UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

BELCHER PHARMACEUTICALS, LLC,

Plaintiff,

v. Case No: 8:17-cv-2353-T-30AAS

HOSPIRA, INC.,

Defendant.

SUMMARY JUDGMENT ORDER

Epinephrine—a drug that is a medical necessity—has been in short supply on and off for nearly a decade. Hospira, Inc. has been supplying epinephrine products since before 1938, when the Food, Drug and Cosmetic Act ("FDCA") was enacted. This meant that Hospira's products, both its ampule and prefilled syringe, were arguably grandfathered and did not require approval by the Food and Drug Administration. Despite Hospira's products never having received official approval, the FDA asked Hospira to ramp up manufacturing to manage the epinephrine shortage in 2010, which Hospira did.

In February 2015, Belcher Pharmaceuticals, LLC began selling its FDA-approved epinephrine ampule (it does not sell a prefilled syringe). By February 2017, there was no longer a shortage of epinephrine ampules like those Belcher sold, so the FDA asked Hospira to discontinue manufacturing its unapproved ampule. The FDA, though, asked Hospira to continue manufacturing its prefilled epinephrine syringe, which was still scarce. Hospira complied with the FDA's requests. Once Hospira stopped manufacturing its epinephrine ampule, Belcher saw an increase in the sales of its epinephrine ampule.

Now Belcher is suing Hospira under the Lanham Act for false advertising and for common law unfair competition. Belcher's causes of action are premised on Hospira allegedly marketing its epinephrine products—both the ampule and prefilled syringe—as FDA-approved when they were not. And Belcher's requested relief for this alleged wrong? For Hospira to pay Belcher any profits Hospira made for doing what the FDA requested and an injunction.

The Court concludes that Hospira—which did everything the FDA requested to manage a severe shortage of a medically necessary drug—is entitled to summary judgment on all claims.

BACKGROUND

The material facts are not in dispute.

Hospira, a subsidiary of Pfizer, manufactures and sells a 1 mg/mL epinephrine ampule and a 0.1 mg/mL, 10 mL prefilled epinephrine syringe. Hospira's predecessor, Abbott Laboratories, marketed and sold epinephrine before 1938 when the FDCA was enacted, which meant its epinephrine products were arguably grandfathered and did not require FDA approval. Historical uses of epinephrine include treatment of cardiac arrest and prolongation of local anesthetics, as reflected on Hospira's product labels and inserts. Hospira's epinephrine products have never received FDA approval.

Epinephrine is manufactured by several companies[1] and had been marketed for over a century without FDA approval until 2012. That is when the FDA approved Adrenalin, an

[1] Epinephrine is manufactured by Hospira, Belcher, PAR Pharmaceuticals, Mylan Pharmaceuticals, and BPI Labs, among others.

epinephrine product manufactured by PAR Pharmaceuticals. Although Adrenalin was approved in 2012, PAR had been selling epinephrine products since the early 1900s.

The FDA considers epinephrine to be a medically necessary drug. Before the FDA's approval of Adrenalin, the FDA's Drug Shortage Staff ("DSS") communicated with Hospira about the shortage of its prefilled syringe. The FDA told Hospira that its syringe was "desperately needed" and commended Hospira for ramping up its production. Epinephrine ampules were also listed on the FDA's drug shortage list from August 2014 to February 2017.

In February 2015—after the FDA advised Hospira about the shortage of its epinephrine products—the FDA approved Belcher's 1mg/mL epinephrine ampule. Belcher does not manufacture or sell a prefilled epinephrine syringe.

In February 2017, the FDA advised Hospira there was no longer a shortage of epinephrine ampules. The FDA asked Hospira to continue manufacturing its prefilled epinephrine syringe, for which there was still a shortage, but told Hospira to stop manufacturing its epinephrine ampule, which Hospira did.

