UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

FEDERAL TRADE COMMISSION; STATE OF NEW YORK; STATE OF CALIFORNIA; STATE OF ILLINOIS; STATE OF NORTH CAROLINA; STATE OF OHIO; COMMONWEALTH OF PENNSYLVANIA; and COMMONWEALTH OF VIRGINIA, *Plaintiffs*, v. VYERA PHARMACEUTICALS, LLC; PHOENIXUS AG; MARTIN SHKRELI, individually, as an owner and former director of Phoenixus AG and a former executive of Vyera Pharmaceuticals, LLC; and KEVIN MULLEADY, individually, as an owner and director of Phoenixus AG and a former executive of Vyera Pharmaceuticals, LLC, *Defendants*.	Case No. 20-cv-00706 (DLC) ECF Case

DEFENDANT MARTIN SHKRELI'S OBJECTIONS TO PLAINTIFFS' [PROPOSED] ORDER FOR PERMANENT INJUNCTION AND EQUITABLE MONETARY RELIEF

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Pursuant to the Court's January 14, 2022 Order (ECF 866), Defendant Martin Shkreli respectfully submits the following objections to the [Proposed] Order for Permanent Injunction and Equitable Monetary Relief, which plaintiffs presented to Mr. Shkreli on January 24, 2022 (the "Proposed Order").[1]

I. OBJECTIONS TO PLAINTIFFS' PROPOSED ORDER

A. Legal Standards for Objections

"In an equity suit, the end to be served is not punishment of past transgression." *Int'l Salt Co. v. United States*, 332 U.S. 392, 401 (1947). "The purpose of the decree, therefore, is effective and fair enforcement, not punishment." *United States v. Nat'l Lead Co*., 332 U.S. 319, 338 (1947) (emphasis added); *see also Hartford-Empire Co. v. United States*, 323 U.S. 386, 409 (1945) ("we may not impose penalties in the guise of preventing future violations"). As a result, the relief granted must "not embody harsh measures when less severe ones will do." 2A Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶¶ 325a (3d ed. 2010).

An injunction must not go any further than necessary to prevent future violations. "[T]he injunction must not 'unduly harm the defendants . . . [by] put[ing] them out of business, but [must] simply ensure that they will conduct their business in a manner which does not violate Section 5 of the FTC Act.'" *F.T.C. v. Ross*, 897 F. Supp. 2d 369, 387 (D. Md. 2012) (quoting *F.T.C. v. Kitco of Nev., Inc*., 612 F. Supp. 1282, 1296 (D. Minn. 1985)), *aff'd,* 743 F.3d 886 (4th Cir. 2014). The court must ensure that any injunctive relief is "narrowly tailored to fit specific legal violations and avoid[s] unnecessary burdens on lawful commercial activity." *Syntel Sterling Best Shores*

[1] Mr. Shkreli submits these objections without waiver of, but preserving, all arguments made in support of Defendants' Motion for Partial Summary Judgment and Defendants' and his individual Proposed Findings of Fact and Conclusions of Law and Pre-Trial Memoranda, including that the monetary relief awarded against him is unavailable under the law and that the injunctive relief awarded against him constitutes an impermissible penalty.

Mauritius Ltd. v. Trizetto Grp., Inc., 15 Civ. 211, 2021 WL 1553926, at *14 (S.D.N.Y. Apr. 20, 2021) (Schofield, J.) (quotation and citation omitted).

Injunctive relief that is too vague is unenforceable pursuant to Fed. R. Civ. P. 65(d), which requires such an order to "state its terms specifically," and "describe in reasonable detail . . . the act or acts restrained or required." *See Howard Opera House Assocs. v. Urban Outfitters, Inc*., 322 F.3d 125, 129 (2d Cir. 2003) (vacating district court's injunction because its terms were too vague). In addition, "[i]njunctions that are overbroad are disallowed." *Ram v. Lal*, 906 F. Supp. 2d 59, 76 (E.D.N.Y. 2012) (holding "that the injunctive relief sought is too broad in its requested scope" and "violates Rule 65"); *see also Ibeto Petrochemical Indus. Ltd. v. M/T Beffen*, 475 F.3d 56, 65 (2d Cir. 2007) (ordering district court to "modify its injunction with a specificity consonant with [Second Circuit's] determination" that "the injunction in this case cuts much too broadly").

