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12 UNITED STATES DISTRICT COURT
13
14 NORTHERN DISTRICT OF CALIFORNIA

15 In re GILEAD SCIENCES SECURITIES)
LITIGATION)

Case No. C-03-4999-SI

16) CLASS ACTION

17 _____)
18 This Document Relates To:)

19 ALL ACTIONS.)
20 _____)

PLAINTIFFS' MEMORANDUM OF
POINTS AND AUTHORITIES IN
OPPOSITION TO DEFENDANTS' MOTION
TO DISMISS THE FOURTH
CONSOLIDATED AMENDED
COMPLAINT

21 Date: June 5, 2009
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24 Judge: Honorable Susan Illston

25 Trial Date: None set

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DEFENDANTS' MOTION TO DISMISS THE FOURTH CONSOLIDATED AMENDED COMPLAINT
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TABLE OF CONTENTS

		Page
1		
2	I. STATEMENT OF THE ISSUES.....	1
3	II. INTRODUCTION	1
4	III. PROCEDURAL HISTORY.....	2
5	IV. STATEMENT OF THE FACTS	2
6	A. The Illegal Off-Label Marketing Scheme Materially Inflated Viread Sales	2
7	B. Defendants’ Off-Label Marketing Resulted in Increased Sales of Viread in	
8	the 2Q2003.....	4
9	C. Defendants Sustained the Illusion of Increased Demand for Viread.....	6
10	V. ARGUMENT.....	8
11	A. Plaintiffs Adequately Pleaded Falsity.....	9
12	1. Defendants’ Created a False Impression of Viread Demand.....	9
13	2. Defendants Had a Duty to Disclose the Illegal Off-Label	
14	Marketing Scheme	11
15	B. The Confidential Witnesses Are Sufficiently Reliable.....	12
16	C. Plaintiffs Adequately Pleaded Materiality	15
17	1. Materiality Should Not be Decided on a Motion to Dismiss.....	15
18	2. Defendants’ Off-Label Marketing Resulted in Material Viread	
19	Sales and Materially Artificially Inflated Viread Demand,	
20	Including During 2Q2003	16
21	D. Plaintiffs Adequately Pleaded Scienter.....	20
22	1. The FAC Raises a Strong Inference that Defendants’ Knew of the	
23	Off-Label Marketing Scheme	21
24	2. Each Individual Defendant’s Knowledge of the Off-Label	
25	Marketing Scheme and Wholesaler Overstocking is Reasonably	
26	Inferred and Corroborated by the Importance of Viread Sales and	
27	Defendants’ Positions at the Company	22
28	3. Insider Stock Sales Support A Strong Inference Of Scienter	23
	4. Viewed Holistically, the FAC Pleads a Strong Inference of	
	Scienter	24
	E. Plaintiffs Adequately Pleaded Control Person Liability.....	25

VI. LEAVE TO AMEND25

1
2
3
4
5
6
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9
10
11
12
13
14
15
16
17
18
19
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2 **FEDERAL CASES**

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4 No. 07-61057-CV, 2008 WL 5749572 (S.D. Fla. Nov. 7, 2008)13

5 *In re AOL Time Warner, Inc. Sec. & “ERISA” Litig.,*
6 02 Civ. 5575, 2004 WL 1810661 (S.D.N.Y. Aug. 12, 2004).....15

7 *In re Adaptive Broadband Sec. Litigation,*
8 2002 U.S. Dist. LEXIS 5887 (N.D. Cal. Apr. 2, 2002).....25

9 *In re Amgen, Inc. Sec. Litigation,*
10 544 F. Supp. 2d 1009 (C.D. Ca. 2008) *passim*

11 *In re Asyst Techs., Inc. Deriv. Litigation,*
12 No. C-06-04699, 2008 U.S. Dist. LEXIS 96834 (N.D. Cal. Nov. 12, 2008)24

13 *Bradley v. Chiron Corp.,*
14 136 F.3d 1317 (Fed. Cir. 1998)15

15 *Brody v. Transitional Hospitals Corp.,*
16 280 F.3d 997 (9th Cir. 2002)11, 12

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18 No. 02-cv-72004, 2005 U.S. Dist. LEXIS 439 (E.D. Mich. Jan. 7, 2005)19

19 *In re Connectics Corp. Sec. Litigation,*
20 2008 U.S. Dist. LEXIS 62515 (N.D. Cal. Aug. 14, 2008) *passim*

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22 588 F. Supp. 2d 1132 (C.D. Cal. 2008)22

23 *In re Daou,*
24 411 F.3d 1006 (9th Cir. 2005)13

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26 548 F. Supp. 2d 1126 (S.D. Cal 2008).....10

27 *Ellingson v. Burlington Northern, Inc.,*
28 653 F.2d 1327 (9th Cir. 1981)15

Eminence Capital L.L.C. v. Aspeon, Inc.,
316 F.3d 1048 (9th Cir. 2003)25

Fecht v. Price Co.,
70 F.3d 1078 (9th Cir. 1995)16

1	<i>Gebhardt v. ConAgra Foods, Inc.</i> ,	16
	335 F.3d 824 (8th Cir. 2003)	
2	<i>In re Genta, Inc. Securities Litigation</i> ,	
3	No. 04-2123, 2005 U.S. Dist. LEXIS 22857 (D.N.J. Sept. 29, 2005).....	23
4	<i>In re Gilead Sciences Sec. Litigation</i> ,	
5	536 F.3d 1049 (9th Cir. 2008)	1, 2, 9, 10
6	<i>Glenbrook Capital Ltd. Partnership v. Kuo</i> ,	
	No. C07-02377, 2008 U.S. Dist. LEXIS 80888 (N.D. Cal. Apr. 3, 2008)	21
7	<i>Higginbotham v. Baxter International, Inc.</i> ,	
8	495 F.3d 753 (7th Cir. 2007)	13
9	<i>In re Immune Response</i> ,	
	375 F. Supp. 2d 983 (S.D.N.Y. 2005)	16, 17
10	<i>Lopez v. Smith</i> ,	
11	203 F.3d 1122 (9th Cir. 2000)	25
12	<i>In re New Century</i> ,	
13	588 F. Supp. 2d 1206 (C.D. Cal. 2008)	24
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15	No. 06 Civ. 3410, 2007 WL. 1976589 (D. Utah July 3, 2007)	15
16	<i>No. 84 Employer-Teamsters v. America West</i> ,	
	320 F.3d 920 (9th Cir. 2003)	16, 17, 22
17	<i>Nursing Home Pension Fund v. Oracle Corp.</i> ,	
18	380 F.3d 1226 (9th Cir. 2004)	8
19	<i>PEA Government Serv's, Inc., v. MPRI, Inc.</i> ,	
20	514 F.3d 856 (9th Cir. 2007)	15
21	<i>In re Petco Animal Supplies Inc. Sec. Litig.</i> ,	
	05-cv-2006, U.S. Dist. LEXIS 97927 (S.D. Cal. July 31, 2006).....	16
22	<i>In re PXRE Group Ltd., Sec. Litigation</i> ,	
23	No. 06 Civ. 3410, 2009 WL. 539864 (S.D.N.Y. Mar. 4, 2009)	15
24	<i>Ronconi v. Larkin</i> ,	
	253 F.3d 423 (9th Cir. 2001)	23
25	<i>In re Silicon Graphics, Inc. Sec. Litig.</i> ,	
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2		
3	<i>South Ferry LP v. Killinger</i> , 542 F.3d 776 (9th Cir. 2008)	20, 22, 23, 24
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5		
6	<i>Tellabs, Inc. v. Makor Issues & Rights, Ltd.</i> , 551 U.S. 308, 127 S. Ct. 2499 (2007).....	13, 20, 24
7		
8	<i>U.S. v. Parke-Davis, Division of Warner-Lambert Co.</i> , 147 F. Supp. 2d 39 (D. Mass. 2001).....	19
9	<i>In re Unumprovident Corp. Sec. Litigation</i> , 396 F. Supp. 2d 858 (E.D. Tenn. 2005).....	15
10		
11	<i>In re Westinghouse Sec. Litigation</i> , 832 F. Supp. 948 (W.D. Pa. 1993).....	19
12		
13	<i>Zucco Partners v. Digimarc Corp.</i> , 552 F.3d 981 (9th Cir. 2009)	13, 14, 20

FEDERAL STATUTES

15	15 U.S.C. § 78u-4(b)(2)	20
16	Fed. R. Civ. P. 8	16
17	Fed R. Civ. P. 9(b)	19
18	Fed. R. Civ. P. 15(a)	1

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1 **I. STATEMENT OF THE ISSUES**

2 1. Whether Plaintiffs sufficiently allege Defendants are liable under: (i) §10(b) of
3 the Securities Exchange Act of 1934 (the “Exchange Act”) for making false and misleading
4 statements of material fact with scienter; and (ii) §20(a) of the Exchange Act as control persons.

