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IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 20-10497

D.C. Docket No. 8:17-cv-02353-JSM-AAS

BELCHER PHARMACEUTICALS, LLC,

Plaintiff-Appellant,

versus

HOSPIRA, INC.,

Defendant-Appellee.

Appeal from the United States District Court
for the Middle District of Florida

(June 24, 2021)

Before MARTIN, GRANT, and BRASHER, Circuit Judges.

GRANT, Circuit Judge:

This case falls at the intersection of two federal statutes. The Food, Drug, and Cosmetic Act—as the name implies—gives the Food and Drug Administration

regulatory and enforcement authority over food, drugs, and cosmetics. That authority extends to product labels. The Lanham Act offers complementary authority to the private sector—it provides competitors with a cause of action to block unfair competition stemming from misleading labeling or advertising. Taken together, these statutes mean that both government authorities and private parties can police the marketplace to prevent misleading advertising.

Belcher Pharmaceuticals decided to sue one of its competitors, Hospira, under the Lanham Act. Belcher alleged that the labels for two of Hospira's drug products falsely implied that the products and their uses were FDA-approved, and that Hospira's misrepresentations allowed it to cut into the sales of Belcher's drug. But that claim did not survive summary judgment; the district court found that resolving it would invade the FDA's enforcement authority under the FDCA. And even if the claim were allowed, the district court held, Belcher had failed to show that Hospira made misleading statements. Belcher now challenges the district court's decision, arguing that its claim was both allowed and supported.

We agree with Belcher in at least one respect. The Lanham Act can peacefully coexist with the FDCA for many drug-related claims, including this one. Still, we affirm the district court's decision. Though Belcher's Lanham Act claim was not precluded by the FDCA, it also was not supported by evidence of any misleading statements on Hospira's labels. Because Belcher never showed that Hospira made representations that misled consumers about the FDA's approval of its drug products, Hospira is entitled to summary judgment.

I.

Injectable epinephrine has been sold in the United States for more than a century. It is used to respond to a variety of conditions, including emergency treatment of allergic reactions.[1] But until 2012, no pharmaceutical company received official FDA approval to market the drug. Manufacturers instead treated their epinephrine products as "grandfathered" drugs, meaning that they were exempt from the FDA's new drug approval procedures. Grandfathered drugs are those that were on the market prior to the passage of the Food, Drug, and Cosmetic Act in 1938 and that contain in their labeling "the same representations concerning the conditions of use as [they] did prior to passage." *See* U.S. Food & Drug Admin., Marketed Unapproved Drugs Compliance Policy Guide: Guidance for FDA Staff and Industry 11 (2011) (FDA Compliance Guide); 21 U.S.C. § 321(p)(1).[2]

In 2012, the FDA approved its first epinephrine product, a 1mg/mL ampule manufactured by JHP Pharmaceuticals.[3] A few years later, Belcher

[1] Another injectable epinephrine product, one not at issue in this case, has become a household name under the EpiPen moniker.

[2] There is no application process to designate a drug as "grandfathered," so manufacturers treat their products as grandfathered based on the statutory definition unless and until the FDA challenges that assumption. *See* FDA Compliance Guide at 11–12. If the FDA brings an enforcement action claiming that a pharmaceutical company is marketing a new drug without FDA approval, the manufacturer may argue that the drug is grandfathered as a defense. *United States v. An Article of Drug (Bentex Ulcerine)*, 469 F.2d 875, 878 (5th Cir. 1972). The parties disagree about whether Hospira's products qualified for grandfathered status. But what matters is that Hospira never claimed that its products were FDA-approved, and that FDA approval is not required for a drug to be on the market. Because the designation is not at issue in this case, we proceed assuming that Hospira's epinephrine products are grandfathered.

[3] An ampule is a "sealed vial made of glass or plastic that contains a sterile medicinal solution." *The American Heritage Dictionary of the English Language* 62 (5th ed. 2011).

Pharmaceuticals followed with its own FDA-approved 1mg/mL epinephrine ampule. These newly approved epinephrine ampules, though, did not push other "grandfathered" epinephrine products out of the market. Hospira, whose predecessor Abbott Laboratories began supplying injectable epinephrine before the FDCA was enacted, marketed two of those epinephrine products: a 1mg/mL ampule and a .1mg/mL prefilled syringe.

Both Belcher's and Hospira's epinephrine products, like other drugs, contained package inserts with indications for use—that is, a list of uses for the drug. Because Belcher had submitted a "new drug application" to the FDA, its indications for use were limited to those the FDA approved: (1) to "increase mean arterial blood pressure in adult patients with hypotension associated with septic shock"; (2) for "induction and maintenance of mydriasis during intraocular surgery"; and (3) for "emergency treatment of allergic reactions (Type 1), including anaphylaxis." Hospira's epinephrine ampule and syringe, on the other hand, were grandfathered, so their indications were not limited to those FDA-endorsed uses. Hospira accordingly listed additional historical uses, claiming, among other things, that its products could be used to treat cardiac arrest and to prolong the effects of anesthetics.

