Life Sciences Securities Litigation Activity in Q4 2017: Digest of Notable Decisions, Settlements, and New Filings

January 23, 2018

Notable Decisions

Federal District Courts

Princeton Ophthalmic, LLC v. Corinthian Ophthalmic, Inc.,
No. 14-CV-05485 (PGS), 2017 WL 4543688 (D.N.J. Oct. 10, 2017).

On October 10, the U.S. District Court for the District of New Jersey denied both plaintiff's and defendant's motions for summary judgment in this action involving allegations that Corinthian Ophthalmic, Inc. ("Corinthian") misrepresented the development status of a device for delivering ocular drugs called "WHISPER." Corinthian is a privately held medical-device company based in North Carolina. The plaintiff alleges that the defendants made certain misstatements in connection with the sale to plaintiff of 19,900 shares of Corinthian's common stock, including statements that WHISPER was capable of sealing drugs in an internal and non-permeable collapsible reservoir, while the defendants knew that the product was not generally able to do so. Similarly, the defendants allegedly misrepresented that the device had "successfully dosed" 81 popular drugs because only a component of the device, and not the device itself, had even been tested—and with mixed results, at that. After recounting the available record, the court concluded that there were still numerous genuine disputes of material fact as to whether Corinthian misrepresented or omitted facts regarding the WHISPER device's engineering capabilities, and accordingly denied both parties' motions.

Patel v. Seattle Genetics, Inc.,
No. C17-41RSM, 2017 WL 4681380 (W.D. Wash. Oct. 18, 2017).

On October 18, the U.S. District Court for the Western District of Washington granted a motion to dismiss the complaint against the defendants, Seattle Genetics, Inc. ("Seattle Genetics") and certain individual executives of the company. The plaintiff class, comprised of holders of Seattle Genetics stock, alleged that Seattle Genetics misled investors regarding the safety of a drug being developed for the treatment of a type of blood cancer. In particular, the complaint alleges that Seattle Genetics repeatedly claimed that the drug was superior to its closest competitor drug, Mylotarg, because it did not share the toxic side effects of Mylotarg, including a high risk of liver disease. According to the complaint, however, Seattle Genetics failed to disclose internal information indicating that its drug actually posed a high risk of liver toxicity. The defendants moved to dismiss, and the court granted the motion. First, the court held that the complaint sufficiently pleaded actionable misrepresentations or omissions based on the defendants' failure to disclose certain toxicity events experienced by patients while simultaneously making positive statements about the absence of significant toxicity. Thereafter, however, the court concluded that the complaint failed to allege facts sufficient to support an inference that the defendants had actual knowledge of the risk of liver toxicity, or acted with recklessness in that regard, at the time they made public representations regarding the drug's safety. Because the court determined that the plaintiffs could cure the deficiencies in an amended complaint, the court granted leave to amend.

Gallagher v. Ocular Therapeutix, Inc.,
No. CV175011SDWLDW, 2017 WL 4882487 (D.N.J. Oct. 27, 2017).

On October 27, the U.S. District Court for the District of New Jersey granted a motion filed by Ocular Therapeutix, Inc. ("Ocular") and several of its executives to transfer three putative class actions to the District of Massachusetts on *forum non conveniens* grounds. The parties agreed that the suit could have been brought in the District of Massachusetts, leaving the court to decide whether it would be in the public and private interest to transfer the case. The court found that the District of Massachusetts was the preferable forum because, among other reasons, Ocular is based there, the class-action plaintiffs are spread across the country and therefore have minimal competing interest in using another forum, and Massachusetts courts may have a stronger interest in litigating a suit aimed at a Massachusetts-based corporation.

In re Psychemedics Corp. Sec. Litig.,
No. CV 17-10186-RGS, 2017 WL 5159212 (D. Mass. Nov. 7, 2017).

