BYU Law Review

Volume 2010 | Issue 1 Article 20

3-1-2010

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Brandon J. Stoker

Recommended Citation

Brandon J. Stoker, *Opening the Rule 10b-5 Floodgates: Ninth Circuit Split in Gilead Sciences Leaves the Loss Causation Pleading Standard in Limbo* , 2010 BYU L. Rev. 301 (2010).
Available at: https://digitalcommons.law.byu.edu/lawreview/vol2010/iss1/20

Opening the Rule 10b-5 Floodgates: Ninth Circuit Split in *Gilead Sciences* Leaves the Loss Causation Pleading Standard in Limbo

I. INTRODUCTION

In the case of *In re Gilead Sciences Securities Litigation*,[1] the Ninth Circuit allowed a class action securities fraud complaint to proceed beyond Rule 12(b)(6) dismissal without any factual basis to demonstrate proximate causation, or more specifically, that plaintiffs' losses were caused by the alleged fraud rather than other confounding factors. The court also approved plaintiffs' causation theory alleging that an "efficient" securities market took three months to incorporate a public fraud disclosure into share prices of the defendant corporation, Gilead Sciences. The standards to which the court held plaintiffs' complaint run contrary, however, to the prevailing loss causation pleading standards among circuit courts, and cut at the policies underlying private securities litigation.

Although pre-discovery pleading standards are not traditionally fraught with heavy evidentiary burdens, Congress and the Supreme Court have imposed heightened pleading requirements for securities suits to cut back on frivolous litigation. The Ninth Circuit threatens to undermine these procedural safeguards by introducing a highly permissive loss causation standard that fails to sift meritorious claims from implausible or highly speculative *in terrorem* securities fraud suits.

II. FACTS AND PROCEDURAL HISTORY

A. The Circumstances Precipitating Litigation

A group of investors who purchased stock in Gilead Sciences, Inc. ("Gilead") between July 14, 2003, and October 28, 2003, brought a class action securities fraud suit against Gilead on December 2, 2005.[2] The plaintiffs' fourth amended complaint

1. 536 F.3d 1049 (9th Cir. 2008), *cert. denied*, 129 S. Ct. 1993 (2009).

2. *Id*. at 1050; *In re* Gilead Scis. Sec. Litig., 2006 WL 1320466, at *4 (N.D. Cal. May 12, 2006).

alleges that Gilead violated, *inter alia*, section 10(b) of the Securities Exchange Act of 1934 and SEC Rule 10b-5 by misleading the investing public to believe that demand for its most popular product was strong without disclosing that unlawful marketing was a significant cause of new sales growth.[3]

Gilead is a biopharmaceutical company that specializes in developing and commercializing medications to treat life-threatening diseases.[4] The company's most successful product is Viread, an antiretroviral medication introduced in 2001 to treat HIV/AIDS.[5] Viread was so successful that Gilead raised the product's price in June of 2003.[6] On July 14, 2003, the first day of the class period, Gilead issued a press release announcing that its second quarter financial results would exceed expectations, driven primarily by the "strong sales growth of Viread."[7] The release explained that Viread sales increased due to "broader prescribing patterns . . . as well as increases in U.S. wholesaler inventory."[8] Two weeks later, on July 31, 2003, Gilead issued another press release disclosing second quarter revenues of $230.7 million, more than half of which related to Viread sales.[9] The same day, an officer of Gilead explained to analysts and other investors that Viread sales would likely fall in the third quarter because wholesalers amassed substantial stockpiles of Viread in anticipation of the product's June price increase.[10] Notwithstanding this caveat, market analysts—including Morgan Stanley, Prudential, and Bear Stearns—continued to predict strong demand for Viread.[11]

Plaintiffs allege that Viread's strong sales performance was driven by illegal "off-label" marketing, which refers to the use of marketing information such as clinical study results on the efficacy of an FDA-approved product that have not been approved by the FDA for inclusion in the product's package labeling.[12] Gilead's off-label

3. *Gilead*, 536 F.3d at 1050–51.
4. *Id.*
5. *Id.*
6. *Id.* at 1051–52.
7. *Gilead*, 2006 WL 1320466, at *1.
8. *Id.*
9. *Id.*
10. *Id.* at *1–2.
11. *Id.* at *2.
12. *In re* Gilead Scis. Sec. Litig., 536 F.3d 1049, 1051 (9th Cir. 2008).

marketing allegedly 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."[13] The company began training sales and marketing employees as early as 2001 with off-label product information, and implicitly or explicitly encouraged them to use the information to sell Viread through and subsequent to the class period.[14] Two confidential witnesses also allege that as much as 85% to 95% of their own Viread sales were the result of off-label marketing.[15]

Gilead's off-label marketing did not go unnoticed by the FDA. On March 14, 2002, the FDA sent an "Untitled Letter" ordering Gilead to cease marketing activities that understate the risk of Viread.[16] Gilead agreed to cease all off-label marketing activity, but the FDA followed up a year later on July 29, 2003, with a "Warning Letter"[17] ("FDA Warning Letter") chastising the company for "oral statements that minimized the risk information and broadened the indication for Viread."[18] Notwithstanding the FDA's public release of the Warning Letter on August 7, 2003, Gilead shares closed at higher prices on both August 7 and August 8.[19]

Although wholesalers and doctors allegedly understood the significance of the FDA Warning Letter—purportedly indicated by declining Viread sales during the third quarter of 2003[20]—plaintiffs

13. *Id.*; *Gilead*, 2006 WL 1320466, at *2.

14. *Gilead*, 536 F.3d at 1051.

15. *Gilead*, 2006 WL 1320466, at *3 n.4. Plaintiffs allege that between $86.7 and $109.82 million of Viread's $115.6 million in sales during the second quarter of 2003 was attributable to off-label marketing. *Gilead*, 536 F.3d at 1052 n.4.

