



# Regulatory Transparency Project

*Unlocking Innovation & Opportunity*

## How Antitrust Overreach is Threatening Healthcare Innovation

Intellectual Property

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This paper was the work of multiple authors. No assumption should be made that any or all of the views expressed are held by any individual author. In addition, the views expressed are those of the authors in their personal capacities and not in their official/professional capacities.

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## I. Introduction

Imagine passing a rigorous test with flying colors, only to be told that you need to start over because you were not wearing the right clothing or you wrote your answers in the wrong color. Does that sound silly? Unfair? That is the scenario in which the American pharmaceutical industry finds itself thanks to overzealous regulators at the Federal Trade Commission who aren't content to let the Food & Drug Administration (the experts in pharmaceutical safety and regulation) and federal courts (which referee disputes between branded and generic drug companies) decide when new drugs are ready to come to market. The consequences of such actions impact people's lives.

The development and widespread availability of safe and effective pharmaceutical products has helped people live longer and better lives. The pharmaceutical industry invests billions each year in research and infrastructure and employs millions of Americans. The industry is closely regulated by many agencies, most notably the FDA, which requires extensive testing for safety and effectiveness before new drugs enter the market. Many thoughtful proposals have been advanced to improve and modernize the FDA's review and approval of new drugs, but there is broad agreement that the FDA's basic role in drug approval serves valid ends.

In recent years, however, other government agencies have played an increasingly intrusive role in deciding whether and when new drugs can enter the market. One such agency is the Federal Trade Commission, which has recently taken steps to block branded drug companies from settling patent litigation with generic drug makers. The FTC substitutes its own judgment for the business judgment of sophisticated parties, simultaneously weakening the patent rights of branded drug companies that spend billions in drug discovery and development and delaying generic drug companies from bringing consumers low cost alternatives to branded drugs. This example of government agencies picking winners and losers—indeed, deciding there should be no winners and losers—harms consumers in the short run by slowing access to drugs and in the long run by weakening innovation.

This paper describes the role of patents in protecting drugs as well as the special patent litigation regime Congress enacted in the 1980s to carefully balance the needs of branded drug companies, generic competitors, and consumers. Although these systems are not perfect, the FTC's overuse of its regulatory powers results in a net loss for American consumers, as described below.

## II. The Vital Role of Patents (and Patent Litigation) in Protecting Pharmaceutical Innovation While Ensuring Access to Generic Drugs

A drug faces a long and uncertain road to market. Scientists often begin by screening hundreds of compounds to discover or identify compounds that show possible potency for continued research and development efforts. The few compounds that advance beyond laboratory and animal testing

then face years of trials in humans. Even then, FDA approval is not guaranteed. A drug that shows promise in the laboratory and effectively treats animals may not work in people. A drug may have serious side effects in humans that outweigh any benefits the drug offers. The timeline from drug discovery to approval averages more than a decade. For every five thousand drugs that start the process in the laboratory, the FDA approves only one. Drug development is a lengthy, risky, and expensive process.

Patents play a key role in allowing drug companies to make massive investments against these long odds. A patent grants a drug company a period of exclusivity for twenty years: from the time the patent is filed until the day it expires. This allows the drug developer to charge a premium price for its newly discovered drug for a limited time. Without robust patent protections, branded pharmaceutical companies would have no way to recoup their R&D investments and no incentive to find new drugs. Once a drug has been discovered, developed, and tested, there are relatively few technological and economic barriers to competitors making copies of that drug.

Innovation does not stop when the FDA approves new drugs. Drug companies often find important new uses for older drugs. Other times they develop new routes of administration for approved drugs—for example, converting large tablets or painful intravenous solutions to oral suspensions that can be more conveniently administered to pediatric patients. Sometimes they develop new formulations, such as extended release formulations that only need to be administered once daily rather than every 6-8 hours, thus improving patient compliance and convenience. And often companies develop new versions of a known compound, such as a salt or an enantiomer, which may be more effective or have fewer side effects. These additional innovations also require time and money. Developing a new use for an existing compound can still cost several hundred million dollars and the result will be eligible for patent protection. The scope of any additional patents may be narrower than the scope of the original patent, thus reflecting the more incremental nature of the innovation. These patents are still valuable because they give a drug company a limited chance to recover the investment it made.

In addition to the profound public interest in discovering and developing new drugs, there is a strong societal interest in timely access to affordable drugs. Lower cost generic drugs become available either when the patents covering a branded drug expire, or when a generic drug company proves in federal court that its product will not infringe the branded company's patents (or that the branded drug company's patents are invalid). Once generic drugs become available, the market for branded drugs changes. Under the laws of most states, pharmacists must substitute the generic drug for the branded drug unless specifically instructed by the patient or physician, so a branded company's sales often drop precipitously once a generic drug enters the market. Put simply, once generic versions of a branded drug enter the market, the branded company's opportunity to recover its investment practically ends.

To strike a balance between ensuring innovators can recover their investments and encouraging the widespread availability of generic drugs, Congress passed the Hatch-Waxman Amendments in 1984.

