

ESTTA Tracking number: **ESTTA612941**

Filing date: **06/30/2014**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

| | |
|------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Proceeding | 91215035 |
| Party | Plaintiff Vertex Pharmaceuticals Incorporated |
| Correspondence Address | LISA M TITTEMORE SUNSTEIN KANN MURPHY & TIMBERS LLP 125 SUMMER STREET BOSTON, MA 02110 UNITED STATES ltittemore@sunsteinlaw.com, sabreu@sunsteinlaw.com |
| Submission | Motion to Dismiss - Rule 12(b) |
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| Signature | /Brandon T. Scruggs/ |
| Date | 06/30/2014 |
| Attachments | Vertex Motion to Dismiss Applicant Counterclaims without exhibits.pdf(150946 bytes) Exhibit 1 - Specimen from Reg 2704913.pdf(4810181 bytes) Exhibit 2 - Specimen from Reg 3531356.pdf(4400197 bytes) |

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

In the Matter of Application:

Serial No.: 85/887,894

Filed: March 27, 2013

Applicant: CHD Bioscience, Inc.

Mark: VERIOX

For: All-purpose disinfectants for medical instruments, healthcare facility surfaces, and for coating medical bandages; irrigation solutions, namely, medical cleansers for wounds; coatings for surgical implants and medical devices, namely, antimicrobial coatings to prevent the growth of viruses, bacteria, spores, biofilms and fungus on various surfaces; antibacterial creams and ointments for use in dental procedures; pharmaceutical preparations for the treatment of pulmonary infections; all-purpose disinfectants (Cl. 5); coatings sold as an integral component for medical sutures, medical bandages and implantable medical devices (Cl. 10)

Published: December 24, 2013

| | | |
|------------------------|---|--|
| VERTEX PHARMACEUTICALS |) | |
| INCORPORATED, |) | |
| |) | |
| Opposer, |) | |
| |) | |
| v. |) | |
| |) | |
| CHD BIOSCIENCE, INC., |) | |
| |) | |
| |) | |
| Applicant. |) | |

Opposition No. 91215035

PLAINTIFF’S MOTION TO DISMISS APPLICANT’S COUNTERCLAIMS

Pursuant to Fed. R. Civ. P. 12(b)(6), 37 C.F.R. § 2.116, and 37 C.F.R. § 2.127(d), Vertex Pharmaceuticals Incorporated (“Vertex” or “Opposer”) hereby moves to dismiss the counterclaims asserted by CHD Bioscience, Inc. (“Applicant”). Under Fed. R. Civ. P. 12(b)(6), a pleading may be dismissed if it fails to state a claim upon which relief can be granted. For reasons discussed below, primarily Applicant’s erroneous understanding of the law regarding

registration of a house mark for pharmaceutical preparations, Applicant's counterclaims fail to state a claim upon which relief can be granted and should therefore be dismissed.

**MEMORANDUM IN SUPPORT OF OPPOSER'S MOTION
TO DISMISS APPLICANT'S COUNTERCLAIMS**

Pursuant to Fed. R. Civ. P. 12(b)(6), Applicant's counterclaims should be dismissed. Applicant's counterclaims for fraud and cancellation are premised entirely on the erroneous premise that Opposer Vertex lacks sufficient use for a "house mark" for pharmaceutical preparations because Opposer Vertex currently only sells two commercial products. First, the USPTO has on numerous occasions accepted Vertex's filings relating to use of its marks in relation to its "house mark" registrations, and Applicant alleges no basis for questioning the veracity or adequacy of these filings. Moreover, the law is clear that, unlike a "full line" of pharmaceutical products, a showing of use in connection with two or three products is sufficient for a "house mark." Second, Applicant ignores Opposer's use of its marks in connection with products in clinical trials, shipments of which are considered use in commerce. Some of these clinical trial products are discussed in the very Annual Report cited by Applicant. Third, Applicant fails to sufficiently allege fraud, relying on mere conclusory recitations of the elements of fraud. For these reasons, Applicant's counterclaims should be dismissed, as discussed in more detail below.

A. Background

Applicant's Application Serial No. 85/887,894 for VERIOX covers "All-purpose disinfectants for medicinal instruments, healthcare facility surfaces, and for coating medical bandages; irrigation solutions, namely, medical cleaners for wounds; coatings for surgical implants and medical devices, namely, antimicrobial coatings to prevent the growth of viruses, bacteria, spores, biofilms and fungus on various surfaces; antibacterial creams and ointments for use in dental procedures; pharmaceutical preparations for the treatment of pulmonary infections;

all-purpose disinfectants.” Applicant’s Answer and Counterclaims, D.I. 6 (filed May 2, 2014) (hereinafter “Applicant’s Counterclaims”), at ¶ 1.

