

Issue Brief

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More Power to Federal Trade Commission over Medicines: What Could Possibly Go Wrong?

Introduction

This year marks the 35th anniversary of the Hatch-Waxman Act, which is generally one of the success stories of government policy in the realm of prescription drug regulation. Unfortunately, the temptation to rewrite that story, giving a larger role to government's often-dubious cast of regulatory characters, could mean plot twists that will not end well for taxpayers.

Finding a Healthy Balance: Innovation and Access in Patent Settlements

As NTU noted in April of this year regarding the Drug Price Competition and Patent Term Restoration Act of 1984 authored by Senator Orrin Hatch (R-UT) and Henry Waxman (D-CA), "the past 35 years of Hatch-Waxman have not been without controversy or tension among competing policy priorities." Nonetheless, the legislation has helped to maintain U.S. leadership in the pharmaceutical space, for the good of patients and taxpayers:

Key Facts:



The Hatch-Waxman Act is a success story of government prescription drug regulation, but new legislation challenges that success.



Congress is considering involving the FTC in drug patent settlements, which is an unnecessary and harmful expansion of government power.



Lawmakers should carefully examine trends in the drug patent market before introducing legislation that would overturn a successful regulatory environment.

Costly innovator drugs have been shown to reduce other expenses in government health programs over the long term, such as surgeries or long hospital stays. On the other hand, generics deliver massive savings over the nearer term to those same programs as well. No other country in the world can boast of such a successful policy environment that both encourages discoveries to reach patients (nearly 90 percent of newly launched drugs worldwide are available here) and controls costs (over 90 percent of prescriptions written in the U.S. are for generics). And the Hatch-Waxman law has had a great deal to do with this success.¹

One key element of contention arising from Hatch-Waxman is the law's provisions granting extended patent lives to businesses that develop lifesaving cures, while also creating an "Abbreviated New Drug Application" (ANDA) process for generic firms to formulate and bring to market subsequent bioequivalents of those cures. ANDA applications automatically trigger a technical proceeding that can result in patent litigation between the "brand" firm and the generic company.² A majority of these proceedings tend to be settled instead, on terms that are patiently negotiated by the two parties to the suit.

For the most part, settlements tend to reflect the pro-taxpayer balance of the Hatch-Waxman law. In past years, legal settlements have in certain cases specified compensation to the generic firm for providing the original manufacturer more time to keep marketing a drug exclusively under its brand name. Still, previous government research has shown that close to 90 percent of cases don't involve such compensation.³

In numerous instances, however, settlements can actually *hasten* the arrival of cost-saving generics to Americans. According to an annual analysis from Lex Machina, the majority of ANDA-triggered cases residing in the Delaware and New Jersey districts (the top two ANDA-related venues) took more than four years to reach termination.⁴ This can be an eternity for patients in need, or for government health program administrators working to keep their budgets under control for the coming fiscal year.

Predictably, the costs of litigation, even if settled prior to termination, can be massive too. One study of generic vs. brand patent challenges from Morgan Stanley Equity Research put the average expense per suit at roughly \$10 million.⁵ Citing data from the American Intellectual Property Law Association, Federal Circuit Court of Appeals Judge Kimberly Moore wrote in a 2011 decision that "[p]atent litigations are among the longest, most time-consuming types of civil actions. ... Moreover, the costs of patent litigation are enormous with an average patent case costing upwards of \$3 million for each side."⁶

Thus, by avoiding protracted, expensive litigation and introducing date-certain marketing paths, everyone *can* win.⁷ But that doesn't mean they will. Enter Congress and the Federal Trade Commission (FTC), with an assist from state public officials.

¹ Sepp, Pete. "Hatch-Waxman Drug Patent Law Meets Middle Age – And Taxpayers Can Celebrate." National Taxpayers Union, April 1, 2019. <https://www.ntu.org/publications/detail/hatch-waxman-drug-patent-law-meets-middle-age-and-taxpayers-can-celebrate>.

