SECURITIES CLASS ACTIONS IN THE LIFE SCIENCES SECTOR

2015 Annual Survey

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INTRODUCTION AND OVERVIEW

This year-in-review addresses developments in securities class actions brought against life sciences companies in 2015. We begin with an overview and analysis of trends in decisions involving life sciences companies with products at two distinct stages of development—pre- and post-FDA approval. Next, we provide summaries of the 34 federal district court and appellate court decisions surveyed. Finally, we catalog the new securities class action complaints filed against life sciences companies in 2015.

At the most basic level the cases analyzed share a common feature. In each, a life sciences company suffered a setback that, when publicized, was followed first by a stock price decline and then by litigation initiated by shareholders seeking to recover investment losses. Such setbacks can, of course, occur at any stage of a company’s development, but in the life sciences sector—given particular issues relating to drug development, regulatory approval, and continued regulatory oversight of manufacturing, marketing and sales activities—the setbacks are clustered in a few obvious stages of a company’s life cycle.

We believe that analyzing legal developments by reference to the stage of drug or device development at which the setback occurs may yield useful insights and assist in risk mitigation. Accordingly, this year-in-review is structured with reference to the following stages:

Pre-Approval: Clinical Trials and Pre-Clinical Studies
Post-Approval: Launch and Marketing of the Product
PRE-APPROVAL: CLINICAL TRIALS AND PRECLINICAL STUDIES

PRECLINICAL DEVELOPMENT

CONDUCT OF PHASES 1-3
of clinical trials and analysis and report of trial results.

SUBMISSION OF APPLICATION FOR REGULATORY APPROVAL OF PRODUCT—
for pharmaceutical products, the New Drug Application; for Class III medical devices, the Premarket Approval Application; and for non-exempt Class I or II medical devices, Premarket Notification under 510(k) of the Food, Drug, and Cosmetic Act.

POST-APPROVAL: LAUNCH AND MARKETING OF THE PRODUCT

LAUNCH STAGE

CONTINUED MONITORING BY AND INTERACTION WITH THE FDA IN THE FOLLOWING AREAS:

Adverse Event Reporting — Reporting of adverse events to the FDA as required by regulation; FDA response and further developments.

Inspection of Facilities — Routine inspection by the FDA, followed by various communications should issues arise and not be resolved — Forms 483, Warning Letters, Complete Response Letters.

Marketing — Regulatory monitoring of marketing efforts, and FDA or other government action if issues arise concerning off-label marketing, Medicare/Medicaid fraud, Foreign Corrupt Practices Act or other statutory or regulatory violations.

Other Regulatory Issues — Changes in label or product design that may trigger regulatory obligations.

NON-REGULATORY ISSUES

Sales, Revenue and Other Financial Projections and Performance
Acquisitions
Other Issues Not Specific to Life Sciences Companies

A setback at any stage will present disclosure issues, and a company will be required to determine when and how best to inform the financial markets of the negative development. Assuming a company’s stock price declines following the disclosure, members of the plaintiffs’ securities bar will review the company’s past statements relevant to the issue and will search for inconsistencies between past positive representations and the current negative development. Plaintiffs’ counsel will then seek to attribute any such inconsistencies to fraud. Given the heightened pleading standards of the Private Securities Litigation Reform Act, plaintiffs’ allegations will be tested at an early stage in the litigation. In nearly all cases, the company will move to dismiss, arguing that plaintiffs have failed to allege facts that create a “cogent” and “compelling” inference that the company made deliberately false statements.¹

DECISIONS ISSUED IN 2015–TRENDS AND ANALYSIS

In this section, we discuss the reported federal decisions issued in securities actions at the pleading stage (or, in a few cases, on summary judgment). Unless otherwise noted, these decisions concern class actions brought under Section 10(b) of the Securities Exchange Act of 1934. In 20 of the 28 cases at the district court level, courts granted defendants’ motions; in the remaining eight cases, the motions were denied at least in part. The appellate decisions stem from plaintiffs’ appeals of orders granting defendants’ motions to dismiss. The appellate courts affirmed dismissal in five of the six cases discussed below and reversed in one. This activity can be represented graphically, as shown on the page opposite.
Decisions related to NON-REGULATORY issues

7 Decisions related to REGULATORY issues

20 Decisions related to the APPROVAL process

11 Decisions related to POST-APPROVAL DRUGS OR DEVICES

3 Decisions related to INFOUSION DEVICES

3 Decisions related to DEFUSION DEVICES

1 Decision related to LAUNCH-STAGE issues

Decisions related to STOCK PROMOTION activities
Before analyzing these decisions, we briefly take note of United States Supreme Court activity in the area of securities litigation generally in 2015. In March 2015, the Court handed down its decision in *Omnicare*, which deals with liability for allegedly misleading statements of opinion.¹ At issue there was whether, for purposes of a claim under Section 11 of the Securities Act of 1933 (involving representations made in stock registration statements), a plaintiff may allege that an opinion statement was untrue simply by pleading that the opinion was objectively wrong, or whether, by contrast, a plaintiff must also plead (and eventually prove) that the speaker did not actually believe the statement. The Court held that in Section 11 cases, as in Section 10(b) cases, a statement of opinion is actionable only if the speaker did not actually hold that opinion—a favorable outcome for securities defendants. But *Omnicare* also provides securities plaintiffs with a potential path to victory in cases in which they allege that an opinion statement is misleading by way of omission. The Court held that reasonable investors, in hearing a statement of opinion, will expect that the speaker has taken certain steps and acquired certain knowledge that forms the basis of that opinion. If the speaker has neither done so nor disclosed that he or she has failed to take such steps, the opinion statement may be misleading by virtue of that omission. This is what might be called the “offensive” use of *Omnicare*, and in two decisions discussed below, *BioScrip* and *Merck*, the courts drew on this approach in reaching results favorable to Section 10(b) plaintiffs.² At the same time, however, the majority of courts that have applied *Omnicare* in life sciences cases in 2015 have done so in defendants’ favor, by dismissing Section 10(b) claims in which plaintiffs were unable to plead subjective falsity.

**DECISIONS RELATED TO DEVELOPMENT-STAGE DRUGS OR DEVICES**

In 2015, by far the largest number of decisions issued by federal courts in securities litigation against life sciences companies involved products at the pre-approval stage. In contrast with the 2014 decisions, which split evenly between victories for companies and victories for plaintiffs in this area, the 2015 district court decisions broke decisively in favor of defendants, with a total of 14 victories on motions to dismiss or summary judgment and only three losses in the decisions catalogued below.³ Appellate decisions were more evenly split, with two victories for defendants in unpublished and fairly cursory decisions and one win for plaintiffs in a more fully analyzed published opinion.

Several themes emerge from the decisions in which companies prevailed. In a number of these cases, plaintiffs complained that the company had hidden the risk that a drug would not be approved or that a trial would not succeed. In assessing these claims, courts have been willing to look closely at the larger record of a company’s public statements, and quite often have concluded that the supposedly hidden risks were in fact revealed. In doing so, courts have drawn on a variety of sources, from the risk disclosures in a company’s SEC filings, to publications in medical or scientific journals, to information on FDA websites.

Another consistent theme, and one that we analyze more fully below, is the recognition that the approval process is one of give and take, and that companies have no obligation to report every comment, question or concern expressed by regulators during that process. The case law has consolidated on this point in 2015 in a way that should prove helpful to companies faulted for not disclosing interim communications with the FDA.

Finally, in several of the favorable decisions, courts have recognized that a company’s public statements in this area often consist of opinions, or deal with future occurrences that cannot be foreseen. In these decisions too, some of which draw on *Omnicare*, the results have been favorable for companies: statements of opinion or prediction are rarely found to be false or misleading, let alone knowingly so.

We now analyze in more detail three topics that arise from the 2015 decisions involving development-stage companies or products: the treatment of interim agency communications; the evolving law on statements of opinion after *Omnicare*; and the role of insider stock sales in the analysis of scienter in close cases.

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2 Complete citation information for the cases discussed in this overview section is provided in the case synopses below.

3 This excludes the three decisions involving stock promotion activities, discussed on pages 9-10 and 32-33.
Interim Agency Communications

In a significant number of decisions this year, courts have confronted claims that defendants committed fraud by failing to disclose negative comments made by the FDA at an interim stage in the approval process. In most—though not all—of these cases, courts have granted companies’ motions to dismiss.

The facts in these cases fall largely into the same basic pattern. At some point before approval, the FDA communicates its concerns about an aspect of the drug candidate or trial design. This may take the form of a written comment in a letter or report, or it may be an oral statement made during a company’s in-person meetings with FDA staff. Unless the company (or the agency) discloses the comment when it is made, investors often will not learn about it until near the end of the approval process, when FDA staff or an advisory committee publicly release comprehensive briefing documents summarizing events from earlier stages in the process.

Plaintiffs’ attorneys who see these comments for the first time when bad news is announced will take the position that the comments constituted material information that the company was required to disclose to the investing public—and that by failing to make such disclosures at the relevant time, the company committed fraud.

In many of these cases, courts begin by making two significant legal points, both favorable to defendants.

First, courts note that Section 10(b) does not impose an affirmative duty to disclose material information. Defendants’ duty under the statute is only to refrain from making false or misleading statements. Courts often cite the Supreme Court’s 2011 Matrixx decision in making this point.4

Second, courts say that companies that routinely interact with the FDA are not required to disclose all of their communications with the agency; in particular, companies need not disclose statements that are less than definitive, or that are part of the give-and-take inherent in the regulatory process. With respect to the latter issue, the Southern District of New York, in two decisions issued in 2015, Sanofi and EDAP (pages 26-27), has usefully compiled 20 years’ worth of case law that can be cited to support the point that companies have no independent duty to disclose interim inquiries or feedback from the FDA.

Applying these two principles, courts have rejected plaintiffs’ claims in the majority of the 2015 decisions that deal with the issue. A good example is Amarin (page 25), where, in a pre-NDA meeting, the FDA called the company’s attention to trials being conducted by third-party drug developers, and told the company that the results of those third-party trials would be “important” in the agency’s evaluation of the company’s own application. Plaintiffs claimed that the company wrongly failed to disclose this information when it first became available. The court rejected the claim, taking as its point of departure the first of the two principles above: Section 10(b) imposes no obligation to disclose, and a disclosure duty arises only where a company has made an affirmative statement that would be rendered misleading by virtue of the omitted information. The court found no such statement in Amarin: the company had never affirmatively characterized the significance of the third-party studies.

Amarin thus requires plaintiffs to demonstrate a very specific connection between the omitted FDA comment and the statements the company did make—something close to a direct contradiction between the two. In Sarepta (page 23), another case in which investors argued that the company had not sufficiently disclosed concerns the FDA raised in pre-NDA meetings, the court explicitly articulated a “contradiction” standard. In rejecting the plaintiffs’ omission theory, the court held that “[d]efendants were under no duty…to delve into the FDA’s specific concerns over the sufficiency of [the company’s] potential NDA, at least absent their making of statements that would contradict such concerns.”

In other cases involving claims that a company failed to disclose negative interim communications, courts have focused on the specific content of the agency’s comments rather than on the exact nature of the company’s public statements. In several cases, courts have found that plaintiffs’ attorneys were overstating the magnitude or definitiveness of what the FDA had said. In Sanofi (page 26), for example, plaintiffs faulted the company for failing to

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disclose the FDA’s comment that it would require greater certainty in results from a single-blind than from a double-blind study. The court rejected that challenge. The court held that although the company could have reported the FDA’s comment, its failure to do so was not misleading, largely because the comment fell short of a definitive statement that an application based on a single-blind study would fail.

The district court decision in VIVUS (page 28) is similar. There, plaintiffs argued that the company had wrongly failed to disclose one regulator’s statement that a drug could not be approved without an additional safety study. The court began with one of the two favorable principles above: the company was “not required to report every communication it had received from a regulator.” The court went on to find that the statement plaintiffs faulted the company for not disclosing represented only the position of a single advisory committee member, and not the position of the committee or agency as a whole.

Much the same was true in EDAP (page 27), where plaintiffs faulted defendants for failing to report the FDA’s concern with the company’s use of metastasis-free survival, as opposed to overall survival, as the primary endpoint in its trial. The court noted that the FDA had told the company that the endpoint it had chosen was less than ideal, but had not stated definitively that it would not accept an application based on a study with that endpoint. The court also distinguished cases in which companies had reported FDA communications but had plainly cherry-picked the information they chose to disclose, announcing the positive aspects of a letter or report but withholding the negative aspects.

Not all of the 2015 decisions in this area have been favorable for companies, however. In the unfavorable cases, as in those decided in defendants’ favor, courts have begun with the premise that Section 10(b) does not impose a freestanding disclosure duty, and that the statute requires disclosure only when necessary to keep a company’s affirmative statements from becoming misleading. But in examining companies’ affirmative statements, these courts have concluded that the omitted information in fact was necessary to prevent misdirection. This was the case in Chelsea Therapeutics (page 20), where the company told investors that the FDA had questioned whether its trials had adequately established a durable treatment effect—but did not disclose that FDA staff had also recommended that the drug not be approved. The trial court granted the company’s motion to dismiss but the Fourth Circuit reversed, holding that this combination of disclosure and non-disclosure with respect to a single communication could support an inference that the company deliberately misled investors.

In Pain Therapeutics (page 30), a summary judgment decision, the court took a broader approach. The company in that case had established the efficacy of the drug for which it sought approval, but faced difficulties showing that the active ingredient in the drug was stable. The FDA sent the company a Discipline Review Letter in which it questioned the methods the company had proposed to address the stability problem. The court concluded that plaintiffs had established a triable omission claim based on the company’s failure to disclose the Discipline Review Letter. Here, the question was not, as it had been in Chelsea Therapeutics, whether a company that elects to discuss a given agency communication becomes obligated to provide additional information about that communication in order to keep its disclosure from being misleading. Instead, the question was whether a company that has discussed an issue relating to its drug candidate takes on a duty to report subsequent interim communications relating to that issue. The court found that the company did take on such a duty: once defendants “chose to make concerns about [the drug’s] stability data public...[they] thereby obligated themselves to disclose significant facts related to the stability of the [drug]” (emphasis added).

Aveo (page 25) reflects a similar analysis. There, plaintiffs faulted the company for failing to disclose that during a face-to-face meeting, FDA personnel had expressed concern about the failure of a trial to meet its secondary endpoint and had recommended that the company complete another trial before submitting its NDA. In holding that plaintiffs had sufficiently alleged false or misleading statements, the court explained that “when a corporation does make a disclosure—whether it be voluntary or required—there is a duty to make it complete and accurate” (emphasis added). In the same vein, the court held that “a failure to disclose FDA’s serious criticism is a material omission.”
The approach taken in Pain Therapeutics and Aveo appears to be significantly broader than—and possibly inconsistent with—the approach adopted in Amarin and other favorable decisions cited above. In those and earlier decisions, courts have emphasized that securities defendants have no duty to provide complete information, and have suggested that a statement becomes misleading by way of omission only if it is contradicted by the omitted information. We believe that the latter approach is the better one, and certainly the one best supported by appellate authority.

