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Drug Wars: Prescription drug companies get hit with a rising tide of lawsuits

Edited By Martin Lasden

America's prescription drug companies better be as adept in the courtroom as they are in the lab. They face a growing wave of lawsuits accusing them of gaming the system to maintain high prices on their products.

Most of these cases fall into one of three categories. In one, brand name companies stand accused of illegally trying to delay the introduction of generic competitors by submitting invalid add-on patents to the Food and Drug Administration before the initial patents are due to expire. In a second category, plaintiffs are going after both brand name and generic drug companies for entering into agreements with each other. For example, in one case the state of California has joined 28 other states in a suit against Aventis Pharmaceuticals and Andrx. The suit claims that Aventis paid Andrx nearly \$90 million not to market a generic version of the heart drug Cardizem CD. And in a third group of cases that has criminal as well as civil implications, pharmaceutical companies are accused of inflating the average wholesale price numbers that they report, which the federal government uses to determine Medicare reimbursement rates.

In San Francisco, Lief Cabraser Heimann & Bernstein has already spent approximately \$1 million on experts and other costs to pursue about a dozen of these cases, according to Joseph Saveri, who heads the firm's antitrust and intellectual property practice group. "There are positive health benefits here," Saveri admits when alluding to the new drugs on the market. "But that said," he adds, "people should not be gouged."

In addition to Lief Cabraser, Milberg Weiss Bershad Hynes & Lerach and Carey & Danis have invested substantial resources into these cases—all on behalf of the Prescription Access Litigation (PAL) project, a Boston-based enterprise that has brought together 71 grassroots organizations in 31 states.

"These are complicated cases," says Lindsay Bower, a deputy attorney general in California who is working on the Cardizem suit. And at least in part that's because these battles are often waged at the place where patent laws and antitrust laws intersect. As Bower observes, "Patent laws give inventors the exclusive right to use innovations for a certain time" to encourage technological progress, while antitrust laws seek to break down monopolies.

From a legislative standpoint, it's a delicate balancing act but one that Congress supposedly accomplished when it passed the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as Hatch-Waxman. That law gave the generics companies the right to market cheaper versions of a drug with only minimal testing. In return, the brand names obtained new legal tools to protect their patents. It seemed like a deal everyone could live with. But in the face of a growing consumer backlash over the cost of prescription drugs, the status quo no longer appears to be politically tenable. This was underscored in October when President Bush called for the closing of certain loopholes that "keep generic drugs off the market for frivolous reasons."

However, even if these loopholes are closed immediately, the dozens of suits already in the pipeline probably won't be affected. As Lief Cabraser's Saveri claims, "The years of overpayments by consumers aren't going to go away."