercised Options[51]

Date	Transaction	Amount	Price	Cost of Options
12/1/2011	Exercised Option	10,000	$20.16	$201,600.00
Total Cost to Doyle of 10,000 Exercised Options				**$201,600.00**

Sales

Date	Transaction	Amount	Price	Proceeds
12/1/2011	Sale	10,000	$23.82	$238,200.00
Total Profit to Doyle for Sale of 10,000 Shares (Proceeds – Cost of Options)				**$ 36,600**

DEFENDANT ROWLAND

Exercised Options

Date	Transaction	Amount	Price	Cost of Options
3/14/2011	Exercised Option	10,000	$5.91	$59,100
3/14/2011	Exercised Option	25,000	$8.86	$221,500
Total Cost to Rowland of 35,000 Exercised Options				**$280,600**

[51] On December 13, 2010 Doyle exercised 10,000 options for a total cost of $141,250. On that same date, he sold 8,363 shares for proceeds of $141,251.07 in order to pay an exercise tax nearly equal to the total amount of the December 13, 2010 exercised options. *See* Doyle Form 4 dated Dec. 15, 2010. This transaction is not included in the above analysis because the difference in purchase price and sale price is negligible, and the purpose of exercising the options and selling the shares was to pay taxes, not to gain profit.

Sales

Date	Transaction	Amount	Price	Proceeds
3/14/2011	Sale	10,000	$18.55	$185,500
3/14/2011	Sale	25,000	$18.58	$464,500
Total Profit to Rowland for Sale of 35,000 Shares (Proceeds – Cost of Options)				**$ 369,400**

165. As shown, Doyle and Rowland's Class Period stock sales were unusual in scope and timing and dramatically out of line with prior trading. Moreover, profits from these trades were substantial relative to Doyle and Rowland's compensation. In 2011, Rowland's salary was $365,000, and Doyle's salary was $354,000.

VIII. LOSS CAUSATION AND ECONOMIC LOSS

166. Defendants' wrongful conduct, as alleged herein, directly and proximately caused damages to Plaintiff and the Class.

167. During the Class Period, as detailed herein, Defendants engaged in a scheme to deceive the market and a course of conduct which artificially inflated the price of ViroPharma's securities by misrepresenting, or failing to disclose, among other things, that the FDA had already informed Defendants prior to the Class Period, and in at least five separate communications, that the Company did not meet the criteria to qualify for marketing exclusivity for Vancocin.

168. ViroPharma's press release, issued on April 10, 2012, informed investors, for the first time, what Defendants knew all along; that Vancocin did not qualify for exclusivity based on the reasons the Defendants had fraudulently touted to the market. As a direct result of this disclosure, the price of ViroPharma securities dropped precipitously. The stock price continued to drop through April 11, 2012 as the full impact of the news was absorbed by the market.

169. The dramatic decline in ViroPharma's stock price at the end of the Class Period was a direct result of the nature and extent of Defendants' misrepresentations being revealed to investors and to the market. The timing and magnitude of ViroPharma's stock price decline negates any inference that the losses suffered by Plaintiff and the other Class members was caused by changed market conditions and/or Company-specific facts unrelated to Defendants' wrongful conduct. Indeed, at the end of the Class Period, while ViroPharma's share price fell as a result of Defendants' fraudulent scheme and conduct being revealed, the Standard & Poor's 500 securities index was relatively stable.

IX. CLASS ACTION ALLEGATIONS

170. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased ViroPharma securities during the Class Period and were damaged thereby. Excluded from the Class are Defendants, the Company's officers, directors, employees, successors, and assigns, and any person, entity, firm, trust, corporation or other entity related to, affiliated with, or controlled by any of the Defendants, as well as the immediate families of the Individual Defendants.

171. This action is properly maintainable as a class action.

172. The Class is so numerous that joinder of all members is impracticable. Throughout the Class Period, ViroPharma stock traded on NASDAQ, a national securities exchange. During the Class Period, there were approximately 70 million shares of issued and outstanding ViroPharma securities. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that the proposed Class consists of at least hundreds or thousands of members scattered throughout the United States. Record owners and other members of the Class may be identified

from records maintained by ViroPharma or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

173. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law as complained of herein.