² For background on Hatch-Waxman and the ANDA process, see Congressional Research Service (2016). "The Hatch-Waxman Act: A Primer" (R44643), https://www.everycrsreport.com/reports/R44643.html#_Toc463343290.

³ Federal Trade Commission (2017). "Agreements Filed With the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in Fiscal Year 2015: A Report By the Bureau of Competition." <https://www.ftc.gov/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-9>.

⁴ Cited in LaMotta, Lisa. "Lilly, Pfizer, Sanofi Lead in Patent Litigation, Report Says." BioPharma Dive, May 3, 2018, <https://www.biopharmadive.com/news/lilly-pfizer-sanofi-lead-in-patent-litigation-report-says/522748/>.

⁵ See Herman, Michael R. "The Stay Dilemma: Examining Brand and Generic Incentives for Delaying the Resolution of Pharmaceutical Patent Litigation." Columbia Law Review, December 1, 2011, (citing at Note 41 Goodman, M., Nachman, G. and Chen, L., "Quantifying the Impact from Authorized Generics." Morgan Stanley Equity Research, 2004). https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2008768.

⁶ See *Ohio Willow Wood Co. v. Thermo-Ply, Inc.*, 629 F.3d 1374, 1376–77 (Fed. Cir. 2011) (Moore, K., concurring). Retrieved from: <https://www.courtlistener.com/opinion/2367411/ohio-willow-wood-co-v-thermo-ply-inc/> (Accessed August 19, 2019).

⁷ A 2009 statement from the generic firm Teva Pharmaceuticals claimed that the patent settlements in which it had been involved up until that time totaled "\$128 billion plus in savings to be delivered to the public by removing 138 years of monopoly protection." Whether such results are typical or not today, taxpayer-funded government health programs that pay for prescription drugs would share in any savings. See "Teva Pharmaceuticals Issues Statement in Response to Federal Trade Commission Claims on Patent Settlements," News Release, June 24, 2009, <https://www.businesswire.com/news/home/20090624006003/en/Teva-Pharmaceuticals-Issues-Statement-Response-Federal-Trade>.

So Much for Winners: Washington Steps In

For several years now, some in Washington and state capitals⁸ have believed that most ANDA legal settlements are inherently nefarious, involving collusion: brand manufacturers settle their patent infringement claim by offering a “reverse payment” to the generic company so the brand retains its market share.

One “solution” House and Senate lawmakers have offered to what they call “pay for delay”: unleash the FTC. In the lower chamber, the House Judiciary and Energy and Commerce Committees cleared a version of a bill (H.R. 1499) called the Protecting Consumer Access to Generic Drugs Act.⁹ Originally sponsored by Rep. Bobby Rush (D-IL), this legislation would require the FTC to use all of its broad enforcement mandate to go after reverse-payment and other marketing delay settlements as if they were traditional “unfair or deceptive acts or practices” under Section 5 of the Federal Trade Commission Act. A version of this bill was subsequently folded into a broad package of prescription drug and other health care policy changes that passed the full House largely along party lines.¹⁰

Because the package containing H.R. 1499 is dead on arrival in the Senate, attention is now focused on a bipartisan bill in the upper chamber sponsored by Sen. Amy Klobuchar (D-MN). The Preserve Access to Affordable Generics and Biosimilars Act (S. 64), supported by Sen. Chuck Grassley (R-IA) as well, takes a somewhat different approach than the Rush bill.¹¹ It provides that “[t]he Commission may initiate a proceeding to enforce the provisions of this section against the parties to any agreement resolving or settling, on a final or interim basis, a patent infringement claim, in connection with the sale of a drug product or biological product.” Unfortunately, the seemingly less harsh approach - permitting instead of requiring FTC to take action - is not much more encouraging.

