Association for Accessible Medicines

Analysis of Federal Regulation of Pharmaceutical Patent Infringement Case Settlements and SB 764

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Introduction

Your organization recently contacted me about SB 764 purporting to regulate "settlement agreements" between brand-name drug patent owners and the generic drug manufacturers that belong to your association.[1] As I understand it, your concern is that SB 764 is an attempt at state pharmaceutical drug regulation, a regulatory area in which states have little experience, and which currently involves a subtle balancing of federal procompetitive antitrust laws with the patent friendly policies expressed in the Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat.1585 as amended (commonly known as the Hatch-Waxman Act). In particular you have asked me to provide an analysis of how the settlement of pharmaceutical patent infringement cases are regulated under federal law, the success of that federal process, and in light of that pervasive federal regulatory system, whether SB 764 is compatible with federal case law and federal constitutional law. I have agreed to provide that analysis for your organization with the understanding that I take no position regarding the policy interests or arguments supporting or opposing SB 764.

Federal Regulation of Pharmaceutical Manufacturers

It isn't surprising that bringing new, often lifesaving medicines to market, requires approval by the U.S. Food and Drug Administration (FDA), following years of rigorous testing, and billions of dollars in costs. Pharmaceutical firms are incentivized to engage in the research and development of new drug products because the federal patent system grants them a monopoly—the right to exclude others from profiting by the patented drug for an often lengthy

[1] The Association For Accessible Medicines (AAM) is a nonprofit, voluntary association representing the leading manufacturers of generic and biosimilar medicines; manufacturers and distributers of bulk active pharmaceutical ingredients; and suppliers of other goods and services to the generic and biosimilar pharmaceutical industry.

period of time. Until 1984, federal law required all pharmaceutical drug products—even those similar in every way relevant to efficacy and safety to an already-approved brand-name drug—to undergo independent and rigorous clinical testing before entering the market. However, in 1984, Congress enacted the Hatch-Waxman Act. The intent of the Hatch-Waxman Act was to continue to incentivize name-brand pharmaceutical firms to make the billion-dollar investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to the market.

To bring competition to the drug market, the Hatch-Waxman Act promotes the entry of generic drugs into the market. Instead of undergoing the lengthy and costly approval process that a new drug faces, generic manufacturers can file an Abbreviated New Drug Application with the FDA. If the generic drug is bioequivalent to a brand-name drug that the FDA has already approved, then the generic can "piggy-back" on the brand-name's prior approval efforts. When a brand-name manufacturer has asserted a patent in its initial drug application, the Hatch-Waxman Act allows the generic manufacturer to certify in its application that the patent is invalid or that the generic drug will not infringe the patent. In response, the brand-name manufacturer will likely file a patent infringement action in federal court. When the brand-name manufacturer files such a case within 45 days, the FDA generally may not approve a generic's application for 30 months. This kind of patent litigation is particularly complex and costly. A 2010 study found that the cost of litigation in this context—a generic challenging a brand-name pharmaceutical patent—was $10 million per case (that number has likely increased significantly over the decade since the study was completed). Under the Hatch-Waxman Act, the parties—brand-name manufacturers and generic manufacturers—must report the terms of any settlement of their patent infringement litigation to the Federal Trade Commission (FTC) and the Antitrust Division of the Department of Justice.

Federal Regulation of Patent Infringement Settlement Agreements

When a brand-name drug manufacturer files a patent infringement action against a generic manufacturer, as with any other civil litigation in the United States, the parties may choose to settle the litigation. As described above, the terms of patent infringement litigation settlement agreements must be reported to the FTC and the Antitrust Division of the Federal Department of Justice, and scrutinized to ensure that the settlements are not inconsistent with

federal procompetitive antitrust policies (encouraging competitive markets to promote consumer welfare). See, e.g., 15 U.S.C. section 1 (Sherman Act prohibition of "restraint[s] of trade or commerce"). The FTC is empowered under federal law to challenge patent infringement settlement agreements in court as violations of the federal antitrust laws. The FTC has alleged that some of those patent infringement cases between brand-name drug manufacturers and generic drug manufacturers have been settled with terms that include the brand-name drug manufacturer paying the allegedly patent infringing generic manufacturer a large sum of money. In return for the payment, the FTC has alleged that the generic manufacturer agreed to delay its entry into the market, resulting in an extension of the brand-name drug manufacturer's monopoly. Those settlement agreements have been referred to as "reverse payment settlements."

