IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

GILEAD SCIENCES, INC., *et al.*, **Plaintiffs** **v.** **MERITAIN HEALTH, INC., *et al.*,** **Defendants.**	**Case No. 1:24-cv-03566-JRR**

MEMORANDUM OPINION

This matter comes before the court on Plaintiffs Gilead Sciences, Inc., and Gilead Sciences Ireland UC IDA's (together, "Gilead") Motion for Temporary Restraining Order and Order to Show Cause for a Preliminary Injunction as to Counts I and II of the Complaint. (ECF No. 11; the "Motion.") The court convened a hearing on Gilead's motion for temporary restraining order on December 13, 2024, and entered a temporary restraining order at ECF No. 48. Following expedited discovery and briefing by the parties, the court convened a preliminary injunction hearing on April 29 and April 30, 2025.[1]

I. THE PARTIES AND WHAT PROMPTED THIS ACTION

Plaintiff Gilead Sciences, Inc., is a public Delaware corporation with its principal place of business in Foster City, California. Plaintiff Gilead Sciences Ireland UC is a private unlimited company organized under the laws of Ireland, with its principal place of business in Carrigtwohill, County Cork, Ireland. Gilead Sciences, Inc., is the ultimate parent of Gilead Sciences Ireland UC.

[1] The facts set forth herein are gleaned from the parties' exhibits and the hearing testimony; some introductory information regarding the parties is drawn from uncontested background descriptions and information provided through the parties' motions papers and post-hearing briefs. The court also takes judicial notice of government public-facing websites, like that of the U.S. Food and Drug Administration.

Gilead is the owner of certain registered trademarks that appear on the packaging, tablets, and Patient Information documents of certain Gilead-branded medicines, including BIKTARVY® – a daily HIV anti-viral treatment drug. Several Gilead-branded medicines are manufactured for distribution and use in countries outside the United States. As explained in more detail below, BIKTARVY®, which is manufactured and distributed in the U.S., and, among other countries, Turkey, is one such example.

Defendant Meritain Health, Inc. ("Meritain"), a New York corporation with its principal office in Amherst, New York, is a third-party administrator ("TPA") that offers self-funded health care benefits administration for plan sponsors and health plans. Meritain is not an insurer and does not issue health insurance policies; rather, Meritain contracts with self-funded[2] employers (Meritain's clients) to manage and administer their employer-funded health benefit plans, including medical and prescription drug benefits of Meritain's clients' employees (or "members"). For an additional service fee, Meritain also administers the prescription benefit plans for about half of its clients through Meritain Pharmacy Solutions ("MPS"), its in-house prescription (or pharmacy) benefits manager ("PBM"). But for clients who opt not to use MPS, Meritain administers those clients' pharmacy benefits through third-party or "carve-out" PBMs.

Meritain does not contract with carve-out PBMs, but rather, as part of its standard client services, Meritain administers its clients' pharmacy benefits obtained through carve-out PBMs (for those clients who opt not to use MPS). When a Meritain client uses a carve-out PBM, Meritain provides the carve-out PBM with its client and member eligibility data pertaining to prescription and other policy benefits; in turn, Meritain processes invoices it receives from a client's carve-out

[2] A self-funded employer refers generally to an employer that pays health plan benefit costs directly as opposed to funding, or paying premiums to a health insurer for, a health insurance plan or policy. Organizations that self-fund their health plans generally do so for greater control over plan benefits and to take advantage of related cost savings.

PBM for prescription benefits claims. Because Meritain is a TPA, and not an insurer, it does not direct or determine what benefits are covered under a client's plan.

Meritain's MPS does not offer internationally sourced drugs; however, clients that want internationally sourced drugs to be available to plan members are free to use carve-out PBMs that provide same. Meritain knows that clients who utilize carve-out PBMs often do so to access internationally sourced prescription drugs. Meritain's contracts with its clients do not prohibit use of carve-out PBMs to access internationally sourced drugs; in other words, Meritain does not condition its TPA services on a client's agreement not to seek prescription drugs from international drug sourcing programs offered by carve-out PBMs.

Defendant ProAct, Inc. ("ProAct"), a New York corporation with its offices in East Syracuse and Governeur, New York, is a PBM. ProAct is 100% employee-owned, with about 180 employees, and has been in business since 1999. ProAct's clients are private- and public-sector employers with self-funded health plans; ProAct (and the industry generally) refers to its self-funding employer clients as "plan sponsors" or "clients." ProAct serves as a carve-out PBM for about 700 plan sponsors (equating to about a half-million members). ProAct typically acquires its clients through brokers who work for the employer plan sponsor. ProAct is a carve-out PBM for certain Meritain clients; and, as is industry standard, Meritain provides ProAct the above-described member eligibility data for all Meritain clients that engage ProAct as their carve-out PBM.

Defendant Rx Valet, LLC ("Rx Valet"), a Georgia limited liability company, is an alternative funding program ("AFP") with its principal place of business in Lawrenceville, Georgia. Rx Valet's customers are typically self-insured employers or employers with a health plan that offers limited pharmacy benefits. Rx Valet is retained by its employer clients or customers to assist their employees in obtaining medications at the lowest possible cost; indeed,

this is what it espouses as the value of its service. Rx Valet's services include sourcing prescription drugs through international pharmacy sources; Rx Valet advertises international prescription drug sourcing on its public website, in written materials distributed to its clients, and during phone calls with employee members during "customer service outreach calls."

Defendant Advanced Pharmacy, LLC ("Advanced Pharmacy"), a Georgia limited liability company, is a pharmacy with its principal place of business in Lawrenceville, Georgia. Advanced Pharmacy provides mail-order pharmacy services exclusively to Rx Valet.

Defendant Gregory Santulli is an individual residing in Lawrenceville, Georgia. Santulli is the founder and CEO of Rx Valet, and the President of Advanced Pharmacy.

Defendant Aqua Enterprise Inc d/b/a Affordable Rx Meds ("Affordable Rx"), a Florida corporation, is a prescription referral service (also known as an online pharmacy or internet pharmacy) with its principal place of business in Sunrise, Florida. Affordable Rx is not a pharmacy; as a prescription referral service, it is an intermediary between patients and international dispensing pharmacies. When contacted by a self-funded employer member (the employee patient) or the member's representative or agent, Affordable Rx facilitates fulfillment of the members' prescription through one of the pharmacies with which it contracts in various foreign countries, and arranges for the foreign pharmacy to ship the prescription drug directly to employee/member patient. Rx Valet is the only AFB with which Affordable Rx does business.[3]

Defendant Fetih Eczanesi is a Turkish retail pharmacy located in Istanbul, Turkey. Although a named Defendant, Fetih Eczanesi has not participated in these proceedings. As set forth below, it is implicated in this action based on its fulfillment of a U.S. patient (referred to as

[3] Throughout this action, through counsel, Defendants Rx Valet, Advanced Pharmacy, Santulli, and Affordable Rx Meds have referred to themselves collectively as "the Quartet;" they are represented by the same counsel. Where convenient, the court has adopted this collective identifying term and does so here.

John Doe throughout this action) prescription for BIKTARVY® with Gilead-branded Turkish BIKTARVY® by way of a downstream referral through the above-described Meritain-to-ProAct-to-Rx Valet-to-Advanced Pharmacy-to-Affordable Rx stream of commerce.

The summary of events that resulted in this action are as follows: Maryland patient John Doe[4] had been taking BIKTARVY® as prescribed by his doctor since at least 2021, and had his prescriptions filled by local Maryland branches of chain retail pharmacies. In January 2024, John Doe changed health insurance providers. With that change, Meritain served as the TPA with ProAct acting as the carve-out PBM. Shortly thereafter, in approximately February 2024, Doe asked his treating physician to send his BIKTARVY® prescription to ProAct for filling through its in-house mail-order pharmacy. But instead of filling the prescription, ProAct declined to fill it, and instructed Doe (via the pharmacist) to contact AFB Rx Valet to have the prescription filled at a cost savings to him.

When Doe contacted Rx Valet, Rx Valet told Doe to have his doctor forward the prescription for BIKTARVY® to Advanced Pharmacy (the mail-order pharmacy that exclusively does business with AFB Rx Valet). In response, and to ensure he could get his medicine, Doe asked his prescribing doctor to send the BIKTARVY® prescription to Advanced Pharmacy (it having not been filled by ProAct); Doe's doctor did as she was asked. A few weeks later, Doe received three bottles (a three-month supply) of BIKTARVY® bearing stickers with the name Affordable Rx – a company with which Doe was unfamiliar and of which he had never heard.

The BIKTARVY® Doe received bore the BIKTARVY® and other Gilead marks with which he was familiar, but the packaging did not look like the BIKTARVY® Doe had previously

[4] John Doe's identity has thus far been protected based on his concern for his privacy in view of his HIV status. No party has objected to reference to him as John Doe and for purposes of this opinion, and given the posture of the case, the court is content to honor that request at this time.

received through his local retail pharmacy and, oddly, the labeling was entirely in a language he did not know: Turkish. (Images of the BIKTARVY® Doe received are at ECF No. 1 at p. 44; *see* ECF No. 11-3, Aff. of Brian Nilstoft, Gilead Executive Director of Commercial Packaging and Labeling, describing manufacturing, labeling, and packaging, and providing images, of US BIKTARVY® packaging and inserts, as compared to the Turkish BIKTARVY® received by Doe) Understandably off-put and confused, Doe reached out to his healthcare provider, a clinic in Howard County, Maryland; the clinic physician contacted Gilead on February 20, 2024, to raise a complaint or concern as to whether patient Doe had received legitimate or authentic BIKTARVY®.

In response, Gilead alerted the U.S. Food and Drug Administration ("FDA") and undertook, in-house, to figure out how John Doe, a Maryland patient with a prescription for U.S. BIKTARVY®, a life-saving drug he had been taking for years, received what appeared to be Turkish BIKTARVY®. As part of this process, at Gilead's request, on February 28, 2024, Doe's clinic shipped the BIKTARVY® John Doe had received to Gilead's Quality Assurance Department. To Gilead's satisfaction, what Doe received appeared to be authentic Turkish BIKTARVY® – which is to say that Doe received legitimate (not counterfeit) BIKTARVY®, but it was BIKTARVY® manufactured, packaged, and labeled for sale in Turkey, in compliance with Turkish laws and regulations. What Doe received was not U.S. BIKTARVY® manufactured, labeled, or packaged in accordance with U.S. law or Gilead's quality control measures implemented for its U.S. pharmaceuticals, as well as those that ensure FDA regulatory compliance. Further, in-house, Gilead examined the unique serial number and QR code that permitted Gilead (through a track-and-trace system run by the Turkish government) to conclude that what Doe had received had been issued by a Turkish retail pharmacy called Fetih Eczanesi, located in Gungoren,

Istanbul. (ECF No. 11-7 ¶ 17, Decl. of Harpreet Dhanota, Director of Gilead's Anti-Counterfeiting and Global Product Security.)

The thrust of the dispute is this: Gilead complains that Defendants import and distribute authentic Gilead-branded BIKTARVY® that Gilead manufactures for exclusive distribution and patient use outside of the United States; and this alleged importation to and distribution within the U.S. for U.S. patient consumption, Gilead complains, violates its Lanham Act rights in its BIKTARVY® mark.[5]

II. GILEAD FILES SUIT

On December 10, 2024, Gilead initiated this action with the filing of its Complaint and Motion.[6] (ECF Nos. 1, 11.) Gilead asserts six claims:

> **Count I**: Federal Trademark Infringement, 15 U.S.C. § 1114(1), against all Defendants;
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> **Count II**: Federal Unfair Competition, 15 U.S.C. § 1125(a) against all Defendants;
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> **Count III**: Unfair Competition Under State Law against all Defendants;
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> **Count IV**: Unjust Enrichment against the Quartet Defendants and Defendant Fetih Eczanesi;
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> **Count V**: Importation of Goods Bearing Infringing Marks, 15 U.S.C. § 1124, against all Defendants; and
>
> **Count VI**: Civil Conspiracy against all Defendants.

(ECF No. 1 ¶¶ 150–91.)

Following notice and a hearing at which all Defendants except Fetih Eczanesi appeared,

[5] The court acknowledges that there are lawful means and bases for importation of non-U.S. drugs into the U.S. for patient use in limited circumstances as set out in the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq*. No such circumstances are relevant to this action.

[6] As mentioned above, the Motion seeks preliminary injunctive relief as to Counts I and II only – titled First Claim for Relief and Second Claim for Relief. The court abbreviates them as Counts I and II for efficiency.

on December 13, 2024, the court issued a temporary restraining order, *inter alia*, restraining Defendants from "engaging in any or all of the following acts in U.S. commerce:"

> 1. Importing, advertising the importation of, or otherwise facilitating the importation of product bearing a Gilead Mark (as defined herein) into the United States from outside the United States . . . .
>
> * * *
>
> 2. Purchasing, selling, distributing, marketing, manufacturing, offering for sale, or otherwise using in United States commerce, or facilitating the importation into the United States, any product bearing a Gilead Mark that has [certain expressed characteristics] . . . .
>
> * * *
>
> 3. Infringing any of the Gilead Marks;
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> 4. Using any logo, trade name or trademark confusingly similar to any of the Gilead Marks which may be calculated to falsely represent or which has the effect of falsely representing that the services or products of any or all of the Defendants or of others are sponsored by, authorized by or in any way associated with Plaintiffs;
>
> 5. Falsely representing any or all of Defendants as being connected with Plaintiffs or sponsored by or associated with Plaintiffs or engaging in any act which is likely to cause the trade, retailers and/or members of the purchasing public to believe that any or all of Defendants are associated with Plaintiffs;
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> 6. Removing from their premises, or discarding, destroying, transferring or disposing in any manner any information, computer files, electronic files, WhatsApp or text messages, business records (including but not limited to e-mail communications) or other documents relating to the Defendants' assets and operations or relating in any way to the purchase, sale, manufacture, offer for sale, distribution, negotiation, importation, advertisement, promotion, or receipt of any products bearing any of the Gilead Marks; and
>
> 7. Assisting, aiding, or abetting any other person or business entity in engaging in or performing any of the activities referred to in subparagraphs (1) through (6) above.

(ECF No. 48 at pp. 1–4.)