5 **II. INTRODUCTION**

6 Plaintiffs’ Fourth Consolidated Amended Class Action Complaint dated December 2,
7 2005 (the “FAC”) satisfies the pleading requirements of the Private Securities Litigation Reform
8 Act (the “PSLRA”), the Exchange Act, and the Federal Rules of Civil Procedure. This Court
9 already found Plaintiffs adequately alleged Defendants engaged in and had knowledge of Gilead
10 Sciences, Inc.’s (“Gilead” or the “Company”) illegal off-label marketing of Viread. Further, on
11 appeal, the Ninth Circuit held the FAC satisfies the pleading requirements for loss causation.
12 *See In re Gilead Sciences Sec. Litig.*, 536 F.3d 1049 (9th Cir. 2008) (“*Gilead*”)

13 The FAC details how Defendants’ fraud was effectuated, what it entailed, the product it
14 involved, when it started, who participated in it or turned a blind eye toward it, and the FDA’s
15 actions arising therefrom.¹ The FAC also demonstrates Defendants’ off-label marketing scheme
16 was material and should have been disclosed. The FAC alleges 75%-95% of domestic Viread
17 sales during the Class Period were caused by off-label marketing by, among other things,
18 providing numerous facts showing a relationship among the off-label marketing of Viread,
19 related sales of Viread, and the manner in which those sales affected Gilead’s Second Quarter
20 2003 (“2Q2003”) financial reports.² In sum, the FAC demonstrates that Defendants’ illegal off-
21 label marketing of Viread was intentional and made Gilead’s Class Period statements false and
22 misleading.

23

24

25 ¹ Key details relating to Defendants’ off-label marketing activities are set forth in the FAC. (¶50
26 through ¶140.) Unless otherwise indicated, “¶__” refers to paragraphs of the FAC.

27 ² In addition, Defendants’ fraud is material because any investor would consider the fact that
28 Gilead’s sales were built on illegal acts to be significant.

1 Because the Ninth Circuit already held the FAC sufficiently alleged loss causation, and
2 because the FAC sufficiently alleges falsity, scienter, and materiality, Defendants' motion to
3 dismiss (the "Motion" or "Mem at ___") should be denied.

4 **III. PROCEDURAL HISTORY**

5 Pursuant to an Order dated October 11, 2005 (the "Order"), Judge Jenkins dismissed
6 Plaintiffs' Third Amended Complaint (the "TAC") for failure to adequately allege loss causation,
7 but found Plaintiffs "adequately alleged that Defendants engaged in an illegal off-label
8 marketing scheme" and that it was "apparent that Plaintiffs have alleged sufficient facts to raise a
9 strong inference that Defendants had knowledge of the company's off-label marketing scheme."
10 Order at 9. On December 2, 2005, Plaintiffs filed the FAC, which Judge Jenkins dismissed with
11 prejudice on May 12, 2006, again finding Plaintiffs had not adequately alleged loss causation.
12 On August 11, 2008 the Ninth Circuit reversed the District Court's dismissal and found Plaintiffs
13 sufficiently alleged loss causation and economic loss. *See Gilead*, 536 F.3d at 1057-58. The
14 case was remanded, and Defendants once again seek dismissal of the FAC.³

15 **IV. STATEMENT OF THE FACTS**

16 Plaintiffs respectfully refer the Court to the FAC as well as the Ninth Circuit's opinion
17 for a full recitation of the facts. *See Gilead*, 536 F.3d at 1050-1054. Set forth below is a
18 discussion of factual allegations in the FAC relating to the arguments made by Defendants in
19 their Motion.

20 **A. The Illegal Off-Label Marketing Scheme Materially Inflated Viread 21 Sales**

22 Gilead is subject to the federal Food, Drug and Cosmetic Act and its implementing
23 regulations, which set forth the manner in which pharmaceutical manufacturers can market their

24
25 ³ On February 6, 2009, Defendants filed a Petition for Writ of Certiorari (the "Petition") with the
26 Supreme Court of the United States seeking reversal of the Ninth Circuit's opinion. On March
27 16, 2009, Plaintiffs filed their brief in opposition to the Petition and on March 31, 2009,
Defendants filed their reply brief.. This Court previously ruled this action would not be stayed
during the pendency of the Petition.

1 products. (¶50.) Pharmaceutical manufacturers may only promote their products consistent with
2 FDA-approved labeling (the “Package Labeling”). (*Id.*) Use of non-FDA approved materials is
3 “off-label” marketing, and is illegal. (¶53.) Sales of Viread, an antiretroviral agent used in
4 combination with other drugs for the treatment of HIV infection, at all relevant times, accounted
5 for nearly 65% of Gilead’s total revenues, and Viread sales were an important measure of
6 Gilead’s performance and stock price. (¶2.) The investing public and Wall Street analysts
7 looked to Viread’s sales in order to gauge whether Gilead’s business was on track and growing.
8 (¶¶2-4.) Defendants, therefore, were motivated to report impressive Viread sales in order to
9 maintain Gilead’s stock price. (¶¶4,7.)

10 Defendants’ marketing plan for Viread always included aggressive off-label marketing.
11 Following Viread’s approval in October 2001, Gilead immediately trained, directed and expected
12 its employees to use off-label information to increase sales of the drug. (*See, e.g.*, ¶¶69-77, 79-
13 84, 87-90.) At national and regional sales meetings, Gilead provided its sales staff with updates
14 regarding ongoing Viread clinical trials, the results of which, until approved by the FDA, were
15 off-label. (¶¶70-71.) Gilead’s sales staff, throughout the country, was given off-label
16 information, trained to use it, and instructed that it was not only acceptable, but encouraged, to
17 off-label market Viread. (¶¶74-79.)

18 Defendants’ egregious conduct did not go unnoticed. Indeed, the FDA twice, in a March
19 14, 2002 letter (the “Untitled FDA Letter”) and again in a July 29, 2003, issued a cease and
20 desist directive to Gilead (the “FDA Warning Letter”), condemning Gilead’s off-label marketing
21 and ordered Gilead to stop the practice.⁴ (¶¶78, 91-121, 125-33.) The Untitled FDA Letter
22 documented Gilead’s off-label marketing – Gilead stated Viread contained “no toxicities,” was
23 “extremely safe,” and was “extremely well-tolerated” – contrary to the FDA Labeling. (¶92.)
24 The Untitled FDA Letter further stated Gilead “engaged in false and misleading promotional
25 activities about the efficacy of Viread,” improperly claimed Viread was “approved for a broad

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27 ⁴ It was company knowledge that Martin was the cause of the Untitled FDA Letter. (¶78.)

1 indication,” and characterized Viread as a “miracle drug.” (*Id.*) The Untitled FDA Warning
2 Letter ordered Gilead to immediately cease making such violative statements. (¶93.) Gilead did
3 not disclose the Untitled FDA Letter or its response thereto, and never stopped its illegal off-
4 label marketing scheme.

5 For the next fourteen months, Gilead continued to hold meeting after meeting, during
6 which it’s sales and marketing team was provided off-label information and instructed on its use
7 to increase Viread sales. (¶¶95-125.) When the FDA Warning Letter was issued, it stated
8 Gilead’s lies were so outrageous they created a new “intended use” for Viread, causing it to be
9 misbranded, and that Gilead’s repeated omissions and misrepresentations regarding Viread
10 caused “significant public health and safety concerns.” (¶¶128-29.) Issued on July 29, 2003, the
11 FDA Warning Letter was not made public until August 7, 2003, and was not “disclosed” by
12 Gilead until August 14, 2003, two weeks after its receipt, when Gilead mentioned it in passing in
13 its 2Q2003 Form 10-Q. (¶199.)⁵

14 Further still, Gilead continues to unlawfully rely on illegal off-label marketing to promote
15 its drugs. On March 9, 2009, the FDA again publicly issued a Warning Letter, rebuking Gilead
16 for “false or misleading” statements that “minimize[d] the serious risks [potential liver injury and
17 the risk of birth defects] associated with [Gilead drug] Letairis,” contrary to the FDA warning
18 label and risk management plan. *See* Lisa Hubbard, R. Ph., letter from the Dept. of Health and
19 Human Services, 1, http://www.fda.gov/cder/warn/2009/Letairis_Letter.pdf.⁶

20 **B. Defendants’ Off-Label Marketing Resulted in Increased Sales of**
21 **Viread in the 2Q2003**

22 Defendants’ continuous off-label marketing of Viread worked: Gilead sold more Viread
23 as physicians prescribed more of it, often for purposes other than those approved by the FDA,

24 ⁵ Judge Jenkins’ Order mistakenly stated Gilead publicly released the FDA Warning Letter on
25 August 7, 2003. *See* Order at 3 n.1. In fact, the FDA released the letter on that date. (¶199.)

26 ⁶ Plaintiffs’ allegations find further corroboration in another civil complaint filed against Gilead,
27 unsealed by this Court on March 17, 2009, which includes similar allegations that Gilead
engaged in an illegal off-label marketing scheme involving Viread, in violation of the federal
False Claims Act.

1 and often based on Gilead’s lies about the true safety profile of the drug. (¶¶141, 158-59.) As a
2 result, an astonishing 75% to 95% of Viread sales arose from off-label promotion. (¶¶141-65.)