This proverbial license to fish from Congress would also give the regulatory agency a much deeper pond in which to drop its hooks. The legislation stipulates that “an agreement shall be presumed to have anticompetitive effects and shall be a violation” of the new act if the settlement involves anything of value being given to the generic firm (the ANDA filer) or any concession to delay the market entry process for the generic drug, with a few limited exceptions. Potentially, and quite ironically, even regulatory waivers to permit generic entry into a market could be considered a thing of value.

And in a twist that will undermine any kind of certainty that the parties might believe to be ironclad, under S. 64 the FTC would have a six-year “shot clock” to review a settlement after those parties file their notice of agreement.¹²

Reason over Presumption: Silver Lining in Cloudy Court Ruling

The FTC’s own data strongly suggest that giving federal regulators a new, expansive role over drug patent settlements is becoming even less justified over time. In 2013, the U.S. Supreme Court ruled 5-3 in *FTC v. Actavis* that “presumptive rules” assuming Hatch-Waxman-initiated patent settlements uniformly mean collusion or conspiracy in the restraint of trade could not apply. Presumptive rules, also called the “quick look” antitrust test, are reserved for cases “where ‘an observer with even a rudimentary understanding

⁸ See, for example, Mahoney, Laura. “California Bill Would Abolish Payments to Delay Generic Drugs.” Bloomberg Law, February 22, 2019, <https://news.bloomberglaw.com/pharma-and-life-sciences/california-bill-would-abolish-payments-to-delay-generic-drugs>.

⁹ See text of bill at <https://www.congress.gov/bill/116th-congress/house-bill/1499/text>.

¹⁰ Although H.R. 1499 cleared two Committees with some bipartisan support, the larger package that came to the House floor contained a number of other provisions to which most Republican lawmakers objected. See, for example, Fram, Alan. “Dems Push Bill on Health Care, Drug Prices through House.” Associated Press, May 17, 2019, <https://www.apnews.com/46a476c9d01347a3a00483d83b7c2419>.

¹¹ See text of bill at <https://www.congress.gov/bill/116th-congress/senate-bill/64/text?format=xml&q=%7B%22search%22%3A%5B%22S.+64%22%5D%7D&r=1&s=1>.

¹² The six-year “shot clock” is also a feature of H.R. 1499. Before it was amended in Committee, H.R. 1499 was also made retroactive to the year 2013. See Kennan, Stephanie. “Pay for Delay Passes House of Representatives for First Time.” JDSupra, May 29, 2019, <https://www.jdsupra.com/legalnews/pay-for-delay-passes-house-of-72606/>. Had this been enacted into law, it could have resulted in chaos reverberating well outside the pharmaceutical patent litigation space.

of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets.”¹³

Rather, the Court held, only a “rule of reason” analysis could be employed in evaluating the merits of government attempts to overturn these patent settlements. This means the economic facts surrounding the business, the reason for a particular remedy, the real effect of the restraint, and other specific criteria must be carefully considered.

The ruling was controversial to conservative justices on the Court, who contended in their dissent that generally the concept of patent “carves out an exception to the applicability of antitrust laws,” and that expanding even the rule of reason to the realm of drug settlement cases was “without any support in statute.” Although this view from the three Justices did not prevail, the majority’s argument did have a silver lining: it blocked the FTC from obtaining unchecked, preemptory veto power over good-faith agreements between private parties.¹⁴ The Court’s decision also sent a plain message to those Members of Congress who suspected that patent settlements were primarily “pay-for-delay” schemes: most need not be viewed this way.