Further to the court's order for preliminary expedited discovery, the parties engaged in approximately two months of expedited discovery – a process punctuated by numerous and frequent discovery disputes, and corollary teleconferences, hearings, correspondence, and orders. Following the close of expedited discovery, Defendants filed their respective oppositions to the Motion; and Gilead replied. (ECF Nos. 111, 113, 114, 151–53, 155–57.) Based on agreed-upon scheduling, the court convened a two-day preliminary injunction hearing on April 29 and April 30, 2025. Following the hearing, the court ordered the parties to submit post-hearing briefs to include proposed findings of fact and argument. (ECF No. 215.) Based on an agreed-upon deadline extension, the parties submitted their post-hearing submissions on May 30, 2025. (ECF Nos. 235, 238, 239, 240, 243.)

III. LEGAL STANDARD, SUBSTANTIVE LAW, AND ANALYSIS

Gilead (through its Motion) seeks a preliminary injunction pursuant to Federal Rule of Civil Procedure 65. "A preliminary injunction is 'an extraordinary remedy' that 'may only be awarded upon a clear showing that the plaintiff is entitled to such relief.'" *Pierce v. N. Carolina State Bd. of Elections*, 97 F.4th 194, 209 (4th Cir. 2024) (quoting *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008)); *see Benisek v. Lamone*, 585 U.S. 155, 158 (2018) (noting that "a preliminary injunction is 'an extraordinary remedy never awarded as of right'"). As such, preliminary injunctive relief is to be "granted only sparingly and in limited circumstances." *St. Michael's Media, Inc. v. Mayor & City Council of Baltimore*, 566 F. Supp. 3d 327, 351 (D. Md. 2021), *aff'd,* No. 21-2158, 2021 WL 6502219 (4th Cir. Nov. 3, 2021), and *aff'd,* No. 21-2206, 2021 WL 6502220 (4th Cir. Nov. 13, 2021) (quoting *Micro Strategy, Inc. v. Motorola, Inc.*, 245 F.3d 335, 339 (4th Cir. 2001)).

A plaintiff seeking preliminary injunctive relief "must establish that 1) they are likely to succeed on the merits; 2) they are likely to suffer irreparable harm absent preliminary relief; 3) the balance of the equities favors the requested injunctive relief; and 4) that relief is in the public interest." *Leaders of a Beautiful Struggle v. Baltimore Police Dep't*, 2 F.4th 330, 339 (4th Cir. 2021) (citing *In re Search Warrant Issued June 13, 2019*, 942 F.3d 159, 170–71 (4th Cir. 2019)). These factors were established by the Supreme Court in *Winter v. Natural Resources Defense Council, Inc.*, 555 U.S. 7 (2008). "[P]laintiff bears the burden of establishing that each of these factors supports granting the injunction."[7] *Direx Israel, Ltd. v. Breakthrough Med. Corp.*, 952 F.2d 802, 812 (4th Cir. 1991) (citing cases); *see St. Michael's Media, Inc.*, 566 F. Supp. 3d at 351 (same).

A. Likelihood of Success on the Merits

1. Lanham Act – Counts I and II[8]

To prevail on its Lanham Act trademark infringement (15 U.S.C. § 1114(1); Count I) and unfair competition (15 U.S.C. 1125(a); Count II) claims, Gilead must show that (1) it owns a legally protectable trademark; (2) Defendants used the trademark in commerce without Gilead's consent; (3) Defendants used the mark "in connection with the sale, offering for sale, distribution, or advertising" of goods or services; and (4) Defendants' use of the mark is likely to cause

[7] "Because preliminary injunction proceedings are informal ones designed to prevent irreparable harm before a later trial governed by the full rigor of usual evidentiary standards, district courts may look to, and indeed in appropriate circumstances rely on, hearsay or other inadmissible evidence when deciding whether a preliminary injunction is warranted." *St. Michael's Media, Inc. v. Mayor & City Council of Baltimore*, 566 F. Supp. 3d 327, 352 (D. Md. 2021), *aff'd,* No. 21-2158, 2021 WL 6502219 (4th Cir. Nov. 3, 2021), and *aff'd,* No. 21-2206, 2021 WL 6502220 (4th Cir. Nov. 13, 2021) (quoting *G.G. ex rel. Grimm v. Gloucester Cnty. Sch. Bd.*, 822 F.3d 709, 725–26 (4th Cir. 2016)).

[8] The court notes that Meritain and ProAct challenge Gilead's standing – specifically, they assert: "At the preliminary injunction stage, Plaintiffs must show they are 'likely' to establish standing as to each defendant. Plaintiffs have not met this burden." (ECF No. 235 at p. 6 (citations omitted); ECF No. 239 at p. 14 n.5) The court addresses their contention below.

confusion, mistake, or deception among consumers.[9] *Rosetta Stone Ltd. v. Google, Inc.,* 676 F.3d 144, 152 (4th Cir. 2012); *Ray Commc'ns, Inc. v. Clear Channel Commc'ns, Inc*., 673 F.3d 294, 300 (4th Cir. 2012); *Lone Star Steakhouse & Saloon, Inc. v. Alpha of Virginia, Inc.,* 43 F.3d 922 (4th Cir. 1995); *see also Thorne Research, Inc. v. Davachi*, No. 2:24-cv-02356-DCN, 2024 WL 4607943, at *5 (D.S.C. Oct. 29, 2024) (noting that "[t]he elements of Lanham Act unfair competition . . . and Lanham Act trademark infringement are all essentially the same")[10]

This action is what is known as a "gray market" or "gray goods" trademark infringement case – where products manufactured for sale and distribution outside the United States, and bearing a legally affixed trademark that is the same as that registered in the U.S., are legally acquired abroad but imported into the U.S. without the consent of the U.S. mark holder. *See generally PepsiCo, Inc. v. F & H Kosher Supermarket, Inc.*, 18 No. 11-CV-0425 (RMM) (ALC), 2011 WL 6181907 (E.D.N.Y. Aug. 26, 2011), adopted in its entirety by No. 11-CV-0425 (RRM) (ALC), 2011 WL 6179269 (E.D.N.Y. Dec. 12, 2011); *Proctor & Gamble Co. v. Xetal, Inc.*, No. 04 Civ. 2820 (DRH) (WDW), 2008 WL 361140, at *1, n.4 (E.D.N.Y. Feb. 8, 2008) (quoting *Gamut Trading Co. v. U.S. Int'l Trade Comm'n,* 200 F.3d 775, 778 (Fed. Cir. 1999)). "The principle of gray market law is that the importation of a product that was produced by the owner of the United States trademark or with its consent, but not authorized for sale in the United States, may, in

[9] "Actual confusion can be demonstrated by both anecdotal and survey evidence." *George & Co., LLC v. Imagination Entertainment Ltd,* 575 F.3d 383, 398 (4th Cir. 2009) (quoting *Tools USA and Equip. Co. v. Champ Frame Straightening Equip., Inc.,* 87 F.3d 654, 661 (4th Cir. 1996)). Further, "while evidence of only a small number of instances of actual confusion may be dismissed as *de minimis*," *see id.* (citations omitted), courts consider the background of the case relative to the number of opportunities for confusion. Here, the parties are at an early stage of the case having only proceeded through preliminary expedited discovery for purposes of the Motion; and, as set forth below, here, there is evidence of actual confusion by way of a complaining U.S. patient, John Doe, who received Turkish BIKTARVY® instead of the U.S. BIKTARVY® he had been taking and expected to receive. Relatedly, the court finds it appropriate, at least at this point, to consider the personal privacy and sensitive nature of a consumer's use of the product at issue here – a drug for treatment of HIV – and whether this would dampen the likelihood that a confused consumer would complain. Notably, John Doe requested anonymity for just this reason.

[10] The court sets forth here the elements for direct liability under the Lanham Act. Below the court addresses theories of contributory and vicarious liability, as well as officer/director direct liability for Lanham Act violations of the business entity the officer or director serves.

appropriate cases, infringe the United States trademark." *Gamut Trading Co.,* 200 F.3d at 777.

Importantly, gray goods cases present a departure from the more common (or perhaps better known) Lanham Act case based on allegations that a defendant's product infringes the plaintiff's mark based on some feature of the defendant's product that (the plaintiff contends) poses a risk of confusion among consumers who may believe they are buying the mark holder's product but – based on confusion as to the source of the goods – buy the infringing product instead. In a gray market case, the allegations don't fit that paradigm. Instead, in a gray goods case, the alleged infringement is not premised on a putative customer duped (intentionally or not) into buying, for example, a bogus look-alike; rather, in a gray goods case, the plaintiff's bundle of rights in its mark is jeopardized or damaged because the defendant has wrested from the plaintiff the right to control the use of its mark to the detriment of the consumer and the mark holder's goodwill and reputation in the market.

To be clear, as relayed above, this case is not about counterfeit pharmaceuticals; Gilead does not complain that Defendants peddle counterfeit BIKTARVY®. Rather, Gilead complains that Defendants import and distribute authentic Gilead-branded BIKTARVY® that Gilead manufactured for exclusive distribution and patient use outside of the United States; and this alleged importation and distribution for U.S. patient consumption, Gilead complains, violates its Lanham Act rights in its BIKTARVY® mark.

a. Theories of Infringement

In addition to direct liability of Defendants Rx Valet, Advanced Pharmacy, Affordable Rx, Santulli, and Fetih Eczanesi, Gilead pursues theories of contributory and vicarious liability as against Meritain and ProAct. Gilead's theory of direct liability as to Defendant Santulli is based on his role as an officer of Defendants Rx Valet (founder/CEO) and Advanced Pharmacy

(President). (ECF No. 11-1 at pp. 49–55.) The court sets forth the salient legal principles below for each theory.

i. Contributory Infringement

"Contributory infringement is a judicially-created doctrine, based on the law of torts, that assigns liability if a defendant facilitates or encourages trademark infringement." *Rosetta Stone Ltd v. Google, Inc.,* 676 F.3d 144, 163 (4th Cir. 2012) (citation modified). The Supreme Court has set forth two bases for contributory trademark infringement. A defendant is liable for contributory trademark infringement if it "intentionally induces another to infringe a trademark, or if it continues to supply its product to one whom it knows or has reason to know is engaging in trademark infringement." *Inwood Labs, Inc. v. Ives Labs, Inc.,* 456 U.S. 844, 853 (1982); *see Rosetta Stone,* 676 F.3d at 164–65 (discussing *Inwood*'s second theory of contributory infringement regarding continued provision of services (not products) to one whom a defendant knows or had reason to know was engaging in trademark infringement).

ii. Vicarious Liability[11]

To establish vicarious liability for trademark infringement and unfair competition, "plaintiff must show the defendant '(1) had the right and ability to supervise the infringing activity; and (2) had a direct financial interest in the infringing activity.'" *Living Legends Awards for Service to Humanity, Inc. v. Human Symphony Found., Inc*., Civ. Act. No. PX 16-3094, 2017 WL 3868586, at *4 (D. Md. Sept. 5, 2017) (quoting *Goldstein v. Metro. Reg'l Info. Sys., Inc.,* No. CV TDC-15-2400, 2016 WL 4257457, at *5 (D. Md. Aug. 11, 2016), in turn quoting *Fonovisa, Inc. v.*

[11] Meritain and ProAct assert that Gilead has "dropped" its vicarious liability theories against them. (ECF No. 235 at p. 22; ECF No. 239 at p. 14 n.5.) The court agrees that Gilead opted not to pursue this theory of liability as to Counts I and II for purposes of the Motion; but Gilead has not made it known to the court that it has withdrawn this theory of liability for purposes of a judgment on the merits. Therefore, the court declines to consider this theory for purposes of the Motion; however, Gilead remains entitled to pursue judgment against Meritain and ProAct on Counts I and II based on a theory of vicarious liability. Nonetheless, for the sake of completeness, the court includes a summary of applicable law on vicarious liability for federal trademark infringement and unfair competition.

Cherry Auction, Inc., 76 F.3d 259, 262-63 (9th Cir. 1996)).

Regarding the first element, a defendant has the "right and ability to supervise the infringing activity" if it "declin[es] to exercise a right to stop or limit it." *Goldstein*, 2016 WL 4257457, at *5 (quoting *Metro-Goldwyn-Mayer Studios, Inc. v. Grokster, Ltd.,* 545 U.S. 913, 930 (2005)). As to the second element, "[a] direct financial interest arises where the infringing activity is a 'draw' for customers and significant financial benefits 'flow directly' from the infringing activity that the defendant helps to facilitate." *Living Legends*, 2017 WL 3868586, at *4 (quoting *Fonovisa*, 76 F.3d at 263).

iii. Officer/Director Direct Liability

As with most, if not all, business torts, an entity's officer or agent may be held personally liable for trademark infringement and unfair competition performed in the name of the business entity if he personally committed, controlled, ratified, or authorized the offending conduct. This has been aptly described as personal liability of the "principal architect" or "moving force" of the infringement. *Brittingham v. Jenkins*, 914 F.2d 447, 458 (4th Cir. 1990) (providing that, "as the principal architect of the underlying infringement, equity requires that [the corporate officer] be held jointly and severally liable for the judgment in this [Lanham Act] case"); *Babbit Elecs., Inc. v. Dynascan Corp.,* 38 F.3d 1161, 1184 (11th Cir. 1994) (*per curiam* with Kaufman, J., senior district judge, D. Md., sitting by designation) (holding that "a corporate officer who directs, controls, ratifies, participates in, or is the moving force behind the infringing activity, is personally liable for such infringement without regard to piercing of the corporate veil"); *Polo Fashions, Inc. v. Craftex,* 816 F.2d 145, 149 (4th Cir. 1987) (holding "[a] corporate official may be held personally liable for tortious conduct committed by him, though committed primarily for the benefit of the corporation. This is true in trademark infringement and unfair trade practices cases");

Microsoft Corp. v. Maryland Micro.com, Inc., No. Civ. JFM–01–3797, 2003 WL 21805213, at *4 (D. Md. July 15, 2003) (citing *Polo Fashions, Inc., supra,* and 4 J. Thomas McCarthy, *McCarthy on Trademarks and Unfair Competition* § 25:24 (4th ed. 2003)).

b. First Sale/Exhaustion Doctrine

Also important to consider is whether the first sale (or exhaustion) doctrine applies in this gray goods Lanham Act action; and if so, how. Generally speaking, the first sale doctrine provides that a mark holder cannot control downstream distribution (resale) of its genuine products. *Sprint Nextel Corp. v. Simple Cell, Inc.,* No. CCB-13-617, 2013 WL 3776933, at *7 (D. Md. July 17, 2013). Importantly, however, "'[t]he first sale doctrine does not apply when an alleged infringer sells trademarked goods that are materially different than those sold by the trademark owner.'" *Id.* (quoting *TracFone Wireless Inc. v. Pak China Group Co. Ltd.,* 843 F. Supp. 2d 1284, 1296–97 (S.D. Fla. 2012)); *see Shell Oil Co. v. Com. Petroleum, Inc.,* 928 F.2d 104, 107 (4th Cir. 1991) (noting the first sale rule applies only to "genuine" products and holding "[a] product is not truly 'genuine' unless it is manufactured and distributed under quality controls established by the manufacturer").