16. *Gilead*, 536 F.3d at 1051.

17. Gilead Sciences, Inc., FDA Warning Letter, MACMIS No. 11723 (July 29, 2003), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM168912.pdf (last visited Jan. 4, 2010).

18. *Gilead*, 536 F.3d at 1052–53.

19. *Id.* at 1053.

20. *Id.* at 1054 (explaining plaintiffs' theory that disappointing third quarter Viread sales were attributable to "lower end-user demand" caused by the FDA Warning Letter). *Contra* Petition for Writ of Certiorari at 13–14, Gilead Sciences., Inc. v. St. Clare, 129 S. Ct. 1993 (2009) (No. 08-1021), 2009 WL 355727 (explaining that Viread end-user demand actually *grew* by up to 17% during the third quarter). Market analysts—including Morgan Stanley and Bear Stearns—attributed Viread's overall sales decline to excessive wholesaler inventory stockpiling during the second quarter, indicating that *second quarter* "end-user demand run rates were actually lower than previously believed. Thus, while Viread demand continue[d] to

allege that the market failed to comprehend the implications of Gilead's off-label marketing activity.[21] In addition, although Gilead acknowledged the FDA Warning Letter in its August 14, 2003, second quarter 10-Q filing,[22] plaintiffs argue that Gilead's failure to discuss the activities giving rise to the letter and the impact the letter would have on Viread sales amounted to a material omission necessary to make Gilead's financial statements *not* misleading.[23] In other words, Gilead failed to disclose that Viread's sales growth was attributable largely to illegal marketing activity, thus artificially inflating both wholesalers' Viread inventory and Gilead share prices.

The investing public, plaintiffs argue, did not appreciate the impact of the off-label marketing until Gilead released its disappointing third quarter Viread sales figures on October 28, 2003, the last day of the class period.[24] The market learned that Viread sales fell significantly below third quarter projections because wholesalers were filling prescriptions with surplus inventory rather than reordering from Gilead at commensurate levels.[25] The following day, Gilead shares fell 12% from $59.46 to $52.00.[26] Plaintiffs explain this loss as the market's realization of the extent to which off-label marketing affected Viread sales, which, taken in light of the August 7 FDA Warning Letter, amounted to a *full* disclosure of Gilead's fraud.[27]

B. District Court Ruling

The district court granted Gilead's Rule 12(b)(6) motion to dismiss,[28] concluding that plaintiffs failed to adequately plead loss causation pursuant to the standard in *Dura Pharmaceuticals, Inc. v.*

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grow," wholesalers filled existing orders with excessive inventory rather than purchasing additional product from Gilead. *Id.* at 13 (second emphasis added).

21. *Gilead*, 536 F.3d at 1053–54.

22. Gilead Sciences, Inc., Quarterly Report (Form 10-Q), at 14 (Aug. 14, 2003).

23. *Gilead*, 536 F.3d at 1053.

24. *Id.* at 1054.

25. *Id.*; *see also* Petition for Writ of Certiorari, *supra* note 20, at 13–14.

26. *Gilead*, 536 F.3d at 1054.

27. *Id. Contra* Petition for Writ of Certiorari, *supra* note 20, at 14 (explaining that Gilead, market analysts, and plaintiffs themselves in previous filings, attributed the *entire* drop in Gilead's stock price on October 29, 2003, to Gilead's underestimation of wholesaler overstocking and lower sales growth in Europe).

28. *In re* Gilead Scis. Sec. Litig., 2006 WL 1320466, at *10 (N.D. Cal. May 12, 2006).

Broudo.[29] The court explained that *Dura* requires plaintiffs to plead proximate causation, but the complaint in this case failed to attribute the loss in Gilead's stock value to the alleged fraud rather than other superseding causes.[30] Specifically, the plaintiffs

> [did] not connect the following chain of events . . . : 1) that Defendants' 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.[31]

III. SIGNIFICANT LEGAL BACKGROUND

A. The Securities Exchange Act of 1934 and Rule 10b-5

The Securities Exchange Act of 1934[32] ("Exchange Act") created the U.S. Securities and Exchange Commission and provides the statutory basis for what courts have recognized as an implied private right of action for securities fraud.[33] Section 10(b) of the Exchange Act, as amended, prohibits the "use or employ . . . [of] any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors."[34] Pursuant to this section, the SEC 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

29. *Id*. at *9–10; *see* 544 U.S. 336, 346–47 (2005).
30. *Gilead*, 2006 WL 1320466, at *9.
31. *Id*. at *9 n.12.
32. 15 U.S.C. § 78a (2006).
33. *See* 15 U.S.C. § 78j(b) (2006).
34. *Id*.

> (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.[35]

Although neither Section 10(b) of the Exchange Act nor Rule 10b-5 expressly provides a private civil remedy for securities fraud,[36] federal courts have inferred such a right since the 1940s.[37] The modern common law rule for private 10b-5 actions—aptly described by the Court as a "judicial oak which has grown from little more than a legislative acorn"[38]—includes the following elements:

> (1) *a material misrepresentation (or omission)*; (2) *scienter, i.e.*, a wrongful state of mind; (3) *a connection with the purchase or sale of a security*; (4) *reliance*, often referred to in cases involving public securities markets (fraud-on-the-market cases) as "transactional causation,"; (5) *economic loss*; and (6) *"loss causation," i.e.*, a causal connection between the material misrepresentation and the loss.[39]

B. The Dura *Loss Causation Pleading Standard*

The Supreme Court laid out the pleading standard for loss causation in *Dura Pharmaceuticals v. Brudo*, a case involving plaintiffs who alleged that they suffered damages by purchasing securities in Dura at artificially inflated prices.[40] The Court rejected the Ninth Circuit's lax pleading standard, which only required plaintiffs to "'establish' . . . that 'the price *on the date of purchase* was inflated because of misrepresentation.'"[41] Reasoning that shareholders who purchase securities at an inflated price may never in fact suffer any losses, the Court held that plaintiffs must allege both

35. 17 C.F.R. § 240.10b-5 (2009) (emphasis added).