While the broader impact of this decision on antitrust and regulation remains to be seen, its particular effect on pharmaceutical patent settlements seems clearer. An FTC analysis published in 2016 noted that “potentially unlawful reverse payment settlements appear to be declining since *Actavis*.”¹⁵ Earlier this year, FTC updated its survey, determining that among the 232 settlement agreements made in 2016, just one may have had “pay-for-delay” issues. This is the lowest ratio with “pay-for-delay” in 15 years.¹⁶

Senator Klobuchar’s legislation effectively seeks to overturn the Court’s ruling and impose the “presumptive rules” the FTC craved, and in the process ignore all the evidence that *Actavis* has indeed curtailed pay-for-delay. Although the legislation purports to let settling parties off the hook if they “demonstrate by clear and convincing evidence that ... the procompetitive benefits of the agreement outweigh the anticompetitive agreements,” the deck is still stacked in the government’s favor. That’s because the legislation also instructs the “fact finder” in any FTC proceeding not to presume an agreement is procompetitive even if it hastens market entry of a generic *before* the brand’s patent expires.

FTC and Settlements: From Policeman to Nanny

The most important point that could get lost in all of this legerdemain is how the bill would alter the relationship between the public and private sectors in pharmaceutical R&D and delivery to patients in a detrimental way that should be all too familiar for limited government advocates. Under presumptive rules, the FTC’s role would be transformed from one of a policeman to that of a gatekeeper – or worse, a nanny.

This is precisely the phenomenon NTU has witnessed and warned about before. In 2015, an NTU Policy Paper entitled “FTC: A Three-Letter Word for ‘Nanny?’” explored the history of FTC’s harmful interference in the development of innovative products and services as well as the availability of everyday items Americans take for granted.¹⁷ From its creation in 1914, the FTC was given a vague, expansive mandate,

¹³ *FTC v. Actavis, Inc.*, 570 U.S. 136, 170, 133 S. Ct. 2223, 2243–44, 186 L. Ed. 2d 343 (2013) (Roberts, C.J., dissenting). Retrieved from: <https://supreme.justia.com/cases/federal/us/570/12-416/> (Accessed August 19, 2019).

¹⁴ The Court demurred on the question of providing more concrete guidance on how future settlements could best pass the “rule of reason” test, mostly leaving the matters to lower courts. This was a missed opportunity to introduce more certainty and stability into settlements as well as drawing clearer lines against unfair “pay-for-delay” schemes.

¹⁵ Towey, Jamie and Albert, Brad. “Is *FTC v. Actavis* Causing Pharma Companies to Change Their Behavior?” Federal Trade Commission, January 13, 2016, <https://www.ftc.gov/news-events/blogs/competition-matters/2016/01/ftc-v-actavis-causing-pharma-companies-change-their>.

¹⁶ “FTC Staff Issues FY 2016 Report on Branded Drug Firms’ Patent Settlements with Generic Competitors.” Federal Trade Commission, News Release, May 23, 2019, <https://www.ftc.gov/news-events/press-releases/2019/05/ftc-staff-issues-fy-2016-report-branded-drug-firms-patent>.

¹⁷ See Sepp, Pete. “FTC: A Three-Letter Way to Spell ‘Nanny?’”. National Taxpayers Union, June 3, 2015, <https://www.ntu.org/publications/detail/ftc-a-three-letter-way-to-spell-nanny>.

accumulating powers from courts, Congress, and other agencies over the subsequent 65 years to the point where it was nearly defunded out of fears it had become unmanageable. It was during the 1970s that the *Washington Post's* editorial board, of all entities, called FTC's campaign to ban or restrict certain ads for sugary foods on children's TV programs "a preposterous intervention that would turn the agency into a great national nanny."¹⁸

The proposal was withdrawn, but the same tensions – and potential for harm – exist at FTC today. The NTU paper identified several characteristics typical of agencies that pose the biggest threats to taxpayers and the economy, among them:

- Vast powers to enforce vague laws whose interpretation is in flux: Like the IRS and tax laws, the FTC can find virtually any justification for pursuing businesses under Section 5 of the Federal Trade Commission Act, which applies to "unfair or deceptive acts or practices" relating to consumers as well as competitors;
- Heavy-handed tactics designed to garner headlines and create fear among citizens or businesses;
- A fear or aversion to change and innovation in the private sector, and a poor capacity to embrace such change in its own institutional practices; and
- Intrusive methods of investigation that impose the burden of proof on the accused, who are often innocent of any wrongdoing.

