

A-\_\_\_\_\_

---

In The  
SUPREME COURT OF THE UNITED STATES  
October Term 2008

---

Gilead Sciences, Inc., *et al.*,  
*Applicants/Petitioners*,

v.

Trent St. Clare, *et al.*,  
*Respondents*.

---

Application for an Extension of Time Within Which to File  
a Petition for a Writ of Certiorari to the  
United States Court of Appeals for the Ninth Circuit

---

APPLICATION TO THE HONORABLE  
ANTHONY M. KENNEDY AS CIRCUIT JUSTICE

---

STEPHEN C. NEAL  
JOHN C. DWYER  
COOLEY GODWARD KRONISH LLP  
Five Palo Alto Square  
3000 El Camino Real  
Palo Alto, CA 94306  
(650) 843-5000

CARTER G. PHILLIPS\*  
ROBERT N. HOCHMAN  
DANIEL A. McLAUGHLIN  
SIDLEY AUSTIN LLP  
1501 K Street, N.W.  
Washington, D.C. 20005  
(202) 736-8000

December 19, 2008

Attorneys for Applicants/Petitioners  
\*Counsel of Record

## **APPLICATION FOR EXTENSION OF TIME**

Pursuant to Rule 13.5 of the Rules of this Court, Applicants Gilead Sciences, Inc., John C. Martin, John F. Milligan, Mark L. Perry, Norbert W. Bischofberger, Anthony Carraciolo and William A. Lee hereby request a 30-day extension of time within which to file a petition for a writ of certiorari to and including February 6, 2009.

### **JUDGMENT FOR WHICH REVIEW IS SOUGHT**

The judgment for which review is sought is *In re Gilead Sciences, Inc. Securities Litigation*, 536 F.3d 1049 (9th Cir. 2008), which is attached as Exhibit 1.

### **JURISDICTION**

The judgment of the United States Court of Appeals for the Ninth Circuit was entered on August 11, 2008. The Court of Appeals issued an order denying a Petition for Rehearing and Petition for Rehearing *En Banc* on October 9, 2008 (attached as Exhibit 2). This Court will have jurisdiction over any timely filed petition for certiorari in this case pursuant to 28 U.S.C. § 1254(1). Under Rules 13.1, 13.3, and 30.1 of the Rules of this Court, a petition for certiorari is due to be filed on or before January 7, 2009.

In accordance with Rule 13.5, this application is being filed more than 10 days in advance of the filing date for a petition for certiorari.

### **REASONS JUSTIFYING AN EXTENSION OF TIME**

Applicants respectfully request a 30-day extension of time within which to file a petition for a writ of certiorari seeking review of the decision of the

United States Court of Appeals for the Ninth Circuit in this case, to and including February 6, 2009.

1. The undersigned counsel of record was recently engaged to prepare the petition in this case. The extension of time is necessary because of the undersigned counsel's need to examine the record and to analyze legal issues in depth in order adequately to prepare the petition.

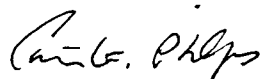
2. The extension of time is further necessary because of other, previously scheduled commitments, including the following upcoming commitments in this Court: (a) filing a petition for certiorari in *Canadian Pacific Railway v. Lundeen* (Nos. 07-1656, 07-1670, 07-1672, 07-1676, 07-1679, 07-1680, 07-1684, 07-1693, 07-1694, 07-1698, 07-1699, and 07-1707 in the Eighth Circuit) on January 8, 2009; (b) filing a respondent's brief on the merits in *United States v. Navajo Nation* (No. 07-1410) on January 9, 2009; (c) presentation of oral argument in *Ministry of Defense of Iran v. Elahi* (No. 07-615) on January 12, 2009; and (d) filing the petitioner's reply in support of certiorari in *Federal Insurance Co. v. Kingdom of Saudi Arabia* (No. 08-640) on January 13, 2009.

3. No prior requests for extensions have been made in this matter.

## CONCLUSION

For the foregoing reasons, Applicants respectfully request that this Court grant an extension of 30 days, to and including February 6, 2009, within which to file a petition for a writ of certiorari in this case.

Respectfully submitted,



STEPHEN C. NEAL  
JOHN C. DWYER  
COOLEY GODWARD KRONISH LLP  
Five Palo Alto Square  
3000 El Camino Real  
Palo Alto, CA 94306  
(650) 843-5000

---

CARTER G. PHILLIPS\*  
ROBERT N. HOCHMAN  
DANIEL A. McLAUGHLIN  
SIDLEY AUSTIN LLP  
1501 K Street, N.W.  
Washington, D.C. 20005  
(202) 736-8000

December 19, 2008

**Attorneys for Applicants/Petitioners**

\*Counsel of Record

CERTIFICATE OF SERVICE

I, Carter G. Phillips, certify that, on this nineteenth day of December, 2008, I caused a copy of the foregoing Application for Extension of Time to be served on the following by first-class mail, postage pre-paid:

