

No. 06-16185

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

In re GILEAD SCIENCES SECURITIES LITIGATION

TRENT ST. CLARE and TERRY JOHNSON,
On Behalf of Themselves and All Others Similarly Situated,
Plaintiffs-Appellants,

vs.

GILEAD SCIENCES, INC., JOHN C. MARTIN, JOHN F. MILLIGAN,
MARK L. PERRY, NORBERT W. BISCHOFBERGER, ANTHONY
CARRACIOLO and WILLIAM A. LEE,
Defendants-Appellees.

Appeal From the United States District Court
for the Northern District of California
Master File No. C-03-4999-MJJ
The Honorable Martin J. Jenkins

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I. INTRODUCTION

Defendants' misdirection is remarkable – but unavailing. This appeal is not about multiple amendments; the operative Complaint is the *first* complaint filed by plaintiffs after the Supreme Court changed the law of this Circuit regarding loss causation in *Dura Pharmaceuticals, Inc. v. Broudo*, 544 U.S. 336 (2005). This appeal is not about leave to amend, defendants' Issue No. 3, which plaintiffs do not raise on appeal. (*Compare* Defendants' Brief ("DB") 4 *with* Appellants' Opening Brief ("AOB") 1) The Complaint amply pleads a short, plain statement that "provides the defendants with notice of what the relevant economic loss might be or of what the causal connection might be between that loss and the misrepresentation" alleged. *Dura*, 544 U.S. at 347. No amendment is necessary. Nor is this appeal about "Life-Saving Drugs." (DB6) Quite the contrary, the essence of plaintiffs' Complaint is that defendants concealed known safety concerns and promoted their drug for unapproved uses, exploiting an incredibly vulnerable, life-threatened population to increase sales, boost Gilead's stock price, and cash in on insider sales – and did so in flagrant violation of FDA rules. (ER31-36¶¶1-16)

The issues on appeal are straightforward. Plaintiffs challenge the district

be disbelieved or challenged by factual findings and adverse inferences at the pleading stage; and (3) is loss causation pled when a Complaint alleges that the challenged event was a “substantial contributing cause” of the loss or is a precise damages analysis required at the pleading stage. In the interest of judicial efficiency, plaintiffs also raise the adequacy of the Complaint’s allegations of falsity, scienter, and materiality so that this Complaint may be upheld and the litigation move forward.¹

Perhaps realizing that the legal issues on appeal are stacked against them, defendants resort to relentless interjection of irrelevant factual issues and inaccurate representations of the record. For example, defendants represent to this Court that the July 29, 2003 (second) FDA warning letter “referred to a single incident at a promotional booth in April 2003” and that it “did not refer to or suggest the broader scheme alleged by plaintiffs.” (DB24 n.6; DB16) The record is squarely to the contrary. When this Court reads the FDA Warning Letter, it will see that in

¹ Defendants incorrectly assert that “Plaintiffs do not appeal the district court’s dismissal of plaintiffs’ section 20(a) claims.” (DB5 n.1) But, the very first sentence of Plaintiffs’ Opening Brief states “[t]his is an appeal from the dismissal of a securities fraud class action alleging violations of §§10(b) *and* 20(a) of the Securities Exchange Act of 1934” (AOB1) The §20(a) claim is also referenced in the Nature of the Case section. (AOB3) The conclusion requests that “the district court’s dismissal should be reversed and the Complaint should be upheld in its entirety.”

of Viread, and (b) that the materially low third quarter financial results and immediate stock price drop following announcement of those results were inextricably interconnected to that drop in prescription rates and wholesalers' overstock levels. (ER85-87¶¶200-05)

The standard of review – which requires this Court to accept those allegations as true, to construe them in the light most favorable to plaintiffs, and to evaluate loss causation on a *notice* pleading standard – is dispositive here. Because plaintiffs' Complaint amply gives notice of their loss causation theory, and also sufficiently alleges falsity, scienter, and materiality, the district court's dismissal should be reversed.

II. ARGUMENT

A. **FACT-BOUND ISSUES TO BE DECIDED AT TRIAL: Defendants' Factual Challenges Are Both Improper at This Stage and Unlikely to Prevail at Trial on a Fully-Developed Record**

Despite the fact that this case is at the pleading stage, defendants raise a variety of fact-bound assertions that they ask this Court to accept as a matter of law to uphold the district court's erroneous dismissal. (DB13, 41) They assert (1) that disclosure of the FDA letter "did not" cause Gilead's stock price to decline – even though the

to the prior year instead of the prior quarter and asserting that analyst reports “contradict” plaintiffs’ allegations – even though the analyst reports are consistent with plaintiffs’ allegations; (3) that defendants cannot be liable because they did not *admit* that the disappointing revenue and earnings results were related to Gilead’s inability to continue off-label marketing; and (4) that defendants should be allowed to evade liability for their fraud and the loss caused to plaintiffs because “the [stock] price recovered nearly half that loss within one day and recovered fully within a month.” *Id.*

None of these factual defenses is appropriate at the pleading stage. Moreover, none is likely to succeed on a fully developed record. All should be rejected at this stage by this Court.