Opposer’s Registration Nos. 2,704,913 and 3,531,356 for VERTEX cover a “house mark for pharmaceutical preparations.” *Id.* at ¶ 2. Opposer has relied on these registrations, in part, to oppose Applicant’s Application Serial No. 85/887,894 for VERIOX. *Id.*

Applicant cites Opposer’s 2013 Annual Report and attaches this document to its counterclaims as Exhibit A. *Id.* at ¶¶ 5-6. Opposer’s 2013 Annual Report notes that since mid-2011, Vertex has obtained FDA approval for and initiated commercial sales of its first two products: KALYDECO (marketed for the treatment of cystic fibrosis) and INCIVEK (marketed for the treatment of the hepatitis C virus). *Id.* at ¶ 6. Applicant asserts that other than its KALYDECO and INCIVEK brands, Opposer “does not offer any other pharmaceutical products *for sale.*” *Id.* at ¶ 8 (emphasis added). Applicant does not address Opposer’s use of its marks in connection with pharmaceutical products in clinical trials. Nor does Applicant address Opposer’s use of its marks in connection with other pharmaceutical preparations, including AGENERASE and LEXIVA for the treatment of HIV.¹

Applicant filed two counterclaims, one for fraud (Count I) and one for cancellation or limitation (partial cancellation) of Opposer’s Registration Nos. 2,704,913 and 3,531,356 (Count II). *Id.* at ¶¶ 15-20; 21-25. Applicant’s grounds for fraud (Count I) appears to be that when Opposer filed various statements of use with the PTO for Opposer’s Registration Nos. 2,704,913 and 3,531,356, Opposer allegedly “knew that it did not have the broad use with pharmaceutical preparations required for a house mark for pharmaceutical preparations.” *Id.* at ¶ 11. *See also id.* at ¶¶ 12-14. Applicant’s grounds for cancellation (Count II) are similar. Applicant alleges

¹ AGENERASE and LEXIVA are HIV protease inhibitor drugs that were part of a collaboration between Opposer Vertex and GlaxoSmithKline. *See* Exhibit A to Applicant’s Counterclaims, at 58-59, F-9, F-34. Opposer Vertex has since sold its rights to the royalties for those products. *Id.*

that the identification of goods “house mark for pharmaceutical preparations” is overly broad with respect to Opposer’s Registration Nos. 2,704,913 and 3,531,356 because Applicant has allegedly “at most only used the mark in commerce with its pharmaceutical preparation KALYDECO for pharmaceutical preparations for the treatment of cystic fibrosis and INCIVEK for pharmaceutical preparations for the treatment of viral diseases.” *Id.* at ¶ 22. Applicant states that Opposer’s mark should either be cancelled or “limited to the goods: pharmaceutical preparations for the treatment of cystic fibrosis and viral diseases.” *Id.* at 8.

B. Legal Standards

“A complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.” *Ashcroft v. Iqbal*, 556 U.S. 662, 663 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). For purposes of a motion to dismiss, the Board must accept all well-pleaded allegations as true and draw reasonable inferences in the non-moving party’s favor. *Smith v. Entrepreneur Media, Inc.*, 2012 WL 10056747, at *2 (TTAB 2012). However, that rule does not apply to legal conclusions. *Rack Room Shoes v. U.S.*, 718 F.3d 1370, 1376 (Fed. Cir. 2013); *Iqbal*, 556 U.S. at 678. “Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.” *Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 555). Additionally, the Board is not required to indulge in unwarranted inferences in order to save a complaint from dismissal. *Entrepreneur Media*, 2012 WL 10056747, at *2; *Juniper Networks Inc. v. Shipley*, 643 F.3d 1346, 1352 (Fed. Cir. 2011). Similarly, a complaint will not suffice if it tenders “naked assertions” devoid of “further factual enhancement.” *Twombly*, 550 U.S. at 557.

In petitioning to cancel a trademark on the ground of fraud, a petitioner must allege the elements of fraud with particularity in accordance with Fed. R. Civ. P. 9(b), made applicable to Board proceedings by Trademark Rule 2.116(a). *Asian & Western Classics B.V. v. Selkow*, 92

U.S.P.Q.2d 1478, 2009 WL 3678263 (TTAB 2009). Under Rule 9(b), the pleadings must contain explicit rather than implied expression of the circumstances constituting fraud. *Id.* Pleadings without allegation of such specific facts are insufficient. *Id.*

It is proper to consider material attached to the counterclaims when deciding a motion to dismiss under Fed. R. Civ. P. 12(b)(6). *See In re Bill of Lading Transmission & Processing System Patent Litigation*, 681 F.3d 1323, 1337 n.9 (Fed. Cir. 2012) (because plaintiff attached substantial material to amended complaints, district court was authorized to consider that material on a motion to dismiss); *General Mills, Inc. v. Kraft Foods Global, Inc.*, 487 F.3d 1368, 1371 n.1 (Fed. Cir. 2007) (considering settlement agreement attached to amended complaint on review of a motion to dismiss).

In deciding whether to dismiss a complaint under Rule 12(b)(6), the Board may also consider matters of public record. *See Sebastian v. U.S.*, 185 F.3d 1368, 1374 (Fed. Cir. 1999). Specimens submitted for trademark registration are part of the public record. TMEP § 904 (“Interested parties ... may view and print images of the specimens in an application or registration file ... Furthermore, once filed, specimens remain part of the [public] record and will not be returned”).