Jack G. Fruchter  
Abraham, Fruchter & Twersky  
One Penn Plaza, Suite 2805  
New York, NY 10119  
(212) 279-5050  
(212) 279-3655 (Fax)

Marc M. Umeda  
Robbins Umeda & Fink, LLP  
610 West Ash Street, Suite 1800  
San Diego, CA 92101  
(619) 525-3990  
(619) 525-3991 (Fax)

Robert S. Green  
Green Welling, LLP  
595 Market Street, Suite 2750  
San Francisco, CA 94105  
(415) 477-6700  
(415) 477-6710 (Fax)

Laurence D. King  
Linda M. Fong  
Kaplan, Fox & Kilsheimer, LLP  
350 Sansome Street, Suite 400  
San Francisco, CA 94104  
(415) 772-4700  
(415) 772-4707 (Fax)

Lori S. Brody  
Kaplan, Fox & Kilsheimer, LLP  
1801 Century Park East, Suite 1460  
Los Angeles, CA 90067  
(310) 439-6006  
(310) 439-6004 (Fax)

James M. Orman  
Law Offices of James M. Orman  
1845 Walnut Street, 14<sup>th</sup> Floor  
Philadelphia, PA 19103  
(215) 523-7800  
(215) 523-9290 (Fax)

Lori G. Feldman  
Milberg, LLP  
One Pennsylvania Plaza  
New York, NY 10119  
(212) 594-5300  
(212) 868-1229 (Fax)

Eric J. Belfi  
Labaton Sucharow & Rudoff, LLP  
100 Park Avenue  
New York, NY 10017  
(212) 907-0878  
(212) 818-0477 (Fax)

Juan Carlos Sanchez  
Class Action Clearinghouse  
Stanford Digital Law Project – Securities  
559 Abbott Way  
Stanford, CA 94305  
(650) 725-0479

Robert A. Jigarjian  
Jigarjian Law Office  
128 Tunstead Avenue  
San Anselmo, CA 94960  
(415) 341-6660

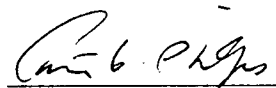
Sanford Svetcov  
Susan K. Alexander  
Coughlin Stoia Geller Rudman & Robbins,  
LLP  
100 Pine Street, Suite 2600  
San Francisco, CA 94111-5238  
(415) 288-4545  
(415) 288-5434 (Fax)

Douglas C. McDermott  
McDermott Newman, PLLC  
1001 Fourth Avenue, Suite 3200  
Seattle, WA 98154  
(206) 749-9296  
(206) 749-9467 (Fax)

Michael M. Goldberg  
Glancy & Binkow, LLP  
1801 Avenue of the Stars, Suite 311  
Los Angeles, CA 90067  
(310) 201-9150  
(310) 201-9160 (Fax)

David J. George  
Robert J. Robbins  
Coughlin Stoia Geller Rudman &  
Robbins, LLP  
120 East Palmetto Park Road, # 500  
Boca Raton, FL 33432  
(561) 750-3000  
(561) 750-3364 (Fax)

Samuel Rudman  
Coughlin Stoia Geller Rudman &  
Robbins, LLP  
58 South Service Road, Suite 200  
Melville, NY 11747  
(631) 367-7100  
(631) 367-1173 (Fax)



---

CARTER G. PHILLIPS



**In re GILEAD SCIENCES SECURITIES LITIGATION.**

**Rick Hartman, on behalf of himself and all others similarly situated; Trent St. Clare; Terry Johnson, Plaintiffs–Appellants,**

v.

**Gilead Sciences, Inc.; John C. Martin; John F. Milligan; Mark L. Perry; Norbert W. Bischofberger; Anthony Carraciolo; William Lee, Defendants–Appellees.**

No. 06–16185.

United States Court of Appeals,  
Ninth Circuit.

Argued and Submitted Dec. 6, 2007.

Filed Aug. 11, 2008.

**Background:** Individual investors brought securities fraud action on behalf of themselves and a proposed class of all individuals who purchased defendant biopharmaceutical company’s publicly traded securities, alleging that company and its top officers misled the investing public by representing that demand for its most popular product was strong without disclosing that unlawful marketing was the cause of that strength. The United States District Court for the Northern District of California, *Martin J. Jenkins, J.*, 2006 WL 1320466, dismissed the action. Investors appealed.

**Holding:** The Court of Appeals, Michael Daly Hawkins, Circuit Judge, held that complaint’s allegations were sufficient to state securities fraud claim.

Reversed and remanded.

**1. Securities Regulation ⇌60.47**

To establish loss causation in a securities fraud action, plaintiff must demonstrate a causal connection between the deceptive acts that form the basis for the claim of securities fraud and the injury

suffered by the plaintiff. Securities Exchange Act of 1934, §§ 10(b), 21D(b)(4), 15 U.S.C.A. §§ 78j(b), 78u–4(b)(4); 17 C.F.R. § 240.10b–5.

