

April 29, 2021

The Honorable David Cicilline Chairman Subcommittee on Antitrust, Commercial, and Administrative Law Washington, DC 20515 The Honorable Ken Buck Ranking Member Subcommittee on Antitrust, Commercial, and Administrative Law Washington, DC 20515

Re: Subcommittee Hearing entitled, "Treating the Problem: Addressing Anticompetitive Conduct and Consolidation in Health Care Markets"

Dear Chairman Cicilline and Ranking Member Buck:

The U.S. Chamber of Commerce appreciates the committee's interest in examining issues related to competition in the health care sector, and we look forward to working with you to improve the strength and effectiveness of our health care markets to better serve the American people.

Given the full committee's oversight of intellectual property (IP) issues and historically strong support for our domestic IP system and related policies, we hope the committee will give due attention to the critical role IP has played in American innovation, especially in the biopharma sector.

The industry's response to the COVID-19 crisis has produced effective vaccines and treatments in record time. America's innovation ecosystem –underpinned by our strong IP framework – enabled the U.S. response to the COVID-19 crisis and supported the development and access to life-saving vaccines, treatments, and medical devices that have saved countless lives throughout the world.

Some have argued that IP policies may need to be revisited in response to the current pandemic; we believe the facts show otherwise. In fact, the <u>numerous collaborations</u> that have led to vaccines and treatments being developed in less than a year were a direct result of our IP system. Witness, Pfizer-BioNTech; Moderna and the U.S. government; and many others. These partnerships between government, academia, and the private sector, which are central to the success of America's multi-stakeholder innovation ecosystem in normal times, gained new visibility and reached unprecedented levels during the pandemic. Such collaborations are enabled by predictable, reliable intellectual property rights that provide a legal and commercial basis for contractual arrangements—such as the nearly 300 and counting industry-to-industry licensing deals that are accelerating vaccine production around the world.

The committee will hear from witnesses who have previously put forth the unsupported premise that our patent system contributes to a lack of competition and access to products. Concerns are likely to be expressed about perceived abuses of the patent system, with terms such as "product-hopping" being used to support this mistaken premise. Again, we believe the facts support the exact opposite conclusion. Our domestic patent system ensures that America is the leader in the "innovation economy," which plays a foundational role in the development of new vaccines and treatments and affords the American people the broadest access of any country in the world to these products. As the world is confronted with numerous COVID-19 virus variants and potential future threats, it is more important than ever that we can respond with new formulations to combat the emerging strains to end this pandemic. Unfortunately, efforts to prescriptively legislate "product-hopping" could limit the ability of the biopharma sector to respond to these new threats. The Chamber fully supports responding to abuse in the marketplace. It is important to note that "product-hopping" can already be found to be unlawful under existing antitrust law and companies have been held liable where such practices lack pro-competitive justifications.

Efforts to expand the law are likely to harm existing research programs that may otherwise lead to future innovations. For example, in coming years there may be generic/biosimilar applications filed for patents related to new vaccines and therapeutics to deal with COVID-19 variants or other threats. Existing manufacturers should not be exposed to antitrust liability if they invest in research programs that changes a vaccine or therapeutic formulation to target a new variant or change the delivery method for such revised or new vaccines or therapeutics, where additive innovations bring real value to patients. Helpful improvements such as enhancing the effectiveness of a vaccine by making it longer lasting and requiring fewer "booster" shots could be deemed as "product-hopping" under various legislative proposals.

Surely, these are not the types of outcome Congress would wish to incur, but they will be the unintended consequence of legislative solutions that overreach the perceived problems they are intended to address.

Those who look beyond antitrust law take a different view seek to limit access to our patent system in a discriminatory manner, seeking different rules for the biopharma sector than other industry sectors. One need only consider the many patents issued on successive generations of cell phone models or other tech industry products to appreciate the essential role "follow-on" patents play in bringing new, innovative products to market.

As the world celebrates "World IP Day" this week, the comments of four former directors of the United States Patent and Trademark Office (USPTO) at an event celebrating World IP Day deserve the committee's attention. All four past USPTO directors, from both Democrat and Republican administrations, stated it is their belief that America remains the leader in innovation and enjoys a strong competitive position in the global marketplace as a direct result of the strength of our domestic IP system, with an emphasis on the critical role of our patent system. All expressed concerns about efforts to weaken our patent framework and how that could undermine the innovation ecosystem it supports and connects.

We urge the full committee to fully explore the evidence that supports maintaining our strong IP system and to reject efforts to weaken the patent policies that allow America to remain the world's leader in innovation.

Thank you for your consideration of these issues. We look forward to working with you and members of the committee going forward.

Sincerely,

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Patrick Kilbride