After the FDA told Hospira to discontinue its epinephrine ampules, the FDA asked Hospira about extending the expiration dates of its prefilled syringe. Hospira sent the FDA its shelf-life analysis, and shortly thereafter the FDA told healthcare providers that the expiration dates for Hospira's prefilled syringe were extended for 9 months past their 21-month expiration date. Hospira's ampules had a 24-month expiration date. By contrast, Belcher's ampule had an expiration date of 12 months, which the FDA later extended to 17 months.

After Hospira's epinephrine ampule was removed from the market, Belcher claims that virtually all Hospira's sales flowed to Belcher. Presumably based on that fact, Belcher sued Hospira in October 2017—just eight months after the FDA told Hospira to stop manufacturing its ampule—arguing that Hospira misled consumers into believing its epinephrine products were FDA-approved. Belcher claims Hospira misled consumers via these advertisements:

1. Hospira's product labels, which include as indications for use that the epinephrine products (a) can treat cardiac arrest, (b) can be administered intravenously, and (c) can prolong the effects of anesthesia;

2. Hospira's misleading advertisements as to its epinephrine products' shelf life on its packaging; and

3. Hospira's comparison of its epinephrine products to Adrenalin, which conveyed the message that its products were generic Adrenalin.[2]

(Docs. 90/92).

SUMMARY JUDGMENT STANDARD

Motions for summary judgment should be granted only when "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any show there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986) (internal quotation marks omitted); Fed. R. Civ. P. 56(c). The existence of some factual disputes between the litigants will not defeat an otherwise properly supported summary

[2] Originally, Belcher claimed that Hospira had 11 false or misleading advertisements but appears to have abandoned all but the three listed above. Belcher, though, never informed Hospira or the Court it was abandoning those claims. This led both Hospira—who spent 15 pages in its summary judgment motion addressing abandoned claims—and the Court to unnecessarily expend resources researching and reviewing the abandoned claims.

judgment motion; "the requirement is that there be no *genuine* issue of *material* fact." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The substantive law applicable to the claimed causes of action will identify which facts are material. *Id.* Throughout this analysis, the court must examine the evidence in the light most favorable to the nonmovant and draw all justifiable inferences in its favor. *Id.* at 255.

Once a party properly makes a summary judgment motion by demonstrating the absence of a genuine issue of material fact, whether accompanied by affidavits, the nonmoving party must go beyond the pleadings through affidavits, depositions, answers to interrogatories and admissions on file, and designate specific facts showing there is a genuine issue for trial. *Celotex*, 477 U.S. at 324. The evidence must be significantly probative to support the claims. *Anderson*, 477 U.S. at 248–49.

This Court may not decide a genuine factual dispute at the summary judgment stage. *Fernandez v. Bankers Nat'l Life Ins. Co.*, 906 F.2d 559, 564 (11th Cir. 1990). "[I]f factual issues are present, the Court must deny the motion and proceed to trial." *Warrior Tombigbee Transp. Co. v. M/V Nan Fung*, 695 F.2d 1294, 1296 (11th Cir. 1983). A dispute about a material fact is genuine and summary judgment is inappropriate if a reasonable jury could return a verdict for the nonmoving party. *Anderson*, 477 U.S. at 248; *Hoffman v. Allied Corp.*, 912 F.2d 1379, 1383 (11th Cir.1990). However, there must exist a conflict in substantial evidence to pose a jury question. *Verbraeken v. Westinghouse Elec. Corp.*, 881 F.2d 1041, 1045 (11th Cir. 1989).

