PUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 25-1828

GILEAD SCIENCES, INC.; GILEAD SCIENCES IRELAND UC IDA,

Plaintiffs – Appellees,

v.

MERITAIN HEALTH, INC.,

Defendant – Appellant,

and

PROACT, INC.; RX VALET, LLC; ADVANCED PHARMACY, LLC; AQUA ENTERPRISE INC., d/b/a Affordable RX Meds; GREGORY SANTULLI; FETIH ECZANESI,

Defendants.

HEALTHHIV; THE ADAP ADVOCACY ASSOCIATION; THE AUTOIMMUNE ASSOCIATION; THE HIV AND HEPATITIS POLICY INSTITUTE; THE INTERNATIONAL FOUNDATION FOR AUTOIMMUNE & AUTOINFLAMMATORY ARTHRITIS,

Amici Supporting Appellees.

No. 25-1829

GILEAD SCIENCES, INC.; GILEAD SCIENCES IRELAND UC IDA,

Plaintiffs – Appellees,

v.

PROACT, INC.,

Defendant – Appellant,

and

MERITAIN HEALTH, INC.; RX VALET, LLC; ADVANCED PHARMACY, LLC; AQUA ENTERPRISE INC., d/b/a Affordable RX Meds; GREGORY SANTULLI; FETIH ECZANESI,

Defendants.

HEALTHHIV; THE ADAP ADVOCACY ASSOCIATION; THE AUTOIMMUNE ASSOCIATION; THE HIV AND HEPATITIS POLICY INSTITUTE; THE INTERNATIONAL FOUNDATION FOR AUTOIMMUNE & AUTOINFLAMMATORY ARTHRITIS,

Amici Supporting Appellees.

No. 25-1849

GILEAD SCIENCES, INC.; GILEAD SCIENCES IRELAND UC IDA,

Plaintiffs – Appellees,

v.

RX VALET, LLC; ADVANCED PHARMACY, LLC; AQUA ENTERPRISE INC., d/b/a Affordable RX Meds,

Defendants – Appellants,

and

MERITAIN HEALTH, INC.; PROACT, INC.; GREGORY SANTULLI; FETIH ECZANESI,

Defendants.

HEALTHHIV; THE ADAP ADVOCACY ASSOCIATION; THE AUTOIMMUNE ASSOCIATION; THE HIV AND HEPATITIS POLICY INSTITUTE; THE INTERNATIONAL FOUNDATION FOR AUTOIMMUNE & AUTOINFLAMMATORY ARTHRITIS,

Amici Supporting Appellees.

No. 25-1850

GILEAD SCIENCES, INC.; GILEAD SCIENCES IRELAND UC IDA,

Plaintiffs – Appellees,

v.

GREGORY SANTULLI,

Defendant – Appellant,

and

MERITAIN HEALTH, INC.; PROACT, INC.; RX VALET, LLC; ADVANCED PHARMACY, LLC; AQUA ENTERPRISE INC., d/b/a Affordable RX Meds; FETIH ECZANESI,

Defendants.

HEALTHHIV; THE ADAP ADVOCACY ASSOCIATION; THE AUTOIMMUNE ASSOCIATION; THE HIV AND HEPATITIS POLICY INSTITUTE; THE INTERNATIONAL FOUNDATION FOR AUTOIMMUNE & AUTOINFLAMMATORY ARTHRITIS,

Amici Supporting Appellees.

Appeals from the United States District Court for the District of Maryland, at Baltimore. Julie R. Rubin, District Judge. (1:24-cv-03566-JRR)

Argued: May 6, 2026 Decided: August 13, 2025

Before AGEE and HARRIS, Circuit Judges, and KEENAN, Senior Circuit Judge.

Affirmed by published opinion. Judge Agee wrote the opinion, in which Judge Harris and Judge Keenan joined.

ARGUED: Michael Paul Beltran, BELTRAN LITIGATION, P.A., Tampa, Florida; Todd William Hesel, SILVERMAN THOMPSON SLUTKIN WHITE, Baltimore, Maryland, for Appellants. Timothy Alan Waters, PATTERSON BELKNAP WEBB & TYLER LLP, New York, New York, for Appellees. **ON BRIEF:** Jonathan W. Garlough, Ellen Matheson, FOLEY & LARDNER LLP, Chicago, Illinois for Appellant Meritain Health, Inc. Christopher Mincher, Ilona Shparaga, SILVERMAN THOMPSON SLUTKIN WHITE, Baltimore, Maryland, for Appellant ProAct, Inc. Michael P. Beltran, BELTRAN LITIGATION, P.A., Tampa, Florida; Rachel Atkin Hedley, Columbia, South Carolina, Michael E. Blumenfeld, Baltimore, Maryland, Jennifer W. Winkler, NELSON MULLINS RILEY & SCARBOROUGH LLP, for Appellants Rx Valet, LLC; Advanced Pharmacy, LLC; Aqua Enterprise, Inc., and Gregory Santulli. Steven M. Klepper, KRAMON & GRAHAM, PA, Baltimore, Maryland; Geoffrey A. Potter, Tara J. Norris, PATTERSON BELKNAP WEBB & TYLER LLP, New York, New York, for Appellees. William A. Sarraille, Washington, D.C., for Amici Curiae.

AGEE, Circuit Judge:

Gilead Sciences, Inc. develops and sells prescription drugs in the United States and abroad, including the HIV drug Biktarvy. The same prescription drug may cost more in the United States than overseas. To reduce these higher domestic costs, some self-funded health plans turn to alternative funding programs ("AFPs"), which import and sell certain brand-name medications that are intended only for foreign sale. The issue in this case is whether the arrangement here likely infringes Gilead's trademarks under the Lanham Act.

After a Maryland patient received a Turkish version of his Biktarvy in the mail, Gilead investigated and discovered a broader importation scheme. That discovery led Gilead to sue those allegedly behind the scheme—the Appellants here—claiming that Rx Valet, LLC, Advanced Pharmacy, LLC, Affordable Rx, and Gregory Santulli (together, the "Quartet") directly infringed its trademarks by importing and distributing foreign-market Gilead-branded drugs and that Meritain Health, Inc. and ProAct, Inc. contributed to the Quartet's infringement by facilitating the scheme.

The district court granted Gilead's motion for a preliminary injunction, enjoining Appellants from advertising, selling, or facilitating the sale of imported Gilead-branded medications in the United States. Appellants appeal. We affirm.

I.

A.

Gilead is a biopharmaceutical company that develops and markets prescription medications worldwide. It owns the registered trademarks that appear on the tablets,

packaging, and accompanying patient information for those medications, including Biktarvy. Although Gilead manufactures and sells many of the same medications for multiple markets, it packages and labels them for the countries in which they are intended to be sold. The events giving rise to this case began with a single nonparty Maryland patient, John Doe, but Gilead's investigation of that lone report uncovered a broader international-sourcing arrangement. To better understand that arrangement, some place setting is needed.

Under a self-funded health plan, an employer, rather than an insurance company, bears the financial risk of its employees' healthcare expenses. By assuming that risk, the employer may reduce costs because it pays claims as they arise rather than prepaying fixed premiums to an insurer. Self-funding also gives employers greater control over how healthcare benefits are structured and administered. They choose not only deductibles, copays, and covered services, but also the vendors and potential cost-savings arrangements used to administer those benefits.

Rather than administer self-funded plans themselves, many employers hire a third-party administrator ("TPA"), such as Meritain, to process claims, prepare plan documents, connect the plan to provider networks, and maintain eligibility information identifying plan members and their available benefits. Employers often entrust the pharmacy benefits part of their self-funded health plan to a pharmacy benefit manager ("PBM"), which designs the plan's formulary and determines at the point of purchase whether a particular prescription claim will be approved.

Meritain, a subsidiary of Aetna and CVS Health, provides PBM services through its affiliate, Meritain Health Pharmacy Solutions ("MPS"), for roughly half of the self-funded plans it administers. *See* J.A. 249, 1159. For the remainder, employers contract with a separate PBM, known as a "carve-out" PBM. ProAct, one of the Appellants here, serves in that role for Doe's employer. Although Meritain isn't a party to the contract between the employer and ProAct, it provides two services relevant here. First, Meritain supplies ProAct with its "patient data stream," so ProAct, as the PBM, can identify plan members and their prescription drug benefits. ProAct uses that information to verify coverage and bill the plan (through Meritain) for covered pharmacy claims. Second, Meritain processes invoices from ProAct, paying them from the plan's account.

An employer's choices don't end with the TPA and PBM. Because the employer ultimately pays its employees' prescription-drug claims, it has a direct incentive to seek alternatives to higher domestic drug prices. Some self-funded employers therefore contract separately with an AFP. As relevant here, AFPs obtain designated medications from foreign pharmacies rather than through a PBM's domestic pharmacy network. The employer—not the PBM—decides what medications to source internationally and contracts with the AFP to obtain them.

