United States Court of Appeals
FOR THE EIGHTH CIRCUIT

No. 04-2958

Alpharma, Inc., A Delaware Corporation,	*	
Plaintiff - Appellant,	*	
	*	Appeal from the United States
v.	*	District Court for the
	*	District of Nebraska.
Pennfield Oil Company, doing business as Pennfield Animal Health, A Nebraska Corporation,	*	
Defendant - Appellee.	*	

Submitted: March 17, 2005
Filed: June 17, 2005

Before MURPHY, HEANEY and SMITH, Circuit Judges.

MURPHY, Circuit Judge.

Alpharma Inc. filed this action against its competitor Pennfield Oil Co., alleging that Pennfield had violated the Lanham Act and state law by falsely advertising that one of its antibiotic animal feed additives was approved for certain

uses by the Food and Drug Administration (FDA). The district court[1] granted Pennfield's motion to dismiss, holding that Alpharma had failed to exhaust administrative remedies. Alpharma appeals, and we reverse.

Alpharma and Pennfield are the only manufacturers of bacitracin methylene disalicylate (BMD), an antibiotic animal feed additive requiring FDA approval under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301-399 (FDCA). Under that Act, the manufacturer of a new animal drug cannot market it for any use until the FDA has approved the company's product as safe and effective for that use. 21 U.S.C. §§ 331; 351(a)(5)-(6); 360b(a)(1)-(2). In 1976, the predecessors of both Alpharma and Pennfield received "interim" FDA approval to market BMD for multiple uses. Antibiotic, Nitrofuran, and Sulfonamide Drugs in the Feed of Animals, 41 Fed. Reg. 8282 (Feb. 25, 1976). This interim approval was codified in 21 C.F.R. § 558.15(g)(1). That regulation did not list the uses for which their BMD had been approved, however, but instead incorporated the statement of uses found in 21 C.F.R. § 558.76.

In the years following the promulgation of § 558.15(g)(1), Alpharma's predecessor sought authorization to market its BMD product for additional uses by submitting numerous supplemental new drug applications to the FDA, some of which were approved. See, e.g., New Animal Drugs for Use in Animal Feeds, 47 Fed. Reg. 18,591 (April 30, 1982) (approving the supplemental application of A.L. Laboratories, Alpharma's predecessor, to market BMD for use in controlling swine dysentery). After approving these applications, the FDA added the new uses to the list in § 558.76 and named Alpharma's predecessor as the only manufacturer who had submitted information in support of their approval. See 21 C.F.R. § 558.76(d)(1). The interim approval provision of § 558.15(g)(1), which had authorized the marketing of both parties' products, was however never amended to distinguish

[1]The Honorable Joseph F. Bataillon, United States District Judge for the District of Nebraska.

between the original uses listed in § 558.76 and those later added following the successful applications of Alpharma's predecessor. The result was an apparent expansion in the number of uses for which the product of Pennfield's predecessor had been approved for marketing. See 68 Fed. Reg. at 47,334.

Pennfield purchased the rights of its predecessor to manufacture and market BMD in 2002, allegedly relying on the interim approval provisions of §§ 558.15(g)(1) and 558.76, as well as confirmations of that approval by FDA officials. According to Alpharma's complaint, Pennfield began marketing the product nationally during the same year with advertisements indicating that its drug had been approved for a variety of uses extending beyond those originally listed in § 558.76. Alpharma further alleges that Pennfield began selling its BMD in 2003 under a label indicating that the product had received FDA approval for the same expanded set of uses.

On March 13, 2003, Alpharma brought an action against the FDA in the United States District Court for the District of Maryland, claiming that the agency had improperly approved Pennfield's sale of BMD for a number of uses or otherwise improperly enabled Pennfield to represent that it had approval for those uses. Alpharma sought a declaratory judgment and injunctive relief. While the Maryland suit was pending, the FDA published two August 8, 2003 notices relating to Pennfield: a notice of proposed rulemaking for the "interim marketing provisions" of § 558.15 to be eliminated, 68 Fed. Reg. 47,272, and a notice of opportunity for hearing addressing the extent of Pennfield's approval to market BMD, 68 Fed. Reg. 47,332. After these notices were published, the FDA and Alpharma filed a Stipulation and Order of Dismissal which acknowledged that the agency lacked any record of Pennfield's having applied for or received approval to market its BMD for seven of the seventeen uses the agency had listed as approved. The Maryland suit was then dismissed with prejudice.