**2. Securities Regulation ⇌60.47**

In establishing loss causation in a securities fraud case, the misrepresentation need not be the sole reason for the decline in value of the securities, but it must be a substantial cause. Securities Exchange Act of 1934, §§ 10(b), 21D(b)(4), 15 U.S.C.A. §§ 78j(b), 78u–4(b)(4); 17 C.F.R. § 240.10b–5.

**3. Federal Civil Procedure ⇌636**

Special pleading rule as to fraud imposes the heightened requirement so that the fraud-action defendant can prepare an adequate answer from the allegations. Fed.Rules Civ.Proc.Rule 9(b), 28 U.S.C.A.

**4. Securities Regulation ⇌60.47**

Individual investors’ complaint against biopharmaceutical company sufficiently alleged a causal relationship between the increase in sales resulting from company’s impermissible off-label marketing of drug Viread, the Food and Drug Administration’s (FDA) warning letter’s effect on drug orders, and the warning letters’s effect on company’s stock price, as required to state a loss causation claim under 10b-5, notwithstanding any limited temporal gap between the time misrepresentation was publicly revealed and subsequent decline in stock value; complaint alleged that stock price dropped immediately after company disclosed less-than-expected revenues resulting from reductions in demand, which in turn, was expressly alleged to have been caused by FDA warning letter as to the company’s impermissible off-label marketing. Securities Exchange Act of 1934, §§ 10(b), 21D(b)(4), 15 U.S.C.A. §§ 78j(b), 78u–4(b)(4); 17 C.F.R. § 240.10b–5.

Susan K. Alexander (briefed and argued), Lerach, Coughlin, Stoia, Geller, Rudman & Robbins LLP, San Francisco, CA, for the plaintiffs-appellants.

John C. Dwyer (briefed and argued), Grant Fondo and Jeffrey M. Kaban (appeared only), Cooley, Godward, Kronish, LLP, Palo Alto, CA, for the defendants-appellees.

Appeal from the United States District Court for the Northern District of California; Martin J. Jenkins, District Judge, Presiding. D.C. No. CV-03-04999-MJJ.

Before: ALEX KOZINSKI, Chief Judge, HAWKINS, and ROBERT E. COWEN,\* Circuit Judges.

MICHAEL DALY HAWKINS, Circuit Judge:

A group of individual investors brought this securities fraud action on behalf of themselves and a proposed class comprising all individuals (collectively, the "Investors") who purchased Gilead Sciences, Inc.'s ("Gilead") publicly traded securities between July 14, 2003, and October 28, 2003 ("class period"). They allege that Gilead misled the investing public by representing that demand for its most popular product was strong without disclosing that unlawful marketing was the cause of that strength.

The district court dismissed under Rule 12(b)(6) of Civil Procedure, holding that the Investors failed to sufficiently allege loss causation. We have jurisdiction under 28 U.S.C. § 1291, and we reverse.

\* The Honorable Robert E. Cowen, Senior United States Circuit Judge for the Third Circuit, sitting by designation.

1. We recount only those facts necessary for understanding the loss causation issue. The complaint, which spans over seventy pages,

## FACTS AND PROCEDURAL HISTORY

### I. The Complaint's Allegations

The Investors' Fourth Amended Complaint ("complaint") alleges violations of sections 10(b) and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. §§ 78j(b), 78t(a), and SEC Rule 10b-5, 17 C.F.R. § 240.10b-5. The complaint names as defendants Gilead and some of its top officers ("Officers").

Taking its allegations as true, the complaint tells the following story about Gilead and its marketing practices.<sup>1</sup>

Gilead is a biopharmaceutical company that specializes in developing and marketing treatments for life-threatening diseases. One of the company's commercial products is Viread, an antiretroviral agent used in combination with other drugs to treat HIV.

Gilead's fortunes, as reflected in its stock price, depended heavily on Viread's commercial success. Sales of Viread amounted to about 65% of Gilead's total revenues at all relevant times of this action. "Wall Street analysts looked to sales of Viread, Gilead's most important and most promoted drug, to gauge whether the Company's business was on track and growing. If Gilead failed to publicly report healthy, growing Viread sales, its stock price would be greatly diminished."