3 Gilead off-label marketing took three forms: (1) marketing to HIV patients co-infected
4 with Hepatitis B virus (“HBV”); (2) marketing Viread as a first-line or initial therapy for HIV
5 infection prior to its approval for such use; and (3) marketing against Viread’s safety profile.
6 (¶¶141-65.) In response to Defendants’ illegal off-label marketing to co-infected HBV patients,
7 the percentage of co-infected patients using Viread rose significantly from pre-Class Period
8 amounts, materially increasing Viread sales. (¶¶152-54.) Defendants also materially increased
9 Viread sales by improperly marketing it as a first-line therapy prior to the FDA’s approval of
10 Viread in “treatment naïve” patients. (¶¶155-57.) Finally, physicians and HIV practitioners
11 across the country prescribed Viread, in response to off-label marketing claims that Viread had
12 no side effects and was safe as a placebo, materially increasing Gilead’s Viread sales and the
13 appearance of demand. (¶¶158-59.) As a result of the illusory demand for the drug and the
14 misleading explanations for increased demand created by the off-label marketing scheme, Gilead
15 was in a position to raise Viread’s price. In line with industry standards, Gilead informed
16 national drug wholesalers of this plan in advance, causing wholesalers to overstock the drug in
17 the 2Q2003 in anticipation of the continued high sales. (¶¶7, 9, 10, 171.) Thus, wholesaler
18 overstocking was inextricably linked to the illegally inflated sales and artificially inflated Viread
19 demand created by Defendants’ off-label marketing scheme.

20 The FAC clearly alleges that due to Defendants’ illegal off-label marketing, a vast
21 majority of Viread’s sales – 75% to 95% – were off-label. According to CW1, 85% to 95% of
22 his/her Viread Sales were a result of off-label marketing. (¶144.) Similarly, 85% to 90% of
23 CW2’s Viread sales resulted from off-label marketing. (¶148.) AIDS specialists across the
24 country also reported routine prescriptions of Viread in response to off-label marketing based
25 upon unsolicited and false safety information received from Gilead. (¶¶152-61.) This massive
26 off-label marketing drove Gilead sales to \$115 million in the 2Q2003, causing Gilead’s 2Q2003
27 domestic Viread sales to be overstated by a stunning amount . (¶¶161-65.)

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C. Defendants Sustained the Illusion of Increased Demand for Viread

Defendants misled the market about Viread demand through their nondisclosure of extensive off-label marketing, allowing Gilead to report extraordinary growth in Viread sales (¶¶149-50, 197), leading investors to believe sales would continue to increase, and leading wholesalers to overstock Viread in anticipation of increased sales. (¶¶166-73.) At the end of the 2Q2003, Gilead issued a press release anticipating its second quarter results would exceed analysts' expectations, stating "[t]he increase in revenue was driven primarily by strong sales growth of Viread" and that Viread sales increased due to "broader prescribing patterns... as well as increases in U.S. wholesaler inventory levels in the second quarter." (¶174) (emphasis omitted). Defendants were also quick to dispel any belief that the sales were temporary due to inventory overstocking. On July 14, 2003, the same day as the press release, Gilead spokeswoman Amy Flood, with the approval of Gilead, stated in *Bloomberg News*: "[t]he main reason for the jump in Viread sales is an increase in prescriptions, not inventory overstocking." (¶179.) All of these statements were materially false and misleading because Gilead and its officers' "marketing and promotional activities for Viread were not in compliance with FDA approved guidelines, violated federal laws, and created serious public health and safety implications for Viread users." (¶175.)

Further, when Defendants made these announcements, it was unknown to investors that 75% to 95% of those sales were the result of off-label marketing. (¶¶135, 138.) Because of Defendants' false and misleading statements and omissions as to the role off-label marketing played in their promotion of Viread, Defendants' off-label marketing scheme remained unknown. Analysts following Gilead were blinded by supposed strong demand for Viread and were unconcerned with how much Viread wholesalers were overstocking, but market analysts and investors did not know that Gilead's favorable reported results, including the wholesaler overstocking, were based on artificially inflated demand caused by an illegal marketing scheme. (¶185.) Defendants' illegal scheme had its intended effect of creating the impression that demand for Viread was strong and, in turn, the stock price soared. (¶180.) On July 14, 2003, the

1 same day as the press release, the price of Gilead closed at \$67.25, up \$7.97 from the previous
2 day's close of \$59.28 per share, a near record high for Gilead. (*Id.*)

3 On August 7, 2003, the FDA made the FDA Warning Letter public. (§191.) Although
4 investors were aware of the letter, they were unaware of the extent to which Gilead's entire
5 business depended on illegal marketing, and did not attribute much significance to it. (§§191-
6 95.) Put simply, because Defendants' illegal conduct was only partially disclosed through the
7 FDA Warning Letter, the market did not recognize the letter's true significance, including how it
8 would negatively impact sales of and demand for Viread. (§195.)

9 Unbeknownst to the market, the disclosure of the FDA Warning Letter did have a
10 negative effect on Viread sales. Physicians, now alerted to Gilead's illegal marketing scheme
11 and to potential safety problems with Viread, were less eager to prescribe the drug to their
12 patients. (§200.) Worse, competitors were now able to use Defendants' illegal scheme to
13 promote competing drugs. (*Id.*) In the weeks following publication of the FDA Warning Letter,
14 Gilead saw a marked drop in August 2003 in prescriptions and sales of Viread, and flattened
15 growth for the rest of the Third Quarter, in comparison to the previous quarters. (§201.)⁷ Thus,
16 the disclosure of the FDA Warning Letter in the Third Quarter resulted in weakened sales and
17 prescriptions that did not demonstrate the artificially inflated strong growth Defendants touted
18 and investors had come to expect. (§203.)

19 Viread's demand and growth problems coupled with the drop in sales and prescriptions
20 immediately following the FDA Warning Letter disclosure influenced wholesalers to draw down
21 much more of their excess inventory than they otherwise would have, letting their supplies of
22 Viread drop to the lowest level in four quarters, well below the industry average. (*Id.*) Yet,
23 despite the doctors' and wholesalers' recognition of the slowing growth of Viread, Defendants
24 kept their mouths shut and continued to make false and misleading statements. On August 14,

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26 ⁷ The exact figures are exclusively in Defendants' and certain third parties' possession, and are
27 not available to Plaintiffs for use at this stage of the litigation.

1 2003, Gilead issued its 2Q2003 10-Q and again stated “[t]he increase in product sales is due to
2 the significant increase in the volume of sales of Viread.” (§197) (emphasis omitted).

3 It was not until October 28, 2003, that Defendants issued a press release revealing Viread
4 sales for the Third Quarter 2003 (“3Q2003”) would be materially less than expected –
5 expectations grounded in the market’s false impression of Viread demand. The disclosure of the
6 FDA Warning Letter along side the disappointing sales finally revealed the true financial
7 circumstances at Gilead, stunning the market. Analysts noted that wholesale stocking levels had
8 reached all time lows and lowered their Fourth Quarter 2003 projections based on “lower-end
9 user demand.” (§§206-08.) This revelation caused Gilead’s stock to fall 12%, or \$7.46 per
10 share, from a high of \$59.46 per share on October 28, 2003 to a low of \$50.27 and closing at
11 \$52.00 per share on October 29, 2003. (§208.) The shocking news also incited a 1,400%
12 increase in trading volume. (*Id.*) Reasonable investors would (and did, as evidenced by the
13 soaring trading volume) consider Defendants’ misrepresentations as important in their decision-
14 making and viewed the information ultimately disclosed about Defendants’ illegal scheme as
15 having altered the total mix of information from both a qualitative and quantitative standpoint.
16 (§209.)

17 **V. ARGUMENT**

18 In considering a motion to dismiss, “all allegations of material fact made in the complaint
19 are taken as true and construed in the light most favorable to the plaintiff.”⁸ *Nursing Home*
20 *Pension Fund v. Oracle Corp.*, 380 F.3d 1226, 1229 (9th Cir. 2004). “The question presented by
21 a motion to dismiss is not whether the plaintiff will prevail in the action, but whether the plaintiff
22 is entitled to offer evidence in support of the claim.” *In re Connecticut Corp. Sec. Litig.*, 2008
23 U.S. Dist. LEXIS 62515, at *8 (N.D. Cal. Aug. 14, 2008) (Illston, J.). Thus, “so long as the
24 Plaintiff alleges facts to support a theory that is not facially implausible, the Court’s skepticism is
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27 ⁸ Internal citations and footnotes are omitted, and emphasis is added, unless otherwise noted.

1 best reserved for later stages of the proceedings when the Plaintiff's case can be rejected on
2 evidentiary grounds." *Gilead*, 536 F.3d at 1057.

3 To state a claim under §10(b) and Rule10b-5, five elements must be established: "(1) a
4 material misrepresentation or omission of fact, (2) scienter, (3) a connection with the purchase or
5 sale of a security, (4) transaction and loss causation and (5) economic loss." *Id.* at 1055. As
6 demonstrated herein, the FAC's falsity, materiality, and scienter allegations provide sufficient
7 detail and satisfy the requested pleading requirements.