On September 30, 2003, Alpharma filed the present action against Pennfield in the United States District Court for the District of Nebraska. Alpharma alleged that the advertisements and labels for Pennfield's BMD falsely advertised that it had been approved by the FDA for a number of uses for which it had not, in violation of the Lanham Act § 43(a), 15 U.S.C. § 1125(a), and the Nebraska Uniform Deceptive Trade Practices Act, Neb. Rev. Stat. §§ 87-301–87-306. The company also contended that Pennfield's practices constituted unfair competition and unjust enrichment under Nebraska common law. Alpharma sought injunctive relief, compensatory, treble and punitive damages, fees and costs.

Pennfield moved to dismiss Alpharma's claims under Federal Rule of Civil Procedure 12(b)(6), arguing that §§ 558.15(g)(1) and 558.76 showed that its product had been approved for the contested uses, that Alpharma's action was an impermissible private attempt to enforce FDCA and FDA regulations, that the Lanham Act was not intended as a means of indirectly enforcing the FDCA and FDA regulations, and that Alpharma's action intruded upon the FDA's discretion and expertise in the area of drug approval and marketing.

The district court granted Pennfield's motion to dismiss, referencing the doctrine of primary jurisdiction but ultimately concluding that the "plaintiff's failure to exhaust" required dismissal. Alpharma, Inc. v. Pennfield Oil. Co., 2004 WL 1562870, *1 (D.Neb. 2004). The court cited a number of factors in concluding that dismissal was proper: the absence of a decision by the FDA clarifying the meaning of "completely confusing historical records" regarding Pennfield's approval to market BMD; the pending FDA actions on issues relating to the case; the FDA's expertise on questions involved; the FDA's responsibility to interpret its own regulations first; and the absence of any indication that exhaustion would be ineffective or futile. Id.

Alpharma appeals the district court's dismissal of its action, arguing that exhaustion and other related doctrines do not apply in this case. We review the

district court's Rule 12(b)(6) dismissal de novo, taking all facts alleged in the complaint as true. Carter v. Arkansas, 392 F.3d 965, 968 (8th Cir. 2004). "A motion to dismiss should be granted only if it appears beyond doubt that the plaintiff can prove no set of facts which would entitle him to relief." Knapp v. Hanson, 183 F.3d 786, 788 (8th Cir. 1999).

Alpharma first argues that the district court erred in dismissing its Lanham Act claim on exhaustion grounds. Under the doctrine of exhaustion, "no one is entitled to judicial relief for a supposed or threatened injury until the prescribed administrative remedy has been exhausted." Myers v. Bethlehem Shipbuilding Corp., 303 U.S. 41, 50-51 (1938); see also Cornish v. Blakey, 336 F.3d 749, 753 (8th Cir. 2003) (requiring exhaustion of "statutory administrative remedies"). The doctrine applies when the plaintiff's claim is "'cognizable in the first instance by an administrative agency alone,'" and does not apply when the relevant agency is unable to grant relief. Harris v. P.A.M. Transport, Inc., 339 F.3d 635, 638 (8th Cir. 2003) (quoting United States v. W. Pac. R.R. Co., 352 U.S. 59, 63 (1956)); Jackson v. Swift Eckrich, Inc., 53 F.3d 1452, 1456 (8th Cir. 1995) (exhaustion "ordinarily requires a plaintiff to pursue relief, when available, from an administrative agency before proceeding to the courts"). Alpharma argues that the Lanham Act does not require that any administrative procedures be exhausted before filing suit, but rather places exclusive jurisdiction to resolve false advertising claims in the district courts. The company also contends that its false advertising claim is not cognizable by the FDA since the agency cannot award the requested damages. Alpharma finally notes that, unlike the plaintiffs in Bradley v. Weinberger, 483 F.2d 410 (1st Cir. 1973), and other cases cited by the district court, it is not seeking review of agency action under the Administrative Procedure Act or any other statute requiring exhaustion.

Alpharma is incorrect in its assertion that district court jurisdiction over Lanham Act claims is exclusive. 15 U.S.C. § 1121(a); Aquatherm Industries, Inc. v. Florida Power & Light Co., 84 F.3d 1388, 1394 (11th Cir. 1996) ("Federal courts do

not have exclusive jurisdiction over an action brought under the Lanham Act."). Nonetheless, the statute does not create administrative procedures for the resolution of false advertising claims brought by Alpharma. See Sandoz Pharmaceuticals Corp. v. Richardson-Vicks, Inc., 902 F.2d 222, 226-29 (contrasting the administrative apparatus of the Federal Trade Commission Act with the civil remedy created by § 43(a) of the Lanham Act). Moreover, the FDA does not have the authority to award the compensatory and punitive damages sought by Alpharma in the present lawsuit. The company's claim was therefore not cognizable by the agency, and it was not required to refrain from litigation until some "administrative process ha[d] run its course." Western Pac. R.R., 352 U.S. at 63.

