DECHERT SURVEY 2022 EDITION: DEVELOPMENTS IN SECURITIES FRAUD CLASS ACTIONS AGAINST U.S. LIFE SCIENCES COMPANIES

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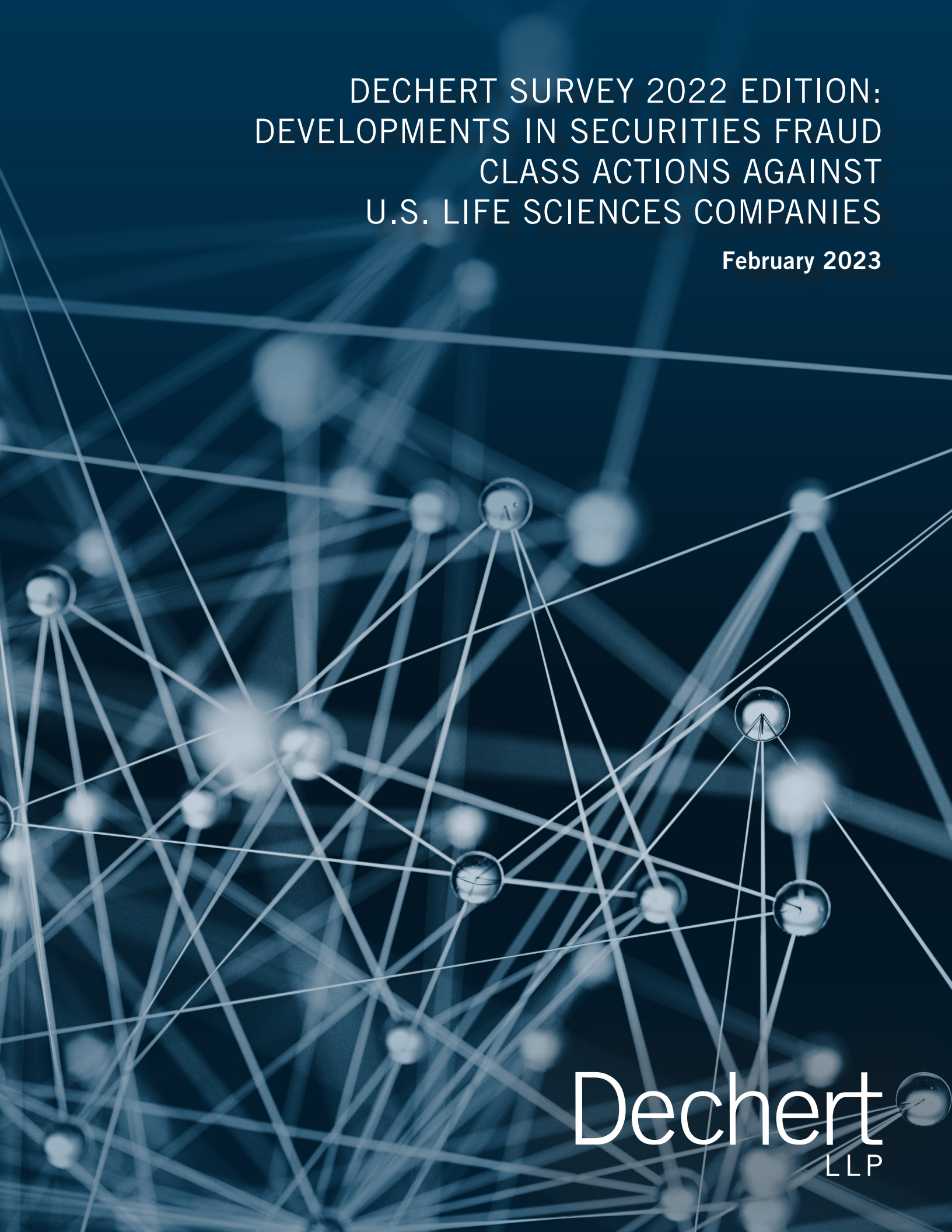

Dechert LLP

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Introduction

In 2022, the total number of securities class action complaints filed remained below the more elevated levels we saw during 2017-2020, but life sciences companies were nonetheless still popular targets among these filings.[1] In this White Paper, we analyze and discuss trends identified in filings and decisions from 2022 so that prudent life sciences companies can continue to take heed of the results.

Plaintiffs filed a total of 43 securities class action lawsuits against life sciences companies in 2022, which represented almost one in four securities class action lawsuits. Filings against life sciences companies in 2022 represented a 27.1% decrease from the previous year, and a 51.1% decrease from five years prior. Of these cases, the following trends emerged:

- Consistent with historic trends, the majority of suits were filed in the Second, Third and Ninth Circuits, with a 54.5% decrease in suits filed in the Ninth Circuit – 22 in 2021 and 10 in 2022. The Third Circuit saw a 44.4% decrease in filings from the previous year – from nine in 2021 to five in 2022. For district courts within these circuits, the Southern District of New York had the most filings, with 10 overall.
- A few plaintiff law firms were associated with about three-fourths of the first filed complaints against life sciences companies: Pomerantz LLP (18 complaints), Glancy Prongay & Murray LLP (five complaints) and Bronstein, Gewirtz & Grossman, LLC and Kessler Topaz Meltzer & Check LLP (tied with four complaints each).[2]
- Slightly more claims were filed in the first half of 2022 than in the second half, with 24 complaints filed in the first and second quarters, and 19 complaints filed in the third and fourth quarters.
- About a quarter of the securities fraud cases brought against life sciences companies (11 cases) were filed against companies with COVID-19-related products and services.

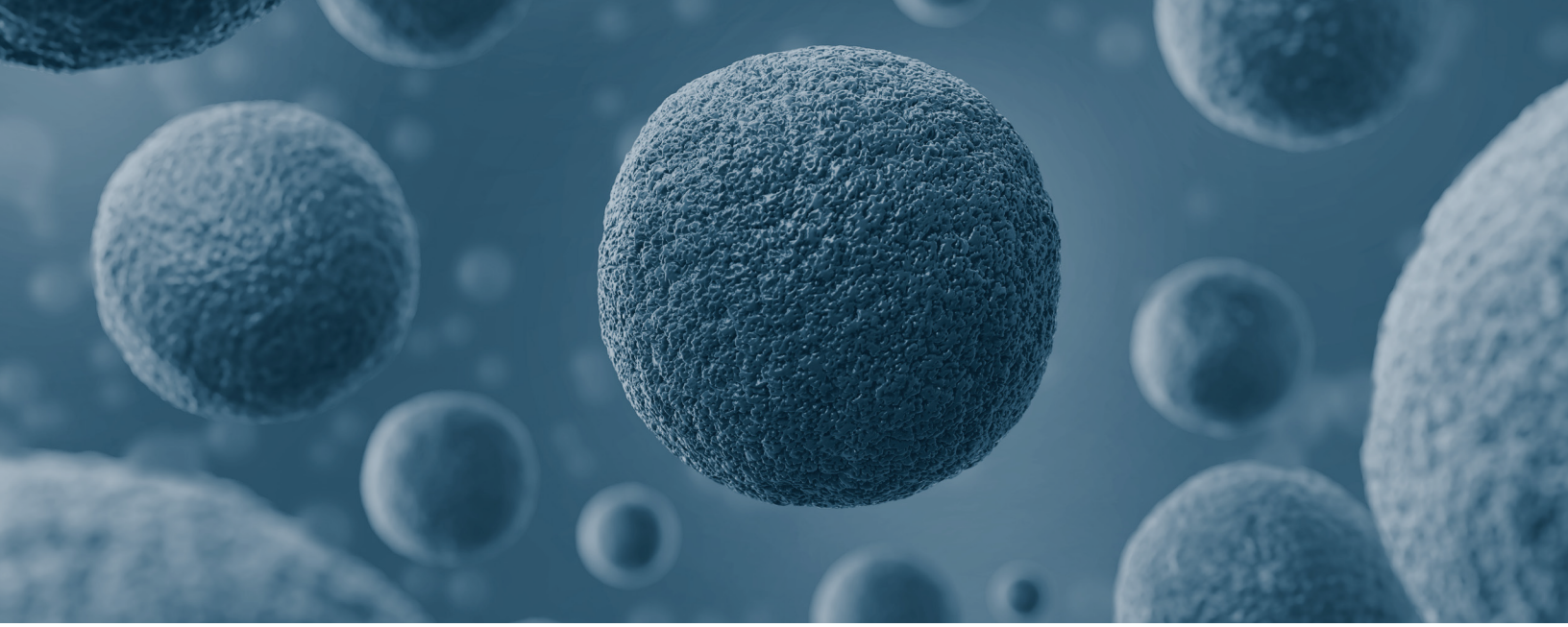
An examination of the types of cases filed in 2022 reveals continuing trends from previous years.

- About 48.8% of claims, or 21 of 43 claims, involved alleged misrepresentations regarding product efficacy and safety,[3] with many of these cases involving alleged misrepresentations regarding certain negative side effects associated with leading product candidates, which could potentially impact the likelihood of Food and Drug Administration ("FDA") approval.
- About 39.5% of the claims, or 17 of 43 claims, arose from alleged misrepresentations regarding the sufficiency of the applications submitted to the FDA.
- Approximately 20.9% of the claims, or nine of 43 of claims, alleged misrepresentations regarding purported unlawful conduct in both the United States and abroad, including (but not limited to) illegal kickback schemes, criminal investigations and inadequate internal controls in financial reporting.

1 In 2022, 197 securities class actions were filed. *Cornerstone Research*, Stanford Univ., *Securities Class Action Clearinghouse: Filings Database*, SECURITIES CLASS ACTION CLEARING HOUSE (last visited Feb. 6, 2023). In 2020, 318 securities class actions were filed while 211 were filed in 2021. *Id.* Cornerstone Research reported 208 class action filings in 2022 and 218 in 2021, which included filings in both federal and state courts. *Securities Class Action Filings 2022 Year in Review*, Cornerstone Research, 1 (2023), https://www.cornerstone.com/wp-content/uploads/2023/01/Securities-Class-Action-Filings-2022-Year-in-Review.pdf

2 These figures are based on the first complaint filed.

3 This category also includes any issues at clinical trial. This category does not include deficiencies at the manufacturing site, nor are product deficiencies that arise from the deficiencies at the manufacturing site included in this category.



