

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK**

GILEAD SCIENCES, INC., <i>et al.</i> ,	:	
	:	
Plaintiffs,	:	Case No. 21-cv-4106 (AMD) (RER)
	:	
v.	:	
	:	FILED <i>EX PARTE</i> AND UNDER SEAL
SAFE CHAIN SOLUTIONS, LLC, <i>et al.</i> ,	:	PURSUANT TO 15 U.S.C. § 1116(d)
	:	AND COURT ORDER (DKT. NO. 20)
Defendants.	:	
	:	
	:	

**MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTIONS FOR
EX PARTE SEIZURE ORDER, TEMPORARY RESTRAINING ORDER,
ASSET FREEZE ORDER, ORDER TO SHOW CAUSE FOR A
PRELIMINARY INJUNCTION, ALTERNATIVE SERVICE, AND
LEAVE TO FILE AN AMENDED COMPLAINT**

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Plaintiffs Gilead Sciences, Inc., Gilead Sciences Ireland UC, and Gilead Sciences, LLC (together, “Gilead” or “Plaintiffs”) submit this memorandum of law in support of their application seeking immediate injunctive relief against several newly added Defendants.¹ Gilead seeks an *ex parte* seizure order against the following newly added Defendants: the “Leader Defendants” Messrs. Rosell, Ralhan, and Mannava; RxWholesale; Scripts Wholesale and USDV Pharma; Medicine Shoppe and PrimeRx; Mr. Fernandez; Invicta and its Principal Mr. Caba; and Gabriel Betesh. Gilead also seeks against *all* newly added defendants both a temporary restraining order (to be followed by a preliminary injunction) and an asset freeze order. Gilead also seeks an order permitting alternate service on certain newly added Defendants and granting leave to file an amended complaint naming the newly added Defendants and asserting new conspiracy-based causes of action.

¹ The newly added Defendants are: Paul Rosell; Med-Connect Enterprises, LLC (“Med-Connect”); Dhruv Ralhan; D&K Healthcare Solutions LLC (“D&K Healthcare”); Venkata Srinivas Mannava; DSP Consulting Inc. (“DSP”); John Panagiotopoulos; Mike Zangari; Riccardo Massana; Streamline RX LLC (“StreamlineRx”); Pavan Mantripragada; MFK Management LLC d/b/a Boulevard 9229 & 9229 Boulevard; Make it Happen Marketing Inc. (“Make It Happen Marketing”); Quan Hernandez; Scripts Wholesale Inc. (“Scripts”); Steven Diamantstein; USDV Pharma LLC (“USDV Pharma”); NER250 LLC d/b/a Scripts Wholesale; Maryland Pharmacies Inc. d/b/a The Medicine Shoppe #1802 (“Medicine Shoppe”); PrimeRX Inc. (“PrimeRx”); Sekar Venkatesh; Omom Pharmaceuticals Inc.; Omom Wholesale CORP. (together with Omom Pharmaceuticals Inc., “Omom”); Gustavo Fernandez; Luis D. Gonzalez Herrero; Jordan Rodriguez Mato; Invicta Wholesale Supply LLC (“Invicta”); Jorge Caba; RXWholesale.com LLC (“RxWholesale”); Gabriel Betesh; Charles Bree; Daniel Gelbinovich; Cesar Castillo Wholesalers LLC f/k/a Cesar Castillo LLC (“Cesar Castillo”); DNS Distributor LLC (“DNS Distributor”); Julio Martin Gonzalez; Pharma Pac Wholesale Corp. (“Pharma Pac”); Angel Toral; Gentek LLC (“Gentek”); Edel Reyes; Rapids Tex Whole Sales Corp (“Rapids Tex”); John Santos; Titan Distribution & Services LLC (“Titan”); Tidy Garages L.L.C. (“Tidy Garages”); Gabriel Delgado Ramirez; CM Pharmaceutical LLC (“CM Pharma”); Jeffrey W. Gafnea; Robert W. Gafnea; JM Smith Distribution Corp. (“JM Smith”); Carlos Hernandez; ASB Wholesale Distributors LLC (“ASB Wholesale”); Silverline Pharma Logistics LLC (“Silverline Pharma”); and Alberto Alonso Diaz (collectively, the “newly added Defendants”).

INTRODUCTION

This is Gilead’s third motion for *ex parte* injunctive relief against willful counterfeiters who are selling dangerous counterfeit HIV and other medications in the United States. Through the first two rounds of *ex parte* seizures, Gilead has removed thousands of bottles of purported Gilead medication, all with confirmed fake pedigrees, from the shelves of gray-market distributor defendants Safe Chain Solutions, LLC (“Safe Chain”) and ProPharma Distribution LLC (“ProPharma”). From the documents it seized, Gilead learned that the distributors purchased the counterfeits from at least seven different fly-by-night counterfeit suppliers, nearly all of whom had abandoned their offices before Gilead’s investigators went to visit them. Those counterfeit suppliers were located throughout the nation, all with different owners and principals, apparently connected only by their sale of large quantities of Gilead-branded HIV medication. When Gilead was able to locate the individuals behind some of those counterfeit suppliers, they invoked the Fifth Amendment, refused to identify the source of their counterfeits, and claimed not to have access to company records.

But from the seized documents and information obtained through third-party discovery, Gilead has learned that the suppliers and distributors are not the disparate actors they appear to be. Rather, the counterfeits are being sold through an organized counterfeiting ring: a large-scale, transnational conspiracy to sell counterfeit Gilead-branded HIV medications into the United States supply chain. The evidence shows that this counterfeiting ring is organized and orchestrated by three ringleaders: Messrs. Ralhan, Rosell, and Mannava (the “**Leader Defendants**”). Gilead accordingly seeks leave to amend its complaint to name the Leader Defendants and other members of the conspiracy, and to bring RICO and other civil conspiracy claims against the various co-conspirators.

The structure of the counterfeiting ring is a classic hub-and-spoke conspiracy. The Leader Defendants move the counterfeits through various fly-by-night (and ultimately expendable) **Supplier Defendants**.² But pharmacies will not buy from a shady, newly formed, unlicensed supplier, and so the conspiracy also needs the **Distributor Defendants**,³ who have the licensure and the established business presence to attract pharmacy customers. And to lure in the pharmacies, the Leader Defendants brought in their own sales force, headed by the **Marketer Defendants**,⁴ to advertise the counterfeits to pharmacies and generate sales. The Leader Defendants introduce the Supplier Defendants to the Distributor Defendants; the Supplier Defendants sell the counterfeits to Distributor Defendants; the Distributor Defendants sell the counterfeits to the pharmacy customers drummed up by the Marketer Defendants; and the Leader Defendants collect a large cut of the profits (and share it with the Marketer Defendants).

The Leader Defendants are the common point of connection with the other conspirators, and have very active roles in the scheme. They not only introduce the Suppliers to the Distributors, but they also closely managed those Supplier-Distributor relationships: they negotiated the prices, relayed offers, took orders, managed inventory levels, and resolved disputes. And if a Distributor Defendant had to break things off with a particular Supplier Defendant because its counterfeits were garnering too much attention, the Leader Defendants introduced a new Supplier Defendant to take its place. On the sales side, the Leader Defendants

² The Supplier Defendants are: Boulevard, Synergy, Gentek, Omom, Rapids Tex, Invicta, and Pharma Pac (and their principals).

³ The Distributor Defendants are: Safe Chain, ProPharma, Scripts, and USDV Pharma (and their principals).

⁴ The Marketer Defendants are: Messrs. Zangari, Massana, and Panagiotopoulos, and StreamlineRx.

paid and supervised the Marketer Defendants, and even brought in some pharmacy customers on their own.

To date, Gilead has identified at least seven Supplier Defendants that participated in the conspiracy under the direction of the three Leader Defendants, as well as three Distributor Defendants who purchased the counterfeits and sold them to pharmacies. And as further described below, Gilead has also identified, and newly named as Defendants, additional co-conspirators, including shell companies that received large sums of money from the Supplier Defendants, either to pay directly for the counterfeits, or to conceal and help distribute the funds to the ultimate recipient of that payment.

Several questions remain unanswered about this conspiracy, including how the Leader Defendants developed their stable of fly-by-night Supplier Defendants and, most pressingly, who is manufacturing and providing the counterfeits to the conspiracy. In light of the Supplier Defendants' refusal to cooperate or produce documents, the relief requested herein, including *ex parte* seizures at the premises of the Leader Defendants and other key members of the conspiracy, represents Gilead's only realistic opportunity at finding the answers to those critical questions.

This case remains first and foremost about patient safety. Defendants are engaged in a massive scheme to sell counterfeit HIV drugs that pose a serious and ongoing physical danger to the American public. Gilead respectfully urges the Court to issue a seizure order, along with the other relief requested in this motion, so that Gilead can put an immediate stop to the newly added Defendants' counterfeiting and continue to track down the counterfeit medications that are flowing through U.S. commerce.

STATEMENT OF FACTS

I. GILEAD’S HIV MEDICATIONS

A. Gilead’s Trademarks

Gilead is the owner of several different registered, well-established, and famous trademarks that appear on the packaging of genuine Gilead HIV medications. Those trademarks and proof of their registration are set forth as Exhibit 1 of the Declaration of Gretchen Stroud, dated August 17, 2021 (“Stroud Decl.”). Ms. Stroud’s declaration also sets forth evidence of the marks’ famousness and use.

B. Gilead’s Medications

Gilead described in prior filings its well-known HIV treatments, including BIKTARVY[®], a complete, one-pill once-a-day prescription medication used to treat HIV, and DESCOVY[®], which when taken once a day as prescribed is approved for use in certain populations as pre-exposure prophylaxis (“PrEP”) – a method of preventing HIV in at-risk, HIV-negative adults and adolescents – to decrease their risk of acquiring HIV through sex. Decl. of Joel Gallant, dated July 21, 2021 (“Gallant Decl.”) ¶¶ 8-13. Gilead has since recovered counterfeits of STRIBILD[®], GENVOYA[®], ATRIPLA[®], and TRUVADA[®], which are other HIV treatment or PrEP medications; VOSEVI[®] and SOVALDI[®], which are hepatitis C medications; and RANEXA[®], which treats chronic angina. Plaintiffs’ Mem. of Law, dated August 19, 2021 at 3.

II. THE DEFENDANTS’ COUNTERFEIT GILEAD-BRANDED MEDICATIONS

In the months leading up to the initial seizures, Gilead learned through patient and pharmacy complaints that counterfeit bottles of its HIV medications were circulating in the pharmaceutical supply chain. *See* Decl. of Susmitha Sunkara, dated July 21, 2021 (“July 21, 2021, Sunkara Decl.”) ¶¶ 4-6. Shockingly, these counterfeit HIV pill bottles were filled with

foreign pills such as headache medicine and antipsychotic drugs that did not treat HIV and had potentially dangerous side effects. *See id.* ¶¶ 16-58. Gilead retrieved several of these counterfeit bottles, tested them both internally and through an outside laboratory, and confirmed them to be counterfeit. *Id.* Gilead also confirmed that it was impossible for the foreign medications inside the counterfeits to have been inserted through an error in the original manufacturing or packaging process. *Id.*; *see also id.* ¶¶ 7-9.

A. The Counterfeits Use Once-Authentic Gilead Bottles but Are Filled with Foreign Medications

Gilead’s HIV medications must be dispensed in their original, sealed manufacturer bottles; unlike many prescription drugs, they cannot lawfully be dispensed in generic pharmacy bottles. July 21, 2021, Sunkara Decl. ¶ 14. For many of the counterfeits, the counterfeiters began with empty authentic Gilead bottles bearing authentic labels. The counterfeiters then refilled those bottles with the foreign drugs, and heat-sealed the bottles with a replica of Gilead’s tamper-evident foil seal. As a result, the counterfeits appeared to be new, sealed, authentic bottles of Gilead medication, when in fact they contained other drugs entirely. *See id.* ¶¶ 16-58.⁵

B. The Counterfeit HIV Medications Pose a Severe Risk to Public Health

Both BIKTARVY® and DESCOVY® come in thirty-tablet bottles, representing a one-month supply of the drug. Gallant Decl. ¶ 14. For patients treating HIV infection, it is important that the patient take the Gilead medication once a day, every day. *Id.* ¶ 15. If a patient skips doses for even a short period of time, the patient faces the risk that the patient’s viral load – *i.e.*, the amount of HIV in their blood – will increase. *Id.* Viral rebound can have severe

⁵ In one instance, a counterfeit appeared to be an original and originally sealed bottle of an older Gilead medication that had its label removed, and had an authentic label for another, newer Gilead medication applied in its place. July 21, 2021, Sunkara Decl. ¶¶ 54-58.

consequences: over time, it can weaken the patient's immune system and increase the possibility of infections; it can result in progression of the disease and lead to the development of AIDS; and it can make patients more likely to infect their sexual partners. *Id.* ¶ 16.

Patients taking DESCOVY for PrEP[®] must also take the medication regularly to receive the prophylactic benefits of the drug. *Id.* ¶ 18. DESCOVY for PrEP[®] is recommended only for certain individuals at risk for HIV infection. *Id.* ¶ 12. Patients who unknowingly discontinue their DESCOVY[®] prophylactic treatment because they have received counterfeit medication are at a higher risk for contracting HIV while still believing they are being protected from infection. *Id.* ¶ 18.

Finally, the foreign drugs inside the counterfeit bottles pose a host of potentially serious risks to patients who have never been prescribed that medication and have no idea they are taking it. The most common foreign drug in recovered counterfeits is the antipsychotic quetiapine, marketed under the brand name SEROQUEL XR[®]. Quetiapine is a prescription antipsychotic medication with a number of known potentially serious side effects that require vigilant medical supervision. *Id.* ¶¶ 22-23. Quetiapine also poses serious dangers to patients with common health conditions, such as high blood pressure, diabetes, and low white blood cell counts, whose conditions must be closely monitored while taking quetiapine. *Id.*

Quetiapine may cause a strong sedated state or drowsiness. *Id.* Patients are also susceptible to fainting when taking quetiapine. *Id.* As noted on the FDA labelling for the drug, these effects are especially acute for first-time users. *Id.* One patient who unknowingly took SEROQUEL XR[®] when he received a counterfeit bottle of BIKTARVY[®] reported that he could not speak or walk afterwards. July 21, 2021, Sunkara Decl. ¶ 23. Patients who are prescribed quetiapine are warned against driving or operating machinery. Gallant Decl. ¶ 22.

In part because of this strong sedative effect, the FDA labelling for quetiapine recommends that new patients be given a small dose – 50 milligrams a day for many conditions – that can be increased over time as the patient’s physician tracks the side effects and monitors the patient’s reaction to the drug. *Id.* ¶ 23. The counterfeit Gilead HIV medication contained 300-milligram tablets of quetiapine. *Id.*

Of course, patients who ingest quetiapine from a counterfeit bottle of HIV medication have no idea that they are taking a medication with these potential side effects and receive no warning of the possible consequences of doing so. They have no idea they are not supposed to drive, operate heavy machinery, or engage in other activities where sedation or drowsiness are dangerous, and as a result are placed in grave danger.