174. Plaintiff is committed to prosecuting this action and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class. Accordingly, Plaintiff is an adequate representative of the Class and will fairly and adequately protect the interests of the Class.

175. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class, including, among others:

(a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) whether statements made by Defendants to the investing public during the Class Period misrepresented or omitted material facts about the business, operations, prospects and management of ViroPharma;

(c) whether the Individual Defendants caused ViroPharma to issue materially false and misleading statements during the Class Period and/or omitted material facts necessary to make statements made not misleading;

(d) whether Defendants acted knowingly or recklessly in issuing materially false and misleading statements and/or omitting material facts necessary to make statements made not misleading;

(e) whether the price of ViroPharma's securities during the Class Period was artificially inflated because of the Defendants' conduct complained of herein; and

(f) whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

176. The prosecution of separate actions by individual members of the Class would create the risk of inconsistent or varying adjudications with respect to individual members of the Class, which would establish incompatible standards of conduct for Defendants, or adjudications with respect to individual members of the Class which would, as a practical matter, be dispositive of the interests of the other members not parties to the adjudications or substantially impair or impede their ability to protect their interests.

177. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

178. Additionally, Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that: Defendants made public misrepresentations or failed to disclose material facts in order to make the statements made not misleading during the Class Period; the omissions and misrepresentations were material;

ViroPharma securities were and are traded in an efficient market as the Company traded on the NASDAQ, and was covered by analysts.

179. Based on the foregoing, this action is properly maintainable as a class action.

X. APPLICABILITY OF PRESUMPTION OF RELIANCE UNDER THE *AFFILIATED UTE* DOCTRINE, AND/OR, IN THE ALTERNATIVE, THE FRAUD ON THE MARKET DOCTRINE

180. Plaintiff is entitled to a presumption of reliance under *Affiliated Ute v. United States*, 406 U.S. 128 (1972), because the claims asserted herein against the Defendants are primarily predicated upon omissions of material fact which there was a duty to disclose in order to make statements previously or contemporaneously made not misleading.

181. Plaintiff is alternatively entitled to a presumption of reliance because, as more fully alleged above, the Defendants made material misstatements and failed to disclose material information regarding ViroPharma's business and its ability to obtain exclusivity for its core drug Vancocin.

182. Plaintiff is entitled to a presumption of reliance under the fraud on the market doctrine because at all relevant times, the market for ViroPharma's securities was an efficient market for the following reasons, among others:

(a) ViroPharma's stock met the requirements for listing on, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;

(b) As a regulated issuer, ViroPharma filed periodic public reports with the SEC and the NASDAQ;

(c) The Company was considered a "well-seasoned issuer" by the SEC, and thus met the eligibility requirements to register its securities using SEC Form S-3, and in fact, did utilize that form on December 23, 2008;

(d) ViroPharma regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and;

(e) ViroPharma was followed by securities analysts employed by major brokerage firms (and others) who wrote reports which were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace. Some of these analysts and firms include:

(i) Auriga USA, LLC - Difei Yang

(ii) Bank of America Merrill Lynch - Rachel McMinn

(iii) Brean Murray, Carret & Co., LLC - Brian Skorney, Frank Longman

(iv) Caris & Company - Mario Corso

(v) Cowen and Company - Phil Nadeau, Nicholas Bishop

(vi) Datamonitor Group

(vii) GlobalData

(viii) Goldman Sachs - Vishnu Gopal, Terence Flynn

(ix) JMP Securities - Liisa A. Bayko, Heather Behanna

(x) J.P. Morgan - Geoff Meacham, Michael E. Ulz, Anupam Rama

(xi) Jefferies & Company, Inc. - Thomas Wei, Thomas Nguyen, Shaunak Deepak, Jeffrey Hung