Although Gilead had a clear incentive to aggressively promote Viread, it was required to comply with federal law, including the Food and Drug Administration's ("FDA") marketing regulations. Generally, those regulations prohibit the market-

offers much greater detail. Because we disagree with the district court on the issue, we frequently quote the complaint to demonstrate that the Investors did in fact explicate the causal logic underlying their theory.

ing of drugs for non-FDA-approved uses, commonly referred to as “off-label” uses. “For example, it would be considered off-label for a company to market a FDA-approved HIV/AIDS drug as also being effective for fighting Hepatitis B infection . . . if such use of the drug had not been reviewed and approved by the FDA and included in the” drug’s FDA-approved package labeling. While physicians are free to prescribe drugs for off-label uses,<sup>2</sup> they rely on the FDA-approved prescribing information to determine which drugs can be used safely and effectively by patients with specific health problems. The FDA approved Viread for use in approximately 40% of the available HIV patient pool. Repeatedly violating the FDA’s off-label marketing regulations in an effort to have Viread prescribed to some of the remaining 60% of available HIV patients, Gilead and its officers:

implemented a scheme to promote and market Viread with off-label, false, and misleading statements in violation of the Federal Food, Drug, and Cosmetic Act. In order to gain market share, artificially increase perceived demand, and increase sales, Gilead officers, executives, and clinical personnel, with the express knowledge and approval of the [Officers], routinely and consistently provided Gilead’s sales and marketing team with off-label information and encouraged, expected, and directed them to use it to sell Viread. . . .

Gilead’s management began preparing Gilead’s sales staff for off-label marketing as early as September 2001, one month

before Viread received FDA approval. Management continued to encourage off-label marketing throughout 2002 and the first half of 2003.

These training efforts produced their intended effect. According to two confidential witnesses who served as Gilead salespeople,<sup>3</sup> Viread “off-label marketing took three forms: (1) marketing to HIV patients co-infected with Hepatitis B; (2) marketing Viread as a first-line or initial therapy for HIV infection; and (3) marketing against Viread’s safety profile.” Ultimately, 75% to 95% of Viread sales resulted from off-label marketing efforts.

The company and its Officers emphasized to the public that they carefully complied with federal and state regulations, when in fact they knew that they were acting unlawfully by aggressively marketing Viread for off-label uses.

The first sign of trouble came on March 14, 2002, when the FDA sent an “Untitled Letter” to Gilead that accused the company of understating the risks of Viread—a form of improper off-label marketing. The letter ordered Gilead to “immediately cease” this practice. On March 21, 2002, per the FDA’s request, Gilead sent a reply that acknowledged receipt of the FDA’s letter and agreed to immediately stop off-label marketing. This was not done. In fact, Gilead’s off-label marketing increased, either at the Officers’ direction or with their knowledge and tacit encouragement.

By June 2003, Gilead’s off-label marketing put it in the position to raise Viread’s price. Consistent with standard industry

2. See 21 U.S.C. § 396; *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 350–51 & n. 5, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001) (explaining that “the FDA is charged with the difficult task of regulating the marketing and distribution of medical devices without intruding upon decisions statutorily committed to the discretion of health care professionals”).

3. One of the confidential witnesses served as “a member of Gilead’s Field Marketing Advisory Committee, a select committee of Gilead sales and marketing staff that periodically met to discuss theories and strategies for marketing and selling Viread.”

practice, Gilead informed national drug wholesalers of this plan in advance of the price increase. The wholesalers (there are the three major ones that purchase approximately ninety percent of drug manufacturers' drugs) typically stockpile drugs in advance of price increases so that they can resell at a higher price to retailers after the increase takes effect.

Because Gilead had "illegally inflated sales and artificially inflated demand for Viread, the major drug wholesalers stockpiled mass quantities of Viread in advance of the June 2003 price increase. This wholesaler stockpiling would not have occurred but for the off-label marketing and the resulting creation of an artificially increased demand for Viread." The stockpiling furthered Gilead's fraudulent scheme by confirming "the impression that Viread was in high demand and that Gilead's financial and operational results were strong."

On July 14, 2003, Gilead issued a press release announcing that it anticipated its second quarter financial results would exceed analysts' expectations, and explaining that the company's success "was driven primarily by strong sales growth of Viread . . . Increasing Viread sales reflect broader prescribing patterns in all commercial markets, as well as increases in U.S. wholesaler inventory levels in the second quarter in anticipation of a Viread price increase."

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." Gilead's promotional scheme was designed to, and did, create the impression that demand for Viread was strong. This campaign was misleading, however, because it was unlawful off-label marketing that was driving prescription volume<sup>4</sup>—and Gilead had already been ordered to cease such marketing.

While securities analysts, for the most part, reacted favorably to the July 14, 2003, press release, Gilead and its Officers felt the need to respond to some analysts' concern that second quarter revenues were primarily attributable to the wholesaler stockpiling, and not a result of strong demand. On the same day that the press release was issued, a Gilead spokeswoman, acting with the knowledge and approval of Gilead and its officers, told Bloomberg News that "[t]he main reason for the jump in Viread sales is an increase in prescriptions, not inventory stocking." This statement was misleading. It created the impression that demand for Viread was strong, which it was, but for reasons that were not well-understood by the public. Omitting the role of off-label marketing in a press release highlighting the drug's success made a true statement (that demand was strong) also a misleading one.

Gilead's financial news had a marked effect on its stock price. On July 14, the price of Gilead shares closed at \$67.25, up \$7.97 from the previous day's closing price of \$59.28 per share. This 13.4% increase represented a near-record high.