1. Plaintiffs’ Complaint *Does* Allege that the FDA Warning Letter Caused Viread Sales to Decrease and Gilead’s Stock Price to Fall

Defendants insist on repeating – as though the issue had not been thoroughly explained in the Complaint and myriad briefs – that Gilead’s stock price did not decrease after the FDA published its second Warning Letter, requiring that Gilead cease its repeated practice of off-label marketing. (DB23, 24 n.6, 50) But, this is both undisputed and irrelevant

understand the scope of the off-label marketing and thus could not understand how the FDA's warning would impact sales." (ER83¶195) *See No. 84 Employer-Teamster Joint Council Pension Trust Fund v. America West Holding Corp.*, 320 F.3d 920, 935 (9th Cir. 2003) (district court dismissal reversed where complaint alleged "no immediate effect on the market price" after the July 14, 1998 disclosure of certain settlement agreements, but alleged that the "stock price dropped 31% on September 3, 1998 when the full economic effects of the settlement agreement and the ongoing maintenance problems were finally disclosed to the market").

The Complaint also explains the chain of events that the FDA Warning Letter triggered, culminating in a significant stock drop when Gilead began to disclose its true financial condition:

Unbeknownst to investors, the disclosure of the FDA Warning Letter had a detrimental effect on Viread sales. Physicians, now alerted to Gilead's illegal marketing efforts and to the safety problems with Viread, were less eager to prescribe it to their patients. Competitors were able to use the FDA Warning Letter as an argument to physicians to choose their own products over Viread. . . . The slow down in growth, coupled with the drop in sales and prescriptions immediately following the FDA Warning Letter disclosure, influenced wholesalers, who monitored sales of Viread very closely in order to gauge how much inventory to keep on hand. . . . wholesalers reduced their inventories of Viread to as little as *two weeks'* supply, far beneath historical levels for Viread, beneath the industry average of 5.8 weeks, and well beneath what would have been

(ER85-88¶¶200-08) Thus, the Complaint plainly *does allege* that the FDA Warning Letter caused Viread sales to decrease and Gilead's stock price to fall. Defendants' answer that the FDA Warning Letter "did not" cause the stock drop is a fact-bound defense that must be made in a motion for summary judgment or at trial on a fully-developed record. Again, the fact that defendants do not agree with plaintiffs' theory does not change the fact that the theory has been pled.

2. Defendants' "Spin" on Viread's Sales Numbers Is Contrary to the Record and Must Await Trial in Any Event – the Complaint Allegations Are Not Contradicted by Attached or Referenced Documents

Defendants ask this Court to step in as a trier of fact – at the pleading stage – to interpret financial results. (DB45-49) As they did in the misleading press releases that they published on October 29, 2003, defendants again work to spin the numbers to conceal their fraud, requesting factual inferences in defendants' favor on falsity and loss causation. But, adverse inference drawing on falsity and loss causation is not allowed by this or any other court at the pleading stage. *In re Daou Sys., Inc. Sec. Litig.*, 411 F.3d 1006, 1013 (9th Cir. 2005) *cert. denied*, __ U.S. __, 126 S. Ct. 1335 (2006) (this Court "accept[s] plaintiffs' allegations as true and construe[s] them in the light most favorable to plaintiffs"), *quoting Gompper v. VISX, Inc.*, 298 F.3d 893, 895

Cir. 2003) (clarifying that as to non-scienter allegations, “we will draw no inferences unfavorable to plaintiffs”).

Moreover, as discussed below, the tortured interpretation that defendants request is unlikely to prevail after a full record is developed. The market’s response shows that after October 28, 2003, Gilead could no longer fully conceal its financial condition and illegal marketing scheme. (ER87¶208) In any event, it is simply not true that the Complaint and judicially noticed documents “contradict” plaintiffs’ allegations.

First, to be clear, Viread sales *decreased* in the third quarter of 2003. The Complaint and attached exhibits show that Viread sales for 3Q 2003 – as compared with the prior quarter – were *down 31%*. (ER86¶205, 116) Defendants – then and now – try to confuse the issue by comparing their sales numbers to the prior year rather than the prior quarter. (ER86¶205; DB45-46) Indeed, defendants’ representation of Viread sales to this Court sharply mischaracterizes the record. (*See* DB46) Describing the Viread sales information summarized in the Morgan Stanley report attached to the Complaint, defendants state “[t]he pattern of peaks and valleys on an upward progression shown during the third quarter of 2003 is consistent with

2003. (ER116) “Down 31%” is a downward trend for that quarter. This supports – rather than contradicts – plaintiffs’ allegations.