(xii) Joseph Schwartz - Mike Schmidt

(xiii) Lazard Capital Markets - Brian Klein

(xiv) Leerink Swann - Michael Schmitz

(xv) Life Science Analytics

(xvi) Maxim Group LLC - Yale Jen, Echo He, Johnny Li

(xvii) Morningstar - Lauren Migliore, Karen Andersen,

(xviii) Oppenheimer & Co. Inc. - Christopher Holterhoff, Angad S. Verma

(xix) Piper Jaffray - Edward A. Tenthoff, Chad J. Messer

(xx) Roth Capital Partners - Yale Jen

(xxi) Stifel Nicolaus - Stephen Willey

(xxii) WBB Securities - Steve Brozak

(xxiii) WJB Capital Group, Inc. - John Newman, Jim Tumbrink

(xxiv) Wright Investors' Service

183. As a result of the foregoing, the market for ViroPharma securities promptly digested current information regarding ViroPharma from all readily and publicly available sources and reflected such information in ViroPharma securities prices. Under these circumstances, all purchasers of ViroPharma securities during the Class Period suffered similar injury through their purchase of ViroPharma securities at artificially inflated prices and a presumption of reliance applies.

XI. NO STATUTORY SAFE HARBOR

184. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. First, many of the identified false and misleading statements and omissions herein are not forward looking statements, but are statements of current and/or historic fact regarding

ViroPharma's core drug Vancocin, Vancocin's new label, and the impact the new label had for obtaining exclusivity for Vancocin. For example the following statements made by the Defendants are statements of current and historical fact:

(a) Statements that the new label had new or changed indications, new conditions of use and/or a new dosing regimen. *See e.g.*, ¶107-112;

(b) Statements that the label information derived from "controlled" clinical data. ¶110;

(c) Statements that efficacy has been demonstrated against the more virulent strain of *c. difficile*. ¶95;

(d) Statements that the CDAD indication is protected by Vancocin's exclusivity. ¶¶95, 110;

(e) Statements that the Company "created an exclusivity proposition" for Vancocin. ¶118, 128;

(f) Statements that legislation "provides ***all antibiotics*** three years of exclusivity if you can update the label with meaningful safety and efficacy data." ¶118;

(g) Statements that the label was updated with "meaningful" safety and efficacy data. ¶¶95, 118;

(h) Statements that the FDA's "behavior to date is consistent with" what the Company had expected. ¶130;

185. Second, several statements that may be considered forward-looking were not accompanied by any cautionary language. For example:

(a) The statements made by Milano at the J.P. Morgan Global Health Conference on January 11, 2012, were not identified as forward looking statements, and failed to

include an oral warning that "actual results could differ materially from those projected," as is required by the statutory safe harbor for oral statements.

186. To the extent that any of the false and misleading statements identified herein are mixed statements of current fact and forward looking projection, the portion of those statements relating to current fact are not protected by the safe harbor.

187. To the extent there were any forward-looking statements that were identified as such at the time made, such statements were knowingly false when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. For example, all of Defendants' Class Period statements regarding Vancocin exclusivity were not accompanied by meaningful cautionary language because:

(a) The risk factors allegedly warned of had already come to pass at the time Defendants made these statements, as the FDA had already determined that the new label did not qualify Vancocin for extended exclusivity; and

(b) The risk factors were incomplete because they failed to include the information conveyed to the Company by the FDA on February 18, 2011, May 20, 2011, May 24, 2011, December 8, 2011 and December 14, 2011.

188. Additionally, Defendants knew that any forward looking statements were false when made because the FDA had already informed them that Vancocin did not satisfy the criteria for exclusivity.

XII. CONTROL PERSON ALLEGATIONS

189. The Individual Defendants are liable as direct participants in the wrongs complained of herein. In addition, the Individual Defendants, by reason of their status as senior executive officers and/or directors, were "controlling persons" within the meaning of Section

20(a) of the Exchange Act and had the power and influence to cause the Company to engage in the unlawful conduct complained of herein. Because of their positions of control, the Individual Defendants were able to and did, directly or indirectly, control the conduct of ViroPharma's business.