Although famously described as complex, the statute's scheme reflects a set of three tradeoffs between branded drug companies, generic drug companies, and consumers:

First, rather than conducting its own safety and effectiveness trials, a generic drug company may rely on certain testing done by the branded company. To rely on this testing, the generic drug company shows that its product is bioequivalent to the branded drug (in other words, that the generic drug will interact with the patient in the same manner as the branded drug).

Second, in exchange for relying on the branded drug company's clinical data, and if the generic company wants to market the generic drug before the patent on a branded drug expires, it can challenge the branded company's patents by asserting that the patents are invalid (as obvious or failing to comply with other technical aspects of the patent statute) or that its product are different enough that they won't infringe the patents. This allows the branded company to bring a suit right away for patent infringement, rather than waiting for the generic company to enter the market, as is normally required to bring a lawsuit in federal court. If the branded company does this, the statute suspends FDA approval of the generic drug for up to 30 months to allow the lawsuit to be resolved. If the branded drug company prevails in the lawsuit by showing that the generic drug would infringe its valid patents, then the FDA may not approve the generic drug for the remaining term of the patent term.

Third, to incentivize generic companies to attempt to bring drugs to market despite the threat of being sued, the first generic company to seek FDA approval and successfully challenge a branded company's patents receives 180 days of market exclusivity without other generic competition, thus allowing the generic company to recoup some of its investments.

Although the Hatch-Waxman regime contemplates litigation as a necessary step of generic drug approval, patent litigation can be expensive, complex, and time-consuming for both sides. Drug patent litigation, as the Supreme Court has observed, is "particularly complex, and particularly costly."<sup>1</sup> Many cases require upwards of \$10 million in fees and costs to litigate.<sup>2</sup> One district court tasked with trying a patent case declared "patent litigation . . . the slowest and most expensive litigation in the United States."<sup>3</sup>

It should be no surprise, then, that branded and generic drug companies often decide that continuing to litigate is not the best choice. Drug patent litigants may decide to settle for a variety of rational reasons. The generic company must weigh the cost of continued litigation against the risk of loss. If it continues to litigate and loses, it will *also* lose its 180 days of marketing exclusivity. It will then have to wait until the patent expires, and it will enter the market along with everyone else. Settling guarantees a date certain for the generic company to enter the market before the patent expires, and in the case of the first-filer, eliminates the risk of losing the 180-day period of market exclusivity. A branded company has equally good reasons to settle. It too must weigh the continued

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<sup>1</sup> *Fed. Trade Comm'n v. Actavis*, 570 U.S. 136, 170 (2013).

<sup>2</sup> See Michael R. Herman, *The Stay Dilemma: Examining Brand and Generic Incentives for Delaying the Resolution of Pharmaceutical Patent Litigation*, 111 COLUM. L. REV. 1788, 1795 n.41 (2011).

<sup>3</sup> *DeLaventura v. Columbia Acorn Trust*, 417 F. Supp. 2d 147, 153 n.7 (D. Mass. 2006).

cost of the litigation and the risk of loss. If it continues to litigate and loses, it will face generic drug entry far sooner than originally planned, in addition to incurring significant fees and costs.

There is also a strong public interest in the settlement of litigation. Civil litigation in federal court places an expensive burden on the already overwhelmed federal court system and diverts resources that drug companies could invest in research. There is an undisputed “strong public interest in the settlement of patent litigation.”<sup>4</sup>

Despite this strong public interest in settlement and parties’ private incentives to settle cases, the FTC has inserted itself at the bargaining table by subjecting settlements to antitrust scrutiny. Although originally done to prevent branded and generic drug companies from gaming the system in order to maintain exclusivity beyond patent expiration or even after it was clear the patents are invalid or not infringed, this scrutiny has had the unintended consequence of chilling good-faith settlements, and indeed, is unwarranted in most patent cases. As the Eleventh Circuit has explained, “[p]atent litigation is too complex and the results too uncertain for parties to accurately forecast whether enforcing the [patent’s] exclusionary rights through settlement will expose them” to antitrust liability and damages.<sup>5</sup> The net result is that no case can be settled without fear of antitrust scrutiny “except for those that the patentee is certain to win at trial and the infringer is certain to lose” (or vice-versa).<sup>6</sup> Most cases are not so predictable, but the risks remain. Yet even when litigation becomes undesirable for both parties involved, a settlement may be disfavored and actively avoided due to the risk of the FTC’s equally unpredictable antitrust scrutiny.

### III. The FTC’s Heavy-Handed Meddling Upsets the Delicate Balance Between Branded and Generic Drug Companies, Hindering Innovation and Harming Consumers

Since the late 1990s, the FTC has devoted substantial resources to combating what it views as anticompetitive behavior on the part of drug companies in the healthcare market. The FTC has interposed its scrutiny even where the FDA has approved drugs and when the branded and generic companies have decided a legal fight is no longer worth having. The FTC’s meddling restricts behavior that is lawful under the Federal Food, Drug, and Cosmetic Act (FDCA). The FTC’s meddling also usurps the regime Congress carefully crafted for resolving patent disputes between branded and generic drug companies.

