United States Court of Appeals
FOR THE EIGHTH CIRCUIT

No. 05-3873

In re: Canadian Import Antitrust Litigation	*	
Eileen Iverson; Hugh Hawkins; Juanita Huseby; David Schafer; Gregory Noonan; Bonnie Koch; Jennifer Mills; Minnesota Senior Federation; United Senior Action, of Indiana; LaPorte County Comprehensive Mental Health Council, doing business as Swanson Center, Inc.; Massachusetts Senior Action Council; Painters District Council No. 30 Health and Welfare Fund; Central Laborers Welfare Fund, on behalf of themselves and all others similarly situated,	*	
Appellants,	*	Appeal from the United States District Court for the District of Minnesota.
National Association of Shareholder and Consumer Attorneys,	*	
Amicus on Behalf of Appellant.	*	
v.	*	
Pfizer, Inc.; GlaxoSmithKline, PLC; Abbott Laboratories, Inc.; Boehringer Ingelheim Pharmaceuticals, Inc., GmbH;	*	

Merck & Co., Inc.; Novartis AG; Wyeth *
Pharmaceuticals, Inc.; Eli Lilly & *
Company; Astrazeneca, PLC, *
*
Appellees. *

Submitted: May 18, 2006
Filed: November 30, 2006

Before LOKEN, Chief Judge, JOHN R. GIBSON, and COLLOTON, Circuit Judges.

COLLOTON, Circuit Judge.

Plaintiffs, a group of consumers and organizations from Minnesota who have purchased prescription drugs in the United States from the defendant drug companies in the United States, filed suit pursuant to § 4 of the Clayton Act, 15 U.S.C. § 15, for damages caused by alleged violations of § 1 of the Sherman Antitrust Act, 15 U.S.C. § 1, and pursuant to § 16 of the Clayton Act, 15 U.S.C. § 26, seeking injunctive relief. Plaintiffs also alleged violations of various state statutes concerning restraint of trade. The gravamen of the complaint was that the defendants unlawfully conspired to suppress the importation of Canadian prescription drugs for personal use. The district court[1] dismissed the federal antitrust claim and declined to exercise supplemental jurisdiction over the remaining state law claims. We affirm.

[1]The Honorable Joan N. Ericksen, United States District Judge for the District of Minnesota, adopting the reports and recommendations of the Honorable Jonathan Lebedoff, Chief United States Magistrate Judge for the District of Minnesota.

I.

The plaintiffs filed suit on May 19, 2004, alleging that the defendants had "engaged in a concerted course of conduct designed to prevent brand name prescription drugs purchased from Canadian pharmacies from entering the United States." (Complaint, R. Doc. No. 1, at ¶ 18). According to the complaint, the conduct eliminated a legal source of prescription drugs and caused American consumers to pay higher drug prices. The plaintiffs alleged that the defendant drug companies engaged in anti-competitive conduct, including: (1) requiring Canadian pharmacies to certify that they were not selling prescription drugs to persons whom the pharmacies knew or should have known were taking the drugs outside the country, (2) monitoring orders of Canadian pharmacies and limiting their purchases to historical levels, (3) creating "blacklists" of pharmacies that were suspected of selling drugs to American consumers and directing wholesalers not to sell to the blacklisted pharmacies, and (4) cutting off supplies to wholesalers who did not comply with their policies. (*Id.* at ¶ 36). The plaintiffs alleged that this conduct violated the Sherman Act, and the antitrust and unfair competition statutes of twenty-three states and the District of Columbia. (*Id.* at ¶¶ 28, 73, 82).

The district court consolidated several similar cases, and the plaintiffs filed an amended complaint on September 30, 2004. The defendants moved to dismiss the complaint for failure to state a claim. *See* Fed. R. Civ. P. 12(b)(6). Two defendants, AstraZeneca PLC and Novartis AG, also moved to dismiss for lack of personal jurisdiction and improper venue. A magistrate judge recommended granting the motion to dismiss on the Sherman Act claims. The report concluded that because the importation of Canadian prescription drugs was prohibited by the Federal Food, Drug, and Cosmetic Act ("FFDCA"), the plaintiffs could not demonstrate that they have an injury "of the kind the federal antitrust laws were designed to prevent." The magistrate judge also recommended that the state-law claims against AstraZeneca and Novartis be dismissed for lack of personal jurisdiction and improper venue.