Second, demand for Viread was also negatively affected by publication of the FDA Warning Letter, alerting physicians to defendants’ off-label marketing. Defendants’ assertion that “demand” for Viread was somehow different than “sales” of Viread is tortured, fact-bound, and unconvincing. (See DB45-46) As a matter of general market economics, “demand” is evaluated based on a company’s “sales” of a particular product. Defendants seek to separate wholesaler purchases (which are based on wholesalers’ evaluation of end-user demand) from doctor’s prescriptions (which also impact end-user demand). *Id.* In short, defendants assert that if inventory build is taken out of the equation, this Court can find as a matter of law that overall demand for Viread was not affected by disclosure of the off-label marketing.

The problem for defendants is that Morgan Stanley already did the math – and it supports plaintiffs’ theory. According to Morgan Stanley, once Gilead’s 3Q 2003 revenues are “normalized for inventory build/draw-down, currency, and price increases,” the “underlying demand growth” in 3Q was 10% as compared with 21% in 2Q and 22% in 1Q.³ (ER117) So, according to Morgan Stanley, Viread’s demand

growth curve took a serious dip in 3Q 2003. Again, this supports – rather than contradicts – plaintiffs’ theory.

The text of the Morgan Stanley report further clarifies that demand for Viread was negatively impacted in 3Q 2003. (ER115) Discussing the multiple problems that affected Viread demand in 3Q, the Morgan Stanley report concludes that “[t]he only lingering fundamental factor among the aforementioned is the fact that end-user demand run rates were actually lower than previously believed. Thus, while Viread demand continues to grow, it is off a lower base.” *Id.* That certain analysts predicted that things might improve in the future – as defendants continue to urge in their brief to this Court (DB46 n.10) – does not alter the fact that 3Q demand was negatively affected by the off-label marketing scheme.

Third, wholesalers did draw inventory down to record low levels. (ER86¶204, 117) The complaint alleges that inventory levels were “at the lowest level they had been in *four quarters*.” (ER86¶204) The Morgan Stanley report confirms this allegation. (ER117) Defendants ask this Court to draw inferences adverse to the Complaint because they assert the inventory levels were not *that* much lower than

earlier in the year. (DB49 n.13) This fact dispute simply must be saved for a fact-finder.

Finally, nothing in the exhibits that are attached to the Complaint or those that were judicially noticed “contradicts” plaintiffs’ allegation that “[p]hysicians, now alerted to Gilead’s illegal marketing efforts and to the safety problems with Viread, were less eager to prescribe it to their patients.” (ER85¶200) Again, in selectively quoting statements to this Court about doctors’ prescription rates, defendants confuse (relevant) 3Q prescription rates immediately after publication of the second FDA Warning Letter with (irrelevant) analysts’ predictions about the future. (DB46-47) The Bear Sterns report is not referencing prescription rates during 3Q 2003 – but rather predicting prescription trends for the future “once Viread-Emtriva co-formulated pill becomes available *in late 2004/early 2005.*” (SER209) The Bear Sterns’ prediction is based on what Bear Sterns believes doctors “expect” for the future, despite the fact that Bear Sterns is aware that market share will be “limited initially.” *Id.*

Further, the overall prescription rate listed in the Morgan Stanley report does in fact show reduced growth over prior quarters and – as pled in the Complaint – reflects

B infection or co-infection of HIV and Hepatitis B, Gilead did finally receive FDA approval of Viread as a first-line HIV therapy in late 2003). (ER58¶99, 73¶155)

Thus, the analyst reports are entirely consistent with plaintiffs' theory that prescriptions dropped immediately following publication of the FDA Warning Letter, as explicitly alleged in the Complaint:

Gilead saw a marked drop in prescriptions and sales in the weeks following the disclosure of the [second FDA Warning] letter. Even after prescriptions and sales recovered late in the Third Quarter, they did not go as high as they would have had the letter not issued.

(ER85¶201) As the Complaint further explains:

[a]lthough precise sales figures in the aftermath of the disclosure of the FDA Warning Letter are exclusively in the hands of Defendants, wholesalers, and certain third party organizations that track prescription drug sales (and are not available to Plaintiffs for use at this stage of the litigation), Morgan Stanley's October 29, 2003 report includes a chart of Viread prescriptions on a weekly basis demonstrating a sharp drop in August 2003, and flattened growth for the rest of the third quarter, as compared to previous quarters.

