

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION**

NOVARTIS AG and
GENENTECH, INC.,

Plaintiffs,

v.

SHARx, LLC and CAMPBELL
HEIGHTS PHARMACY LTD.,

Defendants.

Case No. 4:26-cv-10371

Honorable Shalina D. Kumar
Magistrate Judge Curtis Ivy, Jr.

**DEFENDANT SHARx, LLC's REPLY IN SUPPORT OF ITS
RULE 12(b)(6) MOTION TO DISMISS**

The Court should dismiss the Complaint because it does not allege plausible facts showing (1) SHARx used the Xolair marks in a trademark way, (2) there is likelihood of consumer confusion, or (3) the first sale defense does not apply.¹

I. Plaintiffs Fail to State a Claim for Trademark Infringement

First, dismissal is proper because the Complaint does not plausibly allege that SHARx uses the Xolair mark in a trademark way. To state a claim, Plaintiffs must allege SHARx uses the challenged mark in a way that identifies the source of SHARx's own goods or services, not Plaintiffs'. See *Hensley Mfg. v. ProPride, Inc.*, 579 F.3d 603, 610

¹ Plaintiffs' claims of illegality are a red herring, as Plaintiffs do not (and cannot) bring a cause of action to enforce or restrain any alleged violations of the Federal Food, Drug and Cosmetics Act (FDCA). *Kemp v. Medtronic*, 231 F.3d 216, 236 (6th Cir. 2000) (holding no private right of action exists under the FDCA). Only the federal government may choose to do so. 21 U.S.C. § 337(a).

(6th Cir. 2009) (citing *Interactive Prod. Corp. v. a2z Mobile Office Sol., Inc.*, 326 F.3d 687, 695 (6th Cir. 2003)).

Plaintiffs’ three examples of SHARx’s trademark use fail. ECF No. 32, PageID.9-11. The Complaint does not allege SHARx is a retailer or seller of goods or that it placed a mark on any good. The stickers placed on shipments of Canadian Xolair (that do not mention SHARx) do not plausibly allege that SHARx used the Xolair mark as a trademark to identify SHARx’s own goods. *See* ECF No. 1, PageID.44, ¶ 147. Further, the alleged advertisement to Stark County (*Id.*, PageID.38-39, ¶ 128) and the Prescription Form (*Id.*, PageID.42-43, ¶ 143) truthfully identify SHARx as the source of SHARx’s advertised or offered service—helping clients obtain their medications. Xolair is identified in a “non-trademark way” and “fairly and in good faith.” *See Sazerac Brands, Ltd. Liab. Co. v. Peristyle, Ltd. Liab. Co.*, 892 F.3d 853, 859-60 (6th Cir. 2018).

Second, Plaintiffs wrongly and speculatively conclude that SHARx represents to consumers that it will source U.S. Xolair or FDA-approved Xolair, citing the same alleged advertisement. ECF No. 1, PageID.38-39, ¶ 128. But the advertisement merely identifies Xolair not U.S. Xolair or FDA-approved Xolair. *Id.* Thus, Plaintiffs conflate medications identified by a brand name with FDA-approved medications. Further, Plaintiffs’ suggestion that SHARx misrepresents itself as an authorized distributor of Xolair is wholly absent from the Complaint. ECF No. 32, PageID.433.

Third, “[C]onfusion that is brief or that occurs among individuals who are not familiar with the products in question is entitled to considerably less weight than are

chronic mistakes and serious confusion of actual customers.” *Therma-Scan, Inc. v. Thermoscan, Inc.*, 295 F.3d 623, 634 (6th Cir. 2002) (internal quotations omitted). The clinic employees’ alleged confusion as to why the shipments and packaging looked different does not plausibly allege confusion about the source or origin of the product. ECF No. 1, PageID.30-31 ¶¶ 90, 92, 94. Indeed, the clinic’s inquiry to Genentech about the shipment demonstrates a lack of confusion as to the source of the shipments. ECF No. 1, PageID.31 ¶ 96.

Fourth, Plaintiffs have not plausibly alleged SHARx is liable for contributory infringement. Plaintiffs claim SHARx ignores inducement liability and only focuses on vicarious liability. That is because allegations supporting inducement liability are completely absent from the Complaint. The Complaint’s allegations that SHARx partners with pharmacies as part of the alleged “scheme” amount to legal conclusions couched as facts that must be ignored. ECF No. 1, PageID.42, 43 ¶¶ 143-45.

II. The First Sale Doctrine Applies Because the Product is Genuine and Plaintiffs Made the Initial Sale

Plaintiffs do not allege that the product at issue is not genuine Xolair; that they did not make the first sale to Campbell Heights Pharmacy; or that the Xolair was imported or sold for anything other than its approved purpose. Instead, Plaintiffs rely on distinct cases and speculative assertions that do not plausibly allege claims.

Plaintiffs wrongly characterize this as a “gray goods” case. ECF No. 32 PageID.437. Imported goods that are physically the same and manufactured by the U.S.

trademark holder do not violate trademark law. *Olympus Corp. v. U.S.*, 792 F.2d 315, 321 (2d Cir. 1986) (noting Congress could have amended the Lanham Act to bar gray market goods but chose not to do so); *see also Weil Ceramics & Glass, Inc. v. Dash*, 878 F.2d 659, 674-675 (3d Cir. 1989) (holding goods must be physically different to be actionable under the Lanham Act). The Complaint alleges consumers receive Canadian Xolair, which, like U.S. Xolair, is the same, exact drug manufactured by Plaintiff Novartis.