C. Defendants’ Use of Fraudulent Pedigrees to Sell the Counterfeits

As described in Gilead’s initial papers, the Drug Supply Chain Security Act (“DSCSA”), 21 U.S.C. §§ 360eee *et seq.*, establishes a regulatory regime for the tracking and verification of every sale or transfer of a prescription drug in the United States, implemented specifically to combat counterfeiting. The central feature of the DSCSA is the requirement that every time a prescription drug is sold or transferred, it *must* be accompanied by what is known in the industry as a “pedigree” or “T3” document. *Id.* § 360eee-1(b)(1). Drugs that are sold with a false or suspect pedigree must be quarantined and cannot be sold. *Id.* § 360eee-1(c)(4)(A).⁶

⁶ See also, e.g., FDA, *Pharmacists: Utilize DSCSA Requirements to Protect Your Patients, Guidance Document* (July 3, 2019), <https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/pharmacists-utilize-dscsa-requirements-protect-your-patients> (requiring pharmacies to “[q]uarantine and investigate suspect prescription drugs to determine if they are illegitimate” upon receipt of drugs that may be counterfeit).

Pedigrees must list a chain of custody for every sale of the bottle, going back to the manufacturer. They must also include affirmative statements by the seller, including that the seller purchased the drug from an “authorized” trading partner. An “authorized” trading partner is one who: (1) is a licensed pharmaceutical distributor both in its home state and in the state into which it is selling the drugs; and (2) has registered with the FDA and has met its licensing reporting requirements to the FDA. 21 U.S.C. §§ 360eee(2), (23); *see id.* § 353(e)(1)(A)(ii). It takes mere seconds to confirm whether a distributor is “authorized” under the DSCSA: as required by the statute, the FDA has established a searchable online database of all registered pharmaceutical distributors in the nation, and typing in a distributor’s name will display all of that distributor’s applicable licensures.⁷

As described below, the purported Gilead-branded medications sold by the Defendants were all accompanied by false pedigrees: *i.e.*, pedigrees that fraudulently list a purchase from Gilead or a Gilead-authorized supplier that never occurred. These false pedigrees create a fraudulent chain of custody for the medications, allowing the Defendants to conceal their illegal trade and fraudulently claim their HIV medications come from authorized, legitimate sources. Falsified pedigrees undermine the entire anti-counterfeiting regime established by the DSCSA, which is why it is unlawful to sell a drug with even a suspect pedigree. *Id.* § 360eee-1(c)(4)(A). Moreover, as set forth below, the falsified pedigrees bear unauthorized reproductions of Gilead’s trademarks and are themselves counterfeit under the Lanham Act. *See pp. 48-50, infra.*

⁷ FDA, *Wholesale Distributor and Third-Party Logistics Providers Reporting*, <https://www.accessdata.fda.gov/scripts/cder/wdd3plreporting/index.cfm>.

III. THE LEADER DEFENDANTS: MESSRS. RALHAN, ROSELL, AND MANNAVA’S ORCHESTRATION OF THE PURCHASING, SALE, AND ADVERTISING OF THE COUNTERFEITS

The Leader Defendants, Messrs. Ralhan, Rosell, and Mannava, are three interconnected individuals (one of them a convicted pharmaceutical fraudster), who are responsible for pushing tens of thousands of bottles of purported Gilead-branded medications with fake pedigrees through the United States pharmaceutical distribution chain. Collectively, these three individuals represented a host of disparate fly-by-night counterfeiters, including at minimum Supplier Defendants Boulevard, Gentek, Omom, Invicta, and Pharma Pac. The Leader Defendants negotiated the pricing and sale of those fly-by-night wholesalers’ counterfeit Gilead-branded medications to at least three licensed gray-market distributors: Defendants Safe Chain and ProPharma, and newly added Defendant Scripts. And after establishing these counterfeit pipelines to the licensed distributors, the Leader Defendants went on to organize the advertising and sale of those counterfeits to pharmacies, supervising a sales force and even directly selling to pharmacies on the Distributor Defendants’ behalf.

A. Dhruv Ralhan and His Shell Company, D&K Healthcare

When Safe Chain launched into the business of buying and selling purported Gilead HIV medication in May 2020, it did so through Defendant Dhruv Ralhan (who sometimes went by “Drew”). Mr. Ralhan first connected Safe Chain with the fly-by-night Supplier Defendant Boulevard, and over the course of weeks quickly built up Safe Chain’s brand-new HIV business to include various purported Gilead-branded medications. *See, e.g.*, Decl. of Geoffrey Potter, dated Oct. 13, 2021 (“Oct. 13, 2021, Potter Decl.”), Ex. 113 (Mr. Brosius: “let me know if you can get any or all [of these HIV medications]. I can really have this take off if we do it right.” Mr. Ralhan: “I have it all the HIV, how many[?]”); *id.* Ex. 114. From the start of the relationship, Mr. Ralhan “went through a really long process of negotiation” to negotiate both the

price Safe Chain would pay Boulevard for the counterfeits, as well as the size of his own cut of the profits, arguing that his fees needed to be high “as we are multiple people handling this operation.” *Id.* Ex. 115. Mr. Ralhan managed Safe Chain’s relationship with Boulevard, relaying orders and occasionally making direct use of Boulevard 9229 LLC’s sales email address, 9229sales@gmail.com. *Id.* Ex. 116.

In the ensuing months, Mr. Ralhan introduced Safe Chain to new fly-by-night sources of counterfeit Gilead medication: at minimum, Supplier Defendants Gentek and Omom. Mr. Ralhan once again and directly negotiated the pricing of the purported Gilead HIV medications that Safe Chain purchased from those counterfeiters. *See id.* Ex. 117 (“Dhruv came back at wac -14 for either omom or gentek.”). Mr. Ralhan also handled issues with Safe Chain’s pricing and payments for purported Gilead products sold by the Supplier Defendants. *Id.* Ex. 118 (Charles Boyd complaining about Gentek’s failure to recognize payments, and Mr. Ralhan responding: “You HAVE to include me in these payments just like you do for boulevard.”); *id.* Ex. 119 (Adam Brosius asking Mr. Ralhan to correct the pricing on a purchase of TRUVADA[®], followed by Mr. Ralhan reaching out to Gentek to address the issue).

Mr. Ralhan also conspired to sell counterfeits to and through Distributer Defendant ProPharma. Mr. Ralhan was introduced to Alex Reyes, a ProPharma employee, in early 2021 by his co-ringleader, Defendant Paul Rosell. Oct. 13, 2021, Potter Decl. Ex. 120. In his phone, Mr. Reyes saved Mr. Ralhan’s name as “Dhruv (HIV MEDS).” *Id.* Mr. Ralhan had Mr. Reyes sign a non-disclosure agreement (“NDA”) prior to their discussion of ProPharma’s potential sale of Gilead HIV medication through Mr. Ralhan and his colleagues. *Id.* Mr. Ralhan signed that non-disclosure agreement on behalf of Defendant D&K Healthcare, a shell company that he wholly owns. Decl. of Hannah Coleman, dated Oct. 13, 2021 (“Oct. 13, 2021, Coleman Decl.”), Ex. 39.

In email correspondence, Mr. Ralhan explained that “we” – meaning at minimum himself and Mr. Rosell – “have our own custom software that produces our Pedigree,” and discussed “executing a contract with the” distributors who would be providing the HIV medication. *Id.* Ex. 121. Mr. Ralhan specified that the “[c]ontract will be from my ‘broker’ side.” *Id.*

After the deal was struck and Mr. Ralhan had established the pipeline for counterfeit HIV medications to ProPharma, Mr. Ralhan supervised and resolved disputes among the sales force that was selling the counterfeits to pharmacies on ProPharma’s behalf. Oct. 13, 2021, Potter Decl. Ex. 122. He also submitted some orders directly. *Id.* Ex. 123.

B. Paul Rosell and His Shell Company, Med-Connect

As noted above, Mr. Rosell introduced his co-ringleader, Mr. Ralhan, to Mr. Reyes, and started a three-person group chat titled “ProPharma HIV.” Oct. 13, 2021, Potter Decl. Ex. 120. In October 2020, Mr. Rosell recruited Distributor Defendant ProPharma into the counterfeiting conspiracy. *Id.* Ex. 158. Mr. Rosell disclosed in October 2020 that he was already selling huge volumes of purported Gilead medication (*i.e.*, the counterfeits) through ProPharma’s “two major competitors: Safechain and Scrip[t]s [*sic*]. Safechain is moving about \$5M a week and Scrip[t]s is around \$8M a week.” *Id.* Mr. Rosell’s proposal was that his team would handle both the sourcing of the product – initially, through Supplier Defendant Omom – and the sales to ProPharma’s customers. *Id.* All ProPharma had to do was wait for Mr. Rosell’s team to generate orders from pharmacies, and then ship the counterfeits to pharmacies and collect payment. *See id.* As Mr. Rosell emphasized in his pitch: “**Propharma does not have to provide a sales force.**” *Id.* (emphasis in original). One of ProPharma’s board members responded, “Sounds like a great opportunity to expand and grow with the help of established relationships from Paul [Rosell] and his people.” *Id.*

Pursuant to Mr. Rosell’s plan, ProPharma began purchasing counterfeit Gilead medication from Distributor Defendant Omom in February 2021. Oct. 13, 2021, Potter Decl. Ex. 124. In April 2021, Mr. Reyes announced that ProPharma’s kickbacks from the sales of the counterfeits would now be made “to Paul [Rosell]’s company,” Defendant Med-Connect. *Id.* Ex. 125. *Id.* Mr. Reyes explained that ProPharma would pay Med-Connect, and then Mr. Rosell “will be in charge of disbursements to the teams.” *Id.* Mr. Reyes said Mr. Rosell’s company was the preferred entity to receive payments because “Paul seems to know both sides.” *Id.*

C. Venkata Mannava and his Shell Company, DSP

As with his co-Leader Defendants, Venkata Mannava’s primary role in the conspiracy was to introduce and manage the relationships between fly-by-night Supplier Defendants and the licensed Distributor Defendants. Mr. Mannava is a former pharmacist and a convicted pharmaceutical fraudster. He lost his pharmacist’s license and was barred from participating in federal healthcare plans after being convicted for participating in a criminal scheme to fraudulently bill insurance for expensive HIV and cancer medication that were neither requested by patients nor actually dispensed. Oct. 13, 2021, Coleman Decl. 41. Mr. Mannava was also convicted of forging prescriptions for oxycodone, the narcotic at the center of America’s opioid addiction epidemic. *Id.*

As one of the ringleaders of the counterfeiting scheme, Mr. Mannava used the pseudonyms “Srini K.” and “Vas Manna,” both of which incorporate elements of his full name: Venkata Srinivas Mannava. Through a combination of public-records searches and documents obtained from the ProPharma seizure, Gilead’s investigators were able to definitively identify both of these alternate personas as, in fact, Mr. Mannava. Oct. 13, 2021, Coleman Decl. ¶ 12 & Exs. 42-46.

Using his “Srini K” persona, Mr. Mannava interfaced directly with ProPharma to set up Defendant Pharma Pac, yet another fly-by-night Supplier Defendant, as a vendor. Oct. 13, 2021, Potter Decl. Ex. 126. Mr. Mannava also actively managed ProPharma’s relationship with at least three counterfeit suppliers – Supplier Defendants Omom, Invicta, and PharmaPac – addressing issues such as payments, missing invoices, maintaining a steady supply, and pricing. *Id.* Ex. 127 (“forgot to give you wac-13.5% on descovy [from Omom]. I fixed the price”); *id.* Ex. 128 (“can you provide me with a snapshot of inventory left (separately, for Omom and Invicta)? That way I can plan ahead and make sure you don't have too much on hand.”); *id.* Ex. 129 (“I know this is unconventional, but can you please split the \$3M amount” among Omom, Invicta, and PharmaPac).

Mr. Mannava also used a shell company he founded in March 2021, Defendant DSP, to receive funds for the counterfeits and distribute kickbacks to his co-conspirators. *See, e.g.*, Oct. 13, 2021, Potter Decl. Ex. 128; *id.* Ex. 125; *see also* Oct. 13, 2021, Coleman Decl. ¶ 10 & Ex. 40. DSP received kickback payments directly from the counterfeit suppliers as well. *See* Oct. 13, 2021, Potter Decl. Ex. 130 (Supplier Defendant Invicta paying 10% of its proceeds from counterfeit sales to DSP).

Mr. Mannava also worked on the sales side of the counterfeiting operation. Using his “Vas Manna” persona (often shortened to “Vas M”), Mr. Mannava worked directly as a sales representative, using a ProPharma email address and selling purported HIV medication directly to pharmacies. *E.g.*, Oct. 13, 2021, Potter Decl. Ex. 131 (“This is Vas from ProPharma and I’m your sales rep . . . really look forward to helping you with your HIV orders!”). As “Vas Manna,” Mr. Mannava also worked directly with co-ringleader Mr. Ralhan to add new retail pharmacies to the collection of customers for the counterfeits. *E.g.*, *id.* Ex. 132.

IV. THE MARKETER DEFENDANTS: DEFENDANTS ZANGARI, MASSANA, PANAGIOTOPOULOS, AND STREAMLINERX SELL THE COUNTERFEITS ON BEHALF OF THE DISTRIBUTOR DEFENDANTS

As noted above, the Leader Defendants not only provided the Distributor Defendants access to a stable of counterfeit suppliers, but they also provided the sales force to sell those counterfeits to pharmacies. The heads of the sales force were referred to as “the Canadian Boys”: Defendants Mike Zangari, Riccardo Massana, and John Panagiotopoulos, all of whom live in Canada (together, the “Marketer Defendants”). *See* Oct. 13, 2021, Potter Decl. Ex. 125. The Marketer Defendants were responsible for managing the sales force that advertised and sold counterfeits to pharmacies on behalf of, at minimum, the three Distributor Defendants: Safe Chain, ProPharma, and Scripts. *See id.* Ex. 120.

In February 2021, when ProPharma first joined the counterfeiting scheme, all three of the Marketer Defendants were on an initial kick-off call with Leader Defendants Ralhan and Rosell, as well as a follow-up email chain with the subject line “ProPharma – HIV introduction.” Oct. 13, 2021, Potter Decl. Ex. 133; *see also id.* Ex. 134 (Mr. Panagiotopoulos writing to ProPharma that “I’ll be pushing sales for for [*sic*] along with Dhruv [Ralhan] and Mike [Zangari].”). All three of the Marketer Defendants managed ProPharma’s sales of the counterfeits by receiving emails through the distribution group RXorders@propharmausa.com. Oct. 13, 2021, Potter Decl. Ex. 135. And each of the Marketer Defendants sold purported Gilead products to pharmacies on ProPharma’s behalf. *See id.* Ex. 136.

Defendants Zangari and Panagiotopoulos were also responsible for selling counterfeits on behalf of Safe Chain. Along with Leader Defendant Mr. Ralhan, Messrs. Zangari and Panagiotopoulos shared an email address, brands@pharmasales.com (an email domain owned by co-defendant Adam Brosius) through which they submitted pharmacy orders to Safe Chain. Oct. 13, 2021, Potter Decl. Exs. 137, 138, 139, 140. Messrs. Zangari, Panagiotopoulos, and Ralhan

split the kickback for Safe Chain's sales of counterfeits among the three of them. *See id.* Ex. 141.

The Marketer Defendants utilized a shell company, Defendant StreamlineRx, in connection with their counterfeit sales. StreamlineRx was formed in February 2020, and according to its corporate filings its principal is Defendant Pavan Matripragada. Oct. 13, 2021, Coleman Decl. ¶ 14 & Ex. 47. StreamlineRx's website was registered by Defendant D&K Healthcare, the shell company owned by Leader Defendant Ralhan. Oct. 13, 2021, Coleman Decl. Ex. 49. Streamline advertises itself as a reimbursement manager for pharmacies that boasts it has "proprietary billing methods" that allow pharmacies to "circumvent PBMs" – *i.e.*, the Pharmacy Benefit Managers that set reimbursement rates for insurance plans. Oct. 13, 2021, Coleman Decl. Ex. 48. Defendants Zangari and Ralhan submitted invoices to Safe Chain and requested payment for purported Gilead products through StreamlineRx, using an @streamlinex.net email address. Oct. 13, 2021, Potter Decl. Exs. 142, 143, 144, 115.