36. Blue Chips Stamps v. Manor Drug Stores, 421 U.S. 723, 729–30 (1975).

37. The first federal court to recognize a private civil remedy to securities fraud was the United States District Court for the Eastern District of Pennsylvania in *Kardon v. National Gypsum Co.*, 69 F. Supp. 512, 514 (1946). The U.S. Supreme Court approved the overwhelming judicial consensus in favor of the private 10b-5 action twenty-five years later in *Superintendent of Insurance v. Bankers Life & Casualty. Co.*, 404 U.S. 6, 13 n.9 (1971).

38. *Blue Chips Stamps*, 421 U.S. at 737.

39. Dura Pharms., Inc. v. Broudo, 544 U.S. 336, 341 (2005) (internal citations omitted).

40. *Id*. at 339–40.

41. *Id*. at 342 (internal citations omitted).

economic loss and *proximate causation* to demonstrate loss causation in the complaint.[42]

Though *Dura* identified the minimum pleading requirement for loss causation, it did not define the intricate nuances of that standard. Indeed, the Court held only that a plaintiff must provide a "'short and plain statement' . . . provid[ing] the defendant with 'fair notice of what the plaintiff's claim is and the grounds upon which it rests,'"[43] as well as "some indication of the loss and the causal connection that the plaintiff has in mind."[44] In line with this standard, plaintiffs bear the burden of proving—and thus *alleging*—that their economic loss was caused by the misrepresentation and not by other confounding factors.[45]

C. Fraud-on-the-Market Theory

Class action plaintiffs generally rely on the "fraud-on-the-market" theory (also known as the "semi-strong efficient capital markets hypothesis," or "efficient market theory") to demonstrate reliance, materiality, and loss causation in securities fraud actions. Approving the theory's application to demonstrate reliance in *Basic, Inc. v. Levinson*,[46] the Supreme Court explained, "[t]he fraud on the market theory is based on the hypothesis that, in an open and developed securities market, the price of a company's stock is determined by the available material information regarding the company and its business."[47] In other words, well-developed markets presumptively incorporate all publicly available information into share prices. The legal application of this theory supports the

42. *Id*. at 346 ("[W]e find the Ninth Circuit's approach inconsistent with the law's requirement that a plaintiff prove that the defendant's misrepresentation (or other fraudulent conduct) *proximately caused* the plaintiff's economic loss. . . . Our holding about plaintiff's need to *prove* proximate causation and economic loss leads us also to conclude that the plaintiffs' complaint here failed to adequately *allege* these requirements." (emphasis added)).

43. *Id*. at 346 (quoting Conley v. Gibson, 355 U.S. 41, 47 (1957)).

44. *Id*. at 347.

45. *Id*. at 342–43 ("When the purchaser subsequently resells such shares, even at a lower price, that lower price may reflect, *not the earlier misrepresentation*, but changed economic circumstances, changed investor expectations, new industry-specific or firm-specific facts, conditions, or other events, which taken separately or together account for some or all of that lower price. . . . [O]ne might say that the inflated purchase price suggest that the misrepresentation . . . 'touches upon' a later economic loss. But, . . . [t]o 'touch upon' a loss is not to *cause* a loss . . . ." (emphasis added, internal citations omitted)).

46. 485 U.S. 224, 245–46 (1988).

47. *Id*. at 241 (quoting Peil v. Speiser, 806 F.2d 1154, 1160–61 (3d Cir. 1986)).

presumption that anyone who purchases or sells stock within a specified period *relies* on the integrity of the market price as an accurate reflection of the stock's value in light of all publicly available information.[48] Thus, if a company misrepresents material information to the investing public, all investors presumptively rely on that misrepresentation.[49] Litigants also use this theory to demonstrate materiality by showing that a particular piece of information was significant in light of the market's *reaction* to its disclosure, as well as loss causation by showing a significant market reaction *soon after* the corrective disclosure was made.[50]

While the *Basic* Court did "not intend conclusively to adopt any particular theory of how quickly and completely . . . information is reflected in market price,"[51] the efficient market theory only makes sense when the market reacts *promptly* to corrective disclosures.[52] Nearly all circuit courts describe this as a "quick,"[53] "rapid,"[54] or "immediate"[55] process.[56] If markets do not operate rationally by

48. *Id*. at 246–47; Brief for Former SEC Commissioners and Officials and Law and Finance Professors as Amici Curiae in Support of Petitioners at 5–6, Gilead Scis., Inc. v. St. Clare, 129 S. Ct. 1993 (2009) (No. 08-1021), 2009 WL 720917.

49. The Supreme Court adopted the "fraud on the market" theory as a practical way for class action plaintiffs to demonstrate reliance. To require individualized proof would impose an unreasonable burden on plaintiffs and frustrate class certification in most 10b-5 actions because individual questions would overwhelm common question of law and fact. *Basic*, 485 U.S. at 242.

50. Brief of Amici Curiae, *supra* note 48, at 6–7.

51. *Basic*, 485 U.S. at 248 n.28.

52. Brief of Amici Curiae, *supra* note 48, at 6.

53. *See, e.g.*, *In re* PolyMedica Corp. Sec. Litig., 432 F.3d 1, 19 (1st Cir. 2005) ("[The] market price responds so *quickly* to new information that ordinary investors cannot make trading profits on the basis of such information." (emphasis added)); West v. Prudential Sec., Inc., 282 F.3d 935, 938 (7th Cir. 2002).