"When the products sold by the alleged infringer and the trademark owner contain identical marks but are materially different, consumers are likely to be confused about the quality and nature of the trademarked goods." *Iberia Foods Corp. v. Romeo,* 150 F.3d 298, 303 (3rd Cir. 1998). Accordingly, under the first sale doctrine, generally, the trademark holder does not have a right under the Lanham Act to control unauthorized resales provided the goods are genuine. But where the good are not "genuine," the first sale doctrine does not bar recovery under the Lanham Act.

Therefore, whether the complained of product – here, Turkish BIKTARVY® – is

"genuine" and, therefore, subject to the first sale doctrine, requires the court to evaluate whether Turkish BIKTARVY® is materially different from U.S. BIKTARVY®; or whether Turkish BIKTARVY® is manufactured and distributed under quality control measures sufficiently different from U.S. BIKTARVY®.

i. Material Differences Doctrine

The material differences doctrine provides that a product bearing the plaintiff's mark is infringing under the Lanham Act if that product was not intended (by the mark holder) to be sold in the United States, and is "materially different" than the product authorized (by the mark holder) for sale in the U.S. *Sprint Nextel Corp. v. Simple Cell, Inc.,* No. CCB-13-617, 2013 WL 3776933, at *8 (D. Md. July 17, 2013); *Novartis Animal Health US, Inc. v. Abbeyvet Export Ltd.,* 409 F. Supp. 2d 264, 266 (S.D.N.Y. 2005); *Martin's Herend Imps., Inc. v. Diamond & Gem Trading USA, Co*., 112 F.3d 1296, 1301–1302 (5th Cir. 1997).

The doctrine – and what constitutes a material difference – is flexible; the threshold is low to account for consumer purchasing considerations across a wide spectrum of markets. Specifically, a "material difference" is "no more than a slight difference which consumers would likely deem relevant when considering a purchase of the product." *Zino Davidoff SA v. CVS Corp*., 571 F.3d 238, 246 (2d Cir. 2009) (instructing that "[i]n the context of gray-market goods, in comparing the trademark holder's product with the gray-market product, we apply a low threshold of materiality"); *Davidoff & Cie, S.A. v. PLD Int'l Corp*., 263 F.3d 1297, 1302 (11th Cir. 2001) (providing that "[b]ecause a myriad of considerations may influence consumer preferences, the threshold of materiality must be kept low to include even subtle differences between products"); *Societe Des Produits Nestle v. Casa Helvetia, Inc.,* 982 F.2d 633, 641 (1st Cir. 1992) (explaining that "it is by subtle differences that consumers are most easily confused. For that reason, the

threshold of materiality must be kept low enough to take account of potentially confusing differences – differences that are not blatant enough to make it obvious to the average consumer that the origin of the product differs from his or her expectations;" and "[t]here is no mechanical way to determine the point at which a difference becomes 'material.' Separating wheat from chaff must be done on a case-by-case basis. Bearing in mind the policies and provisions of the Lanham [] Act as they apply to gray goods, we can confidently say that the threshold of materiality is always quite low in such cases").[12]

Relevant here, differences including foreign language packaging and labeling, international units of measure, and deviation from FDA regulations, have been found to satisfy the material differences doctrine. *See Abbott Labs. v. Adelphia Supply USA,* No. 15-CV-5826 (CBA) (MDG), 2015 WL 10906060, at *6 (E.D.N.Y. Nov. 6, 2015) (citing *Original Appalachian Artworks, Inc, Inc. v. Granada Elecs., Inc.*, 816 F.2d 68 (2d Cir. 1987), *Johnson & Johnson Consumer Cos., Inc. v. Aini,* 540 F. Supp. 2d 374 (E.D.N.Y. 2008), and *Helen Curtis, Inc. v. Nat'l Wholesale Liquidators,* 890 F. Supp. 152 (E.D.N.Y. 1995)).

[12] As the *Novartis* court points out: "[o]rdinarily, trademark infringement and the likelihood of confusion is determined by application" of what are known as the *Polaroid* factors. 409 F. Supp. 2d at 266. Those factors, developed by their namesake *Polaroid Corp. v. Polarad Elec. Corp.,* 287 F.2d 492 (2d Cir.1961), and evolved through subsequent years of trial court application and resultant common law, include (but are not limited to) the following: 1) the strength or distinctiveness of the mark; 2) the similarity of the two marks; 3) the similarity of the goods/services the marks identify; 4) the similarity of the facilities the two parties use in their businesses; 5) the similarity of the advertising used by the two parties; 6) the defendant's intent; and 7) actual confusion. *Id; see Bridges in Organizations, Inc. v. Bureau of Nat'l Affairs,* Civ. No. B–19–23, 1991 WL 220807, at *7, *7 n.6 (D. Md. June 24, 1991) (considering *Polaroid* factors as adopted and expanded by *Pizzeria Uno Corp. v. Temple,* 747 F.2d 1522 (4th Cir. 1984)). Application of the *Polaroid* factors "is not useful in the context of gray market goods, since such goods typically utilize the exact same marks, sold in the original packaging legitimately obtained from the manufacturer." *Novartis*, 409 F. Supp. 2d at 266 (citing *Original Appalachian Artworks, Inc. v. Granada Electronics, Inc.,* 816 F.2d 68, 74 (2d Cir.1987) (Cardamone, J., concurring) (stating that the traditional consumer confusion test is difficult to apply for "gray goods")). Similar to this case, in *Novartis*: "[Defendant's] sales involve genuine [Plaintiff-branded] pharmaceuticals . . . . They are neither counterfeit goods nor goods masquerading as genuine by adopting confusingly similar marks; they use the actual marks and the marks are lawfully affixed to them. Under these circumstances, courts have adopted a simpler test, finding a likelihood of confusion if: (1) the goods were not intended to be sold in the United States, and (2) they are materially different from the goods typically sold in the United States." *Id.* (citations omitted).

ii. Quality-Control Doctrine

In addition to utilization of the material differences doctrine, a gray market Lanham Act plaintiff can demonstrate the goods sold by the defendant (here, Turkish BIKTARVY®) are not genuine, and thereby avoid the first sale doctrine, if the goods the defendant places in commerce are manufactured and distributed under quality control measures sufficiently different from those applied by the plaintiff (here, with respect to U.S. BIKTARVY®). Importantly, under this doctrine, it matters not that a defendant demonstrates (or generates evidence of) the safety or good quality of the product it sells; or the existence of quality controls to safeguard the goods or product during the manufacturing and distribution processes. The essential point is that it is the singular right of the plaintiff mark holder to ensure that its desired conditions of manufacturing and distribution are observed as the product makes its way to the consumer; because when a mark holder loses this right, its goodwill, reputation, and related market standing are at material risk. *Shell Oil Co. v. Com. Petroleum, Inc.,* 928 F.2d 104 (4th Cir. 1991); *Amer. Petroleum Instit. v. Cooper,* 718 F.3d 347 (4th Cir. 2013) (quoting and discussing *Shell Oil*'s quality control doctrine holding in the context of evaluation of Lanham Act preemption of North Carolina Blending Statute);[13] *El Greco Leather Prods. Co. v. Shoe World, Inc*., 806 F.2d 392 (2d Cir. 1986).

If a plaintiff demonstrates the offending gray market goods are manufactured and

[13] *American Petroleum Institute v. Cooper* provides additional helpful guidance on application of the quality-control doctrine in the Fourth Circuit as follows:

> *Shell Oil*'s holding is consistent with that in *United States v. Farmer,* 370 F.3d 435 (4th Cir. 2004), a criminal trademark counterfeiting case. In *Farmer,* we upheld the criminal trademark conviction of a defendant accused of purchasing shirts manufactured for (but rejected by) mark holders, affixing the registered mark, and selling the shirts as genuine. We reasoned that, even if the quality of the shirts sold by the defendant was identical to the quality of "genuine" Nike shirts, "[o]ne of the rights that a trademark confers upon its owner is the right to control the quality of the goods manufactured and sold under that trademark." *Id.* at 441 (internal quotation marks omitted). Accordingly, "the actual quality of the goods is irrelevant; it is the control of quality that a trademark holder is entitled to maintain." *Id.* (internal quotation marks omitted).

718 F.3d 347, 360 n.8 (4th Cir. 2013).

distributed under sufficiently different standards (controls) than those implemented by the plaintiff, the goods are not considered genuine under the Lanham Act, and the first sale rule (or exhaustion) does not protect the defendant from liability.

2. Gilead's Marks – Differences Between Turkish and U.S. BIKTARVY®, and Quality Control of Turkish and U.S. BIKTARVY®

It is uncontested, and the court finds, that Gilead owns several well-established, registered trademarks that appear on the packaging and labeling of genuine Gilead-branded medicines sold in several countries, including the U.S. These marks include the trademarks referenced as "Gilead Marks" in the Declaration of Gretchen Stroud, Senior Associate General Counsel, Intellectual Property, at Gilead Sciences, Inc. Among these registered marks is BIKTARVY®. (ECF No. 11-5, Stroud Dec; ECF No. 1 at p. 43 listing Gilead registered marks.) As referenced earlier, BIKTARVY® is an anti-viral drug used for treatment of HIV. BIKTARVY® was developed by Gilead and first approved by the FDA in 2018. Gilead-branded BIKTARVY® is packaged for distribution in the United States in packaging with labeling that bear multiple Gilead Marks. In the United States, Gilead sells only FDA-approved Gilead-branded medicines that are manufactured, packaged, and labeled in accordance with FDA regulations at FDA-inspected facilities.

Gilead also manufactures BIKTARVY® (and other Gilead-branded medicines) for packaging, labeling, sale, and distribution in countries outside the United States, including Turkey. Gilead-branded medicines intended for non-U.S. markets are manufactured, packaged, and labeled to meet the regulations of the country into which they are intended for sale and distribution. International (non-U.S.) Gilead-branded medicines are not intended for sale in the United States – they are not manufactured, packaged, and labeled in accordance with FDA regulations; the FDA has not approved the packaging or labeling of international Gilead-branded medicines, including

Turkish and other non-U.S. BIKTARVY®. For example, in Turkey, Gilead sells BIKTARVY® that has been manufactured at a site in Turkey and that bears Turkish-language labeling.

BIKTARVY® sold in the U.S. and BIKTARVY® sold in Turkey are the same medical formulation but bear many differences. U.S. BIKTARVY® is sold in a labeled bottle with patient information affixed to the bottle in the English language; Turkish BIKTARVY® is sold in a labeled carton with the bottle containing the medication, and the patient information is located inside the carton – all in the Turkish language. (ECF No. 11-3; Decl. of Brian Nilstoft, Executive Director of Gilead's Commercial Packaging and Labeling.) The label on a bottle of U.S. BIKTARVY® displays warnings that read "ALERT: Find out about medicines that should not be taken with Biktarvy" (in red) and "**KEEP OUT OF REACH OF CHILDREN**." *Id.* ¶ 12 (emphasis in original). Neither of these warnings accompanies Turkish BIKTARVY®. *Id.* The label on a bottle of U.S. BIKTARVY® bears the instruction: "Store below 30° C (86° F)." *Id.* Turkish BIKTARVY® contains a temperature instruction only in the Turkish language and the temperature storage indication is only in Centigrade. *Id.* U.S. BIKTARVY® patient information is entirely in English; Turkish BIKTARVY® patient information documents are entirely in Turkish. *Id.* ¶ 13.

The patient information documents affixed to U.S. BIKTARVY® contain "black-box" warnings providing particularly important information for patients, as identified in consultation with the FDA. *Id.* For example, the patient information document provided with U.S. BIKTARVY® contains a black-box warning that the drug may exacerbate Hepatitis B infection for patients co-infected with HIV and Hepatitis B. *Id.* The patient information document provided with Turkish BIKTARVY® does not contain that black-box warning.

The patient information document affixed to every bottle of U.S. BIKTARVY® provides

the Gilead toll-free 1-800 patient hotline. *Id.* No international Gilead-branded medicine or associated international patient information document provides that phone number. The patient information document affixed to every bottle of U.S. BIKTARVY® provides contact information for the FDA. *Id.* No international Gilead-branded medicine or associated international patient information document provides FDA contact information. The patient information document affixed to every bottle of U.S. BIKTARVY® provides: "This Patient Information has been approved by the U.S. Food and Drug Administration." *Id.* No international Gilead-branded medicine or associated international patient information document contains that statement.