On November 7, the U.S. District Court for the District of Massachusetts granted a motion to dismiss a putative class action filed against Psychemedics Corp. ("Psychemedics") and its CEO. Psychemedics is a U.S. corporation that provides laboratory services for drug testing. The plaintiffs alleged that the defendants misled investors by optimistically touting the prospects of business expansion in Brazil, while failing to disclose that Psychemedics' exclusive Brazilian partner was involved in an illicit scheme that violated Brazilian antitrust laws. The defendants moved to dismiss the suit on the grounds that the plaintiffs failed to plead scienter with sufficient particularity. The court granted the defendants' motion because the complaint failed to allege any facts that would support an inference—much less provide direct evidence—that the defendants had any inkling of the Brazilian scheme during the period they were accused of failing to bring the scheme's existence to light, and because the plaintiffs' other efforts to establish scienter were speculative and unconvincing.

In re Aveo Pharm., Inc. Sec. Litig.,
No. CV 13-11157, 2017 WL 5484672 (D. Mass. Nov. 14, 2017).

On November 14, the U.S. District Court for the District of Massachusetts granted class certification for a class comprised of shareholders of Aveo Pharmaceuticals, Inc. ("Aveo"). The plaintiffs allege that Aveo failed to disclose various communications from the FDA expressing significant concern about the safety of tivozanib, a drug the company is developing for the treatment of kidney cancer. Aveo did not oppose certification of the class, and the court accordingly found the class to satisfy the requirements of Rule 23(b)(3). Aveo did, however, dispute the plaintiffs' proposed class period. Aveo argued that the class period should be cut off at April 29, 2013, the last day of trading before the FDA made public a report outlining its safety concerns about tivozanib. The next day (April 30), the FDA released the report before the market opened, and Aveo's shares fell 31.31%. The plaintiff class defined the class period to extend until May 1, 2013, the last trading day before the FDA held a hearing to discuss the April 29 report. That hearing resulted in a near-unanimous vote against approving tivozanib. After the May 2 hearing, Aveo's shares fell nearly 50%. The court held that the plaintiffs' proposed class period was proper, as the committee hearing provided, for the first time, the FDA's complete and definitive view on tivozanib's approval. The report released on April 29 may have disclosed some of the salient data and study conclusions, but the FDA's full view of Aveo's NDA for tivozanib was not revealed until the May 2 hearing. As such, until that time a reasonable investor could still have been misled by Aveo's alleged misrepresentations and omissions.

Huellemeier ex rel. Teva Pharm. Indus. Ltd. Emp. Stock Purchase Plan v. Teva Pharm. Indus. Ltd.,
No. 1:17-CV-485, 2017 WL 5523149 (S.D. Ohio Nov. 17, 2017).

On November 17, the U.S. District Court for the Southern District of Ohio granted a motion by the defendants, Teva Pharmaceutical Industries Limited ("Teva") and three of its officers, to transfer the action to the District of Connecticut, where two class-action suits against Teva were filed earlier in 2017.[1] The plaintiff in this action alleges that Teva made a number of material misstatements and omissions in its financial disclosures, including failing to disclose various investigations by the Department of Justice and the Connecticut Attorney General's Office into suspected price-fixing and violations of the Foreign Corrupt Practices Act. The investigations at issue stemmed from purported collusion between Teva and other generic drug companies to artificially inflate the price of generic drugs. The plaintiff attempted to bring this suit as a derivative action on behalf of all current or former employees who purchased Teva stock through Teva's Employee Stock Purchase Plan during the period at issue, or, alternatively, as a class action on behalf of the same individuals. After concluding that the suit was largely duplicative of the cases filed earlier and pending in Connecticut, the court granted Teva's motion to transfer under the first-to-file rule.

HsingChing Hsu v. Puma Biotech. Inc., et al.,
No. SACV 15–0865 AG (JCGx), 2017 WL 6210803 (C.D. Cal. Dec. 8, 2017).