C. Opposer Vertex’s Current Two Commercial Products Are Sufficient for a House Mark

The central premise behind both counts of Applicant’s counterclaims is the incorrect notion that two commercial products are insufficient to support a house mark. *See Applicant’s Counterclaims*, at ¶¶ 4, 8, 11-14, 22-23. Applicant seems to be confusing the requirements for a “house mark,” *see* TMEP 1402.03(b), with the more demanding requirements of a mark for a “full line of” pharmaceutical products, *see* TMEP 1402.03(c). Simply put, as few as two or three products are sufficient to support a “house mark,” although more may be required to support a

“full line” of pharmaceutical products. *See In re Astra Merck Inc.*, 50 U.S.P.Q.2d 1216, 1999 WL 221657, at *1 (TTAB 1998).

In *Astra Merck*, the relevant mark was used on three drugs. *Id.* at *1. The Board stated that if all of the drug manufacturer’s different pharmaceutical products bear a particular mark in common, then that mark is “obviously functioning as a house mark for that product line, regardless of the exact number of products in that product line.” *Id.* The Board reasoned that to hold the opposite would be to favor large companies with large product lines and to penalize smaller companies with smaller product lines, an obviously inequitable result. *Id.* “Small companies should be eligible for house mark registration as long as they have multiple products in their product line and they use the mark throughout the product line.” *Id.* Therefore, even if Opposer Vertex only had two products that it used its house mark on as Applicant alleges, this would be sufficient use to support a house mark. *See id.* at *1.

D. Applicant Fails to Account for Opposer’s Products in Clinical Testing, Shipments of Which Are Considered Use in Commerce

Additionally, Applicant counts only two Vertex products because it only looks to how many pharmaceutical products Vertex currently offers “for sale.” Applicant’s Counterclaim, at ¶ 8. This fails to account for shipments of Vertex’s drugs in clinical testing. The 2013 Annual Report that Applicant attached to its counterclaims shows that Opposer Vertex currently has at least three drugs currently in Phase 2 clinical trials: VX-135 (an HCV nucleotide analogue used in combination with another drug, an NS5A replication complex inhibitor); VX-509 (a JAK3 inhibitor for patients with rheumatoid arthritis); and VX-787 (a drug candidate for the treatment of influenza A). Exhibit A to Applicant’s Counterclaims, at 1, 9-10.² Additionally, the

² It is proper to consider material attached to the counterclaims when deciding a motion to dismiss under Fed. R. Civ. P. 12(b)(6). *See In re Bill of Lading Transmission & Processing System Patent Litigation*, 681 F.3d 1323, 1337 n.9 (Fed. Cir. 2012) (because plaintiff attached substantial material to amended complaints, district court was authorized to consider that material on a motion to dismiss); *General Mills*,

VERTEX mark has also been used on other pharmaceutical preparations, including AGENERASE and LEXIVA for the treatment of HIV,³ and other pharmaceutical preparations provided to patients during clinical research trials. *See, e.g.*, Exhibit 1 (specimen filed on April 28, 2008 in Registration No. 2,704,913 showing VERTEX mark used with AGENERASE oral solution and INCEL injection vials (for ovarian cancer) as well as clinical trial drugs VX-497, VX-745, VX-148, and VX-702); Exhibit 2 (specimen filed on Sept. 4, 2008 in Registration No. 3,531,356 showing VERTEX mark used with LEXIVA as well as clinical trial drugs VX-765 and VX-770).⁴

Use of a mark on shipments of drugs for clinical testing is sufficient use in commerce to show a protectable trademark interest. *Kythera Biopharmaceuticals, Inc. v. Lithera, Inc.*, --- F. Supp. 2d ----, 2014 WL 683827, at *5 (C.D. Cal. 2014) (plaintiff alleged sufficient facts to show protectable trademark interest where it alleged that its lead product was in Phase III clinical development); *G.D. Searle & Co. v. Nutrapharm, Inc.*, C.A. No. 98-cv-6890-TPG, 1999 WL 988533, at *3-4 (S.D.N.Y. Nov. 1, 1999) (Nutrapharm did not show that Searle failed to use the drug in commerce where Searle relied at least in part on shipments for clinical testing). In the legislative history discussing the 1989 Amendment to the Lanham Act, the Senate Judiciary Committee Report and the House Report cite a pharmaceutical company's shipment to clinical investigators during the FDA approval process as an example of sufficient use in commerce. *Id.* (citing S.Rep. No. 100-515, at 44-45 (1988); H.R. No. 100-1028, at 15 (1988)). *See also*

Inc. v. Kraft Foods Global, Inc., 487 F.3d 1368, 1371 n.1 (Fed. Cir. 2007) (considering settlement agreement attached to amended complaint on review of a motion to dismiss).

³ AGENERASE and LEXIVA are HIV protease inhibitor drugs that were part of a collaboration between Opposer Vertex and GlaxoSmithKline. *See* Exhibit A to Applicant's Counterclaims, at 58-59, F-9, F-34. Opposer Vertex has since sold its rights to the royalties for those products. *Id.*

⁴ In deciding whether to dismiss a complaint under Rule 12(b)(6), the Board may also consider matters of public record. *See Sebastian v. U.S.*, 185 F.3d 1368, 1374 (Fed. Cir. 1999). Specimens submitted for trademark registration are part of the public record. TMEP § 904 ("Interested parties ... may view and print images of the specimens in an application or registration file ... Furthermore, once filed, specimens remain part of the [public] record and will not be returned").