DISCUSSION

Belcher is suing Hospira for false advertising under the Lanham Act and common law unfair competition because Hospira allegedly misled consumers into believing that Hospira's epinephrine products were FDA-approved.[3] It is undisputed that Hospira never explicitly marketed its products as FDA-approved. Rather, Belcher alleges that certain Hospira advertisements misled consumers into believing Hospira's products were FDA-approved. Specifically, Belcher relies on these three advertisements: (1) Hospira's product labels' indications for use; (2) Hospira's shelf-life representations on its packaging, and (3) Hospira's comparison of its products to Adrenalin (an epinephrine product not manufactured by Belcher). The Court concludes that Belcher has not proved any of the alleged advertisements violate the Lanham Act, so the Court will enter summary judgment in favor of Hospira.[4]

To succeed on a false advertising claim under the Lanham Act, "a plaintiff must establish that (1) the advertisements of the opposing party were false or misleading; (2) the advertisements deceived, or had the capacity to deceive, consumers; (3) the deception had

[3] As Belcher clarifies, "Belcher is not claiming that FDA could not allow (via its enforcement discretion) these products to be on the market. Belcher is merely claiming that if a product is on the market, its manufacturer cannot make false statements or mislead customers regarding that products' regulatory status, or the regulatory status of that products' labeling (including indications and shelf-life)." (Docs. 90/92, p. 17).

[4] Because the Court concludes Hospira is entitled to summary judgment on Belcher's Lanham Act claim, Hospira is also entitled to summary judgment on Belcher's common law unfair competition claim. *Nat. Answers, Inc. v. SmithKline Beecham Corp.*, 529 F.3d 1325, 1332–33 (11th Cir. 2008) ("Since Natural Answers is unable to bring an unfair competition claim under the *Lanham Act* under the theory of either false advertising or trademark infringement, it follows that the common law claims based on unfair competition and trademark infringement must fail as well.").

a material effect on purchasing decisions; (4) the misrepresented product or service affects interstate commerce; and (5) the movant has been—or is likely to be—injured as a result of the false advertising." *Hickson Corp. v. N. Crossarm Co.*, 357 F.3d 1256, 1260 (11th Cir. 2004).

For the first element, a plaintiff must show that the advertisement was (1) literally false or (2) literally true "but which implicitly convey a false impression, are misleading in context, or likely to deceive consumers." *Id.* at 1261 (quoting *United Industries Corp. v. Clorox Co.*, 140 F.3d 1175, 1180 (8th Cir. 1998)). "A plaintiff attempting to establish the second kind of falsehood, that an advertisement is literally true but misleading, must 'present evidence of deception' in the form of consumer surveys, market research, expert testimony, or other evidence." *Id.*

Belcher does not claim that any of Hospira's purported advertisements were literally false, but instead argues that the advertisements misled consumers into believing Hospira's epinephrine products were FDA-approved. In a claim such as this, to show that consumers were misled into believing a drug was FDA-approved, a plaintiff must show more than the mere fact that a drug has been placed on the market with standard packaging and inserts. *Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993).

Hospira argues the indications for use and shelf life on its product labels and packaging cannot satisfy the first element of Belcher's Lanham Act claim, thus entitling Hospira to summary judgment on these claims. The Court agrees. These are exactly the sort of claims proscribed by the *Mylan Labs.* court, which explained that "the very *act* of placing a drug on the market, *with standard package inserts often used for FDA-approved*

drugs" fails to state a claim under the Lanham Act because it would usurp the FDA's authority to enforce the Food, Drug, and Cosmetics Act. *Id.* (explaining "Such a theory is, quite simply, too great a stretch under the Lanham Act.") (emphasis added).

That leaves only Belcher's claim that Hospira compared its epinephrine products to Adrenalin, which implied that epinephrine is generic Adrenaline that must have been approved by the FDA. More specifically, Belcher alleges that Hospira compared its product to Adrenalin (1) on its website in an Injectables Product Availability Report, (2) in a "customer facing" product listing on which Hospira lists its epinephrine products via reference to Adrenalin, and (3) in an e-mail response to a drug distributor who inquired if Hospira was marketing the generic version of Adrenalin. (Doc. 90/92, p. 7–8, ¶ 29).[5] The Court concludes none of these alleged advertisements support Belcher's claims.

