

PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 23-2776

SECURITIES & EXCHANGE COMMISSION

v.

DALE B. CHAPPELL; BLACK HORSE CAPITAL LP;
BLACK HORSE CAPITAL MASTER FUND LTD;
CHEVAL HOLDINGS LTD;
MARY E. CHAPPELL, Relief Defendant;
CANDACE M. DURAN, Relief Defendant

Dale B. Chappell, Black Horse Capital LP, Black Horse
Capital Master
Fund Ltd, Cheval Holdings Ltd,
Appellants

On Appeal from the United States District Court
For the District of New Jersey
(D.C. No. 2-23-cv-03769)
District Judge: Honorable John M. Vazquez

Argued
January 17, 2024

Before: JORDAN, BIBAS, and AMBRO, *Circuit Judges*

(Filed: July 9, 2024)

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OPINION OF THE COURT

JORDAN, *Circuit Judge*.

I. BACKGROUND

The Securities and Exchange Commission brought a civil enforcement action against Dale Chappell and three of his investment entities for insider trading in violation of various federal securities laws. In the District Court, the SEC sought

and obtained a preliminary injunction to freeze Chappell's assets. Chappell asks us to vacate that injunction, but, because the District Court appropriately exercised its discretion in imposing it, we will affirm.

A. Factual Background

1. Chappell and the Black Horse Funds

Chappell relinquished his United States citizenship in 2013 and is now a citizen of Malta and a legal resident of Switzerland. He serves as the Chief Scientific Officer and a member of the board of directors of Humanigen, Inc. ("Humanigen" or the "Company"), a biopharmaceutical company. With his wife, he owns eighty-eight percent of Black Horse Capital LP, Black Horse Capital Master Fund Ltd., and Cheval Holdings, Ltd. (collectively, the "Black Horse Funds"),¹ investment funds that, together, are Humanigen's largest shareholder. Chappell has complete control over the Black Horse Funds' investment portfolio, which is "heavily concentrated" in Humanigen stock, so much so that the stock "represent[s] the overwhelming majority of the [Funds'] holdings[.]" (J.A. at 662.)

2. Humanigen's Clinical Study for Lenz

Shortly following the onset of the COVID-19 pandemic, Humanigen sought to obtain emergency use authorization ("EUA") from the United States Food and Drug Administration (the "FDA" or the "Agency") to commercialize

¹ The remaining twelve percent of the Black Horse Funds is owned by twelve other investors.

a drug called lenzilumab, or “Lenz,” to treat inflammation in COVID-19 patients. (J.A. at 656.) The Company had historically “incurred significant net losses and negative operating cash flows[,]” and Lenz was Humanigen’s only product with short-term revenue potential. (J.A. at 143.) With commercialization of Lenz as the goal, in May of 2020, Humanigen commenced a clinical trial with 300 patients.²

A few months later, Humanigen sought feedback from the FDA regarding the clinical trial’s sufficiency to support an EUA. The FDA responded with concern that the clinical trial was too small, and it recommended that Humanigen “increase the sample size of [its] current study” or, “[a]lternatively, ... consider initiating and completing additional studies of an appropriate size prior to submission of [its] EUA request package.” (J.A. at 355-56.) Chappell asserts that, in response to the FDA’s feedback, Humanigen increased the size of its study to approximately 515 patients.

3. The Black Horse Funds’ March Trading Plan

In March of 2020, Humanigen stock was trading at \$1.65 per share in the over-the-counter market.³ The company

² The study was called the “LIVE-AIR” study, and Humanigen characterized it as a “Phase Three” study. (J.A. at 659.)

³ Over-the-counter securities “are traded without being listed on an exchange.” Chris B. Murphy, *Over-the-Counter (OTC) Markets: Trading and Securities*, Investopedia (Mar. 5,

held an initial public offering (“IPO”) on the NASDAQ stock exchange in September of 2020, and, by January of 2021, Humanigen stock had risen to \$20.64 per share. By that time, the Black Horse Funds owned about 14 million shares of Humanigen stock. As a result, Chappell had many tens of millions of dollars in unrealized gains from the Black Horse Funds’ investment in Humanigen stock.

Because of a lock-up period following the IPO,⁴ the first trading window in which Chappell could sell some of his Humanigen shares was in March of 2021. He accordingly set up a 10b5-1 trading plan⁵ for the Black Horse Funds for the

2024), <https://www.investopedia.com/terms/o/otc.asp> [<https://perma.cc/3KLL-2JEH>].

⁴ An IPO lock-up period is “a period of time after a company has gone public when major shareholders are prohibited from selling their shares. During the IPO lock-up[,] company insiders and early investors cannot sell their shares, helping to ensure an orderly IPO and not flood the market with additional shares for sale.” Adam Hayes, *What’s an IPO Lockup? Definition, Purpose, Expiration Strategies*, Investopedia (Feb. 23, 2024), <https://www.investopedia.com/terms/i/ipolockup.asp> [<https://perma.cc/56WG-FHAA>].

⁵ More accurately, Chappell set up a 10b5-1 trading plan for each of the three Black Horse Funds. Because the plans function, in effect, as one plan, we refer to them in the singular.

“Rule 10b5-1 allows insiders to sell company stock by setting up a predetermined plan that specifies in advance the share price, amount, and transaction date.” Adam Hayes, *Rule*

March trading window. The plan set limit prices that were higher than the market price of Humanigen stock at the time he entered the trading plan, so the Humanigen shares held by the Black Horse Funds would be sold only if the stock continued to appreciate in value and reach those limit prices.⁶ During the dates that Chappell's March trading plan was in effect, however, Humanigen's stock price never reached those levels, so the trading plan did not trigger any sales of the stock. If the limit prices had been met, the Black Horse Funds could have sold approximately 9% of their holdings in Humanigen.⁷

10b5-1 Definition, How It Works, SEC Requirements, Investopedia (Feb. 27, 2023), <https://www.investopedia.com/terms/r/rule-10b5-1.asp> [<https://perma.cc/FHJ2-X3LE>]. These plans are created by corporate insiders to protect against insider trading allegations. *Id.*

Humanigen has an insider trading policy that prohibits employees from trading its securities if they are aware of material nonpublic information relating to the company.

⁶ Specifically, the plan contained an initial limit price of \$25, with a second limit price of \$35, meaning that the Black Horse Funds would not execute sales of Humanigen stock unless its market price was at least \$25, with additional sales being triggered if the stock was at least \$35. Chappell asserts that the prices in the March trading plan were set in anticipation of positive results from Lenz's clinical trial.

⁷ Apparently, Chappell had been communicating with multiple brokers to create the trading plan. After executing the March trading plan, Chappell responded via email to another broker who had inquired about getting a plan set up, saying,

4. The FDA's Feedback on Humanigen's Clinical Study

In March of 2021, after Chappell entered his trading plan, Humanigen reported the initial results of its clinical trial and scheduled a pre-EUA meeting with the FDA to discuss them. In advance of the meeting, the FDA sent preliminary comments, stating that, “while available data for [Lenz] are promising, the criteria for issuance of an EUA are unlikely to be met[.]” (J.A. at 768.) It explained that it had “significant concerns that negatively impact the ability to rely on this single trial to support the potential benefit of [Lenz]” and recommended that Humanigen “conduct an additional trial(s) to inform the potential benefit and risk of [its] product[.]” (J.A. at 767-68.)

At the pre-EUA meeting, on April 14, the FDA asked Humanigen if it was going to conduct an additional confirmatory trial. The Company responded that it had an ongoing “ACTIV-5” trial with the National Institutes of Health (the “NIH”) that included a Lenz component, but that it “had no current plans for further clinical trials.” (J.A. at 344.) The FDA replied that the NIH ACTIV-5 trial was “relatively small” and “likely not sufficient to serve as a confirmatory trial[.]” (J.A. at 344.) The Agency “strongly recommended that [Humanigen] conduct an additional confirmatory study and discouraged submission of an EUA at [that] time.” (J.A. at 344.)