Paramount Pictures Corp. v. White, 31 U.S.P.Q.2d 1768, 1994 WL 484936, at *7, n.8 (TTAB 1994) (“commercial use ... should also be construed to encompass various genuine but less traditional trademark uses such as ... shipments of a new drug to clinical investigators from a company awaiting FDA approval”), *aff’d*, 108 F.3d 1392 (Fed. Cir. 1997); TMEP § 901.02. Also, the statute itself, at Section 45 of the Lanham Act, states that a mark shall be deemed to be “used in commerce” when the goods bearing the mark are sold *or transported* in commerce. *G.D. Searle*, 1999 WL 988533, at *3-4.

When Opposer Vertex’s two current commercial products and prior commercial and clinical trial products are taken together, Applicant’s allegation that Opposer does not have the use required for a house mark fails as a matter of law. *See In re Astra Merck Inc.*, 50 U.S.P.Q.2d 1216, 1999 WL 221657, at *1-3 (TTAB 1998) (three drug products were sufficient to support a house mark). Applicant’s allegations are limited to how many products Opposer Vertex offers “for sale.” *See* Applicant’s Counterclaims at ¶ 8. By failing to address products in clinical trials in its counterclaims, Applicant fails to allege sufficient facts to support its counterclaims as a matter of law. Thus, the Board should dismiss Applicant’s counterclaims.

E. Applicant’s Fraud Allegations Are Insufficient

Applicant’s fraud allegations (Count I) are grossly insufficient. A trademark is obtained fraudulently under the Lanham Act only if the applicant or registrant knowingly makes a false, material representation with the intent to deceive the PTO. *In re Bose Corp.*, 580 F.3d 1240, 1245 (Fed. Cir. 2009). There is no fraud if a false misrepresentation is occasioned by an honest misunderstanding or inadvertence without a willful intent to deceive. *Id.* at 1246. Unless the challenger can point to evidence to support an inference of deceptive intent, it fails to establish a fraud claim. *Id.*

Applicant has failed to allege sufficient facts to show a willful intent to deceive. Paragraphs 15 through 20 of Applicant's Counterclaims are little more than conclusory recitations of the elements of a fraud claim. Simply reciting the words "knowingly and willfully making false and/or fraudulent declarations" does not suffice to establish a fraud claim. *See, e.g.,* Applicant's Counterclaims, at ¶¶ 16-17. "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice" to avoid dismissal. *Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 555). Similarly, "naked assertions" devoid of "further factual enhancement" will not save a complaint from a motion to dismiss. *Twombly*, 550 U.S. at 557.

Given the law pertaining to house marks and clinical trial products discussed above, Opposer would be justified in believing that it had sufficient use for a house mark. At worst, if Opposer was wrong (which it is not), Applicant has done no more than allege facts that attempt to show Opposer made a mistake. *See* Applicant's Counterclaims, at ¶¶ 5-8. Applicant has failed to allege sufficient facts to show that Opposer actually knew its position was wrong and then argued that position with a willful intent to deceive the PTO. Without sufficient factual allegations to support that inference, Applicant fails to state a proper claim for fraud. *In re Bose*, 580 F.3d at 1245. There is no fraud if a false misrepresentation is occasioned by an honest misunderstanding or inadvertence without a willful intent to deceive. *Id.* at 1246. Accordingly, the Applicant's fraud counterclaim must be dismissed.

CONCLUSION

In light of the foregoing, justice requires that the Board grant Opposer's Motion to Dismiss the Applicant's Counterclaims.

Dated: Boston, Massachusetts
June 30, 2014

VERTEX PHARMACEUTICALS
INCORPORATED

By its attorneys,

/s/ Brandon T. Scruggs

Lisa M. Tittmore

Steven A. Abreu

Brandon T. Scruggs

SUNSTEIN KANN MURPHY & TIMBERS LLP

125 Summer Street

Boston, Massachusetts 02110-1618

(617) 443-9292

CERTIFICATE OF SERVICE

I hereby certify that a true and complete copy of the foregoing document has been served by email on June 30, 2014 to Applicant's Representative of Record, Mr. John J. O'Malley, Volpe and Koenig P.C., 30 South 17th Street, 18th Floor, Philadelphia, PA 19103, jomalley@vklaw.com.

/s/ Brandon T. Scruggs

Brandon T. Scruggs

01618/05109 2126539.1

EXHIBIT

1



Agenerase[™]
(amprenavir)
Oral Solution
15 mg/mL

NDC 0173-0687-00

Store at controlled room temperature of 25°C (77°F) (see USP).

See package insert for Dosage and Administration.

Agenerase (amprenavir) Oral Solution is not interchangeable on a mg/mg basis with Agenerase (amprenavir) Capsules.

US Patent No. 5,585,397

Licensed from
Vertex Pharmaceuticals Incorporated
Cambridge, MA 02139

AGENERASE is a trademark of the
Glaxo Wellcome group of companies.