Id. Moreover, the Complaint alleges that it was not the drop in prescriptions alone that led to the loss; reduced prescriptions, decreased competitiveness in the market, and wholesalers' dramatic inventory drawdown all contributed to the disappointing third quarter results that caused Gilead's stock price to plummet. (ER85-88¶¶200-08)

In the end, these are fact-bound issues that must be evaluated on a full record and

assertions do not support the district court's erroneous dismissal which must be reversed.

3. Defendants Cannot Avoid Liability Just Because They Did Not Admit Their Fraud

Defendants also cannot avoid liability at the pleading stage – or at any other – because they did not admit their fraud to the investing public. Defendants repeatedly assert that “[b]ecause the disclosure preceding the stock drop made no mention of off-label marketing, these facts cannot suffice to establish the requisite causal connection between the alleged misrepresentation and the stock drop.” (DB44; *see also* DB24) According to defendants, companies can commit fraud and admit the impact of the fraud – and still avoid liability as long as they don't admit *how* they accomplished the fraud.

This Court has already rejected defendants' assertion. *Daou*, 411 F.3d at 1026. No explicit “corrective disclosure” admission is required. In *Daou*, this Court held that allegations that the stock price dropped after “disclosures of [the company's] true financial health . . . , if assumed true, are sufficient to provide [defendants] with some indication that the drop in [the company's] stock price was causally related to [defendants'] financial misstatements reflecting its practice of prematurely

requirement under *Dura* – in pleading or in proof. *Nursing Home Pension Fund v. Oracle Corp.*, No. C01-00988 MJJ, 2006 U.S. Dist. LEXIS 94470, at *35 (N.D. Cal. Dec. 20, 2006) (“several courts have recognized that *Dura* does not require a 10(b) plaintiff to identify a corrective disclosure in order to properly plead or prove loss causation”). In *Oracle*, the court recognized, “the language from which Defendants extract this corrective disclosure requirement speaks only in terms of the ‘truth’ and ‘relevant truth’ reaching the market place.” *Id.*, citing *Dura*, 544 U.S. at 1631-34. Certainly at the pleading stage, “a plaintiff adequately alleges loss causation where a defendant reveals the company’s ‘true financial condition.’” *Id.* at *36, citing *Daou*, 411 F.3d at 1026.

4. Defendants’ “Bounce Back” Theory Is Vitiating by the Plain Text of the Private Securities Litigation Reform Act

Defendants also cannot avoid liability by ignoring the plain text of the Private Securities Litigation Reform Act (“PSLRA”). In the district court and before this Court, defendants continue to suggest that they should be exonerated because Gilead’s stock price – which had fallen 12.5% overnight on a 1400% increase in daily trading volume – “recovered nearly half that loss within one day and recovered fully within a month.” (DP12) Essentially, defendants would have this Court evaluate the amount

damages caused by defendants' fraud are \$1 or \$1 billion, plaintiffs adequately plead a claim.

Moreover, defendants' pleas that the eventual stock price recovery somehow negates the loss caused by the stock price drop were anticipated and rejected by the PSLRA. Simply put, the PSLRA provides a method for calculating the stock price "bounce back." Under the PSLRA's established 90-day "bounce back" provision, an award of damages is limited to the difference between an investors' purchase price and "the mean trading price of that security during the 90-day period beginning on the date on which the information correcting the misstatement or omission that is the basis for the action is disseminated to the market." 15 U.S.C. 78u-4(e)(1).

Here, pursuant to the PSLRA's 90-day "bounce back," defendants are liable for substantial damages – at least tens of millions of dollars – to plaintiffs and the Class. No other analysis is necessary. Plaintiffs are not required to prove the amount of their damages at the pleading stage. *Gebhardt v. ConAgra Foods, Inc.*, 335 F.3d 824, 832 (8th Cir. 2003) (In ruling on a motion to dismiss, "we decline to attach dispositive significance to the stock's price movements absent sufficient facts and expert testimony, which cannot be considered at this procedural juncture, to put this

the amount of those damages is wholly irrelevant to whether plaintiffs have adequately pled a claim.

B. PLEADING ISSUES BEFORE THIS COURT: Plaintiffs' Loss Causation Theory Is Well Pled

Dura explicitly assumes that notice pleading governs loss causation. 544 U.S. at 346. The notice pleading standard requires that plaintiffs articulate a loss causation theory – not that it be weighed against whatever adverse inferences and explanations defendants can concoct. *Id.* at 347. This Court and courts around the country agree that plaintiffs amply plead loss causation by alleging that the fraud was a “substantial cause” of plaintiff’s loss. *Am. West*, 320 F.3d at 935. For each of these reasons, the district court’s dismissal must be reversed.