8 **A. Plaintiffs Adequately Pleaded Falsity**

9 **1. Defendants Created a False Impression of Viread Demand**

10 In order to plead falsity, Plaintiffs must "allege that Defendants' 'omitted to state a
11 material fact necessary in order to make the statements made, in light of the circumstances in
12 which they were made, not misleading.'" January 26, 2005 Amended Order ("Am. Order") at 11
13 n.5. Falsity is alleged by omission where, as here, a defendant was aware of "undisclosed facts
14 tending to seriously undermine the accuracy of the statement." *Connetics*, 2008 U.S. Dist.
15 LEXIS 62515, at *23. The FAC alleges Gilead's illegal off-label marketing scheme⁹ was a
16 known but undisclosed fact, which "seriously undermined" the accuracy of its public statements,
17 that represented Viread's sales were driven by increased demand, when in fact the sales were
18 driven by Defendants' illegal off-label marketing.¹⁰ As noted by the Ninth Circuit above,

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20 ⁹ As Defendants grudgingly acknowledge in a footnote (Mem. at n.14), the Court previously held
21 Plaintiffs adequately allege Defendants engaged in an illegal off-label marketing scheme
22 involving Viread. *See, e.g.*, Am. Order at 12 ("[T]he FDA clearly confirms that Gilead
23 representatives were actively engaging in the off-label marketing with the intent to increase sales
24 of Viread."); Order at 9 ("Plaintiffs have adequately alleged that Defendants engaged in an illegal
25 off-label marketing scheme.").

24 ¹⁰ *See In re Syncor Int'l Corp. Sec. Litig.*, No. 05-55748, 2007 U.S. App. LEXIS 14257, at *4
25 (9th Cir. June 12, 2007) (public statements attributing successful earnings results "solely to
26 legitimate practices" misleading where *plaintiffs* alleged the earnings were attributable in part to
27 certain illegal payments); *In re Amgen, Inc. Sec. Litig.*, 544 F. Supp. 2d 1009, 1034 (C.D. Ca.
2008) (public statements that defendant "marketed its [pharmaceutical] products 'for their
approved indications'" misleading where plaintiffs alleged defendants "at the same time
promoted unapproved uses and increased per-patient dosages through improper means");
Connetics, 2008 U.S. Dist. LEXIS 62515, at *23 (public statement regarding strength of data

1 “[o]mitting the role of off-label marketing in [the July 14, 2003] press release highlighting the
2 drug’s success made a true statement (that demand was strong) also a misleading one.” *Gilead*,
3 536 F. 3d at 1052. Thus, Defendants’ failure to disclose the role of Gilead’s active off-label
4 marketing scheme of Viread sales in their July 14, July 31, and August 14, 2003 public
5 statements created the false impression that the product’s increased sales and wholesaler demand
6 resulted from legitimate business practices rather than from unlawful marketing practices.¹¹

7 While Defendants maintain Gilead’s statements “simply did not create a ‘false
8 impression’ about Viread or the Company’s prospects” because they were “completely
9 accurate,” in the Ninth Circuit, a “statement that is literally true can be misleading and thus
10 actionable under the securities laws.” *In re Dura Pharms., Inc. Sec. Litig.*, 548 F. Supp. 2d
11 1126, 1136 (S.D. Cal 2008) (“*Dura*”); *see also, Amgen*, 544 F. Supp. 2d at 1034 (pharmaceutical
12 manufacturer’s “literally accurate” statements that it “marketed its products ‘for their approved
13 indications’” while it engaged in an undisclosed and illegal off-label marketing scheme “misled
14 investors by implicitly and falsely warranting that there were no illegal practices contributing to
15 that success”).¹²

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20 submitted to FDA misleading where plaintiffs alleged defendants knew undisclosed facts that
tended “to seriously undermine the accuracy of the statement”).

21 ¹¹ Defendants’ false statements during the Class Period included, in addition to the July 14, 2003
22 press release, Gilead Spokeswoman Amy Flood’s statement that “[t]he main reason for the jump
in Viread sales is an increase in prescriptions, not inventory stocking” (¶179); Gilead’s July 31,
23 2003 press release stating that “Viread sales growth was primarily driven by a higher
prescription volume....” (¶183); and Gilead’s Form 10-Q reporting on August 14, 2003,
24 emphasizing the increased sales of Viread without addressing the role of Gilead’s illegal off-
label marketing practices (¶¶197-99).

25 ¹² Contrary to Defendants’ contention, statements by Gilead spokesperson Amy Flood “clearly
26 originated from the defendants” and are actionable inasmuch as they were not the projection or
impressions of a third party. *See Dura*, 548 F. Supp. 2d at 1137-38 (statements in analyst reports
27 are actionable where they are the statements defendants originally made to analysts in the first
instance).

1 **2. Defendants Had a Duty to Disclose the Illegal Off-Label**
2 **Marketing Scheme**

3 Defendants’ contention that “Gilead had no obligation to disclose the alleged off-label
4 marketing activities even if it was really engaged in such practices” (Mem. at 15), is likewise
5 incorrect. As this Court has previously held, a “general” legal duty of disclosure exists, which
6 arises ““whenever a disclosed statement would be ‘misleading’ in the absence of the ‘disclos[ure]
7 of [additional] material facts needed to make it not misleading.”” *Connetics*, 2008 U.S. Dist.
8 LEXIS 62515, at *21; *see also Amgen*, 544 F. Supp. 2d at 1030 (“Rule 10b-5 ‘imposes a duty to
9 disclose material facts that are necessary to make disclosed statements, whether mandatory or
10 volunteered, not misleading.”). There can be little doubt here that Plaintiffs pleaded sufficient
11 facts to demonstrate Defendants had a duty to disclose the illegal off-label marketing scheme as
12 a matter of law. Plaintiffs alleged a systematic promotional scheme twice condemned by the
13 FDA as illegal and controlled at the highest levels of the Company, which generated between 75-
14 95% of all sales of the Company’s marquee product. The off-label marketing scheme drove
15 Viread sales and created a false impression that Viread’s publicly reported sales figures were
16 driven by increased demand.

17 Defendants contend Gilead’s omissions regarding the off-label marketing scheme were
18 not misleading for “similar” reasons to those relied upon by the court in *Brody* in which the
19 Ninth Circuit did not find omissions involving certain undisclosed business dealings of
20 defendants to be misleading. *Brody v. Transitional Hosps. Corp.*, 280 F.3d 997, 1006 (9th Cir.
21 2002). As Defendants themselves quote from the *Brody* opinion, however (Mem. at 16), an
22 omission can be misleading, thereby requiring disclosure if it “affirmatively create[s] an
23 impression of a state of affairs that differs in a material way from the one that actually exists.”
24 *Brody*, 280 F.3d. at 1006; *see also Syncor*, 2007 U.S. App. LEXIS 14257, at *4 (same); *Amgen*,
25 544 F. Supp. 2d at 1034 (same). The plaintiffs’ allegations in *Brody* are distinguishable because,
26 unlike the FAC, they failed to “specify the reason or reasons why the statements made by [the
27 defendant] were misleading or untrue, not simply why the statements were incomplete.” *Brody*,
28 280 F.3d at 1006. To be sure, Plaintiffs’ allegations here explain that Defendants’

1 representations regarding the sources of Viread’s sales were incomplete because they omitted
2 their key source, the illegal off-label marketing scheme. The allegations go further, however,
3 specifying in detail how the omission served to create the false and misleading impression to
4 investors that Viread’s sales were driven by demand and not by off-label marketing. (¶¶141-165.)
5 In short, the omission “affirmatively create[d] an impression of a state of affairs that differs in a
6 material way from the one that actually exists,” and the *Brody* court’s prohibition against
7 application of a “completeness rule” to public statements remains undisturbed. *See Brody*, 280
8 F.3d at 1006-7.¹³

9 **B. The Confidential Witnesses Are Sufficiently Reliable**

10 As recognized by the Ninth Circuit, the FAC pleads specific facts detailing the illegal
11 marketing scheme behind Defendants’ false statements. The detail is provided by two
12 confidential witnesses, which is supported by significant corroborating evidence. “[W]hen the
13 allegations of CW1 and CW2 are considered in light of the FDA’s letters to Gilead, it becomes
14 apparent that Plaintiffs have alleged sufficient facts to raise a strong inference that Defendants
15 had knowledge of the company’s off-label marketing scheme.” *See Order* at 9.

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18 ¹³ Defendants urge the Court to follow the Sixth Circuit’s ruling in *In re Sofamor Danek Group,*
19 *Inc.*, 123 F.3d 394, 400 (6th Cir. 1997), finding that a medical device manufacturer’s failure to
20 disclose its unlawful promotion of the product in public statements reporting growing sales of the
21 product was not misleading, despite its receipt and disclosure of an FDA warning letter regarding
22 the unauthorized promotion prior to the alleged misstatements. (Mem. at 15.) This Court should
23 decline to follow *Sofamor* in favor of more authoritative and well reasoned precedents within the
24 Ninth Circuit. The *Sofamor* court’s ruling that the defendants had no duty of disclosure beyond
25 that of the FDA letter itself improperly imposes a bright line rule at the pleading stage requiring
26 “regulatory action” to have been initiated prior to the nondisclosures, to protect defendants from
27 having to make a public “prediction” that such regulatory action would occur that might not turn
out to be correct. *In re Sofamor*, 123 F.3d. at 402. As courts in the Ninth Circuit recognize,
however, the nature and level of FDA’s scrutiny of Gilead, the degree to which it gave rise to a
duty to disclose the off-label marketing scheme, and the form of disclosure required are all
questions of fact not properly decided on a motion to dismiss. *See, e.g., Connetics*, 2008 U.S.
Dist. LEXIS 62515, at *24 (denying motion to dismiss and finding duty to disclose FDA’s
“preliminary views” regarding the safety profile of the defendant’s pharmaceutical product);
Amgen, 544 F.Supp.2d at 1030 (denying motion to dismiss and finding duty to disclose
defendant’s decision to halt a clinical trial that would resolve FDA concerns about the safety
profile of its pharmaceutical product).