“We are only selling up to 9% of our [Humanigen] stock with the current 10b-5 plan so there is a lot more to come.” (J.A. at 759.)

5. Humanigen's Response to the FDA's Feedback

Three days after the meeting, Humanigen's CFO, who served as the company's securities compliance officer, wrote an email to Chappell and Humanigen's CEO, stating, in relevant part:

We need to disclose the results of the FDA meeting. I think it is fairly clear that the data we currently have as discussed is not adequate for EUA submission. The minutes [from the meeting] will not change that outcome. This is negative news and we have a duty to update the market.

(J.A. at 1382.)

A few days later, Humanigen held a board meeting to discuss the FDA's feedback.⁸ At the meeting, Humanigen's CEO explained that the FDA "was likely to request the Company to initiate an additional confirmatory study[,] but that the Company had received new data from the trial a few days after the FDA meeting and the Agency had not had an opportunity to consider it. (J.A. at 838.) Right after the meeting, Chappell sent an email to the CEO expressing his belief that Humanigen was onto "something very meaningful" (J.A. at 784), since the new data showed that certain untreatable patients "were skewing the entire data set" (Opening Br. at 16). Ultimately, the board decided not to immediately disclose the details of the FDA meeting to the

⁸ Humanigen's CFO attended the board meeting.

public “given the incomplete nature of the data and [because] further data would be furnished to [the] FDA in the near term that may be more compelling.” (J.A. at 838.)

Despite the FDA’s previous discouragements, Humanigen notified the Agency via email on May 4, 2021, that it was planning to submit an EUA for Lenz “within approximately a month[,]” with “additional analyses” and “a more complete data package[.]” (J.A. at 368.) On May 13, the FDA emailed Humanigen a post-meeting comment that acknowledged its May 4 email and “reiterate[d] [its] concerns conveyed during the [pre-EUA] meeting ..., as well as [its] feedback that ... [Lenz] is unlikely sufficient to satisfy the criteria for issuance of an EUA.” (J.A. at 344.) “In lieu of an EUA request, [the FDA] strongly recommend[ed] that [Humanigen] submit a meeting request to further discuss [its] continued development program, ... includ[ing] details regarding additional confirmatory clinical trial(s).” (J.A. at 344.)

On the same day, Humanigen submitted a quarterly financial report to the SEC that disclosed the FDA meeting. The report informed investors that it planned to submit an EUA application for Lenz at the end of May of 2021, mentioned that the FDA requested additional information, and cautioned that “[t]here can be no assurance that the data ... will be sufficient for an EUA or that the FDA will not require additional information in order to grant an EUA.” (J.A. at 902.) The report did not mention the FDA’s specific feedback that Humanigen should conduct an additional confirmatory study before submitting an EUA application.

6. The Black Horse Funds' June Trading Plan

Less than two hours after Humanigen received the FDA's email reiterating its concerns about Lenz's possibility of receiving an EUA, Chappell contacted his stockbroker about setting up a new 10b5-1 trading plan to sell some of the Black Horse Funds' shares of Humanigen stock. The plan was different from the one that he had set up for the March trading window. This time, it called for a limit price below the then-market value of the stock because Chappell wanted "to ensure" that he would be able to sell some of his shares. (J.A. at 540.) In other words, Chappell was willing to sell his shares at a discount to their market value. He was unable to execute his trading plan, however, because Humanigen did not have an open trading window for executives at that time.

Nevertheless, Chappell later sold 475,000 shares of Humanigen stock for approximately \$8.8 million, without a trading plan in effect. He alleges that the sales were "intended to be a first step towards satisfying [his] investors' requests to realize paper gains and hedge the outsized exposure to Humanigen" and "to provide the amount of capital [that he] needed to meet an upcoming mortgage payment." (Opening Br. at 19.)

A few weeks later, Humanigen opened a trading window in June of 2021, and Chappell executed a new trading plan for the Black Horse Funds that again called for a limit price below the Company's stock price at the time. The plan was approved by Humanigen's CFO, although the record does not indicate on what basis the plan was approved or what representations Chappell made to the CFO before he

authorized it. Because Humanigen stock was trading above the plan's limit price, Chappell was able to quickly offload a substantial amount of his Humanigen stock. From June through August of 2021, he sold, in total, 3,835,000 shares of Humanigen stock for net proceeds of approximately \$68 million. That was approximately 25% of the Black Horse Funds' shares of Humanigen stock.⁹

⁹ Prior to the June trading plan, Chappell had attempted to execute a "no-cost collar" strategy with the Humanigen stock under his control. A no-cost-collar "is used to hedge against volatility" and is a stock options strategy "implemented after your long position in a stock experiences substantial gains." James Chen, *Zero Cost Collar: Definition and Example*, Investopedia (May 20, 2023), <https://www.investopedia.com/terms/z/zerocostcollar.asp> [<https://perma.cc/6EH6-E7GD>]. Chappell's proposed arrangement, which involved buying puts at \$17 per share and selling calls at \$30 per share, worked as follows: If Humanigen's stock price rose to \$30 or higher, the Black Horse Funds would have to sell shares to a buyer at \$30 if the buyer exercised the call options; if the stock fell below \$17, the Black Horse Funds could exercise their put options to sell their shares to a buyer for \$17. Thus, by using a no-cost collar, Chappell would have limited both his upside gains and downside losses. Like the June trading plan, the no-cost collar would have applied to roughly 25% of the Black Horse Funds' shares in Humanigen. The no cost-collar was too difficult to implement over the short time horizon, so Chappell abandoned it and, instead, executed the June trading plan.

Shortly after the trading plan was implemented, a former Humanigen board member emailed Chappell asking him why he sold some of his Humanigen stock. Chappell responded that he sold the shares to fulfill his fiduciary duties and because of unknowns related to the COVID-19 pandemic.¹⁰ (J.A. at 1134.) Notably absent from Chappell's response was any mention of the FDA's feedback.

7. The FDA's Denial of the Lenz EUA Application

On June 2, 2021, Humanigen submitted its EUA application for Lenz.¹¹ Instead of conducting a new clinical study before submitting the application, as the FDA had recommended, Humanigen had merely begun discussions with the NIH to expand the existing ACTIV-5 study. A week later, the FDA sent Humanigen a request for information about the expanded ACTIV-5 trial study elements, and cautioned that the "current study elements ... would not be acceptable as a confirmatory study[.]" (J.A. at 1147.) Humanigen responded

¹⁰ Chappell alleges that, in February of 2021, a minority investor in the Black Horse Funds advised him to sell some of the Humanigen stock to cash in on some of the gains. He also asserts that, in March of 2021, he spoke with another investor about "reducing the fund's position in Humanigen." (J.A. at 664.)

¹¹ Humanigen issued a press release on May 28 stating that it had submitted an EUA application for Lenz. But communications from the FDA to Humanigen, including the FDA's letter denying Humanigen's EUA application, indicate that the application was submitted on June 2.

to the FDA by saying that “discussions in relation to the expansion of the ACTIV-5 trial ... to a confirmatory study are ongoing.” (J.A. at 1147.) In the end, the FDA never authorized Humanigen to use the NIH ACTIV-5 study as an additional confirmatory study.

Instead, the FDA denied Humanigen’s EUA authorization request in September of 2021, stating that, “based on the totality of scientific evidence available, ... we are unable to reasonably conclude that [Lenz] may be effective for the treatment of COVID-19 as proposed.”¹² (J.A. at 622.)

¹² The FDA provided the following comment in its letter denying Humanigen’s EUA request:

Your EUA request is based primarily on data from a randomized, double-blind, placebo-controlled trial of [Lenz] for the treatment of hospitalized patients with COVID-19. We note that results for the primary endpoint, ventilator-free survival by Day 28, were not statistically significant using the pre-specified primary analysis method. While an alternative analysis indicated nominal significance for the primary endpoint, there are limitations to interpreting and relying on the results of post-hoc analyses. Given the primary endpoint failed to achieve statistical significance based on the primary analysis, any results of the secondary endpoints would be considered exploratory. Notwithstanding, the treatment comparisons for all key secondary endpoints failed to exclude the null value and do not provide support for

Humanigen publicly announced the denial, causing its stock price to fall nearly 50%. According to the SEC's calculations, Chappell avoided about \$38 million in losses by selling his shares prior to the public announcement disclosing the FDA's denial of an EUA for Lenz.