V. THE SUPPLIER DEFENDANTS: FLY-BY-NIGHT COUNTERFEITERS WHO PARTNERED WITH THE RINGLEADER DEFENDANTS TO SELL TO THE DISTRIBUTOR DEFENDANTS

Through the seizures it has conducted to date, Gilead has identified seven different fly-by-night counterfeiters who sold purported Gilead medications with fake pedigrees: Supplier Defendants Boulevard, Synergy, Gentek, Omom, Rapids Tex, Invicta, and PharmaPac. All of these Supplier Defendants sold large quantities of purported Gilead products with fake pedigrees to the Distributor Defendants, who in turn sold them to retail pharmacies.

A. Boulevard's Alter Ego: MFK Management d/b/a Boulevard 9229

Gilead has already received injunctive relief against Supplier Defendant Boulevard 9229 LLC. As set forth above, Boulevard was the first fly-by-night Supplier Defendant that the Leader Defendants used to sell the counterfeits through Safe Chain. Gilead now knows that

Boulevard's principal, Defendant Peter Khaim, also organized newly added Defendant MFK Management, which lists both "Boulevard 9229" and "9229 Boulevard" as assumed names. Oct. 13, 2021, Coleman Decl. ¶ 18 & Ex. 32. At Boulevard's request, Safe Chain began sending its payments to Boulevard to a bank account owned by "MFK Management LLC d/b/a 9229 Boulevard LLC." Oct. 13, 2021, Potter Decl. Ex. 145. Safe Chain in fact wired approximately \$10 million to MFK Management as payment for Boulevard's counterfeits. Sept. 21, 2021, Potter Decl. Ex. 82.

B. Synergy's Co-Conspirators: Julio Martin Gonzales, Cesar Castillo, and DNS Distributor.

Gilead has also already received injunctive relief against Supplier Defendant Synergy, another fly-by-night counterfeiter, and its principal, Defendant Carlos Vega. During the course of contempt proceedings before this Court, Mr. Vega repeatedly attested that the "true" actor behind Synergy's counterfeiting is a man named Julio Martin Gonzales. Without accepting the incorrect premise that Mr. Gonzales's involvement would in any way absolve Mr. Vega, Gilead now adds Mr. Gonzales as a defendant and seeks injunctive relief against him.

Mr. Vega also claimed during the contempt proceedings that Synergy purchased the counterfeits from two recently formed shell corporations: Defendants Cesar Castillo and DNS Distributor. Synergy's bank records confirm that Synergy paid those two entities most of the proceeds of its counterfeiting. Decl. of Geoffrey Potter, dated Sept. 21, 2021, Ex. 89. And as Gilead has discussed in detail in its prior filings, Defendant Cesar Castillo is a recently-formed Colorado shell company, so-named to intentionally defraud customers into believing that Synergy sourced its counterfeits from the "real" Cesar Castillo, a Gilead-authorized distributor in Puerto Rico. Plaintiffs' Mem. of Law, dated August 19, 2021 at 16-18. Mr. Vega in fact controls Defendants Cesar Castillo and DNS Distributor, and so his attempts to deflect blame

onto them fail Corporate records show that Mr. Vega's co-conspirator and partner in crime, Mr. Martin Gonzalez, is the paper principal of both corporate shells. Oct. 13, 2021, Coleman Decl. ¶¶ 38-40 & Exs. 33, 34. But because the evidence shows that both companies are part of the counterfeiting conspiracy and were used to either directly or indirectly pay for the counterfeits, Gilead seeks injunctive relief as to Cesar Castillo and DNS Distributor as well.

C. Gentek and Its Principal, Edel Reyes

Supplier Defendant Gentek is also a fly-by-night counterfeiter that worked with the Leader Defendants to sell counterfeits to multiple Distributor Defendants. Gentek is newly added as a defendant, but Gilead set forth evidence concerning their counterfeiting in its initial filings before this Court, which Gilead incorporates by reference here. Plaintiffs' Mem. of Law, dated July 22, 2021 at 16-20, 34-35. In summary, Gentek sold 13,489 bottles of purported Gilead medication to Safe Chain, valued at \$39.3 million. Some of Gentek's counterfeits had Seroquel XL, the powerful antipsychotic, inside the bottle instead of Gilead medication. Plaintiffs' Mem. of Law, dated August 19, 2021 at 5. Gilead has confirmed that *all* of Gentek's pedigrees for purported Gilead product are fraudulent. July 21, 2021, Sunkara Decl. ¶ 50; Oct. 13, 2021, Sunkara Decl. ¶ 13.

Gentek is a fly-by-night counterfeiter owned by Defendant Edel Reyes, who registered the company at his home address. Plaintiffs' Mem. of Law, dated July 22, 2021 at 34. It opened its doors just months before it started selling counterfeits to Safe Chain, and abandoned its offices before Gilead's investigators visited them. Decl. of Hannah Coleman, dated July 21, 2021, ("July 21, 2021 Coleman Decl.") ¶¶ 25-29 & Exs. 11, 12.

D. Rapids Tex and Its Principal, John Santos

Supplier Defendant Rapids Tex and its principal, John Santos, are newly added as defendants, but Gilead set forth evidence concerning their counterfeiting in its initial filings

before this Court, which Gilead incorporates by reference here. Plaintiffs' Mem. of Law, dated July 22, 2021 at 21-23, 35-38. In summary, Rapids Tex sold 1,451 bottles of purported Gilead medication to Safe Chain, valued at approximately \$4.5 million. Gilead has confirmed that *every* pedigree for every Gilead product sold by Rapids Tex is fraudulent. July 21, 2021, Sunkara Decl. ¶ 30; Oct. 13, 2021 Sunkara Decl. ¶ 11.

Rapids Tex is licensed only in its home state of Texas and therefore cannot lawfully sell across state lines. July 21, 2021, Coleman Decl. ¶¶ 30-33 & Exs. 13, 14. To sell to Safe Chain, Rapids Tex participated in a "pass-through" scam whereby it fulfilled Safe Chain's orders by selling the bottles on paper to a different, licensed distributor, which then immediately "sold" them to Safe Chain. Plaintiffs' Mem. of Law, dated July 22, 2021 at 36-37.

Safe Chain itself declared, in writing, that multiple bottles of Gilead-branded medication sold by Rapids Tex were "bad/counterfeit," noting that they had "experienced them [*i.e.*, the counterfeits] with another" distributor, and so Safe Chain "could not receive/take" those bottles. Oct. 13, 2021, Potter Decl. Ex. 146. Mr. Santos, Rapids Tex's principal, was copied on that email. *Id.* His response to being told that he had sold counterfeit HIV medication was to say "we will be shipping out today another order." *Id.*

E. Omom and Its Principals, Gustavo Fernandez, Luis D. Gonzalez Herrero, and Jordan Rodriguez Mato

Omom is another fly-by-night Supplier Defendant whose sales to multiple Distributor Defendants was orchestrated by the Leader Defendants. Omom is newly added as a defendant, but Gilead set forth evidence concerning Omom's counterfeiting in its prior briefing before this Court, which Gilead incorporates by reference. *See* Plaintiffs' Mem. of Law, dated Aug. 19, 2021 at 20-23. As stated in that prior filing, Gilead received and tested a counterfeit bottle of BIKTARVY® that Omom had sold to ProPharma, which sold it to a pharmacy. *Id.* at 19-20.

That counterfeit bottle had the wrong pills inside, and a patient reported being sickened by the counterfeit medication. *Id.* at 20. Gilead now knows that Omom sold a total of **over 18,000** bottles of purported Gilead medication to both ProPharma and Safe Chain, valued at over **\$52 million**. Oct. 13, 2021, Potter Decl. ¶ 14. Gilead has confirmed *every* pedigree for Omom’s purported Gilead medications to be fraudulent. Decl. of Susmitha Sunkara, dated Aug. 17, 2021 (“Aug. 17, 2021, Sunkara Decl.”) ¶ 16; Oct. 13, 2021, Sunkara Decl. ¶¶ 12, 14.

Omom is a fly-by-night counterfeiter which made sales using a pseudonymous principal. Plaintiffs’ Mem. of Law, dated August 19, 2021 at 22. In its corporate filings, Omom lists as its principals Defendants Gustavo Fernandez, Luis D. Gonzalez Herrero, and Jordan Rodriguez Mato. Oct. 13, 2021, Coleman Decl. ¶¶ 29-30. Omom abandoned its offices by the time Gilead’s investigators visited it, and at the time of Gilead’s prior filing, Gilead’s investigators had been unable to locate either Omom or any of its principals. *Id.* ¶ 31. Through subpoenaed bank records, corporate filings, and an independent investigation, Gilead’s investigators have now identified and confirmed the location of Defendant Gustavo Fernandez, who among other things is the signatory on Omom’s bank account. *Id.* ¶ 32.

F. Invicta and Its Principal, Jorge Caba

In late May 2021, Invicta became the latest in the stable of Supplier Defendants that the Leader Defendants used to sell ProPharma purported Gilead medication with fraudulent pedigrees. From late May 2021 to the date of Gilead’s seizure against ProPharma in August, Invicta sold 3,987 bottles of Gilead medication worth approximately \$11.8 million. Oct. 13, 2021, Potter Decl. ¶ 14. Gilead has confirmed that the pedigrees for *every* bottle sold by Invicta are fake: those pedigrees all claim that Invicta purchased from Smith Drug Company, a Gilead-authorized distributor, which has never sold anything to Invicta. Oct. 13, 2021, Sunkara Decl. ¶¶ 15.

As with the other counterfeit Supplier Defendants, ProPharma’s relationship with Invicta was managed by the Leader Defendants, with sales arranged by the Marketer Defendants. *E.g.*, Oct. 13, 2021, Potter Decl. Ex. 128 (asking ProPharma to “provide me with a snapshot of inventory left (separately, for Omom and Invicta)? That way I can plan ahead and make sure you don’t have too much on hand”); *id.* (“I pay extra commissions to Mike [Zangari], John [Panagiotopoulos], and Paul [Rosell] ONLY for quantities sold from Invicta inventory”); *id.* Ex. 147 (“Attached are the two POs that I sent to Invicta on Monday.”). Safe Chain also took steps to add Invicta as a supplier in June 2021, but appears not to have completed that process before this Court enjoined Safe Chain from selling Gilead products. Oct. 13, 2021, Potter Decl. Ex. 150.

G. Pharma Pac and Its Principal, Angel Toral

Defendant Pharma Pac is the final counterfeit Supplier Defendant that the Leader Defendants introduced to Distributor Defendant ProPharma. ProPharma began purchasing purported Gilead medication from Pharma Pac on August 4, 2021, just weeks before Gilead executed the seizure at ProPharma’s offices on August 23. Oct. 13, 2021, Potter Decl. Ex. 149. During that short period, Pharma Pac sold over 1,000 bottles of purported Gilead medication to ProPharma, valued at over \$3 million. *Id.* ¶ 14. Gilead has confirmed that *every* pedigree for every purported bottle of Gilead product sold by Pharma Pac is fraudulent – they all list a purported first sale from Gilead to an authorized distributor, but Gilead never made those sales to that authorized distributor. Oct. 13, 2021, Sunkara Decl. ¶ 16.

Pharma Pac’s relationship with ProPharma was managed primarily by Leader Defendant Mannava, using his “Srini K” persona. *See* Oct. 13, 2021, Potter Decl. Ex. 150 (sending ProPharma a “new account application” to set up Pharma Pac as a vendor); *id.* Ex. 151

(supplying ProPharma with a Pharma Pac invoice for purported Gilead medication); *see also id.* Exs. 152, 153.

The evidence shows that Defendant Pharma Pac is a fly-by-night counterfeiter that has stolen the identity of an established, legitimate pharmaceutical company. There is a legitimate business named Pharma Pac, a licensed pharmaceutical repackaging company, which was founded in 1984.⁸ The “Pharma Pac” that sold counterfeits to ProPharma was founded in January 2021, by its owner and principal, Defendant Angel Toral. Oct. 13, 2021, Coleman Decl. Ex. 61. As part of its attempts to pass itself off as its legitimate namesake, Defendant Pharma Pac fraudulently utilizes the legitimate Pharma Pac’s business address on its corporate filings, and even copied the legitimate Pharma Pac’s logo on its pedigrees and invoices. Oct. 13, 2021, Potter Decl. Exs. 154, 155.

H. RxWholesale and Its Principals, Charles Bree, Gabriel Betesh, and Daniel Gelbinovitch

RxWholesale is a fly-by-night pharmaceutical distributor that was founded by Defendant Charles Bree in February 2021. Oct. 13, 2021, Coleman Decl. Ex. 71. RxWholesale lists a business address in Brick, New Jersey – but in a familiar pattern, that office was abandoned by the time Gilead’s investigators visited it. *Id.* ¶¶ 56-59; McAllister Decl. ¶¶ 3-8.

Gilead has confirmed from numerous independent sources that RxWholesale is selling purported Gilead medication with fake pedigrees. For example, discussed at pp. 8-9, *supra* above, AmerisourceBergen Corp. (“ABC”), a Gilead-authorized distributor, provided Gilead a copy of a confirmed fake pedigree that falsely claimed RxWholesale had purchased BIKTARVY® from ABC and sold it to Distributor Defendant Scripts. Oct. 13, 2021, Sunkara

⁸ *See* <http://www.pharmapac.com>.

Decl. ¶ 18 & Ex. 13. Separately, in June 2021 a pharmacy that was directly solicited by RxWholesale asked to see the pedigrees in advance, saw that the pedigrees (falsely) listed ABC as the source of over 500 bottles of Gilead-branded medicines, and shared that pedigree with Gilead's counsel. Oct. 13, 2021, Potter Decl. Ex. 156. And Gilead seized from Safe Chain a copy of RxWholesale's application to become a Safe Chain vendor, completed just before the seizure was executed in July 2021. *Id.* Ex. 157. Defendant Betesh signed the application form as RxWholesale's President, and provided a sample pedigree with its application that once again falsely listed ABC as its source, and which listed the wrong address for Gilead as the manufacturer. *Id.*

Finally, in an unrelated lawsuit filed in New York Supreme Court, a creditor with a security interest in RxWholesale's inventory has alleged that RxWholesale and Scripts conspired to hide millions of dollars' worth of BIKTARVY[®], out of state and out of the reach of the New York City Marshal. Oct. 13, 2021, Coleman Decl. Ex. 73. The creditor, Merchant Capital, was given a blanket security interest in, among other entities, RxWholesale by Defendant Daniel Gelbinovich, whom the evidence indicates is another principal of RxWholesale. *Id.* The creditor attached to its Complaint a copy of an invoice showing that in July 2021 alone, RxWholesale sold nearly a thousand bottles of purported Gilead products to Scripts, all at too-good-to-be-true prices. *Id.*

Like several other Supplier Defendants, RxWholesale has recently abandoned its offices. McAllister Decl. ¶ 8.