1 In the Ninth Circuit, personal sources of information may be relied on if they are
2 described with “sufficient particularity to support the probability that a person in the position
3 occupied by the source would possess the information alleged.” *Oracle*, 380 F.3d at 1233; *see*
4 *also Daou*, 411 F.3d at 1015 (PSLRA satisfied where confidential witnesses are described with
5 specificity, especially where their job description and responsibilities are included).¹⁴
6 Additionally, a complaint may rely on confidential witnesses in two situations: (i) when the
7 complaint relies on both confidential witnesses and other factual information, such as
8 documentary evidence; and (ii) in cases where additional evidence is absent, when the
9 confidential witness is described “with sufficient particularity to support the probability that a
10 person in [said] position would possess the information alleged.” *Zucco*, 552 F.3d at 995. Here,
11 Plaintiffs easily met not only one, but *both* of those standards.¹⁵

12 First, Plaintiffs described both CW1 and CW2 with sufficient particularity to allege they
13 were in a position to have personal knowledge of circumstances demonstrating Defendants’
14 knowledge and intent behind the off-label marketing scheme.¹⁶ (*See* ¶¶39-49 (pleading job titles,
15 descriptions, and responsibilities).) The FAC sets forth particular facts concerning both CW1’s
16 and CW2’s personal knowledge of Defendants’ activities, such as the dates when statements
17 were made by or to Defendants, at which meetings the statements were made, who the
18 statements were made by, and who relied upon the statements. (¶¶ 59-64, 68-71, 74-80, 82-87,

19
20 ¹⁴ In support of their argument that Plaintiffs may not rely on a paraphrased statement by a
21 Gilead spokesperson in a news article, Defendants cite the District Court’s earlier decision in
Oracle, which was overruled by the Ninth Circuit. (*See* Def. Mem. at 14 n.5.)

22 ¹⁵ Defendants rely on a Seventh Circuit decision to support their proposition that the allegations
23 of confidential sources should be discounted. *Higginbotham v. Baxter Int’l, Inc.* 495 F.3d 753,
756-57 (7th Cir. 2007). The Ninth Circuit, however, has specifically decided not to consider
24 whether *Tellabs* requires the discounting of confidential witness statements. *Tellabs, Inc. v.*
Makor Issues & Rights, Ltd., 551 U.S. 308, 127 S.Ct. 2499 (2007); *Zucco*, 522 F.3d at 995. This
25 is especially true where the confidential witnesses provide information based on their own
personal knowledge that is bolstered by corroborating evidence.

26 ¹⁶ The fact that CW1 left Gilead just prior to the Class Period is irrelevant. *See In re 21st*
Century Holding Co. Sec. Litig., No. 07-61057-CV, 2008 WL 5749572, at *7 (S.D. Fla. Nov. 7,
27 2008) (relying on allegations from pre-class period employee to sustain complaint).

1 89-90, 95, 101-123, 138-140, 144, 148-151.) Further, the statements of both CW1 and CW2
2 corroborate each other in that they are based on the witnesses' own experiences within the
3 Company and personal knowledge of Defendants' knowing use of illegal sales tactics and
4 knowing pursuit of the off-label marketing scheme. These are not mere assertions, but specific
5 details of how Defendants misled the market.

6 Second, significant evidence corroborates the confidential witness allegations. The
7 Untitled FDA Letter and the FDA Warning Letter each, standing alone, substantiates both CW1
8 and CW2, and are sufficient to establish that Defendants' statements were false and misleading
9 when made. (¶¶92-93, 125-29.) The FAC also relies upon the detailed and further corroborative
10 statements of several medical practitioners with firsthand experience of Defendants' off-label
11 marketing scheme. (See ¶156 (AIDS-specialist received unsolicited off-label data from Gilead);
12 *Id.* (infectious disease specialists with a large AIDS practice received unsolicited off-label advice
13 on using Viread and wrote prescriptions as a result); ¶158 (medical director of a large AIDS
14 clinic wrote prescriptions for Viread based on false and misleading sales pitches concerning
15 safety profile).)¹⁷ The sum of this corroborative evidence further bolsters the reliability of both
16 CW1 and CW2 and satisfies this Court's standard of reliability for confidential witnesses.

17 In addition to claiming CW1 and CW2 are unreliable, Defendants attack their credibility.
18 Defendants argue CW1 lacks credibility because CW1 is below the Individual Defendants in the
19 corporate hierarchy and that CW1's statements as to the percentage of off-label sales are not
20 plausible. Defendants also assert CW2's statements lack credibility because they are not set
21 forth exactly as they were in an earlier pleading. In effect, Defendants argue this Court should
22 determine the credibility of the witnesses at the pleadings stage. The question for the Court,
23 however, is not whether witnesses are credible, but whether they may be considered reliable. A

24
25 ¹⁷ Defendants attempt to discredit CW1 by suggesting CW1 relies on statements that are hearsay.
26 Even if this Court were to determine that any of CW1's statements are hearsay, those statements
27 are not automatically disqualified from consideration in the scienter calculus. *See Zucco*, 552 F.
3d. at 997.

1 Court may not weigh evidence or entertain a credibility challenge at the pleadings stage of
2 litigation. *In re NPS Pharms, Inc. Sec. Litig.*, No. 06 Civ. 3410, 2007 WL 1976589, at *5 (D.
3 Utah July 3, 2007); *see also In re Unumprovident Corp. Sec. Litig.*, 396 F. Supp. 2d 858, 873
4 (E.D. Tenn. 2005); *In re AOL Time Warner, Inc. Sec. & "ERISA" Litig.*, No. MDL 1500, 02 Civ.
5 5575, 2004 WL 1810661, at *2 (S.D.N.Y. Aug. 12, 2004).¹⁸

6 Based on both personal knowledge and the significant volume of corroborating evidence
7 clearly delineated in the FAC, both CW1 and CW2 are sufficiently reliable to meet the pleading
8 requirements of the PSLRA, and the Motion should be denied.

9 **C. Plaintiffs Adequately Pleaded Materiality¹⁹**

10 **1. Materiality Should Not be Decided on a Motion to Dismiss**

11 Defendants' argument that Gilead's illegal off-label marketing scheme was not a material
12 fact requiring disclosure is flawed at its core. Ignoring even their own acknowledgement that
13 only falsity and scienter are subject to the PSLRA's heightened pleading requirements (Mem. at
14 9), Defendants conflate materiality with falsity, treating materiality as though it too is subject to
15 the heightened standard. As Defendants are aware, the PSLRA did not change traditional
16 pleading rules with respect to materiality, which remains governed by Fed. R. Civ. P. 8. *See No.*

17
18 ¹⁸ Further, any clarification of earlier pleadings may not be used to challenge CW2's credibility
19 because the Court may only focus on the FAC, the pleading currently before this Court. *See In*
20 *re PXRE Group Ltd., Sec. Litig.*, No. 06 Civ. 3410, 2009 WL 539864, at *13 (S.D.N.Y. Mar. 4,
21 2009). Defendants rely on the cases of *Bradley v. Chiron Corp.* 136 F.3d 1317, 1326 (Fed. Cir.
22 1998) and *Ellingson v. Burlington Northern, Inc.*, 653 F.2d 1327 (9th Cir. 1981) to support their
23 assertion that CW2's allegations should be considered a "sham" because the allegations were
24 revised since filing of an earlier pleading. The Ninth Circuit, however, has intentionally declined
25 to follow the holding in *Bradley* and even noted that the holding set forth in *Ellingson*, which is
26 not analogous to the facts here, is no longer good law. *PEA Gov't. Serv's, Inc., v. MPRI, Inc.*,
27 514 F.3d 856, 859 (9th Cir. 2007). The court in *PEA* was faced with a situation where an
amended complaint contained "an allegation that is apparently contrary to an earlier iteration of
the same pleading." *Id.* at 858. The court rejected defendants' charge that plaintiffs had engaged
in "sham pleading," holding that it is improper to strike allegations in a pleading simply because
they are inconsistent with or even contradictory to earlier pleadings. *Id.* at 859. Allowing such a
dismissal would be an impermissible resolution of a case on its merits. *Id.*

26 ¹⁹ In a prior decision, the Court reasoned it was a "close question" whether Plaintiffs
27 demonstrated that the off-label marketing scheme was a material fact that needed to be disclosed.
Order at 10.

1 84 *Employer-Teamsters v. Am. West*, 320 F.3d 920, 946 (9th Cir. 2003) (applying pre-PSLRA
2 standards of materiality to securities fraud claims facing motions to dismiss under the heightened
3 pleading standards of the PSLRA) ; *Gebhardt v. ConAgra Foods, Inc.*, 335 F.3d 824, 830 n.3
4 (8th Cir. 2003). Rather, materiality determinations “require[] delicate assessments of the
5 inferences a ‘reasonable shareholder’ would draw from a given set of facts and the significance
6 of those inferences to him, and these assessments are peculiarly ones for the trier of fact.” *Fecht*
7 *v. Price Co.*, 70 F.3d 1078, 1080-81 (9th Cir. 1995)(citations omitted); *Am. West*, 320 F.3d at
8 934 (same); *In re Petco Animal Supplies Inc. Sec. Litig.*, 05-cv-0823, 2006 U.S. Dist. LEXIS
9 97927, at *42 (S.D. Cal. July 31, 2006) (“[m]ateriality is typically a fact-intensive question”).²⁰
10 As demonstrated herein, Defendants have failed to show that materiality can be decided as a
11 matter of law.