A proposed order, particularly one for injunctive relief, must be "sufficiently clear to [the defendant to know] exactly what would be required of [him] should the preliminary injunction issue." *Sanders v. Air Line Pilots Asso., Int'l*, 473 F.2d 244, 247 (2d Cir. 1972); *see also Schmidt v. Lessard,* 414 U.S. 473, 476 (1974) (vacating injunction and holding that "basic fairness requires that those enjoined receive explicit notice of precisely what conduct is outlawed"); *SEC v. Lorin*, 76 F.3d 458, 461 (2d Cir. 1996) (vacating permanent injunction because it lacked "the requisite specificity" to allow an enjoined party to know what is required of him). "The normal standard of specificity is that the party enjoined must be able to ascertain from the four corners of the order precisely what acts are forbidden." *Sanders*, 473 F.2d at 247. "Rule 65(d) reflects Congress' concern with the dangers inherent in the threat of a contempt citation for violation of an order so vague that an enjoined party may unwittingly and unintentionally transcend its bounds." *Id*. (citing *Int'l Longshoremen's Ass'n v. Phila. Marine Trade Ass'n*, 389 U.S. 64, 76 (1967)).

B. The Proposed Order's Definitions.

Mr. Shkreli objects to three of the Proposed Order's definitions (Section I) because they are vague on their face and overbroad in their application to the Proposed Order's injunctive and monetary relief terms.

1. "Development"

The definition of "Development" is overbroad. By including "all preclinical and clinical research and development activities," the definition extends to conduct that was not at issue in this case. The Court's findings relate to the commercial aspects of Daraprim, specifically the contracts concerning the distribution and sale of Daraprim and the acquisition of Daraprim API. Mr. Shkreli should not be precluded from conduct that does not involve commercialization of pharmaceutical drugs. Additionally, defining Development to pertain to "activities . . . for the purpose of obtaining any and all FDA Authorizations . . . necessary for the . . . import, export . . . and sale of a Drug Product" sweeps in extraterritorial conduct. As drafted, Mr. Shkreli could not work for a foreign corporation on products sold entirely outside the United States if the company also exported Drug Products, that Mr. Shkreli has no involvement with, into the United States. The conduct at issue in this case is restricted to the geographic market of the United States.[2] This Court should not issue an injunction that has extraterritorial application to conduct occurring in foreign markets. *See* Extraterritorial application of Federal Antitrust Laws to acts occurring in foreign commerce, 40 A.L.R. Fed. 343, 2.

2. "FDA Authorization"

The definition of "FDA Authorization" is overbroad, in that it includes Marketing Authorization Applications ("MAA"), which does not appear anywhere in the cited regulation, 21

[2] *See* Opinion, ECF 865, at p. 100 ("the United States is the relevant geographic market").

C.F.R. Part 314, *et seq*. MAAs are applications and official procedures that are submitted to the European Union and United Kingdom for use in those countries. Thus, for the extraterritorial reasons cited above, an MAA should not be included in any definition in the Court's order.

The definition of "FDA Authorization" also includes a "Biologic License Application" ("BLA"). Section I.K.3. A BLA may encompass non-pharmaceutical products, such as medical devices or products. https://www.fda.gov/combination-products/about-combination-products/frequently-asked-questions-about-combination-products. And whether such a product or device constitutes and will be regulated as a biologic or device can be fact-intensive and subjective. The Court's opinion should not be interpreted to extend to the medical device or similarly situated industries. The inclusion of BLA in the definition will lead to confusion as to its scope. Accordingly, this definition is overbroad and disconnected from the Court's findings.

3. "Pharmaceutical Company"

The definition of "pharmaceutical company" is both overbroad and vague. By including "research, Development … of any Drug Product or API," the definition sweeps too broadly. The research and development of pharmaceutical products was not at issue in this case. The Court's findings relate to the commercial aspects of Daraprim, specifically the contracts concerning the distribution and sale of Daraprim and the acquisition of Daraprim API. This definition could be interpreted to preclude Mr. Shkreli from working in any capacity at a university or academic institution—even if his job has nothing to do with pharmaceuticals—if that institution is engaged in research and development of pharmaceuticals. Such a prohibition is unwarranted and goes far beyond the Court's findings and conclusions.

In addition, both "commercialization" and "marketing" are undefined terms that could be interpreted to include restrictions on conduct that is far removed from the anticompetitive conduct

found by the Court. It is unclear, for example, whether Mr. Shkreli would be foreclosed from working in any capacity for an advertising agency that markets pharmaceuticals, even if his job has nothing to do with pharmaceuticals. The reaches of such a broad and vague definition are unlimited and unknown, and Mr. Shkreli would be in danger of unwittingly violating such an order by engaging in lawful conduct that is unrelated to the conduct at issue in this case.