Beginning in 2002, the Ninth Circuit has repeatedly stressed that securities defendants have no “duty of completeness,” and that the irreducible minimum of a Section 10(b) claim is a misleading statement—not an incomplete one. E.g., Brody v. Transitional Hosps. Corp., 280 F.3d 997, 1006 (9th Cir. 2002) (“Rule 10b-5 prohibits only misleading and untrue statements, not statements that are incomplete”) (emphasis in original); Police Ret. Sys. of St. Louis v. Intuitive Surgical, Inc., 759 F.3d 1051, 1061 (9th Cir. 2014) (“We have expressly declined to require a rule of completeness”); In re Rigel Pharm., Inc. Sec. Litig., 697 F.3d 869, 880 n.8 (9th Cir. 2012). Other appellate courts have followed suit. E.g., Indiana Elec. Workers’ Pension Trust Fund v. Shaw Group, 537 F.3d 527, 541 (5th Cir. 2008) (allegedly “incomplete” statements are actionable only if misleading) (citing Brody); Winer Family Trust v. Queen, 503 F.3d 319, 330 (3d Cir. 2007) (same). District courts have relied on these holdings; in 2015 in particular, the Northern District of California did so in a particularly thorough decision in AcelRx (page 26). Thus, to the extent that Pain Therapeutics and Aveo can be read as requiring complete disclosures, they appear to represent a distinctly minority position on this point.

Statements of Opinion

In several decisions involving products at the pre-approval stage, courts have begun to apply Omnicare, the Supreme Court’s 2015 decision dealing with statements of opinion in 1933 Act cases. The simplest application of Omnicare appears in cases where plaintiffs challenge what are plainly statements of opinion but fail to plead facts showing that defendants did not sincerely hold those opinions. Courts in these cases have assumed that Omnicare applies to Section 10(b) claims as well as to 1933 Act claims, and have found that it supports dismissal in such circumstances. This was the case in both Sarepta and Invivo.

A more nuanced application appears in Amarin (page 25), where plaintiffs sought to use Omnicare’s “offensive” holding on omissions to their advantage. As noted, Omnicare holds that a statement of opinion may be actionable if a reasonable investor would assume that the speaker made certain inquiries in the course of forming that opinion and had a reasonable basis for it—but the speaker in fact did not make such inquiries and lacked a basis for the opinion. The plaintiffs in Amarin tried to apply that framework to interim agency communications: they argued that the company’s optimistic opinion statements about approval were actionable under Omnicare because plaintiffs failed to disclose the fact that the FDA had told the company that third-party trials would provide important information about Amarin’s own application. The court rejected that theory, holding that (assuming Omnicare applied to Section 10(b) claims) a reasonable investor would not have expected the basis of the company’s opinion to be any different than the basis that actually existed at the time. (For contrary results in a different regulatory setting, see the discussion of BioScrip and Merck, at pages 10–11 below.)

A final decision illustrates the interaction of the developing law regarding statements of opinion and the existing law concerning disclosure of interim communications. In OvaScience (page 22), the company began testing a product without first filing an Investigational New Drug application, believing that the product qualified for an exemption. The company received, but did not completely disclose, an informal letter in which the FDA stated that, based on limited information, it believed that the product was not exempt. Plaintiffs argued that the company should have disclosed the details of that letter, and the court agreed. The court began with the familiar proposition that companies have no duty to disclose interim FDA communications as an initial matter, and that a duty arises only if the company makes an affirmative statement rendered misleading by virtue of the omitted information. The court then found that the company had made such a statement—it had stated in quarterly filings that it believed the product was exempt but that the FDA “could” disagree. That statement, the court
held, was misleading insofar as the FDA had already told company—albeit not definitively—that it did disagree with the position that the product was exempt.

Nevertheless, the court ultimately granted the company’s motion to dismiss on scienter grounds. The court held that plaintiffs were required to establish that the company knew that the FDA would ultimately hold the product to be outside the exemption, and that plaintiffs had not done so. Certain actions the company took—disclosure of the existence of the letter—were evidence that it subjectively believed its position would be vindicated. Other facts—continuing developments in the FDA’s consideration of the matter—showed an objective basis for that belief. In this way, a statement of opinion that the court had deemed misleading was ultimately not actionable.

**Scien+er and Insider Stock Sales**

Finally, we note that in several decisions at the pre-approval stage, courts have given particular weight to officers’ stock sales where issues of scienter otherwise presented a close call. In Aveo (page 25), discussed above, the court found that defendants owed and breached a duty to report the FDA’s stated concerns about the failure of a trial to meet its secondary endpoint. Ultimately, however, the court dismissed plaintiffs’ claims on scienter grounds. A key factor in the court’s analysis was the absence of insider stock sales.

On the other side of the ledger is Chelsea Therapeutics (page 20). There, too, the district court relied on the absence of stock sales to conclude that plaintiffs failed to adequately plead scienter. But the Fourth Circuit reversed, holding, among other things, that the district court had erred in relying on this factor.

In Vertex (page 23), it was the presence of insider sales that made the case a close one. Defendants in that case conceded that the challenged statements were false: the company had made an error in analyzing clinical trial data and as a result overstated the positive outcome of the trial. The class period was very short—less than a month—and some defendants had made significant stock sales during that period. The court nevertheless granted defendants’ motion to dismiss, finding that defendants had offered benign and plausible explanations of their sales. Even significant stock sales, the court found, could not transform a mistake in analyzing data into a deliberate fraud on the securities markets.

**DECISIONS RELATED TO STOCK PROMOTION ACTIVITIES**

Three decisions were issued in 2015 in a new sub-category of cases—those in which relatively small and thinly capitalized companies with development-stage products have been accused of illegal stock promotion activities. In each case, the company was alleged to have paid authors, through investor relations firms acting as intermediaries, to write favorable articles about the company and its products, thereby boosting stock prices shortly before the company made a public stock offering.

Plaintiffs have pursued various theories of liability arising from this fact pattern. They have argued that the companies made false or misleading statements insofar as they failed to disclose the financial arrangements behind favorable media coverage. Plaintiffs have also asserted that defendants participated in a fraudulent “scheme” involving conduct beyond the making of false or misleading statements. In two cases, plaintiffs have sued the investor relation firms and writers, as well as the company and its officers and directors. And in one case, plaintiffs also brought a separate insider trading claim against officers and directors who sold stock during the period in which the favorable articles appeared.

The 2015 decisions in this area all arose from complaints filed in 2014, following media exposés of alleged stock promotion schemes at several companies. Those exposés were followed by a downturn in stock price, which in turn prompted plaintiffs’ attorneys to enter the picture. The SEC also began investigating certain companies following the publication of the exposés in 2014. It remains to be seen whether more litigation will arise in this area. The cases filed to date have involved a partially overlapping set of investor relation firms and some overlap among outside directors on the various companies’ boards.
In two of the 2015 decisions, Galena and CytRx (page 32), the courts largely denied defendants’ motions to dismiss. In the third, Galectin (page 33), the court granted defendants’ motion. The critical distinction between Galena and CytRx on the one hand and Galectin on the other appears to be that plaintiffs in Galectin did not allege that the company had ultimate authority over the content of the paid articles. The Galectin court held that there is nothing inherently improper in paying for favorable coverage, and that even if a duty to disclose payment terms was breached, that duty belonged to the writers of the articles, not to the company.

DECISIONS RELATED TO POST-APPROVAL DRUGS OR DEVICES

2015 saw fewer decisions involving companies with products already on the market. We survey 11 such decisions below. Leaving aside one decision concerning early launch-stage issues, seven of the 11 relate to unfavorable post-approval regulatory developments. These decisions reflect several significant legal developments or principles. The basic fact pattern in these cases is largely the same. A company is notified by the FDA or another agency that, in the regulator’s view, some aspect of the company’s activity is improper or is being investigated. The company may disclose this immediately or may wait until the regulator has issued a formal notice of violation. The company’s stock price falls on the announcement, and plaintiffs’ attorneys seek to characterize the matter as one not only of regulatory non-compliance, but also of securities fraud. Under an omission theory, plaintiffs argue that the company should have disclosed that it was engaged in the targeted activity. Plaintiffs also try to find affirmative public statements that are arguably inconsistent with the underlying conduct—for example, “our policy is not to engage in off-label marketing,” or “we are in compliance with applicable laws and regulations.”

In five of the seven decisions in this group, the companies prevailed on motions to dismiss or motions for summary judgment. Two of the five favorable decisions were somewhat unusual in that the courts agreed with plaintiffs that defendants had made false or misleading statements—but then dismissed because plaintiffs had not shown that the statements were materially false (Pacira) or knowingly false (Ariad).

One of the most significant decisions in this area is the sole appellate one. In Abiomed (page 36), the First Circuit affirmed dismissal of claims stemming from the FDA’s finding that the company was engaged in off-label marketing—a finding that ultimately led the company to recall all of its marketing materials. Plaintiffs challenged, among other things, the company’s statement in its SEC filings that its policy was not to engage in off-label marketing. The First Circuit, like the district court, rejected the claim. The company had disclosed the relevant underlying conduct, the court held, and was not required to go further and to pejoratively characterize its activities as improper. In other words, the company was not required to agree with the FDA that its actions were illegal: the securities laws had to leave “some room for give and take” between a regulated entity and its regulator. That holding echoes the rulings of many decisions in the pre-approval context (discussed above), in which courts have similarly left “room for give and take” by holding that companies need not disclose every FDA communication relating to approval.

The district court decision in TranS1 (page 39) reflects a similar approach. There, the company engaged in what regulators viewed as billing fraud; plaintiffs then argued that the company also committed securities fraud by failing to disclose that it was engaged in an illegal billing scheme. The court rejected that argument, finding that the company had openly disclosed the actions that regulators deemed improper, and that because plaintiffs had not alleged that the company knew at the time that those actions were improper, there was no fraud. Pacira (page 37), another off-label marketing case, was similar. The court there concluded that because both the company’s marketing activities and the approved label indication were matters of public record, there could be no fraud: investors could judge for themselves whether the company was putting itself at risk of regulatory scrutiny or action.
On the other hand, where plaintiffs can allege both that the company was engaged in activity later deemed to be illegal and that the company was already on notice that regulators were investigating it, plaintiffs may under some circumstances be able to state a claim. This was the case in BioScrip (page 39), where the company learned that it was being investigated for possible violations of anti-kickback laws, but nevertheless included in its SEC filings the statement that it believed it was in compliance with applicable laws and regulations. The court concluded that plaintiffs had pled an omission claim under Omnicare, which, as discussed above, provides investors with a way in which to challenge statements of opinion when certain facts relating the basis of that opinion are not disclosed. The BioScrip court concluded that the existence of an ongoing investigation by regulators is the kind of fact that reasonable investors would expect to be disclosed when a company provides a legal compliance opinion—and that because the company had not disclosed it, plaintiffs had identified an actionable omission.

In other situations, however, courts have concluded that the heavily regulated nature of a life sciences company’s business itself cuts against an inference of fraud. Thus, in Ariad (page 38), the court agreed with plaintiffs that the company had made false or misleading statements by favorably characterizing the safety of its drug despite a high incidence of adverse events. Nevertheless, the court dismissed plaintiffs’ claims, concluding in effect that because the company was subject to constant FDA scrutiny in the area, fraud would not be feasible—and therefore an intent to mislead could not be inferred. In Iradimed too (page 38), the court found that the background of tight regulation in the medical device field undermined plaintiffs’ fraud claims. In that case, the company received a Form 483, which it disclosed as having arisen from a “routine” inspection. Later, based on the same issues identified in the Form 483, the FDA determined that the device at issue was “adulterated,” and ordered the company to cease distribution. The court rejected plaintiffs’ challenge to the term “routine,” observing that inspections in fact are routine in the industry, and that as a result, companies have no duty to disclose all inspections, all Forms 483, or even all Warning Letters. Thus, in this area, as in many of the favorable decisions in the pre-approval setting, courts continue to show a fairly nuanced understanding of the regulatory context in which life sciences companies operate. Where courts apply that understanding, they generally arrive at the conclusion that the regulatory setback a company has suffered does not also amount to a fraud on the company’s investors.

Finally, 2015 saw another chapter in the long-running litigation against Merck in connection with the anti-inflammatory drug Vioxx, which was approved in 1999 and withdrawn from the market in 2004. This multi-district litigation has been active for more than ten years, and has been the subject of multiple appellate proceedings, including a Supreme Court decision in 2010. After extensive discovery and fact development, Merck moved for summary judgment, and the federal district court in New Jersey largely denied that motion in May 2015 (page 40). The court emphasized that Merck was not broadly liable under the securities laws for any and all ostensibly improper conduct related to Vioxx; rather, the securities statutes are more narrowly focused on the accuracy of a company’s public statements about its business. Nevertheless, the court concluded that plaintiffs had presented evidence sufficient to proceed to a jury trial on the issue of whether the company had made false and misleading statements in defending the safety of its drug. The court found that plaintiffs had compiled a record of internal communications that called into question both the accuracy of the company’s statements and the sincerity of its professed belief that the drug was safe. Among other things, the Merck court applied Omnicare in the same “offensive” way that the BioScrip court did, holding that plaintiff had stated actionable omission claims by pointing to internal information that did not fairly align with the opinions the company was expressing publicly.
TABLE AND SHORT SUMMARIES OF 2015 DECISIONS

In this section (pages 14-18), we provide very brief summaries of each of the decisions issued in 2015, organized by stage of a product’s or company’s life cycle. We have grouped the decisions according to outcome, with those in which companies prevailed on dispositive motions listed first. As noted above, life sciences companies largely fared well in securities litigation in 2015. At the pre-approval stage, companies succeeded in winning dismissal in 17 of the 23 cases summarized below. Companies were also more often successful than not in securities litigation arising from post-approval developments; in this area, companies prevailed in 8 of 11 cases.

The page numbers in this section refer to more detailed summaries of the same decisions included in the following section (pages 19-42).
DECISIONS RELATED TO DEVELOPMENT-STAGE DRUGS OR DEVICES

APPELLATE DECISIONS

Zak v. Chelsea Therapeutics Int’l, Ltd., 780 F.3d 597 (4th Cir. 2015) .............................................. 20
FDA denies NDA, questioning whether trial established durable treatment effect; appellate court reverses dismissal based on company’s failure to disclose staff’s negative recommendation.

In re Columbia Labs., Inc., Sec. Litig., 602 F. App’x 80 (3d Cir. 2015) ............................................. 20
FDA raises issues about discrepancy between foreign and domestic sites and rejects NDA; appellate court affirms dismissal, concluding that plaintiffs failed to adequately plead falsity or scienter.

Ingram v. VIVUS, Inc., 591 Fed. App’x 592 (9th Cir. 2015) .......................................................... 21
FDA denies NDA, citing safety issues; appellate court affirms dismissal, concluding that plaintiffs failed to adequately plead falsity or scienter.

DISTRICT COURT DECISIONS

Motion to Dismiss or for Summary Judgement Granted

FDA notifies company that its product does not qualify for a Section 361 exemption and company halts trial; court dismisses on scienter grounds, finding that facts support inference that the company sincerely believed it qualified for the exemption.

Regulatory and other delays push out enrollment and completion dates for Phase 1 trial; court dismisses, finding that plaintiffs failed to adequately allege falsity where challenged completion date projection was provided by the FDA itself.

Company makes error in reporting Phase 2 results and corrects error three weeks later; court dismisses, finding no indication that company executives had responsibility for detecting or ability to detect error.

Company states that it may be able to file NDA based on favorable Phase 2 trial, but after competitor’s Phase 3 trial fails, is unable to do so; court dismisses, finding that company disclosed the allegedly concealed facts and that company’s opinion statements are inactionable.
Phase 2 trial is successful, but Phase 3 trial, involving sicker patients, is not; court dismisses, finding that company disclosed the allegedly concealed facts.

