Life Sciences Securities Litigation Activity in Q3 2017: Digest of Notable Decisions, Settlements, and New Filings

October 18, 2017

Notable Decisions

Federal Courts of Appeals

N. Sound Capital LLC v. Merck & Co.,
Nos. 16-1364, 16-1365, 16-1366, 16-1367, 2017 WL 3278886 (3rd Cir. 2017).

On August 2, the Third Circuit Court of Appeals held that the Supreme Court's decision in *California Public Employees' Retirement System v. ANZ Securities, Inc.*, 137 S. Ct. 2042 (2017), required that the plaintiffs' claims under the Securities Exchange Act of 1934 (the "Exchange Act") be dismissed. According to the court, the plaintiffs' claims that Merck & Co. ("Merck") misrepresented results of a clinical trial and the efficacy of Merck's anti-cholesterol drug, Vytorin, were filed after the expiration of the statute of repose, and no tolling doctrine permitted the claims to be filed when they were.

In re Atossa Genetics, Inc. Sec. Litig.,
868 F.3d 784 (9th Cir. 2017).

On August 18, the Ninth Circuit Court of Appeals partially reversed the district court's dismissal of Section 10(b) and Rule 10b-5 claims against Atossa Genetics, Inc. ("Atossa"), holding that the plaintiffs had sufficiently alleged the falsity and materiality of certain public statements about the company's breast-cancer screening device and a related test. The court determined that certain statements in a Form 8-K filing and by the company's CEO that one of Atossa's cancer diagnostic tests had been cleared by the FDA met the pleading standard for establishing falsity because clearance had not actually been obtained at the time of the statements. Further, the court held that materiality had been pleaded insofar as the test was a major source of revenue for the company and analysts had rated the company based on the claimed FDA clearance. Conversely, the court found that the plaintiffs had failed to plead the falsity of statements that the device used for collecting samples for the test had been cleared because it had, in fact, received 510(k) clearance as a sample-collecting device. At the same time, the court sustained the plaintiffs' claims regarding the company's public description of an FDA warning letter, which the court determined were misleading because they referred only to the FDA's concerns about the device while omitting mention of concerns about the related test. The court also permitted the plaintiffs to proceed with their claims regarding statements by the CEO about "FDA clearance risk," holding that the statements, though arguably opinions, were actionable as misleading under the *Omnicare* standard because they omitted material facts about the CEO's knowledge at the time of the actual prospects for FDA approval.

Corban v. Sarepta Therapeutics, Inc.,
868 F.3d 31 (1st Cir. 2017).

On August 22, the First Circuit Court of Appeals upheld the dismissal of a class-action securities suit against Sarepta Therapeutics, Inc. ("Sarepta"), holding that the plaintiffs failed to plead a "cogent inference of scienter" in connection with optimistic statements about the possibility of FDA approval for a muscular dystrophy drug, eteplirsen. While Sarepta had announced that the FDA was open to considering a new drug application ("NDA") for eteplirsen, the First Circuit concluded that the announcement and other statements made at the time were "replete with caveats." In fact, the original statement of optimism contained so many caveats that the company's stock price actually

dropped. When the FDA later determined that the NDA was premature, causing a significant drop in the price of Sarepta stock, the plaintiffs sued. In sustaining the dismissal, the court explained that the only plausible motive for fraud identified by the plaintiffs was revenue generation, which "falls short of pleading a cogent inference of scienter that can carry the day here." According to the court, the more plausible inference was that "the defendants, perhaps negligently, waxed too optimistically about the FDA's expression of a willingness to consider [a new drug application] for eteplirsen while emphasizing too little the FDA's reservations about such an application." That was not, however, sufficient to plead the requisite scienter under the securities laws. On October 12, the court denied the plaintiffs' petition for rehearing and rehearing *en banc*, leaving the panel's August ruling intact.

Williams v. Globus Med., Inc.,
869 F.3d 235 (3rd Cir. 2017).

On August 23, the Third Circuit Court of Appeals affirmed the dismissal of securities claims under the Exchange Act against Globus Medical, Inc. ("Globus"). The suit alleged that the medical-device company misled investors by issuing guidance that was based on a continued relationship with one of Globus's distributors, even though it allegedly had decided to terminate the distribution relationship. The Third Circuit affirmed the district court's decision on two grounds. First, the court held that Globus did not have a duty to disclose the termination earlier than it did because the plaintiffs had not pleaded facts establishing that the hypothetical risk at issue—that a distribution relationship would end and adversely impact Globus's business—had actually materialized at the time of the relevant statements. Second and alternatively, the court held that the company's forward-looking projections were not actionable because the plaintiffs had not adequately pleaded that the company knew they were false when made.

