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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

SCILEX PHARMACEUTICALS INC., Plaintiff, v. SANOFI-AVENTIS U.S. LLC and HISAMITSU AMERICA, INC., Defendants.	CASE NO. 21-CV-1280 **COMPLAINT** **DEMAND FOR JURY TRIAL**

Plaintiff Scilex Pharmaceuticals Inc. ("Scilex"), by and through its attorneys, alleges as follows for its complaint against defendants Sanofi-Aventis U.S. LLC ("Sanofi") and Hisamitsu America, Inc. ("Hisamitsu") (collectively, "Defendants"):

NATURE OF THE ACTION

1. Through this action, Scilex seeks an award of damages and the entry of injunctive relief to address Defendants' ongoing false and deceptive advertising of their respective over-the-counter ("OTC") lidocaine patch products, namely, Sanofi's IcyHot® Lidocaine Patch, Aspercreme® Lidocaine Patch and Aspercreme® XL Lidocaine Patch, and Hisamitsu's Salonpas® Lidocaine Pain Relieving Gel-Patch (collectively, the "OTC Lidocaine Patches").

2. Lidocaine is a topical anesthetic that is used to treat pain by depressing sensory receptors in the nerve endings in the skin, which prevents pain signals from reaching the brain. The United States Food and Drug Administration ("FDA") first approved lidocaine for topical use in the early 1950s.

3. In 1983, the FDA published the Tentative Final Monography for External Analgesic Drug Products for Over-the-Counter Human Use, 48 Fed. Reg. 5852-01 (Feb. 8, 1983) ("TFM"), which provides permissible language for the labeling, ingredients, and doses for OTC external analgesic products, including those containing 0.5% to 4% lidocaine.

4. In 1999, the FDA approved the first transdermal lidocaine patch, in which 5% topical lidocaine is included in a pressure-sensitive adhesive material that attaches to the skin. The patches are indicated by the FDA only for relief of pain associated with post-herpetic neuralgia ("PHN"), a complication of shingles. The FDA has since approved other prescription-only lidocaine patch products to treat PHN pain. While the FDA has approved these products to treat the symptoms of PHN and to provide temporary pain relief, many patients have experienced various problems with their adhesion and efficacy.

5. These problems led Scilex to develop its ZTlido® (lidocaine topical system) 1.8% product, a patch containing 1.8% lidocaine by weight, which is dissolved in Scilex's proprietary single-layer nonaqueous polymer matrix system, allowing for a thinner patch that both provides superior adhesion to the skin over patches containing 5% lidocaine by weight, and efficiently delivers lidocaine to the area of pain.

6. Extensive scientific studies have demonstrated both the bioequivalence of the 1.8% lidocaine in Scilex's ZTlido® patch to the 5% lidocaine in other companies' FDA-

approved, prescription-only lidocaine patches, as well as the superiority in adhesion of Scilex's ZTlido® patch over other companies' FDA-approved, prescription-only 5% lidocaine patches. The results of these studies show that Scilex's ZTlido® patch delivers the same amount of lidocaine to the area of pain as other companies' prescription-only 5% lidocaine patches. In addition, the superior adhesion of Scilex's ZTlido® patch allows it to adhere to the skin for a full 12 hours and provide pain relief for 24 hours.

7. In 2018, the FDA approved Scilex's ZTlido® product to treat pain associated with PHN. However, doctors routinely prescribe Scilex's ZTlido® product for off-label indications, such as general neuropathic pain, including back and spinal pain. While ZTlido® can be used for such off-label indications, Scilex is precluded by FDA regulations from advertising its product for such indications.

8. In 2003, the FDA issued a proposed rule to amend the TFM to explicitly exclude patches and to classify OTC patches containing analgesic ingredients as Category III products, for which "more data [is] needed" to determine if the products are "generally recognized as safe and effective." *See* External Analgesic Drug Products for Over-the-Counter Human Use; Reopening of the Administrative Record and Amendment of Tentative Final Monograph, 68 Fed. Reg. 42324-01, 42326 (July 17, 2003). Category III products may only be marketed and sold following FDA review and approval of the product and its labeling through a New Drug Application ("NDA") or Abbreviated New Drug Application ("ANDA").

9. In 2016, despite neither complying with the TFM labeling requirements for products containing Category I ingredients nor undergoing the FDA review and approval process for products containing Category III ingredients, Defendants began marketing, distributing and selling their OTC Lidocaine Patches containing 4% lidocaine by weight under the guise of being compliant with FDA regulations. However, Defendants' labeling and marketing of their OTC Lidocaine Patches not only fail to comply with the FDA regulations for OTC lidocaine-containing drug products, but are independently false and deceptive.