- About 25.6% of the claims, or 11 of 43 claims, involved alleged misrepresentations of material information made in connection with proposed mergers, sales, initial public offerings ("IPOs"), offerings and other transactions.[4]

Courts throughout the country issued decisions in 2022 involving securities fraud actions against life sciences companies, including:

- Claims that arose in the development phase, such as cases involving products failing clinical trials that are required for FDA approval or products not approved by the FDA. In these development phase cases, courts were more likely to grant motions to dismiss in full than they were to deny them, either in whole or in part.
- Claims that were independent of or arose after the development process. In these post-development cases, courts were more likely to grant motions to dismiss in full than they were to deny them, either in whole or in part.
- Claims based on the financial management of life sciences companies. In these cases, courts were more likely to deny them in part.

Given the numbers from 2022 and recent years' filings, and accounting for residual impact of the COVID-19 pandemic, there is no indication that the filings of securities claims against life sciences companies are going to slow down any time soon, and plaintiffs continue to have mixed results in surviving a motion to dismiss. The decisions in 2022 resulted in a variety of outcomes, with 21 opinions decided in favor of defendants,[5] 10 opinions[6] denying motions to dismiss and 11 opinions in which only partial dismissal was achieved.[7] These numbers illustrate how life sciences companies remain attractive targets for class action securities fraud claims. Therefore, companies should continue to stay abreast of recent developments and implement best practices to reduce their risk of being sued.

4 It should be noted that 79.1%, or 34 of 43 claims, of all 2022 filings fell in more than one category.

5 Throughout this White Paper, the terms "company" or "defendants" may be used to also include individual officers or directors.

6 This includes two cases where the motions were denied as moot because of settlements. *See In re Sesen Bio, Inc. Sec. Litig.*, No. 21-cv-7025 (S.D.N.Y. Aug. 31, 2022); *Patrick McDermid v. Inovio Pharm.s, Inc. et al.*, 20-cv-1402 (E.D. Pa. Aug. 31, 2022).

7 The opinions were identified by evaluating the dockets of "Healthcare" filings from 2020 and 2021 and reviewing the docket for a disposition decision taking place in 2022. Additionally, opinions were also identified through Westlaw searches of dispositive orders involving the Private Securities Litigation Reform Act ("PSLRA") between January 1 and December 31, 2022 and cross-referencing them against filters in the Securities Class Action Clearinghouse filings by "Healthcare." They may not encompass all dispositive opinions. In many cases, the court dismissed the operative complaint without prejudice and amended complaints are anticipated.
We did not include decisions in which there was a partial order. *See Hashem v. NMC Health PLC, et al.,* No. 2:20-cv-02303 (C.D. Cal. Aug. 16, 2022) (voluntarily dismissed without prejudice). In *NMC Health PLC*, the Partial Order certified the settlement class for settlement purposes only; awarded fees and reimbursement expenses to Co-Lead Counsel; and the Court also awarded each Lead Plaintiff a compensatory award to be paid from the settlement fund.

Life Sciences Companies Remain Popular Targets for Securities Fraud Litigation

In recent years, life sciences companies have been targets of securities fraud lawsuits, and 2022 was no exception. This survey is intended to give an end-of-year overview of life sciences securities lawsuits in 2022. First, we analyze the number of cases filed, including trends relating to the applicable jurisdiction, the types of companies targeted and the parallels between underlying claims. Next, we analyze the securities class action decisions rendered in 2022 and how they impact the legal landscape of life sciences claims. Finally, we set forth issues and best practices life sciences companies should consider in order to reduce the risk of being subject to such suits.

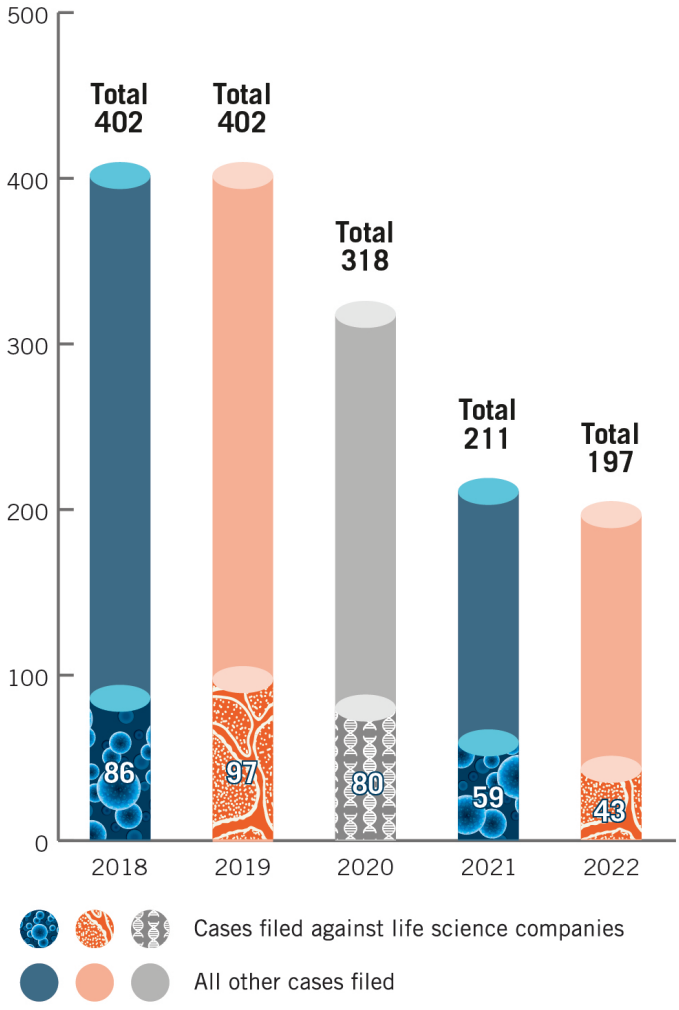
Almost One In Four Securities Class Action Filings Are Against Life Sciences Companies

While in the past, the number of securities fraud class action lawsuits had been steadily increasing since 2012, filings in 2021 and 2022 remained below the historic filing peak of 2017-2020. In 2021, 211 securities fraud class action lawsuits were filed, and in 2022, 197 were filed. These numbers are significantly lower in comparison to the 411, 402, 402 and 318 suits filed in 2017 through 2020, respectively.[8]

Although the overall number of securities lawsuits filed decreased in 2022, the proportion of such actions brought against life sciences companies has only decreased marginally. Indeed, a total of 43 class action securities lawsuits were filed against life sciences companies in 2022 – just under one out of four of all securities fraud class action lawsuits (or 21.8%). This percentage is slightly lower than 2021, where 59 out of 211 securities fraud class actions (or 28%) were filed against life sciences companies.

Figure 1

Number of class action securities fraud cases filed from 2018–2022 (Total cases filed compared to cases filed against life science companies)



8 Throughout this survey, data from prior years is derived from Dechert LLP's 2021 survey on the same topic. *See* Kistenbroker, Joni Jacobsen, Angela Liu, *Dechert Survey: Developments in U.S. Securities Fraud Class Actions Against Life Sciences Companies*, Dechert LLP (Mar. 15, 2022). The number of securities fraud class actions filed and decided in 2022, as well as the number of those brought against life sciences companies, are based on information reported by the *Securities Class Action Clearinghouse* in collaboration with *Cornerstone Research*, Stanford Univ., *Securities Class Action Clearinghouse: Filings Database*, SECURITIES CLASS ACTION CLEARING HOUSE (last visited Jan. 16, 2023). This survey includes litigation and cases involving drugs, devices, deal litigation, and hospital management. As of Jan. 25, 2023, the *Securities Class Action Clearinghouse* has reported a change in securities class action filing totals since Dechert published its previous survey in January 2022. In the 2021 Dechert survey, the Clearinghouse had listed the following totals for the years 2017- 2021, respectively: 411, 402, 402, 324 and 210 whereas the *Securities Class Action Clearinghouse* has the following totals: 411, 402, 402, 318 and 211, respectively.

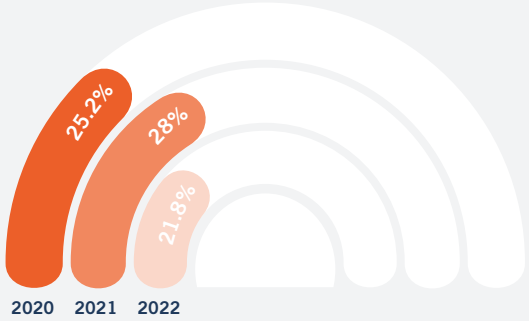
Filing Trends

Over the past year, the number of claims filed against life sciences companies decreased numerically but remained roughly proportional relative to the past three years. In 2022, almost one out of every four securities fraud class action suits targeted a life sciences company (21.8%), while 2021 and 2020 finished with 28% and 25.2%, respectively.[9] The filings in 2022 brought about new and noticeable variations within larger trends, particularly relating to when and where suits were filed, and the nature of the claims involved.