It cannot genuinely be disputed that plaintiffs’ Complaint alleges both a theory of loss causation – and supporting facts. Plaintiffs allege that defendants engaged in off-label marketing of Viread. (ER47-49¶¶59-65) Plaintiffs allege that the off-label marketing materially (and artificially) inflated Gilead’s Viread sales. (ER76¶169) Plaintiffs allege that on July 29, 2003, the FDA issued its second Warning Letter to Gilead, ordering Gilead to cease and desist from its repeated illegal promotion of Viread. (ER80¶182) Plaintiffs allege that immediately following publication of the

wholesalers noticed the drop in prescriptions immediately following publication of the FDA Warning Letter, they chose to draw down much more of the excess inventory than they otherwise would have done. (ER86¶204) Plaintiffs allege that the combined impact of the reduced prescriptions, decreased competitiveness in the marketplace, and reduction in wholesaler inventories caused Gilead's third quarter results to be materially less than expected. (ER86-87¶203-05) Finally, plaintiffs allege that when those materially low third quarter results – Gilead's true financial condition – were announced, Gilead's stock price fell 12% overnight on a volume that was 1400% over Gilead's average daily volume. (ER87¶208)

Indeed, in their brief – though cluttered by some self-serving language – defendants essentially articulate plaintiffs' loss causation theory:

In the Fourth Amended Complaint, plaintiffs allege that doctors became "less eager" to prescribe Gilead's groundbreaking HIV/AIDS drug Viread following the disclosure in early August 2003 that Gilead had received a letter from the FDA regarding an alleged incident involving alleged off-label marketing of Viread. As a result, according to plaintiffs, Gilead experienced a sharp drop in prescription levels (and thus demand) for Viread during the third quarter of 2003, the results of which were announced on October 28, 2003. Plaintiffs claimed that those disclosures caused the temporary drop in the company's stock price on October 29.

(DB2) That is most of plaintiffs' theory of loss causation, except that defendants

the FDA Warning Letter, decreased competitiveness, and wholesalers' drawdown of their supplies to record lows led to the poor financial results. (See ER86¶204)

Thus, by their own description, defendants clearly have notice of plaintiffs' theory. Whether or not defendants agree with it or believe that the evidence at trial will ultimately support it is entirely irrelevant at the pleading stage. Loss causation is amply pled.

Defendants contend, however, that plaintiffs' theory is not correct and "makes no sense." (DB24) But, if defendants' agreement with plaintiffs' theory of liability were a proper precondition, few complaints would ever be upheld. It is not. Just as district courts may not properly dismiss complaints by "disbelieving" allegations (*Neitzke v. Williams*, 490 U.S. 319, 327 (1989)), defendants may not support erroneous dismissals with "disbelief" of their own. The question is what is alleged. The allegations are accepted as "true." *Daou*, 411 F.3d at 1013. Plaintiffs have given defendants notice of their theory of loss causation. That is all that *Dura* requires. 544 U.S. at 346-47.

1. ***Dura* Requires Notice – Not Particularity**

Defendants misstate the rule of the Supreme Court in representing that "[u]nder *Dura*, a plaintiff in a securities fraud case *must plead facts that would demonstrate a*

We concede that the Federal Rules of Civil Procedure require only “a short and plain statement of the claim showing that the pleader is entitled to relief.” Fed. R. Civ. P. 8(a)(2). And we assume, at least for argument’s sake, that neither the Rules nor the securities statutes impose any special further requirement in respect to the pleading of proximate causation or economic loss.

544 U.S. at 346. *Dura* explains that, in the context of loss causation, the “short and plain statement” pleading requirement means that plaintiffs must simply provide “notice of what the relevant economic loss might be or of what the causal connection might be between that loss and the misrepresentation” *Id.* at 347.

Dura’s application of notice pleading is consistent with the Supreme Court’s earlier decision in *Swierkiewicz v. Sorema*, 534 U.S. 506 (2002). There, the Supreme Court confirmed that the only requirement of Rule 8(a)(2) pleading is to “give[] respondent fair notice of the basis for petitioner’s claims.” *Id.* at 514.

Defendants assert – based on a lone decision from the Fourth Circuit that predates both *Dura* and the PSLRA – that every element of a securities fraud claim must be pled with particularity. *Learning Works, Inc. v. The Learning Annex, Inc.*, 830 F.2d 541, 546 (1987). That case is obsolete under *Dura*.

Struggling to establish some interpretation of *Dura* under which plaintiffs’ Complaint would not have amply pled loss causation, defendants rest on two

itself, and holds that loss causation in the securities fraud context is amply pled by notice pleading. 544 U.S. 346.