That's what happened here. In 2024, John Doe, a Maryland resident who had taken Biktarvy to treat HIV for years, enrolled in his new employer's self-funded health plan. Meritain served as the plan's TPA and ProAct served as its carve-out PBM. When Doe tried to refill his Biktarvy prescription, the pharmacy submitted a "test claim" to ProAct. Using the patient data stream from Meritain, ProAct identified Doe, verified his coverage

eligibility, and compared the prescription against his employer's formulary. ProAct then returned an electronic response to the pharmacy—a "system edit"—directing Doe to contact Rx Valet. It also forwarded Doe's rejected claim and patient information to Rx Valet so that Rx Valet could contact him directly.

Gilead's ensuing investigation revealed the reason for rejecting Doe's claim: Doe's employer had separately retained Rx Valet as its AFP and designated certain medications, including Biktarvy, for international sourcing. ProAct's system edit thus directed Doe away from the ordinary domestic pharmacy network to Rx Valet.

ProAct's system edit placed Doe into Rx Valet's "international sourcing program," which Rx Valet markets as a way to reduce prescription-drug costs. Its promotional materials identify numerous Gilead medications, including Biktarvy, as available through that program. But Rx Valet isn't a licensed pharmacy and thus can't receive prescriptions directly from healthcare providers. So it instructed Doe to have his doctor send the prescription to its affiliate, Advanced Pharmacy, a licensed pharmacy that provides mail-order services exclusively for Rx Valet. Gregory Santulli serves as Chief Executive Officer of Rx Valet and President of Advanced Pharmacy.

Advanced Pharmacy, in turn, forwarded Doe's prescription to Affordable Rx, a "prescription referral service" that works exclusively with Rx Valet. Affordable Rx connects patients with foreign dispensing pharmacies: it accepts prescription orders, locates a foreign pharmacy to fill them, and arranges for the pharmacy to ship the medications directly to patients in the United States. Its website identifies available

medications, dispensing pharmacies, manufacturers, and countries of manufacture and shipment.

Following that process, Advanced Pharmacy sent Doe's Biktarvy prescription to Affordable Rx, which arranged for a Turkish pharmacy to dispense the Biktarvy and ship it to Doe. A few weeks later, Doe received Biktarvy packaged for the Turkish market—a version that the Food and Drug Administration ("FDA") had not approved for sale in the United States.

As shown above, the carton and the bottle were labeled in Turkish not English. The accompanying patient information was likewise written in Turkish and omitted labeling and warnings required for Biktarvy that the FDA has approved for distribution in the United States.[1]

[1] The Turkish Biktarvy was authentic in the limited sense that it bore Gilead's legitimate, non-counterfeited trademarks, was manufactured with Gilead's authorization, and was chemically identical to Biktarvy authorized for sale in the United States. As we explain below, however, those characteristics don't necessarily make it "genuine" for Lanham Act purposes.

Concerned about the medication's authenticity, Doe contacted his doctor in February 2024, and his doctor notified Gilead. In turn, Gilead obtained samples for testing, which confirmed that the tablets were authentic Gilead Biktarvy produced in Turkey, packaged for the Turkish market, and intended for sale only in Turkey. Gilead's investigation soon revealed that Doe's experience wasn't an isolated incident. Through the same international-sourcing arrangement, the Quartet arranged for hundreds of bottles of foreign-market Gilead medications to be shipped to patients in the United States. Gilead alerted the FDA, which declined to take enforcement action.

B.

In December 2024, Gilead sued the Quartet, Meritain, and ProAct in the District of Maryland, alleging, among other claims, trademark infringement and unfair competition under the Lanham Act.[2] *See* 15 U.S.C. §§ 1114(1), 1125(a). Gilead alleges that the Quartet directly infringe its trademarks by importing and distributing foreign-market Gilead-branded medications that are materially different from the domestic version. As to Meritain and ProAct, Gilead alleges that they are contributorily liable because they continued supplying services to the Quartet despite knowing, or having reason to know, that the Quartet were infringing Gilead's trademarks.

[2] Gilead brought four other claims: importation of goods bearing infringing marks (15 U.S.C. § 1124), state law unfair competition, unjust enrichment, and civil conspiracy. Those claims aren't before us at this stage as they didn't form the basis of Gilead's preliminary injunction motion. Likewise, Gilead also sued Fetih Eczanesi, the Turkish pharmacy, which defaulted in the district court and isn't a party to this appeal.

Along with its complaint, Gilead moved for a temporary restraining order. After a hearing, the district court entered a TRO enjoining Appellants from continuing to advertise, sell, or facilitate the sale of imported Gilead-branded medications. J.A. 690–95. At Appellants' request, the court extended the TRO and permitted expedited discovery.

Santulli meanwhile moved to dismiss the claims against him for lack of personal jurisdiction under Rule 12(b)(2). The district court denied that motion before deciding Gilead's then-pending preliminary injunction motion.

Following a two-day evidentiary hearing, the district court issued an opinion and order granting Gilead's motion and converting the TRO into a preliminary injunction. The court enjoined Appellants from, among other things, "[i]mporting, advertising the importation of, or otherwise facilitating the importation of product bearing a [defined] Gilead Mark . . . into the United States from outside the United States." J.A. 3361.

Meritain, ProAct, and the Quartet timely noted this interlocutory appeal, and we have jurisdiction under 28 U.S.C. § 1292(a)(1).[3]

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[3] Santulli asks us to exercise pendent appellate jurisdiction and review the denial of his motion to dismiss for lack of personal jurisdiction. That ruling "is a non-final order that is not . . . immediately appealable," which we can review only in two "narrow" circumstances: "(1) when an issue is inextricably intertwined with a question that is the proper subject of an immediate appeal; or (2) when review of a jurisdictionally insufficient issue is necessary to ensure meaningful review of an immediately appealable issue." *Rux v. Republic of Sudan*, 461 F.3d 461, 475 (4th Cir. 2006) (internal quotation marks omitted).

Neither circumstance is present here. Two rulings are "'inextricably intertwined' if 'the same specific question will underlie both the appealable and the non-appealable order, such that resolution of the question will necessarily resolve the appeals from both orders at once.'" *Indus. Servs. Grp., Inc. v. Dobson*, 68 F.4th 155, 167 (4th Cir. 2023) (quoting *Scott v. Fam. Dollar Stores, Inc.*, 733 F.3d 105, 111 (4th Cir. 2023)). That's not so here. To overcome a 12(b)(2) motion, a plaintiff must make a prima facie showing of jurisdiction, (Continued)

II.

To secure a preliminary injunction, a plaintiff must demonstrate that (1) it is likely to succeed on the merits, (2) it is likely to suffer irreparable harm in the absence of preliminary relief, (3) the balance of equities tips in its favor, and (4) an injunction is in the public interest. *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008).

We review the grant of a preliminary injunction for abuse of discretion. *Leaders of a Beautiful Struggle v. Baltimore Police Dep't*, 2 F.4th 330, 339 (4th Cir. 2021) (en banc). Under this deferential standard, we don't reweigh evidence that the district court considered, reviewing factual findings for clear error. *See Mountain Valley Pipeline, LLC v. 6.56 Acres of Land, Owned by Sandra Townes Powell*, 915 F.3d 197, 213 (4th Cir. 2019). "[S]o long as the district court's account of the evidence is plausible in light of the record viewed in its entirety, we may not reverse, even if we are convinced that we would have weighed the evidence differently." *Id.* (cleaned up). Legal conclusions, however, are reviewed de novo. *Salomon & Ludwin, LLC v. Winters*, 150 F.4th 268, 274 (4th Cir. 2025).

A.

We begin with the likelihood of success on the merits. Gilead "need not establish a certainty of success, but it must be clear that [it] is likely to succeed at trial." *Jensen v. Md. Cannabis Admin.*, 151 F.4th 169, 175 (4th Cir. 2025) (cleaned up). The district court

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while securing a preliminary injunction requires it to show a "reasonable probability of ultimate success" on that question. *Visual Scis., Inc. v. Integrated Commc'ns Inc.*, 660 F.2d 56, 59 (4th Cir. 1981). Because the two motions require different standards, review of one is neither "inextricably intertwined" with nor "necessary to ensure meaningful review" of the other. *Dobson*, 68 F.4th at 167. We thus see no basis to exercise pendent appellate jurisdiction over the issue of personal jurisdiction.

concluded that Gilead is likely to succeed on the merits of its direct trademark infringement claims against the Quartet and its contributory trademark infringement claims against Meritain and ProAct. Before turning there, we address two threshold issues: whether the district court erred by not finding that Gilead satisfied its personal jurisdiction burden as to Santulli and whether the Federal Food, Drug, and Cosmetic Act ("FDCA") precludes Gilead's claims.

