



Andrei Iancu, Co-Chair  
David Kappos, Co-Chair  
Judge Paul Michel (Ret.), Board Member  
Judge Kathleen O'Malley (Ret.), Board Member  
Frank Cullen, Executive Director

July 26, 2023

Lytic Jorgenson, PhD.  
Office of Science Policy  
6705 Rockledge Drive, Suite 630,  
Bethesda, MD 20892

Dear Director Jorgenson,

C4IP is a bipartisan coalition dedicated to promoting strong and effective intellectual property rights that drive innovation, boost economic competitiveness, and improve lives everywhere. C4IP appreciates the opportunity to offer comments on the importance of strong intellectual property protections in leveraging the power of NIH-backed research to improve health outcomes and advance U.S. interests in other areas, such as national security.

C4IP stands second to none in our appreciation for the work scientists at the NIH do in advancing basic research. The knowledge gained through this work provides the foundation for partnerships with private-sector enterprises able to bring forth breakthrough medical advances from the research lab all the way to patients.

The work done at NIH is essential. But NIH itself has neither the charter nor the expertise to develop its work into commercial products such as FDA-approved life-saving medications. It is only through licensing arrangements with private companies possessing such experience and expertise that NIH research ultimately reaches the public in the form of new medical treatments and other useful products.

Through purchase agreements between the NIH and the private sector, for example, scientists at Pfizer and BioNTech were able to bring their breakthrough mRNA Covid vaccine to patients in [record time](#). Treatments for HIV/AIDS, the hepatitis vaccine, and countless other products also trace their roots to NIH-licensed research.

But these roots do not mature and bear fruit on their own. They require careful nurturing. Intellectual property protection is the key to the continued success of this system.

Without secure patents and other IP protections, investors and private sector innovators will have insufficient incentive to pursue these risky and expensive research projects. These protections include the ability to sell the ultimate product developed out of patented technology at a price agreed to between the patent holder/developer and any buyer for as long as the patent is in effect.

Any restriction on this ability diminishes the value of a patent -- and, therefore, the willingness of any potential developer to license it and invest in it given the uncertain nature of any returns on the investment at all. Unfortunately, it is the case that many products will fail in the later stages of research and development. Indeed, approximately [90% of drugs](#) don't make it through clinical trials to receive full approval.

Yet discounting that risk and undermining investment incentives is just what some advocates have in mind when they call for the inclusion of a "fair pricing" clause in licenses of NIH research for development. The ability of an outside party, in this case, the government, to decide whether the price of a developed consumer product is "fair" will not lead to less expensive consumer products but to an end to the willingness of private companies to license NIH or other government research discoveries for development (to say nothing over the likely and costly litigation over what is "fair and reasonable"). Government research will sit on shelves gathering dust, to the benefit of no one.

This is not a speculative conclusion but one borne out by the historical record. [Past attempts](#) at the NIH and elsewhere in government to institute similar "fair pricing" policies were ultimately repealed because they chilled private sector investment without "providing an offsetting benefit to the public."

Conversely, when policymakers act to preserve and strengthen our IP system, Americans reap the benefits in the form of new medical treatments and stronger national security, economic growth, and job creation. Fully [50% of yearly GDP growth](#) in the United States comes from expanded innovation.

The partnerships forged between the NIH and the private sector transform valuable research findings into new medical treatments and commercial products. These partnerships are prime examples of the power of intellectual property to advance public health and encourage commercialization that benefits all Americans.

The system as currently constituted works well, not least because of its stability and predictability. NIH should not leave the door open to ongoing uncertainty through further consideration of "fair pricing" or other measures that would undermine intellectual property protection. On the contrary, NIH should close that door firmly to ensure Americans continue to enjoy the fruit of government research through private-sector development.

The Council for Innovation Promotion appreciates your attention to these important issues, and also the opportunity to share our views. Please contact me should you have any questions or require additional information.

Sincerely,

A handwritten signature in black ink, which appears to read "Frank Cullen". The signature is fluid and cursive, with a long horizontal stroke at the end.

Frank Cullen  
Executive Director  
Council for Innovation Promotion