The latter characteristic, in particular, is what the Klobuchar legislation would encourage. Generic and brand companies would no longer have confidence or assurance that their settlements would at least receive a fair review under a "rule of reason" analysis. Instead, their negotiations would proceed almost as if they were under a supposition of guilt, and a nearly impossible-to-meet standard of proof that would deter such negotiations from advancing in the first place.

Granting FTC the flexibility to launch investigations under cover of a presumptive rule likewise puts the agency in the driver's seat of many more interactions among private parties than the rule of reason. As NTU's paper explained, a tendency of FTC in certain policy areas has been to intimidate small and large businesses through investigations and extract concessions through consent decrees requiring draconian regulatory supervision. Under the Klobuchar bill, such a tool could very well be wielded with more frequency against brand and generic companies found to be in "unfair" "collusion," ironically delaying to a *greater* degree the cost savings patients and taxpayers might have been able to obtain under privately negotiated settlement.

According to New York University Law Professor (and Senior Circuit Judge) Douglas Ginsburg and Joshua Wright (writing at the time as a Professor at George Mason University), this "shift toward a more bureaucratic and less litigation-oriented regime" can have many adverse impacts. Among these is the motivation the government has to "settle upon terms that serve its bureaucratic interests," whether that means expanding its mission, rewarding political allies, or "accumulating power over the regulated community."¹⁹

Antitrust policy experts have often explained reasonable versus excessive FTC regulation of the tech sector as the difference between "permissionless innovation" and "mother, may I?"

¹⁸ "The Post's Sweet Talk, Circa 1978." Washington Post Archives, Posted May 19, 2008. Retrieved from: <http://www.washingtonpost.com/wp-dyn/content/article/2008/05/18/AR2008051802379.html> (Accessed August 19, 2019).

¹⁹ See Wright, Joshua D. and Ginsburg, Douglas H. "Antitrust Settlements: The Culture of Consent." Appearing in "William E. Kovacic: An Antitrust Tribute – Liber Amicorum (Vol. I)," February 27, 2013, http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2225894.

Pharmaceutical innovation is hardly “permissionless,” even today. Innovator drugs and generic equivalents developed by private companies occur under a massive burden of government safety and effectiveness regulations, as well as supervised trials and other approval processes, before any of these products ever reach patients’ hands.²⁰

Like the balance between access and affordability established in Hatch-Waxman, the balance between private parties and the government in patent settlements is imperfect but functioning fairly well. Giving FTC an even bigger role than it already has in this process would be a mistake, and could lead to unintended consequences: more protracted, costly litigation, more delays in getting generics to market, less certainty for private actors in the pharmaceutical development sector, less focus on getting products to patients that improve lives, and ultimately a worse fiscal outlook for taxpayer-funded health programs.

Well before he retired from the federal bench, Judge Richard Posner, a renowned antitrust skeptic, wrote that when “there is nothing suspicious about the circumstances of a patent settlement, then to prevent a cloud from being cast over the settlement process a third party should not be permitted to haul the parties to settlement over the hot coals of antitrust litigation.”²¹ Why, then, would Congress want to raise the temperature of those coals through legislation that would undermine the balance between access and competition that the Hatch-Waxman law has accomplished reasonably well? Just as concerning, why would Congress give the FTC more tools to add coals to the fire?

Horror Story or Epic? Congress Has a Choice

Addressing prescription drug costs is arguably the most prominent health care policy issue being debated in Congress today. One reason is because, unlike many other health services whose costs are actually growing faster, a broader segment of patients more frequently encounters direct out-of-pocket payments at the cash register with prescriptions. Yet, the responses from Washington and many state capitals have too often been counterproductive, involving price controls, importation, “rebates” that are merely taxes in disguise, and generally more government interference in an already-distorted marketplace. S. 64 and bills like it²² belong in the counterproductive category as well.

