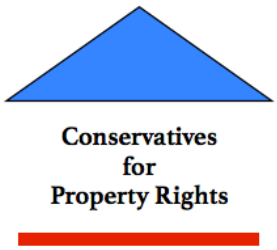

July 27, 2021

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

The Honorable Charles Grassley
Ranking Member
Senate Committee on the Judiciary
224 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Chairman Durbin and Ranking Member Grassley:

Conservatives for Property Rights (CPR), a coalition of organizations representing millions of Americans, has serious concerns about S. 1425, Stop STALLING Act; S. 1428, Preserve Access to Affordable Generics and Biosimilars Act; and S. 1435, Affordable Prescriptions for Patients Act. In their present form, CPR must oppose these bills.

CPR emphasizes the central importance of private property in all its forms — physical, personal, and intellectual. The right to private property ranks among the unalienable rights the Founders referenced in the Declaration of Independence, and patents and copyrights are the only rights for which the U.S. Constitution itself provides. These measures before the committee assault rather than secure private intellectual property rights.

S. 1435 is deeply flawed and overly broad. It would subject virtually any improvements to existing pharmaceutical products that have IP protection to Federal Trade Commission (FTC) heavy-handedness. 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., would face unreasonable, severe antitrust scrutiny. This would have a chilling effect on pharmaceutical innovation and deprive patients suffering serious medical conditions and diseases of better medication options.

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

Going after bad actors who deliberately block generic competition by very modestly changing their existing products is one thing. But "follow-on product" in S. 1435 means "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 goes well beyond minuscule modifications and

encompasses significant improvements, such as changes to treat new diseases and changes the Food and Drug Administration (FDA) classifies as new treatments.

This language would cover a broader set of medicines than ought to be intended. What about new indications that superficially relate to the original indication, but involve significantly different diseases or patient populations? In any reasonable view, these should not qualify for FTC examination or enforcement. The legislation would actually discourage developing new drugs for indications with unmet medical needs, including cancers. And current language adds to the ambiguity. Last Congress, the House Judiciary Committee agreed on a bipartisan correction of this problem. But current Senate language omits these important changes.

The FTC would be charged with using an antitrust hammer against bonafide innovation, despite the fact the Patent and Trademark Office (PTO) has found the changes to meet the criteria of novelty, usefulness, and nonobviousness. In light of the facts of PTO examination and patent issuance and FDA approval for safety and effectiveness, the presumptive anticompetitiveness under S. 1435 would cast a matter of fundamental property rights — exclusivity under a patent — and market competition into such a state that it would most certainly condemn patients to frozen biopharmaceutical progress.

A reasonable approach would be that if FDA determines something is a new product, then it should be treated as a new product. If the PTO issues a patent on a new version of drug, it should be counted as a new, valid invention and thus a bonafide new product. Carving such products from the bill's scope won't unreasonably limit the FTC, as it retains its authorities.

S. 1425 is also overbroad and heavy-handed. It would empower the FTC to go forth and attack filers of so-called "sham" petitions filed with the FDA. Such "covered petitions" would be defined quite broadly. The legislation would establish a rebuttable presumption — in favor of the government — that considers a petition to be a sham. This affront to property rights also is an affront to the rule of law, fairness, and due process.

Also, S. 1428 takes an aggressive posture toward drug patent settlements. S. 1428 would risk disrupting the "patent dance" of the Hatch-Waxman Act, which 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.

This area of relevant law is generally settled and predictable, which the legislation would upset. It serves the interests of drug innovators, generic drugmakers, patients, payers, medical providers, and society. The proof is seen in the fact that about 90 percent of all U.S. prescriptions are now filled with generics, while U.S pharmaceutical firms lead the world in drug innovation. S. 1428 would risk upsetting this balance and backfiring. The legislation would diminish property rights interests and therefore set back the interests of patients, payers, and both brand and generic drug companies. Aiming at "pay for delay" in this aggressive manner would disrupt a mechanism that has served us well.