1.

a.

Santulli contends that the district court erred by concluding that Gilead was likely to succeed on the merits against *him* without first finding "that there is a reasonable probability that it has personal jurisdiction over [him]." Quartet Opening Br. 55. In other words, separate from his challenge to the district court's denial of his Rule 12(b)(2) motion (which we lack jurisdiction to review, *see supra* note 3), Santulli contends the district court needed to, but did not, find that Gilead met the higher "reasonable probability of ultimate success" standard before granting preliminary relief. *Cf. Visual Scis., Inc.*, 660 F.2d at 59. We decline to consider this argument because Santulli never made it below. *See In re Under Seal*, 749 F.3d 276, 285 (4th Cir. 2014). An overview of the timeline makes that clear.

The record shows that Santulli put his personal-jurisdiction defense and Gilead's request for a preliminary injunction on two separate tracks throughout the proceedings below. After Gilead moved for a preliminary injunction, Santulli filed a Rule 12(b)(2) motion arguing that Gilead had not made a prima facie showing of personal jurisdiction. J.A. 1112–22. Although the district court initially planned to address responsive motions

after the preliminary-injunction hearing, Santulli asked it to decide his "individual Rule 12 motion" first. J.A. 1130 ("We respectfully ask the Court to hear Mr. Santulli's Motion to Dismiss before the Preliminary Injunction hearing[.]"). Gilead proposed addressing personal jurisdiction in its preliminary-injunction reply, but Santulli objected and again asked the court to resolve his Rule 12(b)(2) motion separately and before the hearing. J.A. 1442–45, 1467–68. The court agreed and established a separate briefing schedule for that motion. J.A. 1469–70.

The briefing on the two motions overlapped, but Santulli did not make the same argument in both briefs. The Quartet's preliminary-injunction opposition stated in a footnote that Santulli's participation was "subject to and without waiver of his motion to dismiss for lack of personal jurisdiction." J.A. 1383 n.1. The opposition itself made no personal-jurisdiction argument. It didn't invoke the "reasonable probability" standard or ask the court to deny preliminary relief for failing to satisfy it.

In support of his Rule 12(b)(2) motion, Santulli instead focused his jurisdictional argument on the prima facie standard that governs that motion (and rightfully so). His reply supporting his 12(b)(2) motion—filed after preliminary-injunction briefing had concluded—added only in a footnote that a prima facie showing "is not sufficient for a preliminary injunction against a party challenging personal jurisdiction." J.A. 2114 n.4. But the footnote did not identify the "reasonable probability" standard or ask the court to apply it in deciding Gilead's preliminary-injunction motion. The district court denied Santulli's 12(b)(2) motion, concluding that Gilead had made a prima facie personal jurisdiction showing. J.A. 2196–2212.

Santulli points out that the district court had earlier recognized that it could not enjoin a defendant over whom it lacked personal jurisdiction. *See* J.A. 1132. But that observation only generally acknowledged that personal jurisdiction was required for a court to act as to a particular defendant. At no point did Santulli then identify to the court the "reasonable probability" standard or ask the court to apply it.

In short, Santulli placed his 12(b)(2) motion and Gilead's preliminary-injunction motion on separate tracks. On the first, he argued that Gilead had not made a prima facie showing of personal jurisdiction. On the second, he never argued that the court had to find a "reasonable probability" of personal jurisdiction before enjoining him.[4]

To the extent Santulli maintains that the district court had an independent obligation to apply that standard whether he requested it or not, we disagree. To be sure, once a defendant contests personal jurisdiction, the plaintiff bears the burden of establishing it at each stage of the litigation. *See Grayson v. Anderson*, 816 F.3d 262, 268 (4th Cir. 2016). But that doesn't relieve the defendant of the obligation to identify the legal standard he contends governs the court's analysis. Personal jurisdiction is a waivable defense, not a jurisdictional limitation like subject-matter jurisdiction that courts must police sua sponte. *See al-Suyid v. Hifter*, 139 F.4th 368, 374 (4th Cir. 2025). Accepting Santulli's position would require district courts to revisit personal jurisdiction sua sponte each time a case

[4] The district court told Santulli, at the end of the evidentiary hearing on the preliminary injunction, that it would not reconsider the personal jurisdiction question it had resolved against him on the Rule 12(b)(2) motion. Even given this direct opportunity, Santulli did not articulate or argue for application of a different, "reasonable probability" standard. J.A. 3021–22.

advances to a new procedural stage, even without any argument that a different standard applies. There is no basis to impose such a requirement. Because Santulli never argued that the district court had to find a "reasonable probability" of personal jurisdiction before enjoining him, he cannot now fault the court for failing to do so.[5]

b.

Next, Appellants maintain that the FDCA's exclusive enforcement provision bars Gilead's Lanham Act infringement claims. We disagree.

The FDCA and the Lanham Act "complement each other." *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 115 (2014). While the Lanham Act is mainly concerned with "protect[ing] commercial interests against unfair competition, [] the FDCA protects public health and safety." *Id.* A cause of action for trademark infringement lies under the Lanham Act when "[a]ny person . . . without the consent of the registrant . . . use[s] in commerce any . . . registered mark in connection with the sale . . . of any goods . . . [and] such use is likely to cause confusion." 15 U.S.C. § 1114(1)(a). The FDCA regulates the approval, labeling, and distribution of prescription drugs, and entrusts enforcement to the FDA rather than private litigants. *See* 21 U.S.C. §§ 352, 384; *see id.* § 337 (providing that "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States").

[5] To be clear, we don't address whether Santulli waived his personal-jurisdiction defense for the case as a whole—an issue the district court expressly declined to reach and that we lack jurisdiction to decide. *See* J.A. 2211 ("[T]he court declines to reach the question of waiver."). We hold only that Santulli waived the separate argument that the district court couldn't enter a preliminary injunction against him without first finding a reasonable probability of personal jurisdiction.

Appellants first argue that the FDCA forbids Gilead's claims because those claims necessarily require judicial interpretation or enforcement of the FDCA and its implementing regulations. *See, e.g.*, *Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 231 (3d Cir. 1990). Specifically, Appellants contend that resolving the claims requires determining whether the labeling of imported Gilead-branded medications complies with FDA regulations. They do not. As explained below, Gilead's theory of infringement depends on the material differences between domestic and foreign Gilead-branded medications—and not on whether those differences violate the FDCA. Under the facts of this case, comparing two products to determine whether they materially differ for Lanham Act purposes doesn't require interpreting FDA regulations. Indeed, the district court concluded that Gilead was likely to succeed on the merits without first finding an FDCA violation, showing that one doesn't depend on the other.

That distinguishes this case from the authorities on which Appellants rely. In *Sandoz*, for example, the plaintiff brought a Lanham Act false advertising claim, alleging that a drug label was "literally false" because it described an ingredient as "inactive." 902 F.2d at 230–31. But FDA regulations directly govern whether an ingredient is "inactive," and the FDA had yet to speak on the issue. In other words, whether the challenged statement could give rise to liability for false advertising under the Lanham Act turned on interpreting the FDCA and its regulations. For that reason, the Third Circuit concluded that the FDCA precluded the plaintiff's claim. *Id.* at 231. That's not the case here.

Appellants alternatively argue that our decision in *Mylan Laboratories, Inc. v. Matkari*, 7 F.3d 1130 (4th Cir. 1993), precludes Gilead's claims as they rest on an implicit

representation that imported Gilead-branded medications are FDA-approved. Appellants' reliance is misplaced. In *Mylan*, the plaintiff asserted a Lanham Act *false advertising* claim alleging that the defendant falsely implied FDA approval merely by marketing its drugs with package inserts commonly associated with FDA-approved drugs. *Id.* at 1139. We rejected that theory as "too great a stretch under the Lanham Act" absent any statement that the drug had "proper FDA approval." *Id.*

Gilead advances no such FDA-contingent theory here. For example, it doesn't claim that Appellants falsely imply FDA approval by selling imported Gilead-branded medications in the United States. Instead, as explained below, Gilead alleges that the imported products are materially different from the domestic version and thus infringe its trademarks. On that basis, *Mylan* is simply inapposite.

The FDCA doesn't preclude Gilead's Lanham Act claims,[6] so we turn to whether Gilead is otherwise likely to succeed on the merits of them.

[6] The Supreme Court recently held that the FDCA didn't bar a Lanham Act claim relating to food labeling. *See POM Wonderful LLC*, 573 U.S. at 120–21. In doing so, the Court observed that neither the text of the Lanham Act nor that of the FDCA "in express terms, forbids or limits Lanham Act claims challenging [food] labels that are regulated by the FDCA." *Id.* at 113. Moreover, "[a] holding that the FDCA precludes Lanham Act claims challenging food and beverage labels[,]" the Supreme Court explained, "would not only ignore the distinct functional aspects of the FDCA and the Lanham Act but also would lead to a result that Congress likely did not intend." *Id.* at 116.