B. Procedural History

In July of 2023, the SEC filed a complaint in the District Court alleging that Chappell and the Black Horse Funds¹³ engaged in insider trading in violation of Securities Act Section 17(a), Exchange Act Section 10(b), and Exchange Act Rule 10b-5.¹⁴ It alleged that Chappell traded securities on the basis

efficacy. The safety database for [Lenz] in COVID-19 patients was also limited.

(J.A. at 622-23.) *See infra* note 27 for a further discussion of this comment.

¹³ From this point, for simplicity, Appellants Chappell and the Black Horse Funds will be referred to collectively as “Chappell,” unless there is a need to distinguish them.

¹⁴ The relevant text of these statutes and rule are as follows:

Section 17(a) of the Securities Act of 1933 makes it “unlawful for any person in the offer or sale of any securities ... to employ any device, scheme, or artifice to defraud[.]” 15 U.S.C. § 77q(a).

Section 10(b) of the Exchange Act of 1934 makes it unlawful for any person to “use or employ, in connection with the purchase or sale of any security registered on a national

of material nonpublic information – namely, the FDA feedback that Humanigen had received about Lenz being unlikely to qualify for an EUA unless the Company performed an additional confirmatory study. The SEC sought injunctive relief, disgorgement of ill-gotten gains, interest, civil penalties, and an order that Chappell be barred from serving as an officer or director of any publicly traded company.

In addition, it sought and obtained an ex parte temporary restraining order (“TRO”) freezing all of Chappell’s assets. In its order granting the TRO, the District Court found that, “[f]or purposes of freezing assets, the SEC has established a likelihood of success on the merits or that an inference can be drawn that the party has violated the federal securities laws” and that “[t]here is good cause to believe that, unless funds and assets are frozen ... [Chappell] will dissipate, conceal, or transfer from the jurisdiction of this Court assets that could be subject to an order directing disgorgement or the payment of civil money penalties in this action.” (J.A. at 2.)

Later, the District Court held an expedited hearing on whether it should convert the TRO to a preliminary

securities exchange[,] ... any manipulative or deceptive device or contrivance[.]” 15 U.S.C. § 78j(b).

Rule 10b-5 provides that manipulative devices or contrivances include “the purchase or sale of a security of any issuer, on the basis of material nonpublic information about that security or issuer, in breach of a duty of trust or confidence that is owed ... to the issuer of that security or the shareholders of that issuer[.]” 17 C.F.R. § 240.10b5-1(a).

injunction.¹⁵ During the hearing, the Court repeated that, for there to be injunctive relief, “the SEC must show either a likelihood of success on the merits or that an inference can be drawn that a party has violated the federal securities laws.” (J.A. at 18.) The SEC emphasized that there was “a lower bar here than a traditional preliminary injunction” because all that needed to be shown was “an inference ... that there was a violation of the securities law[.]” (J.A. at 20.) After hearing the parties’ arguments, the Court found that “the SEC has certainly met that there’s a likelihood of success” that Chappell violated the insider trading laws “and if not[,] at minimum they have showed an inference that can be drawn” that he violated them. (J.A. at 80.) The Court then converted the TRO to a preliminary injunction, the terms of which mirrored the TRO.

Initially, the asset-freeze component of the preliminary injunction applied to all of Chappell’s assets, “with no modifications or carve-outs[.]”¹⁶ (J.A. at 14.) Prior to the hearing, Chappell had requested a monthly carveout that included \$632,000 for rent and \$7,900 for luxury vehicles. At the hearing, the Court observed that Chappell was living “like royalty,” and it denied his carveout request, without prejudice. (J.A. at 82.) It told Chappell to “come back with more reasonable numbers[.]” (J.A. at 82-83.)

¹⁵ According to the SEC, Chappell refused to be deposed before the hearing and also refused to provide all of the documents that had been requested.

¹⁶ Approximately \$50 million of Chappell’s assets are frozen.

Later, Chappell filed a motion to request an updated living expenses carveout, which included his Humanigen salary, or its equivalent, of \$5,637.50 every two weeks. The SEC consented to that carveout, which the Court granted. In addition, Chappell and the SEC agreed to have the Court appoint a receiver to manage Chappell's assets during the pendency of the case. Chappell has timely appealed the preliminary injunction.

II. DISCUSSION¹⁷

We first consider the standard of proof required for SEC-initiated preliminary injunctions, including asset freezes, and then turn to the District Court's conclusion that Chappell violated insider trading laws. Lastly, we assess whether the other preliminary injunction factors support the injunction that was imposed.

¹⁷ The District Court had jurisdiction under 15 U.S.C. §§ 77t(b), 77v(a), 78u(d), 78u(e), 78u-1, and 78aa. We have jurisdiction pursuant to 28 U.S.C. § 1292(a)(1). “We employ a tripartite standard of review for ... preliminary injunctions. We review the District Court's findings of fact for clear error. Legal conclusions are assessed de novo. The ultimate decision to grant or deny the injunction is reviewed for abuse of discretion.” *Ramsay v. Nat'l Bd. of Med. Examiners*, 968 F.3d 251, 256 n.5 (3d Cir. 2020).

A. The Traditional Preliminary Injunction Standard of Review Applies to SEC-Initiated Preliminary Injunctions.

“Preliminary injunctive relief is an extraordinary remedy, which should be granted only in limited circumstances.” *Ferring Pharms., Inc. v. Watson Pharms., Inc.*, 765 F.3d 205, 210 (3d Cir. 2014) (internal quotation marks omitted). Under the familiar standard of proof, a party “seeking a preliminary injunction must establish that [it] is likely to succeed on the merits, that [it] is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in [its] favor, and that an injunction is in the public interest.” *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). “Generally, the moving party must establish the first two factors and only if these gateway factors are established does the district court consider the remaining two factors.” *Greater Phil. Chamber of Com. v. City of Phil.*, 949 F.3d 116, 133 (3d Cir. 2020) (internal quotation marks omitted). If the gateway factors are met, “[t]he court then determines in its sound discretion if all four factors, taken together, balance in favor of granting the requested preliminary relief.” *Id.* (internal quotation marks omitted).

Despite the well-established four-factor preliminary injunction test, the District Court instead employed a test that the Second Circuit uses for SEC-initiated asset freezes. As discussed further herein, that test considers only whether the agency is likely to succeed on its securities violation claims; it does not consider the irreparable harm, balancing of the equities, or public interest elements of the generally applicable preliminary injunction test. *Smith v. SEC*, 653 F.3d 121, 127-28 (2d Cir. 2011) (“In this jurisdiction, injunctions sought by

the SEC do not require a showing of irreparable harm or the unavailability of remedies at law. Rather, the SEC need only make a substantial showing of likelihood of success as to both a current violation and the risk of repetition.” (internal quotation marks and citation omitted)). In addition, the Second Circuit, when deciding to impose an asset freeze, reduces the level of proof needed to satisfy the likelihood-of-success prong. The SEC needs to show only that an inference can be drawn that a defendant violated the federal securities laws. *Id.* at 128. (“Where an asset freeze is involved, the SEC must show either a likelihood of success on the merits, *or* that an inference can be drawn that the party has violated the federal securities laws.” (emphasis added) (internal quotation marks omitted)).

We take a different path. District courts in this Circuit must apply the normal four-factor preliminary injunction test when considering the SEC’s application for a preliminary injunction.