Figure 2

Life Science Companies

Class action claims against life sciences companies 2020-2022



- **Slight decrease in percentage of claims against large cap companies from previous year.** In 2022, about 39.5% of the life sciences companies named in class action securities fraud complaints had a market capitalization of US$500 million or more.[10] This trend[11] represents a decrease from filings in 2021[12] and 2020.[13] About 34.9% of the total cases filed in 2022 were against life sciences companies with a market capitalization of US$1 billion or more.[14] Of these complaints, three in eight cases were filed against companies with a market capitalization of US$5 billion or more,[15] making up about one sixth of the total cases filed.[16]
- **The Second Circuit saw the highest number of filings, and among district courts, the Southern District of New York saw the highest number of filings against life sciences companies.** In 2022, the Second Circuit saw the greatest number of filings of securities fraud cases against life sciences companies, whereas in 2021, the greatest number of filings was seen in the Ninth Circuit. However, most of the 43 class action securities fraud suits brought against life sciences companies were again filed in courts in the same three federal circuits: the Second Circuit with 13; the Ninth Circuit with 10; and the Third Circuit with five. There were some notable shifts, and these circuits experienced a decrease in filings: The Ninth Circuit saw a 54.5% decrease in complaints filed

9 In 2022, 43 out of a total of 197 lawsuits were brought against a life sciences company, or 21.8%. In 2021, 59 out of a total of 211 lawsuits were brought against a life sciences company, or 28%. In 2020, 80 out of a total of 318 lawsuits were brought against a life sciences company, or 25.2%. In 2019, 97 out of a total of 402 lawsuits were brought against a life sciences company, or 24.1%. *See Dechert Survey: Developments in U.S. Securities Fraud Class Actions Against Life Sciences Companies 2021 (citing Securities Class Action Clearinghouse* in collaboration with *Cornerstone Research*, Stanford Univ., *Securities Class Action Clearinghouse: Filings Database*, SECURITIES CLASS ACTION CLEARINGHOUSE.) The filings include litigation and cases involving drugs, devices, financial management, deal litigation, and hospital management. Cases that were subsequently consolidated or amended were only counted once, unless the subsequent filing received a new docket number, in which case both filings were counted separately.

10 In 2022, of these 43 different life sciences companies were named in class action securities fraud complaints, 17 had a market capitalization of US$500 million or more, or 39.5%. Market capitalization figures are current as of the filing date and were compiled with Yahoo! Finance and Bloomberg.

11 In contrast, 79% of filings, or 34 of 43, were against life sciences companies with a market capitalization of US$2 billion or less. Of these 43 companies, 19 had a market capitalization of less than US$250 million.

12 In 2021, about 50.8% of life sciences companies named in class action securities fraud complaints had a market capitalization of US$500 million or more.

13 In 2020, 59.5% of life sciences companies named in class action securities fraud complaints had a market capitalization of US$500 million or more.

14 In 2022, 15 of 43 cases were filed against these companies. In 2021, that number was 24 of 59, or 40.7%. In 2020, this number was 34 of 80, or 42.7%. In 2019, this number was 37 of 96, or 38.5%.

15 In 2022, seven of 15 securities fraud complaints were filed against life sciences companies with a market capitalization of US$5 billion or more, or 46.7%. In 2021, this number was nine of 24, or 37.5%. In 2020, that number was 14 of 34, or 41.2%.

16 Seven of 43 is 16.3%.

in its district courts. The Third Circuit saw a 44.4% decrease in complaints filed in its district courts. The number of complaints filed in the Second Circuit remained the same as the previous year. For district courts within these circuits, the Southern District of New York had the most filings, with 10 overall. These 10 filings relate to a wide range of topics, including mergers, unlawful conduct, product efficacy and safety, application-related issues, among others. After the Southern District of New York, district courts in California were the second-most popular districts with 10 total filings, all but one were filed in the Northern and Central District of California. In 2022, over half of all securities cases against life science companies were brought in the federal district courts of two states: California and New York. These two states also accounted for the greatest number of filings in 2021.[17] The Third Circuit, normally the circuit accounting for the most securities actions filed against life sciences companies, saw a shift in the distribution of filings among its federal district courts in the past two years: Delaware with one (or 20%), New Jersey with two (40%), the Eastern District of Pennsylvania with two (or 40%) and the Western District of Pennsylvania with none.[18]

- **Four law firms were associated with almost three fourths of the filings against life sciences companies.** In 2022, the four firms with the most filings of securities fraud lawsuits against life sciences companies were Pomerantz LLP, Glancy Prongay & Murray LLP, and Bronstein, Gewirtz & Grossman, LLC and Kessler Topaz Meltzer & Check LLP tied with four complaints each. These firms were listed on 18, five and four complaints respectively, and Pomerantz LLP was selected as lead or co-lead counsel in ten cases thus far. Robbins Geller Rudman & Dowd LLP and Levi & Korsinksy LLP were lead or co-lead counsel in seven cases, and Glancy Prongay & Murray LLP was lead or co-lead in five.
- **Slightly more claims were filed in the first half of 2022 than in the second half.** Of the 43 complaints filed against life sciences companies in 2022, 24 were filed in the first half of the year, and 19 were filed in the second half. When broken down by quarter, 14 complaints were filed in the first quarter, 10 in the second, 14 in the third and only five in the fourth. In 2020 and 2021, slightly more claims were filed in the second half of the year than in the first half.[19]

These figures are generally consistent with historic trends overall, but there were some notable changes in 2022. Though companies with market capitalizations of over US$500 million continued to be popular targets of class action complaints filed against life sciences companies, there was a slight decrease in these filings from previous years. The three federal circuits that dominated filings this year remained consistent with recent years, but it was the Southern District of New York, and not the Northern District of California, that led the pack at the district court level. This year, the firm that had the most filings, Pomerantz LLP, remained consistent. However, the number of filings by Pomerantz LLP decreased from 27 in 2021 to 18 in 2022, or by 33.3%.

17 In 2016, 36 of 67 cases were filed in district courts in California and New York, or 53.7%. In 2017, this number was 35 out of 88, or 39.8%. In 2018, this number was 39 of 86, or 45.3%. In 2019, 53 of 97 cases were filed in district courts in Delaware and New York, or 54.6%. In 2020, 45 of 80 cases were filed in district courts in California and Delaware, or 56.3%. In 2021, 31 of 59 cases were filed in district courts in California and New York, or 52.5%. In 2022, 23 of 43 cases were filed in the district courts of California and New York, or 53.5%.

18 In 2021, filings in the Third Circuit were as follows: Delaware with one or 11.1%; the District of New Jersey with five or 55.6%; the Eastern District of Pennsylvania with three or 33.3%; and the Western District of Pennsylvania with none. In 2020, filings in the Third Circuit were as follows: Delaware with 21 or 72.4%; the District of New Jersey with four or 13.8%; the Eastern District of Pennsylvania with three or 10.3%; and the Western District of Pennsylvania with one or 3.5%. In 2019, filings in the Third Circuit were as follows: the District of Delaware with 29, or 72.5%; the District of New Jersey with nine, or 22.5%; and the Western and Eastern Districts of Pennsylvania with one each, or 5% collectively. In 2018, eight of 18 filings brought in the Third Circuit were filed in the District of New Jersey, or 44%, and seven of those 18 were brought in the District of Delaware, or 38.9%.

19 In 2021, 30 of 59 securities fraud class action complaints filed against life sciences companies were filed in the last two quarters, or 50.8%. In 2020, 44 of 80 securities fraud class action complaints filed against life sciences companies were filed in the last two quarters, or 55%.

Causes Of Action

Although the total number of securities fraud class actions brought against life sciences companies decreased in 2022, the legal issues alleged in those complaints remained consistent with past years. As with other industries, deal litigation also continued to be at the forefront of securities fraud complaints filed against life sciences companies. In addition, the lasting effects of the coronavirus pandemic have emerged as a new trend in 2022: actions against companies in relation to either a COVID-19-related products or services. Of significance, 11 of the 43 cases filed against life sciences companies related to COVID-19 products and services. The filings were greater in the second half of 2022, with nine cases[20] filed, in comparison to the first half of the year, where two cases[21] were filed. For instance, Co-Diagnostics Inc. ("Co-Dx") was sued by its investors in connection with its COVID-19 test.[22] Investors alleged that Co-Dx repeatedly publicized its Logix Smart™ COVID-19 Test and the demand for the product.[23] More specifically, investors alleged that Co-Dx announced that it received Emergency Use Authorization ("EUA") for the product, which would allow it to commence sales of the test to labs by the Center for Medicare and Medicaid Services under the Clinical Laboratories Improvements Act ("CLIA").[24] Moreover, according to the complaint, Co-Dx stated it serviced over 500 centralized lab customers, including about 200 U.S. CLIA labs, 130 foreign labs and approximately 200 labs in India certified by the National Accreditation Board for Testing and Calibration Laboratories.[25] However, investors alleged that Co-Dx failed to disclose that the demand for the product had plummeted in the second quarter of 2020 from US$27.4 million to US$5 million during the prior year period, and therefore claiming that Co-Dx's positive statements about the demand for its product lacked a reasonable basis.

20 *See* Compl., *Freudiger, et al. v. Molecular Partners AG, et al.*, No. 22-CV-05925 (S.D.N.Y. July 12, 2022); Compl., *Nayani, et al. v. LifeStance Health Grp., Inc., et al.*, No. 22-CV-06833 (S.D.N.Y. Aug. 10, 2022); Compl., *MW Gestion, et al. v. 1Globe Cap. LLC, et al.*, No. 22-CV-11315 (D. Mass Aug. 16, 2022); Compl., *Stadium Cap. LLC, et al. v. Co-Diagnostics, Inc., et al.*, No. 22-CV-06978 (S.D.N.Y. Aug. 16, 2022); Compl., *Kain, et al. v. Ampio Pharm., Inc., et al.*, No. 22-CV-02105 (D. Colo Aug. 17, 2022); Compl., *Pieroni, et al. v. Humanigen, Inc., et al.*, No. 22-CV-05258 (D.N.J. Aug. 26, 2022); Compl., *Pugley, et al. v. Fulgent Genetics, Inc., et al.*, No. 22-CV-06764 (C.D. Cal Sept. 20, 2022); Compl., *Schoen, et al. v. Eiger BioPharmaceuticals, Inc., et al.*, No. 22-CV-06985 (N.D. Cal Nov. 8, 2022); Compl., *Ewing, et al. v. Veru Inc., et al.*, No. 22-CV-23960 (S.D. Fl Dec. 5, 2022).

21 *See* Compl., *Modrak, et al. v. Talis Biomedical Corp.*, et al., No. 22-CV-00105 (N.D. Cal Jan. 7, 2022); Compl., *Dal Bosco, et al. v. NRx Pharm., Inc., et al.*, No. 22-CV-00066 (D. Del Jan. 18, 2022).

22 Compl., *Stadium Cap. LLC, et al. v. Co-Diagnostics, Inc., et al.*, No. 22-CV-06978 (S.D.N.Y. Aug. 16, 2022), 1-3.

23 *Id.* at 4.