To accept defendants' position, this Court would have to conclude that when the Supreme Court opined that loss causation pleading requires "some indication" of the loss, it meant "with particularity." Indeed, that is precisely the leap in logic that defendants make in their brief. (DB31) But "some indication" and "a causal connection" are not the same as "with particularity."

Notwithstanding the simple notice requirement, however, plaintiffs *have* pled a factual basis for their loss causation theory – as defendants concede. (DB19-20) Plaintiffs have not merely pled that "defendants' fraud caused plaintiffs' loss."⁴ Plaintiffs have not even rested on pleading that "defendants inflated the value of Gilead stock by illegally marketing its key drug and loss occurred when that inflation came out of the stock" – which would have satisfied *Dura*. Here, plaintiffs plead far more than *Dura* requires and have supported their theory of loss causation with facts that are exceptionally clear. (ER85-87¶¶200-05) Plaintiffs' Complaint alleges that the materially low third quarter financial results – and the resulting immediate stock

drop – were inextricably interconnected to the illegal, off-label marketing which had artificially inflated sales numbers and caused loss when prescription rates and wholesalers’ overstock levels dropped in response to publication of the second FDA Warning Letter, ordering Gilead to cease the illegal, off-label marketing. *Id.*⁵ Plaintiffs’ Complaint gives defendants ample notice of the loss causation theory and more than satisfies the standard established by the Supreme Court in *Dura*. (AOB29-31; ER34¶9, 35-36¶14-16, 85-88¶¶200-08) The district court’s dismissal should be reversed.

2. *Dura* Requires that Plaintiffs Articulate a Loss Causation Theory – Not that the Theory Be Weighed Against Other Possible Explanations

Defendants next brazenly assert that even if notice pleading sufficiently alleges loss causation under *Dura*, “a plaintiff must do more than simply articulate a theory” to plead that notice. (DB32) But, the Supreme Court says just the opposite. *Dura*

⁵ Defendants attempt to distract this Court with an assertion that plaintiffs have “waived” their allegations of Gilead’s intentional underestimation of wholesaler inventory stockpiling in the second quarter of 2003. (DB14 n.4) But, the allegations are not “waived.” Quite the contrary, in the “Nature of the Case,” plaintiffs describe the allegations that defendants “were deliberately reckless in publicly underestimating the related extent of the stockpiling.” (AOB2) Moreover, plaintiffs discuss the interaction of the wholesaler stockpiling with the ultimate loss caused in detail at

holds that that plaintiffs need only provide “notice” or “some indication” of the economic loss and its causal connection to the misrepresentations:

[The complaint should contain] notice of what the relevant economic loss might be or of what the causal connection might be between that loss and the misrepresentation [it should] provide a defendant with some indication of the loss and the causal connection that the plaintiff has in mind.

Dura, 544 U.S. at 347. *Dura* explicitly recognized that this requirement “is not meant to impose a great burden upon a plaintiff.” *Id.*

Defendants assert that plaintiffs’ loss causation theory – which defendants can and do articulate (DB2, 23) – has “a number of fatal flaws.” (DB23) But, the concept of notice pleading – as explicitly stated by the Supreme Court – is not to require plaintiffs to plead evidence to prove their allegations are correct; the concept is to provide defendants notice. *Dura*, 544 U.S. at 346. The fact that defendants may not concede that the theory is correct is irrelevant. Defendants’ “fatal flaws” must await trial.

Defendants struggle to assert that the notice requirement established in *Dura* still has a factual component because courts cannot accepted “unsupported, conclusory allegations.” (DB26) First, two of the three cases on which defendants rely are Rule 9(b) pleading cases where the factual basis requirements are different

required to uphold unsupported legal conclusions – it is not even in the securities fraud context, let alone on the issue of loss causation, and was decided long before *Dura. Clegg v. Cult Awareness Network*, 18 F.3d 752, 754-55 (9th Cir. 1994). Here, there is no unsupported legal conclusion; there is a well-articulated fact-based theory of loss causation.

Truly grasping, defendants try to create a dispute out of the fact that plaintiffs amended their loss causation allegations. As an initial matter, the operative Complaint is the *first* complaint filed in this matter since the Supreme Court changed the law of this Circuit regarding loss causation. Even if it were not, however, the law of this Circuit makes clear that pleading securities fraud is a process of “trial and error.” *Eminence Capital L.L.C. v. Aspeon, Inc.*, 316 F.3d 1048, 1052 (9th Cir. 2003). The fact that loss causation allegations have been refined over amendments is exactly the intended process – not an indication that the current allegations lack credibility, though weighing them is not appropriate at this stage in any event. *Daou*, 411 F.3d at 1013 (this Court “accept[s] plaintiffs’ allegations as true and construe[s] them in the light most favorable to plaintiffs”).

