



Two Recent Decisions Limit Antitrust Plaintiffs' Rights To Bring Price-Fixing Claims

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Within the space of three weeks, two courts – the U.S. Court of Appeals for the Eighth Circuit and the Alameda County, California, Superior Court – issued important rulings ending two antitrust cases based on claims that drug prices in the United States are too high. In the process, the courts limited the rights of plaintiffs to allege conspiratorial conduct in violation of federal and state antitrust laws. In the federal case, the court of appeals held that prescription drug imports from Canada (and elsewhere in the world) violate federal law, and that private plaintiffs lack standing under the Sherman Act to seek redress for an alleged conspiracy to restrain that illegal commerce. The case from Alameda County addressed claims by “indirect purchasers,” concluding that the plaintiff pharmacies could not sue pharmaceutical manufacturers under California’s antitrust statute if they “passed on” any alleged overcharge to their own customers, and therefore had not suffered any damages. While of importance for the pharmaceutical industry, both cases establish rules of wide applicability and, through the clarity of their holdings in areas not often addressed, may influence courts in antitrust cases involving many other industries for years to come.¹

In re Canadian Import Antitrust Litigation

On November 29, 2006, a unanimous panel of the United States Court of Appeals for the Eighth Circuit affirmed the dismissal of *In re Canadian Import Antitrust Litigation – Iverson v. Pfizer Inc.*, No. 05-3873, class action litigation that had been consolidated in the District of Minnesota. The plaintiffs included individuals, a union health benefit plan, and organizations ostensibly representing seniors. They claimed that the defendants – nine major drug companies – had conspired to prevent the importation of certain lower-priced Canadian drugs and had thereby prevented “competition” from that trade to lower U.S. drug prices. The case proceeded against the background of the heated political and public policy debates prompted by importation of certain lower-priced Canadian drugs into the United States, and was ostensibly brought on behalf of all “persons or entities” in the United States who purchased or paid for brand name prescription drugs that were sold both in the United States and Canada. The plaintiffs sought injunctive relief for the defendants’ alleged violations of the Sherman Act, and damages under the antitrust and consumer protection laws of more than two dozen states.²

The central allegation of the case was that each defendant, pursuant to an illegal agreement with the other defendants, took steps to stop importation of its prescription drugs from Canada into the United States. The steps allegedly taken included prohibiting Canadian purchasers from reselling their drugs to the United States and limiting the supply of drugs made available for purchase in Canada. The conspiracy arose, the plaintiffs claimed, because Canadian drugs were subject to governmental price controls and therefore were less expensive than drugs in the free-market United States, and because preventing imports allegedly thus eliminated import “competition” that would have reduced U.S. drug prices.

The defendants moved to dismiss on two grounds. First, they contended that the importation of drugs from Canada violates federal law – the Federal Food, Drug, and Cosmetic Act (the “FFDCA”). Second, they argued that neither the Sherman Act nor its state-law counterparts could be construed to protect and promote “competition” that itself was illegal. The district court (Joan N. Ericksen, J.) agreed, finding that Canadian drugs were “misbranded” under the FFDCA

and that plaintiffs lacked standing to bring claims under the Sherman Act. Judge Ericksen dismissed the plaintiffs' federal claims and declined to exercise supplemental jurisdiction over their state-law claims in the absence of a federal case.

The Eighth Circuit (Colloton, J, with Loken, C.J. and John R. Gibson, J., concurring) addressed two issues in affirming the dismissal of the case: 1) whether prescription drug imports from Canada for personal use violate the FFDCA, and 2) whether a presumed conspiracy among manufacturers to deter such imports could violate the Sherman Act.

As to the food and drug law question, the Court undertook an appraisal of the FFDCA that was notably broad in scope and understanding of the structure and complexities of the statute. The court of appeals agreed with the district court that Canadian labeling regulations required markings that did not comply with U.S. law, and that Canadian drugs therefore were "misbranded" under the FFDCA and could not legally be imported into this country. Specifically, it concluded that the requirement of 21 U.S.C. § 353(b)(4)(A) that drug labels bear the symbol "Rx only" prior to dispensing was not satisfied by use of the Canadian symbol, "Pr," which the plaintiffs had argued was the "functional equivalent" of the U.S. requirement. The Court similarly rejected the plaintiffs' claim that the "pharmacist's exception" - which limits the labeling that must appear on containers dispensed to patients - remedied the illegality, concluding that the provision did not extend to the specific misbranding described above. The holding is significant, as it confirms that the "pharmacist's exception" does not make legal drugs that were misbranded prior to their being dispensed to patients.