On December 8, the U.S. District Court for the Central District of California certified the class in this case involving alleged material misrepresentations and omissions concerning the use, testing, and effectiveness of a drug being developed by Puma Biotechnology, Inc. ("Puma") primarily for the treatment of breast cancer. The alleged inaccuracies relate to the results of clinical trials. The plaintiffs allege that the company overstated the efficacy of the drug compared to a placebo and that the results were not in line with prior trials. The court's ruling evaluated the putative class with respect to the requirements of Federal Rules of Civil Procedure 23(a) and 23(b), and determined that plaintiffs had satisfied each of the requirements necessary for certification as a Rule 23(b)(3) class. Although Puma denies the allegations in the complaint, it did not oppose the certification motion.

Notable Settlements

Todd Schueneman et al. v. Arena Pharm. Inc. et al.,
No. 3:10-cv-01959 (S.D. Cal. filed September 9, 2010).

On November 7, Arena Pharmaceuticals Inc. ("Arena") agreed to a settlement with a proposed class of investors for $24 million. The plaintiff class alleged that Arena had misled investors regarding the safety of a diet drug that the company was developing. The drug was approved by the FDA in 2012 and is currently on the market. However, investors allege that they were harmed because Arena concealed information about a possible link between the drug and cancer, as well as setbacks during the approval process related thereto, which caused a 40% stock drop when revealed to the public. Arena intends to satisfy the settlement amount with $12,025,000.00 in cash and $11,975,000.00 in Arena common stock. The settlement is based on a mediator's proposal by former federal district judge Layn Phillips, which the parties accepted. It comes after the Ninth Circuit Court of Appeals reversed the district court's dismissal of the suit and the putative class plaintiffs defeated a renewed motion to dismiss. The court granted preliminary approval of the settlement on November 30.

[1] The two other cases are: *Ontario Teachers' Pension Plan Bd. v. Teva Pharm. Indus., Ltd.*, No. 3:17-cv-00558 (D. Conn. filed April 4, 2017), and *OZ ELS Master Fund, Ltd. v. Teva Pharm. Indus., Ltd.*, No. 3:17-cv-01314 (D. Conn. filed August 3, 2017).

In re Ariad Pharm. Inc. Sec. Litig.,
No. 13-cv-12544 (D. Mass. filed October 10, 2013).

On November 29, the parties filed a joint motion for approval of a settlement agreement in which Ariad Pharmaceuticals Inc. ("Ariad") agreed to pay $3.5 million to resolve a proposed class action involving allegations that Ariad misled investors about safety issues related to a drug being developed to treat chronic myeloid leukemia. According to the plaintiffs, Ariad improperly continued to express public optimism regarding FDA approval of the proposed labeling of the drug, notwithstanding repeated FDA communications expressing serious concern about the drug's safety. The suit was prompted by the announcement that the FDA had not approved Ariad's labeling proposal. After the district court dismissed the case in March 2015, the First Circuit Court of Appeals reversed with respect to certain alleged misstatements, reviving the case. The district court dismissed defendants' subsequent motion for judgment on the pleadings, and the parties thereafter participated in a mediation with retired district court judge Faith Hochberg, which resulted in the settlement. The court has not yet ruled on the motion for preliminary approval.

Notable New Filings

Smith v. Antares Pharma, Inc., et al.,
No. 3:17-cv-08945-MAS-DEA (D.N.J filed Oct. 23, 2017).

On October 23, the plaintiff filed a putative class action securities suit against Antares Pharma, Inc. ("Antares") and its CEO and CFO. Antares develops pharmaceutical-delivery systems such as needle-free injector systems and transdermal gel technologies. The plaintiff alleges that Antares and the officer defendants made false or misleading statements related to an NDA that Antares filed for Xyosted, one of its lead product candidates. According to the plaintiff, the defendants failed to disclose that Antares had provided insufficient data to the FDA in connection with the NDA and overstated the approval prospects for Xyosted. Antares' stock price dropped when the company disclosed that it had received a letter from the FDA notifying Antares of deficiencies precluding continued discussion of labeling and post-marketing requirements/commitments and, later, a Complete Response Letter from the FDA indicating that it could not approve the NDA in its present form. The case was filed by Lite DePalma Greenberg, LLP and Pomerantz LLP.

Price v. XBiotech, Inc., et al.,
No. 1:17-cv-01023-SS (W.D. Tex. filed Oct. 26, 2017).