Of the three alleged advertisements, the only commercial advertisement actionable under the Lanham Act is the Injectables Product Availability Report.[6] And Belcher

[5] In the Amended Complaint, Belcher alleged that Hospira had a Fact Sheet about generic injectables on its website that misled consumers in conjunction with the Injectables Product Availability Report. (Doc. 37, ¶ 47). But Belcher does not mention the Fact Sheet in its response to Hospira's summary judgment motion, so the Court assumes Belcher no longer intends to rely on that document to support its claims.

[6] To qualify as a commercial advertisement for purposes of the Lanham Act, a statement must be: "(1) commercial speech; (2) by a defendant who is in commercial competition with plaintiff; (3) for the purpose of influencing consumers to buy defendant's goods or services. While the representations need not be made in a 'classical advertising campaign,' but may consist instead of more informal types of 'promotion,' the representations (4) must be disseminated sufficiently to the relevant purchasing public to constitute 'advertising' or 'promotion' within that industry." *Suntree Techs., Inc. v. Ecosense Int'l, Inc.*, 693 F.3d 1338, 1349 (11th Cir. 2012) (quoting *Gordon & Breach Sci. Publishers S.A. v. Am. Inst. of Physics*, 859 F.Supp. 1521 (S.D. N.Y. 1994)).

Belcher mentions a "customer facing" product listing in its response but does not actually provide it. Instead, Belcher cites to internal Pfizer e-mails from 2016, which are not commercial advertisements. (Doc. 93-4). The e-mail to the distributor is also not a commercial advertisement

wrongly relies on the following *ipse dixit* argument to show the Injectables Product Availability Report satisfies the third element of a Lanham Act claim—the deception had a material effect on purchasing decisions. First, Belcher argues (and the Court assumes as true *arguendo*) the Injectables Product Availability Report on Pfizer's website is misleading. Second, Belcher cites to evidence that consumers believed Hospira's epinephrine products were a generic version of Adrenalin approved by the FDA. Thus, Belcher concludes, the Injectables Product Availability Report caused consumers to believe that Hospira's epinephrine products were generic Adrenalin. But there is no evidence to support this conclusion since Belcher has not shown that a single consumer ever viewed the Injectables Product Availability Report or was misled by it. Without evidence that a consumer viewed the Injectables Product Availability Report, Belcher cannot show that the misleading statements had a material effect on purchasing decisions.

Belcher's *ipse dixit* argument is representative of the fatal flaws in all its claims. While Belcher produced evidence that some consumers believed Hospira's epinephrine products were FDA-approved, Belcher was unable to tie those beliefs to actionable acts by Hospira. As noted above, there is no evidence that Hospira explicitly marketed its epinephrine products as FDA-approved. That Hospira's product packaging and inserts listed a shelf life and had indications for use but did not have a disclaimer that the products were not FDA-approved is not enough to support a Lanham Act claim. And there is no evidence that the other alleged commercial advertisements referenced by Belcher were

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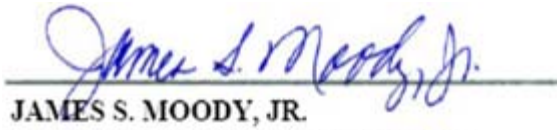
because it was not disseminated sufficiently to the relevant purchasing public. (Doc. 103-1).

even viewed by consumers, much less influenced them on whether to purchase Hospira's epinephrine products over Belcher's. So the Court concludes Belcher failed to present evidence to supports its claims and Hospira is entitled to summary judgment in its favor.

Accordingly, it is ORDERED AND ADJUDGED that:

1. Defendant Hospira, Inc.'s Motion for Summary Judgment (Doc. 77) is GRANTED.
2. The Clerk is directed to enter final summary judgment in favor of Defendant Hospira, Inc. and against Plaintiff Belcher Pharmaceuticals, LLC.
3. All pending motions are denied as moot.
4. The Clerk is directed to close this file.

DONE and **ORDERED** in Tampa, Florida, this 7th day of January, 2020.



JAMES S. MOODY, JR.
UNITED STATES DISTRICT JUDGE

Copies furnished to:
Counsel/Parties of Record