C. The Proposed Order's Permanent Injunction Section.

1. Preamble.

The preamble to Section II states as follows: "IT IS FURTHER ORDERED that Defendant Shkreli is hereby banned and enjoined for life from directly or indirectly participating in any manner in the pharmaceutical industry, including by . . . ." Mr. Shkreli objects to several terms in the preamble.

The term "participating" is undefined, impermissibly vague, and overbroad. Mr. Shkreli cannot be expected to know what conduct is prohibited by this term. One can imagine all kinds of lawful conduct that has no effect on competition in the pharmaceutical industry yet could be deemed to constitute "participating." For example, does "participating" include discussing pharmaceuticals with friends or colleagues in the industry? Does it include working at a pharmacy? *See Sanders*, 473 F.2d at 247; *Howard Opera House Assocs. v. Urban Outfitters, Inc*., 322 F.3d 125, 129-30 (2d Cir. 2003) (vacating injunction because of vague terms and where district court should have included "reference to the specific facts of the case in the order itself" to "tailor the injunction").

The word "indirectly," which was not in the Court's opinion, compounds the vagueness and overbreadth. How one "indirectly" participates in the pharmaceutical industry cannot be known.

In addition, plaintiffs' use of the phrase "including by" before listing the categories of prohibited conduct in subsections II.A-F indicates that other conduct— undefined in the categories listed and unknown to Mr. Shkreli—would also violate the injunction.

2. Subsection II.A & II.B.

Section II.A forbids Mr. Shkreli from "[p]articipating in or directing the research, Development, manufacture, commercialization, distribution, marketing, importation, or sale of a Drug Product or API, whether through compensated or uncompensated employment, consulting, advising, board membership, or otherwise." Section II.B forbids Mr. Shkreli from "[p]articipating in the formulation, determination, or direction of any business decisions of any Pharmaceutical Company."[3] These restraints are vague and overbroad, and potentially sweep in conduct that would have no effect on competition in the pharmaceutical industry. For example, if a friend who happens to work in the industry asks Mr. Shkreli a question that relates to a business decision or the manufacture of a Drug Product, would answering the question violate the injunction? Would doing so be considered "otherwise" participating in the manufacture of a Drug Product under the injunction? There is no way for Mr. Shkreli to know where the boundaries are. Examples like these show that these overbroad and vague restraints have the potential to chill Mr. Shkreli's exercise of his First Amendment rights. Further, plaintiffs' overbroad definition of "Pharmaceutical Company" means that Mr. Shkreli could be deemed to violate the order if he were to work in a non-pharmaceutical role for a large company that does more than just sell pharmaceuticals, such as Costco, Walmart, Johnson & Johnson, etc. Surely, the Court's opinion

[3] Mr. Shkreli incorporates by reference his objections to the Proposed Order's definitions set forth *supra* Section I.B.

could not support an injunction prohibiting Mr. Shkreli from designing the layout of a Costco store, for example.

3. Subsection II.C.

Section II.C prohibits Mr. Shkreli from acquiring or holding an Ownership Interest in a Pharmaceutical Company. This restriction goes far beyond the Court's opinion, which does not mention any such restraint. This section could be interpreted to prohibit a passive investment in a Pharmaceutical Company, without voting rights, which presents no risk of harming competition. Such an investment should be permissible. In addition, because of the breadth of the definition of "Pharmaceutical Company," this provision would preclude Mr. Shkreli from investing in companies, such as Costco, Walmart, and Johnson & Johnson, that sell many products other than pharmaceuticals. This Section also does not address Mr. Shkreli's rights or obligations should a company he invests in later engage in conduct—without any involvement on his part— that would bring that company within the definition of a Pharmaceutical Company. Mr. Shkreli should not be subject to a potential future liability for conduct by third parties in which he is not involved.

In addition, the provision that requires Mr. Shkreli to divest his Vyera shares violates Mr. Shkreli's Fifth Amendment Rights. *See Stop the Beach Renourishment, Inc. v. Fla. Dep't of Envtl. Prot.*, 560 U.S. 702, 715 (2010) (applying the takings clause of the Fifth Amendment to judicial decrees and holding that "[i]f a legislature *or a court* declares that what was once an established right of private property no longer exists, it has taken that property, no less than if the State had physically appropriated it or destroyed its value by regulation.") (emphasis in original) (plurality decision). Alternatively, this requirement constitutes a deprivation of Mr. Shkreli's due process rights. *Id.* at 735-738 (stating that the courts are barred by due process from effectuating a taking of property; "[t]he Court would be on strong footing in ruling that a judicial decision that eliminates

or substantially changes established property rights, which are a legitimate expectation of the owner, is "arbitrary or irrational" under the Due Process Clause.") (Kennedy, J. concurring).