1. All Four Factors of the Preliminary Injunction Test Apply in SEC Cases.

The Securities Act and the Securities Exchange Act provide the SEC statutory bases to move for an injunction when it appears that a party has violated (or will violate) federal securities laws:

Whenever it shall appear to the [SEC] that any person is engaged or about to engage in any acts or practices which constitute or will constitute a violation of the provisions of this subchapter ... the [SEC] may, in its discretion, bring an action in any district court of the United States ... to

enjoin such acts or practices, and upon a proper showing, a permanent or temporary injunction or restraining order shall be granted[.]

15 U.S.C. § 77t(b) (the Securities Act); 15 U.S.C. § 78u(d)(1) (similar language in the Securities Exchange Act).¹⁸ Because of those statutory bases, the Second Circuit does not require district courts to consider all of the traditional preliminary injunction factors before granting such an injunction. *See SEC v. Unifund SAL*, 910 F.2d 1028, 1037 (2d Cir. 1990) (“Since the SEC, in discharging its statutory responsibilities, is relieved of the burden of showing a risk of irreparable injury so that it may secure a preliminary injunction more easily than a private litigant, we should not add to its burden on the merits.” (citation omitted)). Rather, it requires the SEC to show only that there is a likelihood of success that a court will find that a

¹⁸ The Securities Exchange Act provides, in relevant part:

Whenever it shall appear to the [SEC] that any person is engaged or is about to engage in acts or practices constituting a violation of any provision of this chapter, ... it may in its discretion bring an action in the proper district court of the United States ... to enjoin such acts or practices, and upon a proper showing a permanent or temporary injunction or restraining order shall be granted[.]

15 U.S.C. § 78u(d)(1).

securities violation has occurred (or will occur) and risk of repetition before it grants a preliminary injunction.¹⁹ *Id.*

Controlling and well-reasoned precedent compels us to forego the Second Circuit’s approach. In *Weinberger v. Romero-Barcelo*, the Supreme Court clarified when it is appropriate for a statutorily-authorized injunction to displace traditional principles governing injunctive relief. 456 U.S. 305 (1982). The Court acknowledged that “Congress may intervene and guide or control the exercise of the courts’ discretion” in issuing an injunction, but the Court instructed that we should not “lightly assume that Congress has intended to depart from established [equitable] principles.” *Id.* at 313.

¹⁹ The Second Circuit does, however, require a showing of irreparable harm for other statutorily-authorized injunctions. *See Salinger v. Colting*, 607 F.3d 68, 79 (2d Cir. 2010) (overruling its previous precedent that assumed irreparable harm in the copyright context); *Town of Huntington v. Marsh*, 884 F.2d 648, 651 (2d Cir. 1989) (explaining that injunctive relief does not follow automatically upon a finding of statutory violations, including environmental violations).

The First Circuit has rejected the Second Circuit’s approach for SEC-initiated injunctions. *SEC v. Fife*, 311 F.3d 1, 8 (1st Cir. 2002) (“Unlike the Second Circuit, we have not removed irreparable harm from the preliminary injunction inquiry in SEC preliminary injunction actions.”). And the Seventh Circuit has reserved decision on whether it agrees with the Second Circuit. *SEC v. Cherif*, 933 F.2d 403, 408 (7th Cir. 1991) (“We note that the Second Circuit has altered the standard for injunctions requested by the SEC Because the parties have not argued about the propriety of such a modification, we leave the question for another day.”).

It then declared that “the comprehensiveness of this equitable jurisdiction is not to be denied or limited in the absence of a *clear and valid legislative command*.” *Id.* (emphasis added); *see also Hecht Co. v. Bowles*, 321 U.S. 321, 329 (1944) (“We cannot but think that, if Congress had intended to make such a drastic departure from the traditions of equity practice, an unequivocal statement of its purpose would have been made.”). The Court explained that, “[u]nless a statute in so many words, or by a necessary and inescapable inference, restricts the court’s jurisdiction in equity, the full scope of that jurisdiction is to be recognized and applied.” *Romero-Barcelo*, 456 U.S. at 313. In sum, courts must “construe the statute at issue in favor of that interpretation which affords a full opportunity for equity courts to treat enforcement proceedings ... in accordance with their traditional practices, as conditioned by the necessities of the public interest which Congress has sought to protect.”²⁰ *Id.* at 320 (alteration in original) (internal

²⁰ After *Romero-Barcelo*, the D.C. Circuit has rejected the view that injunctions authorized by statute automatically replace traditional equitable standards, explaining that “[s]ome cases antedating *Romero-Barcelo* took the view that mere statutory authorization of injunctive relief displaced equitable standards[.] ... But such cases seem outmoded by *Romero-Barcelo*’s view that displacement of the usual equitable standards requires a clear and valid legislative command.” *United States v. Microsoft Corp.*, 147 F.3d 935, 944 (D.C. Cir. 1998) (internal quotation marks omitted).

Nevertheless, the Eighth Circuit has said that “[i]t is a well-established rule that where Congress expressly provides for injunctive relief to prevent violations of a statute, a plaintiff does not need to demonstrate irreparable harm to secure an injunction.” *Burlington N. R. Co. v. Bair*, 957 F.2d 599, 601

quotation marks omitted). This approach was recently taken in *Starbucks Corp. v. McKinney*, with the Supreme Court eschewing a lower standard for injunctions sought by the National Labor Relations Board and reiterating that, “absent a clear command from Congress, courts must adhere to the traditional four-factor test.” No. 23-367, --- S. Ct. ----, 2024 WL 2964141, at *4 (June 13, 2024).

In *SEC v. Gentile*, we analyzed at length whether the text of the injunction provision in the Securities Exchange Act, 15 U.S.C. § 78u(d)(1), satisfied *Romero-Barcelo*’s “clear statement” rule such that it would require us to depart from traditional equitable principles. 939 F.3d 549, 555-58 (3d Cir. 2019). We explained that “[i]nnumerable acts of Congress explicitly provide for injunctions, and courts must account for the policy judgments exemplified by those statutes when exercising their equitable discretion.” *Id.* at 555-56. “But unless Congress clearly states an intention to the contrary, statutory injunctions are governed by the same established principles of equity that have developed over centuries of practice.” *Id.* at 556 (internal quotation marks omitted).

(8th Cir. 1992). It reasoned that, “[i]n such situations, it is not the role of the courts to balance the equities between the parties.” *Id.* Rather, “[t]he controlling issue is whether Congress has already balanced the equities and has determined that, as a matter of public policy, an injunction should issue where the defendant is engaged in, or is about to engage in, any activity which the statute prohibits.” *Id.* at 601-02. “The proper role of the courts is simply to determine whether a violation of the statute has or is about to occur.” *Id.* at 602.

We specifically discussed the irreparable harm requirement, saying that “the most basic rule of preventive injunctive relief [is] that the plaintiff must show a cognizable risk of future harm.” *Id.* We went on to explain that, “[b]esides being an element of Article III standing for prospective relief, the need to show risk of harm is also a traditional equitable requirement that applies to enforcement agencies pursuing statutory injunctions” and that “Congress must provide a clear statement to substantially depart from traditional equitable principles like that one.” *Id.* at 556-57.

Applying those principles, “[w]e perceive[d] no such intent in the text of § 78u(d)(1)[, i.e., the relevant section of the Securities Exchange Act,]” to depart from traditional equitable principles. *Id.* at 557. We emphasized, rather, that § 78u(d)(1) did not show “an intent – let alone a clear intent – that injunctions should issue automatically on a finding of past violations or without a proper showing of the likelihood of future harm [because it] uses open-ended language that suggests traditional equitable discretion.” *Id.* In sum, “absent much clearer language than is found in the Exchange Act, the entitlement of a plaintiff to an injunction thereunder remains subject to principles of equitable discretion.” *Id.* (brackets omitted).