The district court understandably applied *POM Wonderful*'s directives to the drug label Lanham Act claims here in concluding that they aren't precluded by the FDCA. We need not decide the full scope of *POM Wonderful* here as it's clear that the FDCA doesn't preclude Gilead's claims under the facts of this case.

2.

To prevail on the merits of its direct trademark infringement claims against the Quartet, Gilead must establish, among other things, that the Quartet's use of its marks "is likely to confuse consumers."[7] *Rosetta Stone Ltd. v. Google, Inc.*, 676 F.3d 144, 152 (4th Cir. 2012); *see also Lamparello v. Falwell*, 420 F.3d 309, 13 (4th Cir. 2005) (applying the same elements to 15 U.S.C. §§ 1114 and 1125 claims). This appeal turns on whether the Quartet's importation of authentic Gilead-branded medications intended only for sale and distribution abroad is likely to do just that. Those foreign-sourced medications are classic gray market goods. *See K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 285 (1988) (defining a gray market good as a "foreign-manufactured good, bearing a valid United States trademark, that is imported without the consent of the United States trademark holder").

Trademark law permits the resale of genuine goods bearing a trademark owner's mark, even without the owner's consent in some circumstances. *See Shell Oil Co. v. Com. Petroleum, Inc.*, 928 F.2d 104, 107 (4th Cir. 1991). The reason is straightforward: when the imported product is identical to the domestic version, consumers receive "exactly the bundle of characteristics that they associate with the mark." *Societe Des Produits Nestle, S.A. v. Casa Helvetia, Inc.*, 982 F.2d 633, 641 (1st Cir. 1992). Because consumers get what they expect, there is little risk of confusion.

[7] The other elements—that Gilead owns a legally protectable trademark, that the Quartet used that trademark in commerce without Gilead's consent, and that the use was "in connection with the sale, offering for sale, distribution, or advertising" of goods or services, *Rosetta Stone*, 676 F.3d at 152—are not in dispute on appeal.

Relatedly, "[u]nder what has sometimes been called the 'first sale' or 'exhaustion' doctrine, the trademark protections of the Lanham Act are exhausted after the trademark owner's first authorized sale of that product." *Davidoff & Cie, S.A. v. PLD Int'l Corp.*, 263 F.3d 1297, 1301 (11th Cir. 2001).

So our initial task is to determine whether the internationally sourced Gilead-branded medications at issue are genuine for Lanham Act purposes. Relevant here, there are two ways in which goods bearing an authentic mark are still not genuine: they (1) materially differ from the goods the trademark owner has authorized for sale, *see Nestle*, 982 F.2d at 638, or (2) are manufactured or distributed outside the trademark owner's legitimate quality-control system, *see Shell Oil*, 928 F.2d at 107. [8]

Under the material-differences doctrine, goods aren't genuine if (1) the trademark owner hasn't authorized them for domestic sale, and (2) they materially differ from the goods authorized for sale domestically.[9] *See Nestle*, 982 F.2d at 638. The doctrine reflects a common-sense proposition: consumers who encounter products bearing identical marks

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[8] The Quartet argue that the foreign-sourced medications aren't gray market goods because they're genuine. *See* Quartet Opening Br. 22–23. This argument is misplaced. Whether a good is a gray market good doesn't turn on its genuineness but whether the trademark owner authorized its importation. *See K Mart Corp.*, 486 U.S. at 285.

[9] We haven't yet applied the material-differences doctrine in a gray-market case, but nearly every court of appeals to consider the question has recognized it and none have rejected it. *See Nestle*, 982 F.2d at 638–39 (1st Cir.); *Iberia Foods Corp.*, 150 F.3d at 302–03 (3d Cir.); *Martin's Herend Imports, Inc. v. Diamond & Gem Trading USA, Co.*, 112 F.3d 1296, 1302 (5th Cir. 1997); *Brilliance Audio*, 474 F.3d at 370 (6th Cir.); *R.J. Reynolds Tobacco Co. v. Cigarettes Cheaper!*, 462 F.3d 690, 699–700 (7th Cir. 2006); *Hokto Kinoko Co. v. Concord Farms, Inc.*, 738 F.3d 1085, 1093 (9th Cir. 2013); *Beltronics USA, Inc. v. Midwest Inventory Dist., LLC*, 562 F.3d 1067, 1071 (10th Cir. 2009); *Davidoff & Cie*, 263 F.3d at 1302 (11th Cir.); *Gamut Trading Co. v. U.S. Int'l Trade Comm'n*, 200 F.3d 775, 780–81 (Fed. Cir. 1999).

reasonably expect them to have the same characteristics. Material differences undermine that expectation and therefore create a likelihood of confusion. *See Iberia Foods Corp. v. Romeo*, 150 F.3d 298, 303 (3d Cir. 1998); *Weil Ceramics & Glass, Inc. v. Dash*, 878 F.2d 659, 671 (3d Cir. 1989).

In analyzing material differences, "we apply a low threshold of materiality, requiring 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). What matters to consumers varies by product and market, so "materiality is a fact-based inquiry requiring an examination of the products and markets at issue." *Brilliance Audio, Inc. v. Haights Cross Commc'ns, Inc.*, 474 F.3d 365, 370 (6th Cir. 2007).

The quality-control doctrine—an offshoot of material differences—protects a trademark owner's right to determine the standards under which goods bearing its mark reach consumers. *Shell Oil*, 928 F.2d at 107; *El Greco Leather Prods. Co. v. Shoe World, Inc.*, 806 F.2d 392, 395 (2d Cir. 1986). As the Second Circuit has observed, "[o]ne of the most valuable and important protections afforded by the Lanham Act" is the trademark owner's ability to determine those quality standards. *El Greco*, 806 F.2d at 395. To that end, goods aren't genuine if they are manufactured or distributed without adherence to the trademark owner's "established, legitimate, substantial, and nonpretextual" quality-control measures. *Zino Davidoff*, 571 F.3d at 244. The relevant question isn't whether the goods are actually manufactured or distributed in an inferior way but whether they meet the

trademark owner's quality-control requirements. *See Am. Petroleum Inst. v. Cooper*, 718 F.3d 347, 360 n.8 (4th Cir. 2013); *Shell Oil*, 928 F.2d at 107.

We applied these principles in *Shell Oil*, where a wholesaler purchased genuine Shell-marked oil from authorized distributors. 928 F.2d at 106. Shell required authorized distributors to comply with stringent quality-control standards governing the transportation, storage, and delivery of its bulk oil because the distribution process created a risk of contamination. *Id.* But the wholesaler instead employed its own quality-control procedures, which differed from Shell's requirements. We held that the oil was not "genuine" because it was distributed outside Shell's quality-control system and that marketing the oil under Shell's trademarks according to the wholesaler's quality controls infringed Shell's trademark rights. *Id.* at 107.

The district court here concluded that the internationally sourced Gilead-branded medications that the Quartet imported aren't genuine. In its view, they materially differ from the domestic versions and aren't subject to the same quality control measures. We agree with the district court.

a.

Starting with the material-differences doctrine, it's undisputed that Gilead didn't authorize the importation or sale of these foreign-market medications in the United States. The question at issue is whether the imported goods are "genuine" under the Lanham Act. We conclude that they are not, as the domestic and internationally sourced medications are materially different here. As the district court explained, although domestic and

international Biktarvy, like the other branded Gilead drugs at issue here, contain the same medical formulation, they nonetheless "bear many differences." J.A. 3319.

Those differences begin with the labeling as shown below. For example, U.S. Biktarvy is labeled in English, whereas Turkish Biktarvy is labeled in Turkish (a). The Turkish labels omit much of the information on U.S. Biktarvy labels, including: (b) the "Rx only" symbol; (c) the drug's "National Drug Code" ("NDC") number, which distributors and pharmacies use to identify the medication being dispensed;[10] (d) and (e) warnings directing patients to review medicines that should not be taken with Biktarvy and to keep the medication out of the reach of children; and (f) storage instructions directing that the medicine be kept "below 30° C (86° F)." J.A. 156–57.

Apart from the label, a patient information document is affixed to every bottle of U.S. Biktarvy. That document includes information that is entirely absent from the one that accompanies international Gilead-branded medications. As the district court found, that

[10] The NDC number, according to the FDA, "is a universal product identifier for human drugs" and "identifies the labeler, product, and trade package size." U.S. Food & Drug Admin., *National Drug Code Database Background Information* [https://perma.cc/N3ET-HSGA] (last visited July 21, 2026).

information includes a "black box" warning[11] that discontinuing Biktarvy may exacerbate Hepatitis B infection for those who suffer from Hepatitis B and HIV; FDA contact information; Gilead's toll-free hotline to report adverse incidents; a statement that the document has been approved by the FDA; the "Rx only" symbol; and the medication's NDC number. *See* J.A. 3320.