190. The Individual Defendants because of their positions of control and authority as executives and senior officers and/or directors of the Company, had access to the adverse, undisclosed information about ViroPharma's business through their access to internal corporate documents and information, conversations and associations with other corporate officers and employees, attendance at management and Board meetings and committees thereof, and reports and other information provided to them by the FDA and others in connection therewith. Moreover, each Defendant was involved in ViroPharma's applications to the FDA concerning Vancocin—the Company's most important drug, and the subject of the fraud complained of herein.

191. The Individual Defendants, by virtue of their high-level position with the Company, directly participated in the management of the Company, and were directly involved in the day-to-day operations of the Company at the highest levels. The Individual Defendants participated in drafting, preparing, and/or approving the public statements and communications complained of herein and were aware of, or recklessly disregarded, the material misstatements contained therein and omissions therefrom, and were aware of their materially false and misleading nature. Sales of the Company's core product, Vancocin, and the Company's ability to obtain exclusivity for Vancocin were fundamental, core aspects of ViroPharma's business.

192. The Individual Defendants, as senior officers, executives and/or directors of the Company, were able to and did control the content of the various SEC filings, press releases,

investor presentations and other public statements pertaining to the Company during the Class Period. As senior officers, executives and/or directors of the Company, the Individual Defendants were provided with copies of the documents and statements alleged herein to be materially false and misleading prior to or shortly after their issuance or had the ability and opportunity to prevent their issuance or cause them to be corrected. Accordingly, the Individual Defendants are responsible for the accuracy of the public reports, releases, and other statements detailed herein and are primarily liable for the misrepresentations and omissions contained therein.

193. As senior officers and controlling persons of a publicly-held company whose securities were, during the relevant time, registered with the SEC pursuant to the Exchange Act, and traded on the NASDAQ, the Individual Defendants each had a duty to promptly disseminate accurate and truthful information with respect to the Company's operations and business, and to correct any previously issued statements that were or had become materially misleading or untrue, so that the market price of the Company's publicly-traded stock would be based upon truthful and accurate information. The Individual Defendants' wrongdoing during the Class Period violated these specific requirements and obligations.

194. The Individual Defendants are each liable as a primary participant in a wrongful scheme and course of business that operated as a fraud and deceit on purchasers of ViroPharma's securities during the Class Period, which included the dissemination of materially false and misleading statements regarding the state of its operations and its financial guidance and concealment or omission of material adverse facts. The scheme: (i) deceived the investing public regarding ViroPharma's operations and business, and the true value of ViroPharma's securities; and (ii) caused Plaintiff and other members of the Class to purchase

ViroPharma's securities at artificially inflated prices, and to suffer damages as the stock price which fell as the truth concerning ViroPharma ultimately became known.

195. In making the statements complained of herein, the Individual Defendants, who were senior officers and controlling persons of ViroPharma, were acting on behalf of the Company in the regular course of business. Therefore, each of the statements made by the Individual Defendants is attributable to the Company.

COUNT I

Violation of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against ViroPharma

196. Plaintiff incorporates by reference and realleges each and every allegation contained above as if fully set forth herein.

197. During the Class Period, officers, management, and agents of ViroPharma carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public regarding ViroPharma's business, operations, management and the intrinsic value of ViroPharma's securities; (ii) enable ViroPharma to artificially inflate the price of ViroPharma's securities; and (iii) cause Plaintiff and other members of the Class to purchase ViroPharma's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, ViroPharma took the actions set forth herein.

198. Officers, management, and agents of ViroPharma directly and indirectly, by the use of means and instrumentalities of interstate commerce, the mails, and/or the facilities of a national securities exchange: (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements made not misleading; and (c) engaged in acts, practices, and a course of business

which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for ViroPharma's securities in violation of Section 10(b) of the Exchange Act and SEC Rule 10b-5. ViroPharma is sued as a primary participant in the wrongful and illegal conduct charged herein.

199. ViroPharma, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal the truth about ViroPharma's ability to obtain exclusivity for its core drug Vancocin and its earnings potential, as specified herein.