In dismissing Alpharma's claims the district court also referred to primary jurisdiction. The doctrine of primary jurisdiction "'applies where a claim is originally cognizable in the courts, and comes into play whenever enforcement of the claim requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body.'" Atlantis Exp., Inc. v. Standard Transp. Services, Inc., 955 F.2d 529, 532 (8th Cir. 1992) (quoting Western Pac. R.R., 352 U.S. at 64)). The contours of primary jurisdiction are not fixed by a precise formula. Rather, the applicability of the doctrine in any given case depends on "whether the reasons for the existence of the doctrine are present and whether the purposes it serves will be aided by its application." Western Pac. R.R., 352 U.S. at 64. Among the reasons and purposes served are the promotion of consistency and uniformity within the areas of regulation and the use of agency expertise "'in cases raising issues of fact not within the conventional experience of judges or cases requiring the exercise of administrative discretion." Access Telecomm. v. Southwestern Bell Tel. Co., 137 F.3d 605, 608 (8th Cir. 1998) (quoting Far East Conference v. United States, 342 U.S. 570, 574 (1952)).

When it is determined that primary jurisdiction to resolve an issue lies with an agency, a court otherwise having jurisdiction over the case may stay or dismiss the

action pending the agency's resolution of the question. Jackson v. Swift Eckrich, Inc., 53 F.3d 1452, 1456 (8th Cir. 1995). The doctrine is to be "invoked sparingly, as it often results in added expense and delay." Red Lake Band of Chippewa Indians v. Barlow, 846 F.2d 474, 477 (8th Cir. 1988) (internal quotations omitted).

Alpharma contends that this is not a case in which the primary jurisdiction doctrine should be applied. According to Alpharma, the question of whether Pennfield's product has received FDA approval for certain uses does not require the agency's expertise since its resolution requires only a review of agency materials the district court is fully capable of interpreting. Alpharma notes that the FDA has already provided substantial guidance on the issue by its stipulation in the Maryland case and in its August 8, 2003 notices of opportunity for hearing and proposed rulemaking. Alpharma also argues that there is no issue of consistent or uniform regulation since the question of approval only concerns Pennfield and that substantial delay would resulting from staying or dismissing the case, particularly since the FDA has taken no action since publishing the notices nearly two years ago.

We agree with Alpharma that this is not the rare case requiring "expert consideration and uniformity of resolution." See United States v. McDonnell Douglas Corp., 751 F.2d 220, 224 (8th Cir. 1984) (primary jurisdiction "should seldom be invoked unless a factual question requires both expert consideration and uniformity of resolution"). A determination of whether Pennfield's product has received FDA approval for certain uses turns on the meaning of agency publications in the Federal Register and Code of Federal Regulations. Interpretation of such materials is well within the "conventional experience of judges." See Access Telecomm., 137 F.3d at 608.

The question of whether Pennfield's BMD has been approved as safe and effective is much different from the question of whether Pennfield's BMD should be approved as safe and effective, and it is only the latter that requires the FDA's

scientific expertise. Consistency and uniformity of regulation would also not be jeopardized by judicial resolution of this case since Alpharma has raised only the issue of Pennfield's approval to market a single drug. Finally, an order staying or dismissing this action would almost certainly result in substantial added expense and delay. Nearly two years have passed since the FDA published its August 8, 2003, notices relating to Pennfield's approval, and there is no indication that the agency will soon finalize those actions. We conclude that Alpharma's claims should not have been dismissed on the basis of primary jurisdiction.

Pennfield focuses its argument for affirmance on a related doctrine it extracts from a number of cases brought under the Lanham Act and dealing with FDA issues. It argues that these cases require dismissal of Alpharma's claims. According to Pennfield, the courts in PDK Labs, Inc. v. Friedlander, 103 F.3d 1105 (2d Cir. 1997), Mylan Laboratories, Inc. v. Matkari, 7 F.3d 1130 (4th Cir. 1993), and Sandoz Pharmaceuticals Corp., established that plaintiffs may not bring Lanham Act false advertising claims involving FDCA or FDA regulations because there is no private right of action to enforce these provisions, Congress did not intend for the Lanham Act to be a vehicle for enforcing the provisions indirectly, and the area is within the expertise of the FDA.[2] After examining these cases, we conclude that they do not support Pennfield's arguments here.