Accordingly, district courts in this Circuit must apply the traditional four-factor preliminary injunction test, rather than the Second Circuit’s modified test, before issuing a preliminary injunction sought by the SEC.²¹

²¹ The language in the injunction provision in the Securities Act, 15 U.S.C. § 77t(b), has substantially the same language as the injunction provision in the Securities Exchange

2. The Traditional Likelihood-of-Success Standard Applies to Asset Freezes.

An asset freeze is a type of preliminary injunction. *Deckert v. Indep. Shares Corp.*, 311 U.S. 282, 290 (1940). It is “designed to preserve the status quo by preventing the dissipation and diversion of assets.” *SEC v. Infinity Grp. Co.*, 212 F.3d 180, 197 (3d Cir. 2000). It “is appropriate where it will assist the District Court in preventing defendants from committing further violations[.]” *TKR Cable Co. v. Cable City Corp.*, 267 F.3d 196, 208 n.4 (3d Cir. 2001).

In addition to eliminating three of the four traditional elements of the preliminary injunction standard for SEC-initiated injunctions, see *supra* section II.A.1., the Second Circuit’s approach modifies the “likelihood of success” element when it comes to asset freezes in SEC cases. As noted earlier, in that Circuit the SEC can “show either a likelihood of success on the merits, *or* that an inference can be drawn that the party has violated the federal securities laws.” *Smith*, 653 F.3d at 128 (emphasis added). That modification began with a case called *SEC v. Unifund SAL*, 910 F.2d 1028 (2d Cir. 1990). The Second Circuit reasoned there that “an ancillary remedy may be granted, even in circumstances where the elements required to support a traditional SEC injunction have not been established, and such a remedy is especially warranted where it is sought for a *limited duration*.” *Id.* at 1041 (emphasis added) (citation omitted). The court imposed a thirty-day asset freeze in that case because there was a “basis to infer” that there

Act, *id.* § 78u(d)(1). See *supra* note 18. Accordingly, our holding applies to SEC-initiated injunctions under both 15 U.S.C. §§ 77t(b) and 78u(d)(1).

was insider trading. *Id.* In later cases, however, the Second Circuit has applied that “inference” standard to asset freezes generally, without considering the duration of the freeze.²² *Smith*, 653 F.3d at 128.

We can understand why the SEC likes that approach, but there is no statutory basis for it.²³ Nor can we see any other reason to hold the SEC to a lower burden when it argues for an asset freeze rather than other types of injunctive relief. Accordingly, consistent with the principles stated in *Romero-Barcelo*, courts in this Circuit should apply the traditional “likelihood of success on the merits” standard when deciding whether to impose an asset freeze.

²² It does not appear that any other Circuit has adopted the Second Circuit’s modified “likelihood of success” standard for asset freezes. *See, e.g., Fife*, 311 F.3d at 3, 8 (applying likelihood-of-success standard to an SEC asset freeze); *Cherif*, 933 F.2d at 407-08 (same because the parties in that case agreed that the standard was “the usual one”); *SEC v. Liu*, 851 F. App’x 665, 668 (9th Cir. 2021) (applying “probable success on the merits” standard to an SEC asset freeze injunction); *cf. SEC v. Scoville*, 913 F.3d 1204, 1214 (10th Cir. 2019) (applying likelihood-of-success standard to a preliminary injunction that included an asset freeze).

²³ We requested supplemental briefing from the parties regarding the Second Circuit’s asset freeze standard. The SEC, rather than arguing the Second Circuit’s standard should apply in this case, acknowledged that “this Court need apply only the traditional likelihood of success standard[.]” (SEC Supp. Br. at 1 (internal citations omitted).)

Thus, for the SEC to succeed in this case, it must show that it is likely to succeed on the merits. In other words, “it must demonstrate that it can win[,] ... which requires a showing significantly better than negligible but not necessarily more likely than not” that Chappell violated insider trading laws. *Reilly v. City of Harrisburg*, 858 F.3d 173, 179 (3d Cir. 2017).

B. The District Court Did Not Err in Finding that the SEC is Likely to Succeed on the Merits.

Insider trading occurs “when a corporate insider trades in the securities of his corporation on the basis of material, nonpublic information.” *United States v. O’Hagan*, 521 U.S. 642, 651-52 (1997). To hold someone liable for insider trading, the SEC also “must establish the requisite scienter[.]” *Infinity Grp.*, 212 F.3d at 191. Scienter is a “mental state embracing intent to deceive, manipulate, or defraud.” *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 48 (2011) (internal quotation marks omitted).

Chappell argues that the District Court abused its discretion by making errors of law in its materiality and scienter analyses when it determined that the SEC was likely to succeed on its securities violations claims against him. Our conclusion is to the contrary.

1. The District Court Did Not Err in Concluding That the FDA Feedback Was Material.²⁴

Materiality is a “fact-specific inquiry” that “depends on the significance the reasonable investor would place on the withheld or misrepresented information.” *Basic Inc. v. Levinson*, 485 U.S. 224, 240 (1988). A fact is material if there is a “substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the total mix of information made available.” *Id.* at 231-32 (internal quotation marks omitted).

Chappell asserts that the District Court “ignored the substantial body of law holding that preliminary FDA feedback of the type at issue here is not material.” (Opening Br. at 4.) The “substantial body of law” he principally relies on is *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 516 (S.D.N.Y. 2015), *aff’d sub nom. Tongue v. Sanofi*, 816 F.3d 199 (2d Cir. 2016).

In *In re Sanofi*, a pharmaceutical company repeatedly chose not to disclose interim FDA feedback that expressed concerns over the single-blind design of one of the company’s clinical trials. *Id.* at 519. The FDA told the company that the trials would “not provide substantial support for a license application,” and recommended the use of a double-blind

²⁴ “Materiality is a mixed question of law and fact, and the delicate assessments of the inferences a reasonable shareholder would draw from a given set of facts are peculiarly for the trier of fact.” *Shapiro v. UJB Fin. Corp.*, 964 F.2d 272, 280 n.11 (3d Cir. 1992).

study. *Id.* at 519-20 (internal quotation marks omitted). The company did not disclose that feedback; rather, it continued to publicly state it was optimistic about obtaining FDA approval. *Id.* at 519, 522. After the FDA publicly released a report that “sharply criticized” the company’s submissions, the company’s stock price fell, and lawsuits followed claiming that the company failed to disclose flaws in its clinical trials. *Id.* at 523-24.

The district court in *In re Sanofi* determined that the interim feedback criticizing the single-blind study was not material, explaining that the materiality inquiry is of a “fact-intensive nature” and that “context is important” when determining whether disclosures are misleading. *Id.* at 528, 539, 541. The court reasoned that “much of the information conveyed to [the company] by the FDA was publicly available ... [and that] the FDA feedback specific to the ... clinical trials was part of an ongoing conversation with the [A]gency that defendants had no affirmative legal duty to disclose.” *Id.* at 539.

The court also noted that “courts have rejected claims of material omissions where pharmaceutical companies did not reveal procedural or methodological commentary, or other interim status reports, received from the FDA as to drugs under review.” *Id.* at 541. As the *In re Sanofi* court saw it, “interim ... feedback is not material because it does not express a binding agency decision and is subject to change as the FDA and pharmaceutical companies work together to develop viable clinical trials and approvable licensing applications.” *Id.* at 542.

On the other hand, the opinion in *In re Sanofi* made clear that, “[h]ad the FDA told the company that approval was impossible given the single-blind methodology – essentially, giving advance notice of [the drug]’s certain rejection – [the company]’s failure to disclose that feedback while touting its optimism about FDA approval would have assuredly been a material omission.” *Id.* at 545 n.15.

Chappell does not dispute *In re Sanofi*’s principle that FDA “feedback that is ‘tantamount to a statement that [the drug] could not or would not obtain timely FDA approval’” would be material. (Opening Br. at 39-40 (quoting *Sanofi*, 87 F. Supp. 3d at 541).) In fact, in the District Court, Chappell’s counsel explicitly conceded that “[i]f the FDA said, ‘You are not getting approved. We saw your data, you’re not getting approved,’ yes, that is material.” (J.A. at 34.)