Patients in Phase 3 trial live longer than expected, but after study is unblinded, company learns that this was not attributable to its drug; court dismisses, finding no indication that company could have known of outcome prior to un-blinding.

FDA denies NDA, after previously having recommended that company conduct an additional trial before submitting; court agrees with plaintiffs that company wrongfully failed to disclose earlier recommendation, but dismisses on scienter grounds, finding that company had no incentive to commit fraud.

In re Amarin Corp. PLC, 2015 WL 3954190 (D.N.J. June 29, 2015) ............................. 25
NDA fails after results of third-party studies call into question company’s underlying hypothesis; court dismisses, rejecting claim that company had a duty to disclose facts relating to FDA’s earlier statements concerning the third-party studies.

BLA fails, for reasons relating to single-blind trial design, among others; court dismisses, finding that information relating to FDA’s preference for double-blind studies was publicly available.

Two months after NDA is filed, FDA requests additional data; court dismisses, finding that defendants failed to establish falsity in connection with company’s description of its products and its successful Phase 3 trials.

FDA rejects NDA for drug previously approved in Europe, citing concerns with cross-study comparisons; court dismisses, finding statements inactionable or protected by statutory safe harbor, and rejecting claim that company had obligation to disclose regulators’ negative interim comments.

Company is subject of government investigation into improper financial ties with physicians writing favorable articles about product; after permitting plaintiffs to proceed on a theory of “scheme” liability, court grants summary judgment on statute of limitations grounds.

Company with FDA-approved drug fails to win approval in the European Union; court dismisses, finding that company had no duty to disclose negative interim comments by a single EU regulator.
**Nasyrova v. Immunomedics, Inc.,** 2015 WL 382846 (D.N.J. Jan. 28, 2015); 2015
WL 4388310 (D.N.J. July 15, 2015)

Company developing cancer drug becomes involved in dispute with licensee, which
ends in termination of license agreement; court dismisses, finding that company had no
duty to disclose interim details concerning the deterioration of
the companies’ relationship.

**Motion to Dismiss or for Summary Judgement Denied**


Government agency partnering with company in developing liver drug halts study
when interim review both establishes efficacy and shows that patients are experiencing
abnormalities; company reports only the first reason; court denies motion to dismiss,
finding that plaintiffs adequately pled that partial disclosure was misleading.

**KB Partners I, L.P. v. Pain Therapeutics, Inc.,** 2015 WL 3794769
(W.D. Tex. June 16, 2015) ................................................................................................... 30

FDA rejects NDA, finding that company demonstrated efficacy but not stability of drug
components; court denies summary judgment motion, finding that because company
chose to disclose the stability issue, it took on a duty to disclose significant related facts.


Remand of **Zak v. Chelsea Therapeutics,** above, related to FDA’s rejection of NDA based
on concern with durability of treatment effect; court denies renewed motion to dismiss,
finding that plaintiffs adequately pled falsity.

**DECISIONS RELATED TO STOCK PROMOTION ACTIVITIES**


Media exposé accuses company of paying for and controlling the content of favorable
press coverage without disclosure; court denies motion to dismiss insofar as plaintiffs
allege “scheme” liability and insofar as plaintiffs challenge the company’s own
statements that it did not manipulate stock price.

**In re Galena Biopharma, Inc. Sec. Litig.,** 2015 WL 4643474
(D. Oregon Aug. 5, 2015) .................................................................................................. 32

Media exposé accuses company of paying for and controlling the content of favorable
press coverage without disclosure; court denies motion to dismiss with respect to
“scheme” liability, with respect to the company’s statements that it did not manipulate
stock price, and with respect to certain of the third-party articles deemed to have been
“made” by the company itself.
Media exposé accuses company of paying for favorable press coverage without disclosure; court grants motion to dismiss, holding that paying for favorable press coverage is not in itself improper, and that the duty to disclose such financial arrangements belongs solely to the publisher, not to the company.

DECISIONS RELATED TO POST-APPROVAL DRUGS OR DEVICES

LAUNCH STAGE

Julianello v. K-V Pharm. Co.,--F.3d--, 2015 WL 4032102 (8th Cir. 2015) ............................... 36
FDA grants company’s request for exclusive sales rights under the Orphan Drug Act but tells company, after it has steeply increased drug price, that it will not enforce those rights; appellate court affirms dismissal on the ground that the company could not have predicted FDA’s action.

REGULATORY ISSUES

Appellate Decision

Fire & Police Pension Ass’n of Colorado v. Abiomed, Inc., 778 F.3d 228 (1st Cir. 2015) ................................................................. 36
Company recalls marketing materials following government investigation into off-label marketing; appellate court affirms dismissal, holding that company was not required to anticipate or agree with the FDA’s later conclusions by pejoratively characterizing its own actions.

District Court Decisions: Motions To Dismiss Granted

FDA sends Warning Letters concerning off-label marketing and rejects NDA seeking expanded label indication; court dismisses, finding that plaintiffs failed to plead materially misleading statements in light of publicly available information about both the company’s marketing efforts and the relevant label indication.

After high rate of adverse events is revealed in trial testing approved drug for new application, FDA terminates trial and suspends marketing of the drug; court dismisses, finding plaintiffs failed to establish that company intended to conceal adverse events.

After conducting inspection, FDA concludes that company’s infusion pump is “adulterated” due to unauthorized changes to the approved model; court dismisses on falsity grounds, largely because FDA did not announce its conclusion about adulteration until after company made challenged statements.

**Singer v. TranS1, Inc., 2015 WL 2341907 (E.D.N.C. May 14, 2015) ......................................... 39**

After adverse changes to government billing code, company advises physicians about ways in which to ensure payment, and government accuses company of billing fraud; court dismisses, finding that company openly revealed conduct at issue.

**District Court Decisions: Motion to Dismiss or for Summary Judgment Denied**


Company accepts rebates from drug manufacturer and government files charges under anti-kickback and false claims statutes; court denies motion to dismiss, finding that, in light of earlier government communications, plaintiffs adequately pled falsity and scienter in connection with company’s legal compliance opinion statement.


After study reveals risk of heart attacks, company withdraws its anti-inflammatory drug Vioxx; court denies summary judgment motion, holding that plaintiffs adequately established falsity and scienter in connection with company’s statements that trial results could be attributed to beneficial aspects of comparator drug rather than to adverse aspects of Vioxx.

**NON-REGULATORY ISSUES**

**Fresno County Employees Retirement Ass’n v. Alphatec Holdings, Inc., 607 F. App’x 694 (9th Cir. June 5, 2015) .............................................................. 41**

Company’s prediction of synergies and sales growth following acquisition are not borne out in the short term; appellate court affirms dismissal on falsity grounds.


After stating that it intends to launch its recently approved drug but is also evaluating strategic alternatives, company fails to find an acquirer and files for bankruptcy; court dismisses on falsity grounds.


After initially denying that its business will suffer when shortage of generic drug equivalent to its own product abates, company announces that it expects revenue to drop; court denies motion to dismiss, finding that plaintiffs adequately pled that earlier positive statements were misleading.
In this section (pages 20-33), we provide detailed summaries of decisions in cases arising from developments at the pre-approval stage. As discussed in the "Trends and Analysis" section above, these decisions reflect several developments favorable to companies that experience setbacks in the processes leading to approval. In evaluating claims that companies failed to disclose risks that a drug would not be approved, courts have carefully reviewed companies’ public statements, academic commentary and the FDA’s own announcement; on such records, courts have often concluded that the supposedly hidden risk was in reality revealed. In several decisions, courts have also rejected investors’ claims that a company is required to disclose interim agency communications. These courts have stressed both that companies have no duty to provide complete disclosures and that because the regulatory process is one of give and take, companies need not report every interim development or concern expressed by a regulator. In still other decisions, courts have applied the Supreme Court’s recent Omnicare ruling—relating to opinion statements—favorably to companies.

The detailed summaries also show, however, that the law has not developed in a uniformly positive way in the pre-approval area. As discussed above, a minority of courts have suggested that once a company begins discussing an issue of concern in the approval process, the company takes on a duty to report all subsequent significant developments related to that issue.
APPELLATE DECISIONS

**Zak v. Chelsea Therapeutics Int’l, Ltd.,** 780 F.3d 597 (4th Cir. 2015), reversing dismissal. NDA

Chelsea Therapeutics was the developer of Northera, a treatment for symptomatic neurogenic hypotension. This condition, which is associated with Parkinson’s disease, causes a patient’s blood pressure to drop dangerously when he or she stands up. The company conducted four separate Phase 3 efficacy studies. One of the four, which was the shortest in duration, met its primary endpoint. The second and third did not, and the fourth was abandoned after a negative interim analysis. A Special Protocol Assessment included the statement that the FDA expected two successful studies to support approval. During a 2010 meeting following the completion of the four trials, the FDA reiterated the point that two successful studies were generally required, but also stated that a single study might be sufficient. The company reported that the meeting had been favorable and that the FDA had agreed to accept its NDA. In a 2012 briefing document, FDA staff questioned whether data from a single short trial adequately established a durable benefit. In the same document, the staff recommended against approval. Before the briefing document became public, the company disclosed the staff’s concerns but not the negative recommendation. The Advisory Committee then parted ways with staff, voting in favor of approval—but at the same time noting issues with durability. The FDA denied the application.

Investors challenged the company’s failure to disclose both (1) the FDA’s warning during the 2010 meeting that a single successful study would generally not be enough, and (2) the negative recommendation in the 2012 staff briefing document. The trial court granted the company’s motion to dismiss, holding that while the company’s statements may have been overly optimistic, plaintiffs had not demonstrated scienter, given the company’s many warnings that the FDA could reject the NDA, as well as the fact that company insiders sold no stock during the relevant period. The Fourth Circuit reversed. The appellate court emphasized that the company did not have a standalone duty to disclose negative interim communications from the FDA, but held that the positive statements the company made about the 2010 meeting were rendered misleading in light of the omitted information, and that the same was true of the company’s characterization of the 2012 staff briefing document. For much the same reason, the court held that plaintiffs had created a strong inference of scienter, and that the trial court had erred in concluding that the apparent absence of insider sales rebutted such an inference. A dissenting judge disagreed, finding that the FDA’s communications gave the company ample reason to believe that the agency would be receptive to its NDA, that the company’s public warnings that the FDA might reject the NDA weighed against an inference of scienter, and that the company’s actions in submitting the NDA without gathering additional data further showed that defendants genuinely believed that data from a single study were sufficient.

**In re Columbia Labs., Inc., Sec. Litig,** 602 F. App’x 80 (3d Cir. 2015), affirming dismissal.

Phase 3/NDA. (District court decision is at 2013 WL 5719500.)

Columbia Laboratories was the developer of Prochieve, a drug aimed at reducing the risk of preterm birth. An initial Phase 3 trial failed to show a statistically significant reduction of preterm births, but suggested that the drug was effective in reducing preterm births for women with short cervixes. The FDA told the company that it needed to perform a second study, involving only women with short cervixes, to support approval. The company did so. Overall, the second study showed a statistically significant reduction of preterm births at a 95% confidence level but not at a 99% confidence level. When only United States sites were considered—and the results from sites in Belarus and South Africa were excluded—there was no statistically significant reduction at all. The FDA issued a letter raising concerns about the discrepancy in results from foreign and domestic sites, identifying this as a “potential review issue.” Six months later, the Advisory Panel reviewing the drug voted 13-4 against approval, and the FDA followed the panel’s recommendation.

Investors sued, alleging that the company knew from previous discussions with the FDA that a 99% as opposed to a 95% confidence interval would be applied, and that in light of that fact, the company’s statements characterizing the second study as a success were false and
misleading. Plaintiffs also alleged that the company knew that the discrepancy between domestic and foreign sites’ performance was problematic, but failed to disclose the FDA’s stated concerns on the issue. The district court granted the company’s motion to dismiss and the Third Circuit affirmed. The appellate court concluded that the FDA had neither definitively told the company that a 99% confidence interval would be applied, nor suggested that results had to be statistically significant on a country-by-country basis. The appellate court also found the company’s actions were inconsistent with scienter: the company published the trial results in a professional journal and continued to invest in the product, neither of which it would have done if it had believed the drug would be rejected. The divided nature of the Advisory Panel’s vote further undercut an inference of scienter.

Ingram v. VIVUS, Inc., 591 Fed. App’x 592 (9th Cir. 2015), affirming dismissal.
Phase 3/NDA. (District court decision is at 2012 WL 4477647.)

VIVUS developed Qsymia, a weight control medication. In late 2009, the company reported favorable results in multiple Phase 3 trials, several of which had been conducted under Special Protocol Assessments. When making this and other announcements, the company consistently cautioned investors that FDA approval could not be guaranteed. Information about Qsymia’s possible safety risks was also publicly available, both through published trial data and through information relating to the drug’s two components, which had been approved individually and marketed for decades. In July 2010, two days before the scheduled Advisory Committee meeting, the FDA released its briefing document, and the company’s stock price rose. During the Advisory Committee’s public hearing, reviewers agreed that VIVUS had successfully established Qsymia’s efficacy; some experts, however, raised questions about long-term safety. The Advisory Committee then voted 10-6 against approval, and the company’s stock price fell. (The FDA approved the company’s Qsymia application two years later, and the company filed for approval in the European Union. More recent shareholder litigation related to the latter event is discussed on page 28).

Investors sued, arguing that the company had failed to disclose safety risks apparent from the clinical trial data and had overstated the likelihood that Qsymia would be approved. The district court granted the company’s motion to dismiss. The court found that the company in fact disclosed potential safety risks, and that the FDA’s subsequent conclusion that additional safety data were needed did not render the company’s statements false or misleading when made. The court emphasized the Advisory Committee’s divided vote and favorable finding on efficacy, concluding that VIVUS could not have predicted the outcome of the approval process when it made the challenged statements. The court also relied on the fact that VIVUS’ stock price rose following the release of the FDA’s briefing document. This showed that the only negative information that could have triggered the stock price decline two days later was the outcome of the Advisory Committee vote—which the company could not have predicted. The Ninth Circuit affirmed in a very short memorandum. The appellate court emphasized plaintiffs’ failure to identify any affirmatively false statement and further concluded that no challenged statement was rendered misleading by virtue of omission, as the allegedly omitted information was not material. The Ninth Circuit also agreed with the district court that plaintiffs had not created a compelling inference of scienter.
DISTRICT COURT DECISIONS

Decisions
Development
Stage

Motions to Dismiss or for Summary Judgment Granted


OvaScience developed a fertility treatment called Augment. The company began conducting studies of the treatment without first completing an Investigational New Drug application, believing it was entitled to do so under Section 361 (which exempts certain human cellular and tissue-based products from certain regulations otherwise applicable to biologics). In its February 2013 Annual Report, the company stated that it believed Augment qualified for the exemption, among other reasons, because the treatment involved only minimal manipulation of cells (a requirement under Section 361). The company also noted that the FDA could disagree with its conclusion on minimal manipulation. In April 2013, the company received an informal letter in which the FDA stated that, based on limited information, the Augment process appeared to involve more than minimal manipulation. In two quarterly reports filed in May 2013 and August 2013, the company again stated that it believed Augment was entitled to the Section 361 exemption but that the FDA could disagree. The company did not disclose the content of the April 2013 letter in the quarterly reports or otherwise. In September 2013, the company received another letter from the FDA, this time stating definitively that Augment did not come within Section 361. The company announced that it was suspending its Augment studies and its stock price plummeted.

