



Association for Accessible Medicines v. Becerra, 822 Fed. Appx. 532 (9th Cir. 2020)

Topics Covered: Antitrust, Drug Manufacturers and Pricing

Outcome: Neutral

Issue

The issue in this case was whether California Health and Safety Code Division 114.01, *Preserving Access to Affordable Drugs*, which prohibits certain “reverse payment” or “pay for delay” settlements of patent infringement claims, is valid.

AMA Interest

The AMA opposes reverse payment settlements by pharmaceutical companies to delay the marketing of generic medications.

Case Summary

Reverse payment settlements arise primarily – if not exclusively – in the context of pharmaceutical drug patent infringement suits arising from the Hatch-Waxman Act. Under Hatch-Waxman, once a brand-name company has submitted a new prescription drug to the FDA and gained approval to market it, a manufacturer of a generic drug that is biologically equivalent to the approved brand-name drug can obtain approval to market the generic through an abbreviated FDA procedure known as an Abbreviated New Drug Application (“ANDA”) process.

The ANDA application form requires the generic company to assure the FDA that its drug will not infringe any patents owned by the brand-name drug company. One way to do so is for the generic company to certify that any listed, relevant patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug. This is called Paragraph IV certification. Because Paragraph IV of the ANDA may assert that current patents are invalid or un infringed by the generic product, the Paragraph IV certification can itself be deemed a patent infringement. The brand-name company may then sue the generic drug manufacturer for this infringement. Settlements of the resulting lawsuits sometimes include reverse payments in which the plaintiff, the brand-name drug company, pays the defendant, the infringing generic drug company, a sum of money for a promise that the generic drug company will keep its drug off the market for an agreed-upon length of time – generally, until the patent expires.

California Health and Safety Code Division 114.01 targets these types of settlements. Its purpose is to ensure that a brand-name drug company cannot continue to enforce an otherwise weak patent against generics through reverse payment settlements. The statute imposes a presumption that a settlement agreement involving a brand-name company’s compensating the generic manufacturer for keeping its drug off the market is anticompetitive under California

Antitrust Law. It also levies a substantial civil penalty against the settling companies and any individual who assisted in violation of the law.

Association for Accessible Medicines, a nonprofit association of manufacturers and distributors of generic and biosimilar medicines and ingredients, sued the California Attorney General for injunctive and declaratory relief under a pre-enforcement challenge to Division 114.01. The plaintiff alleged that Division 114.01 violates the Commerce Clause, the Excessive Fines Clause, and the Due Process Clause of the federal constitution and that the federal antitrust and patent laws preempt Division 114.01. The plaintiff moved for a preliminary injunction.

The trial court denied the motion, without prejudice. It acknowledged that the State could conceivably try to enforce Division 114.01 in such a way as to make the enforcement invalid under some or all of the plaintiff's theories. However, under the actual posture of the case, where there was no current enforcement attempt, it would be unduly speculative to find that Division 114.01 was across-the-board invalid. The plaintiff appealed to the Ninth Circuit.

In an unpublished decision, the Ninth Circuit held that the plaintiff had failed to demonstrate legal standing to bring the lawsuit. It vacated the trial court's denial of the preliminary injunction and ordered that the case be remanded and dismissed.

Litigation Center Involvement

The Litigation Center, along with the California Medical Association, filed an *amicus* brief to support the California statute.

Ninth Circuit Court of Appeals Brief