200. Officers, management, and agents of ViroPharma employed devices, schemes, and artifices to defraud while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of ViroPharma's value and performance, which included the making of untrue statements of material facts and omitting material facts necessary in order to make the statements made about ViroPharma's operations and prospects, in the light of the circumstances under which they were made, not misleading, as set forth more particularly herein. Officers, management, and agents of ViroPharma did not have a reasonable basis for their alleged false statements and engaged in transactions, practices, and a course of business which operated as a fraud and deceit upon the purchasers of ViroPharma securities during the Class Period.

201. ViroPharma is liable for all materially false and misleading statements and omissions made during the Class Period, as alleged above, including the false and misleading statements and omissions included in Form 10-K, and 8-K filings, and in public submissions to the FDA.

202. ViroPharma is further liable for the false and misleading statements made by ViroPharma's officers, management, and agents in press releases and during conference calls and at conferences with investors and analysts, as alleged above, as the maker of such statements and under the principle of *respondeat superior*.

203. In addition to the duties of full disclosure imposed on ViroPharma as a result of the affirmative statements and reports made by its officers, management, and agents, or participation in the making of their affirmative statements and reports to the investing public, ViroPharma had a duty to promptly disseminate truthful information that would be material to investors, in compliance with the integrated disclosure provisions of the SEC as embodied in SEC Regulations, including truthful, complete and accurate information with respect to the Company's operations and financial condition so that the Company's share price would be based on truthful, complete and accurate information.

204. The allegations above establish a strong inference that ViroPharma, as an entity, acted with corporate scienter throughout the Class Period, as its officers, management, and agents had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth because they failed to ascertain and to disclose such facts, even though such facts were available to them. Such material misrepresentations and/or omissions were done knowingly or with recklessness, and without a reasonable basis. By concealing these material facts from investors, ViroPharma maintained its artificially inflated share price throughout the Class Period.

205. In ignorance of the fact that ViroPharma's share price was artificially inflated, and relying directly or indirectly on the false and misleading statements and omissions made by ViroPharma, or upon the integrity of the market in which the stock traded, and/or on the

absence of material adverse information that was known to or recklessly disregarded by ViroPharma but not disclosed in public statements by ViroPharma during the Class Period, Plaintiff and the other members of the Class purchased or acquired ViroPharma stock during the Class Period at artificially high prices and were damaged when that artificial inflation was removed from the price of ViroPharma stock as the truth about the Company's practices was revealed.

206. At the time of said misrepresentations and omissions, Plaintiff and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiff, the other members of the Class, and the marketplace known of the truth concerning the Company's inability to obtain exclusivity for its core drug Vancocin, Plaintiff and other members of the Class would not have purchased or acquired their ViroPharma stock, or, if they had purchased or acquired such stock during the Class Period, they would not have done so at the artificially inflated prices which they paid.

207. By virtue of the foregoing, ViroPharma has violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

208. As a direct and proximate result of ViroPharma's wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases and/or acquisitions of ViroPharma stock during the Class Period.

COUNT II

Claim for Violations of Section 10(b) Of The Exchange Act and Rule 10b-5(b) Promulgated Thereunder Against the Individual Defendants

209. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein. This claim is asserted against the Individual Defendants.

210. During the Class Period, the Individual Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public regarding ViroPharma's business, operations, management and the intrinsic value of ViroPharma's securities; and (ii) cause Plaintiff and other members of the Class to purchase ViroPharma's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, the Individual Defendants, and each of them, took the actions set forth herein.

211. The Individual Defendants (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (c) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for ViroPharma's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. The Individual Defendants are sued as primary participants in the wrongful and illegal conduct charged herein.

212. The Individual Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to misrepresent and conceal adverse material information about ViroPharma's ability to obtain exclusivity for its core drug Vancocin and its earnings potential, as specified herein.

213. The Individual Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information, and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of ViroPharma's value and performance and continued substantial growth, which included the making of, or the

participation in the making of, untrue statements of material facts and omitting to state material facts necessary in order to make the statements made about ViroPharma and its business operations in the light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of ViroPharma's securities during the Class Period.