Investors sued, challenging the company’s statements in the Annual Report and two quarterly reports, that it “believed” Augment was exempt under Section 361. The court rejected the challenge to the Annual Report on chronological grounds: that report was issued before the company received the FDA’s initial letter setting forth the tentative conclusion that Augment was not exempt. The court reached the opposite conclusion with respect to the two quarterly reports, which were issued after the company received the letter. The court agreed with plaintiffs that it was misleading for the company to continue to say that it “believed” that Augment was exempt without also disclosing that the FDA had tentatively reached the opposite conclusion—and that to say that the FDA “could” disagree did not solve the problem. Nevertheless, the court dismissed the complaint in its entirety, finding that plaintiffs had fallen short on scienter. The facts pled gave rise to an inference that the company continued to honestly believe that Augment was exempt, even after receiving the FDA’s first letter; among other things, the company disclosed the existence of the letter (though not its precise contents).


InVivo developed the biopolymer Neuro-Spinal Scaffold for treatment of spinal cord injuries. The FDA designated the product as a Humanitarian Use Device and approved an Investigational Device Exemption permitting the company to begin a five-patient pilot study. The company initially predicted that it could complete the study in 15 months—by the end of 2014. As a result of regulatory and other delays, however, the first patient was not enrolled until October 2014, with completion not expected until at least 21 months thereafter. The company’s stock price dropped following announcement of the delays.

Investors sued, contending that InVivo could not possibly have completed the study within the projected 15-month timeframe, and that the company had concealed aspects of the FDA’s approval of the Investigational Device Exemption that would have made this clear to investors. The court disagreed and granted the company’s motion to dismiss. The court found that the 15-month timeframe came from the FDA itself. As to the exemption, while the FDA required InVivo to provide additional information and take certain specified actions in order to ensure eligibility, the FDA did not suggest that the company would be unable to commence the trial before doing so.

Vertex was the developer of a new two-drug combination for the treatment of cystic fibrosis. On May 7, 2012, the company announced favorable results of a Phase 2 trial: 46% of patients experienced an “absolute” improvement of five percentage points and 30% of patients experienced an “absolute” improvement of 10 percentage points. Company executives characterized the results as “really fantastic,” and stated that they had “never seen anything like this.” Three weeks later, on May 29, 2012, the company reported that it had made an error in its earlier announcement, and that the previously released data were in fact relative rather than absolute. This rendered the findings significantly less dramatic, and the company’s stock price fell.

Investors sued, challenging the company’s May 7, 2012 announcement. In contrast with the situation in most cases, the company in this case **conceded** that its announcement had been materially false or misleading. The critical issue was whether the company and its executives **knew** between May 7, 2012 and May 29, 2012 that the results they had reported contained an error. Plaintiffs argued that it should have been clear that the results were too good to be true, but that rather than investigating further, the company had turned a blind eye. The court disagreed, finding no facts suggesting that the individual defendants had either the responsibility or the ability to perform the calculations that would have exposed the error. The company may have been negligent, the court said, but that is not a sufficient basis for a fraud claim. The court also found that the executives’ stock sales during the three-week period at issue made the case closer, but that even there, plaintiffs’ allegations fell short: insider sales during a period of rapid stock price increase are to be expected, and defendants had offered plausible benign reasons for the timing of their sales (trading plans and an imminent departure). **Note:** The facts underlying this litigation also gave rise to an earlier lawsuit, which was dismissed in a decision we discussed in our 2014 review, *City of Bristol Pension Fund v. Vertex Pharmaceuticals, Inc.*, 12 F. Supp. 2d 225 (D. Mass. 2014). The lead plaintiff in the *City of Bristol* action bought stock only after the May 29, 2012 corrective disclosure, and hence had no standing to assert most of the claims alleged.


Sarepta Therapeutics developed Eteplirsen, a treatment for Duchenne Muscular Dystrophy. The cells of patients suffering from this disease are unable to produce dystrophin, a protein necessary for muscle function. Sarepta’s Phase 2 trials were designed to test two hypotheses: that the drug would enable patients’ cells to produce a modified form of dystrophin (tested in the trial via muscle biopsies), and that this dystrophin would improve muscle function (tested in the trial by patients’ performance on a six-minute walk test). The trial successfully demonstrated that the first hypothesis was correct. With respect to the second, the trial did not show a statistically significant increase in muscle function if data from all patients were considered (that is, the intent-to-treat patient population). But if data from those patients who had dropped out of the study were excluded (leaving a modified intent-to-treat population), the results were statistically significant. The company made positive statements about the trial results, and after meeting with the FDA, made further optimistic statements about the possibility of submitting an NDA based solely on Phase 2 results, without needing to proceed to Phase 3. Following the failure of a competitor’s Phase 3 trials, however, the FDA told the company that filing an NDA without additional data would be premature. Share prices dropped steeply.

Investors sued, claiming that the company had misleadingly characterized its trial results by referring to the modified intent-to-treat population, thereby avoiding the unfavorable results that appeared when the entire intent-to-treat population was analyzed. The court rejected the claim, finding that the company had adequately disclosed to investors and the scientific community the results corresponding to both the intent-to-treat and the modified intent-to-treat populations. Plaintiffs also claimed that the company had failed to disclose the FDA’s concerns about an NDA based on the Phase 2 data. The court rejected this claim too, finding that the company had adequately disclosed that the FDA had raised questions relevant to the issue, and that the company had no duty to “delve into” further detail. Finally, the court rejected plaintiffs’
challenge to the company’s statements distinguishing its competitors’ failed Phase 3 trials from its own situation. With respect to all three of the subjects at issue, the court characterized the challenged statements as consisting at least in part of defendants’ opinions, and found, applying Omnicare, that plaintiffs had failed to plead facts showing either that defendants did not subjectively hold the challenged opinions or that defendants had suppressed material facts relating to the bases for those opinions.


Prosensa was the developer of Drisapersen, a treatment for Duchenne Muscular Dystrophy, which causes progressive muscle loss in boys and young men. In 2010, the company initiated Phase 2 and Phase 3 studies. In both, the primary endpoint related to the distance patients could walk in six minutes. In April 2013, the company announced favorable results from the Phase 2 trial, and in June 2013, the FDA granted breakthrough therapy status to the drug. During this period, the company had been planning its IPO, which occurred in July 2013. In September 2013, the company learned that the Phase 3 trial had not been a success, and announced that the drug had failed to meet the primary endpoint. The company’s stock price fell. In response to a question as to why the Phase 3 trial had failed where the Phase 2 trial had succeeded, the company noted that the population in the Phase 3 trial had included older and sicker patients than the population in the Phase 2 trial.

Investors sued, alleging that the company had misleadingly omitted from its IPO Registration Statement the information that the Phase 3 trials included older and sicker patients than the Phase 2 trials, as well as the fact that the Phase 3 trials involved more countries and more sites than the Phase 2 trials. (Plaintiffs asserted claims solely under the 1933 Act.) The court rejected plaintiffs’ claims, finding that the company had not concealed, but in fact had disclosed, the allegedly omitted facts. The court also rejected plaintiffs’ argument that the information at issue was “buried,” and that the company should have highlighted the risk that differences between Phase 2 and Phase 3 would result in the failure of Phase 3. Again, the court found that the information was sufficiently disclosed, and that the company had explicitly noted that Phase 3 trials are more extensive than Phase 2 trials and thus involve more risk. Finally, the court rejected plaintiffs’ suggestion that the company should have known that the Phase 3 trials would fail given the relaxed enrollment criteria, finding this to be an impermissible critique of trial design.


Vical was the developer of Allovectin, a treatment for advanced cases of melanoma. After successful Phase 2 trials, the company and the FDA developed a Phase 3 Special Protocol Assessment pursuant to which the primary endpoint was a response rate 10% greater than the response rate of patients on the control arm, and the secondary endpoint was overall survival. While the Phase 3 trials were ongoing, the company repeatedly revised the completion date for the trial, as patients were living longer than had been expected. Analysts questioned whether this might be the result not of Allovectin, but instead of other melanoma drugs approved during the course of the trial and available to patients on both the control and the treatment arms. In response, the company noted that those new drugs were not available until many months into the trial and that the likelihood that the new drugs were affecting patients’ survival was low. At the same time, however, the company stated that the impact of the new drugs could not be measured until the study was un-blinded. When the study was completed, it turned out that substantial percentages of patients on both arms had taken the new drugs, and that the overall survival rate of patients taking Allovectin was significantly lower than that of patients on the control arm. The company’s stock price fell on the announcement of those results.

Investors sued, alleging that the company knew that patients were taking the newly approved drugs and that this was skewing results. The court rejected that claim. There was no evidence that the company knew or could have known about patients’ use of the new drugs, and defendants straightforwardly outlined the reasons for their belief that the new drugs were not having an impact on the trial. The fact that this belief turned out to be wrong did not mean that
defendants had committed fraud. The court also rejected plaintiffs’ challenge to the company’s statements that it was preparing for the commercial launch of Allovectin. Although plaintiffs alleged that the company had taken only minimal steps to do so, this was not inconsistent with the challenged statements.


Aveo was the developer of Tivozanib, a treatment for advanced renal cell carcinoma, which is a form of kidney cancer. Aveo conducted Phase 3 trials with a primary endpoint of statistically significant improvement in progression-free survival and a secondary endpoint of overall survival. In May 2012, the company reported preliminary results, including an overall survival rate for patients on the drug that was worse than the survival rate for patients on the control. The company also met with the FDA, which expressed concern about the overall survival trend and recommended that the company complete a second trial before submitting an NDA. Over the next several months, the company made positive statements about approval and did not disclose the FDA’s concerns or recommendation that another trial be conducted. In August 2012, the company referred to the FDA’s concerns with overall survival but did not disclose its recommendation for an additional trial. Elsewhere, the company stated publicly that the safety of its drug was superior to the safety of the control. In April 2013, after the company had submitted its NDA, the advisory committee released a briefing document that revealed, among other things, that the FDA had previously recommended that the company perform another trial before submitting the NDA. Shortly thereafter, the FDA rejected the NDA.

Investors sued, claiming that the company had a duty to disclose the content of the May 2012 meeting with the FDA, and that it breached that duty both by failing to discuss the meeting at all until August 2012 and by disclosing only certain aspects of the meeting at that time. The court agreed that plaintiffs had identified actionable omissions. Although the court recognized that defendants had no standalone duty to disclose the content of the meeting, the court held that once a company makes a disclosure, “there is a duty to make it complete and accurate.” The company breached that duty, the court held, by failing to adequately disclose the FDA’s recommendation that another trial be performed. The court further held, under _Matrixx_, that the company’s statements about safety were false or misleading. Finally, the court agreed with plaintiffs that the company had misleadingly omitted information about the conduct of the trials, which allegedly departed in certain ways from the trial protocol. Ultimately, however, the court granted the company’s motion to dismiss, finding that plaintiffs had failed to plead scienter. The individual defendants did not sell stock during the relevant period, and one of them purchased a substantial amount.

_In re Amarin Corp. PLC_, 2015 WL 3954190 (D.N.J. June 29, 2015), motion to dismiss granted without prejudice. Phase 3/NDA.

Amarin developed Vascepa to treat patients with high and very high triglycerides. The FDA approved the drug for a limited indication in 2012. The company also attempted to obtain approval for a broader indication, in which the estimated patient population exceeded 30 million. In connection with that effort, the company in 2009-2010 conducted the ANCHOR trial, a Phase 3 study intended to demonstrate that Vascepa lowered triglyceride levels for patients already taking statins. During a 2008 meeting with the FDA preceding the trial, the agency called the company’s attention to two ongoing long-term studies, conducted by other developers, testing the hypothesis that reducing triglycerides would also reduce major adverse cardiovascular events. The FDA told Amarin that the long-term studies would yield important information, and that if those trials were unsuccessful, this would reduce the likelihood that Vascepa would be approved for the desired indication based solely on ANCHOR. The long-term studies turned out to be unsuccessful, while the ANCHOR trial succeeded. After reviewing Amarin’s NDA, FDA staff issued a briefing document calling into question whether Vascepa offered a meaningful clinical benefit. Five days later, the Advisory Committee reviewing the NDA voted nine to two against recommending approval. The company’s stock price fell after the publication of the briefing document and fell further after the Advisory Committee vote.
Investors sued, alleging that Amarin breached a duty to disclose the details of the 2008 meeting. The court rejected the claim, holding that the company had no duty to provide investors with complete information; its duty was simply to refrain from making affirmatively misleading statements. The company had not made such statements; it had merely said, correctly, that the ANCHOR application process could continue in the absence of successful long-term studies. The court also drew on a line of cases holding that drug developers are not obligated to report FDA staffers’ questions as they arise.


Genzyme, which was acquired by Sanofi, developed Lemtrada, a multiple sclerosis drug. In 2011, the company completed Phase 3 trials, which yielded favorable results. Because Lemtrada is administered intravenously and the drug on the control arm was not, the Phase 3 trials were single-blinded rather than double-blinded: Patients knew which treatment they had received, although investigators did not. In meetings held before and during the trials, the FDA expressed concern over this aspect of the trial design, and suggested that the treatment effect would have to be large to justify approval. The company submitted a Biologics License Application in June 2012. The FDA responded with a “Refuse to File” letter in August 2012; in announcing this development, the company explained that the FDA had merely asked it to modify its presentation of certain data. The company continued to make optimistic statements about approval thereafter. In November 2013, the Advisory Committee recommended against approval, citing issues with trial design among others. In December 2013, the FDA rejected the company’s application and the company’s stock price fell. (Over the next year, the company continued to work with the FDA, submitting a revised application in May 2014 and ultimately winning approval of Lemtrada for certain MS patients in November 2014. More than 30 other countries had also approved the drug by that time.)

Investors sued, challenging the company’s optimistic statements about FDA approval. The court rejected that challenge, finding that the company’s representations were statements of opinion, and as such were actionable only if they were false and if defendants did not actually hold the opinions they articulated. Plaintiffs had not established either prong; among other things, defendants’ business decisions, including expenditures on the trials, showed that they believed in Lemtrada. The court also found that certain challenged statements concerned future events and consequently came within the PSLRA’s safe harbors. For similar reasons, the court rejected plaintiffs’ challenges to the company’s statements that it was preparing for a Lemtrada launch. As for plaintiffs’ claim that the company misleadingly failed to disclose the FDA’s concerns about the single-blind trial design, the court found that publicly available information put investors on notice that the FDA prefers double-blind studies. Finally, the court rejected plaintiffs’ claim that the company concealed issues related to Lemtrada’s side effects, finding that the company had adequately disclosed the information in articles published in medical journals.

**Note:** The Second Circuit affirmed dismissal in *Tongue v. Sanofi*,—2d Cir.—, 2016 WL 851797 (2d Cir. March 4, 2016), the first appellate decision applying *Omnicare*.