Federal District Courts

City of Cape Coral Mun. Firefighters' Ret. Plan v. Emergent BioSolutions Inc.,
No. 8:16-cv-02625-RWT, bench ruling (D. Md. July 7, 2017).

On July 7, the U.S. District Court for the District of Maryland denied a motion to dismiss securities claims against Emergent BioSolutions Inc. ("Emergent"), without issuing a written opinion. In that case, the plaintiffs allege that Emergent issued false and misleading statements regarding ongoing strong demand for its anthrax vaccine and its contract to sell the vaccine to the U.S. government. The lawsuit was filed following revelations that the government was ordering significantly fewer doses of the vaccine than previously had been announced.

Hsingching Hsu v. Puma Biotech., Inc.,
No. 8:15-cv-00865, 2017 U.S. Dist. LEXIS 116488 (C.D. Cal. July 25, 2017).

On July 25, the U.S. District Court for the Central District of California denied for the second time a motion to dismiss securities claims against Puma Biotechnology, Inc. ("Puma") related to its breast-cancer drug, neratinib. In September 2016, the court determined that the plaintiffs had adequately pleaded that Puma overstated the top-line efficacy results and understated the safety results from a Phase III trial of neratinib, which compared extended treatment with neratinib to a placebo in HER2-positive breast cancer patients. Thereafter, the plaintiffs amended their complaint to add new allegations of related misstatements. Puma filed a new motion to dismiss aimed at the new allegations, but the court determined that the statements as pleaded were actionable and not subject to the PSLRA's safe-harbor provisions because plaintiffs sufficiently alleged that Puma had data available at the time that undermined the statements. As the court explained, the defendants could not "benefit from [the] safe harbor by simply saying they 'anticipated' success when, in fact, they had a reasonable belief that defeat was just around the corner." The court also determined that its previous decision about the adequacy of the plaintiffs' scienter allegations was only buttressed by the new allegations in the amended complaint.

Express Scripts Holding Co. Sec. Litig.,
No. 16-03338, 2017 WL 3278930 (S.D.N.Y. Aug. 1, 2017).

On August 1, the U.S. District Court for the Southern District of New York dismissed without prejudice a securities suit against Express Scripts Holding Co. ("Express Scripts"). The suit alleged that Express Scripts had concealed a deteriorating relationship with its largest customer, Anthem, Inc. ("Anthem"), including related to negotiations over pricing in connection with the parties' contract for pharmacy benefit management services. The plaintiffs claimed that Express Scripts had a duty to disclose additional details about its relationship with Anthem after making public statements about the purported strength of the relationship. In dismissing the complaint, the court held that there was no duty to disclose, that silence about the relationship was not misleading given the lack of duty and where the company had said negotiations were ongoing but did not say it was certain about the outcome, and that the plaintiffs had not sufficiently alleged an intent to deceive (i.e., scienter).

Crihfield v. CytRx Corp.,
Nos. CV 16-05519 SJO (SKx), 16-0566 SJO (SKx), 2017 WL 2819834 (C.D. Cal. Aug. 14, 2017).

On August 14, the U.S. District Court for the Central District of California partially dismissed the second amended complaint in a securities suit against CytRx Corp. ("CytRx"). The plaintiff alleged that the company made misleading statements about (i) its compliance with a Special Protocol Assessment (an "SPA") governing a Phase 3 trial for its cancer drug, aldoxorubicin; (ii) the timeline for the trial; and (iii) the progress of the trial. After the court dismissed the suit in June 2017 for failure to plead falsity and scienter, the plaintiff filed an amended complaint challenging the same statements but also adding new allegations. Most notably the plaintiffs added an allegation that the defendants knew *both* that the company had failed to comply with the SPA *and* that its failure to do so could render the SPA non-binding and thereby obviate the FDA's obligation to approve the drug even if the trial was successful. In response to a new motion to dismiss by the defendants, the court held again that a number of the plaintiff's allegations were not actionable. But the court concluded that the new allegations regarding the consequences of the failure to comply with the SPA did adequately plead a securities violation.

Godinez v. Alere Inc.,
No. 1:16-cv-10766, --- F. Supp. 3d ---, 2017 WL 3623160 (D. Mass. Aug 23, 2017).