214. Each Individual Defendants' primary liability arises from the following facts, among others set forth above: (i) they were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (ii) each Individual Defendant, by virtue of his responsibilities and activities as a senior officer and/or director of the Company was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (iii) each Individual Defendant enjoyed significant personal contact and familiarity with the other defendants and was advised of and had access to other members of the Company's management team, internal reports and other data and information about the Company's finances, operations, and sales at all relevant times; and (iv) each Individual Defendant was aware of the Company's dissemination of information to the investing public which they knew or recklessly disregarded was materially false and misleading.

215. The Individual Defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. The Individual Defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing ViroPharma's operating

condition from the investing public and supporting the artificially inflated price of its securities. As demonstrated by the Individual Defendants' misstatements and omissions of the Company's business and operations throughout the Class Period, the Individual Defendants, if they did not have actual knowledge of the misrepresentations and omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

216. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market price of ViroPharma's securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of ViroPharma's publicly-traded securities was artificially inflated, and relying directly or indirectly on the false and misleading statements made by the Individual Defendants, or upon the integrity of the market in which the securities trades, and/or on the absence of material adverse information that was known to or recklessly disregarded by the Individual Defendants but not disclosed in public statements by them during the Class Period, Plaintiff and the other members of the Class acquired ViroPharma's securities during the Class Period at artificially high prices and were damaged when the value of their securities declined upon disclosure of the truth about Defendants' false and misleading statements and omissions.

217. At the time of said misrepresentations and omissions, Plaintiff and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiff and the other members of the Class and the marketplace known the truth regarding ViroPharma's business, operations, and prospects, which were not disclosed by the Individual Defendants, Plaintiff and other members of the Class would not have purchased or otherwise

acquired their ViroPharma securities or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

218. As a direct and proximate result of the Individual Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

COUNT III

Claim for Violation of Section 20(a) of the Exchange Act Against the Individual Defendants

219. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein. This claim is asserted against the Individual Defendants.

220. During the Class Period, the Individual Defendants participated in the operation and management of ViroPharma, and conducted and participated, directly and indirectly, in the conduct of ViroPharma's business affairs. Because of their senior positions, they knew the adverse non-public information about ViroPharma's misstatements of financial guidance and the Company's operations.

221. As officers and/or directors of a publicly owned company, these Defendants had a duty to disseminate accurate and truthful information with respect to ViroPharma's financial condition and results of operations, and to promptly correct any public statements issued by ViroPharma that had become materially false or misleading.

222. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases, and public filings, as well as presentations to securities analysts, money and portfolio managers, and institutional investors, which ViroPharma disseminated in the marketplace

during the Class Period. They were provided with copies of the Company's reports and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause ViroPharma to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of ViroPharma within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of ViroPharma securities.

223. Because of their positions with the Company, and their access to material non-public information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false and misleading statements pleaded herein.

224. Each of the Individual Defendants, therefore, acted as a controlling person of ViroPharma. By reason of their senior management positions and/or being directors of ViroPharma, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause ViroPharma to engage in the unlawful acts and conduct complained of herein. Each Individual Defendant exercised control over the general operations of ViroPharma and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

225. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by ViroPharma.

XIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

A. Certifying this case as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as class representative and its counsel as class counsel;

B. Declaring that the Defendants violated §10(b) and Rule 10b-5 promulgated thereunder and that the Individual Defendants violated 20(a) of the Exchange Act;

C. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

D. Awarding Plaintiff and the Class appropriate compensatory damages;

E. Awarding Plaintiff and the other members of the Class the costs, expenses, and disbursements of this action, including attorneys' and experts' fees and, if applicable, prejudgment and post-judgment interest; and

F. Awarding Plaintiff and the Class such other relief as this Court deems just, equitable, and proper.

XV. JURY DEMAND

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiff hereby demands trial by jury of all issues that may be so tried.