AcelRX developed Zalviso, an opioid pain medication that could be taken sublingually, *i.e.*, under the tongue. Zalviso was designed to improve on IV opioids in several ways, including by eliminating medication “gaps” associated with IV administration (a feature the company discussed in public filings). The company reported favorable Phase 3 results: Zalviso had achieved its primary efficacy endpoints in all Phase 3 trials. The company submitted an NDA, and while that was pending, continued to work on designing a modified delivery device that would reduce the rate of certain errors in administration (called optical system errors). Two months after receiving the NDA, the FDA sent the company a Complete Response Letter in which it requested additional information, including data showing a reduction in the incidence of optical system errors. After the company reported the contents of the letter, its stock price dropped sharply.
Investors sued, challenging the company’s favorable announcement of Phase 3 trial results. The court rejected the challenge, finding nothing false or misleading in the company’s report. Plaintiffs also challenged AcelRx’s statements that Zalviso eliminated the risk of IV-related “gaps.” The court dismissed that claim, too. Contrary to what plaintiffs alleged, AcelRx did not say that Zalviso eliminated all gaps; it said only that the drug eliminated IV-related gaps—which was true. Finally, the Court rejected plaintiffs’ attack on the company’s risk disclosures. Plaintiffs’ theory was that the company misleadingly failed to discuss the fact that it was designing a modified system to address optical system errors. In a thorough analysis of the issue, the court stressed that, under Supreme Court and Ninth Circuit precedent, securities defendants have no obligation to provide complete information, and that AcelRx was accordingly not required to disclose improvements it was making to its product.

In re EDAP TMS S.A. Sec. Litig., 2015 WL 5326166 (S.D.N.Y. Sept. 14, 2015), motion to dismiss granted. NDA.

EDAP, a French company, developed the medical device Ablatherm, a form of high-intensity ultrasound technology designed to treat prostate cancer. Ablatherm had been approved in Europe but not in the United States. The company initiated a study comparing the effects of Ablatherm with those of cryotherapy but had difficulty enrolling a sufficient number of patients for the cryotherapy group, which rendered the study’s results less meaningful than anticipated. Notwithstanding the limited enrollment, the company applied for approval on the basis of that study. After the FDA responded with a Major Deficiency Letter, the company submitted an amendment to the application in which it included comparisons with European data. The Advisory Committee evaluating the drug raised concerns about the significance of the cross-study comparisons, among other things, and the FDA subsequently denied the application on the ground that the company had failed to demonstrate efficacy.

Investors sued, challenging the company’s optimistic comments about approval and about the sufficiency of the efficacy data. The court rejected both challenges. The court found that the company’s comments on developments in the approval process—in which various events were characterized as “milestones,” or “progress”—were too vague to be actionable. Several of the statements also fell within the PSLRA’s safe harbor for forward-looking statements. Meanwhile, statements relating to the sufficiency of the efficacy data were inactionable expressions of opinion, or had not been shown to have been false or misleading; plaintiffs had simply taken the reasons the FDA ultimately gave for rejecting the application and said that it was a foregone conclusion all along that the application would be denied. Finally, the court rejected plaintiffs’ claim that the company fraudulently failed to disclose the concerns raised in the FDA’s Major Deficiency Letter, and in particular the concern that the primary endpoint in the study, metastasis-free survival, might not be appropriate. The court cited the well-established rule that there is no duty to disclose interim communications by regulators, and further found that expressions of concern in the Deficiency Letter were less definitive than plaintiffs had claimed.


Medtronic developed and marketed INFUSE, a bone-growth product approved in 2002. In 2011, reports began to appear, both in scientific journals and in the mainstream media, accusing the company of improper financial ties with the physician consultants who published favorable articles about the studies underlying FDA approval. The Senate investigated, and ultimately concluded that the company “was heavily involved in drafting, editing and shaping the content of medical journal articles authored by its physician consultants who received significant amounts of money through royalties and consultant fees.” Medtronic also developed and sought approval for AMPLIFY, another bone growth product. In January 2011, the company received an initial non-approval letter from the FDA, but did not disclose the letter until several months later, when it had received a second non-approval letter.

Investors sued, alleging false and misleading statements in connection with both products. The company moved to dismiss, and in a 2014 ruling on which we reported last year, the court held that plaintiffs had failed to identify any statements rendered false or misleading by virtue of the alleged wrongdoing associated with INFUSE. At the same time, however, the court found
that plaintiffs had sufficiently alleged a claim under a theory of “scheme” liability, i.e., liability based on allegedly manipulative conduct rather than solely on allegedly false statements. As for AMPLIFY, while the court agreed with the company that it had no independent duty to disclose the non-approval letter, the court also agreed with plaintiffs that the omission became actionable when Medtronic’s CEO stated, in response to an analyst’s question, that the company was “continuing to work with the FDA to figure out kind of where they are on this.” The court was not persuaded by the company’s argument that the non-approval notice was “not an outright rejection,” finding the communication sufficiently negative that investors would have considered it significant.

In 2015, Medtronic moved for summary judgment on statute of limitations grounds, and the court granted the motion. With respect to AMPLIFY, the two-year limitations period began to run when the company disclosed the content of the second non-approval letter. With respect to INFUSE, the court rejected plaintiffs’ argument that the two-year period began to run only when the alleged misconduct was analyzed in an issue of Spine Journal devoted exclusively to INFUSE. The court held that other publications and litigation provided plaintiffs with information sufficient to state a claim well before that date, and that plaintiffs then waited more than two years before filing suit.

**Jasin v. VIVUS, Inc.,** 2015 WL 3809357 (N.D. Cal. June 18, 2015), motion to dismiss granted without prejudice. Marketing Authorization Application (European equivalent of NDA). VIVUS developed Qsymia, a weight control medication. The FDA approved Qsymia in July 2012 and the company began marketing the product in the United States. The company also had a Marketing Authorization Application pending with the European Medicines Agency, for approval of the same drug in the European Union. During a September 2011 meeting with the committee reviewing the MAA, one official (called a co-rapporteur) told the company that it was his position that the product could not be approved without an additional cardiovascular safety study. The company characterized the meeting as “productive,” but also disclosed publicly that the committee had raised a series of issues, including issues related to cardiovascular safety. VIVUS further cautioned investors that EMA approval could not be assured. In September 2012, the EMA notified the company that approval was unlikely. VIVUS’ stock price fell modestly after it announced this news.

Individual investors sued, asserting that VIVUS owed and breached a duty to inform the market of the co-rapporteur’s negative comment at the September 2011 meeting. The court dismissed that claim. The court noted that companies have no obligation to report all interim communications with regulators, and that the allegedly omitted information concerned the position only of a single regulator, not of the committee or agency as a whole. The court also relied on the fact that the company had warned investors that EMA approval could not be guaranteed.


Immunomedics focuses on developing antibody-based products to be used in the treatment of cancer and autoimmune diseases, among other applications. In 2008, the company entered into a licensing and collaboration agreement with Takeda-Nycomed. Under the terms of this agreement, Immunomedics granted Takeda-Nycomed an exclusive worldwide license for a therapeutic compound called Veltuzumab, one of the company’s key products. Takeda-Nycomed was to complete the clinical development, manufacturing, and commercialization of the product for treatment of non-cancer indications. Under the agreement, Takeda-Nycomed would make certain milestone and royalties-based payments to Immunomedics. In May 2013, Immunomedics provided Takeda-Nycomed with a formal notification that because of delays in the development of Veltuzumab, it considered Takeda-Nycomed to be in material breach of the agreement. In September 2013, Immunomedics instituted arbitration proceedings against Takeda-Nycomed, and Takeda-Nycomed issued a notice that it considered the agreement terminated. Subsequently, Immunomedics disclosed in its public filings that the agreement with Takeda-Nycomed had been terminated, and that arbitration proceedings had been instituted. Upon this news, share prices dropped.
Investors sued, claiming that Immunomedics improperly withheld information regarding the precarious state of its relationship with Takeda-Nycomed. Investors alleged that certain positive statements about Veltuzumab’s development and commercial potential were misleading in light of the company’s later revelation that Takeda-Nycomed was in breach of the parties’ agreement regarding the development of Veltuzumab. The court rejected plaintiffs’ claims, finding that the company did not have a duty to advise the public of its efforts to address Takeda-Nycomed’s performance or the existence of uncertainty in this relationship. The court noted that Immunomedics was not alleged to have made explicit statements regarding the durability of the contract with Takeda-Nycomed, guaranteeing future revenues, or otherwise assuring results about Veltuzumab; without such a prior statement, Immunomedics did not have a duty to disclose. The court also noted that in the only statement characterized by investors as false or misleading due to the failure to disclose the May 2013 notice of breach, the company reported that Takeda-Nycomed had decided to concentrate on development of Veltuzumab for a different indication than previously planned. The court rejected plaintiffs’ assertion that this statement falsely suggested that the company’s agreement with Takeda-Nycomed was proceeding without incident.

Motions to Dismiss or for Summary Judgment Denied


Intercept developed obeticholic acid, a treatment for liver ailments. Intercept entered into a cooperative research and development agreement with the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), an agency at the National Institutes of Health. Under that agreement, NIDDK conducted a blinded, multi-center study of the drug. On January 6, 2014, NIDDK advised the company that the trial was being stopped early for two reasons, one positive and one negative. On the positive side, NIDDK had found, under the terms of a planned interim assessment, that the trial had demonstrated the efficacy of the obeticholic acid. On the negative side, NIDDK had also found significant lipid abnormalities (that is, changes in cholesterol levels) in patients who received the drug. NIDDK asked the company to provide a copy of its statement announcing this news before releasing it. The company accordingly forwarded the agency a draft press release, in which it disclosed only the positive reason for stopping the study (and flagged that fact for the agency). NIDDK responded that the decision as to whether to disclose the negative reason too had to be made by the company, but noted that while the positive efficacy finding was the “primary” reason to halt the study, the lipid abnormalities were also “significant.” On January 9, 2014, which was the last day on which Intercept could report the news under SEC rules, the company issued a press release disclosing only the favorable reason for halting the study.

By January 10, 2014, the company’s stock price had risen from approximately $70 to nearly $500. Later on January 10, NIDDK issued its own press release, disclosing the lipid abnormalities as well as the positive efficacy findings. Over the next several days, the stock price dropped to $190.

Investors sued, challenging the company’s disclosure of only the positive and not the negative reasons for halting the study. The class period was unusually short: from January 9 to January 10, 2014. The court denied the company’s motion to dismiss, concluding that plaintiffs had sufficiently pled both falsity and scienter. The court rejected the company’s argument that it reasonably believed the lipid finding was scientifically insignificant, and that it needed to analyze the underlying data before reporting on the issue. That argument, the court found, was inconsistent with NIDDK’s explicit finding that the lipid abnormalities were “significant,” as well as with the communications between NIDDK and the company. The court also rejected the argument that the company had previously disclosed the lipid issue in a prominent medical journal; the court found that the disclosure there related to an earlier, much smaller study, and that the existence of lipid abnormalities in the later study could not be inferred from the disclosures about the earlier study.

Pain Therapeutics was the developer of Remoxy, a controlled-release form of the painkiller oxycodone designed to be resistant to abuse. In 2008, the FDA rejected the company’s original NDA, explaining in a Complete Response Letter that the drug was insufficiently stable—its active ingredient was not released consistently from one batch of the drug to the next (dissolution variability). In announcing the rejection of its NDA, the company stated that the FDA had not required additional efficacy studies but had instead requested “additional non-clinical data.” The company’s partner, King Pharmaceuticals, then took on the responsibility of preparing a second NDA. In 2009, King presented a new dissolution method, which the FDA found reasonable but cautioned would be subject to further testing. In March 2010, King and Pain Therapeutics became aware of a flaw in the new method; they addressed this by introducing a “curing” period, in which the drug would be held for a time before release. King submitted a new NDA in December 2010. In March 2011, the FDA responded with a Discipline Review Letter, in which it criticized the use of the curing period. In public statements thereafter, the company did not disclose the content of the Discipline Review Letter, but instead referred only to the stability issues the FDA had raised years before, in connection with the company’s original 2008 NDA. In June 2011, the FDA issued a Complete Response Letter rejecting the second NDA.

Investors sued, alleging that the company had misleadingly omitted information about the stability problem. The court, after earlier having denied the company’s motion to dismiss, also denied in part its motion for summary judgment. The court rejected plaintiffs’ claims that the company knew that the FDA would reject the second-generation dissolution method developed by King. Nevertheless, the court held that plaintiffs had presented a triable issue of fact on their omission theory. Once defendants chose to discuss the stability issue in March 2011, the court held, defendants took on a duty to “disclose significant related facts.” Those facts included the flaw in the second-generation dissolution method revealed to the company in March 2010, as well as the concerns the FDA articulated in its March 2011 Discipline Review Letter. With respect to scienter, the court’s analysis was similar: if plaintiffs could show that defendants were aware of ongoing stability problems at the time of the challenged statements, then a reasonable juror could conclude that defendants were aware of the danger that investors would be deceived if those problems were not disclosed.

Note: This litigation developed in an unusual way following the court’s denial of defendant’s summary judgment motion. The parties proceeded to trial—but on the morning of jury selection, the court granted the company’s motion for a continuance, based on issues concerning plaintiffs’ counsel’s communications with absent class members. The court subsequently vacated most of its pretrial rulings, including the decision cited above. Plaintiffs then filed an amended complaint, defendants moved to dismiss it, and the court denied the motion for largely the reasons outlined above. K.B. Partners , I, L.P. v. Pain Therapeutics, Inc., 2015 WL7760201 (Dec. 1, 2015).

McIntyre v. Pedder, 2015 WL 5039431 (W.D.N.C. Aug. 26, 2015), motion to dismiss denied. NDA.

This decision follows from the Fourth Circuit’s reversal and remand in Chelsea Therapeutics, discussed on page 20. To recap the facts: Chelsea developed Northera, an orphan drug for the treatment of hypotension. The company conducted four Phase 3 trials. Only one of the four was successful, and that one had a substantially shorter treatment period than the other three. The company submitted an NDA based on data from the successful trial. At various points in the process, the FDA raised concerns about the durability of the drug’s effects, as well as the sufficiency of an application based largely on a single successful trial. Following receipt of the NDA, FDA staff recommended against approval, the Advisory Committee voted in favor of approval, and the agency denied the application. (Two years later, following the submission of a new NDA, the FDA approved the drug.)

The Fourth Circuit reversed the district court’s earlier dismissal of the action on scienter grounds. On remand, the company argued that plaintiffs had failed to identify a false or misleading statement. Plaintiffs conceded that the challenged statements—largely relating to
the company’s optimism about approval—were literally true, but argued that they were rendered misleading by virtue of the company’s omission of information suggesting that the FDA would not approve the drug based on a single successful trial. Without a great deal of analysis, the district court concluded that the question of whether plaintiffs had established a misleading omission was better resolved on summary judgment. Given the Fourth Circuit’s ruling on scienter, the district court may have felt that it had little alternative. The court also took a notably more cautious approach than most to evidentiary issues, and declined to consider FDA documents the company had submitted to support its arguments. Here again, the court may have felt that it was constrained by the appellate decision, in which the Fourth Circuit held that the district court had erred in taking notice of SEC documents showing an absence of insider stock sales during the relevant period. Finally, the court cautioned plaintiffs that the company had strong defenses, and encouraged the parties to settle the litigation.
DECISIONS RELATED TO STOCK PROMOTION ACTIVITIES


CytRx developed oncology drugs, the leading candidate among which was Aldoxorubicin. The company hired a marketing firm, The DreamTeam Group, which oversaw the publication of 14 promotional articles published between September 2013 and February 2014. CytRx’s stock price rose significantly during this period, and the company issued a secondary public offering in January 2014. In February and March 2014, media pieces appeared in which both CytRx and Galena, a former CytRx subsidiary, were accused of improperly paying for stock promotion, of controlling the content of articles ostensibly written by independent third parties, and of failing to disclose their relationships with the promoters and authors. CytRx and its executives were also said to have sold stock while its price was artificially inflated by the stock promotion scheme. CytRx’s stock price fell after the publication of the media exposés.

