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United States Court of Appeals
Tenth Circuit

November 3, 2011

Elisabeth A. Shumaker
Clerk of Court

UNITED STATES COURT OF APPEALS

TENTH CIRCUIT

CODY LABORATORIES, INC., a Wyoming corporation; LANNETT CO., INC., a Delaware corporation,

Plaintiffs–Appellants,

v.

KATHLEEN SEBELIUS, in her official capacity as United States Department of Health and Human Services Secretary; MARGARET A. HAMBURG, in her official capacity as United States Food and Drug Administration Commissioner,

Defendants–Appellees.

No. 11-8001
(D.C. No. 2:10-CV-00147-ABJ)
(D. Wyo.)

ORDER AND JUDGMENT[*]

Before **KELLY**, **LUCERO**, and **GILMAN**,[**] Circuit Judges.

Cody Laboratories, Inc. and Lannett Co., Inc. (collectively, "Cody") appeal the

* This order and judgment is not binding precedent, except under the doctrines of law of the case, res judicata, and collateral estoppel. This court generally disfavors the citation of orders and judgments; nevertheless, an order and judgment may be cited under the terms and conditions of 10th Cir. R. 32.1.

** The Honorable Ronald Lee Gilman, United States Circuit Court Judge for the Sixth Circuit, sitting by designation.

district court's dismissal of their action for declaratory judgment against the federal officials responsible for the Food and Drug Administration ("FDA"). We conclude that one of Cody's claims has been mooted by post-judgment events and that Cody failed to exhaust available administrative remedies with respect to the remaining claim. Exercising jurisdiction under 28 U.S.C. § 1291, we affirm in part and dismiss in part.

I

According to the complaint, Cody has been manufacturing and distributing morphine sulfate, a pain-relieving drug used primarily in palliative care, since 2005. At the time Cody filed its complaint, the company had not received FDA approval for its morphine sulfate product. Cody contends that the product falls under the "grandfather clause" of the Food, Drug, and Cosmetic Act ("FDCA") because morphine sulfate has been used for pain relief in the United States for over a century. See 21 U.S.C. § 321(p)(1) (excepting from the "new drug" definition certain pre-1938 drugs). Based on its alleged grandfathered status, Cody argues the product does not require FDA approval. See 21 U.S.C. § 355(a) (requiring FDA approval for marketing of "new drugs" only).

The FDA claims that the grandfather clause is exceedingly narrow and applies only to drugs that have been marketed in essentially identical form since 1938. As part of an effort to remove unapproved drugs from the market, the FDA sent Cody a warning letter in March 2009 stating that Cody's manufacture and distribution of morphine sulfate was in violation of the FDCA and that "failure to promptly correct these violations may result in legal action." In April of that year, however, the FDA sent another letter to

Cody stating that, in light of availability concerns, the agency would suspend any enforcement action against morphine sulfate manufacturers until 180 days after the FDA had approved a morphine sulfate product.

Although Cody disputed the agency's view in a series of letters and meetings, the FDA did not alter its stance. It stated in no uncertain terms that it considered Cody's product to be an unapproved new drug and reiterated its threats of enforcement action. According to Cody, the FDA also informed the Drug Enforcement Agency ("DEA") of its position on the legality of Cody's product. The DEA subsequently refused to provide Cody the necessary authorization to purchase the raw materials to make morphine sulfate. Cody further claims the FDA contacted its major customers, threatening enforcement action if they continued to purchase Cody's unapproved product.

Meanwhile, in August 2009, Roxane Laboratories, Inc. ("Roxane"), Cody's main competitor in the morphine sulfate market, submitted a New Drug Application ("NDA") for its own morphine sulfate product. Following its policy of granting expedited review of an NDA if no approved alternative drug exists, the FDA quickly reviewed and approved Roxane's NDA in January 2010. Cody submitted an NDA for its product the following month. The company's requests for expedited review were denied.

In March 2010, the FDA informed Cody that it would end the period of suspended enforcement on July 24, 2010, because Roxane's morphine sulfate product had been approved. In response, Cody filed suit seeking to enjoin the FDA from commencing an enforcement action and for declaratory judgment. Cody contended that the FDA acted

arbitrarily, capriciously, and contrary to law in violation of the Administrative Procedure Act ("APA") by: (1) improperly determining that Cody's product is a "new drug" and thus not entitled to grandfathered status under the FDCA; and (2) treating Cody disparately from Roxane in processing the companies' respective NDAs.

Cody moved for a temporary restraining order and a preliminary injunction, which the district court denied. The court subsequently dismissed Cody's complaint for lack of jurisdiction, holding that the FDA had yet to complete "final agency action" under § 704 of the APA. See 5 U.S.C. § 704. Cody timely appealed the dismissal.