In accordance with federal regulations, U.S. BIKTARVY® is labeled with the "Rx only" symbol. *Id.* ¶ 12. No international Gilead-branded medicine is labeled with the "Rx only" symbol. U.S. BIKTARVY® is labeled with the National Drug Code (NDC) associated with BIKTARVY® No international Gilead-branded medicine is labeled with an NDC. *Id.* According to the public FDA website, an NDC label,

> [S]ignifies that th[e] product has been approved by FDA for marketing based upon a review of the safety and effectiveness of the drug, including review of 1) whether adequate and well-controlled investigations show that this drug is safe and effective for use under the conditions prescribed, recommended, or suggested in its labeling; 2) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of this drug and whether they adequately preserve the drug's identity, strength, quality, and purity; and 3) the drug's proposed labeling. [14]

Gilead-branded medicines have temperature storage requirements, which are listed on their FDA-approved labels. As discussed above, U.S. BIKTARVY® has a maximum storage temperature of 86° Fahrenheit, which is reflected on its FDA-approved label. Gilead takes steps to ensure that Gilead medicines shipped internationally into the U.S. are shipped in sealed,

[14] U.S. Food and Drug Admin., *National Drug Code Database Background Information*, https://www.fda.gov/drugs/development-approval-process-drugs/national-drug-code-database-background-information (last visited Jun 24, 2025). The court is entitled to take judicial notice of government websites. *See United States v. Garcia*, 855 F.3d 615, 621 (4th Cir. 2017).

temperature-controlled, and temperature-monitored containers. *Id.* ¶ 24. If a shipment's temperature monitor indicates that the medicine was exposed to temperatures exceeding its maximum range, a "quality event" is triggered. When this happens, the medicine is not released; instead a Gilead quality-assurance team investigates to determine if the medicine remains safe and effective; it is released only upon such affirmative determination. *Id.*

When non-U.S. BIKTARVY® is shipped from a non-U.S. pharmacy (including a pharmacy in Turkey) to a U.S. patient as part of an international sourcing program, if the shipment undergoes conditions in excess of the maximum temperature range, no "quality event" is triggered, which means the Gilead quality-assurance team has no notice to investigate the safety or efficacy of medicine if it were stored in conditions exceeding the maximum range. In accordance with federal law (specifically, the Drug Supply Chain Security Act), U.S. Gilead-branded medicines, including BIKTARVY®, are accompanied by a mandated pedigree identifying every distributor or pharmacy that has taken possession of that particular bottle of medicine, beginning with the first sale from Gilead to one of its U.S. authorized distributors. These pedigrees are required to travel with a bottle of medicine and to be updated every time the bottle changes hands, creating a documented chain of custody (or pedigree) for each bottle of medicine.

The existence of a pedigree for U.S. Gilead-branded drugs (including BIKTARVY®) is essential to patient safety and the ability to identify, for example, where in the chain of custody a quality control problem may have occurred. *Id.* ¶ 25. This enables Gilead to identify with specificity where and how a quality event occurred, which in turn enables Gilead to implement specifically targeted recalls or other corrective measures if and when necessary to ensure patient and drug safety. Gilead medications sold outside of the United States, including Turkish BIKTARVY®, are not accompanied by pedigrees.

Aided by FDA-required measures, which enable Gilead to identify and cure specific quality events or problematic circumstances with the aid of a pedigree, Gilead implements strict quality-assurance protocols for the execution of targeted recalls within the U.S. if there is a quality issue with a medicine. Importantly, targeted recalls are implemented only in the market into which Gilead distributed the affected lot(s), which means recall notices will only be provided to the distributors and other entities to whom Gilead knows an affected lot was distributed. *Id.* ¶ 29. For example, a recall associated with a quality concern with a lot of BIKTARVY® manufactured in Gilead's site in Turkey, which produces BIKTARVY® for use only in the Turkish market, would trigger the issuance of a targeted recall in Turkey, not in the United States.

Gilead sells U.S. BIKTARVY® to select U.S. Gilead-authorized distributors to prevent introduction of counterfeit, adulterated, or otherwise substandard Gilead-branded medicine to U.S. consumers. Gilead discloses these authorized distributors on its public website, which patients and care providers can access and review. International Gilead-branded medicines, including Turkish BIKTARVY®, imported, sold, and shipped to U.S. patients under international sourcing programs are not distributed under the same quality controls as Gilead-branded medicines authorized for sale in the United States.

Based on the foregoing, Gilead has made a strong and clear showing that it will likely succeed in demonstrating that the first sale doctrine does not apply in view of the strong and diverse evidence of material differences between U.S. and non-U.S Gilead-branded drugs, including BIKTARVY®, as well as the quality controls Gilead consistently applies to its U.S. drugs like BIKTARVY that are not applied to non-U.S. Gilead-branded drugs, including Turkish BIKTARVY®.

The court places particular emphasis on evidence of the absence of English language

labeling; the absence of critical patient safety information, including the 1-800 Gilead hotline, as well as contact information for the FDA; the absence of a "black box" warning as to contraindications and potential exacerbation of dangerous co-viral conditions; Gilead's inability to isolate data to deploy targeted recalls and related patient safety protocols due to the lack of bottle pedigree; and the lack of quality/safety event trigger capacity for safe temperature ranges during distributions. In summary, Gilead has presented strong and clear evidence that non-U.S. Gilead-branded drugs, including BIKTARVY®, are materially different from, and subject to far inferior and less diverse quality controls than, their Gilead-branded U.S. counterparts, including BIKTARVY®. Therefore, Gilead has a strong likelihood of proving that non-U.S. Gilead-branded drugs, including BIKTARVY®, are not genuine for purposes of Lanham Act exhaustion principles.

3. Meritain – Contributory Infringement

As a TPA for self-funded employer plans, Meritain offers core administrative services including invoice payment and processing, maintenance of patient eligibility feeds, and patient referrals. Meritain also acts as both TPA and PBM for roughly half of its health-plan clients. According to its Director of Pharmacy Management (Mr. Wisniewski), Meritain understands that importing prescription drugs for U.S. patients is illegal, and can be unsafe and dangerous for U.S. patients, including because of the risk of substandard or counterfeit drugs that may be introduced to the U.S. supply chain. Meritain's in-house policies include what it refers to as an "official company policy," *see* ECF No. 235 ¶ 19, prohibiting it from "support[ing] in any way" international sourcing of prescription medicines. (Hearing Tr. I, ECF No. 222 at 29:12–17.) According to the records before the court, Meritain's business conduct is at material odds with, and does not conform to, its written policy.

In the weeks before issuance of the TRO (on December 13, 2024), Meritain promoted its provision of international sourcing services by pairing clients who seek such services with providers engaged in the business of international sourcing. For example, Meritain advised its salesforce via an MPS training document that it was a "myth" that "MPS does not provide international sourcing as a cost-saving option." (ECF No. 152-16; Hearing Tr. I, ECF No. 222 at 111:8–22.) During this same period near the close of 2024, Meritain developed a "Frequently Asked Questions" document announcing that MPS would refer its members to "best-in-class" vendors for importing prescription drugs to U.S. patients. (ECF No. 152-18.) To be clear, Meritain removed this language from its FAQ document following issuance of the TRO, but, against this backdrop, the court strains to credit Meritain's insistence that it follows its policy.

Further, Meritain's agreement with a company called OptiMed Health Partners or OptiMed, an international prescription drug sourcing outfit, called for Meritain to use "reasonable best efforts" to communicate information about OptiMed's services to Meritain's customers. (Hearing Tr. I, ECF No. 222 at 119:11–120:11; Gilead Hearing Ex. 183 at MRTN004103.) The contract explains that OptiMed "will provide medications . . . directly through its network of U.S.-based pharmacies or through an international network," also known as "personal importation."[15] (Gilead Hearing Ex. 183 at MRTN0004112.) Mr. Wisniewski testified that Meritain later "turned off" that international sourcing program with OptiMed, but no amended or modified contract before the court bears that out. (Hearing Tr. I, ECF No. 222 at 121:19–22.)

Despite its "no international sourcing" policy described above, Meritain (as a TPA) did, in fact, administer and facilitate payment of invoices for international prescription medications for clients' employee members. To be sure, the court appreciates that human errors happen – even

[15] No evidence is before the court that Meritain engaged OptiMed to help members invoke the FDCA personal importation exception per 21 U.S.C. § 384.

despite best efforts to enforce policies to prevent those errors. But the court does not credit Meritain's general explanation in its papers and through its corporate representative that its no-international sourcing formal policy was abided by the very people who, according to Mr. Wisniewski, were subject to policy-compliance training. Rather, Meritain's internal email correspondence suggests interest in and efforts to, at least at the higher echelon of company authority, find work-arounds to shield the company from "compliance" problems while not alienating carve-out PBM using clients whose members sought out international prescription program ("IPP") drugs.

According to Meritain internal emails, in 2020, Meritain processed invoices from a vendor called ScriptSourcing for prescription drugs sourced through an IPP. When Meritain Senior Business Analyst Kari Horton brought light to this issue (including remarking in bolded email text: "we are doing exactly what we said we would not do") and provided detailed documents demonstrating the problem to include an invoice for IPP drugs (one of which included Gilead's international GENVOYA®), Meritain favored its client relationship over compliance with its espoused no-international-sourcing policy. (ECF No. 151-26.) The evidence is that Meritain facilitated payment of bulk invoices it knew included internationally sourced drugs.

In February 2023, Meritain learned of what it referred to internally as the "international sourcing horror story," in which a U.S. patient received counterfeit medicine from ScriptSourcing's IPP, resulting in major physical harm to the patient. A mere four months later, in June 2023, Ms. Horton again rang alarm bells that Meritain continued to do "two things we've repeatedly said we won't do" – (manually) paying invoices for internationally sourced drugs and even doing it for customers using Meritain's in-house PBM, MPS. *Id.* In other words, in the face of what was recognized in-house as a "tragedy" resulting from known risks associated with IPP,

Meritain continued to process IPP invoices for clients in violation of what it espoused as its "policy."

Evidence includes still other examples of Meritain servicing IPP invoices contrary to its policy – and the tension between knowingly facilitating (and paying client invoices for) importation of internationally sourced drugs and a client base that wanted to include IPP as a member option. For example, for at least the six months between December 2021 and May 2022, Meritain paid invoices from AFP SmithRx that included internationally sourced prescription drugs. When concerns were raised in house – again involving Ms. Horton as well as the Head of Rx Market Development and a Senior Pharmacy Benefit Consultant – questions and suggestions were floated about declining to pay SmithRx invoices in whole going forward, and the possibility of trying to "recoup" what had "already been paid for international drugs." (ECF No. 152-8.) Meritain's Jeremy Hensel, echoed by Wisniewski, urged "be careful" because, in essence, customers might pursue other health care benefits systems as a consequence of not processing invoices for international drugs. (Hensel emailed the group chain: "We need to be careful as we are seeing this a lot in the cap and alternate space.") *Id.* Meritain also facilitated payment for member international prescription medicines from CanaRx, ProAct's international mail-order "partner," despite Meritain's attestation (through Mr. Wisniewski's deposition testimony) that it rejects these invoices for payment per its formal policy. (ECF No. 152-9.) Meritain was aware that CanaRx is a vendor that imports international prescription medications into the United States.[16]

Meritain did decline new business with ProAct after it learned it had been paying ProAct

[16] CanaRx has arranged for hundreds of international versions of Gilead-branded medicines to be shipped to ProAct U.S. client members, according to the ProAct spreadsheet introduced as Ex. G-195.

invoices for imported medications, but Meritain resumed its relationship with ProAct shortly thereafter based on Meritain's request that clients it shared with ProAct (as the carve-out PBM) confirm in writing they were not utilizing ProAct's international drug sourcing services. (Hearing Tr. I, ECF No. 222 at 40:18–45:19.) But Meritain never required a commitment from clients or vendors not to "turn [] on" international importation programs after making their initial confirmation, *see* ECF No. 161 at 230:20–231:6); in other words, apart from an assurance, Meritain never contractually conditioned its TPA services on client's not engaging in international drug sourcing through carve-out PBMs. And Meritain rarely refused to provide its TPA invoice administration services with carve-out PBMs it knew engaged in importation of prescription drugs for employee patients.

At bottom, although Meritain installed a no-international sourcing policy, it continued to do business with clients who used carve-out PBMs Meritain had actual knowledge engaged in international drug sourcing. Meritain, it seems at this stage, made a value call; to risk paying invoices for internationally sourced drugs, including through ProAct, rather than risk loss of client relationships it knew involved international sourcing, or to contractually prohibit clients from doing same.

Meritain's employees charged with the task of reviewing prescription drug benefit invoices for payment (the PBM operations team) and – per-policy – rejecting those that sought payment for internationally imported medications were reputed not to undertake their task with appropriate scrutiny. In a February 2024 email, for example, one Meritain analysist described not having "much faith" in this filtering mechanism. (ECF No. 152-34.) In short, Meritain's policy notwithstanding, whether based on economic reality or challenges in parsing out payable versus non-payable invoices, Meritain continued to provide TPA services that included referral to

international drug sourcing PBMs and payment of invoices for internationally sourced drugs for consumption by U.S. member patients.

As reflected above, Meritain maintains a patient eligibility feed with information about patients covered under a given client plan. This feed includes employee hire dates, dates of coverage termination for former employees, the applicable health plan, scope of prescription drug coverage, and other key data. This patient feed is essential to administration of pharmacy benefits – indeed, as Mr. Wisniewski testified, it is the "source of truth" for its PBM vendors. (Hearing Tr. I, ECF No. 222 at 23:25–24:9.) Meritain refers to the carve-out PBMs its customers use as "direct vendors" and provides these direct vendors with access to its patient eligibility data feed, including to those direct vendors it is aware engage in international prescription drug sourcing. Because, without the feed, the carve-out PBM cannot serve a member's prescription benefits needs.

In view of the foregoing as to Meritain's actual knowledge of PBMs passing on invoices for internationally imported drugs for prescriptions held by Meritain's employer members, and because Meritain's data feed is the "source of truth" with essential data for carve-out PBMs to process a prescription drug claim (be it a claim for domestically sourced drugs or those imported from outside the U.S.), Meritain is on notice that its patient eligibility data feed is used by direct vendors (carve-out PBMs) to fill U.S. prescriptions with internationally imported medicines, which are then submitted to Meritain for payment processing. Specifically, the evidence persuades the court that Gilead has made a clear showing that Meritain provides its patient data feed to (among other PBMs) ProAct and is aware that ProAct, as a carve-out PBM, facilitates importation of prescription medicines for U.S. patients, including Gilead-branded medicines like BIKTARVY®.[17] In turn, ProAct provides that same Meritain patient eligibility data feed to

[17] To be clear, the court recites these findings regarding Meritain's relationships and knowledge with respect to ScriptSourcing, SmithRx, and OptiMed because context and credibility are material to the court's evaluation of

entities, including Rx Valet, according to Rx Valet founder and CEO, Mr. Santulli.