54. *See, e.g.*, Gariety v. Grant Thornton LLP, 368 F.3d 356, 367 (4th Cir. 2004) ("[A]n efficient market . . . 'adjusts rapidly to reflect all new information.'" (quoting Jonathan R. Macey & Geoffrey P. Miller, *Good Finance, Bad Economics: An Analysis of the Fraud-on-the-Market Theory*, 42 STAN. L. REV. 1059, 1060 (1990))); Freeman v. Laventhol & Horwath, 915 F.2d 193, 199 (6th Cir. 1990) ("An efficient market is one which rapidly reflects new information in price.").

55. *See, e.g.*, Teamsters Local 445 Freight Div. Pension Fund v. Bombardier, Inc., 546 F.3d 196, 207 (2d Cir. 2008) ("Evidence that unexpected corporate events or financial releases cause an *immediate* response in the price of a security has been considered . . . 'the *essence* of an efficient market and the foundation for the fraud on the market theory.'" (quoting Cammer v. Bloom, 711 F. Supp. 1264, 1287 (D.N.J. 1989))) (emphasis added); Unger v. Amedisys Inc., 401 F.3d 316, 324 (5th Cir. 2005) ("In an efficient market, where information is nearly perfect, material misstatements alter a stock's price almost immediately."); *In re* Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1425 (3d Cir. 1997) ("[E]fficient

quickly incorporating all publicly available information, plaintiffs cannot look to the market's reaction to new information to demonstrate materiality, reliance, or loss causation. Indeed, if the securities markets take months to incorporate new information, no one could ever attribute market behavior to particular stimuli because he could not credibly claim to know whether the market was reacting to new information or progressively incorporating old information. The Supreme Court recognized this principle in *Dura*, warning that "the longer the time between purchase and sale, . . . the more likely that *other factors* caused the loss."[57]

IV. THE NINTH CIRCUIT'S DECISION

The Ninth Circuit reversed the district court, concluding that the plaintiffs' fourth amended complaint sufficiently alleged loss causation to withstand Gilead's motion to dismiss.[58] Writing for the unanimous panel, Judge Michael Daly Hawkins applied the standard that "[s]o long as the complaint alleges facts that, if taken as true, plausibly establish loss causation, a Rule 12(b)(6) dismissal is inappropriate."[59]

A. Proximate Causation and Fact Pleading

Defining the loss causation pleading standard, the court explained that a 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.'"[60] Although the misrepresentation need not be the "sole reason for the decline in value of the securities, . . . it must be a '*substantial cause*.'"[61] The court declined to rule whether Rule 8 or Rule 9(b) of the Federal Rules of Civil Procedure should apply to the loss causation pleading

markets are those in which information important to reasonable investors . . . is immediately incorporated into stock prices.") (internal citations omitted).

56. Brief of Amici Curiae, *supra* note 48, at 6–7.

57. Dura Pharms., Inc. v. Broudo, 544 U.S. 336, 343 (2005) (emphasis added).

58. *In re* Gilead Scis. Sec. Litig., 536 F.3d 1049, 1058 (9th Cir. 2008).

59. *Id*. at 1057 ("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.'" (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 556 (2007))).

60. *Id*. at 1055 (quoting *In re* Daou Sys., Inc., 411 F.3d 1006, 1025 (9th Cir. 2005)).

61. *Id*. at 1055–56 (emphasis added) (quoting Robbins v. Koger Props., Inc., 116 F.3d 1441, 1447 n.5 (11th Cir. 1997)).

standard, holding simply that the complaint must provide "'sufficient detail to give defendants ample notice of [plaintiff's] loss causation theory, and to give us some assurance that the *theory* has a basis in fact.'"[62]

The Ninth Circuit chastised the district court for its "incredulity," explaining that loss causation is more appropriately a matter of proof at trial and should not to be decided on a Rule 12(b)(6) motion to dismiss, unless the plaintiff fails to allege facts that "*plausibly* establish loss causation."[63] Specifically, the court took issue with the district court's unwillingness to accept (1) "'the . . . inference that a public revelation on August 8 *caused* a price drop *three months later* on October 28,'" and (2) the court's finding that a "'slowing increase in demand, alone, [is] too speculative to adequately demonstrate loss causation.'"[64]

Regarding the latter of these issues, the Ninth Circuit found that a "slowing increase in demand" was not too speculative to adequately demonstrate loss causation because, as the plaintiffs allege, "physicians were less eager to prescribe Viread," and competitors used the FDA Warning Letter to discourage Gilead prescriptions.[65] This provided enough factual support to raise a "reasonable expectation that discovery will reveal evidence" of the FDA Warning Letter's effect on Viread demand.[66] Finding that plaintiffs' theories were "not facially implausible," the court advised the district court to reserve its skepticism for later stages of the proceedings.[67] "A well-pleaded complaint," Judge Hawkins concluded, "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."[68]

62. *Id*. at 1056 (emphasis added) (quoting Berson v. Applied Signal Tech., Inc., 527 F.3d 982, 989–90 (9th Cir. 2008)).

63. *Id*. at 1057 (citing *In re* Gilead Scis. Sec. Litig., 2006 WL 1320466, at *7 (N.D. Cal. May 12, 2006)).

64. *Id*. (quoting *In re* Gilead Scis. Sec. Litig., 2006 WL 1320466, at *7, 7 n.10 (N.D. Cal. May 12, 2006)).

65. *Id*. at 1058.

66. *Id*. (citing Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007)).

67. *Id*. at 1057.

68. *Id*. (citing *Bell Atl. Corp.*, 550 U.S. at 555).

