Conservatives
for
Property Rights

May 21, 2024

The Honorable Richard Durbin
Chairman
Senate Committee on the Judiciary
224 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Lindsey Graham
Ranking Member
Senate Committee on the Judiciary
290 Russell Senate Office Building
Washington, D.C. 20510

Dear Chairman Durbin and Ranking Member Graham:

Conservatives for Property Rights (CPR), a coalition of public policy organizations that represent millions of Americans, is pleased to provide input in regard to the Judiciary Committee's May 21 hearing, "Ensuring Affordable & Accessible Medications: Examining Competition in the Prescription Drug Market."

Private property in all its forms — physical, personal, and intellectual — holds central importance under the U.S. Constitution and the American free enterprise model. The right to private property ranks among the unalienable rights the Founders referenced in the Declaration of Independence. Indeed, secure property rights are vital for human flourishing. Without secure private property rights, innovation, consumer choice, and competition do not blossom.

CPR is concerned about aggressive antitrust measures and government price controls, while overlooked is innovation's role in constantly driving dynamic competition by providing more, new, and improved products whose market entry leads to affordability and accessibility.

This imbalance of competition and innovation leads to misguided legislation and policies. That has certainly been the case in recent Congresses. The Stop STALLING Act, Preserve Access to Affordable Generics and Biosimilars Act, and Affordable Prescriptions for Patients Act epitomize such an overbroad and heavy-handed approach. Such measures would actually reduce innovation and thereby reduce biopharmaceutical competition.

The government should not subject to Federal Trade Commission (FTC) heavy-handedness virtually any improvement to existing pharmaceutical products that have intellectual property (IP) protection. Follow-on innovation, such as new formulations, more tolerable versions, those easier to take and stay on schedule, versions having fewer side effects, better manufacturing processes, etc., should not face unreasonable, severe antitrust scrutiny. The heightened regulatory approach would have a chilling effect on pharmaceutical innovation and deprive patients suffering serious medical conditions and diseases of new and improved medication options.

Labeling normal, constructive modifications and iterative improvements to a pharmaceutical as anticompetitive diminishes property rights and short-circuits innovation. What practically every inventor does in any other art would be castigated as “product hopping” in one targeted art.

Going after bad actors who deliberately block generic competition by very modestly changing their existing products is one thing. However, "follow-on product" should not mean "a change, modification, or reformulation to the same manufacturer's previously approved drug or biological product that shares an indication, in whole or in part, with the same manufacturer's previously approved drug or biological product." This type of approach far exceeds minuscule modifications. It encompasses significant improvements, such as changes for treating new diseases and changes the Food and Drug Administration (FDA) classifies as new treatments.

The committee must avoid covering a broad set of medicines and thereby bringing unintended consequences. What about new indications that superficially relate to the original indication, but involve significantly different diseases or patient populations? A reasonable view would not qualify such innovations for FTC examination or enforcement. To do that would discourage developing new drugs for indications with unmet medical needs, including cancers.

The FTC under Chairwoman Lina Khan has rapidly moved to consolidate naked power. Her leadership has overstepped the agency’s authorities, diminished professional staff morale, operated in a hyperpartisan manner, and pursued an unbounded, wildly novel litigation strategy that has led to successive loses because it ignores settled legal principles. Process matters, but the FTC has diminished institutional process and denied parties due process. In addition, the Executive Order on Competition (E.O.) involves an outsized role for the FTC, along with directives that further reduce due process and undermine the objective Consumer Welfare Standard.[1]

Given the FTC’s recent, unbridled record, in which it has wielded and exceeded its powers, the agency should not be handed an antitrust hammer to use against bonafide innovation. No agency, especially not the FTC, should be able to veto a Patent and Trademark Office (PTO) finding that improvements meet the criteria of novelty, usefulness, and nonobviousness. In light of PTO examination and patent issuance and FDA approval for safety and effectiveness, there is no room for presuming anticompetitiveness from such innovative progress. This is a matter of fundamental property rights — exclusivity under a patent. Such a move would throw market competition into a state that would limit patients to older biopharmaceuticals.

A reasonable approach to drug affordability and accessibility would be to regard FDA determinations of a new product as being a new product. If PTO issues a patent on a new version of a drug, it should be regarded as a new, valid invention and thus a bonafide new product.

Moreover, an aggressive posture toward drug patent settlements would risk disrupting the Hatch-Waxman Act framework. Hatch-Waxman employs patent litigation as a vehicle for generic drug entry into the market created through the drug innovator’s patent exclusivity. Hatch-Waxman’s structure balances respect for the patent rights of innovators with introduction of generic versions of those patented medicines in a reasonable timeframe. An undue emphasis on novel antitrust measures directly threatens this law’s innovation-introducing-dynamic-competition model that has worked well for four decades.

---

[1] See CPR statement, “Statement on Biden Executive Order on Market Concentration” (July 12. 2021); and James Edwards, “Biden's Assault on Property Rights Is an Odd Way to Boost Competition,” Real Clear Markets (July 20, 2021).

The Hatch-Waxman model is generally settled and predictable. It serves the interests of drug innovators, generic drugmakers, patients, payers, medical providers, and society. Today, about 90 percent of all U.S. prescriptions are filled with generic medicines, while U.S pharmaceutical firms lead the world in drug innovation. Overreaching legislation or regulation would risk upsetting this balance. Another risk is diminishing the property rights interests of patients, payers, and both brand and generic drug companies.

In closing, then-Assistant Attorney General for Antitrust Makan Delrahim said, "It is a perverse result indeed when the misapplication of the competition laws results in less innovation, less competition, and ultimately, fewer consumer choices."[2] We caution the committee against hurting innovation, competition, and consumer choice. It would be hazardous to misassume static competition in the area of pharmaceuticals. Rather, this art stands among the most "dynamic competition" fields. Patent exclusivity fosters progress in the state of the art, including in the arduous fields of medical innovation, adding a dynamism unmatched in many other sectors of our economy and in the world. Mr. Delrahim noted, "[C]ompetition and consumers both benefit when inventors have full incentives to exploit their patent rights." That lesson should inform the committee's treatment of IP exclusivity. IP exclusivity is not monopolistic conduct in a static competitive setting; rather, it is the pathway to dynamic competition, consumer choice, and affordability as new, competitive products enter the market.

Conservatives for Property Rights appreciates the opportunity to share its perspective on the subject of this hearing.

Respectfully,

James Edwards, Ph.D.
Executive Director
Conservatives for Property Rights

---

[2] See CPR comments to FTC, "Pharmaceutical Task Force, Project No. P212900" (June 25, 2021).