In PDK Labs, a plaintiff who had developed but not yet marketed a weight loss product filed a Lanham Act claim, alleging that PDK had falsely advertised that its own weight loss products had been approved by the FDA. 103 F.3d at 1107.

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[2]Pennfield also cites a number of district court opinions for the same proposition. See Ethex Corp. v. First Horizon Pharmaceutical Corp., 228 F.Supp.2d 1048, 1051-55 (E.D. Mo. 2002); Healthpoint, Ltd. v. Ethex Corp., 273 F.Supp.2d 817, 838-39 (W.D. Tex. 2001); Eli Lilly and Co. v. Roussel Corp., 23 F.Supp.2d 460, 475-80 (D.N.J. 1998); Summit Tech., Inc. v. High-Line Medical Instruments, Co., 933 F.Supp. 918 (C.D. Cal. 1996).

Referencing its earlier holding that a Lanham Act plaintiff must "demonstrate a reasonable interest to be protected against the advertiser's false or misleading claims," the Second Circuit held that the developer lacked standing to bring the action since his product was not yet in competition with the defendant's. Id. at 1111-12 (internal quotations omitted). In so holding, the court remarked that the plaintiff's "dogged insistence that PDK's products are sold without proper FDA approval suggest[ed]...that [his] true goal [was] to privately enforce alleged violations of the FDCA," for which there was no private right of action. Id. at 1113. Pennfield argues that this means that all Lanham Act claims involving FDA approval are impermissible attempts at private enforcement of the FDCA. The case was decided on standing grounds, however, and the court indicated a willingness to consider such a claim if brought by a party in actual competition with a manufacturer who had falsely advertised having FDA approval.

In Mylan Laboratories, a manufacturer of prescription and generic drugs filed a Lanham Act claim against four competitors, alleging that their advertisements had falsely represented both that their products had received FDA approval and that their drugs were "bioequivalent" to the plaintiff's. 7 F.3d at 1137-38. While allowing the bioequivalence claims to go forward, the Fourth Circuit dismissed the claims alleging false representations of approval since plaintiff's complaint had not referenced any "statement or representation in the defendants' advertising which declared 'proper FDA approval.'" Id. at 1138-39. Were manufacturers permitted to file Lanham Act suits in the absence of "some claim or representation that is reasonably clear from the face of the defendants' advertising," the court concluded, the statute would be inappropriately converted into a vehicle for privately enforcing the FDCA. Id. (emphasis in original). Contrary to Pennfield's reading of the case, the Fourth Circuit did not bar all Lanham Act claims involving false representations of FDA approval, but only those where there had not been any claim of approval. Because Alpharma has alleged reasonably clear claims of FDA approval by Pennfield, Mylan Laboratories is inapposite.

Finally, in Sandoz Pharmaceuticals, a cough syrup manufacturer sued a competitor, alleging that the label of the competitor's product falsely listed an ingredient as "inactive" when FDA standards suggested that the ingredient was in fact active. 902 F.2d at 230. The Third Circuit assumed without deciding that false labeling was actionable under the Lanham Act, and concluded that the plaintiff had not shown the defendant's label was false. Id. The FDA had not yet determined whether the ingredient at issue was properly characterized as active or inactive, and the court declined to answer the question first due to the agency's expertise in the area. Id. 230-31. The court did not reject all Lanham Act suits involving drug labeling, and it actually considered the false advertising claim on the merits, refusing only to "determine preemptively how a federal administrative agency will interpret and enforce its own regulations." Id. at 231. Alpharma's claim does not require such a preemptive determination, and Pennfield's attempt to place this case within the reasoning of Sandoz is mistaken.

Our own opinion in Rhone-Poulenc Rorer Pharmaceuticals, Inc. v. Marion Merrell Dow, Inc., 93 F.3d 511 (8th Cir. 1996), contradicts the principle Pennfield tries to extract from the preceding cases. In Rhone-Poulenc, the manufacturer of a drug approved only to treat hypertension, circulated advertisements with statements implying that its product could be freely substituted for a competitor's medication that had been approved for the treatment of both hypertension and angina. Id. at 513, 516. The district court held that the manufacturer's advertisements violated § 43(a) of the Lanham Act by falsely representing that the medication was approved to treat angina. Id. at 514. We affirmed and thus confirmed the viability of Lanham Act claims concerning representations of FDA approval.

For these reasons we reverse the order of dismissal and remand the case to the district court for further proceedings consistent with this opinion.