As a result of this passing along of the patient eligibility data feed, and as described above, a Meritain client member (John Doe) had his prescription for U.S. BIKTARVY® administered by ProAct (as the carve-out PBM Meritain worked with for this particular client). ProAct, in turn, referred Doe (and conveyed the data feed) to AFP Rx Valet to get his prescription filled at the lowest possible cost (the heartbeat of Rx Valet's business). Rx Valet, by way of its exclusive mail order pharmacy, Advanced Pharmacy, had the prescription filled through prescription referral service (or "online pharmacy") Affordable Rx by way of Fetih Eczanesi, a pharmacy in Istanbul, Turkey. And, some days later, Mr. Doe wound up with three bottles of Turkish BIKTARVY®. And thus started the domino effect of Mr. Doe calling his clinic, the clinic complaining to Gilead, Gilead alerting the FDA, Gilead investigating, and ultimately filing suit.

To the view of the court, based on the testimony and documentary evidence offered at the preliminary injunction hearing, Meritain's internal no-international sourcing policy (to ensure it did not run afoul of what its internal emails repeatedly referred to as "compliance") threaten to dampen, or did dampen, Meritain's capacity to attract and maintain clients who wanted the option of internationally sourced prescription drugs because of the associated cost savings versus accessing only U.S.-based prescription formularies. So, while Meritain's MPS did (does) not reach outside of U.S. borders to fill prescriptions, the prospect of losing market share or stature either by contractually prohibiting clients from doing so through carve-out PBMs and/or, in turn, refusing to process carve-out PBM invoices for internationally sourced drugs was, apparently, not

Gilead's likelihood of success on the merits. In the view of the court, these relationships set out plain examples of repeated conduct that runs counter to Meritain's official no-international sourcing policy as a TPA working with carve-out PBMs like ProAct. The court appreciates that a likelihood of success as to Meritain's alleged contributory infringement must be premised on the actions of Defendants whom Gilead seeks to hold directly liable under Counts I and II.

something it was willing to do full stop. To be sure, Meritain has dropped certain carve-out PBMs from those with which it is willing to do business, but the evidence is plain, plentiful, and persuasive at this stage that Meritain's struggle to keep right with law and keep up with market competition fostered a willingness to yield when it determines the juice is worth the squeeze.

Meritain relies on several cases – chiefly, *Perfect 10, Inc. v. Visa Intern. Serv. Assoc.,* 494, F.3d 788 (9th Cir. 2006), and *Size, Inc. v. Network Solutions, Inc*., 255 F. Supp. 2d 568 (E.D. Va. 2003) – in support of its argument that Gilead has not sufficiently demonstrated (and cannot demonstrate) a likelihood of success as to Meritain's alleged contributory infringement. The authority on which Meritain relies clarifies that contributory infringement on grounds that a defendant provided its "product to one whom it knows or has reason to know is engaging in trademark infringement," *see Inwood Labs, Inc. v. Ives Labs, Inc.,* 456 U.S. 844 (1982), and *Rosetta Stone Ltd v. Google, Inc.,* 676 F.3d 144, 163 (4th Cir. 2012), *supra*, cannot rest on conduct that is merely "passive," like processing credit card payments in the case of *Perfect 10*, or registering domain names in the case of *Size, Inc*.

These cases are inapposite. Based on the record before the court, Gilead has made a clear showing of a likelihood of success in demonstrating that Meritain knowingly and repeatedly provided its member employee data feed (Meritain's "source of truth" product with critical benefits coverage member data) to carve-out PBMs it was not merely aware were engaged in international drug sourcing, but to which it referred Meritain clients for precisely that purpose; and that without that Meritain data feed, carve-out PBMs could not service Meritain clients. Gilead has further clearly shown it will likely prove that Meritain had actual knowledge that – contrary to Meritain's written policy – it processed invoices for imported drugs (including Gilead-branded drugs) and that it engaged in deliberate, reflective internal decision-making among Meritain higher-ups to

choose to continue to process invoices for international drugs rather than risk client alienation or negative market consequences. In short, the record before the court does not permit favorable comparison of Meritain to the defendants in the authority on which it relies for this purpose. Providing a critical product without which infringement could not have occurred; continuing to do so despite actual knowledge of alleged infringement conduct; and then paying the invoices showing the alleged infringing conduct is not provision of a merely passive service.

4. ProAct – Contributory Infringement

As a PBM, a core function of ProAct's services are what it refers to as "adjudicating" claims submitted by covered plan members (*i.e.*, client/plan sponsor employees covered by the self-funded plan). ProAct maintains a U.S.-based network of retail, mail order, and specialty pharmacies to which its clients have access. Thanks to modern technology, when a plan member presents a prescription at, for example, an in-network retail pharmacy, upon submission of the prescription to the pharmacist, ProAct's computer system adjudicates the claim in real time – which is to say, in an internet blip of time, the pharmacist is provided coverage information (via ProAct's system). For example, a given prescription may be covered based on the eligibility data ProAct has on file for that member (provided by the TPA) – in which case, the prescription is filled as presented; ProAct pays the pharmacy and, in turn, bills the client.

Part of this real time eligibility verification includes checking (electronically) for what ProAct calls "system edits" (or codes) connected to the particular prescription the plan member is trying to fill. Where an eligibility verification reveals a system edit for whatever drug the member has been prescribed, ProAct's computer system sends the pharmacist a "special instruction" to convey to the member; the "special instruction" includes a message that the prescription is rejected for plan coverage at the U.S. pharmacy. (All of this happens in the blink of an eye while the

member is standing at the pharmacy counter.) In sum, depending on a client's plan benefits, certain drugs generate a system edit when a member tries to fill a prescription for that drug at the neighborhood pharmacy, which effectively results in that U.S. pharmacy declining to fill the prescription.

Relevant to this action, an example of a system edit in action is where a pharmacist is advised (electronically via ProAct's instant verification system) to instruct the member that the particular drug is rejected for fulfillment at that U.S. pharmacy and, instead, the member patient should contact an AFP (like Rx Valet) to fill the prescription (at a reduced or no cost). In such instances, ProAct's system is coded with drug pricing tiers whereby the U.S. patient member is given the (some might say Hobson's) choice of paying a 100% copay for domestic brand-name prescription medicine (like, for example, U.S. BIKTARVY®) (which is to say, the patient pays the full retail drug price out of pocket with no portion of the cost covered by insurance) or contacting the entity to which the patient is referred (like, for example, Rx Valet) to obtain the drug from an international pharmacy for free or at a price far below the 100% copay. In sum, unless a member chooses to pay 100% retail out of pocket for the prescription, ProAct's system edit program delivers the member patient to an entity that engages in international drug sourcing.

Understanding why system edits exist requires a broader appreciation of how self-funded plans can be designed. ProAct's post-hearing brief succinctly explains:

> ProAct is not always the exclusive provider of pharmacy benefit services to its clients. Just as a plan sponsor may "carve out" its pharmacy benefits to a PBM [(*e.g.,* using carve-out PBM ProAct instead of Meritain's in-house MPS)], it may further "carve out" certain parts of its pharmacy benefits plan by contracting with an external vendor to manage some plan features. The services offered by external vendors include various cost-containment solutions, one of which could be international sourcing of prescription drugs.

(ECF No. 239 ¶ 11; citations omitted.)

In other words, if a plan sponsor (a self-funding employer) can save money by having certain pharmacy/drug benefits administered by yet another entity, the sponsor can "carve out" those specific, isolated benefits. So, for example, when a member goes to fill a prescription subject to that special carve out – the pharmacist is instructed by a ProAct-generated code (the "system edit") to advise the member that the prescription is not covered for filling at that pharmacy[18] and to contact the other carve-out external vendor to get the prescription filled. The plan sponsor saves money when, for example, relevant here – the carve-out external vendor gets the drug from an international source for less money than it costs when filled by a U.S. pharmacy. And that is because, generally speaking, brand name drugs like BIKTARVY® are more expensive in the U.S. than in other countries, like India or Turkey; therefore, a plan sponsor may "carve out" certain brand name drugs to take advantage of this plan costs savings.

Although ProAct does not itself internationally source drugs, about 40 percent of its clients use the above-described third-party carve out vendor approach to take advantage of internationally sourced drugs for less money than were those drugs obtained through a U.S.-based manufacturer/seller. For ProAct clients that want international sourcing, ProAct directs them to companies it knows provide international drug sourcing, including Rx Valet and other entities like CanaRx – including for Gilead-branded drugs like BIKTARVY®. But ProAct does more than provide a reference.

ProAct partners with various vendors (that ProAct, it asserts, considers "safe and effective") that engage in international sourcing of medications. ProAct facilitates, and plays an integral role in, those programs by operation of the programmed system edits described above, because when a system edit instructs the U.S. pharmacy (which, of course, dispenses only U.S.

[18] Or, as ProAct corporate representative David Schryver put it, the prescription is "rejected . . . at the point of sale." (Hearing Tr. I, ECF No. 222 at 181:2–7.)

medicines) to reject the prescription, the member patient is referred to one of the entities that ProAct works with to source the prescribed drug through an international source (*i.e.*, to get the prescription filled by a non-U.S. pharmacy that fills the prescription with a non-U.S. version of the drug).

Importantly, after instructing (via a system edit message) the member patient's local pharmacy to decline to fill the prescription as a covered plan benefit, ProAct refers its client's member patient to one of its international sourcing partners, such as Rx Valet, and provides that international sourcing entity (like Rx Valet) with access to the critical patient data feeds from TPAs like Meritain. International drug sourcing entities, like Rx Valet, rely on these data feeds provided by ProAct (by way of the TPA, like, for example, Meritain) to identify eligible patients for its international sourcing programs.[19]

ProAct urges that it does not contract with the international drug sourcing companies to which it refers such plan members, and that when it makes such a referral, it is merely following the terms of the client's plan. But ProAct's involvement does not end at the referral. In many instances, once the member's prescription has been filled with a non-U.S. drug (the member having responded to ProAct's programmed "system edit" by getting the prescription filled through the non-U.S. vendor ProAct suggested), ProAct has paid the invoices for those international medicines as part of its client service. And there can be no question based on the current record before the court that ProAct has actual knowledge that the these carve-out vendors engage in importation of prescription medications, because that is precisely the reason for the system edit and resulting referral.

ProAct and Rx Valet worked together to refer ProAct clients to Rx Valet's international

[19] As described earlier, according to the record before the court, this is precisely what is alleged to have happened to John Doe when he went to his U.S. pharmacy to have his BIKTARVY® prescription filled.

sourcing program for those ProAct clients with pharmacy benefit plans that include international drug sourcing options. By way of example, as relayed above, according to the record before the court, when John Doe went to fill his prescription for U.S. BIKTARVY®, ProAct (the carve-out PBM through TPA Meritain) generated a system edit rejection at the point of sale, and referred Doe to Rx Valet to fill his prescription for BIKTARVY®. According to the direct examination testimony of ProAct's corporate representative, David Schryver, in 2024, ProAct processed and paid for more than 100 claims for internationally sourced Gilead-branded drugs – which included BIKTARVY®.[20] ProAct emphasizes that this represents a small fraction of ProAct's total claims processed for international drugs during that period.

In sum, the court is satisfied that Gilead has made a clear and strong showing that it is likely to succeed on the merits of Counts I and II as against ProAct operating under a theory of contributory liability. Evidence is robust that ProAct, by design, acts as a mechanism and essential conduit of key data and information to deliver plan members with prescriptions for U.S. Gilead-branded drugs to international sourcing vendors like Rx Valet.

5. The Quartet Defendants: Rx Valet, Advanced Pharmacy, Gregory Santulli, and Affordable Rx – Direct Infringement

AFP Rx Valet describes itself as a "pharmacy savings program" that provides "international sourcing" services to provide U.S. patients with prescription drugs from foreign pharmacies. Prior to issuance of the TRO in this action, Rx Valet's website advertised the provision of international Gilead-branded medicines (including display of Gilead registered trademarks), and, through its international sourcing program, Rx Valet ordered international

[20] As briefly referenced above, ProAct also works CanaRx, an international drug importation service ProAct advertises as its "international partner." ProAct assisted in developing CanaRx's international formulary – a list of international medicines that CanaRx offers to ProAct's U.S. members – which, until the issuance of the temporary restraining order, included Gilead-branded BIKTARVY®. Mr. Schryver testified on direct that Gilead's BIKTARVY® was "slated to be removed" from the CanaRx international formulary in January 2025, and Gilead's GENVOYA® had been on the international CanaRx formulary but was removed in July 2024.

Gilead-branded medicines – including Turkish BIKTARVY® – to be delivered to patients in the United States.[21]

As referenced earlier, according to Mr. Santulli (founder and CEO of Rx Valet, and President of Advanced Pharmacy), Advanced Pharmacy is Rx Valet's "contracted pharmacy." (Hearing Tr. I, ECF No. 222 at 226:10–11.) Advanced Pharmacy purchases and sells international Gilead-branded medications, including Turkish BIKTARVY®, for direct shipment to U.S. patients who have been referred to Rx Valet through PBMs (like ProAct) when a self-funded client health plan includes internationally sourced drugs within its formulary. Advanced Pharmacy pays international sourcing vendors (like Affordable Rx) to fill prescriptions for international Gilead-branded medicines for consumption by U.S. patients with prescriptions from U.S. healthcare providers (like John Doe's Howard County clinic physician). According to the record evidence, including testimony of Gregory Santulli, upon receipt of a prescription from a U.S. healthcare provider (like John Doe's clinic), Advanced Pharmacy enters the prescription into its internal database to which Rx Valet employees have access in order to transmit the prescription to Rx Valet's international sourcing connection (like Affordable Rx) to be filled with imported non-U.S. medications.

As set forth earlier, Gregory Santulli is the CEO and founder of Rx Valet, and the president and sole owner of Advanced Pharmacy; he is the sole member of Advanced Pharmacy, and one of three members of Rx Valet. He describes himself as very active and engaged in the business of Rx Valet; he designed its business plan, signed all Rx Valet contracts with health plans for the

[21] The record before the court includes Rx Valet records showing that, in April 2024, Gilead-branded BIKTARVY® and DESCOVY® were among the top 20 drugs Rx Valet obtained through international sourcing; and invoices from international drug sourcing entities Canada Script and RxFree4Me to Rx Valet for international Gilead-branded drugs Rx Valet ordered for delivery to U.S. patients.

provision of international drug sourcing services, and leads "implementation calls" regarding Rx Valet's international sourcing service. As demonstrated by Mr. Santulli's business emails describing the scope of Rx Valet's international sourcing, as well as the company's website, Rx Valet (through Mr. Santulli) describes and advertises its international importation services to include Gilead-branded medicines, including BIKTARVY®. Moreover, although a bookkeeper manages the paperwork and related minutiae, Mr. Santulli is the responsible officer for approval of payments for international medicines from Rx Valet and Advanced Pharmacy.