Ultimately, defendants cannot avoid the fact that plaintiffs have amply noticed a theory of loss causation. The district court dismissal should be reversed.

**3. This Court, Like Circuits Around the Country,
Requires that Defendants' Fraud Is a Substantial
Cause of Plaintiffs' Loss – Not the Only Cause**

Defendants' brief is revealing in its response to the district court's error in holding that plaintiffs needed to plead "what portion" of plaintiffs' loss "should be attributed" to defendants' fraud, beyond the allegation that "the material misrepresentations particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages sustained by Plaintiffs and other members of the Class." (ER88-89¶211) Defendants write that "the district court's statement was not necessary to its decision and thus provides no basis for reversal." (DB52 n.14)

But, the district court's legal error in holding plaintiffs to a higher pleading standard than required by the Supreme Court and this Court is indeed a basis for reversal. This Court has reversed a district court's dismissal of fraud claims, explicitly holding that the "District Court erred in finding that the existence of other factors, . . . precluded Plaintiffs' argument that [the challenged conduct] also contributed to [defendants'] failure to meet its forecasted third quarter earnings." *Am. West*, 320 F.3d at 936. This Court also reversed a district court's dismissal of fraud claims in part on the grounds that "a plaintiff is not required to show 'that a

Here, the district court erred in believing that it needed to evaluate “what portion, if any, of that decrease [in Gilead’s stock price] should be attributed to the alleged misconduct and what should be attributed to other market factors.” (ER183) The law of this Circuit, the Supreme Court, and circuits around the country makes clear that the district court’s analysis was error – and, indeed, a basis for reversal. *Sosa v. Alvarez-Machain*, 542 U.S. 692, 704 (2004); *Emergent Capital Inv. Mgmt., LLC v. Stonepath Group, Inc.*, 343 F.3d 189, 197 (2nd Cir. 2003); *Semerenko v. Cendant Corp.*, 223 F.3d 165, 183-87 (3rd Cir. 2000); *Miller v. Asensio & Co.*, 364 F.3d 223, 229 (4th Cir. 2004); *Caremark, Inc. v. Coram Healthcare Corp.*, 113 F.3d 645, 649 (7th Cir. 1997). Again, because the Complaint allegations amply allege loss causation, the dismissal should be reversed.

C. Plaintiffs’ Complaint Alleges Falsity, Scienter, and a Material Fraud

1. Defendants Concede that Falsity Is Sufficiently Alleged

Defendants do not assert that the district court’s dismissal should be upheld on the basis that plaintiffs failed to plead falsity. (*See* DB24)

2. The District Court Twice Acknowledged that Scienter Is Sufficiently Alleged

letters to Gilead, it becomes apparent that Plaintiffs have alleged sufficient facts to raise a strong inference that Defendants had knowledge of the company's off-label marketing scheme." (ER12, 25)

Defendants now assert that scienter was not properly pled because even though the district court held that plaintiffs alleged "sufficient facts to raise a strong inference that Defendants had knowledge of the company's off-label marketing scheme," the district court did not hold the scheme was material and that defendants had knowledge of the materiality. (DB61) That is not a scienter argument; it is a materiality argument and it is addressed below.⁶

Scienter was amply alleged. CWs 1 and 2 identified each defendant by name (except Carraciolo) and placed them at specific meetings where salespeople were given data to be used for off-label marketing. (ER47-48¶¶61-62, 50¶70, 51-52¶¶75-76, 60¶106, 61-62¶111, 62-63¶115, 63¶117, 64¶121) CW1 stated that 85-95% of his/her sales were achieved through off-label marketing and that s/he used off-label marketing at every single sales contact. (ER54-55¶87, 69¶144) The fact that CW1 left Gilead in May 2003 is irrelevant to his/her knowledge regarding the off-label

marketing which the Complaint alleges began in September 2001. (ER47-49¶¶59-65) Defendants' attacks on CW2 (DB17 n.5; DB58 n.16) are similarly meritless – as well as inappropriate at this stage. *Daou*, 411 F.3d at 1013-16 (holding that plaintiffs' allegations must be accepted as “true” and that identifying witnesses by number and describing “his or her job description and responsibilities . . . sufficiently me[e]ts the PSLRA’s requirements for confidential witnesses”). CW2 has consistently testified about the pressure that Gilead imposed to use off-label marketing and the scope of off-label marking throughout the company. (SER29¶116, 33¶136, 90¶120, 94¶137; ER67-68¶¶135, 138)

Moreover, despite defendants' rhetoric, through allegations about large meetings of sales people and Gilead's “Field Marketing Advisory Committee,” an elite group of Gilead employees responsible for monitoring and shaping Gilead's marketing efforts and advising Gilead management of the progress of those efforts (ER41-42¶¶39-42, 49-56¶¶68-90, 60-64¶¶106-121), plaintiffs did indeed provide “other information” about Gilead off-label marketing beyond CW1's and CW2's “own sales figures.” (*Compare* DB56-57)

Reviewing the CW allegations together with the FDA letters to Gilead – and the

allegations are more than sufficient to raise a strong inference that defendants had scienter of the off-label marketing scheme.