These differences are plainly material. The omitted warnings, prescribing information, FDA-related disclosures, and identifying information are precisely the sort of product characteristics consumers would likely consider relevant when assessing Gilead-branded products. If slight differences in packaging and labeling suffice in the ordinary gray-market case, they certainly suffice where the product is a prescription medication accompanied by different safety information and regulatory disclosures.

Contrary to the Quartet's position, it makes no difference that domestic and international Gilead-branded drugs are chemically identical. Material differences in this context aren't limited to a product's physical composition. In *Nestle*, for example, unauthorized importers sold foreign-market chocolates in the United States. 982 F.2d at 635. Although the chocolates' ingredients were identical to the domestic version, the First Circuit found that the products nonetheless differed in material respects. *Id.* at 642–43. The

[11] A "black box" warning "is the most stringent safety warning the FDA can require from a drug manufacturer." Morgan Coulson, *What is a Black Box Warning?*, Johns Hopkins Bloomberg School of Public Health (Dec. 19, 2025) [https://perma.cc/2P87-LVA4] (last visited July 21, 2026). The "prominent warning is designed to alert health care providers and patients to serious, life-threatening, or permanently disabling risks associated with the drug's use, should an adverse reaction occur." *Id.*; *see also* 21 C.F.R. § 201.57(c)(1).

"boxes, wrappers and trays" were in different colors, and the descriptions on the chocolates' packaging were in different languages. *Id.* at 643. As the court recognized, many of these "subtle" differences were material as they "might well perplex consumers and harm Nestle's goodwill." *Id.*

So too in *Original Appalachian Artworks, Inc. v. Granada Electronics, Inc.*, 816 F.2d 68 (2d Cir. 1987), where the defendant imported dolls intended only for sale in Spain. Although the dolls themselves were identical to the domestic version, they came with Spanish-language adoption papers rather than the English-language papers accompanying dolls sold domestically. *Id.* at 70. The Second Circuit held that the papers' language difference, along with the refusal and inability of "United States' fulfillment houses" to process the dolls' "adopt[ion]" paperwork for the consumer, were material differences likely to confuse consumers.[12] *Id.* at 73.

And consider *Lever Brothers Co. v. United States*, which involved imported dishwashing liquid into the United States that was intended for distribution in the United Kingdom. 877 F.2d 101 (D.C. Cir. 1989). The U.K. bottles were shaped like cylindrical drums instead of the hourglass-shaped bottles used in the domestic market, and their labels displayed different text and graphics. *Id.* at 103. Those packaging differences between the imported products and those authorized for sale in the United States were material. *Id.*

[12] The Quartet argue that *Original Appalachian Artworks* is inapplicable because the Spanish dolls were "manufactured under a geographically restricted license from the trademark holder." Quartet Reply Br. 6. We disagree. It's irrelevant whether goods are manufactured by the trademark holder or a licensee. It's the lack of consent to import—not to manufacture—that's the salient consideration. *See Lever Bros. Co. v. United States*, 877 F.2d 101, 109 (D.C. Cir. 1989).

The same reasoning from those cases applies here. Like the chocolates in *Nestle*, the dolls in *Original Appalachian Artworks*, and the detergent in *Lever Brothers*, the imported medications differ not in their chemical composition but in the information, warnings, labeling, and regulatory materials accompanying them—precisely what a consumer receiving a prescription drug expects to get.

The Quartet counter that none of this matters because a consumer can just look up the missing information online. But that's simply beside the point. The question isn't whether it's possible for a consumer to reconstruct what's missing after the fact—it's whether the product received matches what one reasonably expects when seeing Gilead's mark. The Quartet's theory also assumes one could find the *right* information in the first place, which is especially hard to square with a carton and a bottle labeled in Turkish. A consumer who can't read the foreign label will likely not know whether some English-language page found online actually corresponds to the medicine in hand.[13] Tellingly, the Quartet omit any discussion of why it would be reasonable to inflict this burden on the average consumer, never mind a non-tech-savvy or elderly one.

Doe's experience illustrates the resulting risk of confusion. After receiving Turkish Biktarvy instead of the domestic version he expected, Doe contacted his healthcare

[13] The Quartet argue that they aren't liable for infringement because they "disclos[ed] to end users" that the drugs were internationally sourced. Quartet Opening Br. 29–30. This is nothing but a passing shot argument that the Quartet have failed to develop. *See Grayson O Co. v. Agadir Int'l LLC*, 856 F.3d 307, 316 (4th Cir. 2017) ("A party waives an argument by failing . . . to develop its argument—even if its brief takes a passing shot at the issue." (cleaned up)). Even if the Quartet developed the argument, we agree with Gilead that it's waived because the Quartet didn't raise it before the district court. *See* Quartet Reply Br. 6 n.3.

provider because he questioned whether the medication was authentic. In the end, the differences described above are material, not theoretical, under the Lanham Act.

b.

In addition, domestic Gilead-branded medications are subject to quality control measures that the medications the Quartet import are not. Gilead manufactures both its U.S. and international products abroad—for example, U.S. Biktarvy in Canada, Ireland, and Germany; Turkish Biktarvy in Turkey. But only the domestic version ships in sealed, temperature-controlled, and temperature-monitored containers. *See* J.A. 3320–21. Gilead's FDA-approved labeling states that Biktarvy, for example, shouldn't be exposed to temperatures above 86 degrees Fahrenheit. If a shipment's temperature monitor indicates that the threshold has been exceeded, Gilead initiates a "quality event," during which its quality-assurance team investigates whether the medicine remains safe and effective before it reaches patients. *Id.* The district court found—and the Quartet do not meaningfully dispute—that none of those procedures applies to internationally sourced Gilead medicines imported through the Quartet's channels. Because Gilead is unaware of those shipments, it is unable to monitor their travel conditions or determine whether temperature deviations have compromised the medication before it reaches patients.

Gilead also enforces rigorous traceability requirements. Every bottle distributed in the United States is accompanied by a pedigree identifying each distributor and pharmacy that handled the drug before it reaches the patient. The district court found that those pedigrees are "essential" to patient safety because they allow Gilead to trace a medicine's chain of custody, identify where a quality-control problem occurred, and implement

targeted corrective measures. But non-U.S. Gilead products lack those pedigrees, so Gilead can't trace a medicine's chain of custody to determine the origin of a quality issue.

Nor do internationally sourced medicines remain subject to Gilead's recall procedures. Gilead runs targeted recall protocols for its U.S. medicines, but recall notices are issued only in the country where Gilead distributed the affected lot. The district court found that patients who receive internationally sourced medicines through the Quartet's importation scheme therefore fall outside Gilead's recall system because Gilead can't identify or notify them if an international lot is recalled.

Finally, Gilead distributes its U.S. medicines only through authorized distributors whose identities are publicly disclosed. According to the record, Gilead restricts distribution to a closed network to prevent counterfeit, adulterated, or otherwise substandard Gilead medicines from entering the domestic market. The district court aptly found that the Quartet's scheme bypasses that secure supply chain by obtaining Gilead-branded medicines through unauthorized foreign channels outside Gilead's quality control.

These differences create the very risk of consumer confusion that the quality-control doctrine is intended to prevent. *See Iberia Foods*, 150 F.3d at 299. As the Fifth Circuit explained, an unauthorized distributor's failure to comply with a trademark owner's quality controls can create "a latent product defect." *Matrix Essentials, Inc. v. Emporium Drug Mart, Inc.*, 988 F.2d 587, 591 (5th Cir. 1993). And because "a consumer would not necessarily be aware of the defective condition of the product[,]" they "would thereby be confused or deceived." *Id.* We are presented with the same problem here. A consumer receiving a Gilead-branded medication like the Turkish Biktarvy has no way of knowing

whether it was transported outside Gilead's temperature controls, lacks a verifiable chain of custody, or falls outside Gilead's recall system. Yet the consumer reasonably expects that the medicine bearing Gilead's marks has been subjected to all of these Gilead safeguards.[14]

The Quartet resist this conclusion, first arguing that *Shell Oil* limits the quality-control doctrine to measures designed to prevent contamination. Because Gilead manufactures and seals the medications before distribution, the Quartet contend there is no comparable risk here. In so arguing, the Quartet misread *Shell Oil*. There, we observed that Shell's quality standards were necessary because bulk oil could become contaminated during distribution. 928 F.2d at 106. But that observation explained why Shell's quality controls "were an integral part of the bulk product identified by the marks." *Id.* at 107. The relevant inquiry is whether the trademark owner's quality controls are legitimate, substantial, and integral to the product sold under its marks—not whether they address a particular quality risk. *See id.*; *Zino Davidoff*, 571 F.3d at 246.

