August 20, 2018

Mr. Donald S. Clark
Secretary of the Commission
Federal Trade Commission
600 Pennsylvania Avenue NW
Washington, DC 20580

Comments of Patients for Affordable Drugs, U.S. PIRG, Consumer Action, Institute for Liberty, America's Health Insurance Plans, Consumers Union, Society for Patient Centered Orthopedics, and Coalition to Protect Patient Choice

RE: Competition and Consumer Protection in the 21st Century Hearings, Docket FTC-2018-0055

Dear Mr. Clark and the Commission,

We submit these comments in response to Topic 8, "The role of intellectual property and competition policy in promoting innovation." We support the FTC's dual pronged approach as stated in the request for comments: "antitrust enforcement against harmful business conduct involving intellectual property; and competition advocacy regarding the development of intellectual property law." In particular, we appreciate the FTC's work protecting consumers from anticompetitive abuses of patents and regulatory processes in the pharmaceutical industry.

We write specifically to address the first question in Topic 8, "the adoption and utilization of novel business practices . . . with respect to obtaining or enforcing intellectual property rights, where such practices may be inconsistent with the antitrust laws." Some brand name manufacturers in the pharmaceutical industry have adopted anti-generic strategies to extend their drug monopolies well past the time they would have naturally ended based on patent and other exclusivities. These monopoly extension practices thwart competitive generic and biosimilar entry, keep drug prices high, and allow companies to raise prices on drugs that would have otherwise faced competition. The result is tremendous costs to patients, as well as indirect costs to other healthcare participants and taxpayers. These comments seek to highlight the importance of the FTC's continued work in this area and suggest additional steps the FTC can take.

I. Background: Competition in the Prescription Drug Industry Matters to Patients and Can Significantly Lower Health Care Spending in the United States

The prices of prescription medications are a driving force behind ever-increasing healthcare expenditures. In 2016, Americans spent $323 billion on prescription medications, and drug spending

is expected to reach over $580 billion by 2021.[1] Although pharmaceutical cost increases may be due to a number of factors, the added expense of brand-name medications contributes significantly to the high cost of prescription drugs. In 2016, brand name drugs represented 11 percent of the drugs dispensed but 74 percent of the total drug costs, amounting to $239 billion.[2] The high cost of brand-name drugs can create significant financial burdens for consumers, causing them to have to choose between treatment or living expenses.[3] In a 2017 nationally representative telephone survey of more than 1,200 adults taking a prescription medication, Consumer Reports found that 30 percent of consumers with increased drug costs did not fill their prescription.[4]

Americans pay up to 65% more for drugs than citizens in other Western countries. The U.S. is an outlier in total annual spending on prescription drugs, surpassing $1,000 per person in 2015. President Trump has made lowering drug prices a top priority.[5]

Competition from more affordable generic and biosimilar medicines is a potent solution to the rising drug cost problem, usually reducing drug prices by about 80% from pre-entry prices.[6] Americans saved $253 billion from generic drugs in 2016, alone.[7] But as discussed below, some pharmaceutical companies will seek to block or stall generic competition through anticompetitive behaviors. Patent system abuse and regulatory manipulation are among the worst offenses.

Abuses of the patent system by brand name drug companies can extend government-granted monopolies illegitimately for years. These legal maneuvers by some brand name drug companies keep drug prices high for patients, taxpayers, and other payers of healthcare. They also stifle innovation and medical advancement. These tactics by certain brand name drug companies prevent patients from accessing the affordable, life-saving medicines they need, and they drain our resources to pay for healthcare.