The court of appeals did not stop there. Characterizing the conflicting labeling requirements as just "illustrat[ive]" of a broader basis for finding drug imports to be illegal, the Court concluded that the totality of U.S. drug regulation established a "closed system" requiring drugs sold in this country to be manufactured, packaged, and sold under FDA jurisdiction.³ The failure of Canadian drugs to bear "Rx only" on their labels

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 noncompliant 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).⁴

To the same end, the Court also noted that Congress had twice addressed specifically the question of legalizing drug imports from Canada, and on both occasions had required as a condition that the Secretary of Health and Human Services certify the safety of the practice - a certification that three secretaries in the last two presidential administrations had declined to make. "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."⁵

The Court next considered the question whether a conspiracy among drug manufacturers to deter the illegal importation of Canadian drugs could violate the federal antitrust laws. The Court viewed the issue in terms of standing under Sections 4 and 16 of the Clayton Act, which define

the right of a private plaintiff to obtain monetary and injunctive relief, respectively, for a violation of the Sherman Act, and thus distinguished *FTC v. Indiana Fed'n of Dentists*, 476 U.S. 447 (1986), and related cases in which a governmental entity had brought claims.⁶ Key to the standing question was whether the plaintiffs had alleged “an ‘injury of the type that the antitrust laws were intended to prevent and that flows from that which makes defendants’ acts unlawful.’”⁷ The Court concluded that this requirement could not be met where the injury claimed by the plaintiffs was the failure to enjoy the possible economic benefits of illegal “competition”: “The absence of competition from Canadian sources in the domestic prescription drug market . . . is caused by the federal statutory and regulatory scheme adopted by the United States government, not by the conduct of the defendants.”⁸

The Court also addressed the plaintiffs’ claim that the illegality of prescription drug imports should be ignored as to imports for personal use because the FDA had allegedly failed to enforce the law as a matter of policy in such cases. Again viewing the matter as one of antitrust standing, the Court concluded that the plaintiffs’ allegation, even if true, was not adequately linked to their claim that the defendants’ actions had resulted in higher U.S. drug prices. The “chain of causation” necessary to link U.S. citizens’ travel to Canada to fill prescriptions with a significant effect on U.S. drug prices was “too speculative to support such an assertion.”⁹

Clayworth, et al. v. Pfizer Inc., et al.

The *Clayworth* case also alleged a price-fixing conspiracy by major drug companies, and also included an allegation that an illegal agreement to restrict imports of prescription drugs from Canada had allowed higher U.S. drug prices to be insulated from “competition” from lower-priced Canadian drugs. This case was not brought as a federal class action on behalf of consumers, however, but by more than a dozen pharmacies, on their own behalf, seeking damages under California’s antitrust statute, the Cartwright Act, and California’s Unfair Competition Law. The conspiracy alleged was that the manufacturers had agreed to use Canadian prices as a “floor” for U.S. pricing.

After more than two years of litigation, the defendants filed comprehensive summary judgment motions arguing that the plaintiffs did not have and could not discover evidence of an illegal conspiracy. But cross-motions for summary judgment were also pending with respect to an issue peculiar to the laws of those states that, unlike the federal courts, permit suits by indirect purchasers like the plaintiffs. These latter motions came up for argument first and the Court’s resolution of them, on December 19, 2006, disposed of the whole case.

In the federal courts, a pair of Supreme Court decisions had created a regime in which a price fixing case may only be brought on behalf of “direct purchasers” – customers that purchased directly from the sellers alleged to have conspired. With a few exceptions the direct purchasers, in turn, can sue for the entire amount of any overcharge (trebled by law), irrespective of whether they “pass-on” the alleged overcharge to their own customers. See *Illinois Brick*, 431 U.S. 720 (suit only by direct purchasers); *Hanover Shoe, Inc. v. United Shoe Machinery Corp.*, 392 U.S. 481 (1968) (no “pass-on” defense in federal price fixing actions). The states, by contrast, remained free to enact antitrust laws complementary to the Sherman Act, employing a different regime of standing and damages. *California v. ARC America Corp.*, 490 U.S. 93 (1989). And more than half of the states, including California, have done so, responding legislatively or judicially to the Supreme Court’s *Illinois Brick* decision by specifically authorizing suits by indirect purchasers. While it is clear in these states that an indirect purchaser may sue, the corollary question whether the “pass-on” defense applies has remained unresolved in many states, including California.

The Court first considered the legal question whether a “pass-on” defense is available under California law, and noted that the question had not been resolved either by the California legislature when it confirmed the availability of indirect purchaser claims following the *Illinois Brick* decision, or by courts in the twenty-eight years since the amendment to the Cartwright Act was passed. The Court concluded that a “pass-on” defense should be allowed, and based its decision primarily upon the language of the Cartwright Act and policy considerations that had been made relevant by the *Illinois Brick* and *Hanover Shoe* decisions as well as by other provisions of California law.