Dated: New York, New York
October 19, 2012

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***In re ViroPharma Inc. Sec. Litig.*, Civil Action No. 12-2714, (E.D. Pa.)**

Appendix A: False and Misleading Statements from Supplemental Citizen's Petition

Statement in the Citizen's Petition Supplement	Defendants Failed to Tell ViroPharma Shareholders
The new Vancocin labeling also modified Vancocin's indication and for the first time specifies a recommended dosing regimen.	The December 14, 2011 Letter expressly advised Defendants that the FDA was not approving the label change for a new indication or new dosing regimen. *See* ¶87-88. The FDA told Defendants on February 18, 2011, May 20, 2011, May 24, 2011 and December 8, 2011 that the Genzyme Study was not an adequate and well-controlled study as it related to Vancocin, which the FDA requires to support any change in indication or new dosing regimen. See, ¶¶75-86, 93.
Indeed, Vancocin's indication itself was changed based on the new data, and now includes a new recommended dose of 125 mg q.i.d...	The December 14, 2011 Letter expressly advised Defendants that the FDA was not approving the label change for a new indication or new dosing regimen, and there was no "changed" indication for Vancocin based on the failed Genzyme Study. See ¶¶87-88. The FDA told Defendants on February 18, 2011, May 20, 2011, May 24, 2011 and December 8, 2011 that the Genzyme Study was not an adequate and well-controlled study as it related to Vancocin, which the FDA requires to support any change in dosing regimen. See, ¶¶75-86, 93.
Vancocin's labeling was fundamentally and extensively changed in the new sNDA with numerous new conditions of use.	The FDA told Defendants on February 18, 2011, May 20, 2011, May 24, 2011 and during the December 8, 2011 labeling teleconference that because the Genzyme Study was not an adequate and well-controlled study designed to test Vancocin against a control group, the new Vancocin label could only contain "descriptive" information describing Vancocin's performance in the Genzyme Study. ¶¶75-86. The Genzyme Study was thus inadequate to support a claim of efficacy for a new condition of use. *Id.* Therefore, the changes to the label do not qualify as a "fundamental change." The FDA told Defendants in the December 14, 2011 Letter that the sNDA was not being approved for a new condition of use such as a new indication or dosing regimen. ¶ 87 -88.

Statement in the Citizen's Petition Supplement	Defendants Failed to Tell ViroPharma Shareholders
Vancocin's previous *c. difficile* indication was changed based on the new studies, such that Vancocin is now "indicated for the treatment of *c. difficile* -associated diarrhea."	The FDA expressly told Defendants in the December 14, 2011 Letter that the sNDA was not being approved for a new indication. Thus, Vancocin's indication did not "change" on the new label. ¶¶87 -88. Vancocin had always been indicated to treat CDAD. The purpose of the Genzyme Study was to test non inferiority of tolvamer in CDAD—the infection that Vancocin was already indicated for. ¶¶37, 82. Any subtle language change in the new label was minor, and as the FDA informed Defendants on February 18, 2011, May 20, 2011, May 24, 2011 and December 8, 2011, was merely "descriptive." Thus, there was no change in indication "based on the new studies." ¶¶75-86, 93.
Vancocin's new Clinical Studies section explains what is meant by "C. difficile -associated diarrhea" in the new studies that led to this changed indication, as well as the efficacy endpoint by which resolution of CDAD was measured, and the new recommended Vancocin dose based on these studies…	The December 14, 2011 Letter expressly advised Defendants that the FDA was not approving the label change for a new indication. *See* ¶87-88. The FDA told Defendants on February 18, 2011, May 20, 2011, May 24, 2011 and December 8, 2011 that the Genzyme Study was not an adequate and well-controlled study as it related to Vancocin, which the FDA requires to support any change in indication. See, ¶¶75-86, 93. Thus, the Genzyme Study did not support a "changed indication"for Vancocin.
The new Vancocin studies led to the significant modification of Vancocin's previously labeled "usual" 500 mg to 2 g CDAD daily dosing range. For the first time Vancocin is now labeled with a "recommended" CDAD dose…	The FDA told Defendants on February 18, 2011, May 20, 2011, May 24, 2011 and December 8, 2011 that the Genzyme Study was not an adequate and well-controlled study as it related to Vancocin, which is required by the FDA to support any change in new dosing regimen. See, ¶¶75-86, 93. The FDA told Defendants in the December 14, 2011 Letter that the sNDA approval was not for a new dosing regimen. Moreove, the new "recommended" CDAD dose was subsumed in the old label's dosing range, and thus was not a "significant modification" or a new "recommended" dose. ¶¶87-88, 93.