Plaintiffs rely on *FURminator, Inc. v. Kirk Weavers Enters.*, 545 F. Supp. 2d 685, 690 (N.D. Ohio 2008) for the proposition that goods cannot be genuine where the original sale was not approved by the trademark holder. This reliance is misplaced. Plaintiffs (or their affiliates) made the first sale to Campbell Heights Pharmacy. Aside from a parenthetical to a factually distinct case², Plaintiffs do not allege anywhere that they did not make the original sale (because they did).

The first sale doctrine therefore applies here and bars Plaintiffs' claims. *See Yamaha Corp. of Am. v. U.S.*, 295 U.S. App. D.C. 158; 961 F.2d 245, 251 (D.C. Cir. 1992) (holding "no cause of action arises under the Lanham Act when an American importer imported genuine trademarked items . . . sold overseas by the parent of the American trademark holder."); *see also Sebastian Int'l, Inc. v. Longs Drug Stores Corp.*, 53 F.3d 1073, 1074 (9th Cir. 1995) (holding that "[r]esale by the first purchaser of the original article under the producer's trademark is neither trademark infringement nor unfair competition.").

² In *FURminator*, plaintiff sued defendant after learning that defendant obtained plaintiff's pet products from a third party who had agreed to destroy them.

A. No Exception to the First Sale Doctrine Applies

Plaintiffs incorrectly assert that material differences cannot be dismissed under Rule 12. ECF No. 32 PageID.439. This District has granted a motion to dismiss under Rule 12 in a similar case. *See One Vodka, LLC v. Benchmark Bev. Co., LLC*, No. 21-11456, 2022 U.S. Dist. LEXIS 51677, *6-7, 17 (E.D. Mich. Mar. 22, 2022) (granting defendant’s Rule 12 motion as defendant “did no more than engage in the authorized resale of genuine One Vodka”). Plaintiffs’ assertion that all a plaintiff must do is allege “material differences” misstates the law and should be rejected by this Court. Dismissal under Rule 12(b)(6) is proper.

B. First Sale is Not Defeated by Plaintiffs’ Conclusory Assertions of “Material Differences”

Plaintiffs reliance on *Brilliance Audio, Inc. v. Hights Cross Communs., Inc.*, 474 F.3d 365 (6th Cir. 2007) for the proposition of a low bar of materiality is misplaced. ECF No. 32, PageID.439. In *Brilliance*, the relevant consumer was an audiobook listener, which the court found had a “myriad” of options due to consumer preference. *Id.* at 370. Conversely, the relevant consumer here, a patient who is prescribed Xolair, does not have a preference nor choose their medication. Doctors prescribe medication according to a patient’s symptoms. Consumer-driven distinctions have no relevance here.

Even so, Plaintiffs fail to allege any material differences between US and Canadian Xolair because there are none. Plaintiffs’ arguments contradict themselves. Plaintiffs assert that the use of different temperature units on temperature tags is materially

confusing, yet Plaintiffs themselves use metric units for body weight on the US Xolair labeling. *See* Ex. A to ECF No. 29, § 2.1 “Dosage and Administration.”

Plaintiffs’ reliance on *Gilead* and *Abbott Laboratories* is distinguishable as those cases involve differences not present here. *Gilead Sciences, Inc. v. Meritain Health, Inc.*, 2025 LX 143217, at *37 (D. Md. 2025) (involving Turkish BIKTARVY® packaging with instructions in Turkish); *Abbott Lab. v. Adelphia Supply USA*, No. 15-CV-5826 (CBA) (LB), 2019 U.S. Dist. LEXIS 194268, at *27 (E.D.N.Y. Sep. 27, 2019) (involving non-prescription glucose test strips many not containing English instructions to be used with different meters). The remaining cases cited by Plaintiffs involve fundamentally different types of products – consumer goods that can be purchased directly without a prescription.³

Plaintiffs dismiss SHARx’s remaining arguments as “baseless”, asserting SHARx improperly injected its own facts. ECF No. 32 PageID. 442-3. Yet Plaintiffs alleged no facts showing that quality control standards were compromised. Plaintiffs’ claim that Canadian Xolair is subject to more stringent standards further supports SHARx’s position that there are no meaningful quality control differences. Plaintiffs’ reliance on the absence of a Medication Guide is likewise immaterial, as the same information appears in the Canadian Xolair Prescribing Information. *See* Ex. B to ECF No. 29. All alleged quality

³ *Abercrombie & Fitch v. Fashion Stores of Kentucky, Inc.*, 363 F. Supp. 2d 952 (S.D. Ohio 2005) (clothing items); *Helene Curtis, Inc. v. Nat’l Wholesale Liquidators*, 890 F. Supp 152 (E.D.N.Y 1995) (hair products); *Zip Int’l Group LLC, v. Zenith Foods LLC*, No. 20-CV-3356 (ARR) (PK), 2021 U.S. Dist. LEXIS 223199 (E.D.N.Y. Nov. 18, 2021) (European specialty foods); and *Nestle USA, Inc. v. Best Foods LLC*, 562 F. Supp. 3d 626 (C.D. Cal. 2021) (Nestle food products).

control concerns are theoretical and speculative. Because Plaintiffs fail to allege actual, material differences, their conclusory allegations do not state a claim and should be dismissed.

CONCLUSION

For these reasons, the Court should dismiss the Complaint.

Respectfully submitted,

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Dated: May 1, 2026

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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF filing system, which will send notification of such filing to all counsel of record.

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