I-MAK, a patent-focused research and patient advocacy organization, conducted a study on the twelve best-selling drugs in the United States and found that these drugs each had dozens,

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[1] US prescription drug spending as high as $610 billion by 2021: Report, CNBC (May 4, 2017, 6:12AM), https://www.cnbc.com/2017/05/04/us-prescription-drug-spending-as-high-as-610-billion-by-2021-report.html.
[2] AAM 2017 Generic Drug Access & Savings in the U.S., https://accessiblemeds.org/sites/default/files/2017-07/2017-AAM-Access-Savings-Report-2017-web2.pdf.
[3] Carolyn Y. Johnson, *Expensive specialty drugs are forcing seniors to make hard choices*, Washington Post (Nov. 10, 2017), https://www.washingtonpost.com/news/wonk/wp/2017/11/10/expensive-specialty-drugs-are-forcing-seniors-to-make-hard-choices/?noredirect=on&utm_term=.3f85d932f03e; Bill Walsh, *The Tier 4 Phenomenon: Shifting the High Cost of Drugs to Consumers*, AARP at 3 (2009), *available at* https://assets.aarp.org/rgcenter/health/tierfour.pdf (finding that high drug costs can cause consumer to "forgo basic living expenses").
[4] *How to Pay Less for Your Meds*, Consumer Reports (2017), https://www.consumerreports.org/cro/2012/09/sluggish-economy-forces-americans-to-cut-corners-to-pay-for-medications/index.htm.
[5] Paige Minemyer, *Trump unveils 'American Patients First' plan to bring down drug costs*, Fierce Healthcare (May 11, 2018), https://www.fiercehealthcare.com/regulatory/trump-unveils-american-patients-first-plan-to-bring-down-drug-costs.
[6] *Generic Competition and Drug Prices*, FDA https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm129385.htm.
[7] AAM 2017 Generic Drug Access & Savings in the U.S., https://accessiblemeds.org/sites/default/files/2017-07/2017-AAM-Access-Savings-Report-2017-web2.pdf.

sometimes hundreds, of patents; had extended their patent-protected monopolies to an average of 38 years, far beyond the 20 years the law generally allows; and had increased the price of the drug by an average of 68% since 2012.[8] Four of the top twelve drugs have had price increases of over 100% since 2012: Lyrica (+163%), Enbrel (+155%), Humira (+144%), and Lantus (+114%). Evergreening, or the strategy of extending patent protections over existing products through new patents, is another improper anti-generic strategy used to avoid competition.

FDA Commissioner Scott Gottlieb has called upon brand name drug companies to "end the shenanigans" that prevent competition from generic and biosimilar medicines. "One of the practices that concerns me the most is when branded firms 'game' the system: taking advantage of certain rules, or exploiting loopholes in our system, to delay generic approval – and thereby extend a drug's monopoly beyond what Congress intended."[9]

II. The FTC Has Been An Important Advocate For Competition in the Prescription Drug Industry, But More Work Needs to be Done to Protect Patients

The FTC has a commendable history of aggressively protecting consumers from high drug prices caused by patent abuse and improper gaming of regulatory processes. But the fact remains that pharmaceutical companies have enormous incentives to block market entry of lower-cost generic and biosimilar medicines for as long as possible.

For example, 35 states and the District of Columbia have sued makers of the opioid treatment drug Suboxone for engaging in three different anti-generic strategies: product hopping, REMS program abuse, and filing a sham citizen petition.[10] The case survived a motion to dismiss on September 8, 2017, and is currently ongoing. The charge is that the use of these strategies removed generic competition for a "gold standard" treatment for opioid addiction,[11] unlawfully increasing the cost to treat the ongoing opioid crisis.

Some strategies to maintain perpetual monopolies exploit weaknesses in the patent system's police force to shield patents from attacks on patent quality, and to extend their term artificially. Others exploit chokepoints in the regulatory review process to make it harder for the FDA to approve market entry by generic and biosimilar drugs in a timely manner. Some examples of these tactics include:

- **Evasive Maneuvers to Avoid Patent Challenges.** Inter Partes Review (IPR) is an important tool that Congress enacted as a bi-partisan solution to allow the U.S. Patent and Trademark Office (PTO) to eliminate bad patents efficiently. There are many advantages in allowing the

[8] Overpatented, Overpriced: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving up Drug Prices, I-MAK (2018), *available at* http://www.i-mak.org/overpatented-overpriced-excessive-pharmaceutical-patenting-extending-monopolies-driving-drug-prices/.
[9] FDA, Remarks by Dr. Gottlieb at the FTC (Nov. 8, 2017), *available at* https://www.fda.gov/NewsEvents/Speeches/ucm584195.htm.
[10] In re Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litigation, September 8, 2017, Goldberg, J.
[11] *See*, German Lopez, There's a highly successful treatment for opioid addiction. But stigma is holding it back., Vox.com (Nov 15, 2017), https://www.vox.com/science-and-health/2017/7/20/15937896/medication-assisted-treatment-methadone-buprenorphine-naltrexone