The statutory language allows a plaintiff to recover three times the “damages sustained” by a plaintiff. Cal. Bus. & Prof. § 16750(a). The Court noted that this verbal formulation appears elsewhere in California law, and in those contexts was understood to mean “actual loss”; the Court reasoned that any intention by the legislature to depart from this accepted definition and to allow an indirect purchaser to sue absent any “actual loss” would likely have been shown through the use of different language. The Court acknowledged that a plaintiff could be “presumed to have suffered injury in fact” at the moment it paid an illegally-inflated price for its products, but cautioned that this not be confused with the plaintiff’s need to show actual damages in order to bring a claim for relief. Slip Op. at 20.

The Court’s discussion of policy considerations has potentially wider applicability, in part because they are less California-specific and in part because almost all courts to have addressed the question have based their decisions on a reading of the same policy considerations – ones marked out by the U.S. Supreme Court itself when it crafted the federal remedial scheme. The Court’s principal conclusions were as follows:

- To the extent an indirect purchaser-plaintiff must itself prove that an illegal overcharge was “passed on” to him, principles of fairness and “legal consistency,” slip op. at 18, suggested that the defendants be allowed to make the same arguments;
- Allowing pass-on evidence to be collected during discovery and presented at trial would add to the cost and complexity of litigation, but not prohibitively;
- The “pass-on” defense is consistent with the goals of the antitrust law to allow a plaintiff to recover for its injuries and to deter unlawful conduct, and avoids multiple recoveries for the same violation of law; and
- The problems inherent in precluding a “pass-on” defense should not be remedied by allowing the limited use of such information to allocate damages among plaintiffs through such procedural tools as consolidation, joinder, and coordination, which the plaintiffs had urged. “This seems to sanction inconsistent substantive law because there is a procedural fix. The better course would seem to be to give effect to the phrase ‘damages sustained’ in the substantive law, permit the pass-on defense, and enhance deterrence by making it easier for persons to prosecute their claims and ‘to recover three times the damages sustained.’” Slip Op. at 19 (citation omitted).

The Court then turned to the question whether, assuming the existence of a “pass-on” defense, the defendants were entitled to judgment as a matter of law. The undisputed facts of the case were stark. The plaintiffs had not disputed that all of their purchases and sales could ultimately be related to the drugs’ published “average wholesale price,” and that in connection with the resale of the drugs they would have recovered at least as much additional money as they claim to have been overcharged. Moreover, although alternative theories of damages might have been alleged, the plaintiffs had limited their claims to the actual amount of the alleged overcharge that they paid.¹⁰ On this record, the Court concluded that, even if the conspiracy were proved, the plaintiffs sustained no damages, and thus could not bring suit under the Cartwright Act. The Court cited the same fact in ruling that the plaintiffs could not proceed under California’s famously flexible Unfair Competition Law, Cal. Bus. & Prof. § 17200.

Conclusion

The *In re Canadian Import Antitrust Litigation* and *Clayworth* decisions are of great importance to the pharmaceutical industry, whose ability to prevail on legal issues presented in the politically-charged area of drug pricing has been confirmed. But the decisions also reflect the view that antitrust plaintiffs should not get something for nothing – recovery for injuries allegedly sustained because they were not able to reap the rewards of illegal competition, or for injuries allegedly suffered by others. These cases – both of which remain open as of this writing to further appellate review – add to the body of case law developed over the past fifteen or twenty years that treats claims by antitrust plaintiffs with fairness but discipline.

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- 1 In the interest of full disclosure, we note that Hughes Hubbard was involved in both cases and argued the Eighth Circuit case on behalf of all defendants.
- 2 The plaintiffs were "indirect purchasers," meaning that they bought from intermediary pharmacies rather than directly from the defendant drug manufacturers that were alleged to have conspired. As such, the plaintiffs could not seek damages under federal law. See *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977). The plaintiffs also purported to sue under the laws of the more than two dozen states that, either by special legislation or judicial decision, had declined to follow the federal *Illinois Brick* rule and chosen instead to allow suits for damages to be brought by indirect purchasers. Such suits under state law are discussed below in connection with the *Clayworth* case.
- 3 *In re Canadian Import Antitrust Litigation*, No. 05-3873, 2006 WL 3436309, at *3 (8th Cir. Nov. 30, 2006).
- 4 *Id.*
- 5 *Id.* at *4.
- 6 The defendants argued that no such distinction was necessary, in that none of the governmental cases upholding enforcement actions had involved an alleged conspiracy to prevent illegal competition. In *Indiana Fed'n of Dentists*, for example, the alleged conspiracy was to restrain the lawful practice by dentists of providing x-rays to insurance companies. See 476 U.S. at 465. Nothing in the decision of the court of appeals is inconsistent with this alternative argument.
- 7 *In re Canadian Import*, 2006 WL 3436309, at *4, citing *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977).
- 8 *Id.* at *5.
- 9 *Id.*, citing *Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 540 (1983).
- 10 The Court noted that the plaintiffs might have argued that higher drug prices had reduced demand for drugs generally. The plaintiffs' decision to waive this and other possible alternative theories of damages was apparently undertaken for strategic reasons, perhaps in the hope that it might limit the discovery of plaintiffs.