Affordable Rx's business includes placing orders for international Gilead-branded medicines, including Turkish BIKTARVY®, to be delivered to patients throughout the United States. As described above, by way of the Meritain-to-ProAct-to-Rx Valet-to-Advanced Pharmacy-to-Affordable Rx-to- Fetih Eczanesi pipeline, Affordable Rx sourced and ordered the Turkish BIKTARVY® for delivery to patient John Doe in Maryland. As a prescription referral service (known casually as an "online pharmacy"), Affordable Rx's business is the sourcing and acquisition of non-U.S. medications for direct shipment to U.S. patients. Prior to entry of the TRO, among the medications Affordable Rx advertised on its website were international Gilead-branded medicines and non-U.S. generic versions of Gilead-branded medicines, including BIKTARVY®.

In sum, based on the foregoing findings, the court is well satisfied that Gilead has met its burden to demonstrate a clear likelihood of success as to the merits of Counts I and II as against each of the Quartet Defendants for direct liability for trademark infringement and unfair competition in violation of the Lanham Act. Gilead is likely to prove on the merits that each of them used uncontested Gilead Marks, absent Gilead's consent, in connection with the sale, distribution, advertising, and offering of sale of their respective goods and/or services as described above; and their actions caused actual consumer confusion and are likely to continue to do so if

left unabated by injunctive relief.

6. Fetih Eczanesi – Direct Infringement

Regarding Defendant Fetih Eczanesi, the court is satisfied that Gilead has presented uncontested, credible evidence that Fetih Eczanesi was the Istanbul, Turkey pharmacy source of the Gilead-branded Turkish BIKTARVY® shipment to John Doe (through the Meritain-to-ProAct-to-Rx Valet-to-Advanced Pharmacy-to-Affordable Rx-to-Fetih Eczanesi stream of commerce). Based on the above findings, Gilead has met its burden to demonstrate a clear likelihood of success as to the merits of Counts I and II as against Defendant Fetih Eczanesi for direct liability for trademark infringement and unfair competition in violation of the Lanham Act. Specifically, Gilead is likely to prove on the merits that Fetih Eczanesi used uncontested Gilead Marks, absent Gilead's consent, in connection with the sale and distribution of pharmaceutical drugs and related shipping services; and that its actions caused actual consumer confusion and are likely to continue to do so if left unrestrained.

7. Standing – Meritain and ProAct

As mentioned in footnote 8, *supra*, Meritain (and ProAct by adoption) asserts that Gilead has failed to demonstrate they are "'likely' to establish standing" at the preliminary injunction stage. Meritain and ProAct do not pose a challenge that Gilead's Complaint plausibly alleges facts sufficient to establish standing at the pleading stage; rather they challenge the sufficiency of Gilead's showing of a likelihood of standing to sue Meritain and ProAct at the preliminary injunction stage.

Specifically, in its post-hearing brief, Meritain (and, by adoption, ProAct) asserts that Gilead has failed to establish it has standing because, according to Meritain, "there is no evidence that Meritain 'paid' the invoice for John Doe's BIKTARVY®;" "there is no evidence that Meritain

provided Doe's eligibility feed to any other Defendant;" "there is no evidence that Meritain referred Doe or his plan sponsor to ProAct's or Rx Valet's international sourcing program" – and that at the preliminary injunction hearing, Mr. Wisniewski testified Meritain "has not provided referrals to any vendors who Meritain knows source prescription medications from outside the United States." Further, because Meritain's alleged contributory infringement is built on the alleged direct infringement of other Defendants, Meritain contends the evidence does not support the requisite standing connection (*e.g.*., Gilead cannot rest its likelihood of success against Meritain based on payment of ScriptSourcing IPP invoices).

As set forth by the Supreme Court in the oft-cited *Lujan v. Defenders of Wildlife,* 504 U.S. 555 (1992):

> Over the years, our cases have established that the irreducible constitutional minimum of standing contains three elements. First, the plaintiff must have suffered an "injury in fact"—an invasion of a legally protected interest which is (a) concrete and particularized and (b) "actual or imminent, not 'conjectural' or 'hypothetical,'" Second, there must be a causal connection between the injury and the conduct complained of—the injury has to be "fairly ... trace[able] to the challenged action of the defendant, and not ... th[e] result [of] the independent action of some third party not before the court." Third, it must be "likely," as opposed to merely "speculative," that the injury will be "redressed by a favorable decision."
>
> The party invoking federal jurisdiction bears the burden of establishing these elements. Since they are not mere pleading requirements but rather an indispensable part of the plaintiff's case, each element must be supported in the same way as any other matter on which the plaintiff bears the burden of proof, *i.e.,* with the manner and degree of evidence required at the successive stages of the litigation. At the pleading stage, general factual allegations of injury resulting from the defendant's conduct may suffice, for on a motion to dismiss we "presum[e] that general allegations embrace those specific facts that are necessary to support the claim." In response to a summary judgment motion, however, the plaintiff can no longer rest on such "mere allegations," but must "set forth" by affidavit or other evidence "specific facts," FED. R. CIV. P. 56(e), which for purposes of the summary judgment motion will be taken to be true. And at the final stage, those facts (if controverted) must be "supported adequately by the evidence adduced at trial."

504 U.S. at 560–62 (citations omitted).

On this issue, *Delmarva Fisheries Ass'n, Inc. v. Atlantic States Marine Fisheries Comm'n,* 127 F.4th 509, 514–15 (4th Cir. 2025), is helpful:

> [W]hen plaintiffs meet their burden to establish standing for purposes of the *pleading* stage but fail to show a substantial likelihood of success on the merits—including when they fail to show a substantial likelihood that they have standing—we affirm the denial of the preliminary injunction but allow the case to progress as usual below, rather than remanding with instructions to dismiss for lack of standing. *See Elec. Priv. Info. Ctr. v. U.S. Dep't of Com.*, 928 F.3d 95, 104 (D.C. Cir. 2019) (explaining that it is appropriate to affirm the denial of a preliminary injunction if a plaintiff fails to "establish[ ] a substantial likelihood of standing" at the preliminary injunction stage, but that it is appropriate to remand with instructions to dismiss if a plaintiff "cannot establish standing *as a matter of law*" (internal quotation marks omitted)); *see also Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561, 112 S.Ct. 2130, 119 L.Ed.2d 351 (1992) ("[E]ach element [of standing] must be supported in the same way as any other matter on which the plaintiff bears the burden of proof, *i.e.*, with the manner and degree of evidence required at the successive stages of the litigation.").

It bears repeating that, at the preliminary injunction stage, a plaintiff is not burdened with proving the merits of its claims by a preponderance of evidence such as it would be to prevail on the merits to secure judgment; rather, a plaintiff movant must make a clear showing of a likelihood of success (and satisfy the other *Winter* factors). Here, the court is satisfied that Gilead has established standing in the manner and to the degree necessary for imposition of a preliminary injunction in accordance with Rule 65 and the *Winter* factors, and as guided by the above-cited Supreme Court and Fourth Circuit jurisprudence. Gilead has established to the appropriate degree the requisite injury in fact to their commercial interests; it has persuasively made a strong showing the Meritain (and ProAct) played a material, causative role in that injury (infringement and unfair competition traced to the complained-of conduct); and it has made a strong showing that their commercial injuries are redressable (at least in part) by the requested relief in the Motion.

Specifically, the court is satisfied that Gilead has established a substantial likelihood of standing (to establish a likelihood of success) against Meritain based on a confluence of evidence

before the court. In addition to the above recited findings of fact, the court favorably credits and considers sworn declarations provided regarding fulfillment of John Doe's prescription for BIKTARVY®. Investigator Brian Cairl, Senior Managing Director of K2 Investigations attests (ECF No. 11-4) that Doe's healthcare clinic confirmed to him on review of Doe's file that his health insurance policy was with "Aetna Meritain" at the time he received the Turkish BIKTARVY®. Further, Harpreet Dhanota, Director of Gilead's Anti-Counterfeiting and Global Product Security, attests that John Doe's clinic informed her "that the patient had been prescribed BIKTARVY® for years, but that he now had a new insurance provider, Meritain Health, with a new [PBM], ProAct. The clinic reported that the patient had been referred by ProAct to a company called Rx Valet to fill his BIKTARVY® prescription." (ECF No. 11-7 ¶ 6.)

Adding to this, Mr. Wisniewski expressly testified (on direct examination by counsel for Meritain and on questioning by the court for clarification) that it is industry standard for a TPA to provide the patient eligibility data feed to a client's carve-out PBM. Mr. Wisniewski testified:

> THE COURT: And that process or that function is part of a standard portion of the service that Meritain offers its clients, correct?
>
> THE WITNESS: Correct.
>
> THE COURT: Okay.
>
> BY MR. GARLOUGH: Q. And picking up on that, [Mr. Wisniewski], in your experience in the industry, is that common for the TPA who is responsible for administering health benefits to provide eligibility data to the PBM?
>
> A. Yes, yes. Standard is wherever -- whoever holds the medical plan kind of becomes like the source of truth for any other ancillary vendors that are connecting back to that health plan, and that's where the eligibility will come originate from the health plan, and then go out to kind of all the other ancillary vendors.
>
> Q. So in providing eligibility data to a carve-out PBM, is Meritain doing anything unusual in the industry?

A. No, it's standard practice.

(Hearing Tr. I, ECF No. 222 at 23:19–24:12.)

The court observes further that establishment of Article III standing for purposes of the Motion does not necessitate that Gilead prove or produce evidence that Meritain paid the invoice for the Turkish BIKTARVY® John Doe received. The court is satisfied that Gilead has demonstrated a substantial likelihood of standing (to establish the requisite likelihood of success on the merits) as to Meritain's contributory infringement and unfair competition under Counts I and II at the very least in connection with the provision of its patient eligibility data feed to outfits it knew (or should have known) were engaged in illegal importation of non-U.S. Gilead-branded medicines, including BIKTARVY®; as well as training its salesforce to combat the "myth" that Meritain's services do not include IPP (or IPP access through a "best in class" referral).

With respect to ProAct, the court is well-satisfied that Gilead has met its Article III standing burden as to commercial injury, causal connection, and redressability. The preliminary injunction record evidence is strong as to ProAct's use of the client eligibility data feed (provided by Meritain) to cause Doe's BIKTARVY® prescription to be rejected at the point of sale and to ensure he was passed to ProAct's "partner" Rx Valet for acquisition of non-U.S. BIKTARVY® through international sourcing.

For these reasons, in addition to the myriad factual findings relayed above, the court concludes that Gilead has established Article III standing as to Meritain and ProAct to the degree necessary to maintain this action and the request for preliminary injunctive relief at this juncture of the action. In sum, Gilead has leapt the Article III hurdle.

8. Doctrine of Laches

The Quartet asserts that the doctrine of laches prevents entry of the requested relief.

Therefore, the court recites the applicable law here. "Courts apply laches to address the inequities created by a trademark owner who, despite having a colorable infringement claim, has unreasonably delayed in seeking redress to the detriment of the defendant." *Ray Comms., Inc. v. Clear Channel Comms., Inc*. 673 F3d 294, 300–302 (4th Cir. 2012) (citing *Sara Lee Corp. v. Kayser–Roth Corp.,* 81 F.3d 455, 461 (4th Cir. 1996); *Brittingham v. Jenkins,* 914 F.2d 447, 456 (4th Cir. 1990)). "In determining whether laches operates as a defense to a trademark infringement claim, we consider at least the following factors: (1) whether the owner of the mark knew of the infringing use; (2) whether the owner's delay in challenging the infringement of the mark was inexcusable or unreasonable; and (3) whether the infringing user has been unduly prejudiced by the owner's delay." *Id.* (citations omitted). Because laches is an affirmative defense, the burden of proving laches rests with the defendant proposing its application – here, the Quartet Defendants. *See Ray Comms., Inc.,* 673 F.3d at 307 (citing with favor *Vineberg v. Bissonnette,* 548 F.3d 50, 58 (1st Cir. 2008), for this purpose).

The first factor is determined based on an objective standard. *Ray Comms*., 673 F3d at 301. In evaluating the second factor, the Fourth Circuit advises that "that delay must be measured from the period at which the trademark owner knew or should have known of an infringing use." *Id.* at 304. Courts refer to the analogous state statute of limitations (here, three years per MD. CODE ANN., CTS. & JUD. PROC. § 5-101) as a guide in evaluating whether a delay is unreasonable for purposes of laches; and some circuits impose a strong presumption that laches does not apply if action was pursued within the analogous state limitations period. *Lyons P'ship, L.P., v. Morris Costumes, Inc.*, 243 F.3d 789, 799 (4th Cir. 2001) (explaining that "when federal courts, in the exercise of their equitable power, consider laches, they are guided by the limitations period that they would borrow for actions at law and presume that if an equitable claim is brought within the

limitations period, it will not be barred by laches"); s*ee Lyond Reno Air Racing Ass'n, Inc. v. McCord*, 452 F.3d 1126, 1138–39 (9th Cir. 2006) (same principle); *Tandy Corp. v. Malone & Hyde, Inc.*, 769 F.2d 362, 366 (6th Cir. 1985) (same principle). Finally, claimed prejudice must be established with "specific evidence." *Ray Comms.*, 673 F.3d at 307. Mere delay, the prospect of generalized harm, and the like – absent more – is insufficient. *Id.*

Further, while laches (if proven) "*may* act as a bar to both monetary and injunctive relief under certain circumstances, this result is not automatic." *Id.* at 307 (emphasis in original). "The doctrine [of laches] is sparingly applied where . . . a plaintiff seeks only equitable relief." *See id.* (quoting *Sara Lee Corp. v. Kayser-Roth Corp.*, 81 F.3d 455, 461 (4th Cir. 1996)). Although the present posture of this action is on a motion for preliminary injunction, Gilead's Complaint demands permanent injunctive relief, statutory damages, actual damages, disgorgement of profits, "remedial costs," punitive damages, and attorneys' fees. (ECF No. 1 at pp. 39–40.) Also of note, "in consideration of the public interest, estoppel by laches may not be invoked to deny injunctive relief if it is apparent that the infringing use is likely to cause confusion." *Sara Lee*, 81 F.3d at 461 (citing Thomas McCarthy, *McCarthy on Trademarks and Unfair Competition*, § 31.04 (3d ed. 1995), and *Univ. of Pittsburgh v. Champion Products, Inc.,* 686 F.2d 1040, 1044 (3d Cir. 1982), *cert. denied,* 459 U.S. 1087 (1982)).