Accepting for the sake of discussion that the *In re Sanofi* court was correct in its statements about interim FDA guidance,²⁵ the question of materiality before us is whether, under the facts of this case, the District Court abused its

²⁵ We need not and do not decide that the *In re Sanofi* decision was correct in this regard. It may have been, but it is enough for today to assume it was, since Chappell loses even under that view of materiality. Chappell argues that we have “embraced the reasoning and result set forth in *Sanofi*” in two not-precedential opinions (Opening Br. at 38.) We question that assertion but, in any event, “[w]e do not accept [our NPOs] as binding precedent because, unlike precedential opinions, they do not circulate to the entire court before they are filed.” *Jamison v. Klem*, 544 F.3d 266, 278 n.11 (3d Cir. 2008).

discretion in resting an injunction on the finding that the SEC will likely be able to show that a reasonable investor would have viewed the interim FDA feedback more like an “advance notice of [Lenz’s] certain rejection[.]” *Sanofi*, 87 F. Supp. 3d at 545 n.15, than as a “part of an ongoing conversation[.]” *id.* at 539.

a) *Under the facts of this case, the FDA feedback was akin to a rejection.*

In addition to arguing that the FDA’s feedback “was precisely the sort of preliminary or interim feedback that courts routinely have deemed immaterial for securities law purposes,” Chappell says that the FDA’s comments actually showed there was still hope for EUA approval. (Opening Br. at 1.)

Even if we accept that the FDA’s feedback included some positive comments about Lenz, Chappell’s arguments falter in light of the FDA’s repeated warnings to Humanigen that its only hope for the drug to receive EUA approval was to conduct a second clinical trial. As described by the District Court, here are the facts again, and they show that the District Court’s materiality analysis is not clearly erroneous:

- Before the April 2021 pre-EUA meeting, the FDA sent written comments to Humanigen stating it had “significant concerns that negatively impact the ability to rely on this single trial to support the potential benefit of [Lenz]” and further stating it recommended Humanigen “conduct an additional trial(s)[.]” (J.A. at 767-68.)

- At the pre-EUA meeting, the FDA asked Humanigen if it was going to conduct another clinical trial. Humanigen responded that it had an ongoing “ACTIV-5” trial with the NIH that included a “[L]enz[] arm but had no current plans for further clinical trials.” (J.A. at 344.) The FDA replied that the NIH ACTIV-5 trial was “likely not sufficient to serve as a confirmatory trial[,]” and it “strongly recommended that [Humanigen] conduct an additional confirmatory study[,] and discouraged submission of an EUA at [that] time.” (J.A. at 344.)
- On May 4, 2021, Humanigen notified the FDA that it was “planning to submit an EUA Request within approximately a month” with “additional analyses” and “a more complete data package[.]” (J.A. at 368.) The FDA emailed Humanigen a post-meeting comment to, in part “reiterate [its] concerns ... that ... [Lenz] is unlikely sufficient to satisfy the criteria for issuance of an EUA.” (J.A. at 344.) “In lieu of an EUA request, [the FDA] strongly recommend[ed] that [Humanigen] submit a meeting request to further discuss [its] continued development program, which includes details regarding additional confirmatory clinical trial(s)[.]” (J.A. at 344.)

These several communications from the FDA were clear – Humanigen was not going to receive Emergency Use Authorization for Lenz without conducting a second clinical trial. And Humanigen’s own CFO and securities compliance officer declared that the FDA feedback should be disclosed to

the market.²⁶ Yet, Humanigen submitted the EUA request without disclosing the obviously foreboding feedback to the public and without conducting – and without approved plans to conduct – any further clinical trials, thus practically guaranteeing a rejection.

The District Court, in response to Chappell’s contention that the FDA feedback was not material because it was not a final determination, explained how Humanigen’s decision to submit the EUA request without completing a second clinical trial made it a foregone conclusion that Lenz would not receive Agency approval:

[The FDA] told you [that] you’re going to have to do a number of things to have a real chance of getting this passed[.] [Y]ou don’t do those things, you submit the EUA anyway, it’s [a] foregone conclusion [that] you’re going to get rejected in light of what they told you in April when you haven’t addressed their concerns.

(J.A. at 34.) That is not a clearly erroneous assessment; it is clearly correct. Because Humanigen submitted the EUA request for Lenz without conducting a second clinical trial as instructed by the FDA, the District Court rightly concluded that the SEC has a high likelihood of showing that the Agency’s

²⁶ As previously noted, *see supra* section I.A.5., the Humanigen board ultimately decided not to disclose the feedback to the public because, in its view, the clinical trial data was incomplete.

feedback was so akin to an outright denial of an Emergency Use Authorization as to be material information for investors.²⁷

b) There was no second clinical study.

Despite the factual record, Chappell asserts that there was a second clinical study performed – the NIH ACTIV-5 study. He contends that “Humanigen promptly addressed the FDA’s preliminary concerns by submitting additional evidence and conducting a second study, and continued its efforts to obtain an EUA.”²⁸ (Opening Br. at 1.)

That is not how we read the record. The NIH ACTIV-5 study was not a new confirmatory study; it was an expansion of a study that was already ongoing, and one that the FDA had already said would not qualify as a confirmatory study. Nothing in the record, other than Chappell’s unsupported

²⁷ Chappell also asserts that the FDA denied Humanigen’s EUA application because Humanigen used a particular regression model the FDA found wanting, not because it failed to complete a second study. The record belies that argument. The overall reason for the denial was stated clearly in the denial letter: “[B]ased on the totality of scientific evidence available, ... we are unable to reasonably conclude that [Lenz] may be effective for the treatment of COVID-19 as proposed.” (J.A. at 622.)

²⁸ In his Reply Brief, Chappell doubles down on his assertion that it conducted a second study, even including a header that says, “Humanigen Did Exactly What the FDA Asked[.]” (Reply Br. at 6.)

assertions, suggests that the FDA would have, at some point, approved that expansion as constituting a second clinical study. Indeed, after Humanigen notified the FDA of the expanded NIH ACTIV-5 study, the FDA still strongly encouraged Humanigen to refrain from submitting its EUA request and to discuss the expansion with the Agency. Further, even if the study could have played the confirmatory role the FDA was demanding, it was not complete by the time Humanigen applied for EUA approval.²⁹

c) *The District Court did not improperly rely on the SEC's argument that disclosure fraud cases are inapplicable in the insider trading context.*

Next, Chappell alleges that the District Court committed legal error because it mistakenly relied “on the SEC’s argument that disclosure fraud cases are inapplicable in the insider trading context – an argument that the SEC since

²⁹ Chappell retorts that “[i]t is immaterial that the specifics of ACTIV-5’s expansion were not finalized when the EUA application was submitted because they were finalized and announced well before the FDA rendered decision on the EUA[.]” (Reply Br. at 7 n.4 (citation omitted).) But he points to nothing in the record that shows that the NIH ACTIV-5 study was ever finalized nor that the FDA would have found that the study was sufficient to serve as a confirmatory study.

has abandoned.”³⁰ (Opening Br. at 4.) Chappell’s “point is simply that the materiality standard is the same in both contexts, so cases in the disclosure context are instructive.” (Reply Br. at 13.)

At the District Court hearing, the SEC alleged that Chappell was “trying to conflate the disclosure laws with the insider trading laws.” (J.A. at 21.) It explained that “[n]ot every piece of material information triggers the disclosure laws” (J.A. at 21), and the District Court agreed. When Chappell brought up *In re Sanofi*, the Court responded:

I’m not talking about *Sanofi*. I’m talking about what your client knew when he traded on that stock. ... This is not a disclosure obligation for Humanigen. ... I’m not saying your client had to disclose it. What I’m saying is your client couldn’t trade on it without disclosing it.

(J.A. at 77.)

Chappell asserts that the Court’s response shows that it misunderstood that the materiality standard is the same in both contexts.³¹ A fairer reading of the hearing transcript shows that

³⁰ On appeal, the SEC does not argue that materiality differs depending on whether the case involves disclosure fraud or insider trading.

