California court sides with consumers in generic drug fight

May 7 2015, bySudhin Thanawala

In a win for consumers, the California Supreme Court ruled Thursday that settlement agreements between pharmaceutical companies that keep cheaper, generic drugs off the market may be illegal if they include excessive cash payments.

Consumer advocates say such deals have become more common in the drug industry and add billions of dollars to the drug bills of American patients and taxpayers.

The court ruled unanimously that such "pay-for-delay" deals between brand-name and generic drugmakers can violate the state's anti-trust law.

Such agreements arise when generic companies challenge the patents that allow brand-name companies to exclusively market a drug.

Lawsuits generally follow. If the two sides aren't certain who will win, they often reach a compromise deal that includes a sizable payment from the brand-name company to the generic drugmaker and an agreement by the generic drugmaker to hold off on selling its cheaper drug for some time.

In its ruling, the California high court said plaintiffs in cases challenging those deals must show that any cash payment exceeds the value of legal costs and any other products and services the generic drugmaker has agreed to provide and dispel any other justifications the drugmakers put forward, the court said.

The ruling was the first decision by an appellate-level court about drug settlement agreements since a 2013 U.S. Supreme Court decision that allowed the government to inspect and challenge such deals, said Michael Carrier, a professor at Rutgers School of Law in New Jersey who filed a brief in support of the California plaintiffs.

"This ruling supports the U.S. Supreme Court ruling and makes it tougher for a different court to ignore it and go in a different direction," Carrier said.

Thursday's decision came in a challenge to a $398 million settlement between drugmakers Bayer and Barr Laboratories over the antibiotic Cipro. Barr wanted to market a generic version of Cipro and accused Bayer in 1991 of having an invalid patent for the drug, prompting a lawsuit by Bayer.

As part of the 1997 settlement agreement, Barr agreed to postpone marketing its generic Cipro until Bayer's patent expired. Consumer groups say such deals rob consumers of the savings that would be generated if the generic companies won patent lawsuits and could begin marketing a cheaper, generic version of the drug right away.

Drug companies counter that the deals are fair given the hundreds of millions of dollars it often costs to develop a new drug. The industry also says some agreements actually bring generic drugs on to the market faster, even before the brand-name manufacturer's patent expires.

A call to an attorney for Barr was not immediately returned. Denise Bradley, a spokeswoman for Teva Pharmaceuticals, which acquired Barr, said the company had no comment.

Charles Bird, an attorney for Bayer, said Bayer was not participating in the California Supreme Court case.

Barr had argued that the settlement agreement was clearly legal because it did not extend beyond the patent, itself a monopoly to market the drug . But the California Supreme Court rejected that argument, saying patents were not to be treated as "ironclad."

The court did not rule specifically on the dispute involving Bayer and Barr, and did not invalidate all such agreements. But it reversed a state appellate court ruling and sent the case back down for further proceedings.

The case stemmed from multiple lawsuits by consumers and insurers who said they overpaid for Cipro between the time of the 1997 settlement and 2003, when Bayer's patent was set to expire.