Some two weeks later, the FDA issued a July 29 Warning Letter<sup>5</sup> that chastised

4. The Investors concluded that between \$86.7 million and \$109.82 million of Viread's \$115.6 million in domestic sales during the second quarter of 2003 could be attributed to off-label marketing.

5. The Complaint explains:

According to the FDA's website and the FDA's Regulatory Procedures Manual, warning letters such as this are written communications from the [FDA] to a company notifying the company that the [FDA] considers one or more promotional pieces or practices to be illegal. . . . A warning

Gilead for statements made by one of its sales representatives at the 15th National HIV/AIDS Update Conference in March and April of 2003. The letter stated that the employee “made oral statements that minimized the risk information and broadened the indication for Viread.” It reminded Gilead of the Untitled Letter, expressed the “significant public health and safety concerns raised by these repetitive promotional activities,” and ordered Gilead to make corrective disclosure. Gilead made such disclosure to the conference attendees on November 7, 2003.

On August 7, 2003, the FDA made public its Warning Letter. Gilead’s shareholders and the investing public did not find it very significant, though, because they failed to appreciate the extent of Gilead’s off-label marketing, and thus could not foresee the letter’s impact on Viread’s sales.

The public’s underestimation of Viread’s troubles was reflected in Gilead’s share price. Notwithstanding the public revelation of the letter, shares closed at higher prices than they opened on both August 7 and August 8. Indeed, by the end of August, the stock was trading a few dollars higher than it had been at the beginning of the month, without having experienced any significant fluctuations.

Yet, “[u]nbeknownst 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 invoked the letter in efforts to persuade physicians to switch from Viread to their products. In the remaining weeks of August, there was a “marked drop in prescriptions and sales” of Viread. Although the Investors lack precise sales figures, a Morgan Stan-

ley analyst report shows that Viread prescriptions experienced a “sharp drop” in August 2003, followed by “flattened growth” for the remainder of the third quarter. The prescriptions would have suffered further decline were it not for certain side-effects that made it dangerous for some patients to discontinue using the drug.

The wholesalers observed the initial drop in sales and prescriptions of Viread, and the ensuing slow growth. Because Viread was underperforming relative to the expectations generated by the second quarter reports, the wholesalers drew down much more of their excess inventory than they had originally planned, letting supply of Viread drop to the lowest level in four quarters, and well below the industry average for other drugs.

Although wholesalers recognized Viread’s struggles, the public continued to misunderstand the significance of the Warning Letter. Gilead did nothing to correct that misunderstanding. In its Form 10-Q reporting on the 2003 second quarter, issued on August 14, Gilead persisted in emphasizing the increased volume of Viread’s second quarter sales without discussing the role of off-label marketing. Although the Form 10-Q did briefly address the Warning Letter, it failed to reveal the activities that gave rise to that letter, or the impact the letter would have on sales of Viread.

The Officers exploited the public’s ignorance. In the days between the receipt and public disclosure of the Warning Letter, two of the Officers each sold over \$3 million worth of stock. On August 7, the day the FDA disclosed the letter, Gilead’s Senior Vice President/Chief Financial Officer sold nearly \$700,000 worth of shares. Throughout August, while the market mis-

letter is much more serious than an untitled

letter.

apprehended Gilead's impending troubles, the Officers continued to sell off substantial numbers of shares. This activity was "unusual and suspicious" because this was the first month in which all of the Officers sold stock. More to the point, this was proof that the Officers acted with knowledge or with deliberate recklessness when they issued materially false and misleading documents and statements that were disseminated to the investing public.

Not until October 28, 2003, did the public finally realize the impact of the off-label marketing and the Warning Letter. After the markets closed that day, Gilead issued a press release detailing third quarter financial results. The public learned that Viread sales fell significantly below expectations because there had been substantially more overstocking by wholesalers than previously reported. Accordingly, third quarter prescriptions were filled by wholesalers' existing inventory, and wholesalers did not reorder Viread at a commensurate level. Market analysts attributed the disappointing sales to "lower end-user demand." That lower end-user demand, as noted, was a direct result of the Warning Letter, which had exposed Gilead's unlawful off-label marketing efforts to physicians.

The market was "stunned" by the third quarter results. Share prices closed at \$59.46 on October 28, before the press release was circulated. It may be the case that the market had already begun to slowly incorporate the information regarding Viread's off-label marketing into the share price. But the third-quarter earnings release made the effect of that information inescapably clear. The day after the press release was issued, trading volume of Gilead shares was up 1,400% from its average daily level. The day opened with Gilead's price per share at \$50.69, and closed with a price of \$52 per share, a 12%

decrease from the previous day's closing price.

Summing it all up.