Members of Congress may have valid reasons and good intentions toward recalibrating the patent challenge and settlement process. Both brand and generic parties to these settlements have also weighed in with legitimate concerns about how or whether this process is fair, based on recent experience. Yet the Klobuchar bill is essentially the same type of proposal introduced prior to the *Actavis* decision.²³ At the very least, lawmakers must examine more carefully the latest trends of the settlement process before advancing these bills any further.

Perhaps more critical, before taking another step to grant the FTC or other entities additional authority over *any* area of commerce, Congress must engage more fully on the future direction of antitrust and competition policy in the U.S. For far too long, the agencies enforcing this policy have exercised their statutory latitude and deference in ways that have not served the economy well. The use of consent decrees, “non-law law,” and other tactics highlight the need for reform to so-called Section 5 authority, as

²⁰ For just one example in one area of the pharmaceutical sector, see National Pharmaceutical Council. “Regulatory Barriers Impair Alignment of Biopharmaceutical Price and Value.” April 17, 2018, <https://www.npenow.org/publication/regulatory-barriers-impair-alignment-biopharmaceutical-price-and-value>.

²¹ See *Asahi Glass Co., Ltd. v. Pentech Pharmaceuticals*, 289 F. Supp. 2d 986 (N.D. Ill. 2003). Retrieved from: <https://casetext.com/case/asa-hi-glass-co-v-pentech-pharmaceuticals-inc> (Accessed August 19, 2019).

²² A nearly identical bipartisan bill to S. 64 has been introduced in the House as H.R. 2375 and was reported out of Committee. See <https://www.congress.gov/bill/116th-congress/house-bill/2375/text>.

²³ See, for example, S. 369 (111th Congress), <https://www.congress.gov/bill/111th-congress/senate-bill/369?q=%7B%22search%22%3A%22%5C%22Preserve+Access+to+Affordable+Generics%5C%22%22%7D&s=1&r=8> and S. 27 (112th Congress), <https://www.congress.gov/bill/112th-congress/senate-bill/27?q=%7B%22search%22%3A%22%5C%22Preserve+Access+to+Affordable+Generics%5C%22%22%7D&s=1&r=7>.

well as more safeguards such as a small business advocate's office at FTC.

To its great credit, the current leadership of the FTC has recently been engaging in a fundamental exploration of its current and future roles. Formally entitled "Hearings on Competition and Consumer Protection in the 21st Century," this series of 14 gatherings that concluded in the Spring of 2019 invited expert testimony and public comment on virtually every aspect of issues such as mergers, privacy, high-tech innovations, consumer education, government enforcement tools, and the practical utility of existing statutes. This trove of material can and should serve as the basis for a parallel effort on Congress's part to evaluate its oversight and legislative role with the Sherman and Clayton antitrust acts, along with its other prerogatives. Too much of Congress's focus in this area has been on hearings designed to afford lawmakers the chance to vent over particular companies' behaviors, rather than more deliberative proceedings about the structures of the laws themselves and the importance of upholding free-market principles.²⁴

Be that as it may, policymakers who want to make a helpful difference with pharmaceutical prices should pursue reforms such as better trade agreements that require burden-sharing of drug development costs, improvements to approval and dispensing rules for biosimilars, better oversight of government programs offering drugs to needy patients, and the use of real-time benefits tools in Medicare Part D.

If Americans are to enjoy further success stories in government policy for prescription drugs, the authors of laws and regulations need to recognize the important narratives that have already served taxpayers and patients well. As far as drug patent settlements are concerned, giving government an even bigger byline in future chapters of this policy without careful research would read more like a horror story than an inspiring epic for taxpayers and patients.

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²⁴ See Federal Trade Commission. (2018-2019). "Hearings on Competition and Consumer Protection in the 21st Century." Retrieved from: <https://www.ftc.gov/policy/hearings-competition-consumer-protection> (accessed August 19, 2019).



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