In 2013, the United States Supreme Court in *FTC v. Actavis*, 570 U.S. 136 (2013) held that "reverse payment settlements" that extend the brand-name drug manufacturer's monopoly can have anticompetitive effects that violate the federal antitrust laws. In other words, these settlement agreements can be found to be a restraint of trade if they cause anticompetitive effects that outweigh any procompetitive benefits. *Actavis*, 570 U.S. at 156-59. The Court did not hold that all "reverse payment settlements" are invalid, rather the Court determined that the reverse payment settlement agreements must be reviewed under the federal antitrust analytical paradigm known as the rule-of-reason to determine whether such agreements comport with the procompetitive policies set out in federal antitrust law. *Id*. at 159.

The rule-of-reason inquiry requires courts to apply a complex burden-shifting approach. Initially, the burden is on the FTC to demonstrate the anticompetitive effects of the settlement agreement. For example, a large and unjustified reverse payment (payment from the brand-name manufacturer to the generic manufacturer) creates a likelihood of "significant anticompetitive effects," depending on the size of the payment, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and any other asserted justification. If the FTC succeeds in doing so, then the burden shifts to the brand-name manufacturer to show that the settlement agreement also produced procompetitive benefits. If the brand-name manufacturer establishes that the settlement agreement has some procompetitive effects, then it is up to the FTC to show that any procompetitive effects could have been achieved through less anticompetitive means. Finally, if

the FTC fails to demonstrate that there was a less restrictive way to achieve the procompetitive benefits, the court must balance the anticompetitive and procompetitive effects of the restraint. If the anticompetitive harms outweigh the procompetitive benefits, then the settlement agreement is illegal. *See Impax Laboratories, Incorporated, A Corporation v. Federal Trade Commission*, (5th Cir. April 13, 2021) (applying rule-of-reason methodology).

SB 764 and Compatibility with Federal Law

Section (1)(2) of SB 764 provides in part that in a civil action brought by the Oregon Attorney General against settling pharmaceutical manufacturers, "a court ... shall *presume* that a resolution agreement that ends a dispute over an alleged infringement of a patent, or a violation of other protection for a protected drug, has anticompetitive effects and is a violation of this section, if as part or in connection with the resolution agreement, and alleged infringer: (a) Receives an item of value; or Agrees to limit or stop researching, developing, manufacturing, marketing or selling a competing drug." (Emphasis Supplied)

Section (1)(d)(A) defines item of value as "any tangible or intangible item including, but not limited to: (i) An exclusive license to manufacture, market, distribute or sell a protected drug; or (ii) An agreement that a claimant [brand-name manufacturer] will not manufacture, market, distribute or sell a generic version of a protected drug in competition to the other party to the agreement."

Under the federal rule-of-reason burden shifting approach outlined above, the FTC has the initial burden to demonstrate the anticompetitive effects of a settlement agreement. However, as described above, under SB 764 an Oregon court is required to "presume" that a settlement agreement has "anticompetitive effects" if the generic manufacturer receives in the settlement an "item of value" or agrees to limit or stop researching, developing, manufacturing, marketing, or selling a competing drug. Accordingly, at a sub-constitutional level, SB 764 inverts the initial burden to prove that a settlement agreement has anticompetitive effects, in conflict with the rule-of-reason antitrust methodology, outlined by the United States Supreme Court in *Actavis*.

Under the federal Patent Act, "patent[s] shall be presumed valid" and enforceable. 35 U.S.C. section 282(a). In *Actavis*, the United States Supreme Court recognized that "patent and antitrust policies are both relevant" in determining whether a pharmaceutical patent infringement

case settlement should be subject to antitrust scrutiny. 570 U.S. at 148. That is so because "courts must 'balance' the privileges of [the patent holder] and its licensees under the patent grants with the prohibitions of [antitrust law] against combinations and attempts to monopolize." *Id*. Similarly, the Court in *Actavis* indicated that it is only those settlements in which there is a "large and unjustified" payment from the brand-name manufacturer to the generic manufacturer that should trigger antitrust review. *Id*. at 158-59.