Also, we note that these bills inordinately rely on the FTC as the enforcement agency in each instance. Such confidence is unsettling, given how the FTC under new Chair Lina Khan has rapidly moved to consolidate naked power at the FTC. For example, the FTC moved with dispatch and very limited public notice to rescind the bipartisan 2015 Statement of Enforcement Principles Regarding "Unfair Methods of Competition" (UMC) Under Section 5 of the FTC Act, The FTC has also voted to rescind its bipartisan 1995 Policy Statement on Prior Approval and Prior Notice Provisions in Merger Cases. These actions were effected along party lines.

Further, process matters, but the FTC is now fast diminishing institutional process and eradicating due process. Commissioner Christine Wilson has decried that "both staff input and a dialogue among the Commissioners" is suddenly being replaced by something "more akin to theatre than to the reasoned decisionmaking that should characterize our institution."[1] And "FTC staff has been muzzled externally – agency personnel are forbidden from appearing at any public events. Unfortunately, it appears that staff is being silenced internally, as well."[2] The public had only several days to file comments in these actions.[3] The current agency majority seems to view due process and the Administrative Procedure Act as little more than impediments to current leadership's forcing its will upon a commission constituted by bipartisan membership.

As for due process and the rule of law, FTC is shelving the 1995 policy statement that has served the FTC well. Commissioner Wilson observes that this "policy was adopted in 1995 following nearly nine years of highly resource-intensive litigation undertaken by the FTC against an abandoned transaction. A second, similar transaction undertaken contemporaneously did not receive the same treatment, leading some to question the motives of the agency in pursuing litigation against the first."[4]

Apparently, the policy has been necessary, but not entirely sufficient. The FTC has faced appropriate criticism for its blatantly politicized, arrogant litigation against Qualcomm initiated days before the end of the Obama administration. After four years of protracted litigation, the Ninth Circuit found for Qualcomm, which enjoyed the support of the Departments of Justice (DOJ) and Defense, and against the FTC.

And the FTC's marching orders under the recent Executive Order on Competition (E.O.) involves an outsized role for the FTC, along with directives that will further reduce due process and undermine the objective Consumer Welfare Standard.[5] Significantly, the E.O. instructs the DOJ and the Department of Commerce "to consider whether to revise their position on the intersection of the intellectual property and antitrust laws." This is more directive than suggestion. Moreover, with the E.O. and the rescissions of the 1995 and 2015 policy statements, the FTC is moved closer to becoming a rulemaking body (as it was in the 1970s). Thus, the misplaced confidence these bills put in the FTC should be reconsidered.

In conclusion, 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

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[1] Remarks of Commissioner Christine S. Wilson, Open Federal Trade Commission Meeting, July 21, 2021.

[2] Leah Nylen, et al. "FTC staffers told to back out of public appearances," POLITICO (July 6, 2021), https://www.politico.com/news/2021/07/06/ftc-staffers-public-appearances-498386.

[3] See comments filed with the FTC on the rescinded 2015 statement of enforcement principles (June 30, 2021) and the 1995 policy statement on Hart-Scott-Rodino prior approvals (July 19, 2021).

[4] Wilson.

[5] 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).

innovation, less competition, and ultimately, fewer consumer choices."[6] The legislation before the committee would hurt innovation, hurt competition, and hurt consumer choice. These bills suffer under the misassumption of static competition in the area of pharmaceuticals. However, 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 elsewhere in 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 escapes S. 1425, S. 1428, and S. 1435, whose mistreatment of IP exclusivity as if it were monopolistic conduct in a static competitive setting is compounded by placing overconfidence in the FTC in a way that damages the beneficial Consumer Welfare Standard.

Therefore, Conservatives for Property Rights opposes S. 1425, S. 1428, and S. 1435. We urge the committee to send this legislation back to the drawing board.

Respectfully,

James Edwards
Executive Director
Conservatives for Property Rights

Seton Motley
President
Less Government

Ashley Baker
Director of Public Policy
The Committee for Justice

Curt Levey
President
The Committee for Justice

Kevin Kearns
President
U.S. Business & Industry Council

Jenny Beth Martin
Honorary Chairman
Tea Party Patriots Action

James L. Martin
Founder/Chairman
60 Plus Association

Saulius "Saul" Anuzis
President
60 Plus Association

Dick Patten
President
American Business Defense Council

Jeffrey Mazzella
President
Center for Individual Freedom

Daniel Schneider
Executive Director
American Conservative Union

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