On review of the reports and recommendations, the district court concluded that the plaintiffs lacked standing to pursue their federal antitrust claims because the allegedly anticompetitive behavior discouraged only unlawful importation of drugs and not lawful activity that the Sherman Act was designed to protect. In particular, the court found that drugs imported from Canada, even when imported for personal use, were "misbranded" under the laws of the United States because their labels did not bear the required "Rx only" symbol. After dismissing the federal claims, the court declined to exercise supplemental jurisdiction over the remaining state claims and dismissed them without prejudice. The court also denied the motions to dismiss for lack of personal jurisdiction as moot.

II.

We review the district court's grant of a motion to dismiss *de novo*. *Farm Credit Servs. of Am. v. American State Bank*, 339 F.3d 764, 767 (8th Cir. 2003). A complaint is properly dismissed for failing to state a claim when the plaintiffs can prove no set of facts that would entitle them to relief. *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957).

The district court's decision to dismiss the federal claims was premised on its conclusion that federal law prohibits the importation of prescription drugs from Canada for personal use. Plaintiffs continue to assert that the common assumption that such importation is unlawful is based purely on "myth," and that no federal statute actually precludes a citizen from carrying prescription drugs purchased in Canada into the United States.

The United States Food and Drug Administration ("FDA") repeatedly has expressed the view that virtually all importation of drugs into the United States by individual consumers violates the FFDCA, because the drugs are not approved in accordance with 21 U.S.C. § 355, are not labeled as required by 21 U.S.C. § 352, or

are dispensed without a valid prescription in contravention of 21 U.S.C. § 353(b)(1). The FDA's Office of Compliance has cautioned that "[d]rugs from foreign countries do not have the same assurance of safety as drugs actually regulated by the FDA," due to the risk that counterfeit or unapproved drugs will be sent to consumers, and also because "[w]ithout regulation of repackaging, storage conditions, and many other factors, drugs delivered to the American public from foreign countries may be very different from FDA approved drugs with respect to formulation, potency, quality, and labeling." (Appellees' App. at 8-9). The district court in this case focused on one aspect of the approval process – the labeling requirements – and observed that it is illegal to import drugs whose labels do not comport with the statutory and regulatory requirements.

We agree with the district court's conclusion that the Canadian prescription drugs at issue are not labeled in conformity with federal law, and that importation of the drugs is therefore prohibited. Federal law requires that a drug shall be deemed "misbranded if at any time prior to dispensing the label of the drug fails to bear, at a minimum, the symbol 'Rx only,'" 21 U.S.C. § 353(b)(4)(A), and the introduction of misbranded drugs into interstate commerce is prohibited. *Id*. § 331(a). Drugs that are dispensed by Canadian pharmacies are labeled "Pr," as opposed to "Rx only." Plaintiffs argue that the Canadian symbol is the "functional equivalent" of "Rx only," but federal law does not provide for functional equivalence in labeling. The drugs do not "bear, at a minimum, the symbol 'Rx only,'" and they are therefore "misbranded."

The plaintiffs argue that the even if the drugs are misbranded under federal law when they are distributed to Canadian pharmacists, the American labeling requirements do not apply to the drugs after they are dispensed by a pharmacy, because of the so-called "pharmacist's exception" set forth in 21 U.S.C. § 353(b)(2). That provision says that "[a]ny drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of section 352 of this title," with some exceptions. *Id.* The

exemption in § 353, however, applies only to the requirements in § 352. The "Rx only" requirement appears in § 353(b)(4), and it is not exempted by § 353(b)(2).

More fundamentally, that the Canadian drugs are mislabeled under federal law illustrates why the Canadian drugs are "unapproved" drugs within the meaning of 21 U.S.C. § 355, and thus prohibited from importation on that basis as well. The FFDCA comprehensively regulates the manufacture, importation, and sale of prescription drugs. Before a new drug may be introduced into interstate commerce, the FDA must approve the manufacturing process, labeling, and packaging. 21 U.S.C. § 355(b)(1). The approval process addresses the chemical composition of the drug, *id.* § 355(b)(1)(B), (C), the drug's safety and effectiveness, *id.* § 355(b)(1)(A), and elements of the drug's distribution, such as "the methods used in, and the facilities and controls used for, the manufacture, processing, and packing" of the drug, *id.* § 355(b)(1)(D), and the "labeling proposed to be used" for the drug. *Id.* § 355(b)(1)(F). The approval process is specific to each manufacturer and each product. *See* 21 C.F.R. § 314.50.