10. Using glossy advertisements featuring Shaquille O'Neil and "Dr. Bob" Arnot, among others, along with other highly deceptive packaging and online marketing, Defendants

have embarked on an advertising blitz propagating claims that their OTC products: (a) contain and/or deliver to the area of pain the maximum amount of lidocaine available in patch form; (b) block and/or numb pain; (c) target and/or desensitize aggravated nerves; (d) target more pain receptors than other lidocaine patch products; (e) adhere to the skin and provide pain relief for periods of 8 or 12 hours, depending on the product; (f) are indicated by the FDA for treatment of nerve and neuropathic pain, including back and spinal pain; and/or (g) are FDA-approved, prescription products.

11. In addition to lacking any FDA review or approval for their products' marketing and labeling, Defendants' advertising claims are inaccurate and misleading. Defendants' false and deceptive claims have duped consumers and others into purchasing Defendants' OTC Lidocaine Patches, rather than prescription lidocaine patches produced by Scilex and other FDA-approved, prescription-only lidocaine patch producers. Indeed, the FDA has already recognized that several of the claims Defendants are making with respect to their OTC Lidocaine Patches are misleading to consumers. And cumulatively, Defendants' claims give the false impression that Defendants' OTC Lidocaine Patches are superior, or equivalent, in efficacy to FDA-approved, prescription-only lidocaine patches, such as those offered by Scilex.

12. By making such false and misleading advertising claims through various channels—including their product packaging, online content, social media, and television advertisements—Defendants have achieved their intended goal of increasing their sales and profits by deceiving consumers regarding the nature, characteristics and efficacy of Defendants' OTC Lidocaine Patches, which directly compete with Scilex's ZTlido® patch products. Defendants' unfair and deceptive practices have also caused Scilex to experience significant damages, including an adverse impact on the sales of its ZTlido® products and a diminution of goodwill in its ZTlido® mark, as Defendants have deceived consumers into buying Defendants' patches instead of prescription patches, such as ZTlido®.

13. Based on the foregoing conduct, as alleged in more detail below, Scilex seeks an award of damages against Defendants and the entry of injunctive relief enjoining further dissemination of Defendants' false and deceptive advertising. Such relief is appropriate because

Defendants have violated Sections 43(a)(1)(A) and 43(a)(1)(B) of the Lanham Act (15 U.S.C. §§ 1125(a)(1)(A) & 1125(a)(1)(B)), California's False Advertising Law (Cal. Bus. & Prof. Code §17500) ("FAL"), and California's Unfair Competition Law (Cal. Bus. & Prof. Code § 17200) ("UCL").

JURISDICTION AND VENUE

14. The Court has jurisdiction over the subject matter presented by this Complaint pursuant to 28 U.S.C. § 1331 because it includes a claim of false and deceptive advertising under the Lanham Act (15 U.S.C. §§ 1051, *et seq*.), including 15 U.S.C. § 1121, which expressly provides that claims arising thereunder are subject to federal subject matter jurisdiction.

15. Pursuant to 28 U.S.C. § 1338(b), this Court has supplemental jurisdiction over Scilex's state law claims, in that those claims are joined with substantial and related claims under the Lanham Act. This Court also has supplemental jurisdiction over Scilex's state law claims pursuant to 28 U.S.C. § 1367(a), in that all of Scilex's claims arise out of a common nucleus of operative facts.

16. Venue is proper in this district pursuant to 28 U.S.C. § 1391(a) because a substantial part of the events or omissions giving rise to Scilex's claim occurred in this district, as Defendants conduct substantial business within California, including the marketing, distribution, and sale of their respective products in California, and because Scilex's claims arise from the marketing, distribution and sale of Defendants' respective products in California.

PARTIES

17. Plaintiff Scilex is a Delaware corporation, with its principal place of business at 960 San Antonio Road, Palo Alto, CA 94303. Plaintiff Scilex markets, distributes, and sells the FDA-approved, prescription-strength topical analgesic self-adhesive patch under the brand name ZTlido®. ZTlido® is manufactured by Oishi Koseido Co., Ltd.

18. Defendant Sanofi is a Delaware corporation, with its principal place of business at 55 Corporate Drive Bridgewater, New Jersey 08807. Defendant Sanofi markets, distributes, and sells the IcyHot® Lidocaine Patch, the Aspercreme® Lidocaine Patch, and the Aspercreme® Lidocaine Patch XL, which are manufactured by Chattem, Inc. Defendant Sanofi markets,

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