Nor can we agree that Gilead's transportation-temperature protocols are pretextual. The Quartet contend that Biktarvy can tolerate temperatures exceeding 86 degrees Fahrenheit during shipment without affecting its safety or efficacy. But that simply creates a factual question. The district court reasonably credited Gilead's evidence that its FDA-approved labeling establishes temperature limitations and that Gilead investigates any shipment exceeding those limits before the medication reaches patients. *Cf.* J.A. 163–64,

[14] For that reason, Gilead need not prove that the importation scheme has actually resulted in counterfeit, adulterated, or otherwise defective medicines reaching consumers.

3320–21. The Quartet's competing evidence doesn't convince us that the district court made a "clearly erroneous finding of a material fact." *Leaders of a Beautiful Struggle*, 2 F.4th at 339 (citation omitted). We thus have no license to disturb its findings.

The fact that the Quartet may employ similar (or even better) quality controls fares no better. According to the Quartet, their foreign pharmacy partners maintain temperature controls, report quality events through the country of origin, and communicate foreign recall notices to U.S. patients. This argument conflates product quality with quality control. Trademark law protects the trademark owner's right to control the quality associated with its marks. *See Shell Oil*, 928 F.2d at 107. At bottom, "[i]t is insufficient that [the Quartet] employed [their] own quality standards. Without [Gilead]'s enforcement of its quality controls, the [medications] sold by [the Quartet were] not truly 'genuine.'"[15] *Id.*

* * *

The imported Gilead-branded medications here aren't genuine goods under the Lanham Act. They materially differ from the medications Gilead authorizes for domestic sale and they reach consumers while skirting Gilead's quality-control system. Either defect supports a likelihood of confusion; together, they make Gilead's showing especially strong.

[15] The Quartet also invoke *NEC Electronics v. CAL Circuit Abco*, 810 F.2d 1506 (9th Cir. 1987), arguing that Gilead retains adequate quality control because the domestic and foreign manufacturers are under common control. But *NEC Electronics* involved identical computer chips sold by both the foreign parent and its domestic subsidiary. *Id.* at 1507–08. Here, the foreign-market medications materially differ from the domestic versions and reach American consumers outside the quality-control system Gilead uses for domestic distribution. Common corporate control over the manufacturers does not eliminate those differences.

And because the imported medications aren't genuine, the first sale doctrine doesn't bar Gilead's claims. *See Davidoff & Cie*, 263 F.3d at 1302.

c.

Each member of the Quartet participated in importing, marketing, distributing, or selling non-genuine Gilead-branded medications in the United States without Gilead's authorization. Rx Valet advertised and arranged the program; Advanced Pharmacy processed prescriptions and coordinated foreign fulfillment; and Affordable Rx advertised those medications on its website and sourced and arranged their delivery. As the controlling executive of Rx Valet and Advanced Pharmacy, Santulli designed the international sourcing business, executed contracts for those services, oversaw their implementation, and approved payments for internationally sourced medications.

What Gilead sells in Turkey and what it sells in Maryland share a chemical formula but materially differ and travel through different quality-control systems. Because the imported medications aren't genuine goods, the Quartet's use of Gilead's registered marks in selling those products is likely to cause consumer confusion and therefore likely violates the Lanham Act. We thus agree with the district court that the record shows Gilead is likely to succeed on the merits of its direct infringement claims.

3.

We next consider Gilead's contributory trademark infringement claims against Meritain and ProAct. Although the Lanham Act doesn't explicitly provide for secondary liability, one who "facilitate[s] or encourage[s] [trademark] infringement" is also liable under the "judicially created doctrine" of contributory infringement. *See Rosetta Stone*,

676 F.3d at 163 (cleaned up). To make out a claim for contributory trademark infringement, a plaintiff must prove (1) "underlying direct infringement" by a third party, *id.*; and (2) that the defendant *either* (a) "intentionally induce[d] another to infringe a trademark" *or* (b) continued to supply the product or service to someone that the defendant "knows or has reason to know is engaging in trademark infringement," *Inwood Lab'ys, Inc. v. Inves Lab'ys, Inc.*, 456 U.S. 844, 854 (1982); *Rosetta Stone*, 676 F.3d at 164–65 (applying *Inwood*'s knowledge prong to one supplying services).

The first element is satisfied given our discussion about the Quartet above. As for the second element, although Gilead raised both prongs below, the district court rested its decision solely on the knowledge prong. Because we conclude that the district court didn't err, we need not consider intentional inducement.

The district court concluded that Gilead was likely to succeed on its contributory infringement claims because Meritain and ProAct continued providing services to the Quartet despite knowing—or having reason to know—that the Quartet was importing and distributing infringing Gilead-branded medications. As for Meritain, the court found that it supplied the patient-data stream and claims-processing services necessary for AFPs to source foreign-market Gilead medications. As for ProAct, the court found that it programmed the system edits that redirected patients to the Quartet's international-sourcing program and processed the resulting pharmacy claims.

a.

Meritain and ProAct principally dispute what the knowledge requirement demands. In their view, knowledge can be established only by proof that they were specifically

notified of the alleged infringement and that they nevertheless continued providing services after such notice. Meritain and ProAct contend that they lacked the required knowledge because they had no prior notice of the alleged infringement. Before filing suit, Gilead never sent cease-and-desist letters or otherwise informed them that the Quartet's conduct allegedly infringed Gilead's trademarks, and neither court filings or law enforcement action otherwise put them on notice. Evidence that they generally knew some plans participated in international drug sourcing—or that their services could facilitate such sourcing—is, they argue, insufficient.

Meritain and ProAct misstate *Inwood*'s knowledge requirement. Contributory trademark liability doesn't require a defendant to have been on prior specific notice of infringement before continuing to provide its services to a direct infringer. Under *Inwood*, a defendant is liable if it "continues to supply its product to one whom it knows or has reason to know is engaging in trademark infringement." 456 U.S. at 854. Consistent with *Inwood*, we have explained that "[i]t is not enough to have general knowledge that some percentage of the purchasers of a product or service is using it to engage in infringing activities[.]" *Rosetta Stone*, 676 F.3d at 163. Instead, a "defendant must supply its product or service to 'identified individuals' that it knows or has reason to know are engaging in trademark infringement." *Id.* (quoting *Sony Corp. of Am. v. Universal City Studios, Inc.*, 464 U.S. 417, 439 n.19 (1984)). Prior notice from the trademark holder isn't part of this test.

Our decision in *Rosetta Stone* is instructive. There, we described a spreadsheet Rosetta Stone provided to Google before the suit documenting "approximately 200

instances" of alleged infringement as "[t]he most significant evidence" of Google knowing users were using its services to infringe. *Id.* at 163. Based in part on that evidence, we held that Rosetta Stone had created a genuine dispute over whether Google possessed the requisite knowledge for contributory liability. *Id.* at 164–65. But we never held that prior notice from the trademark holder (or otherwise) was required, only that Rosetta Stone produced sufficient and compelling evidence that Google knew of the alleged infringement.

Perhaps anticipating this view of *Rosetta Stone*, Meritain and ProAct seek to rely on *Tiffany (NJ) Inc. v. eBay Inc.*, 600 F.3d 93 (2d Cir. 2010). But that reliance is misplaced, as *Tiffany* is similarly bereft of support that prior notice is required to satisfy the knowledge requirement. There, Tiffany argued that eBay was contributorily liable because it generally knew counterfeit Tiffany products were being sold on its online marketplace but continued providing its services to the sellers. *Id.* at 106–07. The Second Circuit rejected that theory, explaining that eBay needed "[s]ome contemporary knowledge of which particular listings [were] infringing or [would] infringe in the future." *Id.* at 107. But the court didn't hold that such knowledge could be established only through prior notice. *See Luxottica Grp., S.p.A. v. Airport Mini Mall, LLC*, 932 F.3d 1303, 1314 (11th Cir. 2019) ("[*Tiffany*] did not categorically shift the burden onto trademark holders to provide notice to defendants[.]"). At most, these cases show that evidence of prior notice is one possible way to prove a defendant's knowledge—but a sufficient means in one case does not become a necessary element in the next.

Meritain and ProAct's proposed rule can't be reconciled with *Inwood*'s recognition that liability extends to one who "has reason to know"—or constructive knowledge—of infringement. 456 U.S. at 854; *cf. Luxottica*, 932 F.3d at 1312. "Across the circuits, a consensus has developed that willful blindness is one way to show that a defendant had constructive knowledge in cases of contributory trademark infringement." *Luxottica*, 932 F.3d at 1312. And one is willfully blind when "his suspicion aroused but then deliberately omits to make further enquiries, because he wishes to remain in ignorance." *Al-Sabah v. World Bus. Lenders, LLC*, 160 F.4th 540, 550 (4th Cir. 2025) (citation omitted). If a defendant had the requisite knowledge when he deliberately avoided confirming what he strongly suspected, it follows that knowledge need not always be established through evidence that the defendant knew of the infringement only through prior notice. Indeed, the Second Circuit recognized this precise point. *See Tiffany*, 600 F.3d at 109 ("[I]f eBay had reason to suspect that counterfeit Tiffany goods were being sold through its website, and intentionally shielded itself from discovering the offending listings or the identity of the sellers behind them, eBay might very well have been charged with knowledge of those sales sufficient to satisfy *Inwood*'s 'knows or has reason to know' prong.").