At all relevant times, the material misrepresentations . . . directly or proximately caused or were a substantial contributing cause of the damages sustained by [the Investors]. . . . [Gilead and the Officers] made or caused to be made a series of materially false or misleading statements about Gilead's sales, business, product marketing and promotion, prospects, operations and financial results. These material misstatements had the cause and effect of creating in the market an unrealistically positive assessment of Gilead . . . thus causing the Company's publicly traded securities to be overvalued and artificially inflated at all relevant times.

## II. The District Court's Decision

The district court dismissed the complaint with prejudice. Based on the Investors' allegations and judicially-noticed documents that had been referenced in the complaint, the court concluded that the Investors had failed to adequately plead loss causation as that requirement was articulated in *Dura Pharmaceuticals, Inc. v. Broudo*, 544 U.S. 336, 125 S.Ct. 1627, 161 L.Ed.2d 577 (2005).

Specifically, the district court found the complaint failed to

connect the following chain of events . . . : 1) that [Gilead's and the Officers'] alleged failure to disclose the off-label marketing scheme caused a material increase in sales; 2) that practitioners materially decreased their demand for Viread due to the publication of the FDA Warning Letter; and most importantly, 3) that the alleged decrease in sales due to the FDA letter proximately caused Gilead's stock to decrease three months later[.]

The district court rested its decision exclusively on loss causation, and did not consider whether the Investors sufficiently alleged falsity or scienter.

## DISCUSSION

### I. Standards of Review

“We review de novo the district court’s dismissal of a complaint for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6). On review, we accept the plaintiffs’ allegations as true and construe them in the light most favorable to plaintiffs.” *Gompper v. VISX, Inc.*, 298 F.3d 893, 895 (9th Cir.2002) (citation omitted). “The court need not, however, accept as true allegations that contradict matters properly subject to judicial notice or by exhibit. Nor is the court required to accept as true allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences.” *Sprewell v. Golden State Warriors*, 266 F.3d 979, 988 (9th Cir.2001) (citation omitted), *amended on other grounds*, 275 F.3d 1187 (9th Cir.2001). The complaint is properly dismissed if it fails to “plead ‘enough facts to state a claim to relief that is plausible on its face.’” *Weber v. Dep’t of Veterans Affairs*, 521 F.3d 1061, 1065 (9th Cir.2008) (quoting *Bell Atl. Corp. v. Twombly*, — U.S. —, 127 S.Ct. 1955, 1974, 167 L.Ed.2d 929 (2007)).

### II. Applicable law

Section 10(b) of the Securities Exchange Act of 1934 makes it unlawful “[t]o use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe.” 15 U.S.C. § 78j(b). Pursuant to this section, the Securities and Exchange Commission promulgated Rule 10b–5, which makes it unlawful:

(a) To employ any device, scheme, or artifice to defraud,

(b) To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, or

(c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.

17 C.F.R. § 240.10b–5.

We have identified five basic elements of a Rule 10b–5 claim: “(1) a material misrepresentation or omission of fact, (2) scienter, (3) a connection with the purchase or sale of a security, (4) transaction and loss causation, and (5) economic loss.” *In re Daou Sys., Inc.*, 411 F.3d 1006, 1014 (9th Cir.2005) (citing *Dura Pharms.*, 544 U.S. at 341–42, 125 S.Ct. 1627).

[1,2] Because the district court addressed only loss causation under Rule 10b–5, we will limit our consideration to that issue, “following the general rule [that] a federal appellate court does not consider an issue not passed upon below.” *Miller v. Thane Int’l, Inc.*, 519 F.3d 879, 892 (9th Cir.2008) (alteration in original; internal quotation marks omitted). A plaintiff bears the burden of proving that a defendant’s alleged unlawful act “caused the loss for which the plaintiff seeks to recover damages.” 15 U.S.C. § 78u–4(b)(4). To establish loss causation, “the plaintiff must demonstrate a causal connection between the deceptive acts that form the basis for the claim of securities fraud and the injury suffered by the plaintiff.” *Daou*, 411 F.3d at 1025. The misrepresentation need not be the sole reason for the decline in value of the securities, but it must be a “‘substantial cause.’” *Id.*

(quoting *Robbins v. Koger Props., Inc.*, 116 F.3d 1441, 1447 n. 5 (11th Cir.1997)).

Rule 9(b) of Civil Procedure provides: “In alleging fraud . . . a party must state with particularity the circumstances constituting fraud. . . .” Gilead and the Officers contend that the Investors’ loss causation arguments should be subject to this heightened pleading requirement, although they recognize that the Supreme Court has not decided the issue. See *Dura Pharms.*, 544 U.S. at 346, 125 S.Ct. 1627. The Investors argue that Rule 8(a)(2)’s “short and plain statement” requirement should control loss causation pleading.