On August 23, the U.S. District Court for the District of Massachusetts granted the majority of Alere Inc.'s ("Alere") motion to dismiss a putative class action asserting securities claims against Alere and three of its senior executives. The plaintiffs alleged that Alere, which provides diagnostic testing for diseases and toxicology, violated the securities laws because it (i) failed to fully disclose the extent of alleged material weaknesses in its internal controls related to revenue recognition; (ii) failed to disclose the need to recall its blood coagulation testing products; (iii) failed to disclose alleged billing "improprieties" in two of its divisions; and (iv) failed to disclose that its foreign offices regularly engaged in conduct that allegedly violated the Foreign Corrupt Practices Act. The court dismissed all claims except those relating to the recall of the blood-testing products, holding that the plaintiffs failed to plead facts supporting a strong inference of prior knowledge about the alleged wrongdoing at the time of the relevant statements. As for the recall-related claim, the court concluded that a combination of numerous facts indicating that a recall would be likely created a plausible inference that Alere and that its senior management knew or recklessly hid information about its device and the likelihood of a recall.

PTC Therapeutics, Inc. Sec. Litig.,
16-cv-11224 (KMM) (AH), 2017 WL 3705801 (D.N.J. Aug. 28, 2017).

On August 28, the U.S. District Court for the District of New Jersey partially granted and partially denied a motion to dismiss claims against PTC Therapeutics ("PTC"). The suit was brought after the FDA found the company's new drug application for a drug in development to treat genetic mutations

was facially inadequate for review. The court dismissed claims asserting that the company knew but failed to disclose that it would not be able to meet certain FDA requirements, concluding that the plaintiffs failed to allege with specificity who supposedly knew that information or what they knew. The court also held, however, that the plaintiffs had pleaded facts sufficient to demonstrate that certain statements by the company—that the "totality" or "consistency" of the data showed that the product had a clinically meaningful benefit to patients—were misleading because the product had not been successful for most patients.

Colman v. Theranos, Inc.,
No. 16-cv-06822-NC, slip op. [ECF No. 143] (N.D. Cal. Sept. 6, 2017).

On September 6, the U.S. District Court for the Northern District of California excluded certain investors from a proposed class asserting securities claims against Theranos, Inc. ("Theranos"). The suit was brought by two individuals who bought Theranos shares indirectly through third parties, alleging that Theranos misled the public about the viability of the company's blood-testing technology. The court ordered that the defined class could not include "direct" investors for numerous reasons, including because they had agreed to forum-selection provisions in the relevant purchase agreements that precluded participation in the suit, many of the direct investors already had signed releases, the direct investors' claims were atypical of and conflicted with the plaintiffs', and the plaintiffs agreed to the limited class definition.

In re Dynavax Sec. Litig.,
No. 4:16-cv-06690-YGR, 2017 WL 4005584 (N.D. Cal. Sept. 12, 2017).

On September 12, the U.S. District Court for the Northern District of California granted a motion to dismiss a class-action lawsuit brought against Dynavax Technologies Corporation. The plaintiff investors had claimed that the biopharmaceutical company misrepresented the safety of its Heplisav vaccine for hepatitis B, eventually causing share prices to plunge when the FDA responded to the company's biologics license application by indicating that it was still reviewing certain cardiac events noted during a clinical study. Specifically, the investors' suit was based on their allegation that the company had failed to disclose the cardiac events as "Adverse Events of Special Interest" (or "AESIs"). They later acknowledged, however, that the cardiac issues did not actually qualify as AESIs, and the court therefore dismissed the complaint, holding that the "repeated incorporation of this same mistaken allegation undermines the viability of the entire complaint."

Notable Settlements

Woburn Ret. Sys. v. Salix Pharm. Ltd.,
No. 14-cv-8925, 2017 WL 3579892 (S.D.N.Y. Aug. 18, 2017).

On August 18, the U.S. District Court for the Southern District of New York granted final approval for a settlement in the lawsuit by shareholders against Salix Pharmaceuticals Ltd. ("Salix"). The lawsuit followed Salix's acquisition by Valeant Pharmaceuticals International, Inc., and related to an alleged scheme to manipulate inventory levels to create deceptive financial information. The total settlement consideration was $210 million. The court had granted preliminary approval to the settlement on April 5, 2017.

Rihn v. Acadia Pharm. Inc.,
No. 15-cv-575 (S.D. Cal. case filed Mar. 13, 2015).

On August 29, the plaintiffs requested that the U.S. District Court for the Southern District of California grant final approval of a $2.9 million settlement of in their lawsuit against Acadia Pharmaceuticals Inc. The lawsuit alleges that the company delayed an application for its Parkinson's disease drug and concealed manufacturing issues related to the drug. The court had granted preliminary approval to the settlement on June 9, 2017.

