

TESTIMONY OF

MARC SEDAM

BEFORE THE

HOUSE JUDICIARY COMMITTEE
SUBCOMMITTEE ON COURTS, INTELLECTUAL PROPERTY AND THE INTERNET

TUESDAY, JUNE 6, 2023

Chairman Issa, Ranking Member Johnson, members of the subcommittee:

I am Marc Sedam, former chairperson of the Association of University Technology Managers (AUTM). I also serve as Vice President for Technology Opportunities and Ventures at NYU Langone Health and New York University, though I want to make clear that I am appearing in my personal capacity. I have been in the technology transfer business for almost 30 years, as an inventor, university startup COO, and university leader and have first-hand experience at what it takes to move nascent technologies from lab to the marketplace. As you may be aware, AUTM represents the tech transfer community across the nation and around the world. Over my career I've worked with well over 100 companies who brought new ideas into society for the betterment of humanity.

By way of background, technology transfer refers to how innovations are taken from the lab, evaluated for potential commercial application, and then developed via a patent or other intellectual property rights to be licensed to a commercial entity for future development and commercialization. Ever since the Bayh-Dole Act was passed in 1980, universities and their commercial partners have created over \$1.3 trillion in economic benefit for the nation, including thousands of patents, hundreds of new drugs and other new technologies, and millions of jobs. It has also led to thousands of startup companies, most of which stay in the region around the university where they are formed. University tech transfer is a key component to regional economies.

If there is one overriding principle I have learned during my time in tech transfer, it is that the patent – the acknowledgement of the value of an invention or idea – is the key building block to innovation. Without a strong patent and strong patent rights, inventors have little chance of attracting the venture capital that will develop that invention into a useful drug, technology, or product. The startup company that I ran, Qualyst, was able to operate successfully for over a decade, employing 15 people with high paying jobs, on the back of just a few strong patents until it was sold in a successful exit.

Given the massive importance of patenting to innovation – particularly for university research – it is easy to see why universities in general are not supportive of the TRIPS waiver that was issued last year by the World Trade Organization for COVID-related vaccines. The pandemic presented unprecedented challenges and laid bare inequities of access to vaccine technology globally. But the fact is that the vaccines which were developed in less than a year to fight COVID were the direct result of patent-based research done before the pandemic, which was expanded upon to fight COVID-19. The problem with reaching worldwide populations with vaccines is about distribution infrastructure, not intellectual property.

Three of our nation's leading higher education associations, including AUTM, recently filed comments before the International Trade Commission regarding a second WTO proposal to expand the TRIPS waiver beyond vaccines to include therapeutics and diagnostics. In those comments, we noted that since the approval of the TRIPS waiver for vaccines nearly one year ago, NOT ONE COUNTRY has declared its intent to make use of the waiver. The lack of use or

intent to use the TRIPS waiver is a strong indicator that any further expansion of the waiver to diagnostics or therapeutics would yield a similar result. Thanks to strong patent rights we sit here in this room, slightly more than three years since the COVID pandemic began, with that same pandemic declared over without a single use of the TRIPS waiver.

The waiving of TRIPS is troubling on other levels. If future pandemics emerge, will the precedent of WTO's action cause less willingness by investors and pharmaceutical manufacturers to jump in to solve the next crisis? And let us also be clear. WTO is already signaling that it may want to consider TRIPS waivers for other technologies beyond COVID. Leaders there have discussed whether clean energy technologies might be another appropriate use of TRIPS to help fight climate change. Agricultural advances have also been mentioned. Where does it end?

Talk to any investors in these technologies, as I do every day, and you understand that the less risk we can create around funding already-risky early technologies, the more likely those investors will be to make the investments needed to advance new discoveries. It's a simple calculation, really. Investors and university tech transfer leaders can handle known risks. Technical risk, market risks, development risks. We understand this and are trained to use our best judgement to file patent applications, sign licenses, and start companies with these "known unknowns". But add in *uncertainty* to an already risky situation and you'll stifle innovation, investment, and opportunity. Whether at the U.S. Patent Office or at the WTO, patent uncertainty is an innovation killer. We simply must have a patent system both here and

around the world that provides inventors and investors with the tools they need to move scientific discoveries forward and a clear understanding that those rights, once secured, cannot be arbitrarily taken away or ignored.

This is also why we have raised serious concerns about potential misuse of the “march-in provisions” of the Bayh-Dole Act. There is currently an ongoing process by the government to review its march-in procedures. We believe any loosening of those provisions beyond the limited exceptions included in the original act could have a similarly negative impact on the willingness of our corporate partners to work with us on any number of research projects. The key message to take home is that we all want to see new products and services developed to improve human health and create economic growth. Adding headwinds to the process of protecting and commercializing intellectual property only increases the chances that those early ideas never progress into life changing solutions.

American universities and medical research institutions have helped create most of the major drug discoveries of the past thirty years. With the strong support of the National Institutes of Health and other agencies, our nation has led the world in creating compounds that ultimately have become many of the drugs Americans depend upon every day. But actions such as the TRIPS waiver put that process at risk, and the potential expansion of such decisions to other technologies is simply wrong-headed.

Ultimately, we believe further waivers will simply mean fewer new discoveries, new drugs, or new solutions to global problems. And that serves no one's best interests.

We urge this subcommittee to share its views in opposition to any further expansion of TRIPS waivers. Thank you for your time today and I look forward to any questions you may have.