On October 26, the plaintiff filed a putative class action against XBiotech, Inc. ("XBiotech") and two of its senior executives. XBiotech is a clinical-stage biopharmaceutical company that develops monoclonal antibodies from humans for the treatment of a variety of diseases. During the relevant period, XBiotech was focused on developing Xilonix, an antibody to be used in the treatment of symptomatic colorectal cancer. According to the complaint, the defendants misrepresented the study endpoints for a Phase III registration trial of Xilonix conducted in Europe and failed to disclose that the results of the study were inconclusive, instead touting the study as successful. The plaintiff further alleges that XBiotech made misleading claims about the rate of improvement and extension of lifespan among patients in clinical trials and failed to disclose that its studies would not support the approval of a Marketing Authorization Application by European regulators. The plaintiff claims that XBiotech's stock price dropped approximately 40% in one day "when the truth about the Phase III results" was revealed. The case was filed by Levi & Korsinsky, LLP and The Bilek Law Firm, L.L.P.

Emerson v. Genocea Biosciences, Inc., et al.,
No. 1:17-cv-12137-PBS (D. Mass. filed Oct. 31, 2017).

On October 31, the plaintiff filed a putative class action against Genocea Biosciences, Inc. ("Genocea") and its CEO and CFO. Genocea is a biopharmaceutical company based in Massachusetts that develops novel vaccines and immunotherapies. During the relevant period,

Genocea's lead product candidate was GEN-003, an immunotherapy product for treating genital herpes. The plaintiff alleges that the defendants failed to disclose that Genocea's finances were insufficient to support Phase III trials for GEN-003 and overstated the prospects for GEN-003 in light of the company's financial situation. According to the complaint, when the company revealed the truth about its financial condition by announcing that it was ceasing all GEN-003 spending and substantially downsizing its workforce, Genocea's stock price declined 76.5% in one day. The case was filed by Block & Leviton LLP and Scott & Scott, LLP. A related case was filed by Pomerantz LLP in the District of Massachusetts on November 3 under the caption *Heaney v. Genocea Biosciences Inc., et al.*, No. 17-cv-12168. An additional related cased was filed by Levi & Korinsky LLP under the caption *Walker v. Genocea Biosciences Inc., et al.*, No. 17-cv-12474.

TIAA-CREF Large-Cap Growth Fund, et al. v. Allergan PLC, et al.,
No. 2:17-cv-11089 (D.N.J. filed Nov. 3, 2017).

On November 3, a group of funds filed a securities suit against Allergan, PLC ("Allergan"), alleging that Allergan and its top executives colluded with its competitors in the generic drug market to fix prices for at least seven generic drugs. The drugs identified were key revenue drivers for Allergan. The plaintiff funds allege that Allergan's public statements throughout the period of collusion fraudulently concealed the defendants' illegal conduct and, in doing so, misrepresented the generic drug market's competitiveness, misled investors about both the cause of Allergan's financial success and Allergan's future prospects, and failed to disclose the significant risk of state and federal prosecution. Allergan's share price fell on the news of an industry-wide investigation into price fixing, which implicated Allergan as a possible participant. The case was filed by Seeger Weiss, LLP and Robins Geller Rudman & Dowd, LLP.

Miriyala v. Novan, Inc., et al.,
No. 1:17-cv-00999-UA-JEP (M.D.N.C. filed Nov. 3, 2017).

On November 3, the plaintiff filed a putative class action securities suit against Novan, Inc. ("Novan"), several current and former executives and directors, and a group of underwriters related to alleged misstatements and omissions in the registration statement and prospectus for Novan's IPO in September 2016. Novan is a late-stage pharmaceutical company that develops dermatology therapies. Novan's lead product candidate during the relevant period of the suit was SB204, a topical gel to treat acne. The plaintiff alleges that Novan's statements about two "identical" Phase III clinical trials for SB204 were false and misleading for a variety of reasons, including because the trials were not, in fact, identical. The plaintiff claims that a series of "disclosures" about SB204, including that the two trials were not identical and that some executives were leaving the company, caused several price drops in 2017. The case was filed by McDaniel & Anderson, LLP, Robins Geller Rudman & Dowd, LLP, and Johnson Fistel, LLP.