In re CTI BioPharma Corp. Sec. Litig.,
No. 2:16-cv-00216-RSL (W.D. Wash. case filed Feb. 12, 2016).

On September 1, the plaintiffs filed a motion for preliminary approval of a settlement with CTI BioPharma Corp. ("CTI") in the U.S. District Court for the Western District of Washington. The putative class of investors had sued the company and its executives for allegedly withholding information about patient deaths during clinical trials of a cancer drug, pacritinib. CTI's stock price dropped after the FDA halted trials in response to the deaths. In a complaint filed in February 2016, investors alleged that CTI misled investors about the safety and efficacy of pacritinib and should have disclosed that the drug is dangerous and that the new drug application would likely be withdrawn. The parties agreed to settle the case for $20 million after a mediation conducted by JAMS mediator Jed D. Melnick.

Guaquie v. Albany Molecular Research Inc.,
No. 14-cv-06637 (E.D.N.Y. case filed Nov. 12, 2014).

On September 7, the plaintiffs requested that the U.S. District Court for the Eastern District of New York grant final approval of a settlement with Albany Molecular Research Inc. The suit alleges that the company concealed the fact that a lab it owned in New Mexico had experienced a power outage that contaminated its product. The total settlement amount would be $2.9 million. The court had granted preliminary approval to the settlement on June 26, 2017.

Todd v. STAAR Surgical Co.,
No. 14-cv-05263 (C.D. Cal. case filed July 8, 2014).

On September 11, the plaintiffs submitted for final approval by the U.S. District Court for the Central District of California a settlement in a securities suit against STAAR Surgical Company. The suit alleges that the company failed to disclose that its manufacturing facility lacked adequate manufacturing and testing procedures. The court previously had denied the defendants' motion to dismiss. The parties agreed to settle the case for $7,000,000 after a mediation conducted by Michelle Yoshida of Phillips ADR. The court had granted preliminary approval to the settlement on July 10, 2017.

Harr v. Ampio Pharm. Inc.,
No. 2:15-cv-03474 (C.D. Cal. case filed May 8, 2015).

On September 29, the U.S. District Court for the Central District of California granted final approval to the settlement of a suit by shareholders against Ampio Pharmaceuticals Inc. ("Ampio"). The suit alleged that the company made misleading statements about its drug, Ampion, which was being developed to treat osteoarthritis of the knee. Allegedly, the company made positive comments about a study even though the study's results were tainted because, for example, the drug supply was shipped at the wrong temperature and the study was overseen by a single doctor who lacked independence. The total settlement amount is $3.4 million. The court had rejected a previous settlement on February 8, 2017, because the investors were seeking conditional class certification, which was not permitted at that stage of the litigation. The court had granted preliminary approval to the settlement on April 5, 2017.

Notable New Filings

Luo v. Sinovac Biotech Ltd.,
No. 17-cv-04883 (D.N.J. filed July 3, 2017).

On July 3, a potential class of investors filed a securities suit against Sinovac Biotech Ltd. and several of its executives alleging that the company made misleading statements regarding an alleged bribe paid to a member of the Chinese Food and Drug Administration (the "Chinese FDA"). The China-

based company produces a variety of vaccines. The suit followed the disclosure of documents purporting to show that the company's CEO bribed a member of the Chinese FDA to obtain approval for one of the company's vaccines. The complaint alleged that the company's failure to disclose the purported bribe was material because the alleged misconduct could increase regulatory scrutiny of the company's vaccines and jeopardize outstanding non-binding go-private offers. The case was filed by The Rosen Law Firm P.A. and Bronstein Gewirtz & Grossman LLC. The plaintiffs voluntarily dismissed the suit without explanation on September 6.

Gallagher v. Ocular Therapeutix, Inc.,
No. 17-CV-05011 (D. N.J. filed July 7, 2017).

On July 7, a potential class of investors filed a suit against Ocular Therapeutix, Inc. ("Ocular") alleging that the company made misleading statements about Dextenza, a drug being developed for treatment of post-surgical pain and inflammation, as well as inflammatory dry-eye disease. The complaint alleges that Ocular failed to disclose that more than 50% of lots manufactured contained defective product and that these manufacturing defects could imperil the drug's FDA approval. The case was filed by The Rosen Law Firm P.A.

Mahoney v. Foundation Medicine, Inc.,
No. 17-cv-11394 (D. Mass. filed July 28, 2017).