On June 23, 2011—while this appeal was pending—the FDA approved Cody's NDA. Appellees filed a motion to dismiss the appeal as moot. Although they initially argued that the NDA approval mooted Cody's action in its entirety, appellees now claim the approval moots only Cody's disparate treatment claim. Cody maintains that neither of its claims has been mooted by the NDA approval.

II

"Mootness is a threshold issue because the existence of a live case or controversy is a constitutional prerequisite to federal court jurisdiction." McClendon v. City of Albuquerque, 100 F.3d 863, 867 (10th Cir. 1996). A case becomes moot "when it is impossible to grant any effectual relief." Chihuahuan Grasslands Alliance v. Kempthorne, 545 F.3d 884, 891 (10th Cir. 2008).

We agree with the parties that the approval of Cody's NDA has not mooted its grandfathering claim. If a court were to declare that Cody's morphine sulfate product is

grandfathered, Cody would face a different and apparently lighter regulatory burden. Cody's product will incur a product fee under its NDA from which the company would be exempt if it product were considered a grandfathered drug. The parties also agree that the labeling requirements for grandfathered drugs are distinct, and perhaps less onerous, than those for new drugs. By prevailing on its grandfathering claim, Cody could still obtain meaningful relief in the form of freedom from these burdens. Accordingly, this claim is not moot.

We reach the opposite conclusion as to Cody's disparate treatment claim. Cody argues the FDA improperly granted expedited review to Roxane and refused to do the same for Cody. Despite the fact that we can no longer grant the relief Cody originally requested—an order requiring the FDA to expedite review of its NDA—the company nonetheless asks this court to enter a declaratory judgment that the FDA should have approved its application more quickly. In other words, Cody asks us to issue a "retrospective opinion that [it] was wrongly harmed." See Jordan v. Sosa, 654 F.3d 1012, 1025 (10th Cir. 2011) (citing cases). Article III does not permit such an opinion. See Cox v. Phelps Dodge Corp., 43 F.3d 1345, 1348 (10th Cir. 1994) (a case is moot if the plaintiff's interest is nothing more than "the satisfaction of a declaration that a person was wronged"), superseded on other grounds as recognized in Walker v. United Parcel Serv., Inc., 240 F.3d 1268, 1278 (10th Cir. 2001).

Nor does Cody's disparate treatment claim fall under the exception to the mootness doctrine for disputes that are capable of repetition, but evading review. To fit

within that exception, a litigant must show a reasonable expectation that it would be subjected to the same adverse action in the future. See Murphy v. Hunt, 455 U.S. 478, 482 (1982). Thus, for its disparate treatment claim to qualify, Cody would have to establish a "demonstrated probability," Johansen v. City of Bartlesville, 862 F.2d 1423, 1426 (10th Cir. 1988) (quotation omitted), that: (1) Cody would submit an NDA for another unapproved drug and request that the agency expedite its review; (2) one of Cody's competitors would also submit an NDA for the same drug and request expedited review; and (3) the FDA would deny Cody's request for expedited review but grant it to the competitor. Cody asserts that it intends to file NDAs for two other unapproved drug products it currently markets, that it plans to request expedited review of those applications, and that it expects its competitors to do the same. But Cody has not given us reason to expect that the agency will deny Cody's request for expedited review while granting that of its competitors. Thus, we conclude that Cody has not carried its burden of demonstrating its claim is capable of repetition, but evading review. Accordingly, we dismiss Cody's disparate treatment claim as moot.

III

Mootness aside, we cannot reach the merits of Cody's grandfathering claim unless the FDA has engaged in "final agency action" under the APA. See 5 U.S.C. § 704. Final agency action "mark[s] the consummation of the agency's decisionmaking process" and is action "by which rights or obligations have been determined, or from which legal consequences will flow." Bennett v. Spear, 520 U.S. 154, 178 (1997) (quotations and

citations omitted). We apply the concept of finality in a flexible and pragmatic manner. See Abbott Labs. v. Gardner, 387 U.S. 136, 149 (1967), overruled on other grounds, Califano v. Sanders, 430 U.S. 99, 105 (1977). Final agency action can come in the form of a "series of agency pronouncements rather than a single edict," Ciba-Geigy Corp. v. EPA, 801 F.2d 430, 435 n.7 (D.C. Cir. 1986), and the "label an agency attaches to its action is not determinative," Continental Air Lines, Inc., v. Civil Aeronautics Bd., 522 F.2d 107, 124 (D.C. Cir. 1975).

Cody urges us to conclude that the FDA took final agency action by issuing warning letters, confirming its position in subsequent correspondence with Cody, and engaging in "de facto enforcement actions" by notifying the DEA and Cody's customers of the agency's views.