I. CM Pharma and Its Principals, Robert and Jeffrey Gafna

Supplier Defendant CM Pharma is an Alabama drug distribution company owned and operated by Defendants Robert and Jeffrey Gafna. Oct. 13, 2021, Coleman Decl. ¶¶ 47-49 & Exs. 66, 67. CM Pharma is licensed to distribute pharmaceuticals only in Alabama, making it

unlawful for CM Pharma to ship across state lines. 21 U.S.C. §§ 360eee(2), (23); *see id.* § 353(e)(1)(A)(ii).

In April 2021, CM Pharma sold 100 bottles of purported BIKTARVY[®] to Safe Chain. Oct. 13, 2021, Potter Decl. Ex. 181. Safe Chain complained that CM Pharma failed to provide pedigrees for the BIKTARVY[®], noting, “The man I spoke with Jeff [Gafna] kind of gave me some run around like answer about why we haven’t received them... seemed really odd.” Oct. 13, 2021, Potter Decl. Ex. 159 (ellipses in original). On April 16, 2021, CM Pharma finally sent Safe Chain pedigrees that all claimed that Gilead sold the product directly to Invicta, one of the fly-by-night Supplier Defendants, which then sold the product to CM Pharma. *Id.* Ex. 160. Those pedigrees are, of course, fraudulent: Gilead never sold any products to Invicta. Oct. 13, 2021, Sunkara Decl. ¶ 15.

Safe Chain continued to complain about the lack of communication from CM Pharma, writing on April 19, “I have still not yet received anything from CM Pharma about the product we have sitting here.” Oct. 13, 2021, Potter Decl. Ex. 161. Safe Chain appears to have eventually sent the medication back a few days later. *See id.* Ex. 162.

In sum, the evidence is clear that CM Pharma and its principals were responsible for selling purported Gilead products that it acquired from Invicta, a known fly-by-night counterfeiter. Those purported Gilead products were accompanied by knowingly and obviously fraudulent pedigrees. The fact that Safe Chain eventually sold the counterfeits back to CM Pharma and/or Invicta does not, of course, absolve CM Pharma or its principals of their liability for their willful trafficking of counterfeit HIV medication.

VI. THE NEW DISTRIBUTOR DEFENDANTS: SCRIPTS, USDV PHARMA, AND THEIR PRINCIPALS

A. Scripts and Its Principal, Steven Diamantstein

Defendant Scripts is a pharmaceutical distributor located in Brooklyn, owned and operated by Defendant Steven Diamantstein. Oct. 13, 2021, Coleman Decl. Ex. 50. Like the other Distributor Defendants, Scripts is a properly licensed distributor that operates in the gray market, selling discounted prescription drugs outside of authorized distribution channels. And like the other Distributor Defendants, Scripts worked with the Leader Defendants to willfully sell counterfeit Gilead HIV medication to U.S. pharmacies.

Gilead knew Scripts had sold counterfeits before it learned of Scripts's role in the larger conspiracy. In January 2020 and again in March 2021, Gilead learned of complaints that Scripts had sold counterfeit Gilead medication to a pharmacy, which subsequently dispensed it to a patient. Oct. 13, 2021, Sunkara Decl. ¶¶ 18-19 & Exs. 13, 14. Both of those counterfeit bottles of Gilead medication contained antipsychotic medication inside: one had high-dose Seroquel XL, and another had generic aripiprazole, another antipsychotic medicine in the same class as Seroquel. *Id.* Gilead and its outside laboratory identified evidence of tampering. *Id.* In April 2021, Gilead engaged in a series of correspondence and meetings with Scripts' counsel about its sale of counterfeit Gilead medication. Scripts refused to provide the documents and information Gilead requested about the counterfeits, although it did say it would stop purchasing from Supplier Defendant Gentek, which sold Scripts the counterfeits. Oct. 13, 2021, Potter Decl. Ex. 163.

In late July 2021, Gilead separately received a communication from ABC, one of its authorized distributors, forwarding a fraudulent pedigree for Gilead medication that Scripts had sent to a pharmacy in Texas. Oct. 13, 2021, Sunkara Decl. ¶ 20 & Ex. 15. The pedigree claimed

that Gilead had sold the bottles of BIKTARVY[®] to ABC, which had sold them to Defendant RxWholesale, which had sold them to Scripts. *Id.* ABC confirmed that the purported sale from ABC to RxWholesale was false and never occurred. *Id.* In late September 2021, a pharmacy contacted Gilead's counsel with another fake pedigree from RxWholesale, which falsely listed over 500 bottles of Gilead-branded medications as coming from ABC. *Id.* ¶ 21 & Ex. 16.

From information collected at the last round of seizures, Gilead now knows that Scripts worked with the Leader and Marketer Defendants to sell large quantities of counterfeit Gilead HIV medication from numerous illicit suppliers, not only Gentek. As noted above, the Leader Defendants told ProPharma in March 2021 that they were selling "\$8M a week" in HIV medication through Scripts. Oct. 13, 2021, Potter Decl. Ex. 158. Gilead has also received copies of advertising emails that the Marketer Defendants' sales force sent out on Scripts's behalf. *Id.* Ex. 164; *see also id.* Ex. 165 (identical email sent on behalf of ProPharma, but erroneously keeping Scripts's name in the pitch); *id.* Ex. 166 (pharmacy reacting to sales pitch made on behalf of ProPharma by writing, "what happened to Scripts Wholesale?").

B. USDV Pharma and Its Principal, Jeff Beetley

USDV Pharma is a pharmaceutical wholesaler that was founded in April 2021 and received its New York drug wholesaler license on August 7, 2021. Oct. 13, 2021, Coleman Decl. ¶¶ 19, 21, 23 & Exs. 52, 54. USDV Pharma was incorporated by Defendant Steven Diamantstein, the owner of Defendant Scripts, and it is located in the same building as Scripts: Scripts occupies the third floor of the building, and USDV occupies the second floor. *Id.* The Diamantstein family owns the entire building. *Id.*

On LinkedIn, Defendant Jeff Beetley holds himself out as the CEO of USDV Pharma. *Id.* ¶ 22 & Ex. 53. Mr. Beetley is also a Scripts employee whose job duties included selling Scripts's purported Gilead HIV medication. Oct. 13, 2021, Potter Decl. Ex. 167. For example,

when ABC provided Gilead a copy of Scripts's fake pedigree in late July 2021, it provided the corresponding invoice that listed Mr. Beetley as the Scripts employee responsible for the sale.

Oct. 13, 2021, Sunkara Decl. Ex. 15.

In sum, USDV Pharma (1) has the same owner as Scripts; (2) is located directly downstairs from Scripts in the same family-owned building; (3) employs as its CEO a Scripts employee who recently sold purported Gilead medication with fake pedigrees; and (4) was founded just as Scripts's sale of counterfeit Gilead medication was taking off. The evidence demonstrates a strong likelihood that USDV Pharma is involved in Scripts' counterfeiting and/or has evidence of that counterfeiting, and so Gilead requests that the seizure order encompasses USDV Pharma's offices in addition to Scripts'.

VII. THE CO-OWNED PHARMACY AND COUNTERFEIT DISTRIBUTOR: MEDICINE SHOPPE, PRIMERX, AND THEIR PRINCIPAL, SEKAR VENKATESH

A. Medicine Shoppe

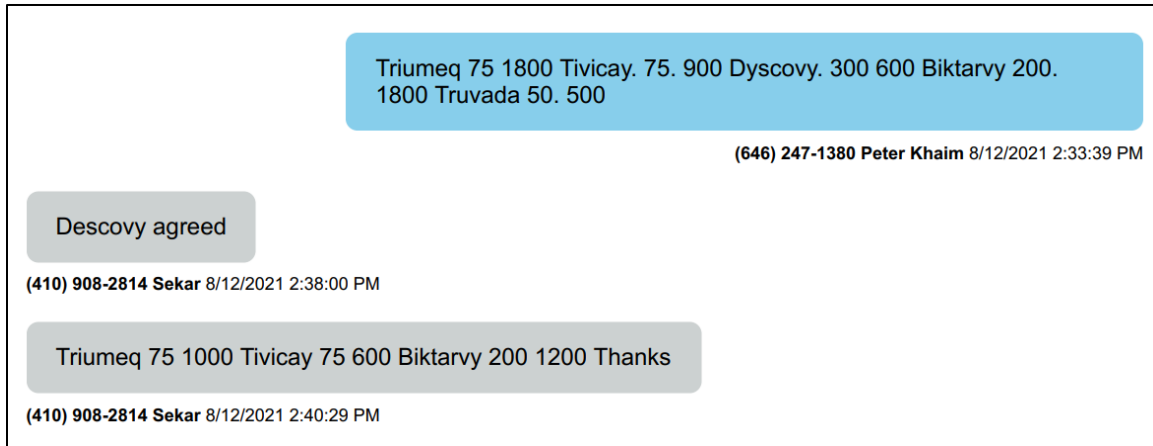
Defendant Medicine Shoppe – *i.e.*, Maryland Pharmacies Inc. d/b/a Medicine Shoppe #1802 – is a single franchisee of a national pharmacy chain, owned and operated by Defendant Sekar Venkatesh.⁹ It is a modestly sized retail pharmacy in a medical office complex in suburban Silver Spring, Maryland. McCarty Decl. ¶ 4. Gilead discussed Medicine Shoppe in its initial filings before this Court. *See* Plaintiffs' Mem. of Law, dated July 22, 2021 at 16-18, 26. As set forth in those filings, Gilead tested and confirmed to be counterfeit two bottles of Gilead medications that the Medicine Shoppe had purchased from Safe Chain and then dispensed to

⁹ All references to "Medicine Shoppe" in these papers are to this particular store, not to the franchisor or any other "The Medicine Shoppe" franchisees.

patients – one in October 2020, one in February 2021. July 21, 2021, Sunkara Decl. ¶¶ 16-21, 34-38.

At the time of these incidents, Gilead treated Medicine Shoppe as a victim. It is now clear that the opposite is true: Medicine Shoppe is a willful large-scale counterfeiter. Despite having twice been informed it purchased from Safe Chain dangerous counterfeit HIV medication – including a bottle that contained high-dose Seroquel, the potent antipsychotic – Medicine Shoppe continued making massive purchases of purported Gilead HIV medication from Safe Chain. Potter Decl. 168. In total, Medicine Shoppe purchased **over 1,300** bottles of purported Gilead medication from Safe Chain, paying Safe Chain **\$3.8 million**. Oct. 13, 2021, Potter Decl. Ex. 168. All of those bottles had fake pedigrees, and Medicine Shoppe purchased the vast majority of them *after* it knew Safe Chain was selling counterfeit Gilead HIV medication with foreign medication inside. *Id.* Indeed, Medicine Shoppe – the single store in suburban Maryland – was one of Safe Chain’s top three biggest customers for counterfeit Gilead medication. Oct. 13, 2021, Potter Decl. Ex. 168; *id.* ¶ 15. Medicine Shoppe continued buying large volumes of counterfeit Gilead medication from Safe Chain until Gilead executed the July 26, 2021 seizure. *See* Oct. 13, 2021, Potter Decl. Ex. 168.

But losing Safe Chain as a supplier did not stop Medicine Shoppe’s attempts to buy counterfeits: it simply went straight to Safe Chain’s counterfeit suppliers. When Gilead executed the second round of seizures on August 23, 2021, its investigators seized a cell phone from Defendant Peter Khaim, the principal of the counterfeit Supplier Defendant Boulevard. On Mr. Khaim’s phone was a text chain with Defendant Sekar Venkatesh, Medicine Shoppe’s owner, directly negotiating the purchase of very large quantities of purported Gilead medications:



Oct. 13, 2021, Potter Decl. Ex. 169; *see also id.* Ex. 170 (continuing to negotiate over price).¹⁰

This text chain lists the medication, the number of bottles, and the proposed price: for example, Mr. Khaim offers BIKTARVY®, 200 bottles, for \$1800 each – a discount of approximately 45% off WAC – and Mr. Venkatesh pushes for a substantially lower price of \$1200. At these prices and quantities, Mr. Venkatesh clearly knew the prescription medication he was haggling over was not authentic, lawfully acquired Gilead medication.

The sheer volume of Medicine Shoppe’s purchases from Safe Chain, and the similarly huge quantities Mr. Venkatesh was seeking to purchase directly from Mr. Khaim, make it extremely implausible that all of these counterfeits were being dispensed to patients through the Medicine Shoppe. There is no reason to believe that a single modest, non-specialized retail pharmacy franchisee in suburban Maryland would legitimately dispense that volume of HIV medication to patients in the normal course of business. As explained immediately below, Mr. Venkatesh was almost certainly selling most of his stock of counterfeit Gilead medication through his pharmaceutical distribution company, PrimeRx.

¹⁰ Gilead’s investigators have confirmed that the “Sekar” in Mr. Khaim’s phone is indeed Defendant Sekar Venkatesh. Oct. 13, 2021, Coleman Decl. ¶ 27.

B. PrimeRx

As Gilead has learned, Mr. Venkatesh owns not just Defendant Medicine Shoppe, but also a pharmaceutical distribution company, Defendant PrimeRx. Oct. 13, 2021, Coleman Decl. Ex. 56. PrimeRx lists its business address as the exact same address and suite number in Silver Springs, Maryland as Defendant Medicine Shoppe. *Id.* PrimeRx is registered as a pharmaceutical wholesaler with the FDA and holds licenses in a handful of states, including New York. *Id.* ¶ 26 & Ex. 57.

As it turns out, PrimeRx has done business with Distributor Defendant ProPharma. In March 2021, PrimeRx filled out onboarding paperwork with ProPharma that stated it was a “secondary wholesale drug distributor” and listed its ProPharma “rep” as “Drew” – *i.e.*, Leader Defendant Dhruv Ralhan. Potter Decl. Ex. 171. Although it listed itself as a wholesaler, PrimeRx does not appear to have made any sales to ProPharma – rather, PrimeRx used ProPharma to purchase even more counterfeit Gilead HIV medication. From June 14, 2021, to August 18, 2021, PrimeRx purchased 374 bottles of purported Gilead medications from ProPharma, all with fake pedigrees, paying over \$1 million. Oct. 13, 2021, Potter Decl. ¶ 15 & Ex. 172. In making those counterfeit purchases from ProPharma, PrimeRx worked directly with Leader Defendant Mannava. *Id.* Ex. 173. Gilead does not know where PrimeRx subsequently re-sold those counterfeits, or the additional counterfeits it almost certainly received from Medicine Shoppe, but aims to find out at the requested seizure.

VIII. THE ASSET HOLDER DEFENDANTS: CO-CONSPIRATORS WHO RECEIVED PAYMENTS FOR THE COUNTERFEITS

A. JM Smith and Its Principal, Carlos Hernandez

Defendant JM Smith is a shell company registered in New Jersey, with Defendant Carlos Hernandez listed as its owner and principal. Oct. 13, 2021, Coleman Decl. ¶ 50 & Ex. 68. JM

Smith was founded in May 2021, around the same time that the fly-by-night Supplier Defendant Invicta started selling counterfeit Gilead medication to ProPharma. *Id.* In June and July 2021, Invicta routinely wired the profits of its counterfeiting to JM Smith in several transactions ranging between \$100,000 to \$400,000, totaling approximately \$1.3 million. Oct. 13, 2021, Potter Decl. Ex. 133.