Inwood itself confirms that the relevant inquiry is whether the defendant knew—or had reason to know—that the users of its services are engaging in infringing conduct. 456 U.S. at 854. There, Ives manufactured a trademarked prescription drug sold in distinctive blue and blue-red capsules. *Id.* at 847. Generic manufacturers marketed chemically equivalent drugs in capsules of the same colors. *Id.* Ives sued the generic manufacturers for contributory trademark infringement, alleging that pharmacists substituted the generic

capsules for the brand-name drug while dispensing them under Ives' trademark. *Id.* at 849–50.

Concurring in the judgment only, Justice White expressed concern that the majority "silently acquiesce[d] in a significant change in the test for contributory infringement." 456 U.S. at 861 (White, J., concurring in the judgment). After setting out the inducement-or-knowledge standard, the majority responded to Justice White and made clear that it "approve[d]" of the standard that Judge Friendly had articulated below in the Second Circuit. *Id.* at 854 n.13. And, as Judge Friendly put it, a

> manufacturer or wholesaler would be liable [under the Lanham Act] if [1] he suggested, even if only by implication, that a retailer fill a bottle with the generic capsules and apply Ives' mark to the label, or [2] continued to sell capsules containing the generic drug which facilitated this to a druggist *whom he knew or had reason to know was engaging in the practices just described*.

Ives Lab'ys, Inc. v. Darby Drug Co., 601 F.2d 631, 636 (2d Cir. 1979) (emphasis added).

Distilling these principles, the relevant inquiry is whether Meritain and ProAct continued providing their services to the Quartet while knowing or having reason to know that the Quartet was importing and distributing Gilead-branded medications that weren't genuine. On this record, we discern no error in the district court's conclusion that they had that knowledge.

b.

Starting with Meritain, the record contains ample evidence that it knew or should have known it was facilitating the importation of Gilead medications despite its written policy against doing so. According to Meritain, it doesn't integrate or support programs that permit clients to internationally source prescription drugs not approved for use in the

United States; it doesn't pay international-sourcing charges; it refuses to connect clients with international-sourcing vendors; and it communicates that policy to clients. Meritain also contends that it requires carve-out PBMs such as ProAct to attest that they won't submit invoices for internationally sourced drugs.

The district court concluded, and understandably so, that Meritain's conduct often contradicted its written policy. Rather than refuse to support international sourcing, the record shows Meritain continued providing its patient data stream and invoice-processing services to those it knew were internationally sourcing drugs, including Gilead-branded ones.

Meritain's own records illustrate its disregard for its stated policy. One of its clients used ScriptSourcing, an AFP, to obtain internationally sourced drugs. In an internal email from December 2020, a Meritain analyst identified a ScriptSourcing invoice showing that Meritain processed and paid for imported Gilead-branded drugs, including Genvoya. S.J.A. 5496–98. The analyst warned that she had "**grave concerns that *we are doing exactly what we said we would not do here***." S.J.A. 5497 (emphases in original). Jeremy Wisniewski, Meritain's Director of Pharmacy Management, responded: "That's exactly what this is – an invoice for internationally sourced meds." S.J.A. 5496. Wisniewski later testified that Meritain, despite its policy, nevertheless continued paying those invoices as a "client service." J.A. 1932–33.

What's more, the record shows that ScriptSourcing wasn't an isolated incident. In April 2023, another Meritain analyst alerted several executives, including Wisniewski, that ProAct was submitting, and Meritain was paying, claims from CanaRx (another AFP) for

internationally sourced drugs. S.J.A. 6139–40. The analyst warned: "**[T]he CanaRx claims are coming through the PBM files mixed in with all their other claims; we have no way of knowing which may truly be from CanaRx.** So basically we[] *are* supporting this international program, even though we say we won't." S.J.A. 6140 (emphases in original).[16] Meritain's response did little to address the problem. It required clients that used ProAct as a carve-out PBM to confirm at enrollment that they were not participating in an AFP. But as the district court found, this measure left Meritain's clients free to adopt an AFP later. As Wisniewski testified, Meritain didn't ask existing clients whether they'd done so, nor did it require them to commit not to do so in the future.

Meritain's marketing materials lend further support to Gilead's position. Shortly before this suit was filed, MPS, Meritain's PBM arm, launched a marketing campaign declaring it a "Myth" that it "does not provide international sourcing." S.J.A. 6167. An accompanying "Frequently Asked Questions" document stated that MPS would support international sourcing and connect its clients with AFPs for that purpose. *See* S.J.A. 6171–72. Internal emails likewise embraced the campaign. Shawn Shapiro, Meritain's Vice President for MPS, told Mr. Wisniewski, "I really like the truth vs. myth theme," S.J.A. 6174, and later urged that it was "[g]ood to start plastering this all over the market," S.J.A.

[16] There's also evidence in the record that Meritain paid invoices for internationally sourced drugs from CanaRx, including emails between ProAct employees about a client that switched from Meritain to a new TPA. S.J.A. 6109. The plan worked with CanaRx and wanted its new TPA to process the CanaRx invoices like Meritain did before. *See id.* ("In the past, Meritain would pay all CanaRx invoices on behalf of [the plan]."). One of Meritain's witnesses agreed that CanaRx "only do[es] international," and testified that when Meritain sees CanaRx, "we immediately think of international sourcing." J.A. 1941.

6202; *see also* S.J.A. 6203 (email from Mr. Shapiro stating: "One [sic] its back in our hands with the international language, let's send this to all ends of the earth").

Meritain also knew or should have known that internationally sourced Gilead-branded medications, like other imported brand-name drugs, materially differed from the domestic versions. A 2023 Meritain advertisement warned that "the health risks of using imported prescriptions make this something we consider unsafe for clients and members," and listed various "dangers that should be considered." J.A. 1964. Among them, imported drugs "[a]ren't approved by the [] FDA" and "[l]ack important information" found on U.S. labels and patient instructions, including the NDC number, which Meritain said was "important drug information." *Id.* As discussed above, the district court identified many of these same differences as material in concluding that the imported medications weren't genuine.[17]

The same is true of ProAct. The district court found that nearly half of ProAct's clients source drugs internationally. For those clients, "ProAct directs them to companies it knows provide international drug sourcing, including Rx Valet and [] CanaRx—including for Gilead-branded drugs like Biktarvy." J.A. 3333; *see* S.J.A. 5696 ("[W]e [ProAct] have partnered with RxValet to help you save time and money on all your pharmacy needs."); S.J.A. 5697–98; *see also* S.J.A. 6804–09 (confirming that ProAct's system edits were programmed for Gilead-branded medicines). ProAct included RxValet savings analysis projections in pricing proposals to prospective clients, highlighting

[17] We note that Meritain is no amateur in this field but an independent subsidiary of CVS Health, one of the largest health conglomerates in the world.

anticipated savings from internationally sourced Gilead-branded medications. And ProAct's corporate representative testified that, in 2024 alone, ProAct "processed and paid for more than 100 claims for internationally sourced Gilead-branded drugs." J.A. 3335.

ProAct wasn't a clueless bystander; it knew or had reason to know that those imported medications materially differed from their domestic counterparts. David Schryver, the president of ProAct, testified that international medications are accompanied by different labels and patient materials, often in foreign languages and using different units of measurement. He acknowledged that the FDA requires labeling and patient information for medications sold in the United States to be in English, whereas medications manufactured for sale in countries such as Turkey would instead bear labeling in Turkish. S.J.A. 6891. Schryver further testified that, before this lawsuit, he understood Turkish Biktarvy to be chemically different from U.S. Biktarvy. *See* S.J.A. 6896. That testimony alone undermines ProAct's claim that it lacked knowledge of the differences between imported and domestically authorized Gilead medications.

Even more telling, ProAct received a memorandum in March 2019 explaining that CanaRx—an AFP with which it worked—received an FDA warning letter the month before. Schryver testified that he reviewed CanaRx's response, which in turn quoted the FDA's letter. *See* S.J.A. 6928–29. The letter explained, among other things, that CanaRx's internationally sourced drugs, including Gilead-branded ones such as Truvada, may "be different in size, shape or color," S.J.A. 6082; "fail to bear adequate warnings against use" where it may be dangerous, S.J.A. 6085; and "do not have the same assurance of safety and efficacy as drugs subject to FDA oversight," S.J.A. 6083. As before, the district court

identified many of those differences as material for purposes of trademark infringement. At the very least, that evidence gave ProAct reason to know that the very medications it helped import differed in the same respects that rendered them non-genuine and thus infringing under the Lanham Act.