It appears that every court to consider the question has held that an FDA warning letter does not constitute "final agency action." See, e.g., Biotics Research Corp. v. Heckler, 710 F.2d 1375, 1378 (9th Cir. 1983); Holistic Candlers & Consumer Ass'n v. FDA, 770 F. Supp. 2d 156, 161-62 (D.D.C. 2011); Clinical Reference Lab., Inc. v. Sullivan, 791 F. Supp. 1499, 1503-04 (D. Kan. 1992), rev'd sub nom. on other grounds, United States v. Undetermined No. of Unlabeled Cases, 21 F.3d 1026 (10th Cir. 1994); Estee Lauder, Inc. v. FDA, 727 F. Supp. 1, 4-5 (D.D.C. 1989); IMS Ltd. v. Califano, 453 F. Supp. 157, 160 (C.D. Cal. 1977).

But this case involves more than a warning letter, and Cody points to two cases where courts have found finality in agency actions that bear some similarity to the FDA's

other moves here. See Ciba-Geigy, 801 F.2d at 436-39 (concluding that EPA's unequivocal articulation of its position in series of communications constituted final agency action); PDK Labs, Inc. v. Ashcroft, 338 F. Supp. 2d. 1, 11-12 (D.D.C. 2004) (finding final agency action when DEA refused to issue a letter of no objection to a drug company's supplier).[1]

We need not grapple with these authorities, however, because Cody's failure to avail itself of available administrative remedies defeats its claim even if we were inclined to hold that the FDA's action were otherwise final. See Darby v. Cisneros, 509 U.S. 137, 146 (1993) ("When an aggrieved party has exhausted all administrative remedies expressly prescribed by statute or agency rule, the agency action is final for the purposes of [5 U.S.C. § 704] and therefore subject to judicial review . . . ." (quotations omitted)). FDA regulations allow entities aggrieved by agency action to file a citizen petition for administrative review. See 21 C.F.R. § 10.25(a); see also 21 C.F.R. § 10.45(b) ("A request that the Commissioner take or refrain from taking any form of administrative action must first be the subject of a final administrative decision based on a petition submitted under § 10.25(a) . . . ."). Courts have often dismissed suits against the FDA for failure to utilize the citizen petition procedure. See, e.g., Holistic Candlers & Consumer

[1] Cody also claims that Rutherford v. United States, 542 F.2d 1137 (10th Cir. 1976), controls this case. In Rutherford, we considered the scope of the FDCA's grandfathering clause, but the opinion does not make clear the nature of the agency action under consideration. Moreover, the opinion contains no discussion of the finality requirement. Without even a passing mention of the dispositive issue in the present case, it provides little assistance.

Ass'n, 770 F. Supp. 2d at 163; Ass'n of Am. Physicians & Surgeons, Inc. v. FDA, 539 F. Supp. 2d 4, 21-24 (D.D.C. 2008).

Cody correctly notes that, because the citizen petition procedure is a regulatory rather than a statutory creation, we have discretion to waive the exhaustion requirement. See McCarthy v. Madigan, 503 U.S. 140, 144 (1992), superseded on other grounds as recognized in Booth v. Churner, 532 U.S. 731, 740 (2001). In determining whether waiver of the exhaustion requirement would be proper, we "balance the interest of the individual in retaining prompt access to a federal judicial forum against countervailing institutional interests favoring exhaustion." McCarthy, 503 U.S. at 146.

Cody argues that it will be unduly prejudiced if forced to exhaust because the FDA is sometimes dilatory in substantively responding to citizen petitions. At least one court has found these delays sufficiently prejudicial to waive the administrative exhaustion requirement. See Bracco Diagnostics, Inc. v. Shalala, 963 F. Supp. 20, 30 (D.D.C. 1997). But at this stage, following approval of Cody's NDA, the only advantage Cody seeks is a slightly different regulatory burden. It is clear that Cody would not be unduly—or even significantly—prejudiced by following FDA regulations and filing a citizen petition. Cf. Bracco, 963 F. Supp. at 30 (waiving exhaustion requirement because plaintiff would lose "millions" if forced to wait for a response).

Cody also argues that it should be exempt from the exhaustion requirement because the FDA is "biased or has otherwise predetermined the issue before it." See McCarthy, 503 U.S. at 148 (citation omitted). Cody has made no credible showing of

bias. Moreover, although it is apparent that FDA officials do not believe that Cody's product falls within the grandfathering exception, the agency has made this initial determination in the absence of a factual record—indeed, this is one of Cody's chief complaints. In contrast, if Cody were to follow the regulations and file a citizen petition, the agency would have to undertake a full review of the factual record and public comments. See 21 C.F.R. § 10.30(b), (d). Given that grandfathering status hinges on the fact-intensive history of the drug's marketing and use, we do not anticipate that the agency will blindly refuse to consider evidence submitted by Cody. Accordingly, we decline to consider Cody's grandfathering claim prior to exhaustion of the company's administrative remedies.

IV

For the foregoing reasons, the district court's dismissal of Cody's grandfathering claim is **AFFIRMED**. Cody's disparate treatment claim is **DISMISSED** as moot.

Entered for the Court

Carlos F. Lucero
Circuit Judge