While the defendants' coordinated stock sales may not be sufficient to establish scienter on their own, they are further support of already strong scienter allegations. Specifically, between the date the FDA issued the second Warning Letter to Gilead and the date that the FDA made the letter public, defendants Perry and Bischofberger sold more than \$3,000,000 worth of stock each. (ER84-85¶199) Defendant Milligan sold almost \$700,000 worth of stock on the day that the Warning Letter was published. *Id.* Defendant Martin sold more than \$3,000,000 worth of stock the next day. *Id.* This was the first and only time all of the defendants sold their stock during one coordinated time period. In combination with the already strong scienter allegations, these facts provide additional weight. *Florida State Bd. of Admin. v. Green Tree Fin. Corp.*, 270 F.3d 645, 663 (8th Cir. 2001) (defendants' fact challenges to motive allegations cannot be resolved on a motion to dismiss). Cumulatively, scienter is amply alleged.

3. Materiality Is Sufficiently Alleged

The Complaint alleges substantially more than CW1's and CW2's "own sales figures" to allege the materiality of the off-label marketing scheme in inflating

use of off-label marketing to materially increase Gilead's sales of Viread. (ER68-76¶¶141-165) Defendants do not – and cannot at this stage – dispute the detailed allegations of company-wide meetings promoting off-label marketing (ER59-64¶¶101-23, 67-68¶138), enormous pressure on individual sales people to use off-label marketing (ER60-61¶108), and actual dialogue among drug sales representatives regarding which off-label tactics were generating the most sales. (ER71¶151) Nor can defendants dispute that the FDA seemed to think that the off-label marketing was material in writing about the “significant public health and safety concerns raised by these repetitive promotional activities.” (ER109) Cumulatively, these allegations are more than ample to plead materiality – particularly in light of the Supreme Court's holding that materiality is decided as a matter of law only when “reasonable minds cannot differ on the question.” *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 450 (1976). This Court should uphold the Complaint in its entirety and allow this litigation to finally proceed.

III. CONCLUSION

For the foregoing reasons, the district court's dismissal should be reversed and the Complaint should be upheld in its entirety.

DATED: January 23, 2007

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RULE 32(a)(7)(C) CERTIFICATE

The undersigned counsel certified that Appellants' Reply Brief uses a proportionally spaced Times New Roman typeface, 14-point, and that the text of the brief comprises 6,944 words according to the word count provided by Microsoft Word 2002 word processing software.

A handwritten signature in black ink, appearing to read "Susan K. Alexander", written over a horizontal line.

SUSAN K. ALEXANDER

DECLARATION OF SERVICE BY MAIL

I, the undersigned, declare:

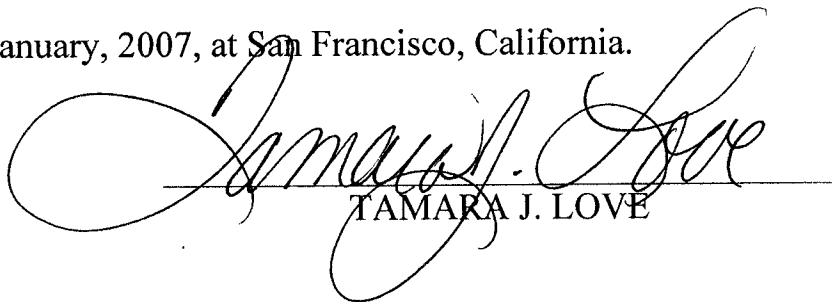
1. That declarant is and was, at all times herein mentioned, a citizen of the United States and employed in the City and County of San Francisco, over the age of 18 years, and not a party to or interested party in the within action; that declarant's business address is 100 Pine Street, Suite 2600, San Francisco, California 94111.

2. That on January 23, 2007, declarant served the **APPELLANTS' REPLY BRIEF** by depositing a true copy thereof in a United States mailbox at San Francisco, California in a sealed envelope with postage thereon fully prepaid and addressed to the parties listed on the attached Service List.

3. That there is a regular communication by mail between the place of mailing and the places so addressed.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 23rd day of January, 2007, at San Francisco, California.



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