In an increasingly familiar pattern for counterfeiters working with the Leader Defendants, JM Smith is an illegitimate shell company brazenly attempting to steal the identity of a real authorized distributor. One of Gilead’s sixteen authorized distributors for its HIV medications is Smith Drug Company,¹¹ which is a subsidiary of JM Smith Corp., a privately held South Carolina corporation that has been in business since the 1940s. Oct. 13, 2021, Coleman Decl. ¶ 51. The New Jersey shell company, Defendant JM Smith Distributor Corp., has no connection with the real JM Smith Corp. Rather, the shell company is intended to give the appearance of legitimacy to Invicta’s counterfeits, which were accompanied by fraudulent pedigrees claiming that the medications came from Smith Drug Company. Oct. 13, 2021, Potter Decl. Ex. 174. Indeed, one ProPharma customer insisted on returning purported Gilead medication after calling the real JM Smith to verify one of those fraudulent pedigrees, which confirmed that JM Smith was not “a part of the supply chain as documented on the pedigree received.” *Id.* Ex. 175.

B. Titan, Tidy Garages, and Their Principal, Gabriel Delgado Ramirez

Defendants Titan and Tidy Garages are two Florida limited-liability corporations with no pharmaceutical licensure and no known or apparent connections to the pharmaceutical industry. Oct. 13, 2021, Coleman Decl. ¶¶ 45-46. Titan was founded by Defendant Gabriel Delgado

¹¹ <https://www.gilead.com/purpose/medication-access/authorized-distributors>.

Ramirez on August 31, 2020. *Id.* ¶ 45 & Ex. 64. A few days later, Mr. Ramirez filed for reinstatement of Tidy Garages, which had been founded years earlier by a third party and had gone inactive. *Id.* ¶ 46 & Ex. 65. When he reinstated Tidy Garages, Mr. Ramirez listed himself as the new agent and manager. *Id.*

On June 21, 2021, Mr. Ramirez opened a Chase bank account for Titan. Over the ensuing five weeks, the counterfeit Distributor Defendant Omom deposited over \$2 million into Titan Distribution's newly opened account in several installments. Oct. 13, 2021, Potter Decl. Ex. 176. Those deposits from Omom constituted the vast majority of Titan's receipts during that period. *Id.* In that same time period, Omom also deposited \$62,845.50 to Tidy Garages in multiple transactions. *Id.* Each deposit from Omom to Titan and Tidy Garages referenced an invoice number. *Id.*

In total, from June 21 to July 30, 2021, Omom deposited \$2.19 million into the Titan and Tidy Garages accounts. *Id.* During that same period, Omom received approximately \$3 million in payments for the counterfeits it sold to Safe Chain. *Id.* The money deposited with Titan and Tidy Garages thus represents the great majority of Omom's counterfeiting revenues during that time period.

Omom's only business is selling counterfeits, and Titan appears to have opened its bank account for the express purpose of receiving millions of dollars from Omom. The evidence thus demonstrates that Titan, Tidy Garages, and Mr. Ramirez are part of the counterfeiting conspiracy: they are either receiving payment for the counterfeits Omom sold, or are helping disguise and distribute Omom's revenues to the party that is receiving the ultimate payment.

C. Silverline Pharma, ASB Wholesale, and Their Principal, Alberto Alonso Diaz

Defendants Silverline Pharma and ASB Wholesale are both Florida limited-liability corporations founded by Defendant Alberto Alonso Diaz on the same day, March 12, 2021. Oct. 13, 2021 Coleman Decl. ¶¶ 52-53 Exs. 69, 70.

As noted above, Defendant Titan received approximately \$2 million from the fly-by-night counterfeiter Omom. Shortly thereafter, Titan wrote two checks: one to Defendant ASB Wholesale for \$287,053, and another to Silverline Pharma for \$212,297. Oct. 13, 2021, Potter Decl. Ex. 177. Both payments referenced an invoice number in the memo line. *Id.*

Just as the evidence shows that Titan received proceeds of Omom's counterfeiting as payment for, or to facilitate payment for, Omom's purchase of the counterfeits, Titan's immediate payment of those counterfeiting proceeds to Silverline Pharma and ASB Wholesale evidences that they, too, are co-conspirators that are either receiving or distributing payment for the counterfeits.

D. Make It Happen Marketing and Its Principal, Quan Hernandez

Make It Happen Marketing is a New York Corporation that was formed on June 22, 2016 by Defendant Quan Hernandez. Oct. 13, 2021, Coleman Decl. ¶ 63 & Ex. 74. Make It Happen Marketing's corporate filings list no principal place of business or any corporate officers, and the company has been past due to file its corporate statement with New York State since at least June 2018. *Id.* Despite its apparent inactivity, between February 18 and March 30, 2021, Make It Happen Marketing received a series of sixteen checks for tens of thousands of dollars each from Defendant MFK Marketing d/b/a Boulevard 9229, totaling over \$1.1 million during the six-week span. Potter Decl. 178. During that same period, Boulevard was receiving millions of

dollars of payments from Safe Chain, into the same MFK Marketing d/b/a Boulevard 9229 account, for its sale of counterfeit Gilead HIV medication. Sept. 21, 2021, Potter Decl. Ex. 83.

The record reveals another connection between Make it Happen Marketing and Defendant Boulevard. An attorney named Rina Esterov filed Make it Happen Marketing's certificate of incorporation, and the same attorney also filed the certificate of incorporation for Instacare Pharmacy, an entity that appears in the falsified Boulevard 9229 pedigrees as an intermediary distributor of the counterfeits. Oct. 13, 2021, Coleman Decl. ¶ 63 & Ex. 75; Oct. 13, 2021, Potter Decl. Ex. 179.

Boulevard is a fly-by-night counterfeiter with no business other than the selling of counterfeit medications. Boulevard's transferring over a million dollars' worth of its counterfeiting proceeds to Make It Happen Marketing demonstrates that the latter is part of the conspiracy, and either received payment for supplying the counterfeits, or is helping disguise and distribute Boulevard's revenues to the party which is receiving the ultimate payment.

ARGUMENT

Gilead respectfully submits that the extraordinary facts of this case and the serious public health risk presented by the products sold by Defendants make it clear that Gilead is entitled to the relief it seeks in this motion.

I. THE COURT SHOULD GRANT LEAVE FOR GILEAD TO AMEND ITS COMPLAINT

As set forth above, through the execution of this Court's prior seizure orders and through expedited third-party discovery, Gilead has uncovered a transnational counterfeiting conspiracy and several key co-conspirators. Gilead therefore seeks to amend its pleadings to add the new defendants and assert new conspiracy-based claims, including civil RICO. Under Rule 15(a), leave to amend pleadings "shall be freely given when justice so requires." Here, Gilead has

moved expeditiously to investigate the counterfeiting and discover the new facts that are the basis of its amended pleadings. Gilead is also well ahead of the January 8, 2022 deadline to amend pleadings set forth in the Case Management Order by Judge Reyes. Gilead therefore respectfully requests that the Court grant Gilead permission to file its proposed Second Amended Complaint.

II. GILEAD IS ENTITLED TO AN *EX PARTE* SEIZURE ORDER

Gilead seeks an *ex parte* seizure order pursuant to the Trademark Counterfeiting Act of 1984, 15 U.S.C. § 1116(d)(1). Gilead seeks the seizure to occur at nine locations: the residences of each of the three Leader Defendants; the residence of Mr. Fernandez, the principal of Supplier Defendant Omom; the offices of Supplier Defendant Invicta; the residence of Mr. Caba, the principal of Invicta; the residence of Mr. Betesh, the principal of RxWholesale; the offices of Distributor Defendants Scripts and USDV Pharma, which are two floors of the same building; and Medicine Shoppe's suite in a medical office complex.

Passed in response to “an ‘epidemic’ of commercial counterfeiting,” *see* S. Rep. No. 98-526, 98th Cong., 2d Sess. 5 (1984), reprinted in 1984 U.S.C.C.A.N. 3627, 3631 (citing *Montres Rolex, S.A. v. Snyder*, 718 F.2d 524, 528 (2d Cir. 1983), *cert. denied*, 465 U.S. 1100 (1984)), the Counterfeiting Act permits a court to grant an *ex parte* order of seizure in “[c]ivil actions arising out of [the] use of counterfeit marks,” including seizure of counterfeit goods and “records documenting the manufacture, sale, or receipt” of the counterfeit goods. 15 U.S.C. § 1116(d)(1)(A). As Congress explained in the Senate Report accompanying this bill, “[t]he reason for this provision is that many counterfeiters, once given notice that their fraudulent operations have been discovered, will immediately dispose of the counterfeit goods and make it impossible for the trademark owner ever to bring them to justice.” 1984 U.S.C.C.A.N. at 3629.

A. Gilead Satisfies All the Requirements for an *Ex Parte* Seizure Under the Counterfeiting Act

The Counterfeiting Act enumerates several prerequisites for obtaining an *ex parte* seizure order. *See* 15 U.S.C. § 1116(d)(4)(B).¹² Gilead has satisfied all of them. Gilead therefore respectfully requests that the Court issue an *ex parte* seizure order. A proposed order is being filed simultaneously with this motion.

1. An order other than an *ex parte* seizure order is not adequate to achieve the purposes of the Lanham Act (15 U.S.C. § 1116(d)(4)(B)(i))

As set forth below, the Lanham Act's goals are to protect manufacturers' marks and goodwill, to allow manufacturers to control the quality of their products, and to protect the American consumer from confusion. *See* pp. 37-52, *infra*. Here, the newly added Defendants are each engaged in the reckless, wholesale distribution of counterfeit, dangerous prescription HIV medications. Moreover, the Defendants that are the subject of the requested seizure order are key co-conspirators in a well-organized, large-scale, transnational counterfeiting ring. The counterfeits are trafficked through a series of fly-by-night suppliers, each of which exists as a separate cell with no visible connection to the others, and each of which is ultimately expendable: the counterfeit suppliers consistently abandon their offices before Gilead can make contact with them, and then the Leader Defendants assign a new supplier to fill the gap in the supply chain.

¹² The Counterfeiting Act separately requires plaintiffs to notify the local U.S. Attorney before seeking an *ex parte* seizure. 15 U.S.C. § 1116(d)(2). Gilead has done so. Oct. 13, 2021, Potter Decl. ¶ 8 & Ex. 112. In its proposed seizure order, Gilead has also included a provision requiring a seizure bond pursuant to 15 U.S.C. § 1116(d)(4)(A).

The Leader Defendants themselves operate only in the background, and are careful to keep their names off the paper trail as the counterfeits are sold. Gilead learned of the Leader Defendants only by seizing Safe Chain and ProPharma's email servers and the cell-phone texts and Microsoft Team Chats of its employees. One of the Leader Defendants, Mr. Mannava, is a convicted pharmaceutical fraudster, and used two pseudonyms in connection with his supervision of the counterfeiting ring. If Gilead is to stop this counterfeiting ring and uncover who is manufacturing the counterfeits, it cannot do so through serving discovery requests through normal service of process. The only feasible means of stopping the Defendants, collecting the evidence of their counterfeiting, and tracing the distribution of these counterfeits is through an *ex parte* seizure.

As recognized by Congress in enacting the Counterfeiting Act, counterfeiters are more likely than not to dispose of or conceal the counterfeit goods when confronted with a trademark action. 130 Cong. Rec. H 12076, 12080 (“[M]any of those who traffic in counterfeits have become skilled at destroying or concealing counterfeit merchandise when a day in court is on the horizon.”). Accordingly, courts have regularly issued *ex parte* seizure orders against entities, such as the Defendants here, who have been shown to be distributing counterfeit products in the secondary market for drugs and medical supplies. *See, e.g., Johnson & Johnson et al. v. Advanced Inventory Management, Inc. d/b/a eSutures.com et al.*, No. 20-cv-341 (N.D. Ill.) (involving counterfeit surgical devices); *Johnson & Johnson et al. v. XS Supply, LLC et al.*, No. 8:19-cv-1673 (M.D. Fla.) (involving counterfeit surgical hemostats); *Abbott Labs. et al. v. H&H Wholesale Servs., Inc.*, No. 17-cv-3095 (CBA) (LB) (E.D.N.Y.) (involving counterfeit blood-glucose test strips); *Johnson & Johnson v. Stone Medical Group, LLC*, No. 15-cv-3221 (PKC) (LB) (E.D.N.Y.) (involving counterfeit blood-glucose test strips); *Johnson & Johnson v. South*

Pointe Wholesale, Inc. et al., No. 08-1297 (SLT) (SMG) (E.D.N.Y.) (involving counterfeit blood-glucose test strips).

The Counterfeiting Act's provision for *ex parte* seizures was enacted for precisely these types of defendants: willful counterfeiters relying on fake pedigrees (to conceal the true origin of the counterfeits) who continue their large-scale counterfeiting in the face of indisputable evidence that they are selling infringing product. Moreover, Gilead respectfully submits that the facts here are far more grave than in the typical counterfeiting case envisioned by the statute, because the counterfeits at issue consist of fake medication intended to treat or prevent a life-threatening medical condition, HIV. Congress recognized that the slow wheels of ordinary civil procedure, which rely on the voluntary compliance of honest litigants, are not adequate to address counterfeiting. It is difficult to envision a more appropriate use for the potent procedural mechanism created by the Counterfeiting Act than to rapidly trace and seize dangerous counterfeit HIV medication from a large-scale counterfeiting ring.

2. Gilead has not publicized the requested seizure (15 U.S.C. § 1116(d)(4)(B)(ii))

Gilead has not publicized the requested seizure. In connection with Gilead's opening papers, the Court issued a sealing order that remains in effect. Dkt. No. 20. Gilead has filed the instant papers, and the other filings made in connection with it, under seal and *ex parte*. The Court agreed with Gilead's last oral request before the Court to maintain this case under seal while Gilead's investigation continues.

3. Gilead is likely to succeed in showing that the persons against whom seizure would be ordered used a counterfeit mark in connection with the sale, offering for sale, or distribution of goods or services (15 U.S.C. § 1116(d)(4)(B)(iii))

As demonstrated above, the evidence shows that the newly added Defendants have engaged in distributing, selling, and offering for sale a variety of counterfeit Gilead medicines

with counterfeit packaging, including counterfeit pedigrees, that falsely bear Gilead's registered trademarks. *See* pp. 8-28, *supra*. And Gilead has set forth evidence proving that these Defendants are members of a large-scale hub-and-spoke counterfeiting conspiracy. Gilead is more than likely to succeed on its counterfeiting claims, and that is more than sufficient to satisfy this statutory criterion. *See* pp. 47-52, *infra*.

4. An immediate and irreparable injury will occur if such seizure is not ordered (15 U.S.C. § 1116(d)(4)(B)(iv))

As discussed below, Gilead (and others) are being irreparably harmed as Defendants' dangerous counterfeit medications are currently being distributed to, and used by, patients in the United States. *See* pp. 52-53, *infra*. Seizing the counterfeit product and the documentation concerning its sale and distribution is a necessary first step to prevent the newly added Defendants from continuing to sell the counterfeits, to identify the suppliers and other members of the counterfeiting ring, and to warn customers who may have purchased counterfeit product. Until that happens, Gilead and the public are and will remain irreparably injured.

5. The matter to be seized will be located at the place identified in the application (15 U.S.C. § 1116(d)(4)(B)(v))

The requested seizure will take places at nine locations, discussed below in turn.

Gilead's investigators identified each of the three Leader Defendants, Messrs. Ralhan, Rosell, and Mannava, by using details in the seized Safe Chain and ProPharma documents and then running public records searches. *See* Oct. 13, 2021, Coleman Decl. ¶¶ 3-12. Gilead's investigators located Mr. Ralhan's current residence as 556 3rd St. N in Saint Petersburg, Florida; Mr. Rosell's current residence at 16621 SW 64th Terrace in Miami, Florida; and Mr. Mannava's current residence as 88 Roosevelt Ave, Apt. 309, in Carteret, New Jersey. *Id.* As set forth in their accompanying Declarations, Gilead's investigators have recently visited all three

residences and confirmed that respective Leader Defendants are living at those locations. Cross Decl. ¶¶ 4-10, Gonzalez Decl. ¶¶ 7-11, Guiseppone Dec. ¶¶ 4-8.