Pelletier v. Endo Int'l PLC, et al.,
No. 2:17-cv-05114-JP (E.D. Pa. filed Nov. 14, 2017).

On November 14, the plaintiff filed a putative class action against Endo International plc ("Endo") and three former or current executives asserting securities claims related to an alleged generic price-fixing scheme. The plaintiff alleges that Endo, an Irish pharmaceutical company that acquired Par Pharmaceutical Companies Inc. ("Par") in 2015, made false and misleading statements about the competitive advantages of the Par acquisition—including by failing to disclose that Par colluded with its industry peers to fix generic drug prices in violation of the federal antitrust laws—which were unsustainable given that they were derived at least in part from Par's illegal conduct. The plaintiff claims that, as Par's allegedly illegal conduct was revealed to the public through a series of disclosures, the stock drops associated with those revelations harmed investors. The case was filed by Pomerantz LLP and Pribanic & Pribanic.

Forman v. Meridian Bioscience, Inc., et al.,
No. 1:17-cv-00774-SJD (S.D. Ohio filed Nov. 15, 2017).

On November 15, the plaintiff filed a putative class action against Meridian Bioscience, Inc. ("Meridian") and its CEO and CFO based on allegations that Meridian presented a deceptively optimistic business outlook while concealing concerns voiced by the FDA regarding blood-testing systems of a company that Meridian acquired in 2016. The plaintiff alleges that Meridian falsely touted the high accuracy of the blood-testing technology in several SEC filings while, in fact, the tests provided inaccurate results, as confirmed by an FDA press release warning consumers about the inaccuracy of the tests. According to the complaint, Meridian's stock price dropped approximately 8% when it was revealed that the testing systems were not accurate. The case was filed by Levi & Korsinsky, LLP and Perantinides & Nolan Co., L.P.A.

Hague v. Acorda Therapeutics, Inc., et al.,
No. 1:17-cv-08997-DLC (S.D.N.Y. filed Nov. 17, 2017).

On November 17, the plaintiff filed a putative class action against Acorda Therapeutics, Inc. ("Acorda") and several senior executives claiming that Acorda made false and misleading statements about a drug that it acquired. Acorda is a biotechnology company that specializes in the development of therapies for neurological disorders. In January 2016, Acorda announced an agreement to acquire Biotie Therapies Corporation ("Biotie"). In its press release announcing the acquisition, Acorda stated that it would acquire worldwide rights to tozadenant, a drug that Biotie was developing to treat Parkinson's disease, which was in Phase III clinical trials. Acorda completed the Biotie acquisition in September 2016. On November 15, 2017, Acorda disclosed that several deaths occurred during tozedenant's final-stage studies, and that, as a result, Acorda had suspended any new enrollment in the long-term safety studies. The plaintiff alleges that Acorda failed to disclose that tozadenant entailed significant undisclosed safety risks and overstated tozadenant's approval prospects and commercial viability (as well as the related benefits of the Biotie acquisition). The plaintiff alleges that Acorda's stock price dropped nearly 40% when the news of the patient deaths were disclosed, which caused investors significant damages. The case was filed by Pomerantz LLP.

Rose v. Array Biopharma Inc., et al.,
No. 1:17-cv-02789-KLM (D. Colo. filed Nov. 20, 2017).

