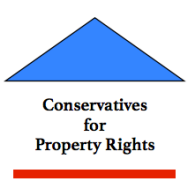

May 7, 2020

Dear Member of Congress:

We write to express strong opposition to the idea several Democratic lawmakers are pushing: To deny patents, exclusivity, and property rights to biomedical innovators, targeted specifically at those working furiously on vaccines, diagnostics, therapies, and cures for the COVID-19 scourge. While the proposal is said to apply only to medicines for COVID-19, even that limitation would be dangerous, disruptive, and unacceptable. Therefore, Congress must exercise prudence and good judgment and reject this shortsighted idea.

The proposal calls for three exclusivity-stripping measures to be included in a COVID-related bill. Biopharmaceutical companies would be denied the following essential patent and private intellectual property rights:

- "[E]xclusivity for any COVID-19 vaccine, drug, or other therapeutic—whether it has been developed with U.S. taxpayer dollars and publicly funded, or not."
- Sale of "any COVID-19 vaccine, drug or therapeutic at an unreasonable price, whether or not it has been developed with U.S. taxpayer dollars."
- "Full transparency," dictated as "publicly report[ing] the total expenditures of the manufacturer on: research and development, disaggregated by clinical trial phase and the percentage of those total expenditures that was derived from federal funds; materials and manufacturing; and meeting statutory standards and carrying out postmarket requirements of the Federal Food, Drug, and Cosmetic Act."

To float such stunted concepts demonstrates complete, perhaps willful ignorance of America's great assets, patents and exclusivity. The U.S. patent system was founded on exclusivity for limited duration to the "first and true inventor." The right to exclude others from the newly created property of an invention, including from making, selling, using, or importing a protected invention such as a drug, is balanced by full disclosure of the invention. This "patent bargain" of exclusivity for the patentee and technological learnings for everybody else, including the patentee's competitors, has served the United States and the American people exceptionally well. It has yielded the Founders' goal of "progress of science and useful arts."

Moreover, to deny exclusivity provided by patents or regulatory means, for government to dictate price, or to require disclosure of sensitive proprietary commercial information for an invention demolishes the foundation of America's private property rights-centered IP system and our innovation ecosystem. This would be a tragedy of immeasurable degree—not only for COVID sufferers, but patients fighting any disease, virus, or malady. It would benefit competitors like China and be a national and economic security setback for America.

We have full confidence in urging rejection of the exclusivity- and IP-destroying proposal. We are in good company.

Ranking Democratic Member of the U.S. Senate Judiciary Subcommittee on Intellectual Property Chris Coons recently said, "I am having conversations about vaccines and vaccine development and bio–defensive measures. If you want a world–class biopharma industry, you got to pay attention to whether or not a company that invents something or develops something new is actually able to recover their costs. And whether they can recover their costs and make a profit largely depends on the IP environment in which they're operating."

Joseph Allen, Democratic Sen. Birch Bayh's Judiciary staffer responsible for the landmark legislation known as the Bayh-Dole Act, which celebrates its 40th anniversary this year, highlights how government price controls—euphemistically called "reasonable pricing"—don't work. Allen writes: "The result wasn't a lowering of prices but a collapse of partnerships with [the National Institutes of Health after it put such price controls in licensing terms in the 1990s]. Here's what then NIH Director Harold Varmus said when he rescinded the provision in 1995: '… the pricing clause has driven industry away from potentially beneficial scientific collaborations with (NIH) scientists without providing an offsetting benefit to the public.'"

Health and Human Services Secretary Alex Azar has warned, ""We would want to ensure that we work to make it affordable, but we can't control that price because we need the private sector to invest. . . . Price controls won't get us there."

Dr. Anthony Fauci of the NIH regards private-sector drug firms operating in the free market as indispensable: "We always need a pharmaceutical partner. . . . I can't think of a vaccine, even one in which we've put substantial intellectual and resource input, that was brought to the goal line without a partnership with industry. So this is a very natural process that we're doing right now." Further, "I have not seen in my experience situations in which we were involved in the development of a vaccine, particularly for low- and middle-income countries that really needed it, where the pharmaceutical companies priced it out of their reach."

The practical role of IP and regulatory exclusivity, market-based pricing, and confidential proprietary information amidst multiple competitors moving fast to develop competing products, on a biopharmaceutical invention or something else, boils down to giving the owner an open field to commercialize the invention—which often costs many times that of invention. Exclusive rights are critical to raising private investment for developing the product

and the market for it, hopefully succeeding commercially and thereby recouping up-front research-and-development costs, as well as fund future R&D.

Thus, preserving exclusivity for the patent or regulatorily provided term of any forthcoming COVID-19 drug is vital to finding effective medicines for the next virus. The cumulative benefit across the innovation ecosystem is seen today in already having more than 300 clinical trials on potential COVID medicines, in sequencing this novel coronavirus in weeks instead of months or years, in the pace of identifying antiviral candidates in just 2-3 months, and realistically expecting a vaccine in 12-18 months rather than 10 years.

Therefore, we urge Congress to spurn the destruction of the dynamo at the heart of America's innovation: intellectual property and free enterprise. Do not let these misguided proposals become part of any legislation. Send them back to the pit full of bad ideas.

Respectfully,

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* Organization names appear for identification purposes.