Additionally, the "Provided however" paragraph is particularly problematic. First, the language is vague, in that it is unclear what would happen if the receiver appointed in *Koestler v. Shkreli*, 1:16-cv-7175 (S.D.N.Y.) sells *some* of Mr. Shkreli's shares and returns the rest to Mr. Shkreli. Moreover, if shares are returned to him, Mr. Shkreli would be required to sell those shares within sixty (60) days, which deprives Mr. Shkreli of the ability to sell the shares for fair market value (*i.e.*, just compensation). Vyera is a closed corporation whose shares are not freely traded and are not listed on any public marketplace. It is unduly burdensome and a violation of his Fifth Amendment rights, to force a sale of Mr. Shkreli's shares within sixty (60) days.

4. Subsection II.D.

Section II.D of the Proposed Order prohibits Mr. Shkreli from "[t]aking any action to directly or indirectly influence or control the management or business of any Pharmaceutical Company." This language is vague and overbroad for the same reasons as we discussed above with respect to Section II's preamble. The term "influence" is undefined and impermissibly vague. Would Mr. Shkreli be prohibited from using Twitter or a blog to discuss the pharmaceutical industry if it somehow, unbeknownst to him, influenced a pharmaceutical company's management or business? This is another restraint that has the potential to chill Mr. Shkreli's exercise of his First Amendment rights.

5. Subsection II.F.

Section II.F prohibits Mr. Shkreli from "Obtaining, holding, or exercising any voting or other shareholder rights in a Pharmaceutical Company, including rights assigned to Defendant Shkreli by an Entity or individual, including rights assigned in connection with Shkreli's transfer

of Ownership Interest in a Pharmaceutical Company to the Entity or individual." This section is also overbroad, in that it would prevent Mr. Shkreli from acquiring voting or other shareholder rights in companies, such as Costco, Walmart, and Johnson & Johnson, that sell many products other than pharmaceuticals. This would constitute an unwarranted restraint on lawful conduct that is far removed from the facts of this case, and that would have no effect on competition in the pharmaceutical industry.

D. The Proposed Order's Monetary Judgment Section

1. Sections III.A.-B.

In Section III.A of the Proposed Order, plaintiffs concede that the Court's $64.6 million judgment is subject to a set-off for the monetary relief that the Corporate Defendants agreed to pay the Plaintiff States as part of the settlement. But the proposed order provides that Mr. Shkreli must pay $64.6 million within 30 days of entry of the order, and that the amount of the set-off be only that amount "already paid" by the Corporate Defendants. Section III.B. This is contrary to applicable state and federal law. The amount of the set-off should instead be the full amount the Corporate Defendants agreed to pay in the settlement, $40 million.

New York law is clear that where "a release or a covenant not to sue or not to enforce a judgment is given to one of two or more persons liable or claimed to be liable . . . it reduces the claim of the releaser against the other tortfeasors to the extent of any amount stipulated by the release or the covenant, or in the amount of the consideration paid for it, or in the amount of the released tortfeasor's equitable share of the damages under article fourteen of the civil practice law and rules, ***whichever is the greatest***." NY CLS Gen Oblig § 15-108 (emphasis added). This Court has applied Section 15-108(a) to federal claims brought before the Court. *First Fed. Sav. & Loan Asso. v. Oppenheim, Appel, Dixon & Co.*, 631 F. Supp. 1029, 1030, 1035-1036 (S.D.N.Y. 1986) (applying NY CLS Gen Oblig § 15-108 to a federal securities law claim).

Regardless of the fact that a portion of the settlement amount is to be paid out over time, plaintiffs have agreed to a settlement in which they released their claims against the Corporate Defendants and Mr. Mulleady in exchange for the Corporate Defendants' agreement to pay up to $40 million over a period of ten years. Accordingly, $40 million should be set-off from the $64 million judgment, and Mr. Shkreli should be ordered to pay $24.6 million.