Here, as the Quartet complains, several months – 10, in fact – passed between the time Doe's clinic lodged a quality complaint/concern with Gilead and when Gilead instituted this action. In that time, Gilead immediately alerted and worked with the FDA to address regulatory non-compliance and concerns about patient safety. Also during that time, Gilead conducted an in-house evaluation of what happened to figure out how (and why) a U.S. BIKTARVY® patient received shipments of international (Turkish) BIKTARVY® from a pharmacy he had never heard

of and did not ask to fill his prescription; Gilead's effort also included working with the Turkish government to track the source of the shipment to Defendant Fetih Eczanesi in Istanbul.

Assuming, without finding, that the Quartet meets the objectively evaluated first factor as to when Gilead knew of the alleged infringement, the court finds the delay (from January/February 2024 to December 2024) is not unreasonable. The court finds it reasonable and appropriate that Gilead waited to pursue litigation while it worked with the FDA – the regulatory agency charged, in part, with ensuring patient and drug safety through compliance with federal regulations; it is reasonable and appropriate that Gilead considered that it might be able to avoid the devotion of resources (of all manner) to litigation if the FDA might effectively solve the problem and protect its (and patients') interests.

Further, rather than file action absent a reasonably clear picture of the "who, what, where, why, when," and risk lodging wobbly or unfounded allegations and claims, Gilead acted prudently and appropriately conservatively both from a Rule 11 perspective and a merits perspective. *See Sara Lee,* 81 F.3d at 462 (discussing the "conundrum" mark holders often face between "rushing immediately into litigation" with "little or no evidence" and thus risking the appearance of "'shooting from the hip'" and waiting and risking a laches affirmative defense). In this instance, the delay in time was not rooted in a lack of diligence by any stretch. And, although not determinative, the court notes that Gilead initiated action well within Maryland's analogous statute of limitations. Finally, as set forth herein, Gilead has clearly demonstrated a strong likelihood of success as to continued customer confusion in connection with its Lanham Act Counts I and II. As noted above, "in consideration of the public interest, estoppel by laches may not be invoked to deny injunctive relief if it is apparent that the infringing use is likely to cause confusion." *Id.* at 461 (citations omitted).

As to the third factor, the Quartet has deduced no evidence of prejudice resulting from the 10-month delay.

Therefore, the doctrine of laches poses no bar to Gilead's requested relief in its Motion.

9. Unclean Hands

The Quartet asserts that Gilead is not entitled to relief based on the doctrine of unclean hands, an affirmative defense to equitable claims under the Lanham Act.[22] *See e.g.*, *De Beers LV Trademark Limited v. DeBeers Diamond Syndicate, Inc.,* No. 04 Civ.4099 (DLC), 2005 WL 1164073, at *3 (S.D.N.Y. May 18, 2005); *Warner Bros., Inc. v. Gay Toys, Inc.,* 724 F.2d 327, 334 (2d Cir. 1983).

> "The doctrine of unclean hands is based on the principle that since equity tries to enforce good faith in defendants, it no less stringently demands the same good faith from the plaintiff." *Dunlop-McCullen v. Local 1-S, AFL-CIO-CLC,* 149 F.3d 85, 90 (2d Cir.1998) (citation omitted). Misconduct that is "unrelated to the claim to which it is asserted as a defense," however, "does not constitute unclean hands." *Id.* (citation omitted). Thus, "the defense of unclean hands applies only with respect to the right in suit." *Id.* (citation omitted).

De Beers, 2005 WL 1164073, at *3.

In other words, unclean hands in the context of the Lanham Act is an affirmative defense to liability where the defendant demonstrates that the plaintiff acquired its rights in the mark under circumstances involving the plaintiff's bad faith. This is materially distinct from a defendant's complaint that the plaintiff has engaged in objectionable market conduct with its product bearing the mark at issue in the action.

[22] The Quartet does not reference unclean hands in its post-hearing brief at ECF No. 238, but has asserted its application several times to this point, including in its opposition to the Motion at ECF No. 114 and several times during the period of expedited discovery (through discovery dispute papers). Inasmuch as the court invited the parties to use post-hearing briefing for proposed findings of fact and otherwise as they saw fit, the court does not construe the Quartet to have abandoned its unclean hands argument, and so the court addresses its application.

No facts, evidence, or argument has been presented to suggest that Gilead acquired its rights in any of its registered marks – including without limitation BIKTARVY® – under means suggestive of bad faith, dishonesty, fraud, or ill motive. At this juncture, the doctrine of unclean hands has no application and poses no bar to Gilead's requested relief in the Motion.

10. Federal Food, Drug, and Cosmetic Act – 21 U.S.C. § 301, *et seq*.

Defendants Meritain and ProAct urge that Gilead conflates the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301, *et seq*.; the "FDCA") with the Lanham Act.

The FDCA "is designed primarily to protect the health and safety of the public at large." *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 108 (2014) (citing 21 U.S.C. § 341 and other authorities); *see also Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993) (same). Relevant here, with certain discretely regulated exceptions not relevant here, the FDCA prohibits the importation of prescription drugs from overseas by anyone other than the manufacturer. *See* 21 U.S.C. § 384.

"The Lanham Act is primarily intended to protect commercial interests . . . . It provides a private remedy to a commercial plaintiff who meets the burden of proving that its commercial interests have been harmed by a competitor's false advertising," trademark infringement, unfair competition, and related commercial torts set forth in the Act. *Mylan Labs., Inc.*, 7 F.3d at 1139 (quoting *Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 230 (3d Cir. 1990)); *see also POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 107 (2014) (providing: "[t]hough in the end consumers also benefit from the [Lanham] Act's proper enforcement, the cause of action is for competitors, not consumers").

Importantly, the FDCA does not provide a private right of action. 21 U.S.C. § 337 (providing that all FDCA actions "shall be by and in the name of the United States" except for

certain actions which states may bring). Accordingly, where a private action brought under the Lanham Act necessarily requires a court interpret or apply the FDCA to reach the merits, the plaintiff's action is disallowed as an improper effort to conscript the Lanham Act as a "vehicle by which to enforce the FDCA." *Impact Apps., Inc. v. Concussion Mgmt, LLC*, No. 19-3108, 2021 WL 978823, at *5 (D. Md. Mar. 16, 2021) (quoting *Mylan Labs.*, 7 F.3d at 1139)).

As well explained by *Impact Apps*:

> For example, "a plaintiff may not maintain a Lanham claim alleging only that the defendant has failed to disclose that the FDA has not approved its product." Nor may a plaintiff bring a claim "that the very *act* of placing a drug on the market ... somehow implies (falsely) that the drug had been 'properly approved by the FDA.'" Such theories are, "quite simply, too great a stretch under the Lanham Act." However, affirmative misrepresentations, including an explicit false statement of FDA approval, are generally actionable, even if the product is regulated by the FDA.

2021 WL 978823, at *5 (quoting *Braintree Labs., Inc. v. Nephro-Tech, Inc.*, No. 96-2459-JWL, 1997 WL 94237, at *6 (D. Kan. Feb. 16, 1997), and *Mylan Labs., Inc.*, 7 F.3d at 1139).

It bears mentioning that, while the holdings of *Impact Apps* and the cases cited therein remain good law and are not in question, those cases relate to false advertising claims under the Lanham Act – where the plaintiffs alleged that the very presence of the defendant's product on the market improperly and incorrectly implied to the consuming public that the product was FDA-approved, and, as such, affirmatively misrepresented the product in the vein of Lanham Act false advertising. Those courts soundly concluded that the actions sounded in the FDCA not the Lanham Act, because the plaintiff's claim relied on the too-attenuated, transitive line of thought that the defendant's product's presence on a store shelf implied FDA clearance and thus amounted to the false or misleading statement of fact a Lanham Act false advertising claim requires; and, because of this, the actions were more akin to standing in the shoes of a "hoodwinked" consumer (*POM Wonderful LLC,* 573 U.S. at 108), which is the job of the FDCA, versus redeeming a competitor's

commercial injury (which is the domain of the Lanham Act). In sum, the "mere" placement-on-the-store-shelf-as-statement-of-false-fact was the bridge too far referenced by the *Impact Apps* court (referring to the theory as "too great a stretch"). And, while not determinative of the inquiry, it bears reminding the reader that the instant action does not include a Lanham Act false advertising claim; and the Motion seeks injunctive relief on Counts I and II for trademark infringement and unfair competition.

Drilling down, it's not an either or thing. Simply because a defendant's conduct violates the FDCA does not remove a plaintiff's entitlement to pursue claims under the Lanham Act if the requisite elements are met. Said another way, the FDCA does not bar (or preempt) recovery under the Lanham Act simply because the claim (be it for infringement, unfair competition, or false advertising) is founded on allegations of conduct also prohibited by the FDCA, provided adjudication of the Lanham Act claim does not require interpretation or application of the FDCA. Indeed, where an action includes alleged conduct that at once amounts to violations of the Lanham Act and the FDCA, the statutes are happy bedfellows according to the Supreme Court.

The Supreme Court's in-depth analysis of the intersection of the Lanham Act and the FDCA in *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102 (2014), offers a rather helpful education. There, POM Wonderful (makers of pomegranate juice drinks) brought a false advertising Lanham Act action against Coca-Cola for deceptive labeling of a drink product as "pomegranate blueberry." The parties tussled over the effect, if any, of the FDCA on the Lanham Act action.

> Beginning with the text of the two statutes, it must be observed that neither the Lanham Act nor the FDCA, in express terms, forbids or limits Lanham Act claims challenging labels that are regulated by the FDCA. . . . [T]he FDCA, by its terms, does not preclude Lanham Act suits. In consequence, food and beverage labels regulated by the FDCA are not, under the terms of either statute, off limits to Lanham Act claims. No textual provision in either statute discloses a purpose to

> bar unfair competition claims [].
>
> This absence is of special significance because the Lanham Act and the FDCA have coexisted since the passage of the Lanham Act in 1946. . . .
>
> The Lanham Act and the FDCA complement each other in major respects, for each has its own scope and purpose. Although both statutes touch on food and beverage labeling, the Lanham Act protects commercial interests against unfair competition, while the FDCA protects public health and safety. The two statutes impose "different requirements and protections."
>
> The two statutes complement each other with respect to remedies in a more fundamental respect. Enforcement of the FDCA and the detailed prescriptions of its implementing regulations is largely committed to the FDA. The FDA, however, does not have the same perspective or expertise in assessing market dynamics that day-to-day competitors possess. Competitors who manufacture or distribute products have detailed knowledge regarding how consumers rely upon certain sales and marketing strategies. Their awareness of unfair competition practices may be far more immediate and accurate than that of agency rulemakers and regulators. Lanham Act suits draw upon this market expertise by empowering private parties to sue competitors to protect their interests on a case-by-case basis. By "serv[ing] a distinct compensatory function that may motivate injured persons to come forward," Lanham Act suits, to the extent they touch on the same subject matter as the FDCA, "provide incentives" for manufacturers to behave well. Allowing Lanham Act suits takes advantage of synergies among multiple methods of regulation. This is quite consistent with the congressional design to enact two different statutes, each with its own mechanisms to enhance the protection of competitors and consumers.

POM Wonderful LLC v. Coca-Cola Co., 573 U.S. 102, 113–17 (2014) (citations omitted).[23]

Nothing in Count I or Count II (or the Motion generally) calls upon the court to evaluate or apply the FDCA. The FDCA poses no barrier to Gilead's requested relief in its Motion.

11. Summary – Likelihood of Success on the Merits

For the reasons, and based on the findings, set forth above, the court finds that Gilead has made a strong and clear showing that it is likely to prevail on the merits of its Lanham Act trademark infringement (15 U.S.C. § 1114(1); Count I) and unfair competition (15 U.S.C. 1125(a);

[23] While this action is about drugs and not drinks, the Court's analysis pertains.

Count II) claims as against all Defendants – specifically, for contributory infringement as to Defendants Meritain and ProAct; and direct infringement as to Defendants Rx Valet, Advanced Pharmacy, Affordable Rx, and Fetih Eczanesi, as well as Defendant Gregory Santulli, as the principal architect and motivating force of the infringement and unfair competition of Defendants Rx Valet and Advanced Pharmacy. With respect, specifically, to the element of likelihood of confusion among consumers, the court credits the account of John Doe as an example of actual confusion to satisfy this element for Rule 65 purposes; further, the broad record evidence as a whole with respect to Defendants' industry practices demonstrates a clear likelihood of success as to this element of Counts I and II.

B. Irreparable Harm

A plaintiff seeking a preliminary injunction must "demonstrate that irreparable injury is *likely* in the absence of an injunction." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008) (emphasis in original) (citing cases). "To establish irreparable harm, the movant must make a 'clear showing' that it will suffer harm that is 'neither remote nor speculative, but actual and imminent.'" *Mountain Valley Pipeline, LLC v. 6.56 Acres of Land, Owned by Sandra Townes Powell*, 915 F.3d 197, 216 (4th Cir. 2019) (quoting *Direx Israel, Ltd. v. Breakthrough Med. Corp.*, 952 F.2d 802, 812 (4th Cir. 1991)). Irreparable harm is harm that "cannot be fully rectified by the final judgment after trial." *Id.* (quoting *Stuller, Inc. v. Steak N Shake Enters.*, 695 F.3d 676, 680 (7th Cir. 2012)).