Omom's corporate filings indicated that Mr. Fernandez became Omom's sole officer in December 2020. Oct. 13, 2021, Coleman Decl. Ex. 28. Gilead's investigators were initially unable to locate Mr. Fernandez because of the commonness of his name and a lack of other personally identifying information. Gilead's investigators were eventually able to locate Mr. Fernandez based on information received in response to a third-party subpoena served on Omom's bank, which identified Mr. Fernandez as the signatory on Omom's account, and listed his home address. *Id.* ¶ 32. Gilead's investigators confirmed Mr. Fernandez's identity based on public-record searches, and confirmed that Mr. Fernandez is currently residing at the address listed with Omom's bank, 2012 SW 124th Place in Miami, Florida. *Id.*; Gonzalez Decl. ¶¶ 12-20. Because Omom has no other known location, Gilead seeks a seizure at Mr. Fernandez's home.

Invicta's business address as listed on its corporate records is 1126 Industry Drive in Tukwila, Washington. Oct. 13, 2021, Coleman Decl. Exs. 59, 60. Invicta's Washington business address is an office and warehouse unit approximately 1,000 square feet large with a small parking lot in front. Invicta's name appears on signage to the side of the front entrance to the building. Jentges Decl. ¶ 4. On three occasions some weeks apart, Gilead's investigators confirmed that Invicta's principal, Mr. Caba, parked a rental car in Invicta's otherwise empty parking lot. *Id.* at ¶ 7. When Mr. Caba was inside, the investigator found Invicta's front door locked, and received no answer when he knocked. *Id.* at ¶ 8. Gilead identified the rental car as Mr. Caba's by subpoenaing records from the rental car company to which the license plate was registered. Oct. 13, 2021, Potter Decl. Ex. 180.

Through public-record searches and information in on banking records, Gilead's investigators determined that Mr. Caba's current residence is 2295 Bermuda Dr. in West Palm Beach, Florida. Coleman Decl. ¶ 36. Gilead's investigators have confirmed Mr. Caba is currently living at that residence. Gonzalez Decl. ¶¶ 4-6. Because Mr. Caba lives across the country from Invicta's offices in Washington, and because he was at all times spotted driving a rental car when he visited those offices, the evidence suggests that Mr. Caba occasionally travels to Washington on Invicta business, but at other times remains home in Florida. Gilead therefore seeks to conduct the seizure both at Invicta's offices and at Mr. Caba's residence.

Defendant RxWholesale recently abandoned its corporate offices. McAllister Decl. ¶ 8. When Gilead's investigators first visited RxWholesale, there was a note on the door indicating nobody was coming to that location, and leaving a phone number to call with inquiries. *Id.* at ¶ 6. That phone number was for Mr. Betesh, RxWholesale's principal. Oct. 13, 2021, Coleman Decl. ¶ 58. Gilead's investigators have identified Mr. Betesh's residence, 2020 E 8th St. in Brooklyn, based on public-records searches, and have verified Mr. Betesh is currently residing at that location. *Id.*; *see also* Kestel Decl. ¶¶ 4-7

Defendant Scripts has offices on the third floor of 5006 16th Avenue in Brooklyn, NY. Oct. 13, 2021, Coleman Decl. Ex. 50. Defendant USDV Pharma occupies the second floor of the same building. *Id.* Ex. 52. The building itself is owned by the family of Mr. Diamantstein, who owns both Scripts and USDV Pharma. *Id.* Ex. 54. Gilead's investigators have confirmed that both offices on both floors of the building are active businesses. McAllister Decl. ¶¶ 10-14. USDV Pharma is, like Scripts, a licensed pharmaceutical distributor, but USDV Pharma just received its pharmaceutical distribution licensure in the past several weeks. Finally, the President of USDV Pharma is also a Scripts employee who recently sold purported Gilead

medication with fake pedigrees on Scripts's behalf. *See* pp. 23-24, *supra*. Gilead submits that this evidence makes it highly probable that USDV Pharma is either working with Scripts to sell counterfeits, or, at minimum, that some of Scripts' inventory and/or documentation about the counterfeits is likely to be stored in USDV Pharma's location the floor below. Gilead therefore seeks a seizure order listing both the second and third floors of the building.

Defendant Medicine Shoppe and Defendant PrimeRx both list their business address in corporate filings as 10313 Georgia Avenue, Suite 101, in Silver Spring, Maryland. Oct. 13, 2021, Coleman Decl. Exs. 55, 56. Gilead's investigators have visited that location and confirmed that it is an open and active business. McCarty Decl. ¶¶ 7-11.

6. The harm to the applicant of denying the application outweighs the harm to the legitimate interests of the persons against whom seizure would be ordered (15 U.S.C. § 1116(d)(4)(B)(vi))

Defendants have no legitimate interest in selling counterfeit Gilead medication, and no legitimate interest in selling prescription medication that cannot lawfully be sold because it is the subject of a fake pedigree. *See Koon Chun Hing Kee Soy & Sauce Factory, Ltd. v. Kun Fung USA Trading*, No. 07-CV-2568 (CPS), 2007 WL 9723382, at *5 (E.D.N.Y. July 19, 2007) (“[T]o the extent that items seized are counterfeit, defendants have no legitimate interest in the physical goods to be seized.”). The Defendants therefore cannot suffer any harm from the seizure of such goods. The individual Defendants likewise have no legitimate interest in storing counterfeits or documents concerning the counterfeits at their personal residences. Gilead, on the other hand, has a very strong interest in protecting the public's health and safety, as well as its own trademarks and goodwill, from the counterfeits that Defendants are selling. *See* pp. 6-8, *supra*.

7. Defendants would destroy, move, hide, or otherwise make such matter inaccessible to the court, if the applicant were to proceed on notice to such persons (15 U.S.C. § 1116(d)(4)(B)(vii))

As noted above, Congress determined in passing the Counterfeiting Act that counterfeiters “have become skilled at destroying or concealing counterfeit merchandise when a day in court is on the horizon.” 130 Cong. Rec. H12076, at 12080. Here, the counterfeits are bottles of prescription HIV medication: small, lightweight, easily movable, and extremely high-value products. Tens of millions of dollars’ worth of these products can fit in the trunk of a car and be driven away on a moment’s notice. And the evidence shows that the Defendants maintain records of the sale of these counterfeits electronically, making them easy to delete *en masse*.

As also noted above, the Defendants that are the subject of the requested seizure order are key members of an organized, large-scale, transnational conspiracy. The orchestrators of the counterfeiting ring, the Leader Defendants, work in the background, and operate through a seemingly endless series of recently formed, fly-by-night counterfeiter entities that can and do quickly disappear when they are found out. The evidence leaves no room for serious question that the Leader Defendants are purposefully flooding the market with counterfeit Gilead HIV medication, and are doing so in a manner meant to evade detection.

Supplier Defendants Omom, Invicta, RxWholesale are all fly-by-night counterfeiters who sold to at least one (and in the case of Omom and Invicta, multiple) Distributor Defendants. They of course knew they were selling massive amounts of purported Gilead medication with fake pedigrees, since they knew they had not actually purchased the medications from the authorized distributors listed on those pedigrees. Invicta attempted to cover up its illegal sales by sending its profits to Defendant JM Smith, a shell company established to trick customers into thinking Invicta worked with the longstanding legitimate pharmaceutical supplier JM Smith Corp. For its part, Omom not only abandoned its offices, but its principals operated under

pseudonyms. And finally, RxWholesale also abandoned its offices shortly before Gilead's investigators arrived, and are alleged to have conspired with Distributor Defendant Scripts to conceal counterfeit Gilead product from state authorities.

Scripts, a newly added Distributor Defendant, was directly confronted with the fact that it had sold multiple counterfeit Gilead HIV medications that actually had potent antipsychotic drugs in the bottle. Scripts refused to cooperate with Gilead's investigation, insisted that its suppliers were legitimate and trustworthy, and continued selling purported Gilead medication with fake pedigrees. The evidence shows that Scripts is a willful counterfeiter and knowing member of the counterfeiting conspiracy, working with the Leader Defendants and having the Marketer Defendants sell counterfeit Gilead medications in its name.

Medicine Shoppe learned in October 2020 that it had sold a patient a bottle of fake HIV medication that actually contained a potent antipsychotic. A few months later it learned that another one of its patients had received counterfeit Gilead medication, and Gilead discussed the matter with Medicine Shoppe directly. If Medicine Shoppe were a law-abiding entity and/or cared about the health and safety of its patients, it would have stopped buying counterfeits from Safe Chain. Instead, it doubled down and became one of Safe Chain's biggest customers for purported Gilead HIV medication. And when Safe Chain's counterfeiting was shut down by this Court's Temporary Restraining Order, Medicine Shoppe's principal simply turned to negotiating directly with one of Safe Chain's counterfeit suppliers, Boulevard, for large quantities of counterfeit Gilead medication at impossibly low prices.

By knowingly trafficking counterfeit Gilead medications, these Defendants engaged in criminal counterfeiting. *See* 18 U.S.C. § 2320. They also committed the crime of selling misbranded drugs, which is one of very few federal strict-liability crimes, and which carries

substantial jail time when done knowingly. 21 U.S.C. § 331. As detailed above, they also committed a host of violations of the DSCSA. And, of course, both the corporate and individual Defendants are all subject to extensive civil liability for their actions, including under the Lanham Act and civil RICO. The incentives for Defendants to cover up their criminal behavior are clear. The newly added Defendants are precisely the type of defendants that Congress had in mind when it authorized *ex parte* seizure orders in the Counterfeiting Act.

B. The Seizure Order Should Include All Gilead Products

As set forth in Gilead's previous applications, Gilead has already seized confirmed counterfeits of a wide variety of Gilead medications, including BIKTARVY[®], DESCOVY[®], TRUVADA[®], GENVOYA[®], ATRIPLA[®], VOSEVI[®], RANEXA[®], STRIBILD[®], and SOVALDI[®]. Aug. 17, 2021, Sunkara Decl. ¶¶ 6-13. Gilead was able to recover those counterfeits because both of the Seizure Orders previously issued by this Court permitted Gilead to seize all Gilead products on the premises. Moreover, there is little risk of harm to the Defendants, because these purported Gilead products are all sold with fake pedigrees, and so are not legally salable in any event. 21 U.S.C. § 360eee-1(c)(4)(a)(i). For these reasons, as well as those stated in Gilead's prior applications, which are incorporated here by reference, the Court should include all Gilead products in the scope of the requested seizure order.

C. This Court Has Authority to Order Seizures Anywhere in the United States

Gilead set forth in its opening papers the authority showing this Court has the authority to issue an *ex parte* Seizure Order to occur anywhere in the United States, not just this District; Gilead incorporates that authority by reference. *See* Plaintiffs' Mem. of Law, dated July 22, 2021, at 54-55. This Court's previously issued Seizure Orders permitted Gilead to execute

seizures in various U.S. states where the seizure targets were located, and the same should be true of the requested seizure order.

III. GILEAD IS ENTITLED TO A TEMPORARY RESTRAINING ORDER AND A PRELIMINARY INJUNCTION

“Federal courts have long recognized the need for immediate injunctive relief in trademark infringement cases due to the amorphous nature of the damage to the trademark and the resulting difficulty in proving monetary damages.” *Multi-Local Media Corp. v. 800 Yellow Book, Inc.*, 813 F. Supp. 199, 202 (E.D.N.Y. 1993). Here, Gilead seeks a temporary restraining order to stop the newly added Defendants’ trafficking of counterfeit Gilead medication and ensure that evidence, including the counterfeit product itself, is preserved. To obtain such relief, Plaintiffs must demonstrate “that [they are] likely to succeed on the merits, that [they are] likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in [their] favor, and that an injunction is in the public interest.” *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). Gilead easily meets all of those elements and therefore is entitled to immediate injunctive relief.

A. Gilead Has a Strong Likelihood of Success on the Merits

Among other claims, Gilead has alleged various causes of action against the newly added Defendants for violating Gilead’s trademark rights under the Lanham Act and state law. Gilead can prevail on its trademark claims by showing “(1) that it owns a valid, protectable trademark; (2) that the defendants used the registrant’s trademark in commerce and without consent; and (3) that there was a likelihood of consumer confusion.” *Proctor & Gamble Co. v. Quality King Distribs., Inc.* 123 F. Supp. 2d 108, 113 (E.D.N.Y. 2000); *see also Tanning Research Labs., Inc. v. Worldwide Imp. & Exp. Corp.*, 803 F. Supp. 606, 608-09 (E.D.N.Y. 1992).

None of these elements is remotely in question here. Gilead owns multiple distinct, valid registered trademarks for the products at issue. Second Stroud Decl. ¶ 4. Defendants are “using” those marks in interstate commerce by advertising, buying, and selling counterfeit Gilead drugs. There also can be no dispute that Defendants are not authorized to use Gilead’s marks to sell counterfeits. *Id.* ¶¶ 16-18.

1. The Bottles and the Pedigrees Are Counterfeits, and Consumer Confusion Is Established as a Matter of Law

The fact that the counterfeits were manufactured in part by using once-authentic Gilead packaging does not, of course, alter the fact that these are counterfeit products – *i.e.*, products in bottles bearing Gilead’s registered marks without permission, when in fact the bottles contain an entirely different product than those indicated by the marks. *E.g.*, *Westinghouse Elec. Corp. v. Gen. Circuit Breaker & Elec. Supply, Inc.*, 106 F.3d 894, 900 (9th Cir. 1997) (“When an original mark is attached to a product in such a way as to deceive the public, the product itself becomes a ‘counterfeit’ just as it would if an imitation of the mark were attached.”); *U.S. v. Petrosian*, 126 F.3d 1232, 1233-34 (9th Cir. 1997); *Cartier v. Aaron Faber Inc.*, 512 F. Supp. 2d 165, 169 (S.D.N.Y. 2007) (holding that watches that retained the manufacturer’s original marks, but were significantly altered by the defendant, “constitute ‘counterfeit’ merchandise for purposes of the Lanham Act.”). Moreover, separately from the bottles, each of the fake Instructions for Use is a counterfeit that contains unauthorized reproductions of Gilead registered trademarks.

Moreover, independent of the counterfeit bottles with foreign pills and the counterfeit Instructions for Use, each of the Defendants’ fake pedigrees are themselves counterfeits within the meaning of the Lanham Act. *See* 15 U.S.C. § 1116(d)(1); *id.* § 1141(1)(a). The fake pedigrees reproduce without permission Gilead’s registered trademarks, *e.g.* BIKTARVY®. *See id.* (counterfeits must be of a registered mark). The fake pedigrees are unquestionably used “in

connection with the sale, offering for sale, or distribution of” Gilead’s medications. *Id.* And the fake pedigrees reproduce Gilead’s trademarks without permission in order to make false and fraudulent statements concerning, among other things, the origin and authenticity of the Gilead products. *See id.*; *see also Coty Inc. v. Cosmopolitan Cosmetics Inc.*, 432 F. Supp. 3d 345, 349, 352-353 (S.D.N.Y. 2020) (defendant’s removal or obscuring of “production code” on packaging, done to conceal that it was “diverting the products outside of authorized distribution channels,” rendered product counterfeit within the meaning of the Lanham Act because the altered packages “bear Plaintiffs’ registered trademark, are not authorized for resale, and are sold in an ‘intentionally fraudulent’ manner” that concealed the fact they had been altered).