24 *Id.* at 2.

25 *Id.* at 3.

Consistent with complaints filed in 2021, one group of cases filed against life sciences companies in 2022 involved misrepresentations regarding product efficacy and safety, including negative side effects of leading product candidates and/or issues with clinical trial, which could at times impact the likelihood of FDA approval. For instance, Centessa Pharmaceuticals plc ("Centessa"), according to the complaint, is a clinical-stage pharmaceutical company that discovers, develops and delivers medicines to patients and the products in its "development pipeline" includes, "lixivaptan, a vasopressin V2 receptor small molecule inhibitor in Phase 3 clinical development for the treatment of autosomal dominant polycystic kidney disease ('ADPKD'); and ZF874, a small molecule pharmacological chaperone folding corrector of the Z variant of the DNA encoding protein alpha-1-antitrypsin ('A1AT'), which is in Phase 1 clinical development for the treatment of A1AT deficiency ('AATD'), among other products."[26] However, plaintiffs brought suit against Centessa alleging that the offering documents were false and/or misleading as they failed to disclose, among other things, that lixivaptan was less safe than Centessa had represented, Centessa overstated lixivaptan's clinical and commercial prospects, ZF874 was less safe than Centessa had represented, and Centessa had overstated ZF874's clinical and commercial prospects while downplaying the drug's safety issues.[27] This information, according to the complaint, came to light after a series of press releases that led to a "precipitous decline" in the market value of Centessa's securities.[28]

Another group of complaints unique to life sciences companies arose from misrepresentations regarding regulatory hurdles, the timing of FDA approval or the sufficiency of applications submitted to the FDA.[29]

Notably, six of these filings involved COVID-19-related products and services.[30] Recently, in December 2022, investors brought a securities class action complaint against Veru, a biopharmaceutical company focused on developing medicines for COVID-19 and other viral and acute respiratory distress syndrome ("ARDS")-related diseases, and for the management of breast and prostate cancers.[31] The drug that is the subject of the litigation is sabizabulin (VERU-111) which, according to the complaint, was developed by Veru for the treatment of COVID-19 in hospitalized patients at high risk for ARDS.[32] While Veru originally developed sabizabulin for treatment of prostate cancer, the FDA granted Veru's COVID-19 Fast Track designation.[33] The plaintiffs alleged that Veru misled its shareholders to believe that the data from the Phase 3 trial was sufficient to support the request of EUA as well as the submission of a New Drug Application ("NDA") without any further studies.[34] However, according to the complaint, the share price dropped by 54% upon the news that the FDA Pulmonary-Allergy Drugs Advisory Committee ("AdCom") voted against granting Veru's EUA request indicating that there was no direct evidence that supported the drug's antiviral activity.[35] While the AdCom recommendations are not binding, according to the complaint, the FDA typically follows AdCom's recommendations.[36]

Another group of complaints alleged other unlawful conduct, including but not limited to, illegal kickback schemes and forms of financial malfeasance.[37]

26 Compl., *Fernandes, et al. v. Centessa Pharm. plc, et al.*, No. 22-CV-08805 (S.D.N.Y. Sept. 28, 2022), 2.

27 *Id.* at 6.

28 *Id.* at 7-14.

29 Such suits comprised 17 of the 43 cases filed, or 39.5%. This category also includes allegations where the product efficacy or safety, including clinical trials, was misrepresented and could have impact the likelihood of an application.

30 *See* Compl., *Ewing, et al. v. Veru Inc., et al.*, No. 22-CV-23960 (S.D. Fla. Dec. 5, 2022); Compl., *Schoen, et al. v. Eiger BioPharmaceuticals, Inc.*, et al., No. 22-CV-06985 (N.D. Cal. Nov. 8, 2022); Compl., *Pieroni, et al. v. Humanigen, Inc.*, et al., No. 22-CV-05258 (D.N.J. Aug. 26, 2022); Compl., *Kain, et al. v. Ampio Pharm., Inc.*, et al., No. 22-CV-02105 (D. Colo. Aug. 17, 2022); Compl., *Freudiger, et al. v. Molecular Partners AG, et al.*, No. 22-CV-05925 (S.D.N.Y. July 12, 2022); Compl., *Dal Bosco, et al. v. NRx Pharm., Inc.*, et al., No. 22-CV-00066 (D.Del. Jan. 18, 2022).

31 Compl., *Christopher K. Ewing, et al. v. Veru Inc., et al.*, (S.D. Fla.), 25, 30.

32 *Ewing, et al. v. Veru Inc., et al.*, No. 22-CV-23960 (S.D. Fla. Dec. 5, 2022) at 3.

33 *Id.*

34 *Id.* at 4.

35 *Id.* at 41.

36 *Id.* at 14.

37 Such complaints comprised 9 of the 43 filings reviewed, or 20.9%.

In one case, investors sued Fulgent Genetics, Inc. ("Fulgent"), a company that provides COVID-19, molecular diagnostic and genetic testing services to both physicians and patients in the U.S. and abroad, according to the complaint.[38] Investors alleged that Fulgent had been conducting unnecessary laboratory testing, it engaged in improper billing practices in relation the laboratory testing, and it provided or received remuneration in violation of the Anti-Kickback Statute and Stark Law.[39] According to the complaint, the unlawful conduct came to light after Fulgent disclosed it received a civil investigative demand issued by the U.S. Department of Justice indicating this was the subject of the investigation.[40] Additionally, Fulgent disclosed that the SEC was conducting an investigation regarding reports filed with the SEC from 2018 through the first quarter of 2020.[41] Investors alleged that as a result of these disclosures, Fulgent's stock price fell US$11.02 per share, or 17.29%, over the following two trading sessions, to close at US$52.72 per share on August 8, 2022.[42]

Another group of the cases involved alleged misrepresentations and omissions related to proposed mergers, acquisitions, IPOs, offerings and other transactions.[43] Many of these transaction-related complaints contain similar allegations.[44] For example, Kiromic BioPharma, Inc. ("Kiromic"), a target discovery and gene editing company, focused on developing immuno-oncology therapeutics for the treatment of blood cancers and solid tumors, was sued by its investors who alleged it had made false and misleading statements in connection with the offering documents.[45] According to the complaint, at the time of its public offering, Kiromic presented itself as a target discovery and gene editing company, focused on developing immuno-oncology therapeutics for the treatment of blood cancers and solid tumors.[46] Even though it did not have any immunotherapy products on the market at the time, Kiromic had an Investigational New Drug ("IND") application pending with the FDA.[47] The offering documents indicated that, unless the FDA imposed a clinical hold, Kiromic would be able to commence clinical trials within thirty days of the IND applications.[48] According to the complaint, a clinical hold is where the FDA issues an order to delay or suspend new or existing clinical trials with respect to an applicant's products and, as a result of a clinical hold, there may be no testing for the drug on any new or existing patients.[49] The investors alleged that Kiromic failed to disclose the clinical hold, despite their knowledge that one had been issued on each application before the filing of the Prospectus and Registration Statement, as the thirty days of submitting the IND applications had lapsed.[50] The investors alleged that this would have detrimental effects because many IND applications that are put on clinical hold remain so for over a year, and addressing the issues by the FDA may come at a significant expense.[51] Investors also pointed out that clinical holds are rarely issued, but if they are, the most common reasons are clinical and product quality issues.[52] As a result, investors filed Sections 11, and 12(a)(2) of the Securities Act and Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder, claims against Kiromic.[53]

38 Compl., *Pugley, et al. v. Fulgent Genetics, Inc., et al.*, No. 22-CV-06764 (C.D. Cal Sept. 20, 2022), 2.

39 *Id.*

40 *Id.* at 4.

41 *Id.*

42 *Id.* at 5.

43 Such suits comprised 11 of the 43 cases filed, or 25.6%.

44 *See, e.g.*, Compl., *Patterson, et al. v. Cabaletta Bio, Inc., et al.*, No. 22-CV-00737 (E.D. Pa. Feb. 28, 2022) (Exchange Act and Securities Act claims, alleging in part that Cabaletta issued offering documents that failed to disclose that the "top-line data of the Phase 1 Clinical Trial indicated that DSG3-CAART had, among other things, worsened certain participants' disease activity scores and necessitated additional systemic medication to improve disease activity after DSG3-CAART infusion."); Compl., *Freudiger, et al. v. Molecular Partners AG, et al.*, No. 22-CV-05925 (S.D.N.Y. July 12, 2022) (Exchange Act and Securities Act claims, alleging in part that Molecular Partners issued offering documents in which they made false and/or misleading statements that "ensovibep was less effective at treating COVID-19 than Defendants had led investors to believe" and "accordingly, the FDA was reasonably likely to require an additional Phase 3 study of ensovibep before granting the drug EUA.").

45 Compl., *Karp, et al. v. Kiromic BioPharma, Inc., et al.*, No. 22-CV-06690 (S.D.N.Y. Aug. 5, 2022), 2-14.

46 *Id.*

47 *Id.*

48 *Id.*

49 *Id.*

50 *Id.* at 5-9.

51 *Id.*

52 *Id.* at 56.

53 *Id.*

Last, another noteworthy trend in 2022 has been the number of life sciences companies that are incorporated abroad but have still been subject to securities lawsuits in the United States, which is in line with general securities litigation trends across all industries.[54] For instance, investors brought suit against Aurinia Pharmaceuticals Inc. ("Aurinia"),[55] a Canadian biopharmaceutical company that develops and commercializes therapies to treat various diseases with unmet medical need in Japan and the People's Republic of China ("China").[56] Based on the complaint, Aurinia's only product is LUPKYNIS, which it offers for the treatment of adult patients with active lupus nephritis.[57] After a series of press releases and earnings calls touting its operational highlights and financial results, Aurinia was sued by its investors for allegedly failing to disclose that it was experiencing declining revenue and that its 2022 sales outlook for LUPKYNIS would fall short of expectations.[58] According to the complaint, once Aurinia issued a press release announcing its results for the 2021 fourth quarter and year end, the stock price fell about 24%, and this suit ensued.[59]

Similar to years' past, the common themes of these complaints show the unique challenges life sciences companies face as issuers, but also involve commonalities with securities litigation filings on the whole. First, these filings continue to show that negative side effects in clinical trials can create a claim for securities fraud if it appears that management is attempting to conceal or downplay these effects, or subsequently overstating the trial's results and prospects of FDA approval. The same holds true regarding the product's safety and viability. The filings also continue to indicate that companies cannot inflate investors' expectations of FDA approval and must ensure that the company's risk disclosures and cautionary warnings are robust, and just as important, that executives' statements regarding the likelihood of approval are measured and in no way misleading. Moreover, the filings show life sciences companies face challenges similar to those faced by other non-life sciences issuers, particularly challenges relating to disclosures in the sale or merger of life sciences companies. In addition, similar to other non-U.S. issuers, those life sciences companies with headquarters located outside of the U.S. are not immune from suit and may still be targets of securities class actions in the U.S. While these filings show that life sciences companies face unique challenges when it comes to securities fraud, they also continue to reveal how these companies still risk being sued for more common forms of securities fraud claims as well.