While "[m]ere injuries, however substantial, in terms of money, time and energy necessarily expended in the absence of [an injunction] are not enough," *see Roe v. Dep't of Def.*, 947 F.3d 207, 228 (4th Cir. 2020), *as amended* (Jan. 14, 2020) (quoting *Di Biase v. SPX Corp.*, 872 F.3d 224, 230 (4th Cir. 2017)), "irreparable harm may still occur in extraordinary

circumstances, such as when monetary damages are unavailable or unquantifiable." *Handsome Brook Farm, LLC v. Humane Farm Animal Care, Inc.*, 700 F. App'x 251, 263 (4th Cir. 2017). For instance, "economic damages may constitute irreparable harm where no remedy is available at the conclusion of litigation." *Mountain Valley Pipeline, LLC v. W. Pocahontas Properties Ltd. P'ship*, 918 F.3d 353, 366 (4th Cir. 2019).

Relevant here, 15 U.S.C. 1116(a) provides in part:

> The several courts vested with jurisdiction of civil actions arising under this chapter shall have power to grant injunctions, according to the principles of equity and upon such terms as the court may deem reasonable, to prevent the violation of any right of the registrant of a mark registered in the Patent and Trademark Office or to prevent a violation under subsection (a), (c), or (d) of section 1125 of this title. A plaintiff seeking any such injunction shall be entitled to a rebuttable presumption of irreparable harm upon a finding of a violation identified in this subsection in the case of a motion for a permanent injunction or upon a finding of likelihood of success on the merits for a violation identified in this subsection in the case of a motion for a preliminary injunction or temporary restraining order.

15 U.S.C. § 1116(a).

Amendment to the Lanham Act in 2020 "was meant to codify the presumption already recognized by many courts in trademark infringement cases." *Under Armour, Inc. v. Exclusive Innovations, Inc.*, No. SAG-20-03427, 2021 WL 2042320, at *6 (D. Md. May 21, 2021) (citing *Lone Star Steakhouse & Saloon, Inc. v. Alpha of Va., Inc.*, 43 F.3d 922, 939 (4th Cir. 1995)); *see El Pollo Rico, LLC v. Wings & Pollo, LLC*, No. 21-CV-2346, 2022 WL 2916168, at *2 (D. Md. July 25, 2022) (discussing same). Indeed, the Fourth Circuit has previously recognized the same, explaining that "irreparable injury regularly follows from trademark infringement." *Lone Star Steakhouse & Saloon, Inc. v. Alpha of Virginia, Inc.*, 43 F.3d 922, 939 (4th Cir. 1995) (citing *Wynn Oil Co. v. American Way Service Corp.,* 943 F.2d 595, 608 (6th Cir. 1991)); *see Entrepreneur Media, Inc. v. JMD Ent. Grp., LLC*, 958 F. Supp. 2d 588, 596 (D. Md. 2013) (recognizing same).

In addition to the aforementioned presumption, Gilead argues the threat of irreparable harm is to Gilead's reputation and goodwill as well as public health and safety, explaining that Defendants' "illegal importation of international Gilead medication" that is not FDA-approved, without FDA-approved labeling or patient information documents. (ECF No. 11-1 at pp. 46–47.) The court agrees and finds that Gilead has resoundingly demonstrated it will likely suffer irreparable harm absent preliminary injunctive relief – even in the absence of the above-described presumption. The risk of harm to Gilead's good will and reputation among the patient and healthcare providing relevant community is stark and acute. Further the court's above assessment that Gilead has made a strong showing that it will likely demonstrate actual or likely consumer confusion further anchors the court's conviction that Gilead's reputation as a provider of safe, life-saving medicines may be irretrievably tarnished absent injunctive relief.

In addition to the Quartet Defendants' laches affirmative defense, all Defendants assert that the lag in time between Gilead's first alert to the John Doe complaint and initiating this action weighs against a finding of irreparable harm in the absence of a preliminary injunction. (ECF No. 111 at pp. 28–29; ECF No. 113 at pp. 23–26; ECF No. 114 at pp. 33–34.) The court is unpersuaded. To be sure, Gilead had an array of choices before it upon notice that it had a problem on its hands when Doe's clinic reached out. Defendants are correct – Gilead waited to file suit; but Gilead did not sit on its hands waiting to sustain additional potential harm. And while reasonable minds can, and do, differ about what paths Gilead could have or should have pursued – and what considerations it weighed in making those choices – prompt complaint to the federal agency tasked with regulating and overseeing drug safety, to include illegal importation of non-U.S., non-FDA-approved drugs is a sensible place to start. Further, in accordance with the jurisprudence cited above, a 10-month delay while Gilead sought assistance from the FDA and tried to piece together

what happened through its private pursuit of investigative fruit on its own nickel does not, in the eyes of this court, militate against a finding of irreparable harm.

1. Mootness/Voluntary Cessation

Meritain and ProAct urge that their assurances that they have ceased the allegedly infringing activity hobble Gilead's irreparable harm argument, thus rendering preliminary injunctive relief inappropriate. To be sure, a defendant's representation that it has voluntarily ceased challenged conduct is an important factor to consider in evaluating a plaintiff's contention of irreparable harm. *See generally*, *JTH Tax, Inc. v. ITS Fin., LLC,* 2:08cv271, 2008 WL 11512368 (E.D. Va., Dec. 15, 2008); *Lance Mfg., LLC v. Voortman Cookies Ltd.*, 617 F. Supp. 2d 424 (W.D.N.C. 2009).

> As the Fourth Circuit has stated, "it is well established that a voluntary discontinuance of challenged activities by a defendant does not necessarily moot a lawsuit." *Lyons P'ship, L.P. v. Morris Costumes, Inc.,* 243 F.3d 789, 800 (4th Cir.2001) (quoting *United States v. Jones,* 136 F.3d 342, 348 (4th Cir.1998)). One exception to this well-established rule is that a request for injunctive relief may be rendered moot where "there is no reasonable expectation that the wrong will be repeated." *Lyons,* 243 F.3d at 800 (quoting *United States v. W.T. Grant Co.,* 345 U.S. 629, 633, 73 S.Ct. 894, 97 L.Ed. 1303 (1953)). Defendants bear a "heavy burden" in establishing mootness "because otherwise they would simply be free to return to their old ways after the threat of a lawsuit has passed." *Lyons,* 243 F.3d at 800 (quoting *Iron Arrow Honor Soc'y v. Heckler,* 464 U.S. 67, 72, 104 S.Ct. 373, 78 L.Ed.2d 58 (1983) (per curiam)).

Lance Mfg., LLC, 617 F. Supp. 2d at 431 (citing *Lyons v. P'Ship, L.P. v. Morris Costumes, Inc.*, 243 F.3d 789 (4th Cir. 2001) in evaluation of whether mootness of harm barred preliminary injunction).[24]

[24] ProAct argues that Gilead "misstates the standard" (ECF No. 239 at p. 24) with its citation to *Lyons* as setting forth the general principle of law on the question of mootness applicable here, because *Lyons* dealt with the question of mootness in the context of a permanent injunction. As set forth above, however, *Lyons'* recitation of the law on mootness (via voluntary cessation) extends beyond the question of whether entry of permanent injunctive relief is appropriate, and includes the impact of potential mootness in determining whether preliminary injunctive relief is appropriate. *See, e.g.*, *Lance Mfg., LLC* and *JTH Tax, Inc., supra,* citing *Lyons* on the question of mootness in the context of preliminary injunctive relief. And while the court appreciates the practical and legal distinctions ProAct points out vis-à-vis mootness in the context of permanent versus preliminary injunctive relief, the principles set forth

The court is not persuaded that the parties' representations of voluntary cessation overcome Gilead's demonstration of irreparable harm absent issuance of preliminary injunctive relief. Specifically, the court is unpersuaded that there is no reasonable expectation that the alleged wrong will not be resumed or repeated absent an injunction. Importantly, neither is the court sufficiently convinced or persuaded that the alleged wrongs are not on-going. One need only observe the standard industry practices evidently adopted by the parties as a matter of course; the very nature of the parties' industry practices on record before this court militate against persuasion by expressions of voluntary cessation.

As set forth above, the court is well persuaded that Meritain's enunciation of its formal no-international-sourcing policy was not, in fact, followed. Not by a long shot. And while some well-meaning Meritain actors made efforts to shed light on and correct obvious policy infractions and failures, Gilead is well on its way to proving that Meritain's leadership basically decided what degree of "compliance" problems it was willing to tolerate to preserve its client base and market status. In this action, the very nature of the record evidence offers the court cold comfort that attestations regarding voluntary cessation extinguish irreparable harm – which is to say, the evidence that Meritain says one thing and does another is deeply problematic insofar as crediting its assertions of voluntary cessation to avoid an injunction.

The court is likewise unpersuaded that ProAct's attestations of mootness draw the sting from harm to Gilead's good will and market interests absent preliminary injunctive relief. The court has material concerns regarding the evidence of ProAct's past practice of assuring individuals in the industry that it was not engaging in international sourcing when, in fact, it was. (*See, e.g.,* ECF No. 152-43.) Here, ProAct assures the court it has, effectively, turned off client

in *Lyons* are applicable to this case, and the court applies them bearing in mind that the stage of this action is, as ProAct correctly notes, not at a final relief stage.

system edits for Gilead-branded medications (ECF No. 113-1; *see* ECF No. 239 at pp. 23–24). Against the backdrop of the evidence before the court, however, the court is not persuaded of the reliability of this fix. But, the problem is more complex than credibility. This forward-looking remedial measure, which can easily be turned back on for lack of a better phrase, does not render moot and offers no curative effect as to plan members who continue to get their prescriptions for U.S. Gilead-branded drugs re-filled by a ProAct international sourcing partner (like Rx Valet or CanaRx) following ProAct's pre-TRO "rejection at the point of sale."

ProAct's reliance on *Epic Tech, LLC v. Raleigh Startup Solutions, LLC*, 5:23-CV-136-D, 2023 WL 4492495 (E.D.N.C. June 5, 2023), does not persuade the court to find mootness with respect to the request for injunction. The plaintiffs in *Epic Tech* asserted the defendants were liable for "knowingly and intentionally selling and distributing counterfeit software" in violation of the plaintiffs' intellectual property rights. 2023 WL 4492495, at *2. The court denied the plaintiffs' motion for temporary restraining order and preliminary injunction on grounds that the plaintiffs offered no reason for their delay in filing suit, as the plaintiffs had confirmed the defendants were selling counterfeit software and, unlike Gilead, "undertook no action" to do anything about it for many months. 2023 WL 4492495, at *3–4.

Adding to that, the *Epic Tech* court discerned no need for emergency relief because most of the defendants had (through counsel or declaration) attested that they were no longer selling the challenged software product and would not do so for the duration of the case; and, the court expressly discredited the plaintiffs urgence, that without an injunction, the defendants could "conceal" evidence of their alleged wrongdoing. The court was unmoved because the plaintiffs "provided no evidence" that the defendants had ever concealed evidence of their alleged infringement. 2023 WL 4492495, at *4. To be clear, the court here makes no finding that counsel

or any corporate representative has concealed or destroyed evidence subject to discovery in this action; rather the court alights on this distinction from the instant facts because here the evidence is replete with evidence tending to show an effort to avoid detection of involvement with internationally sourcing drugs.

In sum, based on problematic credibility; the nature of their industry practices; the ease with which the voluntary cessation guardrails could be ignored or removed; and the continuing harm to Gilead's interest as described above, neither Meritain nor ProAct persuades the court that assertions of their respective voluntary cessation of the alleged infringing conduct sufficiently diminishes the specific and certain irreparable harm Gilead's interests will suffer absent entry of a preliminary injunctions.

C. Balance of Equities and Public Interest

The third factor the court considers in whether to issue preliminary injunctive relief is whether "the balance of equities tips in [Gilead's] favor." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008)). Courts "must balance the competing claims of injury and must consider the effect on each party of the granting or withholding of the requested relief," with "particular regard for the public consequences in employing the extraordinary remedy of injunction." *Id.* at 24 (quoting *Amoco Prod. Co. v. Vill. of Gambell, AK*, 480 U.S. 531, 542 (1987)); *see Ass'n of Am. Publishers, Inc. v. Frosh*, 586 F. Supp. 3d 379, 397 (D. Md. 2022) (same). The court considers "the 'harm to the plaintiff if the injunction is erroneously denied versus harm to the defendant if the injunction is erroneously granted.'" *Students for Fair Admissions v. United States Naval Acad.*, 707 F. Supp. 3d 486, 509 (D. Md. 2023) (quoting *Planned Parenthood of Ind. & Ky., Inc. v. Adams*, 937 F.3d 973, 980 (7th Cir. 2019)). The final factor the court considers is whether an injunction is in the public interest. *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008).

The court addresses these factors here together; inasmuch as the subject matter (availability of prescription medications) results in some overlap in discussion of these factors. But, to be clear, the court has considered each factor fully on its own as required.

Here, the balance of equities favors injunctive relief. To begin, having nothing to do with the Lanham Act, with exceptions not relevant here, importation into the U.S. of prescription medication is illegal under the FDCA. Defendants will not be heard to complain that they will suffer business hardship by this court's order that they comport their business practices with pre-existing law. And, as assessed above, the court is persuaded that Gilead's commercial interests and entitlements will (continue to) be damaged irreparably if Defendants are permitted to engage in conduct the court is persuaded is likely to be proven (on the merits) to be violative of the Lanham Act

On the issue of equity and public interest, Defendants urge that U.S. patients may suffer if the court enjoins Defendants' importation of non-U.S. Gilead-branded drugs, like BIKTARVY®, because U.S. BIKTARVY® is expensive. Surely, they are correct that U.S. BIKTARVY® is expensive (for some, prohibitively so) and the court appreciates the struggle that can present for patients. But, here again, the court is unpersuaded that this weighs against injunctive relief. While perhaps imperfect, there are – as all Defendants acknowledge – government and prescription assistance programs (also known as co-pay assistance programs) in place and in which Gilead participates to help off-set the financial strain often associated with a course of medical care involving expensive drugs. As Mr. Santulli testified, such "copay assistance programs were put in place by the drug manufacturers, God bless." (Hearing Tr. I, ECF No. 222 at 228:24–25.)

IV. CONCLUSION

For the reasons set forth herein, the Motion (ECF No. 11) seeking a preliminary injunction

shall be granted in part and denied in part. A separate order follows. As for the issue of bond, the court finds that continuation of the bond set in place in the Temporary Restraining Order at ECF No. 48 remains appropriate per Federal Rule 65(c).

June 24, 2025

/S/

Julie R. Rubin
United States District Judge