May 10, 2023

The Honorable Vern Buchanan
Chairman
Subcommittee on Health
House Ways and Means Committee
1139 Longworth House Office Building
Washington, D.C. 20515

The Honorable Lloyd Doggett
Ranking Member
Subcommittee on Health
House Ways and Means Committee
1139 Longworth House Office Building
Washington, D.C. 20515

Dear Chairman Buchanan and Ranking Member Doggett:

I write on behalf of the Council for Innovation Promotion (C4IP) regarding the Health Subcommittee's upcoming hearing on "policies that will have negative effects on medical innovation and reduce patient access to therapies."

C4IP is a bipartisan coalition chaired by two former directors of the U.S. Patent and Trademark Office (USPTO) appointed by presidents of different parties. C4IP believes a strong and effective patent system is the single most important driver of U.S. innovation. Patents bolster U.S. economic competitiveness while incentivizing the creation of products and technologies, including medical innovations, that benefit the entire world.

We hope that the Subcommittee on Health's hearing will not be an opportunity for harmful attacks on the U.S. patent system. Misinformed activists increasingly argue that drug companies are "gaming" the patent system by filing duplicative patents meant to exclude generic competitors from entering the market with affordable treatment options.

This is just false. The USPTO only issues patents for new, non-obvious, and useful innovations. And patents within the same "patent family" expire at the same time. So, obtaining multiple patents on the same drugs wouldn't extend the length of time that the original drug formula is protected from copycats.

More importantly, this misleading narrative relies on the mistaken assumption that filing multiple patents for a single medicine is a sign of malfeasance. On the contrary, additional patents granted after a drug's initial FDA approval reflect critical, life-saving "follow-on" research.

In the years after a medicine is first approved, developers often continue working to improve its formula, dosage, and delivery mechanism to reduce side effects and boost patient adherence. Sometimes, developers even discover that a medicine initially approved to treat one condition can treat one or more other illnesses. This is particularly common in certain fields, like oncology. Lifesaving post-approval development should be celebrated and encouraged, not bemoaned.

Crucially, if a post-approval discovery yields a new patent, the original formulation of a medicine is not impacted. Patenting an extended-release version of a particular drug, for instance, would not alter the exclusivity period of the original version.

Stripping inventors of the ability to patent follow-on discoveries, as some activists advocate, would hamper IP-driven innovation in all sectors of the U.S. economy. Virtually every step taken to improve medical science, manufacturing, or technology is follow-on. Inventors build on their own progress and the progress of others.

Just like inventors in any other sector, drug developers would have little reason to invest in the R&D and clinical trials necessary to make incremental improvements to existing medications if follow-on discoveries couldn't be patented. Lawmakers must resist turning follow-on research into a financial liability. We should all want to increase -- rather than shrink -- the number of medical advances generated by post-approval research.

Lastly, attacks on follow-on patents reflect a broader belief that the patent system somehow stands between patients and lifesaving, innovative therapies. Nothing could be further from the truth. Rather than reducing patient access to therapies, robust patent rights underlie the R&D pipeline that continues to deliver breakthrough treatments and cures. Last year, the FDA approved 37 novel drugs. In 2021, it approved 50.

These new medicines would not have been possible if inventors and investors lacked confidence in the reliability of the patent system. Without a predictable period of market exclusivity, the enormous investment required to develop just one new drug could not be justified.

And without this initial innovation, patients will never benefit from cheaper generics down the road. The United States has one of the highest generic use rates in the world -- nine in 10 U.S. prescriptions are filled with generics. Far from being broken, the intellectual property system is working as lawmakers intended, by giving innovators enough protection to invest in new products, while also ensuring those products ultimately become available to consumers as cheap generics once patent protections expire.

C4IP appreciates the Subcommittee's focus on promoting greater innovation and competition while ensuring patient access to breakthrough therapies. But efforts to weaken our nation's world-leading patent system -- and IP protections more broadly -- work directly against these goals.

We hope the upcoming Health Subcommittee hearing will be a forum for an evidence-based debate about healthcare policy, not baseless attacks on patent protections.

Sincerely,

Frank Cullen
Executive Director
Council for Innovation Promotion