54 Approximately 13.9%, or 6 of 43 cases, filed in 2022 were against non-U.S. issuers incorporated across five countries. In 2021, 16.9%, or 9 of 53 cases were filed against non-U.S. issuers. *See* Kistenbroker, et al., at 9, n. 52.

55 Compl, *Ortmann, et al. v. Aurinia Pharm. Inc., et al.*, No. 22-CV-02185 (E.D. New York Apr. 15, 2022), 2, 12, 1-9.

56 *Id.*

57 *Id.* at 2.

58 *Id.* at 19-25, 3.

59 *Id.* at 5, 27-29.

2022 Class Action Securities Fraud Decisions in the Life Sciences Sector

There was a slight increase in securities fraud decisions by courts involving life sciences companies in 2022, likely due to the loosening of the COVID-19 lockdown protocols and the reopening of courts. Compared to 2021 when Dechert identified 38 such decisions, Dechert identified 43 decisions this year using the same criteria.[60] These decisions fall under three broad categories: (i) cases involving claims that arose in the development phase, such as cases involving a drop in stock price after the failure of a clinical trial, and cases involving overly optimistic statements regarding FDA approval of a drug or device; (ii) cases involving claims arising independent of or after the development process; and (iii) cases involving the financial management or general mismanagement of life sciences companies (*e.g.*, alleged market manipulation or improper accounting). As in the previous two years, the majority of these decisions address alleged violations of Sections 10(b) and 20(a) of the Exchange Act.

Court Decisions Regarding Alleged Misrepresentations During Product Development

Life sciences companies face significant risk during the developmental stage of a drug or device. Companies naturally want to promote new products and ensure that potential investors are aware of attractive opportunities. When those products perform well during trials and are ultimately approved by the FDA, they may then succeed in the market and reward the company and its investors. However, when products in development underperform or outright fail during clinical trials, plaintiffs' firms around the country pursue securities fraud class actions to recover for the purported harm to investors arguing that the defendants somehow misled the public. Thus, when new products fail clinical trials, or if the FDA declines to approve the new product, life sciences companies can (and should) expect plaintiffs' firms to review public filings in an effort to bring forth allegations that the life science company mischaracterized or exaggerated trial results and/or failed to warn investors of significant risks that the product would not be approved.

In 2022, courts issued 43 opinions – a slight uptick from the 39 decisions identified using similar criteria in 2021.[61] Of those 43 opinions, 23 include allegations of misrepresentations during product development. In some cases, stock prices fell after a drug or device did not meet efficacy or safety expectations, resulting in claims that the company misrepresented test results in order to improperly bolster stock prices. In others, plaintiffs alleged that defendants made false or misleading misrepresentations regarding the likelihood of a product's FDA approval including that the companies withheld or mischaracterized FDA advice or warnings during development. Additionally, the COVID-19 pandemic presented novel issues for life sciences companies. Several cases involved alleged misrepresentation after the FDA either refused to grant an EUA for a proposed COVID-19 test, or a EUA was revoked after concerns regarding tests were raised.

Unlike in 2021, where courts took a moderate approach and dismissed nine of the 14 product development matters in whole,[62] and one in part,[63] the courts in 2022

60 *See supra* note 9.

61 Kistenbroker, et al. at 10.

62 *Id.*

63 *Id.*

favored granting the motions to dismiss in their entirety with 12 of 23 motions granted.[64] Four of the motions to dismiss were denied in their entirety,[65] two were denied as moot due to settlement,[66] four were denied in part and granted in part,[67] and in one case a default judgment was granted.[68]

Similar to 2021, defendants frequently challenge and defeat securities class action claims by arguing that they did not act with scienter when making statements during product development. In a notable case from 2022, *In re Sona Nanotech Inc. Securities Litigation*,[69] the District Court of the Central District of California granted defendant Sona Nanotech's motion to dismiss with prejudice due to plaintiff's failure to adequately plead any actionable misrepresentation or omission, or scienter. In *Sona*, the court addressed allegations in plaintiff's Second Amended Complaint ("SAC") that Sona made misleading statements related to the development of a saliva based COVID-19 test.[70] Specifically, plaintiff alleged Sona's statements that "it had been granted Health Canada Investigational Testing Authorization for a clinical trial of the Sona Saliva C-19 Rapid test"[71] and Sona's confirmation that "it had received research ethics board approval for its clinical trial of the Sona Saliva C-19 rapid test"[72] "were misleading because: (1) despite a significant decrease in individuals contracting COVID-19 after vaccines began rolling out in Canada, Sona proceeded to design and conduct a clinical study for its Saliva Test in Toronto; (2) Sona struggled to ensure its technology could work for the Saliva Test even in a laboratory setting; (3) as a result, Sona would be forced to halt its clinical trial for its Saliva Test; and (4) Sona would be unable to financially capitalize on the need for rapid detection of COVID-19 in its acute phase, a need that was being fulfilled by other antigen tests."[73] The SAC further alleged that subsequent to these statements, Sona announced that it was discontinuing its saliva test "due to inadequate test sensitivity with clinical saliva samples and challenges with patient recruitment and enrollment in the study."[74] The SAC alleges that Sona's stock price fell 70% upon this announcement.[75]

The court granted Sona's motion to dismiss, explaining that the misrepresentations in the SAC were not misrepresentations at all.[76] "The statements – which disclosed the beginning of a saliva-based test trial, the progress of that trial, and the failure of that trial – [were] literally true, so they were not misrepresentations."[77] The court found that the vague allegations in the SAC that the defendants knew these statements were untrue but declined to disclose unidentified material facts failed to demonstrate these statements are actionable omissions, noting that "[a] plaintiff 'hard-pressed to build a fraud case' from publicly disclosed information."[78]

64 *Kim, et al. v. Allakos Inc., et al.*, No. 20-cv-1720 (N.D. Cal. Dec. 6, 2022); *In re Astrazeneca PLC Sec. Litig.*, No. 21-cv-722 (S.D.N.Y. Sep. 12, 2022); *Klein, et al. v. Iterum Therapeutics plc, et al.*, No. 21-cv-4181 (N.D. Ill. Dec. 28, 2022); *In re Talis Biomedical Sec. Litig.*, No. 22-cv-105 (N.D. Cal. Dec. 9. 2022); *In re Sorrento Therapeutics, Inc. Sec. Litig.*, No. 20-cv-966 (S.D. Cal. Apr. 11, 2022); *In re Sona Nanotech Inc. Sec. Litig.*, No. 20-cv-11405 (C.D. Cal. March 18, 2022); *Dresner v. Silverback Therapeutics, Inc.*, et al., No. 21-cv-1499 (W.D. Wash. Nov. 4, 2022); *Paxton v. Provention Bio, Inc. et al.*, No. 21-cv-11613 (D.N.J. Aug. 4, 2022); *In re Neovasc Inc. Sec. Litig.*, No. 20-cv-9313 (S.D.N.Y. Feb. 1, 2022); *Chapman, et al. v. Fennec Pharm. Inc., et al.*, No. 20-cv-812 (M.D. N.C. Mar. 2, 2022); *Leung, et al. v. bluebird bio, Inc., et al.*, No. 21-cv-10335 (D. Mass. Apr. 21, 2022); *Cachia, et al. v. BELLUS Health Inc., et al.*, No. 21-CV-2278 (S.D.N.Y. Sept. 21, 2022).

65 *See City of Birmingham Relief and Ret. Sys. et al. v. Acadia Pharm., Inc. et al.*, No. 21-cv-762 (S.D. Cal. Sept. 27, 2022); *In re BioMarin Pharm. Inc. Sec. Litig.,* No. 20-cv-6719 (N.D. Cal. Jan. 6, 2022); *Gelt Trading, Ltd., v. Co-Diagnostics, Inc., et al.*, No. 20-cv-368 (D. Utah Mar. 9, 2022); *In re Fibrogen, Inc., Sec. Litig.*, No. 21-cv-2623 (N.D. Cal. July 15, 2022).

66 *See In re Sesen Bio, Inc. Sec. Litig.*, No. 21-cv-7025(S.D.N.Y. Aug. 31, 2022) and *McDermid v. Inovio Pharm., Inc. et al.*, No. 20-cv-1402 (E.D. Penn. Aug. 31, 2022).

67 *See In re Chembio Diagnostics, Inc. Sec. Litig.*, No. 20-cv-2706 (E.D.N.Y. Feb. 23, 2022); *Sinnathurai v. Novavax, Inc.*, et al., No. 21-cv-2910 (D. MD. Dec. 12, 2022); *Busic, et al. v. Orphazyme A/S, et al.*, No. 21-cv-3640 (N.D. Ill. Aug. 11, 2022); *Pardi, et al., v. Tricida, Inc., et al.*, No. 21-cv-76 (N.D. Cal. July 29, 2022).

68 *Sanchez, et al. v. Decision Diagnostics Corp., et al.*, No. 21-cv-418 (C.D. Cal. Dec. 5, 2022).

69 *In re Sona Nanotech Inc. Sec. Litig.*, No. 2:20-cv-11405(C.D. Cal. Mar. 18, 2022).

70 *Id.*

71 *Id.* at 2.