B. Fraud-on-the-Market Theory and Loss Causation Timing

Turning to the district court's concern over the three month delay between the off-label marketing disclosure on August 8 and the drop in Gilead's stock price on October 28, the Ninth Circuit "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.'"[69] Instead, courts must engage in a "fact-specific inquiry" to determine the functional efficiency of a particular market.[70]

As applied to this case, the Ninth Circuit's *America West* standard purportedly provides that a "limited temporal gap" of even three months between the date Gilead's off-labeling marketing was publicly revealed and the subsequent drop in share prices "does not render [the] plaintiff[s'] theory of loss causation *per se implausible*."[71] The court reasoned that because the market was not aware that off-label marketing was the "cornerstone" of Viread sales,[72] and the drop in share prices occurred immediately after Gilead disclosed disappointing third quarter revenues—purportedly caused by declining end-user demand[73]—the market did not comprehend the full extent of Gilead's fraud until October 28, 2003. Plaintiffs allege, moreover, that the purportedly lower end-user demand was caused by the FDA Warning Letter in August.[74] Thus, physicians reasonably could have responded to the FDA Warning Letter by prescribing alternative medications while the investing public failed to appreciate the letter's significance.[75]

Ultimately, the Ninth Circuit found that the complaint sufficiently alleged "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."[76]

69. *Id*. at 1057–58 (quoting No. 84 Employer-Teamster Joint Council Pension Trust Fund v. Am. W. Holding Corp., 320 F.3d 920, 934 (9th Cir. 2003)).

70. *Id*. at 1058 (quoting *Am. W. Holding*, 320 F.3d at 934).

71. *Id*. (emphasis added).

72. *Id*. at 1056.

73. *Id*. at 1058. *Contra* text accompanying note 20.

74. *Id*.

75. *Id*.

76. *Id*. at 1057.

IV. ANALYSIS

The Ninth Circuit's opinion in *Gilead* is problematic for two reasons: first, the plaintiffs' theory is not "plausible" because it is inconsistent with prevailing securities law, or more specifically, it undermines the fraud-on-the-market theory upon which plaintiffs' very claims hinge. Additionally, the court did not require plaintiffs to show proximate causation by alleging facts that would allow the court to ascribe some rough proportion of the whole loss to the alleged fraud rather than other confounding factors. Although the court's general loss causation standard—that plaintiffs must "allege[] facts that, if taken as true, plausibly establish loss causation"[77]—does not facially contradict *Dura*, the court did not rigorously apply its own pleading standards to the facts at hand in *Gilead*. More importantly, the Ninth Circuit set an impermissibly lax loss causation pleading bar by overlooking Congress's objectives in contemporary securities litigation reforms.

A. Policies Underlying Modern Securities Regulation

The pleading standard for loss causation in a Rule 10b-5 action must be informed by the competing policies underlying securities regulation: to maintain public confidence in the securities markets by deterring fraud and compensating aggrieved shareholders,[78] while also tempering antifraud measures to prevent vexatious litigation.[79] Congress has recognized that "[p]rivate securities litigation is an indispensable tool with which defrauded investors can recover their losses," and that private lawsuits "promote public and global confidence in our capital markets and help to deter wrongdoing and

77. *Id.* (citing Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007)).

78. Dura Pharms., Inc. v. Broudo, 544 U.S. 336, 345 (2005) (citing Randall v. Loftsgaarden, 478 U.S. 647, 664 (1986)) (reasoning that securities markets seek to maintain public confidence "by deterring fraud, in part, through the availability of private securities litigation"); *see also* United States v. O'Hagan, 521 U.S. 642, 658 (1997); Affiliated Ute Citizens v. United States, 406 U.S. 128, 151 (1972) ("[T]he 1934 Act and its companion legislative enactments embrace a 'fundamental purpose . . . to substitute a philosophy of full disclosure for the philosophy of caveat emptor and thus to achieve a high standard of business ethics in the securities industry.'" (quoting SEC v. Capital Gains Research Bureau, 375 U.S. 180, 186 (1963))).

79. *Dura*, 544 U.S. at 347; Blue Chips Stamps v. Manor Drug Stores, 421 U.S. 723, 739 (1975) ("There has been widespread recognition that litigation under Rule 10b-5 presents a danger of vexatiousness different in degree and in kind from that which accompanies litigation in general.").

guarantee that corporate officers, auditors, directors, lawyers and others properly perform their jobs."[80] The Supreme Court has thus emphasized that pleading standards must "preserv[e] investors' ability to recover on meritorious claims."[81]

Notwithstanding this need, Congress and the Supreme Court have pruned back the 10b-5 "judicial oak" to protect defendants from frivolous litigation.[82] The *Blue Chips Stamps* Court warned that 10b-5 securities claims are uniquely vulnerable to vexatiousness because they offer a high settlement value to plaintiffs.[83] These cases typically involve a significant and costly amount of discovery requiring extensive deposition of corporate officers and associates and the concomitant opportunity for extensive discovery of corporate documents.[84] Securities fraud suits can also frustrate normal business activity of the defendant—which is completely unrelated to the lawsuit—and damage corporate goodwill.[85] In addition, because 10b-5 actions often turn on the credibility of competing testimony, many cases are difficult to dispose of prior to trial other than by settlement.[86] Thus, even an objectively weak claim has a settlement value to the plaintiff—in light of the many burdens borne by the defendant—so long as he prevents the suit from being resolved against him by dismissal or summary judgment.[87]

To curb this threat, Congress enacted the Private Securities Litigation Reform Act of 1995 ("PSLRA"),[88] which requires plaintiffs to prove, *inter alia*, "that the act or omission of the defendant . . . *caused* the loss for which the plaintiff seeks to recover damages."[89] The Supreme Court in *Dura* made clear that loss

80. H.R. REP. NO. 104-369, at 31 (1995) (Conf. Rep.); *see* Merrill Lynch, Pierce, Fenner & Smith, Inc. v. Dabit, 547 U.S. 71, 80–81 (2006).

81. Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 322 (2007) ("Our task is to prescribe a workable . . . standard . . . geared to the PSLRA's twin goals: to curb frivolous, lawyer-driven litigation, while preserving investors' ability to recover on meritorious claims.").

82. Congress explicitly passed the Private Securities Litigation Reform Act of 1995 to provide "protections to discourage frivolous litigation." H.R. CONF. REP. NO. 104-469, 32 (1995).

83. Blue Chips Stamps v. Manor Drug Stores, 421 U.S. 723, 739 (1975); *see* Merrill Lynch, Pierce, Fenner & Smith, Inc. v. Dabit, 547 U.S. 71, 80–81 (2006).

84. *Blue Chips Stamps*, 421 U.S. at 740–41.

85. *Id*. at 740.

86. *Id*. at 742.

87. *Id*. at 740.

88. Pub. L. No. 104-67, 109 Stat. 737 (1995).

89. 15 U.S.C. § 78u-4(b)(4) (2000) (emphasis added).

causation must not only be proven at trial, but *alleged* in the plaintiff's complaint.[90] To require anything less, the unanimous Court reasoned, "would bring about harm of the very sort the statutes seek to avoid."[91]

Echoing the warning in *Blue Chips Stamps*, the *Dura* Court emphasized that a relaxed pleading standard would allow plaintiffs with "largely groundless claim[s] to simply take up the time of a number of other people, with the right to do so representing an *in terrorem* increment of the settlement value, rather than a reasonably founded hope that the [discovery] process will reveal relevant evidence."[92] The PSLRA and other judicially-wrought standards thus forge a reasonable pleading bar against "nuisance filings, targeting of deep-pocket defendants, vexatious discovery requests and manipulation by class action lawyers."[93] These limits recognize that anti-fraud regulations do not provide investors with "broad insurance against market losses," but rather protect them against the economic losses that misrepresentations and omissions *actually* cause.[94]

B. Fraud-on-the-Market and "Plausibility"

The Ninth Circuit requires 10b-5 plaintiffs to allege "facts that, if taken as true, *plausibly* establish loss causation."[95] This standard is facially consistent with other circuits, which generally require plaintiffs to plead factual allegations that provide a reasonable, non-speculative basis to believe that plaintiffs can ultimately prove the

90. Dura Pharms. v. Broudo, 544 U.S. 336, 346 (2005) ("Our holding about plaintiffs' need to *prove* proximate causation and economic loss leads us also to conclude that the plaintiffs' complaint . . . [must] *allege* these requirements.").

91. *Id.* at 347 ("[A]llowing a plaintiff to forgo giving any indication of the economic loss and proximate cause that the plaintiff has in mind would bring about harm of the very sort the statutes seek to avoid.").

92. *Id.* (quoting Blue Chips Stamps v. Manor Drug Stores, 421 U.S. 723, 741 (1975)).

93. Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 320 (2007) ("Setting a uniform pleading standard for § 10(b) actions was among Congress' objectives when it enacted the PSLRA. Designed to curb perceived abuses of the § 10(b) private action—'nuisance filings, targeting of deep-pocket defendants, vexatious discovery requests and manipulation by class action lawyers,'— . . . the PSLRA installed both substantive and procedural controls." (internal citations omitted)).

94. *Dura*, 544 U.S. at 345 (citing Basic, Inc. v. Levinson, 485 U.S. 224, 252 (1988)).

95. *In re* Gilead Scis. Sec. Litig., 536 F.3d 1049, 1057 (9th Cir. 2008) (citing Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007)) (emphasis added).

elements of causation at trial.[96] The Ninth Circuit's *application*, however, diverges from the prevailing standard. In evaluating the *Gilead* plaintiffs' allegations, the court required only that the theory not be "facially implausible."[97] Indeed, the court allowed plaintiffs' complaint to proceed beyond 12(b)(6) dismissal without any proof that the alleged misrepresentation caused the loss rather than *other* confounding factors, and relied upon a causation theory that facially contradicted legal principles underlying the plaintiffs' claim.[98] The Ninth Circuit's understanding of "plausibility" is thus impermissibly lax.

Requiring plaintiffs to demonstrate a *plausible* proximate link between the alleged fraud and the economic loss ensures that only reasonably well founded claims proceed to discovery pursuant to the policy objectives articulated in the PSLRA and the Court's 10b-5 jurisprudence.[99] "Plausible" means that the plaintiff's *theory* of causation is generally sound and logically consistent with prevailing securities law, not that the plaintiff will actually be able to *prove the facts* supporting his theory.[100] This standard provides a critical procedural hurdle against frivolous litigation, ensuring that discovery is not used as a fishing expedition to uncover facts necessary to piece together a plausible case theory.[101]

96. *See* Brief of Petitioner-Appellant, *supra* note 20, at 4. The Fifth and Seventh Circuits apply Federal Rule of Civil Procedure 9(b) to securities fraud claims, which requires allegations to be pled with "particularity." *See* Catogas v. Cyberonics, Inc., 292 F. App'x 311, 312–14 (5th Cir. 2008); Tricontinental Indus., Ltd. v. PricewaterhouseCoopers, LLP, 475 F.3d 824, 839 n.10, 842–43 (7th Cir. 2007). The Second, Fourth, and Eight Circuits, while not applying Rule 9(b), still require "sufficient factual information to provide the 'grounds' on which the claim rests, and to raise a right to relief *above a speculative level.*" Schaaf v. Residential Funding Corp., 517 F.3d 544, 549 (8th Cir. 2008) (emphasis added), *cert. denied*, 129 S. Ct. 222 (2008); *see also* Lattanzio v. Deloitte & Touche LLP, 476 F.3d 147, 158 (2d Cir. 2007); Teachers' Ret. Sys. v. Hunter, 477 F.3d 162, 186 (4th Cir. 2007).