Investors sued the company and its officers and directors, as well as one of the authors of the favorable articles. In connection with the public offering, plaintiffs brought claims under Sections 11 and 12(a)(2) of the 1933 Act against both the company and the underwriters of the offering, alleging that the offering documents contained false or misleading statements. As to Section 10(b), plaintiffs challenged statements made in the articles commissioned by the DreamTeam; plaintiffs also challenged statements the company made in its own name. The court dismissed the claims in which plaintiffs sought to hold the company liable for statements made in the articles, finding that plaintiffs had failed to show that the company “made” or controlled the content of those statements. On the other hand, the court denied the company’s motion to dismiss with respect to most of the company’s own statements, including (1) the statement in an underwriting agreement that the company had not manipulated its stock price, and (2) discussions of risk in SEC filings that did not include risks related to stock promotion. The court also allowed plaintiffs to move forward with a claim for “scheme” liability, finding that defendants had engaged in allegedly deceptive conduct beyond the making of false or misleading statements—conduct that included the hiring of the investor relations firm and the payment of writers. Finally, the court denied the company’s and underwriters’ motions as to the Section 11 claim but granted the motion with respect to the Section 12(a)(2) claims on standing and other statutory grounds.


Galena was spun off from CytRx Corporation (see preceding blurb) in 2007. Like CytRx, Galena developed oncology drugs, including NeuVaxTM, for the treatment of breast cancer. Galena also sold a form of fentanyl. The company hired two investor relations firms, The DreamTeam Group and Lidingo; between August 2013 and February 2014, those firms placed numerous favorable articles about Galena and its stock on investment websites. The company’s stock price rose during this period, and six of the company’s officers and directors sold significant portions of their holdings between January and February of 2014. In February and March of 2014, media pieces began to appear in which the company was accused of carrying out a misleading brand-awareness campaign by, among other things, paying writers to promote its stock without disclosing that payment and exercising control over the content of articles written by purportedly independent third parties. The company’s stock price dropped following the media exposés. The SEC also commenced an investigation. In August 2014, the company’s CEO resigned.

Investors sued Galena, various of its officers and directors, DreamTeam and its principal, Lidingo and its principal, and one of the writers of the articles at issue. All defendants moved to dismiss and the court largely denied the motions. As in CytRx, plaintiffs were permitted to move forward with Section 10(b) false statement claims based on the company’s own statements in (1) an underwriting agreement, and (2) the risk disclosure sections of other SEC filings. In contrast to CytRx, plaintiffs were also permitted to move forward with false statement
claims against the company based on third-party articles commissioned by the DreamTeam; the court found that plaintiffs had sufficiently alleged that the company itself had “made” the statements at issue, insofar as the company had had control over the content of the articles. (The court did not find this to be the case with the articles commissioned by Lidingo, however.) The court also concluded that plaintiffs had sufficiently alleged “scheme” liability under Section 10(b) against the company and all but one of the insiders, and against the investor relations firms, their principals and the writer defendant. Finally, the court permitted plaintiffs to move forward with their insider trading claims against all but one of the officers and directors who had sold stock during the relevant period.


Galectin, which developed treatments for cancer and for liver disease, began Phase 1 trials of its leading drug candidate in the latter half of 2013. During the same period, the company worked with four investor relations firms, including The DreamTeam Group. As the company reported developments in the clinical trials, the investor relations firms worked to have articles published calling attention to the positive announcements. The company also launched a stock offering during this period. In July 2014, two media pieces appeared in which the company was said to have improperly used paid stock promoters. The company’s stock price fell more than 50% following the appearance of these pieces.

Investors sued, accusing the company of making false or misleading statements of the same kind at issue in _CytRx_ and _Galena_—that is, statements in the favorable articles by third-party writers as well as the company’s own statements in (1) an underwriting agreement, in which the company said that it had not manipulated stock prices, and (2) the risk disclosure sections of other SEC filings, which did not include risks associated with the use of stock promoters. Plaintiffs also alleged “scheme” liability. The company and its officers and directors (the only defendants in the case) moved to dismiss and the court granted the motion in its entirety. With respect to the false statement claims, the court found that the company could not be liable for statements in the favorable article written by third parties; plaintiffs had failed to plead facts showing that the company was the “maker” of those statements. (This was also the case in _CytRx_; in _Galena_, the court found that the company “made” the statements in articles placed by one of the two investor relations firms at issue but not the other.) In contrast with the courts in _CytRx_ and _Galena_, the court also dismissed claims based on the company’s own statements in the underwriting agreement and risk disclosures. The court found that plaintiffs had failed to establish that those statements were false or misleading, noting that “[i]t may seem odd to the uninitiated, but nothing in the securities laws bars the issuer of a regulated security from paying an analyst for a stock recommendation." The court further held that to the extent there was a duty to disclose payment terms, that duty belonged not to the company but to the writers of the articles. Finally, the court dismissed plaintiffs’ “scheme” claim, finding that plaintiffs had failed to allege any actionable conduct beyond the making of the allegedly false or misleading statements.
DECISIONS RELATED TO POST-APPROVAL DRUGS OR DEVICES

In this section (pages 36-42), we provide detailed summaries of decisions in cases arising from developments at the post-approval stage. As discussed above, in “Trends and Analysis,” companies have prevailed in these cases more often than not. Several courts have rejected investors’ attempts to turn cases of regulatory non-compliance—involving, for example, off-label marketing or improper billing—into cases of securities fraud. Particularly when companies engage openly in the conduct questioned by regulators, courts conclude that investors were not misled. In other cases, however, courts have been willing to follow plaintiffs in making the leap from non-compliance to fraud, particularly where plaintiffs can anchor their theory of fraud on a company’s legal compliance statements.
LAUNCH ISSUES


K-V Pharmaceutical held the rights to Makena, a drug designed to reduce the risk of pre-term labor for at-risk pregnant women. In 2011, the FDA granted the company’s request for exclusive sale rights under the Orphan Drug Act, pursuant to which the agency may provide seven years of patent-like sales exclusivity to manufacturers of drugs used to treat diseases affecting fewer than 200,000 people. K-V decided to price the drug at $1,500 per dose, with a complete course of treatment totaling $30,000. K-V informed investors of its planned pricing strategy, as well as its belief that health insurers would cover the drug because the costs associated with pre-term birth were still higher. The company also explained that it would offer financial assistance to patients below a certain income level. As to competition, K-V told investors that it did not believe that off-label compounding pharmacies would join the market for Makena. When Makena’s pricing structure was revealed, however, considerable backlash erupted from the public. In response, the FDA announced that it would not take enforcement action to protect the company’s exclusive rights against competing compounders. K-V’s stock price plummeted. Investors sued, claiming that K-V knew or should have known that charging $1,500 per dose would hinder the drug’s commercial success. The Eighth Circuit affirmed the district court’s dismissal. The court found that K-V’s statements that the FDA would enforce exclusivity were forward-looking, and that they fell within the PSLRA’s safe harbor provision because they were accompanied by meaningful cautionary statements. The court also noted that the company could not have predicted the FDA’s future actions with respect to exclusivity at the time the company made the challenged statements.

**Note:** This decision affirms In re K-V Pharmaceutical Co. Securities Litig., 2014 WL 1272452 (E.D. Mo. Mar. 27, 2014), which we discussed in last year’s report.

REGULATORY ISSUES

Appellate Decisions

Fire & Police Pension Ass’n of Colorado v. Abiomed, Inc., 778 F.3d 228 (1st Cir. 2015), affirming dismissal. Off-label marketing.

Abiomed sold medical devices designed for circulatory support. The company’s most important product, a micro heart pump, called the Impella 2.5, was approved in 2008. After approval, the company included in its marketing materials a comparison between Impella and its principal competitor, an intra-aortic balloon pump. Beginning in January 2010, Abiomed received an Untitled Letter, a Warning Letter and a Follow-Up Letter from the FDA. The subject of all three letters was the same: in the FDA’s view, the comparison with the balloon pump was improper because Impella had not been approved for the use to which the comparison related. Abiomed disclosed the letters and related meetings with the FDA in quarterly SEC filings. After continued FDA scrutiny, Abiomed recalled all of its marketing materials. Following the recall, the company learned that the Justice Department was also investigating it for off-label marketing. When the company announced the investigation and the recall of marketing materials, its stock price fell. The FDA later issued a Close-Out Letter, stating that the company had adequately addressed the violations identified in the Warning Letter.

Investors sued, claiming that the company had (1) failed to disclose that revenue growth was the result of off-label marketing, (2) falsely stated that its policy was not to engage in off-label marketing, and (3) minimized the FDA’s concerns by stating that it was working with the agency toward a resolution. The First Circuit affirmed the district court’s dismissal, rejecting each of the three theories. The first—the revenue theory—depended on a long chain of inferences not sufficiently alleged. The second and third failed for a common set of reasons. The court concluded that it was not misleading for the company to state that its policy was to refrain from off-label marketing when it also disclosed that the FDA had sent it warning letters on
the subject, and when it cautioned investors that regulators might not agree with its judgments about what constituted improper marketing activities. The company was not required to agree with the FDA by pejoratively characterizing activities it believed at the time were appropriate. Instead, the securities laws had to leave “some room for give and take between a regulated entity and its regulator.”

Note: This decision affirms Simon v. Abiomed, Inc., 2014 WL 1413638 (D. Mass. Apr. 10, 2014), which we discussed in last year’s report.

District Court Decisions: Motions to Dismiss or for Summary Judgment Granted


Off-label marketing.

Pacira received approval for its anesthetic, Exparel, in 2011. The drug was approved for use in only two procedures, bunionectomies and hemorrhoidectomies, and only for use over 24 hours. Sales of the drug accounted for approximately 90% of the company’s revenue in 2013 and 2014. During that time, Pacira marketed Exparel aggressively, stating publicly that the drug provided up to 72 hours of pain relief and was being used by physicians for a broad range of procedures beyond bunion and hemorrhoid removals. The company also announced positive results from a trial testing Exparel as a femoral nerve block that could be used in knee surgeries. In May 2014, Pacira filed an sNDA in which it sought approval for the use of Exparel in knee surgeries. In September 2014, Pacira received a Warning Letter in which the FDA stated its view that the company was engaging in off-label marketing by targeting uses beyond the two approved procedures. When Pacira disclosed the letter, its stock price dropped. In October 2014, the company announced that it had missed Q3 2014 revenue estimates, and its stock price dropped further. After a rebound following more favorable news, Pacira announced that the FDA had rejected its sNDA, that the Justice Department was now investigating it for off-label marketing, and that, in light of these developments, it was suspending its 2015 financial guidance. The stock dropped again, this time steeply.

Investors sued, alleging that Pacira had misleadingly omitted from its public statements (1) the fact that the company was engaged in off-label marketing, and (2) the fact that this would cause the FDA to reject the sNDA. Defendants moved to dismiss and the court granted the motion. The court noted, first, that the company did not dispute that it had engaged in the practices that allegedly constituted off-label marketing; rather, defendants’ position was that they had engaged in those practices openly, and that they believed the practices were aggressive but not illegal. While crediting this analysis, the court found that plaintiffs had sufficiently pled that certain of the company’s statements were false or misleading—the statements in SEC filings that Exparel could be used for up to 72 hours and could be used for a broad range of procedures. Nevertheless, the court concluded that the defendants were entitled to dismissal because plaintiffs had not shown that these statements were materially misleading. The court applied the “truth-on-the-market” doctrine, under which challenged statements are viewed within the larger context of information available to investors. The court found that the market knew which uses Exparel had been approved for, and that, armed with that information, investors should also have known that statements about use for 72 hours and use for procedures other than bunion and hemorrhoid removal were problematic, and that the company was at risk of regulatory action. The court further rejected plaintiffs’ claim that the company wrongly failed to state that its marketing practices would cause the FDA to reject its sNDA: no facts plaintiffs alleged showed that the agency denied the application for that reason. The court therefore dismissed all claims. In a somewhat unusual move, however, the court also reached the issue of scienter, reasoning that plaintiffs might succeed in establishing falsity in an amended complaint, in which case scienter would be relevant. Even more unusually, the court held that plaintiffs’ scienter allegations were adequate—despite the fact that their falsity allegations were not.

Ariad was the developer of Ponatinib, a treatment for chronic myeloid leukemia. In September 2010, the company began the PACE trial, which was designed to test the efficacy and safety of the drug as a second-line treatment, i.e., one to be used after an initial front-line treatment has failed. In June 2012, the company announced favorable interim results, including “clear evidence of a favorable safety and tolerability profile.” In July 2012, the company submitted interim trial results to the FDA, including an adverse event incidence of 8% of patients. At the same time, the company began the EPIC trial, which tested the drug as a front-line treatment. In December 2012, the FDA approved Ponatinib for second-line use—but also required the company to lower the dose and to include a “black box” warning label disclosing the incidence of adverse events. The company’s stock price dropped. In August 2013, Ariad submitted additional data from the PACE trial, showing that the rate of adverse events had risen from 8% to nearly 12%. In October 2013, the FDA terminated the EPIC trial and suspended the marketing of the drug for the PACE indication. The stock price dropped further.

Investors sued, alleging that the company had concealed information about ongoing dose reductions during the course of the PACE trial and had concealed and made statements inconsistent with the incidence of adverse events both before and after approval. The court agreed with plaintiffs that the company had misleadingly minimized the dose reductions. The court also accepted plaintiffs’ argument that, under Matrixx, the company owed and breached a duty to disclose adverse events to investors as they occurred. Ultimately, however, the court dismissed both sets of claims, finding that plaintiffs had not established that defendants had an intent to conceal material information. That conclusion was based in part on the fact that the company operated under very close FDA scrutiny; the court’s reasoning seems to have been that because concealment was not feasible as a practical matter, an intent to conceal could not be inferred. The court also rejected plaintiffs’ allegations about insider selling as evidence of scienter; plaintiffs had not tied specific stock sales to possession of specific pieces of information. Finally, the court dismissed Section 11 claims against the company and the underwriters of two class-period stock offerings. The court found that plaintiffs had failed to establish that negative information in defendants’ possession at the relevant time amounted to a “trend,” the disclosure of which is mandated in offering materials.


Iradimed manufactured an infusion pump used to administer medicine intravenously during MRI scans. In June 2013, the company learned that a part of the pump’s software could provide an incorrect recommended value for the pump’s flow rate, which could in turn lead to serious health problems or even death. Iradimed recalled the pump and made significant changes to its software. Iradimed did not notify the FDA of the software update or obtain premarket clearance for it. In April 2014, the FDA conducted an inspection of Iradimed’s facilities to follow up on the product recall. At the end of the inspection, the FDA issued a Form 483 noting eight categories of deficiencies, including the observation that the company had not adequately established procedures for design review and design change. The FDA did not at that time take the position that Iradimed’s pumps were adulterated, nor did it instruct Iradimed to stop selling the pumps. In July 2014, the company conducted an IPO. In its IPO registration statement, the company disclosed and described the Form 483, which it said was issued as a result of a “routine” FDA inspection. In September 2014, Iradimed announced it had received a Warning Letter in which the FDA had concluded that the pump was adulterated as a result of the significant software changes, and had ordered the company to cease selling the pump and to submit a new Section 510(k) application for approval. Share prices fell.