On July 28, investors filed a class-action securities suit against Foundation Medicine, Inc. ("Foundation") alleging violations of the Exchange Act. Foundation develops, manufactures and sells genomic-analysis diagnostic tests for solid and circulating cancers. The complaint alleges that the company made false and misleading statements and/or failed to disclose adverse information regarding (i) the reimbursement process and likelihood of Medicare coverage for Foundation's tumor tests; and (ii) the company's financial guidance. The case was filed by Robbins Geller Rudman & Dowd LLP, Hutchings Barsamian Mandelcorn LLP, and Levi & Korsinsky LLP.

Shanawaz v. Intellipharm. Int'l Inc.,
No. 17-cv-05761 (S.D.N.Y filed July 28, 2017).

On July 28, a potential class of investors filed a securities suit against Intellipharmaceutics International Inc. ("Intellipharma") alleging that the company misled investors about how certain it was that its abuse-deterrent opioid painkiller Rexista actually prevented abuse. According to the plaintiffs, Intellipharma failed to disclose that it had not conducted a human abuse liability study in support of its New Drug Application for Rexista. Similarly, they allege that the company did not include sufficient studies to support abuse-deterrent label claims for the drug and that it failed to submit related data in support of its New Drug Application. The case was filed by Levi & Korsinsky LLP. A similar suit was filed in the same court by Pomerantz LLP and Bronstein, Gewirtz & Grossman, LLC, on August 10 under the caption *Braverman v. Intellipharmaceutics International Inc., et al.*, No. 17-cv-6045.

OZ ELS Master Fund Ltd. v. Teva Pharm. Indus. Ltd.,
No 3:17-cv-01314 (D. Conn. filed Aug. 3, 2017).

On August 3, a group of affiliated hedge funds accused Teva Pharmaceutical Industries Ltd. and former executives of lying to investors about its alleged rigging of generic drug prices, causing its stock price to drop when government agencies started investigating the drugmaker and rumors about potential criminal charges began circulating. The action, which was filed by Bernstein Litowitz Berger & Grossmann LLP, was not brought as a putative class action, but instead on behalf of the named funds only. A similar case was filed on behalf of a putative class of investors in the Eastern District of Pennsylvania by Kaufman, Coren & Ress, P.C., on August 21 under the caption *Elliot Grodko, et al. v. Teva Pharmaceutical Industries Ltd.*, *et al.*, No. 17-cv-03743.

Huang v. Depomed, Inc.,
No. 17-cv-04830 (N.D. Cal. Filed Aug. 18, 2017).

On August 18, investors filed a class-action securities suit against Depomed, Inc. following a disclosure by the company that it had received an information request from a member of the U.S. Senate related to the promotion of opioids, as well as subpoenas from the Maryland Attorney General and the U.S. Department of Justice. The complaint alleges that the company engaged in questionable practices in connection with its sales and marketing of opioid products, which subjected it to the risk of increased legal and regulatory scrutiny, and that the company misled investors by failing to disclose those risks. The case was filed by Pomerantz LLP.

Critchley v. Dr. Reddy's Labs. Ltd.,
No. 3:17-cv-6436 (D.N.J. filed on Aug. 25, 2017)

On August 25, a proposed class of investors filed a class action against Dr. Reddy's Laboratories Ltd. ("Dr. Reddy's") and several of its executives, alleging that the company misled investors about quality-control issues at its Indian manufacturing facilities, following U.S. and German regulators' raising concerns about those facilities. The plaintiffs claim that the company and its executives told investors that it had appropriate quality-control policies in place for its facilities. The company later revealed that the FDA had sent a warning letter saying that Dr. Reddy's failed to control record access and data changes, to properly investigate discrepancies, and to follow written procedures to ensure products were sterile. The complaint also alleges that a German regulator revoked one of the company's subsidiary's compliance certificate. The case was filed by The Rosen Law Firm P.A.

DeSmet v. Intercept Pharm. Inc,
No. 17-cv-07371 (S.D.N.Y. filed September 27, 2017)

On September 27, a putative class-action securities suit was filed against Intercept Pharmaceuticals Inc. ("Intercept") alleging that the company made materially false and misleading statements regarding its business and the safety of its lead product candidate, a bile acid analog for the treatment of primary biliary cholangitis. The suit follows a letter sent by Intercept warning physicians of overdose risks associated with the product, advising them that the drug had been connected to liver injury and even death, and a subsequent letter issued by the FDA with similar warnings. The case was filed by Pomerantz LLP.

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