72 *Id.*

73 *Id.*

74 *Id.*

75 *Id.*

76 *Id.* at 6-7.

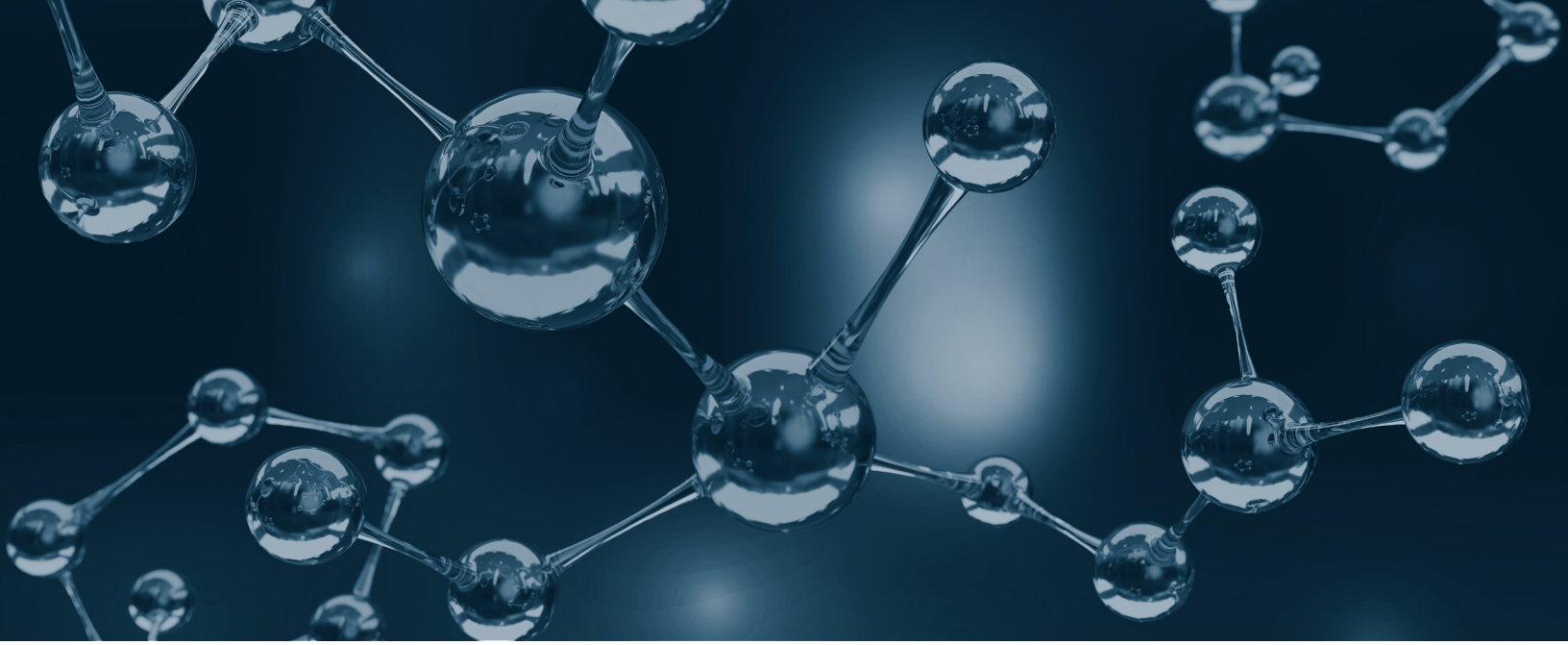
77 *Id.* at 6.

78 *Id.*

Thus, plaintiff failed to identify any actionable misrepresentation or omission. As to scienter, the court noted that while plaintiff provided a stronger showing of scienter than in its First Amended Complaint, the allegations were still insufficient to demonstrate scienter under the standard articulated in *Tellabs, Inc. v. Makor Issues & Rights, Ltd*.[79] Under *Tellabs*, "[t]he inquiry…is whether all the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets the standard."[80] While the court found that plaintiff did a thorough job of explaining a plausible financial motive for Sona to lie about a COVID-19 test it knew was faulty, pointing to a finding of scienter under the *Tellabs* balancing analysis, the court noted that the fact that plaintiff failed to allege defendants sold their stock at inflated prices weighed against a finding of scienter.[81] Further, the court held that alleged omissions based on nothing more than presumed access to unidentified information as a result of defendants' roles as corporate officers were insufficient to allege scienter.[82] Plaintiff also "fail[ed] to overcome the key defect the Ninth Circuit recognized in *Nguyen v. Endologix, Inc.*: Allegations that a company invested in a U.S. clinical trial and made promising statements about FDA approval but knew that the FDA would eventually reject the product – had no basis in logic or common experience."[83] Instead, "the more plausible inference is that the company made optimistic statements about its prospects for FDA approval because its U.S. testing looked promising, not because the company was quixotically seeking FDA approval for [Emergency Use Authorization] it knew was destined for defeat."[84] Accordingly, the court found that plaintiff failed to allege scienter that is "at least as compelling as any opposing inference of nonfraudulent intent."[85] The court stated that while plaintiff could paint a picture of inventors that were so desperate for money they used the COVID-19 pandemic as a way to dupe investors, "the more plausible inference [was] that Sona simply was unsuccessful in developing antigen tests for COVID-19."[86] In sum, plaintiff's Section 10(b) claim failed because plaintiff did not allege sufficient facts to support an actionable misrepresentation or omission, or a strong inference of scienter.

In the context of alleged misrepresentations relating to product development, courts also dismissed cases on grounds that the plaintiffs (i) failed to meet their burden of alleging material misstatements or omissions with the particularity required by the Private Securities Litigation Reform Act's ("PSLRA"), or (ii) failed to allege an actionable misstatement as the challenged statements were protected by the PSLRA's safe harbor for forward-looking statements or were "mere puffery".[87] The PSLRA's safe harbor protects forward-looking statements from being actionable where those statements are identified as forward-looking and "accompanied by meaningful cautionary statements."[88] As such, statements about the likelihood of regulatory approval are protected under the PSLRA's safe harbor because they are "classically forward-looking as they address what defendants expect[] to occur in the future."[89] For example, *In re Astrazeneca PLC Securities Litigation*, plaintiffs brought suit against biopharmaceutical company, AstraZeneca, regarding the development of a potential recombinant adenovirus vaccine to combat COVID-19.[90] This vaccine candidate, known as AZD1222, was based on "tried and tested vaccine approaches," and not based on "novel mRNA technology."[91] Plaintiffs alleged that defendants made materially false and/or misleading statements when they failed to disclose adverse facts pertaining to the Astrazeneca's business, operations, and financial conditions.[92] For example, plaintiffs allege that defendants failed to disclose that initial clinical trials

79 *Id.* at 7-8 (referencing *Tellabs*, 551 U.S. at 322-23).
80 *Id.* at 8.
81 *Id.*
82 *Id.* at 9.
83 *Id.* (citing *Nguyen v. Endologix, Inc.*, 962 F.3d 405, 417 (9th Cir. 2020)).
84 *Id.* (citing *Nguyen*, 962 F.3d at 408).
85 *Id.* at 9 (citing *Tellabs*, 551 U.S. at 314).
86 *Id.*
87 *See, e.g.*, *In re Astrazeneca PLC Sec. Litig.*, No. 21-cv-722 (S.D.N.Y Sept. 12, 2022) (referencing *Novak v. Kasaks*, 216 F.3d 300, 315 (2d Cir. 2000)).
88 15 U.S.C. § 78u-5 (c)(1)(A)(i). The safe harbor also protects forward-looking statements that were not made with actual knowledge they were false.
89 *In re Astrazeneca PLC Sec. Litig.*, No. 21-cv-722, at 19 (citing *Gillis v. QRX Pharma Ltd.,* 197 F. Supp. 3d 557, 585 (S.D.N.Y. 2016)).
90 *In re Astrazeneca PLC Sec. Litig.*, No. 21-cv-722.
91 *Id.* at 1.
92 *Id.* at 7.



for their COVID vaccine, AZD1222, had "suffered from a critical manufacturing error, resulting in a portion of trial participants receiving half the designed dosage" and that "clinical trials for AZD1222 consisted of a patchwork of disparate patient subgroups, each with subtly different treatments, undermining the validity and import of the conclusions that could be drawn from the clinical data across these disparate patient populations," among others.[93]

Here, the District Court for the Southern District of New York found that the complaint must be dismissed pursuant to the PSLRA because it failed to satisfy the PSLRA's particularity threshold.[94] Over the course of the clinical trials, defendants made statements regarding the status and potential efficacy of the vaccine, which plaintiffs claimed were materially false and misleading.[95] For example, during an investor and analyst call in July 2020, defendants stated that "our data shows that we're getting a good level of neutralizing antibody presentation in the patients that are vaccinated with the 2 doses as well as a good T cell response[]" and reported that "[t]he study remains on track . . . we've dosed now nearly 12,000 patients around the world, in the U.K., Brazil and South Africa, and we're about to start the Phase III program in the U.S."[96] Specifically, the court found that the complaint failed to demonstrate why and how each statement was materially false or misleading.[97] Instead, the court explained that "in boilerplate fashion, the amended complaint identifies statements throughout the class period, italicizes them within long block quotes, and then, after each one, repeats a copy-and-pasted list of omissions."[98] Additionally, the court found that plaintiffs could not base a claim on the allegation that defendants failed to disclose that "AZD1222 was unlikely to be approved for commercial use in the U.S. in the short term"[99] because, the court explained, any statements about the potential for regulatory approval are classically forward-looking statements and all statements made by defendants regarding "the likelihood of approval were accompanied by adequate cautionary language."[100]

Finally, many of the statements challenged by plaintiffs were not actionable under Section 10(b) because they were "mere puffery."[101] The statements at issue included (i) AstraZeneca's CEO's statement that AstraZeneca was "moving quickly but without cutting corners" and (ii) the individual defendant Menelas Pangalos's statement "that the Phase II/III trial remained 'on track', without disclosing alleged widespread flaws in design, errors in execution, and a failure to properly coordinate and communicate with regulatory authorities and the general public."[102]