Investors sued, alleging that the company had misleadingly omitted from the registration statement and subsequent communications the critical fact that the pump was adulterated. The court rejected that claim, given that the FDA did not state its view that the pump was adulterated until after the challenged statements were made. Plaintiffs also challenged the company’s description of the Form 483, including the use of the term “routine.” The court rejected this claim, too, noting that inspections in fact are routine in this highly regulated sector.
industry, and that companies do not have an absolute duty to disclose all FDA inspections, all Form 483s, or even all Warning Letters. The complaint also fell short on scienter grounds: The company disclosed the recall, disclosed the Form 483, and disclosed its actions in response to the Form 483. None of this was consistent with an intent to defraud.

**Singer v. TranS1, Inc., 2015 WL 2341907 (E.D.N.C. May 14, 2015), motion to dismiss granted with prejudice. Medicare/Medicaid fraud.**

TranS1 was a medical device company whose primary product, the AxiaLIF, was used during spinal surgeries. The AxiaLIF was originally assigned a billing code in Category 1. Such codes provide a fixed value for reimbursement by insurers. In 2008, the American Medical Association changed AxiaLIF's billing code to a Category 3 code, which covers experimental procedures. Category 3 codes do not provide a set value for reimbursement, and many insurers will not pay for treatments, drugs or devices in Category 3. Because physicians are accordingly reluctant to use Category 3 devices, TranS1 counseled the surgeons using the AxiaLIF to employ billing methods that would minimize the Category 3 problem and maximize the chance of reimbursement. A former employee filed a *qui tam* action challenging this conduct as unlawful. Various government agencies investigated and ultimately agreed with the *qui tam* plaintiff that the company’s actions in counseling physicians on billing methods were improper. The government’s view was that through the alternative billing methods TranS1 promoted, physicians were receiving reimbursement—including reimbursement from Medicare and Medicaid—to which they were not entitled. The government took the position that the company had violated both anti-kickback and false claims statutes. The matter was ultimately resolved through a $6 million payment TranS1 made to settle the *qui tam* action.

Investors sued, challenging the same physician-counseling practices that had given rise to the *qui tam* action, and alleging that defendants had made false or misleading statements by failing to disclose that the company was engaged in an illegal billing scheme. The court rejected plaintiffs’ claims and granted defendants’ motion to dismiss. The court found that defendants had not concealed but in fact had openly discussed the company’s actions in training physicians to code around the Category 3 problem. What defendants did not disclose was that these actions were illegal—but no facts plaintiffs alleged showed that defendants knew this at the relevant time. Nor were plaintiffs correct in asserting that the company had urged physicians to *omit* the Category 3 code; instead, the company instructed physicians to use it in conjunction with other, reimbursable codes. The court also concluded that plaintiffs failed to allege scienter: among other things, defendants did not conceal but publicly discussed the coding problem and the actions they were taking in response.

**District Court Decisions: Motions to Dismiss or for Summary Judgment Denied**


BioScrip provided healthcare services of various kinds. Among other things, it operated specialty pharmacies and sold prescription discount cards through its PBM division. In October 2012, the company was served by the Justice Department with a Civil Investigative Demand (CID), pursuant to which the government was investigating potential violations of anti-kickback and false claims statutes. The activity at issue concerned rebates and referrals provided to BioScrip by Novartis, one of whose drugs BioScrip distributed. In September 2013, the government told BioScrip that it was considering civil charges against the company. BioScrip announced this to the market, along with its prior receipt of the CID, which it had not previously disclosed. The company’s stock price fell. The government ultimately did file civil charges, and the company paid $15 million to resolve the matter. During the same period, BioScrip experienced setbacks in its PBM division. Revenue from that division fell from $27 million in Q1 2013 to $17 million in Q2 2013, largely as the result of the loss of a single important customer. The company’s stock price fell on this announcement too. Investors sued, alleging fraud as to (1) statements relating to the company’s legal compliance and (2) statements relating to the strength of PBM’s business. Because the company undertook two public stock offerings during the relevant period, plaintiffs also brought 1933 Act claims against
the company and its underwriters. All parties moved to dismiss, and the court denied the motions in large part. Most significantly, the court applied *Omnicare*, decided only days earlier, in a pro-plaintiff manner. In connection with the CID, plaintiffs challenged the company’s statement, in various SEC filings, that it was in compliance with applicable laws and regulations. The court explained that, under *Omnicare*, “a legal compliance statement may be deemed misleading if, although sincerely held, it is formed on the basis of an omitted fact, not disclosed by the speaker, that would likely conflict with a reasonable investor’s own understanding of the facts conveyed by that statement.” The court then concluded that the existence of the CID was just such an omitted fact, and that the company’s failure to disclose the CID when it made its statement about legal compliance was therefore actionable under *Omnicare*. The court also found actionable a series of statements that there could be “no assurance” that the company would not be subject to investigation or scrutiny by government entities. Once the company raised this subject, the court held that it had a duty to be “accurate and complete,” and statements that left out the existence of the CID did not meet that standard. On the subject of PBM, however, the court ruled for defendants: although the court concluded that the company’s positive statements about Q2 2013 prospects were misleading, it also found that plaintiffs had not pled facts sufficient to show that the company knew that it would lose a major customer and revenue source. The court largely repeated these rulings with respect to the 1933 Act claims, save for the fact that it permitted plaintiffs to move forward with their PBM theory under the 1933 Act claims (as scienter is not an element of those claims) and dismissed a portion of one claim on the ground that plaintiffs had not established standing.


**Safety issues.**

Merck launched Vioxx, an anti-inflammatory medication, in 1999 and withdrew it in 2004 after it had been linked to cardiovascular problems. Before Vioxx was approved, Merck conducted 60 clinical trials. One of the 60, Protocol 023, showed an imbalance in patients’ prostaglandin metabolites, such that a substance in the body that inhibits blood clots (prostacyclin) was being reduced, with no corresponding reduction in another substance that promotes clotting (thromboxane). Vioxx was approved notwithstanding that result, which was only very tentatively connected with any problems patients might experience. After approval, a different study, called VIGOR, was completed. This study showed that patients taking Vioxx were five times more likely to suffer myocardial infarctions than patients taking a different anti-inflammatory drug, naproxen. The company began investigating whether this might be the result of beneficial effects of naproxen rather than adverse effects of Vioxx (the naproxen hypothesis). The company made various public statements backing the naproxen hypothesis, defending the safety of Vioxx, and asserting that there was no evidence that Vioxx caused cardiovascular problems. In 2004, Vioxx was withdrawn and Merck’s stock price fell. Investors sued, challenging both pre-approval and post-approval statements. After a decade of litigation and extensive discovery, the company moved for summary judgment. The court largely denied the motion. The court granted the motion with respect to four challenged statements predating the conclusion of the VIGOR study. The court found that plaintiffs had not shown that Protocol 023 called the safety of Vioxx into question to such an extent as to render the company’s positive statements about the drug false or misleading. The court largely denied defendants’ motion with respect to 19 post-VIGOR statements, in which the company promoted the naproxen hypothesis and otherwise defended the safety of Vioxx. The court found that the evidence was mixed. While some evidence showed that the company genuinely believed in the naproxen hypotheses, and that scientific analysis supported it, other evidence pointed in the other direction—including an FDA warning letter faulting the company for selectively presenting the naproxen hypothesis in its public statements. Where evidence is mixed, summary judgment is inappropriate, and a case must proceed to trial. The court frequently cited *Omnicare* in its analysis of challenged opinion statements. The court recognized that *Omnicare’s* application to Section 10(b) claims was uncertain, as Section 10(b) claims include a scienter requirement and the claims at issue in *Omnicare* itself did not. Nevertheless, the court largely adopted *Omnicare’s* analysis, holding that plaintiffs’ attack on the company’s opinion statements was viable insofar as plaintiffs had marshaled
evidence suggesting that defendants did not actually hold the opinions they professed, as well as evidence suggesting that those opinions did not fairly align with the underlying facts. Finally, in an explanatory overview relevant to nearly every decision in this survey, the court emphasized the difference between claims that a company has acted improperly and claims for securities fraud, which deal not with corporate conduct generally but more narrowly with the accuracy of a company’s public statements about its business.

NON-REGULATORY ISSUES

Fresno County Employees Retirement Ass’n v. Alphatec Holdings, Inc., 607 F. App’x 694 (9 Cir. June 5, 2015). Sales and sales forecasting following acquisition.

Alphatec designs, manufactures and markets devices for the surgical treatment of spine disorders. In December 2009, Alphatec announced that it had entered into an agreement to acquire a French company called Scient’x. Alphatec made positive statements about the benefits of the deal, noting that it would provide the company with an increased global presence with cross-selling opportunities, with synergies in distribution, marketing and administration. Alphatec issued an earnings forecast projecting 20 percent year-over-year growth. In August 2010, Alphatec announced lower than expected second quarter results and cut its revenue guidance. The company disclosed that it was taking longer than expected to integrate Alphatec products into Scient’x’s distribution system and to get Scient’x’s products into Alphatec’s inventory. On this news, stock prices dropped.

Investors sued, claiming that Alphatec had failed to disclose issues related to the quality of Scient’x’s products. In particular, plaintiffs claimed that Scient’x’s products were obsolete, defective or lacking sufficient documentation for sale in the U.S., all of which made integration into Alphatec’s product line difficult. The Ninth Circuit affirmed the district court’s dismissal. The court concluded that plaintiffs had not adequately pled falsity with respect to Alphatec’s positive statements about merger synergies. The court also concluded that none of the challenged statements was adequately alleged to have been connected to the issue of the quality of Scient’x’s inventory.


Savient developed Krystexxa, a drug for the treatment of chronic gout. In November 2010, Savient filed a 10-Q in which it stated that its initial strategic plan had been to seek a sale of the company after Krystexxa was approved by the FDA, but that because it had not succeeded in finding an acquirer, it had decided to focus on launching the drug. The company also stated that it would continue to “evaluate available strategic alternatives.” Savient repeated this language in subsequent SEC filings. In November 2011, Savient varied the language somewhat, then stating that while its board would evaluate strategic alternatives “from time to time,” the company was proceeding with the launch of Krystexxa. In March 2013, Savient retained Lazard Freres to explore a sale. This was not disclosed. Meanwhile, in April, May and August 2013, the company stated that its cash holdings were sufficient to support continued operations for the next 12 months. In September 2013, however, Savient announced that its plans for restructuring had changed, and that it consequently could run out of cash by early 2014. In October 2013, the company announced that it would file for bankruptcy—its share price fell from approximately $.57 to $.07.

Investors sued Savient’s officers and directors, challenging both the company’s statements about strategic plans and its statements about the sufficiency of its cash. The court rejected both claims and granted defendants’ motion to dismiss. As to the strategic plans, plaintiffs’ theory was that when the company introduced the term “from time to time” in November 2011, this signaled a reduced interest in finding an acquirer, and that therefore when the company retained Lazard in 2013, it had a duty to disclose that it had shifted course and was now focused on being acquired. The court disagreed. The “from time to time” language did not, in fact, signal a change in course. In any event, the company consistently said that it was planning a launch but at the same time was also considering alternative options—and plaintiffs had not shown that this was untrue. As to
the statements about the sufficiency of cash, the court found that these were projections and hence protected by the PSLRA’s safe harbors for forward-looking statements.


**Decreasing drug demand.**

Spectrum was the developer of Fusilev, a purified form of leucovorin, which is used to reduce the toxicity of chemotherapy for patients suffering from colorectal cancer. Fusilev consisted solely of the active ingredient in leucovorin. Generic leucovorin, by contrast, contains both active and inactive ingredients. Fusilev cost four times as much as generic leucovorin. The FDA approved Fusilev in 2011. Because generic leucovorin was, at that time, in short supply, sales rose quickly. In 2012, the shortage of the generic drug began to abate and demand for Fusilev correspondingly began to decline. Analysts questioned the continued strength of Fusilev sales; through February 2013, however, Spectrum continued to say that the increased availability of generic leucovorin would not have a negative impact on its business. In March 2013, the company announced that it expected Fusilev revenue to drop sharply. Share prices fell in response.

Investors sued, alleging that defendants knew that demand was declining and made statements inconsistent with this. Defendants moved to dismiss, and in a relatively cursory decision, the court denied the motion. The court rejected defendants’ argument that their statements were shielded by the PSLRA safe harbor. Although some of the statements were indeed forward-looking, they were not accompanied by meaningful cautionary disclosures: a disclosure that left out the fact that demand was declining was not meaningful. The court also concluded that the challenged statements, even if literally true, were misleading in context. Finally, the court found that plaintiffs had pled facts supporting a strong inference of scienter: given defendants’ statements that they closely monitored demand, they must have known that demand was declining before the made their corrective disclosure in March 2013.
In 2015, 39 securities fraud class actions were filed against companies in the healthcare sector. Of these, 24 actions were filed against companies with development stage drugs or devices. An additional four actions involve regulatory issues with mature products. The remaining eleven actions concern issues not specific to life sciences companies.

New filings in 2015 by stage of drug or product development:

<table>
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<th>DRUG LIFECYCLE</th>
<th>SECURITIES FRAUD CLASS ACTIONS FILED IN 2015</th>
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<tr>
<td>PRE-APPROVAL</td>
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<td>POST-APPROVAL</td>
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<td>(for example, off-label marketing)</td>
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<td>Non-regulatory issues</td>
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<td>(for example, missed guidance or financial statement issues)</td>
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1 We take this figure and list of actions from the Stanford Securities Class Action Clearinghouse. This list includes those cases categorized by Cornerstone Research as within the “healthcare sector” but excludes deal litigation. We have also excluded three cases that do not relate to any drug or medical device and are therefore outside the scope of this analysis: (1) MedBox, Inc., concerning a vending machine that dispenses medical marijuana; (2) Nobilis Health Corp., concerning ambulatory surgery centers; and (3) AAC Holdings, Inc., concerning facilities that provide inpatient substance abuse treatments for individuals with drug and alcohol addiction.
NEW FILINGS IN 2015
BY CIRCUIT

- Ninth Circuit: 16 new filings
- First Circuit: 6 new filings
- Tenth Circuit: 3 new filings
- Second Circuit: 4 new filings
- Third Circuit: 5 new filings
- Fourth Circuit: 2 new filings
- Seventh Circuit: 1 new filing
- Fifth Circuit: 1 new filing
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<td>CLOVIS ONCOLOGY, INC.</td>
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SUMMARY OF ALLEGATIONS

DEVELOPMENT STAGE; STOCK PROMOTION  Plaintiffs allege that the company's financial statements were false and misleading due to the company's use of a paid stock promoter to artificially inflate stock price.

DEVELOPMENT STAGE  Plaintiffs challenge statements related to the conduct of the company's CEO, Martin Shkreli. Plaintiffs allege that the company failed to disclose that Shkreli was involved in an illegal scheme concerning the sale of stock of a separate company, and further allege that the company’s positive statements about business prospects were rendered misleading by virtue of that omission.

DEVELOPMENT STAGE  Plaintiffs challenge the company’s statements about its tool for the rapid diagnosis of hospital-acquired bacterial infections. Plaintiffs allege that the company claimed that its product could reduce turnaround time by eliminating the need for bacterial blood culturing, but that, in fact, the product did not eliminate that need.