PTO to police its own patent-granting decisions: PTO reexamination of granted patents is cheaper, and faster, and benefits from the greater technical expertise PTO holds to review patents than generalist judges. When IPR eliminates a bad patent, it cancels a government-granted monopoly and allows free-market competition to lower prices. IPR is a thorn in the side of patent-system abusers, because IPR makes it easier to get rid of the bad patents they rely on to drive up drug prices. Drug maker Allergan has attempted to evade review of the patents on its blockbuster drug Restasis by transferring them to a Native American tribe, which then claimed that the tribe's sovereign immunity protected the patents from challenge through IPR. A separate, federal court found Allergan's patents invalid, and Allergan is appealing that decision. Certain interests have doubled down on attacking IPR – attempting to transform the outrage behind this case into a larger attack against the legitimacy of IPR. Brand name pharmaceutical companies want to eliminate the IPR process altogether, which would make it harder to challenge patents that do not protect valuable innovation. Senators Tom Cotton, Claire McCaskill, and others are working to address this abuse through legislation. But we urge you to also continue to keep it as a focus of your enforcement efforts.

- **Non-Innovation Patenting.** Brand name drug companies often attempt to bury competition from generic and biosimilar drugs indefinitely, by finding ways to acquire new patents for older existing medicines. These later patents are often not "new and useful," as required by the Patent Act, and thus are invalid and certainly not innovative. Allergan's well-publicized Restasis patents illustrate this phenomenon well. Allergan was able to obtain new patents on its dry-eye drug by making unfounded allegations that the company had made novel discoveries about the drug. A federal judge eventually threw these patents out, finding that Allergan had persuaded the PTO to issue the patents through "more advocacy than science."[12] These patents could have cost patients an additional $10.7 billion if the court had not been asked to scrutinize Allergan's claimed "inventions."

  AbbVie Inc.'s rheumatoid arthritis drug Humira is the world's best-selling prescription drug in the world, with over $16 billion in U.S. sales per year. Humira was approved in 2002, and it now makes more revenue annually than all of the NFL teams' combined revenue. According to AbbVie's CEO, the drug company has created a "patent estate" around the drug. Its initial patent would have expired in 2016, but within the three years before that, the company applied for and obtained over 75 patents that would extend its monopoly to 2034 – and keep this enormously expensive treatment inaccessible to many patients, while burdening the healthcare system as a whole.[13] At least one of these patents has already been thrown out, because the PTO later found that AbbVie's claimed "novel" use of the drug had already been well known and published in a medical journal prior to AbbVie's patent application.[14] Yet in

[12] Jon Swedien, US District Court Invalidates Four Restasis Patents, Market Scope (Oct. 20, 2017), available at https://market-scope.com/breaking-post/us-district-court-invalidates-four-restasis-patents/.
[13] See Cynthia Koons, This Shield of Patents Protects the World's Best-Selling Drug, Bloomberg Businessweek (Sept. 7, 2017), available at https://www.bloomberg.com/news/articles/2017-09-07/this-shield-of-patents-protects-the-world-s-best-selling-drug.
[14] Matthew Bultman, PTAB Invalidates Humira Patent In Coherus Challenge, Law360 (May 17, 2017), available at https://www.law360.com/articles/925184/ptab-invalidates-humira-patent-in-coherus-challenge.

order to break AbbVie's perpetual monopoly, generic companies must engage in time-intensive, expensive patent litigation, meanwhile allowing the drug company to continue to profit as a result of its anticompetitive, government-granted monopoly.

A recent study found 75% of all pharmaceutical patents issued between 2005 and 2015 were issued on old, previously patented medicines, not new drugs.[15] In short, while we should all be grateful for truly innovative medicines, it appears that much of the claimed "innovation" from brand name drug companies stems from their legal departments instead of their labs.