Drugs that are manufactured and distributed in Canada are not approved pursuant to this statutory framework. The approval process requires, among other things, that a manufacturer provide "the proposed text of the labeling for the drug." 21 C.F.R. § 314.50(c). Because foreign labeling differs from domestic labeling, approval granted to a particular manufacturer for a particular product to be distributed in the United States does not constitute approval of another drug – even one with the same chemical composition – to be distributed in Canada with different labeling, and then imported into the United States.

This is not, as plaintiffs would have it, merely a "hyper-technical" violation of the FFDCA. It is, rather, a manifestation of a congressional plan to create a "closed system" designed to guarantee safe and effective drugs for consumers in the United States. *Vermont v. Leavitt*, 405 F. Supp.2d 466, 472 (D. Vt. 2005). Drugs that are not

properly labeled for sale under federal law sometimes may be similar in substance to those that are sold legally within the United States. In other cases, however, they may be drugs with chemical compositions that are not yet approved by the FDA, drugs not manufactured in accordance with FDA rules, or drugs not transported or stored in a manner that is deemed safe by the FDA. The plaintiffs have attempted to limit this action to drugs that are "the same" as drugs sold legally in the United States except for the labeling, but the labeling requirements cannot be segregated from other FFDCA requirements in this way. Instead, they work in conjunction with the other statutory standards and FDA regulations to create a system that excludes non-compliant and potentially unsafe pharmaceuticals. This "closed system" ensures that approved prescription drugs are "subject to FDA oversight" and are "continuously under the custody of a U.S. manufacturer or authorized distributor," thus helping to ensure that the quality of drugs used by American consumers is consistent and predictable. *United States v. Rx Depot, Inc.*, 290 F. Supp.2d 1238, 1241-42 (N.D. Okla. 2003).

Congress recently has legislated against the backdrop of this closed system with respect to the very topic of the importation of prescription drugs from Canada. In 2000 and 2003, Congress enacted amendments to the FFDCA that would permit limited importation of certain prescription drugs from Canada by pharmacists, wholesalers, or individuals, 21 U.S.C. § 384(b), (j), but only if the Secretary of Health and Human Services first certifies that the importation would "pose no additional risk to the public's health and safety" and that it would "result in a significant reduction in the cost of covered products" for American consumers. 21 U.S.C. § 384 (*l*); *see* Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. No. 108-173, § 1121, 117 Stat. 2066, 2464-69 (2003); *see also* Medicine Equity and Drug Safety Act, Pub. L. No. 106-387, § 745, 114 Stat. 1549A-35 (2000). Three Secretaries of Health and Human Services in the last two presidential administrations have declined to make the requisite certifications. (Appellees' App. at 109, 111-13); *Montgomery County v. Leavitt*, 445 F. Supp.2d 505, 510 (D. Md. 2006).

That Congress created a special procedure for authorizing importation of prescription drugs from Canada supports our conclusion that the pre-existing system established by the FFDCA does not permit such importation. While it is true that no federal statute by its express terms bans importation of prescriptions drugs from Canada, such an explicit country-by-country prohibition is unnecessary to accomplish the task. By creating the comprehensive regulatory system described above, Congress has effectively precluded importation of these drugs absent the sort of special authorization contemplated by 21 U.S.C. § 384.

Plaintiffs argue alternatively that even if personal importation of prescription drugs from Canada is illegal, they nonetheless may pursue an action under the federal antitrust laws based on the defendants' allegedly anti-competitive behavior. Unlike a governmental entity, however, *see, e.g.*, *FTC v. Indiana Fed'n of Dentists*, 476 U.S. 447 (1986), a private plaintiff must demonstrate that he has suffered an "antitrust injury" as a result of the alleged conduct of the defendants, and that he has standing to pursue a claim under the federal antitrust laws. Because § 4 of the Clayton Act was designed primarily as a remedial provision, private plaintiffs proceeding thereunder must prove an "injury of the type that the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful." *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977). Injunctive relief under § 16 of the Clayton Act is likewise available only to plaintiffs who have suffered an injury cognizable under § 4. *Cargill, Inc. v. Monfort of Colo., Inc.*, 479 U.S. 104, 111-13 (1986).