PHASE 1/2  Plaintiffs claim that the company fraudulently failed to disclose adverse facts regarding the effectiveness of two of its drugs, Brilacidin and Kevetrin. Contrary to the company’s statements, plaintiffs allege Brilacidin is not effective in combating skin infections and Kevetrin is not capable of activating the p53 gene, which suppresses tumors. In addition, plaintiffs allege that the company’s president and director did not earn a PhD in pharmacology at Harvard, although he publicly claimed to have done so.

PHASE 1/2  Plaintiffs allege that the company made false or misleading statements about the prospects for treatments for cancerous and degenerative diseases. According to plaintiffs, one of the company’s technologies had been associated with multiple patient deaths and lacked meaningful market value. Plaintiffs also claim that the company used paid stock promoters and failed to disclose that fact.

PHASE 1/2/3  Plaintiffs challenge the company’s statements about its DCVax platform technology, which uses a patient’s own immune system to attack cancer. Two products are at issue: DCVax-L, a brain and ovarian cancer treatment, and DCVax-Direct, a treatment for various kinds of inoperable solid tumor cancers. Plaintiffs allege that the company made statements regarding the results of the DCVax-Direct trial that were not grounded in reliable data, that the company engaged in a fraudulent stock promotion campaign, and that German regulators required additional information in order for the DCVax-L trial to continue uninterrupted.

PHASE 2  Plaintiffs allege that the company misrepresented the nature and significance of the results of clinical trials for Rociletinib, a lung cancer treatment.

PHASE 2B  Plaintiffs allege that the company made false or misleading representations in its Registration Statement by failing to disclose poor results, including a high incidence of serious adverse events, from a Phase 2b study of its anemia drug. Investors who purchased IPO shares sued after the company released the negative results and its stock price fell.
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**SUMMARY OF ALLEGATIONS**

**PHASE 2A**  Plaintiffs allege that the company made false and misleading statements concerning the design of a Phase 2a study of a drug for an advanced form of age-related macular degeneration. According to plaintiffs, the company failed to disclose that the study was not designed to show any statistical significance between the active and control groups in the study’s secondary endpoints.

**PHASE 2B**  Plaintiffs allege that the company made false and misleading statements regarding the prospects for a genetic enzyme replacement therapy. According to plaintiffs, the company failed to disclose, in connection with its Phase 2b trial, that an earlier Phase 2 trial had been too small to be indicative of success on the later Phase 2b trial. Share prices dropped after the company announced that the Phase 2b trial did not meet its primary or secondary endpoints.

**PHASE 2 COMPLETE**  Plaintiffs challenge statements related to the company’s topical treatment for wrinkles around the eyes, which uses botulinum toxin type A. Plaintiffs allege that the company falsely claimed to be in a Phase 3 clinical trial even though the FDA had rejected the company’s Phase 2 plan. Plaintiffs further allege that the company failed to disclose that the FDA had disagreed with how the company measured the drug’s efficacy and considered such disagreement an impediment to the success of the company’s Phase 3 plan.

**PHASE 2/3**  Plaintiffs allege that the company made misrepresentations about adverse events in clinical trials of its anti-obesity drug Beloranib. According to plaintiffs, the company misled the public by confirming that a patient had died in its Phase 3 trial but not disclosing that the patient had died while taking Beloranib rather than a placebo.

**PHASE 3**  Plaintiffs challenge the company’s statements relating to three clinical studies of a drug intended to treat liver failure. Plaintiffs allege that the company failed to disclose that each study was not of stand-alone significance, that the studies were so interrelated that the failure of one would lead to failure of the others, and that if one study were to fail, the company would not conserve cash in order to continue the other trials.

**PHASE 3**  Plaintiffs challenge statements relating to the company’s Phase 3 trials of the colorectal cancer drug Xilonix. Plaintiffs allege that when the company announced that it expected enrollment of its European study to be complete in the second half of 2015, defendants should have known that there were serious enrollment problems and that such a target was therefore not feasible. Stock prices fell when the company announced that a large number of enrolled patients had dropped out or had not completed all required testing.

**PHASE 3**  Plaintiffs allege that the company made material misrepresentations about the development of Gevokizumab, a drug intended to treat an inflammatory disorder most commonly involving the eyes. According to plaintiffs, the company led investors to believe that a Phase 3 study of the drug would succeed. Stock prices fell when the company announced that the study had not met its primary endpoint.
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<td>VENAXIS, INC.</td>
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SUMMARY OF ALLEGATIONS

PHASE 3  Plaintiffs challenge the company’s statements concerning a catheter lock solution used to prevent catheter-related bloodstream infections and to keep catheters clear. Plaintiffs allege that the company made false and misleading statements about partnership discussions and about the soundness of its Phase 3 trial design, as well as overstating the drug’s clinical and cost effectiveness relative to protocols already in use. Plaintiffs also allege that the company failed to disclose its use of paid stock promoters.

PHASE 3  Plaintiffs challenge the company’s statements about a treatment for osteoarthritis. Plaintiffs allege that the company failed to disclose that the clinical research organization it retained to conduct a Phase 3 trial lacked independence. Plaintiffs also allege that the company shipped the trial drug supply to clinical sites at lower temperatures than permitted by drug specifications.

PHASE 3  Plaintiffs allege that the company made false and misleading statements about the effectiveness of an eye drop used to lower intraocular pressure for patients with glaucoma or ocular hypertension. Specifically, plaintiffs allege that Phase 3 testing had shown that the drug was no more effective than its most widely prescribed competitor, but that the company nevertheless expressed confidence in the drug’s ability to outperform that competitor.

PHASE 3  Plaintiffs allege that the company made false or misleading statements about the prospects for a treatment for Parkinson’s disease psychosis. After reporting positive Phase 3 results for the treatment and claiming it was on track to submit an NDA in the first quarter of 2015, the company disclosed that it was revising the projected submission date to the second half of 2015. The stock price dropped following that announcement.

PRE-NDA  Plaintiffs claim that the company made false and misleading statements regarding the potential for Evomela, a cancer treatment, and the progress of its NDA. According to plaintiffs, the company knew the FDA was unlikely to approve Evomela because the drug was not materially different from other drugs on the market, and because similar drugs were not toxic.

PRE-NDA  Plaintiffs allege that the company misleadingly stated that a meeting with the FDA affirmed the company’s confidence in its forthcoming NDA for Migalastat. According to the complaint, the FDA actually expressed concerns about the NDA at the meeting in question. When the company announced two weeks later that it was not on track to submit the NDA in 2015, its stock price fell.

510(K) PRE-MARKET NOTIFICATION  Plaintiffs challenge statements related to the company’s test for the identification of patients at low risk for acute appendicitis. The company filed a 510(k) premarket submission for the test. Plaintiffs allege that the company’s positive statements about 510(k) clearance were misleading, insofar as the test failed to meet applicable criteria and the company lacked a reasonable basis to conclude that study results were sufficient to support clearance.
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## SUMMARY OF ALLEGATIONS

### NDA
Plaintiffs challenge statements relating to the company’s “dual opioid” drugs, which combine two opioid painkillers. Plaintiffs allege that the company failed to disclose that it had received a no-agreement letter from the FDA, in which the agency stated that it did not agree with the company’s study design. Plaintiffs also allege that the study was deceptively designed. After the FDA rejected the drug and then rejected an appeal of its initial decision, the company’s stock price fell.

### NDA
Plaintiffs challenge statements relating to the company’s breast cancer drug candidates. Plaintiffs allege that the company initially stated that it was working on an NDA for approval of a drug candidate for metastatic breast cancer, and only belatedly disclosed that its initial NDA would, in fact, be aimed at approval of a drug for an early-stage breast cancer indication. With respect to the early stage indication, the company needed to submit additional safety data, which pushed out the timeline for the NDA filing. Stock prices fell on that disclosure.

### POST-APPROVAL; REGULATORY ISSUES
Plaintiffs claim that the company, which develops and sells implants for aesthetic use, made misleading statements regarding the risks inherent in its exclusive reliance on its contract manufacturer, as well as risks related to contamination at the manufacturing plant.

### POST-APPROVAL; REGULATORY ISSUES
Plaintiffs challenge the company’s statements about its joint replacement implants, which are individually sized and shaped to fit each patient’s anatomy. The company initiated a voluntary recall of some of its knee replacement product systems; plaintiffs’ theory is that public statements regarding quality control were false or misleading.

### POST-APPROVAL; REGULATORY ISSUES
Plaintiffs challenge the company’s statements about its anti-obesity drug. The FDA required the company to conduct a post-approval study to evaluate the effects of long-term treatment. Plaintiffs allege that the company improperly disclosed interim results of the study, despite having been previously admonished by the FDA against doing so.

### POST-APPROVAL; REGULATORY ISSUES
Plaintiffs challenge the company’s statements about regulatory activity relating to its sale of biomaterials for soft tissue repair. The company received civil subpoenas from the Office of the Inspector General and the Department of Health and Human Services related to its sales and marketing activities. Plaintiffs allege that the company made false or misleading statements, insofar as it failed to disclose that it was engaging in the conduct that was the subject of those subpoenas.

### POST-APPROVAL; CHALLENGE TO FINANCIAL STATEMENTS
Plaintiffs allege that the company, which focuses on regenerative medicine, overstated revenues from several contracts and failed to follow GAAP standards.
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<tr>
<th>COMPANY</th>
<th>DATE</th>
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<tr>
<td>VALEANT PHARMACEUTICALS INTERNATIONAL, INC.</td>
<td>10/23/2015</td>
<td>D.N.J.</td>
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<tr>
<td>GLOBUS MEDICAL, INC.</td>
<td>9/29/2015</td>
<td>E.D.P.A.</td>
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<tr>
<td>BIOGEN, INC.</td>
<td>8/18/2015</td>
<td>D. Mass.</td>
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<td>ISORAY, INC.</td>
<td>5/22/2015</td>
<td>C.D. Cal.</td>
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<tr>
<td>THE SPECTRANETICS CORP.</td>
<td>8/27/2015</td>
<td>D. Col.</td>
</tr>
<tr>
<td>INOGEN, INC.</td>
<td>3/13/2015</td>
<td>C.D. Cal.</td>
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Table of New Filings in 2015
POST-APPROVAL; NON-REGULATORY ISSUES Plaintiffs allege that the company improperly failed to disclose various facets of its relationship with a network of specialty pharmacies. Plaintiffs allege that the company should have disclosed both the fact that it was using specialty pharmacies to boost sales and the risks attendant on such a relationship.

POST-APPROVAL; NON-REGULATORY ISSUES Plaintiffs allege that the company, which develops medical devices to treat patients with musculoskeletal disorders, failed to disclose that its relationship with a significant distributor was deteriorating, and that this was causing the company’s financial performance to suffer. When the company revised its revenue guidance, citing operating challenges, its stock price fell.

POST-APPROVAL; NON-REGULATORY ISSUES Plaintiffs allege that the company made false and misleading projections about its 2014-2015 financial prospects; those projections were based largely based on the growth potential of the MS drug Tecfidera. When the company lowered its expectations and released revised revenue guidance, its stock price fell.

POST-APPROVAL; NON-REGULATORY ISSUES Plaintiffs allege that the company made false and misleading statements concerning radioactive “seeds” used in cancer radiation therapy. According to plaintiffs, the company selectively edited information about a study involving the seeds, and thereby overstated the drug’s effectiveness and overlooked the fact that patients who did not take the drug experienced treatment outcomes comparable to patients who did.

POST-APPROVAL; NON-REGULATORY ISSUES Plaintiffs challenge the company’s statements about its insulin infusion products, including a new incarnation of an insulin pump. According to plaintiffs, the company failed to disclose that demand was slowing and that it was facing difficulties with sales and marketing efforts, leading to uneven financial performance. Share prices dropped when the company announced lower than expected earnings.

POST-APPROVAL (OUTSIDE THE US); NON-REGULATORY ISSUES Plaintiffs allege that the company, in its Secondary Offering filings, failed to disclose that patients who received its Augment fertility procedure did not achieve a pregnancy success rate significantly higher than the rate achieved without the Augment procedure.

POST-APPROVAL (OUTSIDE THE US); NON-REGULATORY ISSUES Plaintiffs challenge the company’s statements about medical devices used in minimally-invasive cardiovascular procedures. After acquiring the drug-coated balloon assets of Covidien, the company made positive statements about its financial outlook. According to plaintiffs, the company failed to disclose that it faced increasing competition, that its sales force optimization efforts were inadequate, and that it lacked adequate internal controls.

POST-APPROVAL; CHALLENGE TO FINANCIAL STATEMENTS Plaintiffs allege that the company’s financial statements were false and misleading and that the company falsely claimed that it had effective internal controls.
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<th>COMPANY</th>
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<tr>
<td>AKORN, INC.</td>
<td>3/4/2015</td>
<td>N.D. Ill.</td>
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<tr>
<td>ERBA DIAGNOSTICS, INC.</td>
<td>12/1/2015</td>
<td>S.D. Fla.</td>
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</table>

Plaintiffs allege that the company made false and misleading statements in its financial disclosures after acquiring two companies. Plaintiffs allege that having failed to integrate the new subsidiaries into its centralized accounting system, the company was not able to include related financial information in SEC filings or timely complete assessment of its internal control over financial reporting.

Plaintiffs allege that the company made false or misleading statements about its business operations and prospects. After the company announced that its previously issued financial statements were incorrect, share prices dropped.
SUMMARY OF ALLEGATIONS

POST-APPROVAL; CHALLENGE TO FINANCIAL STATEMENTS  Plaintiffs allege that the company made false and misleading statements in its financial disclosures after acquiring two companies. Plaintiffs allege that having failed to integrate the new subsidiaries into its centralized accounting system, the company was not able to include related financial information in SEC filings or timely complete assessment of its internal control over financial reporting.

POST-APPROVAL; FINANCIAL STATEMENT RESTATEMENT  Plaintiffs allege that the company made false or misleading statements about its business operations and prospects. After the company announced that its previously issued financial statements were incorrect, share prices dropped.
ABOUT THE PRACTICE

Securities and Shareholder Litigation

Publicly traded companies can face securities and other shareholder suits following disappointing announcements or stock declines. Life sciences companies have industry-specific events and disclosure issues, including those relating to drug development, regulatory approval, and continued regulatory oversight of manufacturing, marketing and sales activities that can trigger litigation or investigations. Our lawyers understand the securities laws and the intersection of industry-specific issues relevant to life sciences companies.

Sidley is a leader in the securities class action litigation and has successfully represented many life sciences clients in recent securities and shareholder cases, challenging various claims made by Plaintiffs’ counsel. Sidley’s securities litigation practice team includes true first chair trial lawyers and experienced appellate lawyers in many offices, and some of our partners have the unusual experience of having tried securities class actions. And, we are able to work collaboratively, through a coordinated team of professionals in a variety of practices, in order to provide clients with comprehensive representation.

Life Sciences

On four continents, Sidley’s Global Life Sciences team offers coordinated cross-border and national advice on Food, Drug and Medical Device Regulatory, Life Sciences Enforcement, Litigation and Compliance, Healthcare Regulatory, Products Liability, Intellectual Property, Corporate and Technology Transactions, Securities and Corporate Finance, International Trade and Arbitration, FCPA/Anti-Corruption, Antitrust/Competition, Environmental/Nanotechnology. Globally rated as one of the top life sciences practices, our team includes former senior government officials, medical doctors and leaders in various life sciences fields.
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