The FTC has devised a series of novel theories to justify treating lawful behavior as anticompetitive and worthy of enforcement action and legislative changes. These theories have been adopted—and adapted—by state antitrust enforcers as well as private antitrust plaintiffs. The FTC has conducted industry-wide investigations and prepared massive reports on supposed anticompetitive conduct to

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<sup>4</sup> *Foster v. Hallco Mfg. Co., Inc.* 947 F.2d 469, 477 (Fed. Cir. 1991).

<sup>5</sup> *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1308 (11th Cir. 2003).

<sup>6</sup> *Id.*

recommend legislative changes despite neither the branded nor generic drug industry seeking such changes. These changes to the law would restrict or punish patent owners and even patent challengers. The FTC has, on its own initiative, made the already volatile world of drug development more uncertain and more hostile, ultimately resulting in less innovation and fewer choices for consumers in the short term (e.g., generic options) and long term (e.g., new drugs).

The FTC's aggression extends to the courtroom. For nearly two decades, the FTC and other antitrust plaintiffs have attacked patent settlements reached by branded and generic drug companies. As explained above, the regulatory scheme for new drugs gives rise to an unusual type of patent litigation in which the generic drug company—the defendant—is not at risk of money damages for infringement because litigation generally occurs before the generic drug has obtained FDA approval and enters the market. Because of this unusual arrangement, where each side had to yield something of value to the other at the settlement table, a patent owner occasionally pays a settlement to the defendant (rather than forgiveness of damages, which is typically not an option) in exchange for the defendant agreeing to slightly delay the launch of its generic drug. Other considerations, such as the generic company agreeing to source materials from the branded company or other business or research partnerships, are not uncommon.

Beginning in the 1990s, the FTC took the position that such settlements were a categorically illegal restraint of trade. Courts did not agree, as modern antitrust jurisprudence recognizes that declaring something categorically illegal in the absence of more facts and details is dubious. Courts generally concluded that a settlement within the scope of the patent—where the defendant agreed to remain off the market no more than already required by the patent but perhaps longer than a successful court challenge—did not itself violate the antitrust laws. Yet the FTC persisted in arguing its position to the Supreme Court. In the 2013 *Actavis* case, the Supreme Court declined the FTC's invitation to find reverse payment settlements categorically anticompetitive, ruling instead that these settlements must be evaluated under antitrust law's "rule of reason," which is a detailed look at all the relevant facts and circumstances of the individual case.<sup>7</sup> Still undeterred in the wake of *Actavis*, the FTC continues to argue that a variety of patent settlements are anticompetitive and accuse district courts of misinterpreting *Actavis*.

The FTC's basic position is that antitrust scrutiny is triggered when the patent owner offers anything of value beyond the litigation expenses that settlement would save. Any patent owner who tries to entice a generic competitor to settle by offering anything more than litigation costs is treated suspiciously by the FTC. Even if the settlement is a complex corporate transaction that involves manufacturing and promotion deals or other products—where both parties might benefit beyond merely the ending of a lawsuit—the FTC's basic position is to presume an antitrust violation.

Not surprisingly, the FTC's overzealous actions against drug makers make it very difficult to settle pharmaceutical patent litigation without branded and generic drug companies both expecting an antitrust case, which may itself end up effectively revisiting the patent issues the parties sought to move beyond by settling. Companies still try to craft agreements that eliminate the risk that both

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<sup>7</sup> 570 U.S. 136, 156.

face in litigation while ensuring that generic market entry occurs well before patent expiry, but no matter the terms, the FTC stands ready to argue that the companies should not have settled. In the end, these parties seem to want patent litigation cases to continue to final judgment, even when this is not in the interest of the branded companies, generic drug companies, consumers or the federal court system.

The FTC has also started to interfere with the ordinary cycle of incremental innovation in the drug industry. Incremental drug innovation is both commonplace and can be medically important. New dosage forms and routes of administration can make life-sustaining drugs easier to administer to new populations. New formulations, such as extended release formulations, can simplify dosing, thus increasing patient compliance.

In recent years, however, the FTC has targeted these patents. The chief complaint advanced by the FTC is that incremental innovations are trivial advances and do not deserve patent protection. Where the branded company replaces an older version of its product with the patented new version, the FTC accuses the branded company of “product hopping” to force the market to move to new drugs. The problem with this argument is threefold. First, these innovations have satisfied the requirements of the Patent Act. Second, if they are indeed trivial, the patents will likely be held invalid in federal court when challenged by generic competitors. Third, if the branded company’s new product does not provide better outcomes, insurers are unlikely to cover the product and will instead require a patient to use the generic version of the branded company’s first product. The FTC’s actions are thus a solution in search of a problem.

#### IV. Conclusion

The FTC’s goals may be well-intentioned, but its intrusion into domains that other, more expert agencies already oversee and comprehensively regulate is troubling. By substituting its own agenda for the business judgment of sophisticated parties in the marketplace, the FTC has overreached its proper role and begun to disrupt the cycle of investment, product development, recoupment, further incremental advancement, and risk management that drives the creation of new drugs that save lives and promote greater public health.