93 *Id.*
94 *Id.* at 13.
95 *Id.* at 4-5.
96 *Id.* at 3.
97 *Id.* at 13-14.
98 *Id.* at 13.
99 *Id.* at 19.
100 *Id.*
101 *Id.* at 17.
102 *Id.*

The court stated that statements such as working "without cutting corners" or staying "on track" do nothing more than "reflect 'statements that are loosely optimistic regarding a company's well-being'"[103] and are "so vague, broad, and non-specific that a reasonable investor would not rely on [them]."[104]

Court Decisions Regarding Alleged Misrepresentations After Product Development

While statements made during product development are carefully monitored by plaintiffs, life sciences companies can still face liability after a product is developed. Dechert identified seven instances of a court addressing fraud claims that arose after a drug or device's development process. Of the seven cases, four of the motions to dismiss were granted in whole,[105] two were dismissed in part[106] and one motion to dismiss was denied.[107]

In one of the cases, *Industriens Pensionsforsikring A/S, et al. v. Becton, Dickinson and Company, et al.*, the plaintiff alleged that defendants violated Section 10(b) of the Exchange Act.[108] The court previously granted defendants' motion to dismiss plaintiff's SAC for failure to state a claim, and noted that since then, the plaintiff had repleaded with additional details but the gravamen of the plaintiff's complaint did not change.[109] Becton, Dickinson and Company ("Becton") is a medical technology company engaged primarily in the manufacturing and selling of medical devices, instrument systems, and reagents and its business is comprised of three business segments: BD Medical, BD Life Sciences and BD Interventional.[110]

Becton acquired CareFusion Corp. ("CareFusion"), a medical technology company, in 2015, which gave Becton the right to manufacture, market, and distribute the Alaris infusion pump system and associated technologies.[111] The FDA classifies infusion pumps under the Class II designation that "indicates that a product may causes a temporary or reversible health problem, or that there is a slight chance that it will cause serious problems or death."[112] The TAC alleged that Becton made numerous statements that were misleading due to their failure to acknowledge severe issues relating to Alaris' performance and ongoing FDA scrutiny of the device.[113] These statements were made at various conferences, press releases, and other public filings, and after Becton issued a voluntary recall notification where it announced it was to address specific software issues – Becton did not disclose that the FDA informed Becton that it needed 510(k) clearance for the previously implemented software changes.[114] Of significance, the recall notice did not disclose that Alaris would be unavailable for sale, Becton later disclosed this through a Form 8-K in which it stated that the FDA required Beckton to obtain a 510(k) clearance and that it was required to halt all Alaris sales.[115]

The court did not dismiss the Third Amended Complaint ("TAC") as to Becton and found that plaintiff adequately pleaded material misstatements or omissions; that Becton's risk disclosures were not protected under the PSLRA safe harbor provisions; that plaintiff established facts sufficient to support a strong inference of scienter as to an individual defendant and by extension, to Becton; and plaintiff established loss causation.[116] The court found that plaintiff sufficiently alleged material misstatements or omissions and pointed to the fact that the TAC "bolstered over its predecessor by allegations derived by new and knowledgeable confidential witnesses," and thus

103 *Id.* at 17 (citing *In re Lulumon Sec. Litig.,* 14 F. Supp. 3d 553, 572 (S.D.N.Y. 2014), *aff'd*, 604 F. App'x 62 (2d Cir. 2015)).

104 *Id.* (citing *Galestan v. OneMain Holdings, Inc.*, 348 F. Supp. 3d 282, 297-98 (S.D.N.Y. 2018)).

105 *See Sneed Jr. v. AcelRxPharmaceuticals, Inc., et al.,* No. 21-cv-4353 (N.D. Cal. Sept. 28, 2022); *Benoit Albiges, et al. v. Endo Int'l plc, et al.,* No. 20-cv-7536 (D.N.J. Aug. 17, 2022); *Rice, et al., v. Intercept Pharm., Inc., et al.,* No. 21-cv-36 (S.D.N.Y. Mar. 21, 2022); *Richfield v. PolarityTE, Inc., et al*, No. 21-cv-561 (D. Utah Sept. 13, 2022).

106 *See Industriens Pensionsforsikring A/S, et al. v. Becton, Dickinson and Co., et al.*, No. 20-CV-2155 (D.N.J. Aug. 11, 2022); *Jevons, et al. v. Boston Sci. Corp., et al.*, No. 21-cv-10033 (D. Mass. Dec. 20, 2022).

107 *See Sheet Metal Workers Nat'l Pension Fund, et al. v. Bayer Aktiengesellschaft,* No. 20-cv-4737 (N.D. Cal. May 18, 2022).

108 No. 20-CV-2155 (D.N.J. Aug. 11, 2022) at 1.

109 *Id.* at 1.

110 *Id.* at 2-3.

111 *Id.* at 3.

112 *Id.* at 5; n4.

113 *Id.* at 12.

114 *Id.* at 16.

115 *Id.*

116 *Id.* at 18-42.

adequately plead that the defendants were obligated, but failed, to disclose the material issues.[117] Further, the court found that at the time Becton issued the 10-K, the risk that Alaris faced imminent delays was manifest, irrespective of whether that risk had yet impacted the company's bottom line.[118] Additionally, the court found that plaintiff had established facts sufficient to support a strong inference of scienter as to an individual defendant and, by extension, as to Becton.[119] In its reasoning, the court pointed to plaintiff's reliance on a confidential witness and explained that "[w]hen considered holistically these allegations suffice to meet Plaintiff's burden of providing the 'who, what, when, where and how' of the Individual Defendants' knowledge of the relevant and undisclosed facts."[120] Lastly, the court found that plaintiff sufficiently plead loss causation reasoning that the TAC adequately plead the link between the misrepresentations and the plaintiff's loss following the disclosure of the FDA's views, the need for 510(k) clearance, and contemporaneous comments by various investment analysts regarding the previously known information regarding the severity of the regulatory issues and software issues previously minimized as upgrades.[121]

Court Decisions Regarding Financial Management

Though life sciences companies must obviously navigate the risks associated with development of new drugs and devices, they also encounter securities-law risks common to all public companies. In 2022, courts issued thirteen opinions in cases involving allegations of financial management, including: business prospects, artificially inflating prices and disclosures relating to mergers or IPOs, among other claims. Of the cases Dechert identified, the outcomes varied, with five cases being dismissed in whole in favor of defendants,[122] six more being dismissed in part[123] and two in which plaintiffs prevailed on defendants' motions to dismiss.[124]

An example of an opinion in this category includes allegations that a company made false or misleading statements to artificially boost a company's growth and earnings. For example, in *Hunter, et al., v. Elanco Animal Health Inc., et al.* ("Elanco"),[125] plaintiffs alleged that Elanco and its officers violated federal securities law by engaging in a scheme to deceive and defraud investors of the true value of Elanco's common stock.[126] More specifically, plaintiffs alleged that defendants had artificially boosted Elanco's earnings and growth by "stuffing" product distribution channels "far in excess of end-user demand."[127] Plaintiffs claimed this, along with false and misleading representations about Elanco's growth and financial situation, led to the artificial inflation of Elanco's stock prices.[128] The District Court for the Southern District of Indiana granted defendants' motion to dismiss, but declined to dismiss with prejudice, finding that finality was inappropriate, and allowed plaintiffs the opportunity to seek leave to amend.[129]

Elanco developed, manufactured and marketed animal health products for companion animals, such as dogs

117 *Id.* at 20.
118 *Id.* at 27.
119 *Id.* at 32.
120 *Id.* at 32-33.
121 *Id.* at 41-42.

122 *See Hunter, et al., v. Elanco Animal Health Inc., et al.,* No. 20-cv-1460 (S.D. Ind. Aug. 17, 2022)*; Kong, et al., v. Fluidgm Corp., et al.,* No. 20-cv-6617 (N.D. Cal. Feb. 14, 2022)*; Habelt, et al. v. iRhythm Techs., Inc., et al.,* No. 21-cv-776 (N.D. Cal. Mar. 31, 2022)*; Gabbard v. PharmaCielo Ltd., et al.,* No. 20-cv-2182 (C.D. Cal. Jan. 12, 2022)*; Abadilla, et al., v. Precigen, Inc., et al.,* No. 20-cv-6939 (N.D. Cal. May 31, 2022).

123 *See Bachaalani Nacif, et al. v. Athira Pharma, Inc., et al.*, No. 21-cv-861 (W.D. Wash. July 29, 2022); *iAnthus Cap. Holdings, Inc. Sec. Litig.*, No. 20-cv-3898 (S.D.N.Y. Sept. 28, 2022); *Mart, et al., v. Tactile Sys. Tech., Inc., et al.*, No. 20-cv-2074 (D. Minn. Mar. 31,2022); *Halman Aldubi Provident and Pension Funds Ltd., v. Teva Pharm Indus. Ltd, et al.*, No. 20-cv-4660 (E.D. Penn. Mar. 25, 2022); *Kasilingam v. Tilray, Inc., et al.*, No. 20-cv-3459 (S.D.N.Y. Sept. 28, 2022).; *Strougo v. Mallinckrodt Public Limited Company*, 20-cv-10100 (D.N.J).

124 *See Del Cnty. Emps. Ret. Sys., et al. v. AdaptHealth Corp., et al.*, No. 21-cv-3382 (E.D. Penn. June 9, 2022); *Hayden, et al., v. Portola Pharm., Inc., et al.,* No. 20-cv-367

125 No. 20-cv-1460 (S.D. Ind. Aug, 17, 2022).

126 *Id.* at 1-2.

127 *Id.*

128 *Id.* at 2.