Under SB 764, section (1)(1) a resolution agreement containing the grant of an "exclusive license to manufacture, market, distribute or sell a protective drug" is presumptively anticompetitive unless the settlement also provides that the generic manufacturer may bring the generic drug into the market "before the expiration of: (1) The patent for or a right related to the patent for the protected drug." Section (1)(3)(b)(B) also prohibits a court from "presum[ing] that: The patent * * * for the protected drug was enforceable." These sections of SB 764 directly contravene the presumed validity of patents under federal law, diminish the value of a federally recognized patent, and are inconsistent with the delicate balancing of patent and antitrust polices identified by the Court as necessary in *Actavis*. *See King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F. 3ed 388, 394 (3d Cir. 2015) (The Hatch-Waxman Act "balance[s]" competing federal objectives—making available more low-cost generic drugs, while valuing patent monopolies to incentivize beneficial pharmaceutical advancement.). *See also* 35 U.S.C. 261 (recognizing that exclusive licenses are a valid form of license)

Congress has authority under the Supremacy Clause to preempt state laws. Whether Congress has exercised that authority turns on congressional intent, i.e., whether Congress intended to preempt state law. *See Cipollone v. Liggett Group, Inc*., 505 U.S. 504 (1992) (describing preemption doctrine). Congress may indicate its pre-emptive intent through a statute's express language or through its structure and purpose. *Jones v. Rath Packing Co*., 430 U.S. 519, 525 (1977). Preemptive intent may also be inferred if the scope of the statute indicates that Congress intended federal law to occupy the legislative field or if there is an actual conflict between the state and federal law. *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995). A state law that conflicts with federal law is "without effect." *Cipollone* at 505 U.S. 516. There is more that can be said about the operation of SB 764 that conflicts with federal patent and antitrust law. However, the direct conflicts described above between SB 764 and the federal

Patent Act are more than sufficient to trigger a colorable claim that SB 764 is preempted by the pervasive federal antitrust and patent laws.[2]

Conclusion

The United States Supreme Court in the *Actavis* case clearly stated that not all "reverse payment settlement agreements" constitute a restraint of trade in violation of federal antitrust law. As explained above, determining whether "reverse payment settlement agreements" of drug patent infringement cases authorized by the Hatch-Waxman Act are an illegal restraint of trade, involves a nuanced application of federal patent law and federal antitrust law. That form of federal regulation is working.

As described above, pharmaceutical manufacturers are required to report annually to the FTC and Federal Department of Justice, the settlement terms of patent infringement litigation (Hatch-Waxman patent settlements). The FTC annually reports the number of those settlements and the terms (FTC Report of Branded Drug Firms' Patent Settlements with Generic Competitors). Those reports confirm that since the United States Supreme Court decision in *Actavis* in 2013, "reverse payment settlement agreements" have steadily decreased. For example, by 2017, of the 226 final patent infringement case settlements reported to the FTC, only 20 final settlements included payment of compensation to the generic manufacturer and some restriction of the generic manufacturer's entry into the market. In 17 of those 20 settlements, the compensation paid to the generic manufacturer was $7 million or less in litigation fees, which the Court in *Actavis* indicated may constitute a justified payment. More importantly, in 78 percent of the reported settlements, the generic manufacturer received rights not only to the patents at issue in the litigation, but also to licenses or covenants not to sue for all the patents that the brand-

[2] SB 764 has wording similar to AB 824, a California law also intended to evaluate the settlement agreements of patent infringement cases between brand-name drug manufacturers and generic drug manufacturers, and to authorize large civil penalties against those manufacturers that enter into an "adverse payment settlement agreements." AB 824 is currently challenged in the United States District Court for the Eastern District of California, on the grounds that AB 824 violates the Dormant Commerce Clause, is preempted by federal law, and violates the federal constitutional prohibition on excessive fines. See *Association For Accessible Medicines v. Xavier Becerra, in his official capacity as Attorney General of California*, Case no. 2:20-cv-01708-TLN-DB.

name manufacturer controls at any time after the settlement that might cover the generic product.[3]

The pervasive federal regulatory scheme that exists today is more than sufficient to promote the entry into the market of generic drugs, lower drug costs, and protect consumers. SB 764 presumes that a settlement that includes the grant of an exclusive license is anticompetitive—undermining the presumption under federal law that patents are valid and enforceable. Given the apparently intended broad application of the Bill (perhaps even reaching settlements of patent infringement cases in other economic spheres), it is likely that SB 764 will increase the cost of patent litigation, and decrease the incidence of settlements between brand-name manufacturers and generic manufacturers, thereby decreasing the flow of generic drugs into market, contrary to the intent of the Hatch-Waxman Act.

Finally, there appear to be numerous direct conflicts between SB 764 and the relevant pervasive federal regulation that currently exists. Those conflicts will likely trigger colorable sub-constitutional and constitutional arguments regarding federal preemption. Accordingly, it is likely that, should SB 764 become law in its current form, it will be immediately challenged in court on numerous grounds that will likely last for years.

[3] See https://www.ftc.gov/news-events/press-releases/2020/12/ftc-staff-issues-fy-2017-report-branded-drug-firms-patent.