12 **2. Defendants’ Off-Label Marketing Resulted in Material Viread**
13 **Sales and Materially Artificially Inflated Viread Demand,**
14 **Including During 2Q2003**

15 Plaintiffs adequately allege that Gilead’s illegal off-label marketing scheme had a
16 material impact on the Company’s finances. “[A] fact is material if there is a ‘substantial
17 likelihood’ that a reasonable investor would consider it important in his or her decision
18 making.” *See In re Immune Response*, 375 F. Supp. 2d 983, 1020 (S.D.N.Y 2005) (quoting *Am.*
19 *West*, 320 F.3d at 934). Here, Plaintiffs allegations show well beyond the requirements of Fed.
20 R. Civ. P. 8 that Gilead’s illegal off-label marketing scheme resulted in material Viread sales and
21 artificial demand. The FAC details with a high degree of specificity both the manner in which
22 the scheme caused sales of Viread to increase by 75%-95%, including during the 2Q2003,
23 (¶¶141-65), and the relationship among Defendants’ off-label marketing, sales of Viread, and the

24 ²⁰ “In other words, materiality depends on the significance the reasonable investor would place
25 on the withheld or misrepresented information.” *Immune Response*, 375 F. Supp. 3d at 1021.
26 Materiality determinations are particularly suited for the trier of fact, and this presumption can
27 *only* be overcome if the omitted fact, taking into consideration all of the circumstances, is so
obviously immaterial that reasonable minds could not differ. *Am. West*, 320 F.3d at 934.
Notably, an immediate market reaction is not required to find that misrepresentations or
omissions are material. *See id.*

1 Company's 2Q2003 reports. That Defendants orchestrated and encouraged illegal marketing,
2 misled the public as to the source of 75% to 95% of all domestic Viread sales, and were
3 admonished twice by the FDA, would have been material to a reasonable investor. *See Am.*
4 *West*, 320 F.3d at 934-5 ("reasonable investor would find significant the information regarding a
5 company's deferred maintenance costs, unsafe maintenance practices, and possible sanction . . .
6 and would consider the potential effects of each of these facts on the **overall economic health of**
7 **the company** as 'significantly altering' the 'total mix' of information made available") (emphasis
8 added); *Immune Response*, 375 F. Supp. 2d at 1021 (materiality met where "Plaintiffs allege that
9 Defendants' misstatements of fact formed a false basis for its investors' perceptions").²¹

10 Taking the collective allegations of the FAC as true, it is clear that Gilead's company-
11 wide Viread sales were materially artificially inflated as a direct result of the illegal off-label
12 marketing scheme. Plaintiffs' allegations are more than adequately supported by: (1) the
13 intensity and frequency with which Gilead ordered its sales force to use off-label marketing to
14 sell Viread;²² (2) the pressure put on CW1's and CW2's to actually utilize off-label marketing;
15 (3) the volume of CW1 and CW2 Viread sales caused by off-label marketing;²³ (4) the FDA

17 ²¹ A reasonable investor would consider Defendants' misrepresentations and omissions in their
18 July 14, 2003 press release, July 13, 2003 *Bloomberg News* statement, July 31, 2003 press
19 release, August 14, 2003 Form 10-Q, and October 28, 2003 press release as important to decision
20 making and would have viewed these misrepresented facts as having significantly altered the
21 total mix of information made available about Gilead from both a quantitative and qualitative
22 standpoint. (¶209.)

23 ²² The FAC details how the off-label marketing scheme was taught at all levels of the Company,
24 including at national and regional meetings, and that it uniformly inflated Gilead's Viread sales
25 numbers and demand for the drug. These facts explain and sufficiently allege that the illegal
26 Viread marketing led to massive amounts of increased Viread prescriptions and sales, and gave
27 the market expectations of additional rapid growth. In fact, Defendant Martin, in a *Forbes*
28 article, admitted that, to reach its goal of increased prescriptions, Gilead had to use marketing to
convince physicians to switch patients to Viread. (¶6.) The increase in Viread prescriptions
(albeit artificially inflated due to off-label marketing) was an important product demand
indicator. Defendant Martin admitted as much in Gilead's October 28, 2003 press release. (¶5.)

²³ The FAC delineates the substantial amounts of Viread sold off-label, describes the specific
data that forms the basis of those percentages, and applies those percentages to articulate well-
grounded estimates of how much Defendants' off-label marketing inflated Gilead's overall
revenues and sales figures for Viread, including during the 2Q2003. (¶¶144-50.) All told, as a
result of the massive amounts of off-label sales, Gilead's 2Q2003 domestic Viread sales of

1 letters, which evidence that sales people other than CW1 and CW2 were illegally marketing
2 Viread, consistent with Defendants' directives; (5) the statistical evidence of the levels of off-
3 label sales; and (6) the familiarity that CW1 and CW2 had with other Gilead sales people and
4 their knowledge that other Gilead sales people used off-label marketing to sell Viread.²⁴ (¶164.)

5 Despite the foregoing, Defendants incorrectly assert "plaintiffs fail to provide an
6 adequate basis" for making an inference that off-label marketing accounted for 75% to 95% of
7 all Viread sales. (Mem. at 17.) First, Defendants' argument ignores most of Plaintiffs'
8 allegations, including that a Medical Director of a large AIDS clinic in Washington, D.C. wrote
9 numerous prescriptions for Viread *based on false representations by Gilead marketing*
10 *representatives* – the same representations identified as illegal in the FDA's letters to Gilead.
11 (¶158.) The collective first-person accounts of the confidential witnesses and health care
12 practitioners, along with the FDA letters, combine to bolster the allegations that off-label
13 marketing resulted in material sales. Second, Defendants again attempt to sever the link between
14 their off-label marketing and actual off-label prescriptions by citing authority for the

15
16 \$115.6 million were overstated by approximately \$95.95 million, and Gilead's 3Q2003 domestic
17 sales of \$59.4 million were overstated by approximately \$49.3 million. (¶¶150, 197, 205.)

18 ²⁴ The indisputably material percentages of off-label Viread sales are based both on CW1's and
19 CW2's own off-label marketing of Viread and their first-hand accounts of the practice at Gilead.
20 CW1's and CW2's accounts of the significant details of Defendants' systematic and pervasive
21 off-label marketing scheme, and how it was implemented, strongly suggest that their experiences
22 at Gilead were neither atypical nor uncommon, and that neither CW1 nor CW2 was "regionally
23 isolated," such that their experiences should not be extrapolated throughout the Company.
24 (¶138.) Specifically, CW1's and CW2's experiences at numerous national meetings, in addition
25 to CW1's experiences on Gilead's elite Field Marketing Advisory Committee ("FMAC"),
26 demonstrate that their off-label experiences were national in scope. (¶¶41, 60-66, 69-77, 104-06,
27 110-11, 116-17, 119-22, 151.) Indeed, the FMAC was comprised of a select committee of
Gilead sales and marketing staff from various regions of the country, as well as high-ranking
Gilead officers, that met periodically to engage in frank discussions regarding theories and
strategies for selling Viread. (¶¶41, 87-88, 102-03, 113.) At the intimate FMAC meetings, CW1
was exposed to other Therapeutic Specialists and Gilead executives who would discuss what
illegal off-label sales tactics worked best to sell Viread. (¶¶87-88, 102-03, 113.) From these
meetings, CW1 estimated with reasonable certainty that other Gilead sales people sold material
amounts of Viread through off-label marketing. Notably, although CW2 was not a member of
the FMAC, CW2 did attend numerous national and regional meetings where CW2 received the
same directives as all other Viread sales people – to sell Viread with illegal, off-label
information. (¶¶48, 60-62, 69-77, 79, 83, 89, 104-06, 110-11, 114, 116-17, 119-22.)