129 *Id.* at 57. As of December 7, 2022, Plaintiff's Motion to Amend/ Correct the Amended Complaint is pending.

and cats, and food animals, such as cattle and poultry.[130] Elanco was the fourth-largest animal health company in the world, prior to its IPO, with US$2.9 billion in revenue in 2017.[131] Elanco generated revenue primarily through product sales to customers that are third-party wholesale distributors of Elanco's products.[132] These wholesale distributors sold to customers such as veterinary clinics for companion animal products, or cattle and dairy farms for food animal products.[133] Elanco generally recognized revenue at the time their product was shipped to their customers – which was consistent with generally accepted accounting principles ("GAAP").[134] In their complaint, plaintiffs alleged, among other claims, that defendants had engaged in a scheme of "fraudulent channel stuffing" and "made misstatements or omissions."[135] "Channel stuffing" refers to when a company ships more product to its distributors than the company thinks it can sell.[136] However, as the court pointed out: channel stuffing is not inherently fraudulent, and a "certain amount of channel stuffing could be innocent and might not even mislead – a seller might have a realistic hope that stuffing the channel of distribution would incite his distributors to more vigorous efforts to sell the stuff lest it pile up in inventory."[137] Further, the court stated that channel stuffing only becomes fraud when the company books revenue on the basis of goods shipped to distributors but not really sold as the buyers can still return the goods.[138] This practice creates a "short-term illusion of increased demand between the time when the company sends the extra product down the line and the time when the distributors return the unwanted excess."[139]

The District Court for the Southern District of Indiana found that plaintiffs' channel stuffing allegations failed because plaintiffs did not allege any accounting violations. The court explained that this was fatal to their claims as the only type of channel stuffing that is fraudulent is when it is used to "book revenues on the basis of goods shipped but not really sold because the buyer can return them."[140] Further, there were no allegations that Elanco was shipping to distributors any unordered products, nor were there any allegations that the distributors were returning large amounts of products based on either the fact that products had not been ordered or distributors were not able to sell them.[141] Rather, the court found that plaintiffs "simply and repeatedly" alleged that Elanco's sales practices "induced distributors to purchase 'far in excess of demand' and in excess of their 'needed inventory.'"[142] The court also found that plaintiffs repeated assertions regarding the allegation that sales exceeded demand or the needed inventory were merely generalized assertions that failed to meet the stringent requirements of the PSLRA and Rule 9(b).[143] Additionally, the court called into question plaintiffs' heavy reliance on confidential witnesses and found such allegations failed to meet the PSLRA standards of reliability.[144] Ultimately, the court found that plaintiffs failed to adequately plead a channel stuffing scheme, and therefore it did not need to consider whether plaintiffs adequately plead defendants made misstatements or omissions about such scheme.[145]

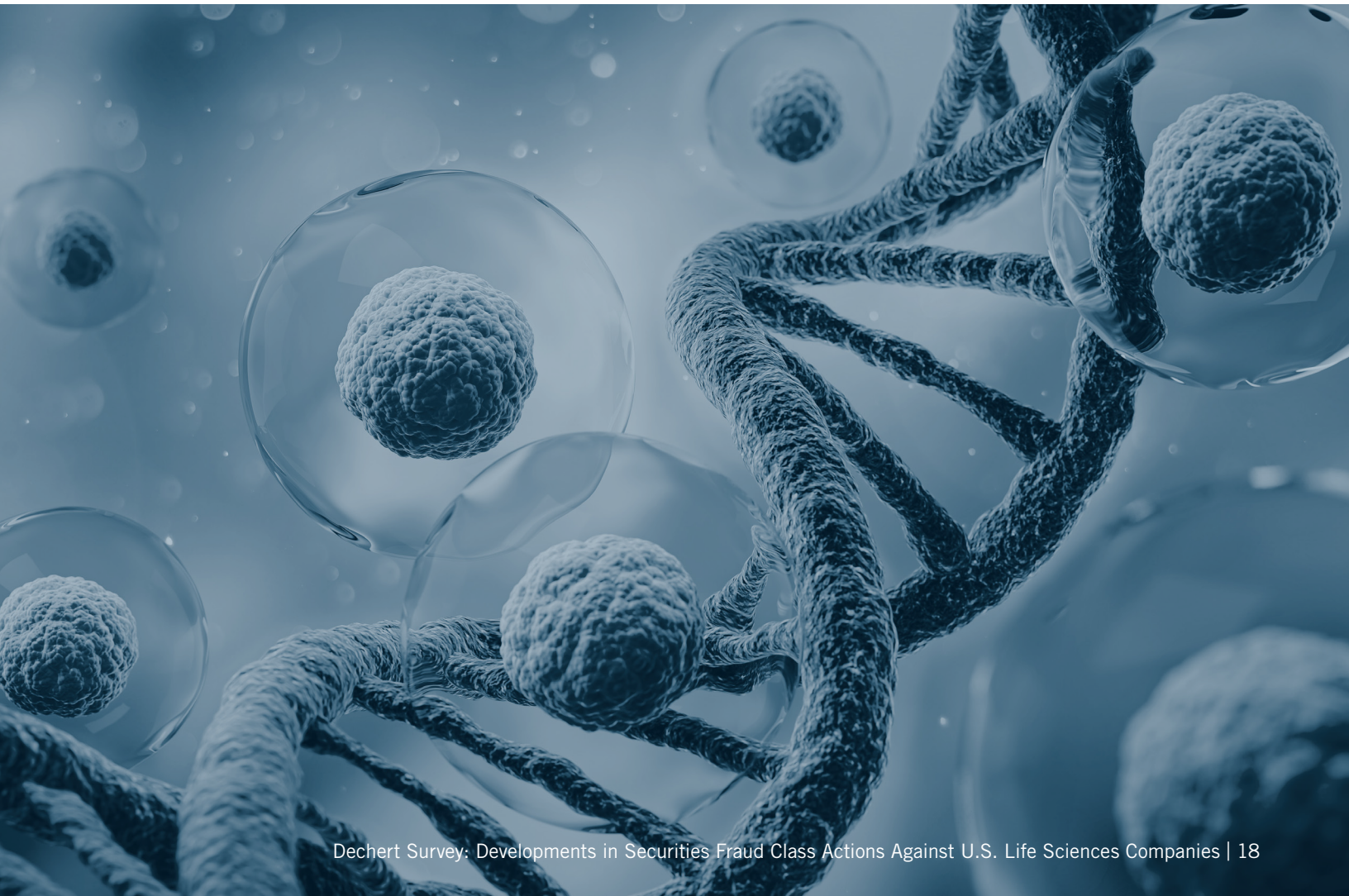
130 *Id.* at 4.
131 *Id.*
132 *Id.*
133 *Id.*
134 *Id.*
135 *Id.* at 40.
136 *Id.*
137 *Id.* at 40-41.
138 *Id.*
139 *Id.*
140 *Id.*
141 *Id.* at 42.
142 *Id.*
143 *Id.* at 42-43.
144 *Id.* at 50-51.
145 *Id.* at 53.

Minimizing Securities Fraud Litigation Risks

Life sciences companies continue to be a popular target for class action securities fraud claims. While many of the companies discussed above were successful in defending against these claims, companies should be cautious and take steps to reduce the risk of being targeted in a securities fraud class action. Below is a list of practices that life sciences companies should consider:

- Companies should develop a long-term response plan to potential triggering events and update their plans to respond to market conditions. Companies should strive to avoid any inconsistency in public statements and fight the urge to respond instinctively without identifying known risks or considering non-public information.
- In particular, many life sciences companies encounter regulatory setbacks, such as negative side effects in clinical trials, clinical trial failures, receipt of complete response letters, etc. When these are disclosed to the market, it may trigger a stock price drop. Companies should exercise care when making any disclosures to ensure that they disclose both the positive and negative results, including potentially negative information learned after the preliminary results are issued. Companies should ensure that internal disclosure regimens and processes are well documented and consistently followed.
- Smaller life sciences companies are susceptible to securities class actions and should work with counsel to ensure that they adopt a disclosure plan. Disclosure plans should not be limited to cover written disclosures made in press releases or SEC filings, but should also include any statements made by executives during analyst calls. Company websites should also be continually updated.
- Life sciences companies are not immune to issues that may cut across all industries, and accordingly they should be prepared to make appropriate disclosures relating to transactions, business prospects, operations, financials, etc.
- Courts often have the benefit of hindsight to determine whether a product is defective by considering what defendants could or should have done differently. For example, courts often consider the existence of safer alternatives and the ability of the defendant to eliminate a product's dangerous characteristics. Companies should consider not only whether a given product is defective on its own, but how it compares to potential alternative designs or formulations and how its benefits balance the risks.
- Because deal litigation has been at the forefront in filings against life sciences and other companies, material disclosures to investors relating to the transaction should contain detailed explanations about the history of the transaction, alternatives to the transaction, reasons for the recommendation, the terms of the transaction, fairness opinions, conflicts of interest, among other issues.
- Even if incorporated abroad, life sciences companies that are non-U.S. issuers may be targeted in the U.S. despite events occurring that may not be U.S. specific.
- Regarding statements made in public filings, courts continue to weigh in on opinion statements and the law is continuing to evolve. Be aware that opinion statements should be reasonably held and not conflict with information that would render the statements misleading.

- Forward-looking information about a drug or device should be clearly identified as such and distinguished from historical fact. Analyst calls and webcasts should also identify certain disclosures as forward-looking statements.
- Risk disclosures that are current, relevant and upfront help to ward off securities class actions. Companies should ensure that public statements and filings contain not only general disclaimers relating to forward-looking statements but also appropriate "cautionary language" or "risk factors" that are specific and meaningful, and cover the gamut of risks throughout the entire drug product life cycle – from development to commercialization.
- Be aware that former employees in all departments, not just those relating to clinical trials, may become confidential witnesses for shareholder plaintiffs. Educate employees about not sharing confidential information with others and limiting social media about the company.
- Develop and publish an insider trading policy to minimize the risk of inside trades, including 10b5-1 trading plans and trading windows. Class action lawyers aggressively monitor trades by insiders to develop allegations that a company's executives knew "the truth" and unloaded their shares before it was disclosed to the public and the stock plummeted. Regulators are also cautious that corporate insiders use Rule 10b5-1 plans in ways that are not consistent with the objectives of the rule and will start monitoring 10b5-1 trading plans that are canceled or terminated based on later-obtained material nonpublic information.
- Work with insurers to hire qualified counsel with experience defending securities class action litigation on a full-time basis.



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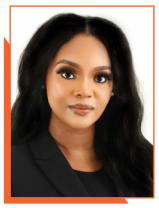

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