97. *Gilead*, 536 F.3d at 1057.

98. Brief of Petitioner-Appellant, *supra* note 20, at 4.

99. *See* Dura Pharms., Inc. v. Broudo, 544 U.S. 336, 346 (2005) ("The [PSLRA] . . . makes clear Congress' intent to permit private securities fraud actions for recovery only where plaintiffs adequately allege . . . the traditional elements of causation and loss.").

100. The Ninth Circuit seemed to blur the distinction between evaluating plaintiffs' causal *theory* and the likelihood that plaintiffs could actually prove the *facts* underlying that theory, suggesting that both should be reserved "for later stages of the proceedings" rather than 12(b)(6) dismissal. *Gilead*, 536 F.3d at 1057.

101. H.R. REP. NO. 104-369, at 31 (1995) (Conf. Rep.) (lamenting "abusive" litigation tactics, including "the routine filing of lawsuits . . . with only [a] faint hope that the discovery process might lead eventually to some plausible cause of action"); Blue Chips Stamps v. Manor Drug Stores, 421 U.S. 723, 740–42 (1975).

The Ninth Circuit's criticism of the district court in *Gilead* was misguided because the district court found that plaintiffs' *theory* of causation was implausible, not that plaintiffs could not prove the *facts* supporting that theory.[102] Indeed, the plaintiffs' theory facially contradicts "fraud-on-the-market" principles explicitly adopted in *Basic* and presumed by Congress in the Securities Acts.[103] In their complaint, plaintiffs allege that although the SEC issued a public corrective disclosure revealing Gilead's off-label marketing activity—*the alleged fraud*—on August 7, 2003, the market did not comprehend the magnitude of this fraud until after a "limited temporal gap" of nearly three months when Gilead issued its third-quarter financial results on October 28, 2003. Yet, plaintiffs simultaneously allege that drug wholesalers and doctors understood the implications of the SEC's off-label marketing letter and scaled back purchases and prescriptions, respectively.[104] In other words, although medical professionals and wholesalers understood the implications of the FDA Warning Letter, its significance, inexplicably, never dawned upon market analysts, investment bankers, individual investors, and other market participants.

This simply does not comport with the fraud-on-the-market theory. *Basic* instructed that the "fraud-on-the-market" presumption is built upon the idea that well-developed markets efficiently incorporate *all* publicly available information into share prices.[105] Moreover, legal application of this theory necessarily presumes that markets incorporate public information *quickly*.[106] If markets do not comprehend and efficiently incorporate public information, the *Gilead* plaintiffs cannot credibly rely on the market price as an accurate representation of share value based on all public information, nor can they use the market's reaction to new information to demonstrate materiality or loss causation.

Although the Ninth Circuit explained that securities markets are subject to "distortions," and courts must therefore engage in "fact-specific inquiry," the court curiously omitted any discussion of how a reasonable investor could fail to comprehend the magnitude of the August 7 Warning Letter, and, more importantly, how the October

102. *Gilead*, 536 F.3d at 1057.
103. Brief of Amici Curiae, *supra* note 48, at 9–11.
104. *Gilead*, 536 F.3d at 1053, 1058.
105. Basic, Inc. v. Levinson, 485 U.S. 224, 241–42 (1988).
106. *See supra* text accompanying notes 51–57.

28 earnings disclosure revealed anything *new* other than declining Viread sales. The October 28 disclosure did not explain the extent of Gilead's off-label marketing activity, nor did it attribute the declining sales to the FDA Warning Letter. Indeed, many analysts attributed the decline in Viread sales to wholesalers' excessive buildup during the second quarter in anticipation of Viread's price increase rather than to declining end-user demand, which may have actually grown during the third quarter.[107]

Instead, the market may have sensibly discounted the FDA Warning Letter in light of other factors.[108] In any event, because the October 28 disclosure did not reveal anything new that the market could not apprehend from the August 7 disclosure, the plaintiff's theory of causation is facially implausible. The Ninth Circuit's holding that an "efficient" market can take three months to incorporate public information into share prices is also inconsistent with the prevailing understanding of the fraud-on-the-market theory.[109]

C. Pleading Proximate Causation

The most glaring problem with the Ninth Circuit's opinion is the court's disregard for the *Dura* proximate causation pleading standard, which follows from *Dura*'s admonition that a plaintiff cannot ignore superseding contributory causes when pleading loss causation.[110] A plaintiff's causal theory will unravel if his loss can be explained more accurately as a product of changed economic circumstances, investor expectations, or industry-specific conditions.[111] Thus, a plaintiff must allege facts that allow the court

107. Brief of Petitioner-Appellant, *supra* note 20, at 13–14 (explaining that Viread end-user demand actually *grew* by up to 17% during the third quarter).

108. At least one of the off-label applications advertised by Gilead has since been approved by the FDA. *See U.S. Food and Drug Administration Approves Viread(R) for Chronic Hepatitis B in Adults*, MEDICAL NEWS TODAY, Aug. 12, 2008, http://www.medicalnewstoday.com/articles/117958.php (last visited Jan. 28, 2010) (announcing the FDA's approval of Viread for hepatitis B patients). In addition, Gilead's annual revenue has grown by more than 600% in six years, from $868 million in 2003 to more than $5.3 billion in 2008. *See* Gilead Sciences, Inc., Annual Report (Form 10-K), at 42 (Feb. 27, 2009). Thus, in light of Gilead's long-term growth potential and Viread's expanding medical applications, the market could have consciously discounted the significance of the FDA Warning Letter in August of 2003.