1 uncontroversial proposition that drugs can be and are prescribed for off-label uses. (Mem. at 18.)
2 However, the FAC alleges an explosive growth in off-label sales coupled with Gilead's
3 aggressive off-label marketing scheme. (¶149.) The inference that the growth in off-label
4 prescriptions was directly tied to the marketing, particularly where, as here, the combination of
5 specific witnesses and third party data corroborate that particular prescriptions resulted from off-
6 label marketing is reasonable and sound. (¶¶151-52, 156, 158-65.) Indeed, it is difficult to
7 imagine what else Defendants would have the Plaintiffs do, short of actually interviewing every
8 doctor who ever prescribed Viread. Statistical evidence of off-label prescriptions (¶¶154-65),
9 coupled with extensive descriptions of off-label marketing, personal accounts of salespersons
10 and physicians, and the FDA letters, are more than sufficient, at the pleadings stage, to raise an
11 inference that material amounts of Viread sales and prescriptions resulted from Defendants' off-
12 label sales pitches.²⁵ The inferences, proposed by Defendants, that, despite Plaintiffs' allegations
13 of a pervasive, illegal marketing scheme, designed by the Company's top officials and rigidly
14 enforced for a period of years, the scheme had no meaningful effect on physician's prescribing
15 patterns is nothing short of bizarre. Defendants would have this Court believe that they went to
16 such trouble to increase sales without ever noticing that their efforts were entirely unnecessary.
17 Defendants' arguments should be rejected as Plaintiffs' materiality allegations far exceed the
18 standards of notice pleading.²⁶

20 ²⁵ As previously recognized by the Court, Plaintiffs are not required to detail the impact of
21 Gilead's off-label marketing on a sale-by-sale basis. January 26, 2005 Order at 3. *See also U.S.*
22 *v. Parke-Davis, Division of Warner-Lambert Co.*, 147 F. Supp. 2d 39, 49 (D. Mass. 2001) (*qui*
23 *tam* complaint satisfied Fed R. Civ. P. 9(b) without having to identify "every ineligible
24 prescription" that resulted from defendant's illegal off-label marketing scheme where, as here,
"the complaint amply details both a general framework" of the illegal scheme and "provides
more specific information on the individuals, locations, the precise statements alleged to be false
and time-frames involved.").

25 ²⁶ Even if the Court, given the totality of the allegations in the FAC, continues to view
26 materiality as a "close question," "[a]t the motion to dismiss stage of litigation, doubts about
27 materiality should be resolved in favor of the non-movant." *In re Westinghouse Sec. Litig.*, 832
F. Supp. 948 (W.D. Pa. 1993). *See also In re CMS Energy Sec. Litig.*, No. 02-cv-72004, 2005
U.S. Dist. LEXIS 439, at *22-23 (E.D. Mich. Jan. 7, 2005) (dismissal at the pleading stage on
lack of materiality allegations inappropriate unless the "alleged misrepresentations or omissions

1 **D. Plaintiffs Adequately Pleaded Scienter**

2 Defendants’ challenges to Plaintiffs’ scienter allegations also fail. The PSLRA requires
3 plaintiffs to plead “with particularity facts giving rise to a strong inference that the defendant
4 acted with the required state of mind.” 15 U.S.C. § 78u-4(b)(2). The Ninth Circuit has
5 interpreted this standard to require that plaintiffs plead particular facts giving rise to a strong
6 inference of deliberate recklessness. *See Oracle*, 380 F.3d at 1230. In *Tellabs*, the Supreme
7 Court held that when conducting a scienter inquiry, a court must determine “whether *all* of the
8 facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any
9 individual allegation, scrutinized in isolation, meets that standard.” *Tellabs*, 127 S. Ct. at 2509.
10 Additionally, when determining whether the pleaded facts give rise to a strong inference of
11 scienter, “the court must take into account plausible opposing inferences.” *Id.* at 2517. The
12 Ninth Circuit has interpreted *Tellabs* to mandate a more liberal scienter standard than was
13 previously employed in this Circuit:

14 [*Tellabs*] suggests that perhaps *Silicon Graphics*, *Vantive*, and *Read-Rite* are too
15 demanding and focused too narrowly.... while a high level of detail is required under the
16 PSLRA, a court should look to the complaint as a whole, not to each individual scienter
allegation as *Silicon Graphics* suggests. Thus, *Tellabs* counsels us to consider the totality
of the circumstances, rather than to develop separately rules of thumb for each type of
scienter allegation.

17 *South Ferry LP v. Killinger*, 542 F.3d 776, 784 (9th Cir. 2008)(citing *Tellabs*, 127 S. Ct. at
18 2511).²⁷ As shown below, the FAC’s allegations raise a strong inference of scienter.

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23 are so obviously unimportant to an investor that reasonable minds cannot differ on the question
of materiality”).

24 ²⁷ Defendants cite one case decided since *Tellabs* and *South Ferry* transformed the pleading of
25 scienter. (*See* Mem. at 18-25 (citing *Zucco*, 552 F.3d at 1006).) As Defendants acknowledge in
26 their Statement of Amended Decision, however, *Zucco* has been amended with contrary
27 language to conform with *Tellabs* and *South Ferry* such it now supports Plaintiffs’ position. *See*
Statement of Amended Decision, 2 (filed 3/16/09) (replacing the language “must still be more
compelling than an alternative innocent explanation” with “must still be at least as compelling as
an alternative innocent explanation”).

1 **1. The FAC Raises a Strong Inference that Defendants’ Knew of**
2 **the Off-Label Marketing Scheme**

3 Defendants contend “none of Plaintiffs’ allegations, individually or collectively”
4 adequately allege scienter, brazenly ignoring the Court’s prior finding of scienter with respect to
5 the illegal off-label marketing scheme. Mem. at 18. As previously noted *supra*, the Court has
6 already held that: “Plaintiffs have alleged sufficient facts to raise a strong inference that
7 Defendants had knowledge of the company’s off-label marketing scheme.” Order at 9. Further,
8 the FAC adequately alleges Defendants’ knowledge of the connection between Gilead’s off-label
9 marketing activities and its false and misleading 2Q2003 reports with the requisite specificity. In
10 the Ninth Circuit, “[b]ecause falsity and scienter in private securities fraud cases are generally
11 strongly inferred from the same set of facts,” the Court of Appeals has “incorporated the dual
12 pleading requirements of 15 U.S.C. §§ 78u-4(b)(1) and (b)(2) into a single inquiry.” *Glenbrook*
13 *Capital Ltd. P’ship v. Kuo*, No. C07-02377, 2008 U.S. Dist. LEXIS 80888, at*19 (N.D. Cal. Apr.
14 3, 2008). As detailed in the discussion of materiality herein, the FAC alleges with a high degree
15 of specificity Defendants’ awareness (1) that their illegal off-label marketing scheme resulted in
16 material Viread sales and artificial demand; and (2) of the connection between the scheme, sales
17 of Viread, and the Company’s 2Q2003 reports. *See supra* at 15; *Syncor*, 2007 U.S. App. LEXIS
18 14257, at *5 (finding “the same basic facts that allege falsity also allege scienter” where, as here,
19 plaintiffs’ confidential witness was alleged to have been present at a meeting in which
20 defendants discussed the illegal conduct the nondisclosure of which the court had found to be
21 false and misleading).

22 Based on the Court’s prior ruling that Plaintiffs alleged sufficient facts to raise a strong
23 inference that Defendants had knowledge of the Company’s off-label marketing scheme, coupled
24 with the FAC’s well pleaded allegations detailing the relationship between the scheme and its
25 false and misleading 2Q2003 reports, the Court can, and should, infer Defendants knowingly
26 misrepresented Gilead’s 2Q2003 sales.

1 **2. Each Individual Defendant’s Knowledge of the Off-Label**
2 **Marketing Scheme and Wholesaler Overstocking is**
3 **Reasonably Inferred and Corroborated by the Importance of**
4 **Viread Sales and Defendants’ Positions at the Company**

5 Under the “core operations inference,” knowledge of “facts critical to a business’s core
6 operations” may be imputed to individual corporate officers in support of a finding of scienter.
7 *South Ferry*, 542 F.3d at 782. In *South Ferry*, the Ninth Circuit held that core operation
8 allegations can satisfy the PSLRA’s scienter requirement in three different ways: (a) “the
9 allegations may be used in any form along with other allegations that, when read together, raise
10 an inference of scienter that is ‘cogent and compelling, thus strong in light of other
11 explanations’”; (b) “such allegations may independently satisfy the PSLRA where they are
12 particular and suggest that defendants had actual access to the disputed information”; and (c)
13 “such allegations may conceivably satisfy the PSLRA standard in a more bare form, without
14 accompanying particularized allegations, in rare circumstances where the nature of the relevant
15 fact is of such prominence that it would be ‘absurd’ to suggest that management was without
16 knowledge of the matter.” *Id.* at 786.

17 Here, the FAC satisfies all three standards. Viread is crucial to Gilead’s profitability and
18 was the Company’s flagship product. (¶¶2, 4.) In such circumstances, courts within the Ninth
19 Circuit have found that knowledge of the nature and import of a company’s “core operations” --
20 in this case the illegal off-label marketing campaign driving sales of Gilead’s leading product --
21 may be imputed to the Individual Defendants in support of a finding of scienter.²⁸ In the
22 pharmaceutical context in particular, courts widely recognize that, “[c]omprehensive knowledge”

23 ²⁸ See *South Ferry*, 542 F.3d at 785 (allegations regarding management’s role in a corporate
24 structure and the import of the allegedly misstated corporate information at issue satisfied
25 scienter alongside “allegations about management’s exposure to factual information within the
26 company”); *America West*, 320 F.3d at 943 n.21 (finding it “absurd” to contend even that
27 outside directors, much less corporate managers, would not discuss and be knowledgeable of
28 highly significant FAA investigations or negotiations); *In re Countrywide Fin. Corp. Sec. Litig.*,
588 F. Supp. 2d 1132, 1189 (C.D. Cal. 2008) (defendant’s position within a company can
support a strong inference of scienter when the alleged misrepresentations relate to the
company’s core operations, and may do so standing alone where it is “absurd to suggest” that a
defendant did not know).