2. Section III.D.

Section III.D provides for an escrow account for all payments in excess of $24.6 million. For the reasons set forth above, there should be no escrow account, because Mr. Shkreli should not be required to pay more than $24.6 million. But if the Court disagrees, Section III.D is nonetheless unduly burdensome and vague. If Mr. Shkreli is required to pay additional funds into an escrow account pursuant to Section III.D, those funds should be held in an interest-generating account, with Mr. Shkreli to receive the benefit of any interest on monies refunded to him pursuant to the provision. Further, Plaintiff States' attempt to retain monies for undefined "attendant expenses for the administration and distribution of such funds and repayment of out-of-pocket expenses" should be rejected for vagueness, as it leaves such retention entirely to the discretion of the Plaintiff States.

3. Section III.E.

Section III.E requires Mr. Shkreli to provide the Plaintiff States with his Social Security Number or Taxpayer Identification Number within 10 business days of entry of the order. There is no basis for the Plaintiff States to require that Mr. Shkreli provide them with his Social Security Number or Taxpayer Identification Number. Mr. Shkreli objects to this unwarranted disclosure of his Personally Identifiable Information.

4. Section III.F.

Section III.F, ordering that Mr. Shkreli "relinquishes dominion and all legal and equitable right, title, and interest in all assets transferred pursuant to this Order" and "may not seek the return of any assets except as explicitly permitted in Paragraph III.D of this Order" would prevent Mr. Shkreli from moving to stay or appealing the order. This provision is therefore an obvious violation of his constitutional right of due process and access to the courts, and should be stricken in its entirety.

5. Section III.G.

Section III.G, ordering that Mr. Shkreli "has no right to challenge any actions that Plaintiff States, or their representatives, may take pursuant to this Equitable Monetary Relief Section of the Order" would permit the Plaintiff States to violate the terms of this section of the order—by, for example, failing to refund to Mr. Shkreli monies to which he would be entitled under Section III.D—without Mr. Shkreli having any recourse. It would also prevent Mr. Shkreli from defending himself against any further action, judicial or otherwise, the Plaintiff States may take against him. This provision is another obvious violation of his constitutional right of due process and access to the courts, and should be stricken in its entirety.

E. The Proposed Order's Compliance Reporting Requirements Section

Section IV.B.1 requires Mr. Shkreli to verify that "he is not directly or indirectly participating in any manner in the pharmaceutical industry." For reasons set forth above in the discussion of Section II of the Proposed Order, this language is impermissibly vague.[4] Moreover, any such verified statement should include only a verification by Mr. Shkreli that he is in

[4] The vagueness is compounded by the fact that the term "pharmaceutical company" is not capitalized in this section, raising the question as to whether it refers to the defined term (which itself is vague) or something else.

compliance with the order, similar to analogous provisions in the settlement involving the Corporate Defendants and Mr. Mulleady. Section IV.B.1 would require Mr. Shkreli, if he has not fully satisfied the monetary judgment, to submit with each compliance report tax returns, a "full and complete accounting" of all his assets, and of all assets he has "transferred, sold or otherwise disposed of" during the previous 12 months. This type of information should be required of Mr. Shkreli only in a collection action, after the Plaintiff States have satisfied their burden of proving they are entitled to such information. Its inclusion in this order is overbroad and unduly burdensome. For these reasons, Mr. Shkreli objects to Sections IV.B.1 and 2 in their entirety.

F. The Proposed Order's Access to Information Section

Section V. would require Mr. Shkreli to make himself available for an interview, and provide to plaintiffs "access to inspect and copy all books, ledgers, accounts, correspondence, memoranda, tax returns, financial statements and all other records and documents in Defendant Shkreli's possession or control that relate to compliance with this Order," upon "5 days' notice." These provisions are unduly burdensome, unreasonable, and potentially unconstitutional. First, 5 days' notice is obviously unreasonable and serves no purpose other than to unduly burden Mr. Shkreli. Second, the "books and records" provision is a common provision in FTC orders directed at companies, but makes little sense for individuals, who are not required to keep records as businesses are. Third, the access provision is impermissibly vague. It is unclear what records would "relate to compliance with" the order, or who would make this determination. Nor is it clear where the inspection would take place—at Mr. Shkreli's residence? If this is plaintiffs' intent, such access by a government agent to an individual's private residence would constitute an unwarranted invasion of privacy that may present constitutional issues. For these reasons, Mr. Shkreli objects to Section V of the Proposed Order in its entirety.

II. CONCLUSION

For all of the foregoing reasons, Mr. Shkreli respectfully requests that the Court grant his objections to plaintiffs' Proposed Order for Permanent Injunction and Equitable Relief.

Dated: January 28, 2022

Respectfully submitted,

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