109. Brief of Amici Curiae, *supra* note 48, at 9–11.

110. Dura Pharms., Inc. v. Broudo, 544 U.S. 336, 343 (2005).

111. *Id.*

to ascribe some rough proportion of the whole loss to the alleged fraud rather than other superseding factors. The *Dura* Court further explained that, all things being equal, the longer the time between the purchase and sale of the security, the more likely other factors caused the loss.[112]

While a plaintiff must prove that the alleged fraud was a "substantial cause" of the loss to recover damages at trial, the pleading standard only requires him to establish a reasonably well-founded basis for believing that he will be able to prove substantial causation at trial.[113] This is a practical standard that bars largely groundless claims with only a faint hope that discovery will reveal some plausible course of action,[114] while preserving for trial plausible claims with a "reasonably founded hope that the [discovery] process will reveal relevant evidence"[115] necessary to substantiate the finer elements of proportional causation.

Although the Ninth Circuit recognized this principle in *Gilead*—explaining that while a misrepresentation need not be the "*sole* reason for the decline in value of the securities . . . it must be a *substantial cause*"[116]—the *Gilead* opinion lacks any discussion of proximate causation, "substantial cause," or alleged facts that could allow the court to ascribe some rough proportion of the total loss to Gilead's off-label marketing. Indeed, the Ninth Circuit rebuked the district court's so-called "incredulity" for rejecting the plaintiffs' deficient *theory* of causation, explaining that plaintiffs' complaint need only offer "sufficient detail to . . . give [the court] some assurance that theory has a basis in fact."[117]

Yet, the court also failed to identify any facts in the complaint providing assurance that plaintiffs' loss causation theory has a basis in fact. Significantly, market analysts' explanations of the drop in Gilead's stock prices contradict that of the plaintiffs. Many analysts attributed the decline to excessive wholesaler buildup and declining sales growth in Europe. End-user demand for Viread actually *grew*

112. *Id.*

113. *See In re* Gilead Scis. Sec. Litig., 536 F.3d 1049, 1055–56 (9th Cir. 2008).

114. H.R. REP. NO. 104-369, at 31 (1995) (Conf. Rep.) (lamenting "abusive" litigation tactics, including "the routine filing of lawsuits . . . with only [a] faint hope that the discovery process might lead eventually to some plausible cause of action").

115. *Dura*, 544 U.S. at 347.

116. *Gilead*, 536 F.3d at 1055–56 (emphasis added).

117. *Id.* at 1056 (internal quotations omitted).

during the third quarter. Moreover, even if plaintiffs demonstrated that the decline in Viread sales growth was somehow linked to the FDA Warning Letter, they still would not demonstrate a causal connection with the stock price decline three months later in October. As even the *Dura* Court warned, the longer the time between public disclosure of the alleged fraud and the drop in share prices, the less likely the fraud caused the loss.

V. CONCLUSION

The Ninth Circuit has introduced in *Gilead Sciences* a highly permissive pleading standard that allows complaints to proceed beyond Rule 12(b)(6) dismissal so long as the theory of causation is not "facially implausible," regardless of whether plaintiffs allege facts demonstrating proximate causation. The court also construes the word "plausible" to include theories of causation manifestly inconsistent with the fraud-on-the-market theory—a principle underlying virtually all securities litigation claims. This standard betrays the statutory and common law limitations on private securities litigation designed to bar highly speculative or implausible complaints. Indeed, the Ninth Circuit's understanding of loss causation permits any plaintiff class that has lost share value to search retrospectively for a potential cause, plead a logically inconsistent and factually unsubstantiated causal link, and proceed beyond the critical dismissal stage to discovery.[118] This effectively transforms the private securities claim into an insurance policy against market losses.[119]

Though the *Gilead Sciences* court would leave evaluation of a plaintiff's loss causation theory to the latter stages of litigation,[120] Congress and the Supreme Court have recognized that frivolous litigation must be stopped *before* the costly discovery process

118. The *Gilead* plaintiffs plead three different theories of causation before prevailing on appeal with their Fourth Amended Complaint. The first and most plausible theory alleged that Gilead's material misstatement was understating the *extent of wholesalers' stockpiling* during the second quarter. This was subsequently verified in the October disclosure. *In re* Gilead Scis. Sec. Litig., 2006 WL 1320466, at *4 (N.D. Cal. May 12, 2006).

119. *See Dura*, 544 U.S. at 345 ("[T]he statutes make [private securities fraud] actions available, not to provide investors with broad insurance against market losses, but to protect them against those economic losses that misrepresentations actually cause.").

120. *Gilead*, 536 F.3d at 1057 ("[Other circuits have] 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.' . . . We agree." (emphasis added)).

begins.[121] Even unmeritorious complaints that survive dismissal offer an enormous settlement value to defendants.[122] Thus, as the only gatekeepers against *in terrorem* securities suits, federal courts must employ Rule 12(b)(6) with a more rigorous standard than that offered by the Ninth Circuit.

Brandon J. Stoker[*]

121. H.R. REP. NO. 104-369, at 31, (1995) (Conf. Rep.); *Dura*, 544 U.S. at 347; *see also* Bell Atl. Corp. v. Twombly, 550 U.S. 544, 558 (2007) (When the allegations in a complaint, however true, could not raise a claim of entitlement to relief, "'this basic deficiency should . . . be exposed at the point of *minimum expenditure of time and money* by the parties and the court.'" (emphasis added)).

122. *See* Blue Chips Stamps v. Manor Drug Stores, 421 U.S. 723, 739 (1975).

* J.D. candidate, April, 2010 J. Reuben Clark Law School, Brigham Young University.