The two companies' epinephrine products overlapped on the market for two years. Hospira discontinued its ampule after that, but continued to produce and market an epinephrine syringe. As the law of supply and demand might predict, Belcher started to see an uptick in profits for its own ampule after Hospira's partial exit. And once Belcher realized that it had been losing sales to Hospira's

unapproved products for the last several years, the company sued in federal district court for unfair competition under the Lanham Act.[4]

The Lanham Act, known primarily for its federal trademark provisions, also allows industry competitors, like Belcher, to sue for unfair competition based on misleading advertising, which includes misleading labeling. *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 107 (2014). To prevail on its false advertising claim, Belcher needed to prove that Hospira made "false or misleading" statements and that "the statements deceived, or had the capacity to deceive, consumers." *Hi-Tech Pharms., Inc. v. HBS Int'l Corp.*, 910 F.3d 1186, 1196 (11th Cir. 2018) (quotation omitted). Belcher pointed to Hospira's package inserts—which contained the unapproved indications for use—for the allegedly misleading statements.[5] It did not contend that the indications themselves presented false information; instead, it argued that these inserts gave the false impression that Hospira's epinephrine products (along with their indications) were approved by the FDA. Belcher thought that this gave Hospira a competitive advantage, as its products seemed "safer and/or more effective" than Belcher's.

After discovery, Hospira moved for summary judgment, arguing both that Belcher's claim "improperly asks the Court to make determinations about the safety, efficacy, and legality of Hospira's products," and that Belcher "failed to

[4] Belcher also pleaded additional counts, including tortious interference and common law unfair competition, but those were dismissed or disposed of at the summary judgment stage and not appealed.

[5] At summary judgment, Belcher asserted additional Lanham Act claims based on other statements by Hospira. The court granted summary judgment for Hospira on the remaining claims and Belcher appealed only the court's decision on the package insert statements.

produce any evidence" supporting its allegations of false advertising under the Lanham Act. The district court agreed. While Belcher claimed that Hospira's package inserts "misled consumers into believing Hospira's epinephrine products were FDA-approved," the court held that Belcher needed to "show more than the mere fact that a drug has been placed on the market with standard packaging and inserts." Otherwise, the court said, it would "usurp the FDA's authority to enforce the Food, Drug, and Cosmetic Act."

The court added that Belcher's case also suffered from other "fatal flaws." Though Belcher offered evidence that "some consumers believed Hospira's epinephrine products were FDA-approved," it was "unable to tie those beliefs to actionable acts by Hospira." The fact that Hospira's package inserts included unapproved indications for use was simply "not enough to support a Lanham Act claim." The court entered summary judgment in favor of Hospira, which Belcher now appeals.

II.

We review the grant of summary judgment de novo, viewing the evidence in the light most favorable to the nonmoving party. *Tracy v. Fla. Atl. Univ. Bd. of Trs.*, 980 F.3d 799, 811 (11th Cir. 2020). We may affirm the district court "on any basis the record supports," regardless of whether that basis was "addressed, adopted or rejected by the district court." *Fla. Wildlife Fed'n Inc. v. U.S. Army Corps of Eng'rs*, 859 F.3d 1306, 1316 (11th Cir. 2017) (quotation omitted).

III.

A.

The Lanham Act and the FDCA, along with their prohibitions on misbranding, have operated side by side for 75 years. *See* Lanham Act, Pub. L. No. 79-489, 60 Stat. 427 (1946); Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938). Though questions have occasionally arisen in the lower courts about whether the FDCA's misbranding provisions preclude Lanham Act false advertising claims for FDCA-regulated products, the Supreme Court only recently laid that issue to rest—at least for food and beverage labels.

In *POM Wonderful LLC v. Coca-Cola Co.*, the Supreme Court considered whether a private competitor could bring a Lanham Act claim challenging an FDA-regulated beverage label. 573 U.S. at 111. The answer was a unanimous yes—a conclusion that followed naturally from the text and structure of the two statutes. *Id.* at 113–16. Starting with the text, the Court observed that "neither the Lanham Act nor the FDCA, in express terms, forbids or limits Lanham Act claims challenging labels that are regulated by the FDCA." *Id*. at 113. And the FDCA's preemption provision reinforced the Court's reading: it forbids a "State or political subdivision of a State" from imposing additional requirements for food and beverage labeling, but says nothing about other federal laws. *Id*. at 114–15 (quoting 21 U.S.C. § 343-1). Given that context, the absence of an express federal preclusion provision spoke volumes.

The Court was also clear that the structures of the two acts "reinforce the conclusion drawn from the text." *Id.* at 115. In fact, the Lanham Act and the

FDCA "complement each other in major respects." *Id*. Though both statutes address food and beverage labeling, the Lanham Act "protects commercial interests against unfair competition," while the FDCA "protects public health and safety." *Id*. Because competitors can sue for false advertising under the Lanham Act, they are able to protect their commercial interests against false advertising even if the FDA declines to use its limited resources to pursue enforcement measures. So those Lanham Act suits actually help the FDA police the market. *See id.* at 115–16 ("Allowing Lanham Act suits takes advantage of synergies among multiple methods of regulation.").