1 of regulatory developments involving a pharmaceutical firm's leading product may be imputed
2 to the highest ranking members of the firm. *See In re Genta, Inc. Secs. Litig.*, No. 04-2123, 2005
3 U.S. Dist. LEXIS 22857, at *21 (D.N.J. Sept. 29, 2005) (collecting cases). Here, Defendant
4 Martin, whose comments, according to CW1 and CW2, caused the issuance of the FDA Untitled
5 Letter, was Gilead's CEO and was intimately involved in the promotion of Viread. (¶79.) The
6 remaining Individual Defendants, who were each, at a minimum, Gilead vice-presidents, were
7 also involved in the promotion of Viread and in attendance at many of the national Company
8 meetings where off-label tactics were encouraged. (¶¶61-64, 70-78, 102-104, 109, 114-15, 117-
9 21.) The Individual Defendants' positions with the Company, coupled with the paramount
10 importance of Viread sales and prescriptions during the Class Period, support an inference that
11 the Individual Defendants were aware of their misstatements of wholesaler inventory levels,
12 whether viewed in the context of Plaintiffs' other allegations or standing alone.²⁹

13 3. Insider Stock Sales Support A Strong Inference Of Scienter

14 The Court previously held insider stock sales alone are insufficient to plead scienter.³⁰
15 Under *Tellabs*, however, insider stock sales may now further corroborate and bolster Plaintiffs'
16 other scienter allegations. *See South Ferry*, 542 F.3d at 78 ("*Tellabs* counsels courts to consider
17 the "totality of the circumstances, rather than to develop separately rules of thumb for each type
18 of scienter allegation.")³¹ As previously shown herein, Plaintiffs alleged additional

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20 ²⁹ Other allegations of the FAC corroborating Plaintiffs' "core operations" allegations include the
21 Untitled Letter and FDA Warning Letters themselves, and the statements of several medical
22 practitioners. *See supra* at 14.

22 ³⁰ In its prior ruling, the Court relied upon the pre-*Tellabs* decisions *Ronconi v. Larkin*, 253 F.3d
23 423, 434 (9th Cir. 2001) and *In re Silicon Graphics, Inc. Sec. Litig.*, 183 F.3d 970, 985 (9th Cir.
24 1999), both of which, unlike the case at bar, involved Complaints in which there were no facts
25 pled in support of scienter beyond stock sales. Curiously, although Defendants, aware of
26 *Tellabs*, devote a section of their brief in which they purport to take a holistic view of the FAC's
27 allegations, that section focuses almost exclusively on the Individual Defendants' stock sales.
(Mem. at 24-25.)

26 ³¹ Additionally, *Tellabs*' flexible standard precludes an exclusive use of the *Silicon Graphics*
27 factors with respect to insider stock sales. *Countrywide*, 588 F. Supp. 2d at 1187. Rather, "[t]he
28 Court finds an additional factor useful for this case: whether innocent explanations for trading-
related conduct are economically rational. This requires straightforward *Tellabs* balancing -- are

1 corroborating facts sufficient to raise a strong inference that Defendants were aware of the illegal
2 off-label marking scheme as well as the connection between the scheme and sales of Viread. *See*
3 *infra* at 24.³²

4 **4. Viewed Holistically, the FAC Pleads a Strong Inference of**
5 **Scienter**

6 In *Tellabs*, the Supreme Court stated that in determining whether scienter has been
7 adequately plead, “[t]he inquiry . . . is whether *all* of the facts alleged, taken collectively, give
8 rise to a strong inference of scienter, not whether any individual allegation, scrutinized in
9 isolation, meets the standard.” *Tellabs*, 127 S. Ct. at 2509. The requisite inference “need not be
10 irrefutable . . . or ‘even the most plausible of competing inferences.’” *Tellabs*, at 2510. Rather,
11 it need only be “at least as compelling” as any opposing inference one could draw from the facts
12 alleged. *Id.*³³

13 Taken as whole, the FAC sufficiently pleads scienter. *See, e.g., In re New Century*, 588
14 F. Supp. 2d 1206, 1228, 1233 (C.D. Cal. 2008) (observing *Tellabs* cautions courts to view
15 scienter holistically). As demonstrated herein, Defendants knowingly, or with deliberate
16 recklessness, failed to disclose that their illegal off-label sales scheme materially inflated Viread
17 sales, and thus, the company’s 2Q2003 financial reports. Defendants’ proposed “competing
18 inferences” – that Defendants’ statements were intended “to convey a realistic assessment of

19 the innocent explanations at least as cogent and compelling as inferences that encourage a
20 scienter finding?” *Id.* Here, Defendants fail to provide an innocent explanation for their
21 significant insider trading.

22 ³² Should the Court find the insider sales do not bolster Plaintiffs’ scienter allegations, which
23 they do, the stock sales inquiry ought not to detract from Plaintiffs’ scienter allegations as a
24 whole. *See, e.g., Amgen*, 544 F. Supp.2d at 1033, 1035 (“Plaintiffs have pled facts raising the
25 strong inference that Defendants were surreptitiously marketing the off-label uses of [certain
26 drugs]... where defendants’ “stock sales neither add nor detract from Plaintiffs’ scienter
27 arguments.”).

28 ³³ *See also South Ferry*, 542 F.3d at 784 (“[t]he Supreme Court’s reasoning in *Tellabs* permits a
series of less precise allegations to be read together to meet the PSLRA requirement. . . . Vague
or ambiguous allegations are now properly considered as part of a holistic review when
considering whether the complaint raises a strong inference of scienter”); *In re Asyst Techs., Inc.*
Deriv. Litig., No. C-06-04699, 2008 U.S. Dist. LEXIS 96834, at * 37 (N.D. Cal. Nov. 12, 2008)
(allegations as a whole demonstrate “a sufficient inference of scienter....”).

1 Viread’s demand” (Mem. at 24); that Defendants were holding on to their valuable stock during
2 the Class Period (*Id.*); that the increased Viread sales were the result of increased acceptance of
3 Viread in federal programs (Mem. at 17-18 n.8) – are all implausible. Even if the Court finds
4 any of Defendants’ proposed inferences to be plausible, in no event are they more compelling
5 than those alleged in the FAC.

6 **E. Plaintiffs Adequately Pleaded Control Person Liability**

7 The FAC adequately alleges a primary violation of §10(b) and Rule 10b-5, and that the
8 Individual Defendants controlled the primary violator. *In re Adaptive Broadband Sec. Litig.*,
9 2002 U.S. Dist. LEXIS 5887, at *58-59 (N.D. Cal. Apr. 2, 2002) (“the fact that the named
10 individual defendants held important positions in the company is sufficient at the pleadings
11 stage”). Plaintiffs allege the Individual Defendants held active, executive positions in the
12 Company. (¶¶25-32.) Thus, Plaintiffs have adequately alleged a *prima facie* case under §20(a)
13 of the Exchange Act.

14 **VI. LEAVE TO AMEND**

15 Should the Court determine that the FAC does not meet PSLRA pleading requirements,
16 Plaintiffs respectfully request leave to amend pursuant to Fed. R. Civ. P. 15(a). “Generally, Rule
17 15 advises the court that ‘leave shall be freely given when justice so requires.’ This policy is ‘to
18 be applied with extreme liberality.’” *Eminence Capital L.L.C. v. Aspeon, Inc.* 316 F.3d 1048,
19 1051 (9th Cir. 2003) (citations omitted). The Ninth Circuit has “‘repeatedly held that a district
20 court should grant leave to amend even if no request to amend the pleading was made, unless it
21 determines that the pleading could not possibly be cured by the allegation of other facts.’”
22 *Connetics*, 2008 U.S. Dist. LEXIS 62515, at *9 (quoting *Lopez v. Smith*, 203 F.3d 1122, 1130
23 (9th Cir. 2000)). Here, since the operative complaint in this action was filed prior to the
24 Supreme Court’s *Tellabs* ruling and its progeny of cases applying the Court’s pleading standards,
25 Plaintiffs should be granted leave to amend the complaint to comport with the current pleading
26 standard should this Court find the allegations of the FAC to be insufficient.

1 Dated: April 14, 2009

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2
3
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1 **PROOF OF SERVICE**

2 I, Mercedes Gallagher, declare that I am over the age of eighteen (18) and not a party to
3 the within action. I am employed in the law firm of Kaplan Fox & Kilsheimer LLP, 350
4 Sansome Street, Suite 400, San Francisco, California 94104.

5 On April 14, 2009, I used the Northern District of California's Electronic Case Filing
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7 **PLAINTIFFS' MEMORANDUM OF POINTS AND AUTHORITIES IN**
8 **OPPOSITION TO DEFENDANTS' MOTION TO DISMISS THE FOURTH**
9 **CONSOLIDATED AMENDED COMPLAINT**

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11 constitutes service. According to the ECF/PACER system, for this case, the parties served are as
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1 On this date, I served the below parties:

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7 I declare under penalty of perjury under the laws of the United States of America and the
8 State of California that the foregoing is true and correct.

9 Executed April 14, 2009, at San Francisco, California.

10

11

/s/ Mercedes Gallagher
Mercedes Gallagher

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28 PLAINTIFFS' MEMORANDUM OF POINTS AND AUTHORITIES IN OPPOSITION TO
DEFENDANTS' MOTION TO DISMISS THE FOURTH CONSOLIDATED AMENDED COMPLAINT
CASE NO.C-03-4999-SI