³¹ The Supreme Court has indicated that the materiality standard is the same in both the insider trading and disclosure contexts: “We find no authority in the statute, the legislative history, or our previous decisions for varying the standard of

the District Court did not improperly apply the law to find that the FDA feedback was material. Rather, the Court correctly undertook a context-based approach to determine whether the FDA feedback was material:

Critically we look at Humanigen because we have to determine materiality based on the facts and circumstances. ... [Lenz] was the only potential viable product [of the Company's] at the time. It's also unrefuted that besides that product Humanigen had no product sales, had suffered significant net losses, and had negative operating cash flows. That's important from a materiality standpoint, because at this point all the eggs are in the basket of Lenz as far as Humanigen is concerned, and they're going to sink or swim with this one particular antibody. Whether they sink or swim at this point is going to be whether or not they get the EUA from the FDA.

(J.A. at 64-65.) Thus, the District Court did what Supreme Court precedent instructs, “assessing [] materiality ... [as] a fact-specific inquiry that requires consideration of the source,

materiality depending on who brings the action or whether insiders are alleged to have profited.” *Basic Inc. v. Levinson*, 485 U.S. 224, 240 n.18 (1988) (citing *Pavlidis v. New England Patriots Football Club, Inc.*, 737 F.2d 1227, 1231 (1st Cir. 1984) (“A fact does not become more material to the shareholder’s decision because it is withheld by an insider, or because the insider might profit by withholding it.”)).

content, and context[.]” *Siracusano*, 563 U.S. at 43 (internal quotation marks and citation omitted). And the District Court, in effect, acknowledged the reasoning of *In re Sanofi*, but found that the case was distinguishable:

I understand if you’re negotiating with a regulatory agency and they say, “At this stage it’s insufficient, but if you do A, B, and C, there may be an opportunity.” ... But here the FDA said, “This is what we’re going to need,” and your clients didn’t do it.

(J.A. at 34.) We see no error in that analysis.

As a final argument regarding materiality, Chappell asserts that “the sparse reasoning described by the District Court was insufficient to justify its finding regarding materiality[.]” (Opening Br. at 43.) He is wrong. Several times throughout the hearing, the Court signaled that the FDA feedback, taken in toto, was material because it was very much like a final Agency order. Moreover, the Court recapped its materiality finding at the end of the hearing:

So was it material? Yes. In light of the size of Humanigen, its losses, its business not doing very well and then only having one viable product, yes. This was a bet-the-company product.

...

And of course you look at the decline in the stock price by approximately 50 percent on higher volume sales once it was determined on September 9th of 2021 publicly that the EUA

was not going to be approved. I don't think materiality is a close call in this case.

(J.A. at 80-81.)

The District Court summed it up succinctly – “the bottom line is this: The FDA in so many words said [that y]ou’re not going to get [the EUA] unless you do another confirmatory trial.” (J.A. at 75.) Considering that Humanigen never undertook nor planned to undertake a second study, the District Court did not err in concluding that the SEC met its burden to show there is a likelihood of success in proving that the FDA feedback was material.

2. The District Court Did Not Err in Concluding that the SEC Will Likely Be Able to Show That Chappell Acted with Scienter.

As stated previously, scienter is a “mental state embracing intent to deceive, manipulate, or defraud.” *Siracusano*, 563 U.S. at 48 (internal quotation marks omitted). It can be demonstrated by circumstantial evidence. *McLean v. Alexander*, 599 F.2d 1190, 1198 (3d Cir. 1979) (“Circumstantial evidence may often be the principal, if not the only, means of proving bad faith.”). Specifically, “[i]nsider trading in suspicious amounts or at suspicious times is probative of bad faith and scienter.” *In re Apple Computer Sec. Litig.*, 886 F.2d 1109, 1117 (9th Cir. 1989).

Chappell says the District Court “disregarded the compelling evidence that [he] acted in good faith,” “improperly failed to hold the SEC to its burden of showing

likelihood of success as to scienter[,] and, further, shifted the burden to [him] to adduce additional and superfluous evidence when there was patently no requirement to do so in this posture.” (Opening Br. at 4.) None of his arguments succeed.

a) The District Court did not disregard Chappell’s evidence.

Chappell asserts that the District Court did not seriously address the evidence of good faith in his trading activity.³² He alleges that he “had for months been planning to sell a minority of his ... Humanigen stock – since well before receiving the FDA feedback – for reasons entirely unrelated to the FDA’s feedback.” (Opening Br. at 2.) He contends that his “decision to sell ... his Humanigen stock was driven by: (1) a desire to realize some paper gains in the stock of a company in which the Black Horse [Funds] had invested significant capital, and

³² Chappell asserts the seven following facts in an attempt to show that he acted in good faith when executing the trades: (1) Humanigen’s board, securities compliance officer, and outside securities counsel were briefed in detail about the FDA’s feedback; (2) Humanigen’s board decided not to make an immediate disclosure about the feedback; (3) Humanigen made disclosures about the FDA feedback on its Form 10-Q; (4) the securities compliance officer opened the trading window for insiders after the disclosures; (5) Chappell sought and obtained all relevant approvals to trade Humanigen shares; (6) Chappell had sought to reduce his exposure to Humanigen through a no-cost collar; and (7) when that proved unworkable, he again obtained approval for the subsequent trading plan through which he sold his stock.

(2) well known uncertainty as to whether the rollout of vaccines would shrink the market for COVID-19 treatments[.]”³³ (Opening Br. at 26.)

But he provides no good answer for the damning evidence of a sudden shift in pricing and volume between his March and June trading plans, a change that came after the FDA provided its feedback on Lenz’s clinical trial. As the District Court explained, those alterations in his trading plans are evidence of scienter:

It just doesn’t make sense. He’s not a hedge fund manager, he’s never hedged in this stock before. Now all of a sudden when he thinks his ship is about to come in, when they’re about to get the brass ring, they’re going to get EUA approval for this drug that they now think they can use for the antibody they can now use for COVID-19 side effects[,] ... that now, once you’ve held onto it for this long, five years, now you’re going to say, “I’m going to get rid of it at 25 percent at a lower price than I was willing to sell a month before I met with the FDA?” It’s suspicious and it goes to scienter.³⁴

³³ In addition, Chappell alleges that the proceeds from his first sale were to “provide the amount of capital [he] needed to meet an upcoming mortgage payment.” (Opening Br. at 19.)

³⁴ The District Court stated further:

It doesn’t make any sense. If he’s bullish on the stock in early 2021 and he’s willing to do it at

(J.A. at 63-64.)

Chappell attempts to counter the District Court’s finding by pointing to facts that, in his view, show that the timing and parameters of the changes between the March and June trading plans do not reflect scienter. First, he says that, prior to the FDA feedback, Chappell “communicated with multiple brokers about his plans to sell a significant portion of the [his] Humanigen holdings” (Reply Br. at 24) and that he told one broker that there was “a lot more to come” after the attempted 9% selloff via the March trading plan (J.A. at 759). While that evidence lends support to Chappell’s argument that he wanted to sell more shares, it does not explain why, especially if he believed that Lenz was about to get EUA approval, he decided to sell shares at a discount after the FDA feedback, when he was previously willing to sell them only at a premium.

[§]25 [a share], why isn’t he still bullish on it and going to wait out his investors, whatever their size may be, because now his ship has come in? It doesn’t make any sense he’s going to start unloading a massive amount of stock when he thinks he’s going to get FDA approval.

...

He wasn’t hedging at all. He didn’t start hedging until five years in. I could understand if he was running this as a hedge, but he holds it for four and a half, five years and now he’s going to worry about a hedge when he thinks he’s about to get the biggest success of his career?

(J.A. at 38-40.)

Second, Chappell contends that it is false to say that he initiated communications with a broker less than two hours after Humanigen received the FDA's negative post-meeting feedback, because he emailed his broker about setting up a new trading plan before he was personally in receipt of the FDA post-meeting comment. What he fails to mention, but what the SEC points out, is that "[s]tarting twenty-eight minutes after Humanigen received [the] FDA's May 13, 2021, post-meeting comment strongly discouraging the company from submitting an EUA application for [Lenz], [which was sent to Humanigen's CEO,] Chappell spoke on the phone with [the] CEO several times." (Answering Br. at 15.) Thus, it can reasonably be inferred that Chappell was informed of the post-meeting comment's contents prior to contacting his broker, even if he did not personally receive a copy of the FDA's comment until later.