For food and beverage labels, then, the answer is clear—Lanham Act suits can go forward. But Hospira insists that the FDA's heightened regulation of pharmaceutical products means we cannot extend *POM Wonderful*'s rule to the drug label context. We cannot agree—nothing in the text of the Lanham Act or the FDCA suggests a different rule for drug products. *Id.* at 113–16. Nor does the FDA's regulatory role for drug products convince us that a different rule is necessary. Even in the food and beverage context, the Supreme Court recognized the significance of the FDA's regulatory role: "Enforcement of the FDCA and the detailed prescriptions of its implementing regulations is largely committed to the FDA." *Id*. at 115. But it also saw a role for private action: the FDA "does not have the same perspective or expertise in assessing market dynamics that day-to-day competitors possess," and the Lanham Act harnesses that expertise by motivating competitors to challenge certain misleading labels. *Id*. Nothing about those two points is different in the drug industry.

That said, some differences do exist. For example, the Supreme Court contrasted the FDA's lack of preapproval procedures for food and beverages with its more rigorous approval measures for new pharmaceutical products. *See id.* at 116. And it is well understood that drug approval is a demanding and complicated process. So there may be reasons to disallow label challenges involving certain drug claims that call on courts to contradict a conclusion of the FDA or to make an original determination on an issue committed to the FDA's discretion.[6] Indeed, our own Court has approvingly cited cases recognizing that Lanham Act claims may be barred if their resolution requires an original determination that is committed to the FDA, such as "whether a drug is 'new,' and whether it can be lawfully marketed under the FDCA." *Hi-Tech Pharms.*, 910 F.3d at 1199 (quotations omitted) (citing *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 928 (9th Cir. 2010); *Hi-Tech Pharms., Inc. v. Hodges Consulting, Inc.*, 230 F. Supp. 3d 1323, 1330 (N.D. Ga. 2016)).

But this case is not about those potential exceptions. For starters, Belcher's challenge is to drug-package inserts that—like food and beverage labels—have *not* received preapproval from the FDA and that Hospira believes do not require preapproval. Belcher is thus not asking us to contradict any regulatory conclusion reached by the FDA. Nor does Belcher's claim ask us to make any original

[6] Hospira notes that some courts have considered whether the primary jurisdiction doctrine, rather than the preclusion doctrine, may bar these types of claims. *See, e.g.*, *Alpharma, Inc. v. Pennfield Oil Co.*, 411 F.3d 934, 937–39 (8th Cir. 2005). But that doctrine is not applicable in this case, where no one is asking the Court to decide an issue for which the FDA has special expertise. So we decline to consider whether that doctrine would more broadly apply to other Lanham Act drug labeling claims.

determination that only the FDA could make—such as whether the indications for use are safe or effective, or whether Hospira's drug is approved or grandfathered. Instead, this case falls within the core of *POM Wonderful*'s rule that the FDCA does not categorically preclude Lanham Act claims. The only question at issue here is whether Hospira's package inserts falsely imply that its epinephrine products or the package insert claims that go along with them are FDA-approved. Nothing in the FDCA prohibits a competitor from bringing that kind of claim.

B.

Though the FDCA does not preclude Belcher's Lanham Act claim, it takes more to survive summary judgment. A Lanham Act plaintiff has a fundamental burden to prove that the defendant made false or misleading statements in its advertisements and to show that those statements "deceived, or had the capacity to deceive, consumers." *Hi-Tech Pharms.*, 910 F.3d at 1196; *see* 15 U.S.C. § 1125. And though the false advertisements do not need to be "literally false," they must at least "implicitly convey a false impression," be "misleading in context," or be "likely to deceive consumers." *Hi-Tech Pharms.*, 910 F.3d at 1196 (quotation omitted).

The fatal flaw for Belcher's case is that it does not offer any such evidence. The company claims that Hospira's package inserts are misleading because they falsely imply FDA approval of the drugs and their indications—but it never shows how or where. Hospira's inserts never claimed FDA approval, nor does Belcher point us to any language that hints at it. As best we can tell, Belcher relies solely on the existence of the drug and its inserts on the market. That is simply not

enough. To raise a genuine issue of material fact, Belcher needed to offer at least some evidence not only that customers erroneously believed that Hospira's products were FDA-approved, but that a specific representation or statement by Hospira created that misconception. We agree with the district court that Belcher failed to offer that evidence here.

* * *

The Lanham Act and the FDCA continue to operate as complementary—not preclusive—statutes. Companies can protect their commercial interests by suing competitors for false advertising, even for products regulated by the FDA. But to do so, they need to point us to some false or misleading statement. Because Belcher did not, we affirm the district court's grant of summary judgment to Hospira.

AFFIRMED.