Glaxo Wellcome Inc.
Research Triangle Park, NC 27709
Made in England

GlaxoWellcome

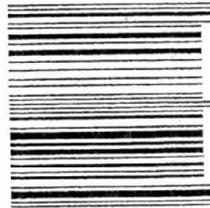


Agenerase[™]
(amprenavir)
Oral Solution
15 mg/mL

240 mL

Each mL contains 15 mg
of amprenavir.

Rx only



N 0173-0687-00 5

4113632
Rev. 4/99

WORK ORDER#: 615799

CLIENT: VERTEX PHARMACEUTICALS INC.

LABEL COPY PAGE 8 OF 15

PROJECT: VX99-497-003 *MASTER LABEL APPROVALS*

REV# 01 DATE - 03/29/00

ONE PANEL CODED SHIPPER LABEL
Kit No. XXX
Patient No. XYYYY (TO BE APPLIED AT THE TIME OF DISTRIBUTION)
CONTENTS: 1 SHIPPER x 1 KIT x 4 DISPENSERS x 24 BOTTLES
LASER PRINTED IN BLACK

Patient No. XYYYY

Vertex Clinical Study Medication
Kit No. XXX
Protocol VX99-497-003

1 shipper x 1 kit x 4 dispensers x 24 bottles of VX497 or Placebo
for administration as directed by clinical protocol.
The contents were prepared and manufactured under cGMP conditions.
Store at Controlled Room Temperature 59°F - 86°F
Avoid Excessive Humidity
Keep out of reach of children.
Caution: New Drug - Limited by United States
law to investigational use.


 Sponsor: Vertex Pharmaceuticals Incorporated
 130 Waverly Street, Cambridge, MA 02139 USA
 

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|--------------------------------|----------------------------------|--------------------------------|------------------------|
| <u>ALMEDICA</u> | <u>ALMEDICA</u> | <u>ALMEDICA</u> | CLIENT APPROVAL |
| Prepared By: <u>H. Kurpius</u> | QA-Review By: <u>[Signature]</u> | Checked By: <u>[Signature]</u> | By: _____ |
| Date: <u>03/29/00</u> | Date: <u>4/5/00</u> | Date: <u>4/5/00</u> | Date: _____ |

ALMEDICA

ALMEDICA SERVICES CORP. 150 HOPPER AVE, WALDWICK, NJ 07463 Tel(201)444 - 0300 Fax(201)444 - 9153 Form Rev. 01/04/99

WORK ORDER#: 639100

CLIENT: VERTEX PHARMACEUTICALS INC.

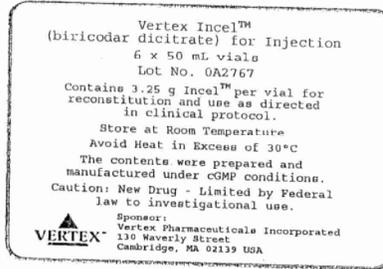
LABEL COPY PAGE 2 OF 3

PROJECT: INCEL™

REV# 00 DATE - 08/08/00

MDR Trial

ONE PANEL OPEN BOX END LABEL
Vertex Incel™ (bircodar dicitrate) for Injection
Lot No. 0A2767
6 x 50 mL vials
2/BOX
LASER PRINTED IN BLACK



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|------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|
| <p>ALMEDICA</p> <p>Prepared By: <u>D. Suppiah</u></p> <p>Date: <u>08/08/00</u></p> | <p>ALMEDICA</p> <p>QA-Review By: <u>Prayash B. Pruznick</u></p> <p>Date: <u>8/09/00</u> <u>8/09/00</u></p> | <p>ALMEDICA</p> <p>Checked By: <u>Donna Kowarska</u></p> <p>Date: <u>8/9/00</u></p> | <p>CLIENT APPROVAL</p> <p>By: <u>[Signature]</u></p> <p>Date: <u>76-Aug-00</u></p> |
|------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|

Bottle Label:

| | | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>VERTEX Protocol: VX00-853-105 Randomization No.: Contents: Each bottle contains 14 tablets. Directions: Take 1 tablet every morning on an empty stomach, at least one hour before a meal or two hours afterwards. Store at room temperature 15°-30° C (59°-86°F). Keep this and all medication out of reach of children. Caution: New Drug - Limited by Federal Law to Investigational Use. Mfg. for Vertex Pharmaceuticals, Inc. Cambridge, MA 02139-4242 USA</p> | <p>VERTEX Protocol: VX00-853-105 Randomization No.: Contents: Each bottle contains 14 tablets. Directions: Take 1 tablet every morning on an empty stomach, at least one hour before a meal or two hours afterwards. Store at room temperature 15°-30° C (59°-86°F). Keep this and all medication out of reach of children. Caution: New Drug - Limited by Federal Law to Investigational Use. Mfg. for Vertex Pharmaceuticals, Inc. Cambridge, MA 02139-4242 USA</p> | <p>Unblinding Panel covered by scratch off laminate.</p> <div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 10px auto;"><p>This vial contains: Group X Medication Xxmg amcodar. Lot No.: XXXXXXXX</p></div> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Carton Label:

| |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>VERTEX Protocol: VX00-853-105 Randomization No.: Contents: Four (4) bottles each containing 14 tablets. Directions: Take 1 tablet every morning on an empty stomach, at least one hour before a meal or two hours afterwards. Store at room temperature 15°-30° C (59°-86°F). Keep this and all medication out of reach of children. Caution: New Drug - Limited by Federal Law to Investigational Use. Mfg. for Vertex Pharmaceuticals, Inc. Cambridge, MA 02139-4242 USA</p> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

WORK ORDER #: 703501

CLIENT: Vertex Pharmaceuticals Inc.