On November 20, the plaintiff filed a putative class-action securities suit against Array Biopharma, Inc. ("Array"), it former CEO and CFO, and its current CFO, alleging that the defendants made false and misleading statements about the sufficiency of data from clinical trials of a new cancer drug. Array is a biopharmaceutical company that specializes in developing small-molecule drugs to treat cancer. One of Array's lead cancer drugs was evaluated in multiple trials and combinations, including a Phase III study against a comparable drug in patients with a certain type of melanoma that it used as a basis for an NDA filed with the FDA. The plaintiff alleges that although the defendants repeatedly claimed that the Phase III study met its primary endpoint of extending median progression-free survival as compared with the comparable drug, the study actually failed to demonstrate sufficient clinical benefit to support FDA approval. According to the complaint, the defendants were aware that this lack of supporting data meant that the cancer drug was unlikely to receive FDA approval. When Array informed the market that it was withdrawing the NDA based on the lack of sufficient data, the company's stock price dropped. The case was filed by Berens Law LLC and Levi & Korsinsky, LLP. A related case was filed by Pomerantz LLP, also in the District of Colorado, on November 28 under the caption *Nauman v. Array Biopharma Inc.*, No. 17-cv-02848.

Gagnon v. Alkermes plc, et al.,
No. 1:17-cv-09178-WHP (S.D.N.Y. filed Nov. 22, 2017).

On November 22, the plaintiff filed a putative class action against Alkermes plc ("Alkermes") and its CEO and CFO alleging that the defendants failed to disclose that Alkermes engaged in deceptive marketing that drove unsustainable revenues. Alkermes is a biopharmaceutical company focused on

the development of treatments for, among other diseases, addiction. The plaintiff alleges that Alkermes systemically engaged in deceptive marketing campaigns to influence policymakers to choose its addiction-drug for use in addiction-treatment programs over more scientifically proven and efficacious alternatives. This scheme allegedly subjected Alkermes to heightened regulatory and legislative scrutiny, such that its reported revenues were unsustainable and its financial statements were false and misleading. In June 2017, a press report allegedly revealed Alkermes' marketing tactics and the absence of any science supporting claims of its addiction drug's efficacy, which the plaintiff claims caused the company's stock price to decline. On November 6, 2017, the United States Senate announced that it was opening an investigation into Alkermes' sales practices for the addiction treatment; the plaintiff claims that news of the investigation caused the stock price to drop again. The case was filed by Pomerantz LLP and Bronstein, Gewirtz & Grossman, LLC.

Westmoreland Cnty. Emp. Ret. Sys. v. OvaScience, Inc. et al.,
No. 17-CV-12312-IT (D. Mass. filed Nov. 22, 2017).

On November 22, the plaintiff filed a putative class action against OvaScience, Inc. ("OvaScience"), certain of its senior executives and directors, and the underwriters of a January 2015 secondary offering. OvaScience develops new treatments for infertility. One of OvaScience's treatments is designed to improve the health of a woman's eggs by using mitochondria from the woman's egg-precursor cells. The plaintiff alleges that OvaScience "hyped" that treatment but failed to disclose in its offering materials that the science behind the treatment was untested and that the patients who had received the treatment in 2014 did not achieve a pregnancy success rate that was significantly higher than the rate achieved without OvaScience's treatment. The plaintiff also alleges that the defendants made false or misleading statements about why OvaScience conducted certain clinical trials outside of the United States and about its expected profitability. The case was filed by Hutchings Barsamian Mandelcorn, LLP and Scott + Scott LLC.

If you have any questions regarding the matters covered in this publication, please contact any of the lawyers listed below or your regular Davis Polk contact.

Bruce K. Dallas	**650 752 2022**	**bruce.dallas@davispolk.com**
Alan F. Denenberg	**650 752 2004**	**alan.denenberg@davispolk.com**
Michael S. Flynn	**212 450 4766**	**michael.flynn@davispolk.com**
Sophia Hudson	**212 450 4762**	**sophia.hudson@davispolk.com**
Deanna L. Kirkpatrick	**212 450 4135**	**deanna.kirkpatrick@davispolk.com**
Edmund Polubinski III	**212 450 4695**	**edmund.polubinski@davispolk.com**
Neal A. Potischman	**650 752 2021**	**neal.potischman@davispolk.com**
James P. Rouhandeh	**212 450 4835**	**rouhandeh@davispolk.com**
Richard D. Truesdell, Jr.	**212 450 4674**	**richard.truesdell@davispolk.com**
Brian S. Weinstein	**212 450 4972**	**brian.weinstein@davispolk.com**