Both Meritain and ProAct knew, or had every reason to know, what they were facilitating. Meritain supplied the data and claims-processing services that let AFPs source Gilead medications abroad; ProAct programmed the system edits that steered patients to those programs and processed the resulting claims. Both did so knowing the medications they helped import weren't genuine. That's enough to satisfy *Inwood*'s knowledge prong.

c.

Meritain and ProAct lastly argue that Gilead failed to prove that they exercised sufficient control over the alleged means of infringement. The district court didn't analyze the case through that lens, and correctly so. Neither *Inwood* nor our precedent recognizes "degree of control" as a separate element of contributory infringement.

As just described, the Supreme Court held in *Inwood* that a defendant is contributorily liable if it "intentionally induces" trademark infringement or "continues to supply its product to one whom it knows or has reason to know is engaging in trademark infringement." 456 U.S. at 854. Thirty years later, we extended that same rule to defendants who provide services rather than products. *See Rosetta Stone*, 676 F.3d at 163–65. Neither decision distinguishes between product and service providers, much less requires service providers to exercise a particular degree of control over the means of infringement.

Meritain and ProAct's argument instead traces to several out-of-circuit decisions. To the extent those decisions actually impose the control requirement that Meritain and ProAct advance, we do not find them persuasive. In *Hard Rock Cafe Licensing Corp. v. Concession Services, Inc.*, the Seventh Circuit held that *Inwood* applied to a flea market operator that knowingly permitted vendors to sell counterfeit goods on its premises. 955 F.2d 1143, 1148–49 (7th Cir. 1992). The Ninth Circuit followed suit in *Fonovisa, Inc. v. Cherry Auction, Inc.*, another flea-market case, holding that the operator could be contributorily liable because, although it did not supply the counterfeit recordings themselves, it supplied the marketplace through which they were sold. 76 F.3d 259, 264–65 (9th Cir. 1996). That court later extended its reasoning to other internet intermediaries, including a domain-name registrar who only registered domain names and routed internet traffic, *see Lockheed Martin Corp. v. Network Sols., Inc.*, 194 F.3d 980, 985 (9th Cir. 1999), and credit-card processors that processed payments for websites selling allegedly infringing goods, *see Perfect 10, Inc. v. Visa Int'l Serv. Ass'n*, 494 F.3d 788, 793, 807 (9th Cir. 2007). In doing so, the Ninth Circuit added a requirement that's notably absent from *Inwood*: service providers must exercise "[d]irect control and monitoring of the instrumentality used by a third party to infringe the plaintiff's mark." *Lockheed Martin*, 194 F.3d at 984.

That requirement finds little support. Neither *Hard Rock* nor *Fonovisa* held that direct control over the means of infringement is an independent element of contributory liability when the defendant provides services. *Hard Rock* held only that *Inwood* isn't limited to manufacturers and distributors because a flea market operator that knowingly

permits trademark infringement on its premises may likewise be contributorily liable. 955 F.2d at 1148–49. Likewise, *Fonovisa* observed that although the flea market operator "is not alleged to be supplying the recordings themselves, it is supplying the necessary marketplace for their sale in substantial quantities." 76 F.3d at 265. Neither court purported to add a third element of direct control to *Inwood*'s two-part test. *Lockheed Martin* nevertheless injected a new requirement that considers whether a defendant has "[d]irect control and monitoring of the instrumentality used by a third party to infringe the plaintiff's mark." 194 F.3d at 984.

We decline to make the same leap. *Rosetta Stone* extended *Inwood* to service providers without the gloss adopted by the Ninth Circuit. Neither *Inwood* nor the decisions of the other circuit courts invoked support treating "degree of control" as a separate element of contributory trademark infringement.[18] Whether a defendant supplies products or services, contributory liability in this circuit is governed by *Inwood*'s inducement-or-knowledge standard.

* * *

[18] We note that even if we were to apply a "control" requirement, we would find it satisfied here. Meritain and ProAct "suppl[y] the necessary marketplace" for the Quartet's importation of unauthorized Gilead-branded drugs by referring patients to buy from those international importers, providing key data to enable the importers' fulfillment of the prescription, and often paying the invoice after the fact. *Lockheed Martin*, 194 F.3d at 984 (internal quotation marks omitted). They also "monitor" the means of infringement through both their referrals to and contracts with infringing international importers on the front end, and their payment of invoices on the back end. *Perfect 10*, 494 F.3d at 807. This degree of control and monitoring gives Meritain and ProAct the "power to . . . directly stop" the infringement at issue here. *Id.*

In sum, we conclude that Gilead satisfies the first preliminary injunction requirement: it's likely to succeed on the merits of its Lanham Act claims against Meritain, ProAct, and the Quartet.

B.

We now turn to irreparable harm, the second *Winter* factor. 555 U.S. at 22. Given our conclusion that Gilead is likely to succeed on the merits of its Lanham Act claims, the Trademark Modernization Act of 2020 provides for a "rebuttable presumption of irreparable harm[.]" 15 U.S.C. § 1116(a); *cf. Lone Star Steakhouse & Saloon, Inc. v. Alpha of Va., Inc.*, 43 F.3d 922, 939 (4th Cir. 1995) (explaining that "irreparable injury regularly follows from trademark infringement"). The district court concluded that Appellants failed to rebut that presumption, and even without it, Gilead "resoundingly demonstrated it will likely suffer irreparable harm absent preliminary injunctive relief[,]" and that the "risk of harm to Gilead's good will and reputation among the patient and healthcare providing relevant community is stark and acute." J.A. 3353.

Appellants argue that the 10-month period between Gilead's first becoming aware of John Doe's complaint in February 2024 and filing suit in December 2024 rebuts any presumption of irreparable harm. After Gilead learned that Doe received Turkish Biktarvy, it didn't immediately file suit but asked Doe to send the medication to its quality assurance team to investigate. Gilead also reported the incident to the FDA and undertook a broader investigation into the scheme before filing suit. The district court found that those efforts didn't militate against a finding of irreparable harm:

> 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.

Id.

Taking issue with the district court's finding, Appellants rely on *Tough Traveler, Ltd. v. Outbound Products*, 60 F.3d 964 (2d Cir. 1995), to argue that "the presumption of irreparable harm 'is inoperative if the plaintiff has delayed either in bringing suit or in moving for preliminary injunctive relief.'" Quartet Opening Br. 46 (quoting *Tough Traveler*, 60 F.3d at 968). But *Tough Traveler* recognizes that delay does not undermine irreparable harm when it results from "the plaintiff's [] good faith efforts to investigate the alleged infringement." 60 F.3d at 968. That's what the district court found occurred here, and Appellants haven't come close to showing that its finding was an abuse of discretion.[19]

[19] Quite peculiarly, Appellants assail the district court's irreparable-harm finding based in part on its observation that the Quartet "deduced no evidence of prejudice resulting from the 10-month delay." J.A. 3346. They argue on appeal that a critical witness passed away during that period, "leaving [them] without his institutional memory or assistance in marshalling evidence." Quartet Opening Br. 52. But the district court made its "no prejudice" finding when rejecting Appellants' laches defense vis-à-vis Gilead's likelihood of success on the merits, not when assessing irreparable harm. After all, when determining the viability of a laches defense to a trademark infringement claim, courts consider "at least" three factors, including whether any delay was unduly prejudicial to the infringing user. *Ray Commc'ns, Inc. v. Clear Channel Commc'ns, Inc.*, 673 F.3d 294, 300–302 (4th Cir. 2012). Appellants don't challenge the district court's rejection of their laches defense on appeal, and the factors that are relevant to that assessment shed no light on the irreparable harm assessment. Their reliance on that finding is therefore misplaced.

C.

We end with the remaining *Winter* factors—the balance of equities and the public interest. 555 U.S. at 22. As for the equities, the district court reasoned that Appellants had little interest in continuing conduct that federal law prohibits. Balancing that consideration against the irreparable harm to Gilead's commercial interests, the court concluded that these factors favor injunctive relief.

Appellants argue that a preliminary injunction undermines the public interest because American consumers benefit from the lower costs of imported prescription medications. And because there's no risk of harm from the importation of those authentic drugs, Appellants maintain that the balance of the equities doesn't support an injunction. But that argument assumes the imported medications are genuine merely because Gilead manufactured them and their chemical formulation is the same. As explained above, they are not. Appellants give us no basis to disturb the district court's contrary findings.

III.

For the reasons discussed above, and having otherwise considered the parties' arguments, the district court didn't abuse its discretion in granting Gilead's preliminary injunction motion. That decision is therefore

AFFIRMED.