Third, Chappell argues that "the high limit price in the March Plan[] simply reflects that [he] had to set up the plan[] before announcement of the phase 3 data and had to guess weeks in advance how much the stock price might appreciate after the data was unblinded." (Reply Br. at 25.) Even if that were true, though, it does not explain, as the District Court noted, why Chappell was not "bullish" in June after the FDA feedback, if he indeed was not treating that feedback as seriously detrimental. (J.A. at 38.)

Fourth, Chappell says that the no-cost collar arrangement he attempted in June, see *supra* note 9, supports his argument that he believed, at that time, that the stock was going to appreciate. Not so. While such a transaction would have allowed Chappell to capture some (but not necessarily all)

of the potential upside gains if the stock appreciated in value, a no-cost collar would have also allowed him to minimize his losses if the stock price decreased considerably, by locking in sales at a price above the fallen market price. Chappell in fact admits that one of the reasons he tried to execute a no-cost collar arrangement was to “reduc[e] downside exposure” while avoiding “a negative signal to the market” that an outright sale would potentially send. (J.A. at 682.) So, the no-cost collar argument is no proof against a finding of scienter.

b) The District Court did not shift the burden to Chappell.

Chappell further argues that the District Court shifted the burden of proof from the SEC to him. For example, he points to the District Court’s questions at the hearing asking him why he had not submitted affidavits from the Humanigen insiders who approved the sales. He also complains about the Court asking him for evidence that the stock’s trading volume would have allowed him to sell more than 25% of his stock. We are persuaded, however, by the SEC’s assertion that the District Court was not burden-shifting but rather was “appropriately scrutiniz[ing] the credibility of Chappell’s claim of good faith by asking for corroborating documentation[.]” (Answering Br. at 53.) The Court was unpersuaded by Chappell’s “cherry-picked” declaration and exhibits and wanted further support for his bald assertions. (Answering Br. at 53.)

Lastly, Chappell contends that the reasoning offered by the District Court was insufficient to sustain a finding of scienter. But the Court explained in detail why it found that Chappell had the necessary mindset:

And as to the requisite scienter, ... you get that type of letter from the FDA which in so many words says, “We strongly recommend you do a confirmatory trial and talk before you submit your EUA[,]” and you submit the EUA anyway, [which] you had ... at best ... a negligible chance of getting through and most likely [a] zero percent chance of getting through.

Then we have the fact that Mr. Chappell sold a lot more than 9 percent, inconsistent ... with his prior lack of trading[.] ... [He] went from 9 percent to 25 percent and also at a much lower price. The FDA has sufficiently shown through circumstantial evidence that Mr. Chappell had the requisite scienter when he made these trades.

(J.A. at 81-82.) We discern no error in the District Court’s conclusion that the SEC has met its burden to show a likelihood of success in demonstrating that Chappell acted with scienter in his trading activities.

C. The Other Factors of the Preliminary Injunction Standard Support a Preliminary Injunction.

The District Court did not analyze the irreparable-harm, balance-of-the-equities, or public-interest prongs of the preliminary injunction test at the hearing it held. But “[w]e may affirm the district court’s grant of a preliminary injunction and asset freeze on any grounds supported by the record.” *Fife*,

311 F.3d at 8. Here, Chappell is eager for an answer as to whether the injunction is valid,³⁵ and we will oblige.

As for the irreparable-harm requirement, the District Court, in its order granting the TRO (which was incorporated into the preliminary injunction), found that there would be irreparable harm without an injunction because “[t]here [was] good cause to believe that, unless funds and assets are frozen ... [Chappell] will dissipate, conceal, or transfer from the jurisdiction of this Court assets that could be subject to an order directing disgorgement or the payment of civil money penalties in this action.” (J.A. at 2.) Chappell never contested that finding, so any argument that it was incorrect is forfeited. *Cf. Vickers v. Superintendent Graterford SCI*, 858 F.3d 841, 852 n.11 (3d Cir. 2017) (explaining that, generally, “an issue not raised in an appellant’s opening brief is [forfeited]”).

³⁵ After oral argument, the SEC amended its complaint, which Chappell says further delays the District Court’s resolution of the case. He subsequently filed a letter complaining that the length of time to trial is an additional hardship warranting a lift of the asset freeze. While the duration of a preliminary injunction is a factor we consider when reviewing an injunction’s appropriateness, we do not believe the trial schedule to be so far into the future as to be unduly onerous. The SEC has set forth serious allegations that Chappell violated securities laws, and there is a significant risk of capital flight were we to vacate the asset freeze. But we take his implicit point that the validity of the injunction needs to be addressed, and we do so now.

Even if he had challenged the irreparable-harm finding, the challenge would surely have failed. Chappell's apparent (on this record) willingness to trade on inside information to avoid losses makes us wary that he would also, but for the preliminary injunction, seek to conceal assets to avoid a potential future order directing him to disgorge an amount equal to the losses he avoided. Moreover, he lives in a foreign country, which creates a risk that he will be able to place assets out of the reach of United States' authorities. And, as the District Court observed, Chappell spends lavishly, so assets needed for disgorgement may well also be dissipated without an asset freeze. Thus, the irreparable harm requirement is satisfied.

The third preliminary injunction factor requires us to "balance the parties' relative harms; that is, the potential injury to the plaintiffs without this injunction versus the potential injury to the defendant with it in place." *Issa v. Sch. Dist. of Lancaster*, 847 F.3d 121, 143 (3d Cir. 2017). At this stage, a court should also consider "the possibility of harm to other interested persons from the grant or denial of the injunction." *Reilly*, 858 F.3d at 176. Chappell avoided approximately \$38 million in losses, so there is a substantial potential injury to Humanigen shareholders if Chappell is able to successfully move assets out of the reach of future judgment creditors, especially if the SEC prevails in obtaining disgorgement. On the other side of the scale, if the preliminary injunction is maintained, Chappell's assets are mostly frozen, but he still maintains his Humanigen salary (or an equivalent amount) of \$5,637.50 every two weeks, and he has received other relief

from the freeze.³⁶ While he may have to live more frugally than he has been accustomed to, he certainly will not be living like a pauper. Furthermore, the Court appointed a receiver to manage Chappell's assets during the pendency of this case. For those reasons, the equities significantly favor upholding the injunction.

The fourth factor requires us to determine whether the injunction is in the public interest. "As a practical matter, if a plaintiff demonstrates both likelihood of success on the merits and irreparable injury, it almost always will be the case that the public interest will favor the plaintiff." *Am. Tel. & Tel. Co. v. Winback & Conserve Program, Inc.*, 42 F.3d 1421, 1427 n.8 (3d Cir. 1994). Here, affirming the injunction is clearly in the public interest. Corporate insiders have a duty to the investing public to disclose material information before trading on that information themselves. *United States v. O'Hagan*, 521 U.S. 642, 652 (1997) (explaining that "a relationship of trust and confidence exists between the shareholders of a corporation" and corporate insiders, which "gives rise to a duty to disclose or to abstain from trading because of the necessity of preventing a corporate insider from taking unfair advantage of uninformed stockholders" (internal quotation marks and citation omitted) (cleaned up)). Facilitating the proper enforcement of that duty is all to the good.

³⁶ Pursuant to a joint stipulation by the parties, the District Court released from the asset freeze, among other things, up to \$300,000 for Chappell's legal fees, approximately \$162,000 per academic year for his children's educational expenses, and \$50,000 for his wife.

Accordingly, the preliminary injunction factors weigh in favor of the relief granted by the District Court.

III. CONCLUSION

For the forgoing reasons, we will affirm the District Court's order granting the preliminary injunction.