Because Defendants sold counterfeits, including once-authentic Gilead bottles and were intended to look exactly like new, sealed, genuine Gilead product, likelihood of consumer confusion is established as a matter of law. *See El Greco Leather Prods. Co. v. Shoe World, Inc.*, 806 F.2d 392, 396 (2d Cir. 1986) (holding “it is plain” that the sale of products that are “not genuine” violates the Lanham Act); *Omega Importing Corp. v. Petri-Kine Camera Co.*, 451 F.2d 1190, 1194 (2d Cir. 1971) (Friendly, C.J.) (“The probabilities of confusion from the sale of another [product] bearing the identical name are too obvious to require detailed proof.”); *Koon Chun Hing Kee Soy & Sauce Factory*, No. 04-CV-2293 (JFB) (SMG), 2007 U.S. Dist. LEXIS 1404, at *32-33 (E.D.N.Y. Jan. 8, 2007); *Lorillard Tobacco Co. v. Jamelis Grocery, Inc.*, 378 F. Supp. 2d 448, 455 (S.D.N.Y. 2005); *Philip Morris USA, Inc. v. Felizardo*, No. 03-CV-5891(HB), 2004 U.S. Dist. LEXIS 11154, at *18 (S.D.N.Y. June 17, 2004) (“[C]ounterfeit marks are inherently confusing.”); *Gucci Am., Inc. v. Duty Free Apparel, Ltd.*, 286 F. Supp. 2d 284, 287 (S.D.N.Y. 2003) (“[C]ounterfeits, by their very nature, cause confusion.”); *Procter & Gamble Co.*, 123 F. Supp. 2d at 115 (“It would be difficult to imagine a clearer case of consumer

confusion than the instant case in which defendants, acting in direct competition with the plaintiff, sold counterfeit products on which plaintiff's registered marks appear in their entirety.” (citation omitted)).¹³

2. Each Defendant Is Individually Liable for Its Role in the Counterfeiting

Generally speaking, the counterfeits at issue were purchased, sold, shipped, and paid for through corporations and other business entities. The corporate entities that bought or sold counterfeits are, of course, liable for their infringement. But any Defendant, including individual officers or agents of corporate entities, who was “a moving, active, conscious force behind the defendant corporation's infringement” is also individually liable, on a joint-and-several liability basis. *KatiRoll Co. v. Kati Junction, Inc.*, 33 F. Supp. 3d 359, (S.D.N.Y. 2014); *see Matsunoki Grp., Inc. v. Timberwork Or., Inc.*, 2009 U.S. Dist. LEXIS 37573, at *9 (N.D. Cal. Apr. 16, 2009) (“A plaintiff may show that a corporate employee is [a] moving, active, conscious force behind the infringing activity by demonstrating that [he or she] direct[ed], control[led], ratifie[d], or participate[d] in the infringing activity.”). Thus, there may be – and in large-scale operations, almost always are – multiple Defendants who are individually liable for the same company's counterfeiting. In other words, it is no defense to argue that others “had more significant roles in executing the operation.” *See Innovation Ventures, LLC v. Ultimate One Distib. Corp.*, 176 F.Supp.3d 137, 173, 178 (E.D.N.Y. 2016).

¹³ Because counterfeit marks are inherently confusing, there is no need to analyze the so-called *Polaroid* factors to determine the likelihood of confusion between the genuine and the counterfeit goods. *Jamelis Grocery*, 378 F. Supp. 2d at 455 (citing *Polaroid Corp. v. Polarad Elecs. Corp.*, 287 F.2d 492, 495-96 (2d Cir. 1961)). Counterfeits create consumer confusion as a matter of law. *Id.*

For example, a person or entity involved in paying for counterfeits, including effecting wire transfers, is subject to individual liability as an active and moving force. *Id.* at 173, 178. Here, the evidence shows that several of the Supplier Defendants paid for the counterfeits they sold by transferring a portion of the revenue of their sales to one of the Asset Holder Defendants. *See pp. 31-35, supra.* Regardless of whether the Asset Holder Defendants supplied the counterfeits in the first place, or whether their role is to launder or concealed the payments and distribute them to the upstream supplier, they are directly liable as an active and moving force. *See id.*

Moreover, as described in detail above, the Defendants are engaged in an organized counterfeiting conspiracy. In addition to their civil liability under RICO, for which counterfeiting is a predicate act, the Defendants are liable for conspiring to violate the Lanham Act. Under the Lanham Act, a “civil conspiracy occurs when the parties have reached a unity of purpose or a common design and understanding, or a meeting of the minds in an unlawful arrangement. A conspiracy must be looked at as a whole, and acts which are in themselves legal lose that character when they become constituent elements of an unlawful scheme.” *Transgo, Inc. v. Ajac Transmissions Parts Corp.*, 768 F.2d 1001, 1020-21 (9th Cir. 1985) (citations and internal quotation marks omitted); *cf. Gmurzynska v. Hutton*, 355 F.3d 206, 211 (2d Cir.2004) (accepting that co-conspirators are liable under the Lanham Act, but finding no liability because plaintiff failed to prove an underlying Lanham Act violation).

3. The Defendants Are Willful Infringers, but Gilead Needs Establish Only Strict Liability

Notably, while there is extremely strong evidence that each of the Defendants knowingly and intentionally engaged in the sale of counterfeits, trademark infringement is a strict-liability offense. *Sunward Elecs., Inc. v. McDonald*, 362 F.3d 17, 25 (2d Cir. 2004) (“[I]t is well

established that wrongful intent is not a prerequisite to an action for trademark infringement . . . and that good faith is no defense.” (citations and internal quotations omitted); *Hard Rock Café Licensing Corp. v. Concession Servs., Inc.*, 955 F.2d 1143, 1152 n.6 (7th Cir. 1992) (“Sellers bear strict liability for violations of the Lanham Act.”); *Taubman Co. v. Webfeats*, 319 F.3d 770, 775 (6th Cir. 2003); *Philip Morris USA Inc. v. Shalabi*, 352 F. Supp. 2d 1067, 1073-74 (C.D. Cal. 2004). Therefore, defendants are liable under the Lanham Act regardless of whether they were aware of the counterfeit nature of the products they sold and their accompanying fake pedigrees. *Id.*; *Philip Morris USA Inc. v. Liu*, 489 F. Supp. 2d 1119, 1122 (C.D. Cal. 2007). Gilead’s Lanham Act claims are not merely likely, but virtually certain to succeed.

B. Gilead Is Suffering Irreparable Harm as a Result of Defendants’ Activities

Because Gilead has demonstrated a likelihood of success on the merits on its Lanham Act claims, it is entitled to a rebuttable presumption of irreparable harm as a matter of law pursuant to the Trademark Modernization Act of 2020. 15 U.S.C. § 1116(a).

Even without that presumption, where, as here, a Lanham Act plaintiff has succeeded in showing a likelihood of confusion, irreparable injury “almost inevitably follows.” *Omega Importing Corp.*, 451 F.2d at 1195. The reason is simple: “because the losses of reputation and goodwill and subsequent loss of customers that Plaintiff will suffer are not precisely quantifiable[,] remedies at law cannot adequately compensate Plaintiff for its injuries.” *Pretty Girl, Inc. v. Pretty Girl Fashions, Inc.*, 778 F. Supp. 2d 261, 270 (E.D.N.Y. 2011); *see also Church of Scientology Int’l v. Elmira Mission*, 794 F.2d 38, 44 (2d Cir. 1986) (“[A]llowing defendants the opportunity to reduce the marks’ reputational value and goodwill by its continued unauthorized use constitutes the irreparable harm that is requisite to the issuance of the preliminary injunction.”); *New York City Triathlon, LLC v. NYC Triathlon Club, Inc.*, 704 F. Supp. 2d 305, 325 (S.D.N.Y. 2010) (“It is well-settled that a trademark owner’s loss of goodwill

and ability to control its reputation constitutes irreparable harm sufficient to satisfy the preliminary injunction standard.”).

There is no question that Defendants’ sale of dangerous counterfeits of Gilead’s life-saving HIV medications is causing great harm to Gilead’s goodwill, and that its continued sale will irreparably harm Gilead. Second Stroud Decl. ¶¶ 14-18. Immediate injunctive relief is, therefore, necessary to prevent further damage to Gilead’s reputation and goodwill – and, of course, to patient health and safety, none of which can be undone.

C. The Balance of Equities Tips Decisively in Gilead’s Favor

Here, the equities emphatically support the issuance of a temporary restraining order. First and foremost, the counterfeit products pose a serious threat to patient health and safety. *See* pp. 2, *supra*. Quite apart from the harm to Gilead’s goodwill, this threat to public health justifies immediate injunctive relief. *See, e.g., Burger King Corp. v. Stephens*, No. 89-CV-7691, 1989 U.S. Dist. LEXIS 14527 at *33 (E.D. Pa. Dec. 6, 1989).

Because the law recognizes no excuse for selling counterfeit goods, the harm to Gilead should the requested injunction be denied far outweighs the harm to Defendants if their conduct is preliminarily enjoined. Each and every sale of counterfeit Gilead medication infringes Gilead’s trademarks, causes harm to Gilead’s reputation, and places patients at risk. *See Microsoft Corp. v. ATEK 3000 Computer, Inc.*, No. 06-CV-6403 (SLT)(SMG), 2008 U.S. Dist. LEXIS 56689, at *17 (E.D.N.Y. Jul. 23, 2008). The Defendants have no right to sell counterfeit Gilead medication, and no right to buy or sell medication with fraudulent pedigrees. *See* p. 32, *supra*. Defendants thus cannot validly claim hardship based on the proposed injunctive relief.

D. An Injunction Is in the Public Interest

The public interest in an injunction is self-evident in this case. It is in the public interest to prevent the sale of potent antipsychotics and other medication being sold in bottles

masquerading as authentic Gilead HIV medication. It is also in the public interest to prevent confusion and protect informed choice when patients' health is at stake. *Cytosport, Inc. v. Vital Pharms., Inc.*, 617 F. Supp. 2d 1051, 1081 (“When a trademark is said to have been infringed, what is actually infringed is the right of the public to be free of confusion and the synonymous right of the trademark owner to control his products’ reputation.”) (E.D. Cal. 2009) (internal citation omitted); *Int’l Kennel Club of Chicago, Inc. v. Mighty Star, Inc.*, 846 F.2d 1079, 1092 n.8 (7th Cir. 1988) (“[T]he relevant consideration in determining whether the public interest will be disserved by the grant of an injunction is the consumer’s interest in not being deceived about the products they purchased.” (alteration omitted)).

IV. GILEAD IS ENTITLED TO AN *EX PARTE* ORDER FREEZING DEFENDANTS’ ASSETS

As part of its efforts to immediately remove this counterfeit medication from the U.S. market, Gilead also seeks an asset freeze against the newly added Defendants. Gilead received and executed a substantially identical Asset Freeze Orders against the Defendants previously named in this action (with the exception of certain pharmacy defendants against whom Gilead did not move for any injunctive relief). Gilead seeks the same order with regard to the newly added Defendants. Now that Gilead has uncovered the large-scale conspiracy that ties these Defendants together, the need for an asset freeze is even more apparent.

Under the Lanham Act, Gilead is entitled to an accounting and disgorgement of Defendants’ illicit profits from their sale and distribution of counterfeit Gilead medication that bears Gilead’s trademarks. An *ex parte* asset freeze order will maintain the status quo, which includes preserving Gilead’s ability to recoup the profits that Defendants earned from the sale of the counterfeit Gilead medication. This relief is not merely consistent with, but critical to, putting an immediate stop to Defendants’ sale of counterfeits in the United States. Moreover,

this relief is routinely granted in counterfeiting cases. The asset freeze order proposed here is functionally identical to the Court's earlier orders in this case, as well as an order that was recently granted by another court in an anti-counterfeiting case, which is attached as Exhibit 4 to the First Potter Declaration.

A. Legal Standard for Asset Freezes under the Lanham Act

Where, as here, a plaintiff seeks lost profits and equitable remedies under the Lanham Act, 15 U.S.C. §§ 1116(a) and 1117, a federal court has the “inherent equitable powers to order preliminary relief, including an asset freeze, in order to assure the availability of permanent relief.” *Levi Strauss & Co. v. Sunrise Int’l Trading, Inc.*, 51 F.3d 982, 987 (11th Cir. 1995). The Second Circuit has joined its “sister circuits to have considered the issue” in holding that in trademark infringement actions, “the district court ha[s] the inherent equitable authority to issue [an] Asset Freeze Injunction.” *Gucci Am., Inc. v. Bank of China*, 768 F.3d 122, 130, 132 (2d Cir. 2014); *see also Reebok Int’l, Ltd. v. Marnatech Enters.*, 970 F.2d 552, 559 (9th Cir. 1992) (because “the Lanham Act authorizes the district court to grant [plaintiff] an accounting of [defendants’] profits as a form of final equitable relief, the district court ha[s] the inherent power to freeze [defendants’] assets in order to ensure the availability of that final relief.”); *Balenciaga Am., Inc. v. Dollinger*, No. 10 Civ 2912 (LTS), 2010 U.S. Dist. LEXIS 107733, at *22-24 (S.D.N.Y. Oct. 8, 2010) (collecting cases); *CSC Holdings, Inc. v. Redisi*, 309 F.3d 988, 996 (7th Cir. 2002) (“[S]ince the assets in question ... were profits of the [defendants] made by unlawfully stealing [the plaintiffs’] services, the freeze was appropriate and may remain in place pending final disposition of this case.”); *Motorola Inc. v. Abeckaser*, No. 07-cv-3963, 2009 U.S. Dist. LEXIS 40660, at *8 (E.D.N.Y. May 14, 2009); *N. Face Apparel Corp. v. TC Fashions, Inc.*, No. 05-cv-9083, 2006 U.S. Dist. LEXIS 14226, at *10 (S.D.N.Y. Mar. 30, 2006) (In counterfeiting cases, “[d]istrict courts have the ‘authority to freeze those assets which could [be] used to satisfy

an equitable award of profits.’’). The purpose of such an order is ‘‘to preserve the possibility of an effective accounting of [the counterfeiter’s] profits and the return of the profits fraudulently obtained.’’ *Reebok*, 970 F.2d at 560. The requested injunctive relief will preserve the status quo and will also help secure the participation of the Defendants in this litigation.

Motions for an asset freeze under the Lanham Act are evaluated under the familiar standard for a preliminary injunction. *See Shamrock Power Sales, LLC v. Scherer*, No. 12-cv-8959, 2016 U.S. Dist. LEXIS 144773, at *6 (S.D.N.Y. Oct. 18, 2016); *see also Lorillard Tobacco Co. v. Montrose Wholesale Candies & Sundries, Inc.*, No. 03-cv-4844, 2005 U.S. Dist. LEXIS 28917, at *48 (N.D. Ill. Nov. 8, 2005).

B. Gilead Has a Strong Likelihood of Success on the Merits

As set forth above, *see* pp. 5-31, *supra*, the evidence leaves no room for doubt that the Defendants have sold counterfeit Gilead HIV medication with counterfeit pedigrees, which is all that Gilead needs to establish to prevail on its strict-liability Lanham Act claims.