Statement in the Citizen's Petition Supplement	Defendants Failed to Tell ViroPharma Shareholders
The new Vancocin studies also modified Vancocin's indication and for the first time included a recommended dose…	The FDA told Defendants in the December 14, 2011 Letter that the sNDA approval was not for a new indication or dosing regimen. ¶¶87-88, 93. Vancocin had always been indicated to treat CDAD. The purpose of the Genzyme Study was to test non inferiority of tolvamer in CDAD—the infection that Vancocin was already indicated for. ¶¶37, 82. Any subtle language change in the new label was minor, and as the FDA informed Defendants on February 18, 2011, May 20, 2011, May 24, 2011 and December 8, 2011, the Genzyme Study was not an adequate and well-controlled study as it related to Vancocin. See, ¶¶75-86, 93. Thus, there was no change in indication "based on the new studies" approved by the FDA. *Id.* It was misleading to refer to the failed Genzyme Study as the "new Vancocin studies…" in light of the above.
Vancocin's new exclusivity-protected labeling is extensive.	The new labeling was not "exclusivity-protected" for the reasons set forth in ¶¶96 and 99.
Generics also would have no indication, or recommended dosing regimen.	The December 14, 2011 Letter specifically informed Defendants that the label approval was not for a new indication or dosing regimen, ¶¶87-88. The new labeling was not "exclusivity-protected" for the reasons set forth in ¶¶96 and 99. Accordingly, generics would not be precluded from using the indications and dosing regimen on either the new or old Vancocin labels since the indications and dosing would not be protected by exclusivity.

Statement in the Citizen's Petition Supplement	Defendants Failed to Tell ViroPharma Shareholders
…the protected Vancocin labeling information derives from new controlled clinical data demonstrating the safety and efficacy of an old drug, as well as recommended dose for the drug…	The new labeling was not "exclusivity-protected." ¶¶96, 99. As the FDA informed Defendants on February 18, 2011, May 20, 2011, May 24, 2011 and December 8, 2011, the Genzyme Study was not an adequate and well-controlled study as it related to Vancocin. See, ¶¶75-86. Thus, the new label was not derived from "*new controlled clinical data demonstrating the safety and efficacy of"* Vancocin. As Defendants were well-aware from the December 14, 2011 Letter, the sNDA approval was not for a new recommended dose. ¶87-88.
Vancocin's CDAD indication, however, was one of the new changes to the Vancocin labeling approved in the recent sNDA, such that it is protected by Vancocin's new 3 year exclusivity. Therefore, to comply with the indication regulation and become approvable, generic vancomycin drug products must wait until Vancocin's 3 year exclusivity expires.	Vancocin had always been indicated to treat CDAD. The purpose of the Genzyme Study was to test non inferiority of tolvamer in CDAD—the infection that Vancocin was already indicated for. ¶¶37, 82. Defendants were expressly told by the FDA in the December 14, 2011 Letter that the sNDA approval was not for a new indication. ¶¶87-88. The new labeling was not "exclusivity-protected" for the reasons set forth in ¶¶96 and 99, and since there was no exclusivity, generic competitors did not have to wait three years to become approvable. *Id.*
Vancocin's CDAD indication is protected by Vancocin's new 3 year exclusivity, as explained above. Even if ANDA labeling could carry Vancocin's new indication and dosing regimen . . .	Vancocin was not protected by "new 3 year exclusivity." ¶¶96, 99. Defendants were expressly told by the FDA in the December 14, 2011 Letter that the sNDA approval *was not* for a new indication or dosing regimen. ¶¶87 - 88. ancocin had always been indicated to treat CDAD. The purpose of the Genzyme studies was to test non inferiority of tolevamer in CDAD—the infection that Vancocin was already indicated for. ¶37, 82.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing Amended Class Action Complaint for Violation of the Federal Securities Laws was served on the following parties via U.S. mail and electronic mail on October 19, 2012.

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