[3] We need not resolve this issue today. Rule 9(b) imposes the heightened requirement so that the fraud-action defendant “can prepare an adequate answer from the allegations.” *Odom v. Microsoft Corp.*, 486 F.3d 541, 553 (9th Cir.2007) (internal quotation marks omitted). As we explain below, the Investors’ complaint offers “sufficient detail to give defendants ample notice of [their] loss causation theory, and to give us some assurance that the theory has a basis in fact.” *Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982, 989–90 (9th Cir.2008). Therefore, under either Rule 8 or Rule 9, the Investors have sufficiently pleaded loss causation.

### III. The Sufficiency of the Complaint

The district court identified *Dura Pharmaceuticals* as the authority that doomed the Investors’ complaint. *Dura* featured plaintiffs who alleged that they “paid artificially inflated prices” for *Dura*’s securities and “suffered damages thereby.” *Dura*, 544 U.S. at 339–40, 125 S.Ct. 1627 (alterations, emphasis, and quotation marks omitted). The court below had held that loss causation was established merely

by demonstrating that share prices on the date of purchase were inflated. *Broudo v. Dura Pharms., Inc.*, 339 F.3d 933, 938 (9th Cir.2003).

The Supreme Court reversed, and held that an inflated purchase price alone is not enough to establish loss causation. *Dura*, 544 U.S. at 342, 125 S.Ct. 1627. More is required of plaintiffs—particular allegations as to “what the relevant economic loss might be,” and “what the causal connection might be” between the fraud alleged and the economic losses actually suffered. *Id.* at 347, 125 S.Ct. 1627.

The complaint in this case is meaningfully different from that in *Dura Pharmaceuticals*. The Investors here identify a specific economic loss: the drop in value on October 29, 2003, that followed the October 28 press release. They also allege that this loss was caused by Gilead’s misrepresentations. They provide abundant details of Gilead’s off-label marketing, and they assert that this led to higher demand for Viread, which in turn inflated Gilead’s stock price.<sup>6</sup> As summarized in the complaint’s introduction,

[T]he market was not told that off-label marketing was the cornerstone of demand. This mistaken impression of demand led to, among other things, wholesaler overstocking in reaction to an anticipated price increase. When the truth about [Gilead’s and the Officers’] off-label marketing was disclosed, however, [they] could no longer maintain the sales growth levels that investors had come to expect, and Gilead’s stock price dropped accordingly.

Assuming, then, that the Investors’ theory is sound and that they can prove all that they allege, the district court erred by

6. The complaint includes one concrete example of how Gilead’s stock price was directly inflated by Viread’s sales performance: the 13.4% rise in share value triggered by Gi-

lead’s positive statements about demand for Viread on July 14, 2003, the first day of the class period.

holding that *Dura Pharmaceuticals* compelled dismissal of this action.

The dismissal order below, though, suggests that the district court was unwilling to make these assumptions. The district court found that the complaint contained “too many logical and factual gaps.”

[4] Based on our own review, we find the complaint sufficiently alleges a causal relationship between (1) the increase in sales resulting from the off-label marketing, (2) the Warning Letter’s effect on Viread orders, and (3) the Warning Letter’s effect on Gilead’s stock price.

Perhaps what truly motivated the dismissal was the district court’s incredulity. The court expressly identified two allegations it was unwilling to accept. First, it could not make “the unreasonable inference that a public revelation on August 8 caused a price drop three months later on October 28.” Order Granting Defs.’ Mot. to Dismiss at 11. Second, with respect to the Warning Letter’s impact on Viread sales, the court found “a slowing increase in demand, alone, too speculative to adequately demonstrate loss causation.” *Id.* at 12 n. 10.

As an initial matter, we note that a district court ruling on a motion to dismiss is not sitting as a trier of fact. It is true that the court need not accept as true conclusory allegations, nor make unwarranted deductions or unreasonable inferences. *Sprewell*, 266 F.3d at 988. But so long as the plaintiff alleges facts to support a theory that is not facially implausible, the court’s skepticism is best reserved for later stages of the proceedings when the plaintiff’s case can be rejected on evidentiary grounds. “[A] well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of those facts is improbable, and that a recovery is very remote and unlikely.” *Bell Atl. Corp. v. Twombly*, — U.S. —, 127 S.Ct. 1955,

1965, 167 L.Ed.2d 929 (2007) (internal quotation marks omitted).

There is no exception to this rule for the element of loss causation. The Third Circuit has stated that “loss causation becomes most critical at the proof stage,” and has cited scholarly authority stating that it is normally inappropriate to rule on loss causation at the pleading stage. *McCabe v. Ernst & Young, LLP*, 494 F.3d 418, 427 n. 4 (3rd Cir.2007) (internal quotation marks omitted). Similarly, the Second Circuit has held that loss causation “is a matter of proof at trial and not to be decided on a Rule 12(b)(6) motion to dismiss.” *Emergent Capital Inv. Mgmt., LLC v. Stonepath Group, Inc.*, 343 F.3d 189, 197 (2d Cir.2003). *But see Lentell v. Merrill Lynch & Co.*, 396 F.3d 161, 172–77 (2d Cir.2005) (failure to plead any facts supporting loss causation warranted 12(b)(6) dismissal of complaint).