C. Defendants Are Likely to Dissipate Assets, and Gilead Will Suffer Additional Irreparable Harm If Their Assets Are Not Frozen

Counterfeiters like Defendants make their living by secrets and subterfuge, and therefore are likely to ‘‘hide their allegedly ill-gotten funds’’ if their assets are not frozen. *Reebok*, 970 F.2d at 563; *accord Chanel, Inc. v. Classic-Bag-Shop*, No. 19-cv-60492, 2019 U.S. Dist. LEXIS 42688, at *10 (S.D. Fla. Mar. 14, 2019) (‘‘In light of the inherently deceptive nature of the counterfeiting business ... Plaintiff has good reason to believe Defendants will hide or transfer their ill-gotten assets beyond the jurisdiction of this Court unless those assets are restrained.’’). When engaged in the practice of selling fake HIV medication with an entirely different drug inside, serious civil and criminal exposure is a given. Each Defendant operates outside of and in violation of the law while doing business in a heavily regulated industry, and each depends on

fraud and subterfuge to sell its highly illegal product in U.S. commerce. The record evidence strongly supports the conclusion that the Defendants will conceal or dissipate their illegal profits when given the chance. See *Lorillard Tobacco Co.*, 2005 U.S. Dist. LEXIS 28917, at *56 (“In this case, the Lanham Act provides [Plaintiffs] with the equitable remedy of recovering [Defendants’] profits. In such cases, courts have generally concluded that an asset freeze is appropriate to ensure that permanent equitable relief will be possible.” (quoting *Levi Strauss & Co.*, 51 F.3d at 987; *Reebok*, 970 F.2d at 559)).

Moreover, the Defendants here are engaged in an organized counterfeiting conspiracy that operates through an ever-increasing series of seemingly unconnected fly-by-night entities that routinely abandon their offices before Gilead’s investigators knock on their warehouse door. The conspiracy as a whole is set up to split the risk and the profits among multiple entities that can disappear with the money at on moments’ notice.

1. The Leader Defendants

The Leader Defendants have orchestrated and controlled the conspiracy’s use of a string of fly-by-night entities to sell the counterfeits. Gilead has detailed above how each of the Leader Defendants personally facilitated the sales from the fly-by-night Supplier Defendants to the Distributor Defendants, but their names never appear on an invoice, shipping record, pedigree, or other paperwork as the counterfeits get pushed through the supply chain. The evidence leaves no room for doubt that the Leader Defendants are knowingly running a criminal counterfeiting conspiracy that is set up to evade detection and limit the losses caused by any particular member getting caught. There is no reason to believe that any funds of theirs left unfrozen will ever be seen again.

2. The Marketer Defendants

The Marketer Defendants work directly with and for the Leader Defendants, and get paid through the Leader Defendants' shell companies. They supervised a sales force dedicated to selling counterfeit HIV medication to pharmacies by assuming the identities of the Distributor Defendants and reaching out to retail pharmacies. And it is almost certainly no coincidence that the Marketer Defendants – referred to as “the Canadian Boys” – are the only known members of the conspiracy to live outside the United States: as direct marketers and salespeople they are among the most visible members of the conspiracy, and their foreign residence insulates them from risk of prosecution and affords them time to go underground. An asset freeze is the only feasible way to ensure their participation in this litigation, and to prevent their assets from dissipating.

3. The Supplier Defendants

The fly-by-night Supplier Defendants are prototypical counterfeiters against whom courts routinely grant asset freezes. Gilead's experience has borne this out: the Supplier Defendants have almost universally closed up shop and gone underground before Gilead's investigators can make contact. And Gilead now knows that the Supplier Defendants are all part of the same conspiracy, linked through the Leader Defendants, and are in fact intended to sell the counterfeits for as long as they can before getting caught, and then disappear. The need for an asset freeze against these defendants is manifest.

4. The Newly Added Distributor Defendant, Scripts

Scripts fits the same mold as previously named Distributor Defendants Safe Chain and ProPharma, both of whom are currently the subject of an asset freeze order. The Distributor Defendants are critical members of the counterfeiting conspiracy: they provide the licensure and the pretense of legitimacy necessary to take the counterfeits out of the hands of shady fly-by-

night entities and get them on the shelves of retail pharmacies (and from there, into the hands of unsuspecting patients). As with the previously named distributors, every pedigree that Gilead has seen for Gilead medications sold by Scripts is fraudulent. Indeed, Scripts continued buying and selling counterfeits, including from fly-by-night entities like RxWholesale, even after being told it had twice sold fake bottles of HIV medication with antipsychotic pills inside, and refused to meaningfully cooperate with Gilead's investigation into those dangerous counterfeits. Scripts should not be given the opportunity to hide or spend its counterfeiting profits.

5. Medicine Shoppe and PrimeRx

Medicine Shoppe and PrimeRx, both owned by Mr. Venkatesh, both made high-volume purchases of counterfeit Gilead medication *after* Mr. Venkatesh received multiple patient complaints about the counterfeit Gilead HIV medication his pharmacy had dispensed, including a bottle that had high-dose antipsychotics in the bottle. Even after Gilead put a stop to Safe Chain's counterfeiting, Mr. Venkatesh simply turned to Safe Chain's fly-by-night suppliers and directly negotiated the purchase of hundreds upon hundreds of counterfeit bottles at discounts impossible for legitimate product. Mr. Venkatesh knowingly put patients at risk in order to make illicit profits, and he and his companies simply cannot be trusted to maintain their ill-gotten gains during the pendency of this action.

6. The Asset Holder Defendants

As noted above, Gilead does not know (but hopes to soon find out) who is manufacturing and supplying the counterfeits to the Supplier Defendants. But the evidence from bank subpoenas shows some Supplier Defendants paid for the counterfeits by taking large portions of the proceeds of their sales and transferring them to the Asset Holder Defendants. The Asset Holder Defendants could be actual counterfeit suppliers, or they could be shell companies used to launder or mask the transfer of the counterfeit revenues before distributing payment to the

actual upstream supplier. Whether they are suppliers or ensure that illicit profits make their way to the counterfeit suppliers, they are knowing members of the conspiracy who ensure the counterfeiting can continue (and continue to be profitable).¹⁴ And regardless of whether they are suppliers or money launderers, the risk that these defendants would dissipate the counterfeiting proceeds if given the opportunity is plain. In light of the evidence that these Defendants have directly received the proceeds of counterfeiting, the court should freeze their accounts and prevent them from further dissipating these illicit funds.

D. The Balance of the Equities Strongly Favors Gilead

The balance of harms also heavily weighs in favor of an asset freeze. The evidence shows that Defendants knowingly sold counterfeit medications in violation of the Lanham Act. Any harm an asset freeze may cause to Defendants was “brought upon themselves with their tactics of deception and underhandedness.” *Lorillard Tobacco Co.*, 2005 U.S. Dist. LEXIS 28917, at *58. By comparison, the harm caused by Defendants’ actions – both to unsuspecting patients and to Gilead’s trademarks and goodwill – is clear.

To the extent that the Defendants can demonstrate – contrary to the overwhelming evidence – that their assets are not the fruits of their counterfeiting, they can make such a

¹⁴ Gilead also notes that, in the alternative, the Court may bind the Asset Holder Defendants to an asset freeze order pursuant to Rule 65(d)(2)(C), which provides that an injunction may cover not just a defendant and its employees and agents, but also “other persons who are in active concert or participation with” them. Here, the evidence shows that the Asset Holder Defendants are working in active concert and participation with the Supplier Defendants by either receiving payments for the counterfeits or working to conceal, launder, and/or distribute the Supplier Defendants’ proceeds from counterfeiting. Thus, in issuing an asset freeze order against the Distributor Defendants, the Court may specifically name the Asset Holder Defendants as entities “in active concert or participation with” the Distributor Defendants. *See S.E.C. v. Homa*, 514 F.3d 661,665 & n.5 (7th Cir. 2008); *see also Gucci Am., Inc.*, 768 F.3d at 137 (citing *Homa* with approval).

showing to the Court and have the freeze lifted or amended. *See Balenciaga Am*, 2010 U.S. Dist. LEXIS 107733, at *24-26. Defendants can also move to have sufficient funds released to pay their lawyers and other necessary expenses. Gilead, on the other hand, will have no recourse if the Defendants dissipate their assets. *See Dong v. Miller*, No. 16-CV-5836, 2018 U.S. Dist. LEXIS 48506, at *41-42 (E.D.N.Y. Mar. 23, 2018). Once hidden or removed from the Court's reach, there is very little that can be done to recover a counterfeiter's assets.

E. The Public Interest Is Served by an Asset Freeze

An asset freeze is in the public interest because it will help secure the Defendants' participation in this lawsuit and ensure they do not continue to purchase and sell counterfeits during the course of litigation. *See Std. & Poor's Corp. v. Commodity Exch., Inc.*, 683 F.2d 704, 711 (2d Cir. 1982) (“[A] court of equity ... may go much further both to give or to withhold relief in furtherance of the public interest than where only private interests are involved.”). There will be no harm to the public from the asset freeze, as there is no shortage of legitimate distributors who can deliver authentic Gilead medication to any pharmacy in the nation.

F. The Asset Freeze Should Be Global in Scope and *Ex Parte*

This Court's Asset Freeze Orders against the Defendants named in Gilead's original and First Amended Complaints have no geographical limitations and was issued *ex parte*, and Gilead respectfully requests that the Court do the same here. Gilead set forth in its opening brief authority stating the asset freeze should be global in scope and *ex parte* and incorporates that authority by reference here. Plaintiffs' Mem. of L., dated July 22, 2021 at 74-76.

V. THE COURT SHOULD PERMIT ALTERNATIVE E-MAIL SERVICE

Finally, Gilead respectfully seeks permission to serve certain newly added Defendants via email, pursuant to Federal Rules of Civil Procedure 4(e)(1) and 4(f)(3). Specifically, Gilead seeks permission to serve by email pursuant to Rule 4(f)(3) on the three Marketer Defendants,

who are based in Canada: Messrs Zangari, Massana, and Panagiotopoulos. Gilead seeks permission to serve by email pursuant to Rule 4(e)(1) on the following U.S.-based Defendants: Luis D. Gonzalez Herrero, Jordan Rodriguez Mato, Julio Martin Gonzalez, Angel Toral, Gabriel Delgado Ramirez, Edel Reyes, and John Santos. Gilead has included provisions allowing such alternative service in the proposed Temporary Restraining Order submitted herewith.

1. Alternative Service Upon the Canadian Defendants Pursuant to Rule 4(f)(3)

The Marketer Defendants are all Canadian residents, and the evidence shows they did all their work for the conspiracy via email and phone calls. Rule 4(f)(3) provides that this Court may order that parties outside the United States be served by any “method that is reasonably calculated to give notice,” including any “means not prohibited by international agreement, as the court orders.” Thus, “[s]ervice pursuant to subsection (3) is ‘neither a last resort nor extraordinary relief. It is merely one means among several which enables service of process on an international defendant.’” *In re Grana y Montero S.A.A. Sec. Litig.*, No. 17-CV-1105, 2019 WL 259778, at *3 (E.D.N.Y. Jan. 9, 2019) (quoting *Rio Props., Inc. v. Rio Int’l Interlink*, 284 F.3d 1007, 1015 (9th Cir. 2002)). Thus, there is no requirement that plaintiffs attempt other forms of service before the Court provides for alternative service under Rule 4(f)(3). *Restoration Hardware, Inc. v. Lighting Design Wholesalers, Inc.*, No. 17 Civ. 5553, 2020 WL 4497160 (S.D.N.Y. Aug. 5, 2020) (collecting cases).¹⁵ “The decision as to whether to allow alternative

¹⁵ Here, even if Gilead had addresses with which to attempt service through the Hague Convention (it does not), Gilead respectfully submits that use of the Hague Convention would lead to an unacceptable delay of service upon the Marketer Defendants. First, Gilead is seeking immediate injunctive relief because of the danger to public health posed by this counterfeiting ring. Second, Gilead is also seeking immediate injunctive relief, including seizures, against the Marketing Defendants’ co-conspirators, including the Leader Defendants. If service is delayed,

service ‘by other means’ lies within the discretion of the court.” *Fabbro v. Balke*, No. 19-CV-5764-ENV-SJB, 2020 WL 3525692, at *3 (E.D.N.Y Jun. 29, 2020).

As set forth above, the Marketer Defendants are members of the counterfeiting ring that are supervised by, and paid by, the Leader Defendants. Gilead does not know where the Marketer Defendants reside: they appear to have done their work for the counterfeiting ring entirely by email and occasional phone calls, and Gilead could not find any of their physical addresses in the seized documents or in any Defendant’s public corporate records. Oct. 13, 2021, Coleman Decl. ¶ 64. “Case law is replete with instances where service by electronic means [including email] has been authorized under Rule 4(f)(3) because the defendant’s location could not be determined and there was evidence that the defendant had been using the electronic mail accounts.” *Restoration Hardware*, 2020 WL 4497160, at *9 (collecting cases). As with all Defendants for whom Gilead is seeking alternative email service, Gilead has searched the seized documents for email addresses used by the respective Defendants, and the proposed order provides for email service on all of those email addresses.

Finally, email service against Canadian Defendants is permissible under Rule 4(f)(3) because international law does not prohibit email service. *See Fabbro*, 2020 WL 3525692, at *3 (collecting cases finding email service upon Canadian defendants not prohibited by international law and permissible under Rule 4(f)(3)). Specifically, Canada is a signatory to the Hague Convention, and the Hague Convention does not prohibit e-mail service. *Id.*

those co-defendants will doubtlessly tip off the Marketing Defendants, who will have opportunity and strong incentive to flee, dissipate assets, and destroy evidence.

2. Alternative Service Upon Defendants Located in the United States Pursuant to Rule 4(e)(1)

The evidence demonstrates that remaining Defendants against whom Gilead seeks alternative service are located in the United States. Rule 4(e)(1) provides that service upon domestic defendants may be made “following state law ... where the district court is located.” New York law provides that if standard service is “impracticable,” service may be made “in such manner as the court ... upon motion without notice, directs.” N.Y. C.P.L.R. § 308(5) (natural persons); *id.* § 311(b) (corporate entities). Under these provisions,

A plaintiff can demonstrate that service by conventional means is “impracticable” by making diligent, albeit unsuccessful, efforts to obtain information regarding a defendant's current residence, business address or place of abode. Impracticability does not require proof of due diligence or of actual prior attempts to serve a party under the other provisions of the statute.

GP Acoustics (US), Inc. v. J&V Audio, Inc., 2017 WL 11570459, at *2 (S.D.N.Y. Sept. 13, 2017) (quotations and internal quotation marks omitted). Here, Gilead’s investigators, who have successfully tracked down several Defendants who abandoned their offices and did not want to be found, have used the same techniques and diligence to locate the remaining newly added Defendants, but have been unable to do so. Coleman Decl. ¶ 64. Moreover, the newly added Defendants for whom Gilead seeks leave to serve by email have all used email in their business transactions, and Gilead seeks to serve them at all of their known email addresses. *Id.* Under these circumstances, New York federal district courts have found email service to be appropriate under the C.P.L.R., and thus under Fed. R. Civ. P. 4(e)(1). *GP Acoustics*, 2017 WL 11570459, at *1 (collecting cases).

CONCLUSION

For the reasons stated above, the Court should grant Gilead’s motion for an *ex parte* seizure order, a temporary restraining order (to be followed by a preliminary injunction), and an

asset freeze order, and should award any other and further relief that the Court may deem just and proper. Proposed orders for the requested relief are being filed simultaneously herewith.

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Respectfully submitted,



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