The requisite antitrust injury must "reflect the anticompetitive effect either of the violation or of the anticompetitive acts made possible by the violation," and represent "the type of loss that the claimed violations . . . would be likely to cause." *Brunswick Corp.*, 429 U.S. at 489. To determine whether the requirements of antitrust standing are satisfied, we also consider the causal connection between the alleged antitrust violation and harm to the plaintiff, the directness or indirectness of the

asserted injury, and the degree to which the alleged damages are speculative in a § 4 action. *Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 537-45 (1983); *see Cargill*, 479 U.S. at 110 n.5.

We agree with the district court that plaintiffs have not established antitrust standing to pursue their federal antitrust claims. Plaintiffs allege that they are injured by increased prices for prescription drugs in the United States, which they say result from their inability to import less expensive drugs distributed by Canadian pharmacies. As we have explained, however, the importation of drugs from Canada is prohibited by federal law. The absence of competition from Canadian sources in the domestic prescription drug market, therefore, is caused by the federal statutory and regulatory scheme adopted by the United States government, not by the conduct of the defendants. Consequently, the alleged conduct of the defendants did not cause an injury of the type that the antitrust laws were designed to remedy. *See RSA Media, Inc. v. AK Media Group., Inc.*, 260 F.3d 10, 15 (1st Cir. 2001) (plaintiff lacked antitrust standing where it "was not excluded from the market for outdoor billboards because of [defendant's] threats," but rather "because of the Massachusetts regulatory scheme that prevents new billboards from being built"); *City of Pittsburgh v. West Penn Power Co.*, 147 F.3d 256, 265 (3d Cir. 1998) (City suffered no antitrust injury and had no antitrust standing because "any injury suffered by the City did not flow from the defendants' conduct, but, rather, from the realities of the regulated environment in which all three were actors"); 2 P. Areeda & H. Hovenkamp, *Antitrust Law* § 338, at 320 (2d ed. 2000) (explaining that antitrust standing is lacking where "a force other than the antitrust violation fully accounts for the plaintiff's injury").

The plaintiffs do allege that prior to the alleged anti-competitive conduct of the defendants, Americans were able to import prescription drugs from Canada for personal use, because the FDA declined to enforce a legal prohibition on personal importation of Canadian drugs. They do not allege, however, that the government's lack of enforcement resulted in the injury alleged in their complaint – *i.e.*, increased

prices for prescription drugs in the United States – presumably because the chain of causation would be too speculative to support such an assertion. To establish antitrust standing based on higher drug prices in the United States, the plaintiffs would have to prove that absent the alleged anti-competitive conduct of the defendants, pharmacists and wholesalers in Canada would sell additional prescription drugs to American consumers, Americans routinely would travel to Canada to fill their prescriptions, those consumers would avoid enforcement when transporting their prescriptions illegally across the border, and the number of consumers engaging in this illegal behavior would be so large as to drive down prices in the United States. These "vaguely defined links" in the chain of causation, even if alleged by the plaintiffs, would be insufficient to establish antitrust standing. *See Associated Gen. Contractors*, 459 U.S. at 540.

Finally, the plaintiffs argue that the district court abused its discretion when it dismissed their state law claims. When a district court dismisses federal claims over which it has original jurisdiction, the balance of interests usually "will point toward declining to exercise jurisdiction over the remaining state law claims." *Carnegie-Mellon Univ. v. Cohill*, 484 U.S. 343, 350 n.7 (1988); *see also Gibson v. Weber*, 433 F.3d 642, 647 (8th Cir. 2006); 28 U.S.C. § 1367(c)(3). The district court's decision to dismiss the state law claims was in accord with these principles. The advent of the Class Action Fairness Act, Pub. L. No. 109-2, 119 Stat. 4 (2005), and the potential for the future removal of the state claims to federal court, are not sufficient grounds to require the district court to retain federal jurisdiction.

The judgment of the district court is affirmed.