- **Product Hopping.** Product hopping is a tactic brand name drug companies use to prevent generic competition by forcing patients to switch to new formulations of a drug, with new patents, often with little or no therapeutic difference. These newer versions can be protected by new patents that unjustifiably give brand name drug makers new monopoly leases on old patent lives. Product hopping has sometimes been found to be anticompetitive. For example, the State of New York successfully challenged the forced switch of patients using the Alzheimer's drug Namenda, saving patients an estimated $7.7 billion over 10 years.[16]

- **Regulatory Gridlock by Citizen Petition.** Filing citizen petitions with the FDA allows the public to raise concerns with the FDA, and is often completely legitimate. However, brand name drug companies have filed sham petitions with the obvious intent to slow the FDA's generic approvals.[17] These blocking petitions force FDA to address the merits of every petition, requiring considerable time and draining FDA resources. A recent study found that 92% of these petitions are filed by brand name drug makers, and that the FDA denies 92% of petitions filed, suggesting that an overwhelming majority of them are filed to delay, rather than for legitimate reasons.[18] For example, according to an enforcement action brought last year by the FTC, ViroPharma engaged in a delay campaign that involved filing 24 "citizen" petitions, over a period of several years, to stall the entry of a generic Vancocin competitor.[19]

While we encourage the FTC to continue to monitor the marketplace for this misconduct and take appropriate enforcement actions, FTC enforcement alone cannot provide the complete solution to these problems. The FTC should continue to vigorously protect consumers from specific instances of harm, while supporting efforts at the FDA and in Congress to explore long-term solutions for the entire industry.

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[15] Robin Feldman, Connie Wang, May your Drug Prices Ever Be Green, SSRN, (Oct. 29, 2017) https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3061567.

[16] See Joel Mitnick, John Treece and Allison Reimann, Second Circuit Holds 'Product Hopping' May Violate Antitrust Laws, New York Law Journal (July 13, 2015), available at https://www.sidley.com/-/media/publications/second-circuit-holds-producthopping-may-violate-antitrust-laws.pdf.

[17] See Robin Feldman et al., Empirical Evidence of Drug Pricing Games – A Citizen's Pathway Gone Astray, 20 Stan. Tech L. Rev 39 (2017), available at https://law.stanford.edu/wp-content/uploads/2017/10/Empirical-Evidence-of-Drug-Pricing-Games—A-Citizens-Pathway-Gone-Astray-.pdf.

[18] Carrier, Michael A. and Minniti, Carl, Citizen Petitions: Long, Late-Filed, and At-Last Denied (August 30, 2016). 66 American University Law Review 305 (2016). Available at SSRN: https://ssrn.com/abstract=2832319.

[19] https://www.ftc.gov/news-events/press-releases/2017/02/ftc-charges-shire-viropharma-inc-abused-government-processes.

III. We Recommend That the FTC Take the Following Actions

- **Investigate and take enforcement action against anticompetitive and sham patent maneuvers.** The FTC's enforcement against anticompetitive patenting actions by brand name pharmaceutical companies is a crucial safety net for American consumers. FTC should work with the PTO and the FDA to investigate patent and regulatory gamesmanship by brand name drug companies. When warranted, FTC should take legal action to stop sham and anticompetitive transactions that unnecessarily delay generic drug and biosimilar competition.

- **Assist Congress in developing strong legislation.** The FTC is not only an important enforcement agency, it also has an important role in assisting Congress and other agencies in drafting and implementing policies through the FTC's powers under Section 6 of the FTC Act. The FTC has, throughout its history, used these powers to study industries and issue reports and recommendations that have guided legislation and rulemaking. The FTC should offer assistance to future legislative efforts through, for example, conducting a study on the anti-generic strategy of evergreening and abuse of the patent and regulatory systems.

If you have any further questions, please feel free to contact David Balto at david.balto@dcantitrustlaw.com.

Respectfully submitted,

Patients for Affordable Drugs
U.S. PIRG
Consumer Action
Institute for Liberty
America's Health Insurance Plans
Consumers Union
James Rickert, MD for Society for Patient Centered Orthopedics
Coalition to Protect Patient Choice