We agree. So long as the complaint alleges facts that, if taken as true, plausibly establish loss causation, a Rule 12(b)(6) dismissal is inappropriate. This is not “a probability requirement . . . it simply calls for enough fact to raise a reasonable expectation that discovery will reveal evidence of” loss causation. *Bell Atl.*, 127 S.Ct. at 1965.

The district court’s concern about the elapse of time between the public issuance of the Warning Letter and the drop in price recalls our holding in *No. 84 Employer-Teamster Joint Council Pension Trust Fund v. America West Holding Corp.*, 320 F.3d 920 (9th Cir.2003) (internal quotation marks omitted). There, a Rule 10b-5 defendant argued that its alleged misrepresentations were per se immaterial because the injurious drop in stock price took place more than one and a half months after the market learned the truth about the misrepresentations. *Id.* at 934. We rejected “a bright-line rule requiring an immediate market reaction” because

“[t]he market is subject to distortions that prevent the ideal of a free and open public market from occurring.” *Id.* (internal quotation marks omitted). Instead, we held that courts must engage in a “fact-specific inquiry.” *Id.* (internal quotation marks omitted).

We believe that *America West’s* discussion of materiality applies with equal force to the loss causation requirement. A limited temporal gap between the time a misrepresentation is publicly revealed and the subsequent decline in stock value does not render a plaintiff’s theory of loss causation per se implausible.

Our review of the Investors’ complaint convinces us that the October drop in stock price was plausibly caused by the Warning Letter. Importantly, the drop occurred immediately after Gilead disclosed less-than-expected revenues resulting from the reduction in wholesalers’ Viread inventories, which analysts ascribed to lower end-user demand. That lower end-user demand, in turn, is expressly alleged to have been caused by the Warning Letter. In this light, the market did react immediately to the corrective disclosure—the October 28 press release. The Warning Letter, which discussed only two instances of off-label marketing, would not necessarily trigger a market reaction because it did not contain enough information to significantly undermine Gilead’s July 2003 pronouncements concerning demand for Viread. It is not unreasonable that physicians—the targets of the off-label marketing—would respond to the Warning Letter while the public failed to appreciate its significance.

The district court also erroneously concluded that a slowing increase in demand is too speculative to establish loss causation. Had the Investors alleged that the Warning Letter eliminated all sales resulting from off-label marketing, it would be very unlikely that demand would continue

to increase, since the complaint asserts that 75% to 95% of sales were caused by off-label marketing. But they do not allege that, and we see no reason why the court cannot proceed to the evidentiary stages to determine the extent of the Warning Letter’s impact on the growth of demand for Viread.

The complaint specifically alleges that physicians were less eager to prescribe Viread, and competitors used the Warning Letter to lure Viread customers to other drugs. This is “enough fact to raise a reasonable expectation that discovery will reveal evidence”—or the lack thereof—of the Warning Letter’s effect on demand. *Bell Atl.*, 127 S.Ct. at 1965.

#### CONCLUSION

For the foregoing reasons, the district court improperly granted Gilead’s and the Officers’ Rule 12(b)(6) motion. The Investors have sufficiently alleged loss causation and economic loss. We leave it to the district court to determine whether they have sufficiently alleged the other elements of their claims.

**REVERSED and REMANDED.**



**UNITED STATES of America,  
Plaintiff-Appellee,**

v.

**Ron PARK; Mary Park, Defendants-  
Appellants.**

**No. 06-35886.**

United States Court of Appeals,  
Ninth Circuit.

Argued and Submitted April 11, 2008.

Filed Aug. 11, 2008.

**Background:** Federal government brought suit against owners and operators



FILED

UNITED STATES COURT OF APPEALS

OCT 09 2008

FOR THE NINTH CIRCUIT

MOLLY C. DWYER, CLERK  
U.S. COURT OF APPEALS

In re: GILEAD SCIENCES SECURITIES  
LITIGATION.

No. 06-16185

D.C. No. CV-03-04999-MJJ  
Northern District of California,  
San Francisco

RICK HARTMAN, on behalf of himself  
and all others similarly situated; TRENT  
ST. CLARE; TERRY JOHNSON,

Plaintiffs - Appellants,

ORDER

v.

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

Defendants - Appellees.

Before: KOZINSKI, Chief Judge, HAWKINS, and COWEN,\* Circuit Judges.

The panel has voted to deny the petition for rehearing. Chief Judge Kozinski and Judge Hawkins have voted to deny the petition for rehearing en banc. Judge Cowen has recommended denying the en banc petition.

---

\* The Honorable Robert E. Cowen, Senior United States Circuit Judge for the Third Circuit, sitting by designation.

The full court has been advised of the petition for rehearing en banc and no Judge has requested a vote on whether to rehear the matter en banc. Fed. R. App. P. 35.

The petition for rehearing and petition for rehearing en banc are DENIED.