LABEL APPROVAL PAGE 1

PROJECT: Protocol VX01-745-201- 3rd Packaging

REV# 00 DATE - 05/25/01

ONE PANEL OPEN BOTTLE LABEL
* COHORT 1 *
Contents: 68 VX-745 125 mg capsules
LASER PRINTED IN BLACK

Vertex Clinical Study Medication

Protocol VX01-745-201 Batch No. B00265

Pt# _____ Pt Initials _____ Date Dispensed _____

Take 2 capsules three times daily every 6-8 hours with 6-8 oz of water within 30 minutes of eating a meal or snack (take 2 capsules in the morning, 2 midday, and 2 before bed)

Contents: 68 VX-745 125 mg capsules
Keep out of reach of children.
Store at controlled room temperature 59°F - 86°F

Caution: New Drug Limited by United States law to investigational use.
Vertex Pharmaceuticals Incorporated
130 Waverly Street
Cambridge, MA 02139 USA



| | | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|
|  Prepared By: <u>B. Kowarska</u> Date: <u>5/25/01</u> |  Checked By: <u>Bonca Kowarska</u> Date: <u>5/25/01</u> |  QA-Review By: <u>MM</u> <u>Arad</u> Date: <u>5-29-01</u> <u>5/29/01</u> | CLIENT APPROVAL By: <u>[Signature]</u> Date: <u>5/1/01</u> <u>04-Jun-01</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|

Quintiles Clinical Supplies

LABEL TEXT APPROVAL DOCUMENTATION SHEET

| | | |
|--------------------------------|------------------------|-----------------------------------------------|
| Client: Vertex Pharmaceuticals | Protocol: VX02-148-101 | Quintiles Clinical Supplies Proposal# 1487004 |
|--------------------------------|------------------------|-----------------------------------------------|

Label Text File Name = 1487004Qkit.V2.LBZ
 File Description = Single panel label for quarterly carton, Icelandic translation

Label stock# L402.1
 Label color: white
 Blinding stock# NA

Printer Driver: PCL 6

Protocol Number/ Númer rannsóknaráætlunar VX02-148-101

Kit#/Samstæða # XXXXX
 Store Refrigerated Between 2-8°C
 Geymið við 2°C-8°C (í kæli)

Retest Date/Dagsetning endurprófunar: XX-XXX/XXX-XXXX
 Patient Initials/Upplafstafr sjúklings: _____

This carton contains a 3 month supply of blister cards containing capsules of VX-148 and/or placebo for oral administration.

Þessi pakki inniheldur 3ja mánaða birgðir af þynnupökkningum sem innihalda hylki með VX-148 og/eða lyfleysu til inntöku.

Directions: Take four capsules every twelve hours with food and water.
 Leiðbeiningar: Takið fjögur hylki í senn á tólf tíma fresti með mat og vatni.

May include colouring agent E110. See your study physician for more information.
 Getur innihaldið litarefni E110. Nánari upplýsingar fást hjá rannsóknarlækni.

CAUTION: For Clinical Trial Use Only.
 ADVÖRUN: Aðeins til nota í klínískum rannsóknum.

KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.
 GEYMIÐ FAR SEM BÖRN HVORKI NÁ TIL NÉ SJÁ.

Manufactured by/Framleitt af:
 RP Scherer
 2725 Scherer Drive
 St. Petersburg, FL 33716 USA



Sponsor/Kostfremendur:
 Vertex Pharmaceuticals Incorporated
 130 Waverly Street
 Cambridge, MA 02139 USA

| SAMPLE LABEL QCS APPROVAL | |
|------------------------------|---------|
| DATE | INITIAL |
| 29 July 02 | SS |
| 29 July 02 | KW |

| SAMPLE LABEL CLIENT APPROVAL | |
|---------------------------------|--------------------|
| DATE | NAME |
| 31-51-02 | <i>[Signature]</i> |
| 01 Aug 02 | <i>[Signature]</i> |
| 01 Aug 02 | <i>[Signature]</i> |
| 31-July 02 | <i>[Signature]</i> |

RA
QA
Cindy

If acceptable, please sign and date form and return original to:

Quintiles Clinical Supplies, 12000 Commerce Parkway, Mount Laurel, NJ 08054

If timing is an issue, please fax copies to (856) 727-0924

If changes are needed, make corrections directly on label and return forms without signing

(Ref: SOP 9.1 and 9.4) Form 10015303.XLS 27 JUL 01

METRICS INC.
CTM PACKAGING AND LABELING RECORD

| | |
|----------------------------------------|-------------------------------------|
| Product Placebo for VX-702 Capsules | Metrics, Inc. Batch No. 2A001-P2 |
|----------------------------------------|-------------------------------------|

Client Approval of CTM Labels

Proposed Label



VERTEX
Placebo for VX-702 Capsules
(For Oral Administration)

Metrics, Inc. Batch No. 2A001-P2 Quantity: 100 Capsules/Bottle
 Store at 2-8°C Retest Date: February, 2003

Directions: For dosing as detailed in Vertex clinical study protocol
 VX02-702-004

Caution: New Drug-Limited by United States Law to Investigational Use Only
 "For Clinical Trial Use Only"

KEEP ALL MEDICINES OUT OF REACH OF CHILDREN

| | |
|--------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|
| <p>Sponsor Vertex Pharmaceuticals, Inc. 130 Waverly Street, Cambridge, MA 02139</p> | <p>Manufacturer Metrics, Inc. 1240 Sugg Parkway Greenville, NC 27834</p> |
|--------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|

Client Approval: David Roberts 10th Oct-02
 (Name) (Date)

Bruce Aronson 10/10/02

[Signature] 10-OCT-02

Robert Walden 10/10/02

[Signature] 10/10/02

| | |
|------------------------------------|-----------------------|
| Responsible Scientist: <u>P.S.</u> | Date: <u>10/10/02</u> |
| QA Review by: <u>[Signature]</u> | Date: <u>10/10/02</u> |

METRICS INC.
CTM PACKAGING AND LABELING RECORD

| | |
|-------------------------------------------------------|-------------------------------------|
| Product VX-702 Capsules, 2.5 mg VX-702 per capsule | Metrics, Inc. Batch No. 2A003-P1 |
|-------------------------------------------------------|-------------------------------------|

Client Approval of CTM Labels

Proposed Label

| | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------|
|  VERTEX VX-702 Capsules, 2.5 mg VX-702 per Capsule (For Oral Administration) | |
| Metrics, Inc. Batch No. 2A003-P1 | Quantity: 100 Capsules/Bottle |
| Store at 2-8°C | Retest Date: February, 2003 |
| Directions: For dosing as detailed in Vertex clinical study protocol VX02-702-004 | |
| Caution: New Drug-Limited by United States Law to Investigational Use Only "For Clinical Trial Use Only" | |
| KEEP ALL MEDICINES OUT OF REACH OF CHILDREN | |
| Sponsor Vertex Pharmaceuticals, Inc. 130 Waverly Street, Cambridge, MA 02139 | Manufacturer Metrics, Inc. 1240 Sugg Parkway Greenville, NC 27834 |

Client Approval: David Roberts 10th Oct-02
(Name) (Date)

[Signature] 10/10/02

[Signature] 10-10-02

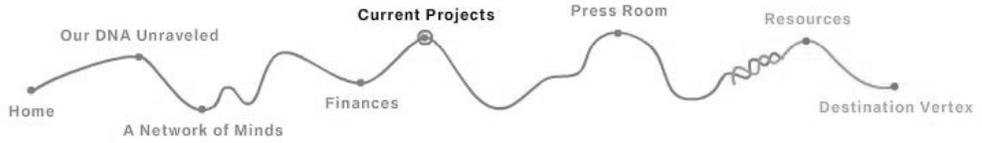
[Signature] 10/10/02

[Signature] 10/10/02

| | |
|------------------------------------|-----------------------|
| Responsible Scientist: <u>P.L.</u> | Date: <u>10/10/02</u> |
| QA Review by: <u>[Signature]</u> | Date: <u>10/10/02</u> |

EXHIBIT

2



Current Projects

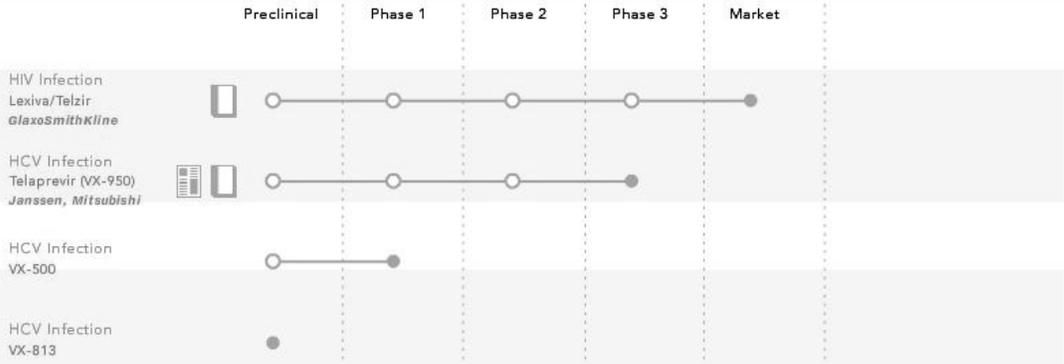
Adjust Font Find things fast here... Search

The opportunity to redefine the treatment of major diseases is what drives everyone at Vertex. Our development portfolio represents the fruit of these efforts. Spend some time here and look around. Click on the pipeline chart to get information on our development programs and links to selected published articles. Go further and see how, just maybe, disease challenges may be overcome with innovation.

Development Pipeline

Click on product or disease for more information. Mouse over chart for more information.

- Drug Candidates
- Development Paradigms
- Clinical Trials
- Investigator Database
- Strategic Alliances
- Press Releases



HCV Infection
VX-813



Bacterial Infection
VX-883



Cystic Fibrosis
VX-770
CF Foundation



Cystic Fibrosis
VX-809
CF Foundation



Cancer
MK-0457 (VX- 680)
Merck



Cancer
VX-689
Merck



Cancer
AVN-944 (VX-944)
Avalon



Rheumatoid Arthritis
VX-702



Inflammatory Diseases
VX-509



Vertex Clinical Study Protocol VX06-770-101

" For Clinical Trial Use Only "

**"Caution New Drug - Limited by Federal law to investigational use."
Investigational Drug. To be used by Qualified Investigator Only**

KEEP OUT OF REACH OF CHILDREN.

Store refrigerated. Keep bottle tightly closed.

Contains: 35 Placebo tablets

Lot/Batch No.: XXXX

VERTEX™

Study Sponsor:

Vertex Pharmaceuticals Incorporated

130 Waverly Street, Cambridge, MA 02139 USA

1 617 444 6777

Protocol Number / Numéro de protocole: VX04-765-301

Kit Number: / Nécessaire n°: XXXX Contents: 60 tablets / Contenu: 60 comprimés

Lot No.: / Lot n°: XXXX

Expiry Date: / Date de péremption: XX-XXXX

Bottle #2 "VX-765, 300 mg Tablets" or "Placebo Tablets" for Oral Administration

Bouteille n°2 « VX-765, comprimés de 300mg » ou « Comprimés placebos » pour administration par voie orale

Directions: Take two tablets from bottle #2 by mouth every 8 hours, as directed by the study physician.

Mode d'emploi: Prendre deux comprimés de la bouteille n° 2 par la bouche, à toutes les 8 heures, selon les indications du médecin de l'étude.

"Caution New Drug - Limited by US Law to Investigational Use."

"Caution Investigational Drug - To be used by Qualified Investigators Only."

<< Attention - drogue nouvelle - utilisation restreinte aux fins de recherche en vertu des lois des États-Unis >>

<< Attention - drogue expérimentale - utilisation réservée aux chercheurs qualifiés. >>

Store below 86° Fahrenheit (30° Celsius)

Garder à une température inférieure à 30° Celsius

KEEP OUT OF REACH OF CHILDREN.

GARDER HORS DE LA PORTÉE DES ENFANTS.

Study Sponsor/Commanditaire de l'étude:

Vertex Pharmaceuticals Incorporated

130 Waverly Street

Cambridge, MA 02139 USA

Manufactured by/Fabriqué par:

Melrice

1240 Sugg Parkway

Greenville, NC 27834 USA

**VERTEX**

Vertex Clinical Study Protocol VX06-770-002

Contains: 35 VX-770, 50mg, tablets

Directions: For administration as detailed in Vertex Clinical Study Protocol VX06-770-002

" For Clinical Trial Use Only "

"Caution New Drug - Limited by Federal law to investigational use."

KEEP OUT OF REACH OF CHILDREN.

Store refrigerated. Keep bottle tightly closed.

Allow 1 hour after removal from refrigerator before opening.

Lot/Batch No.: XXXX

Manufactured by:
Aptuit
10245 Hickman Mills Dr.
Kansas City, MO 64137



Study Sponsor:
Vertex Pharmaceuticals Incorporated
130 Waverly Street,
Cambridge, MA 02139 USA

Vertex Clinical Study
Protocol VX05-950-104



I. XXXXX

II. 16547

III. 02/2007



IV. _____ V. _____

VI. _____

VII. _____

Vertex Pharmaceuticals Incorporated
130 Waverly Street
Cambridge, MA 02139 USA

L146008

VX07-950-108



Vertex Pharmaceuticals Incorporated
130 Waverly Street,
Cambridge, Massachusetts 02139, USA
+1 617 444 6777

(I) VX07-950-108

(II) _____

(III) _____

(IV) _____

(V) _____

(VI) 209681

(VII) 08/2010

(VIII) 2007-004720-20

| | |
|--------------------------------|----|
| Polish..... | 1 |
| German (Germany, Austria)..... | 2 |
| Hebrew (Israel)..... | 3 |
| Italian..... | 4 |
| French (France)..... | 5 |
| French (Canada)..... | 6 |
| Spanish (Spain)..... | 7 |
| Spanish (Argentina)..... | 8 |
| English (Australia)..... | 9 |
| English (UK)..... | 10 |
| English (US)..... | 11 |

#3

Tell your patients about the
Patient Support Coupon Card.
 They may receive up to \$50 off
 their out-of-pocket costs for 2 years.*

*Subject to eligibility. Restrictions apply.



LEXIVA
 fosamprenavir calcium
 700 MG TABLETS

Information for the Healthcare Provider

Healthcare Provider, please do the following:

1. Write and sign a prescription for Lexiva.
2. If you are filling a prescription, please provide the patient with a copy of the Patient Support Coupon Card.
3. If you are filling a prescription, please provide a copy of the Patient Support Coupon Card to the patient.

Information for the Patient

Present this card to your pharmacist when you pick up your Lexiva. This card will be used to apply for a discount on your Lexiva. The card is valid for 2 years from the date of issue.



VERTEX

WE LIFE

GSK GlaxoSmithKline

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