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Committee on Ways and Means
Subcommittee on Trade Hearing on Advancing America's Interests at the World Trade Organization's 13th Ministerial Meeting
February 7, 2024

Mr. Chairman, Ranking Member Blumenauer, Members of the Subcommittee on Trade, thank you for this opportunity to share my perspective, as the co-founder and President of a small biopharmaceutical company based in South Dakota on the proposed expansion of an IP waiver for COVID-19 therapeutics and diagnostics now before the WTO. The stakes for the United States could not be higher, and I commend this Subcommittee for airing these issues.

There is no objective evidence suggesting a waiver of IP rights would do anything to improve access to COVID-19 therapeutics around the world. Rather, a waiver of IP rights would significantly disrupt the economic model by which innovative biotech startups like SAB Biotherapeutics have successfully advanced medical science to meet global health challenges, create jobs, and maintain our country's leadership in this critical field.

Historically, the United States has been a leader in the promotion of the international rule of law protecting intellectual property. The recent absence of that leadership at the WTO has been a disturbing development that has already undermined the ability of companies like mine to raise the capital necessary to continue our work. It is vital that the U.S. representatives at the 13th Ministerial Conference of the WTO strongly oppose any weaking of the TRIPS agreement and continue U.S. support for strong international enforcement of IP rights.

About SAB Biotherapeutics

SAB Biotherapeutics is a clinical-stage, publicly traded biopharmaceutical company employing around 65 people, primarily in South Dakota, but with employees in Florida, Illinois, Iowa, Kentucky, Massachusetts, Minnesota, Missouri, New York and Pennsylvania, uniquely focused on the development of powerful and proprietary immunotherapeutic polyclonal human antibodies to treat and prevent infectious diseases, immune and autoimmune disorders, and oncology. Our development programs harness the body's natural defense system to address infectious diseases, as well as immunological, gastroenterological, and respiratory diseases that have significant mortality and health impacts on immunocompromised patients, with a current focus on Type 1 Diabetes.

I am the co-founder of SAB Biotherapeutics and have served as President, and formerly as CEO since 2014. I have been in biopharma leadership roles for over 30 years leading initiatives to develop infectious disease, cancer, and autoimmune immunotherapies and have raised over $800 million in capital to develop biopharmaceutical platform technologies. I am on the Board of Directors of the Biotechnology Innovation Organization (BIO) and founded, served as President, and remain as an advisor to South Dakota Biotech.

SAB Biotherapeutics developed a COVID-19 therapeutic candidate which represents a highly-differentiated treatment option that provides a highly-specific match against the complexity, diversity, and the mutations SARS-CoV-2 presents. Our novel human polyclonal antibody candidate may have value both therapeutically, as a treatment for patients infected with the virus, and for immediate protection (passive immunity) when a vaccine is not an option. Our drug candidate was designed to be produced in large scale without the need for human convalescent plasma, blood donations, or serum.

SAB's technology platform leverages the natural human immune response to develop next-generation, fully human polyclonal antibody therapeutics, extending both the safety and potency of antibodies. These highly efficacious antibodies have proven to neutralize and block disease, and also address future mutations. SAB's platform represents, for the first time, the ability to produce targeted, fully human, high potency polyclonal therapies on a commercial scale.

Underlying our technology platform is a robust IP portfolio, including a patent which has recently been granted by the USPTO, which we have leveraged to secure investment and foster research collaborations related to COVID-19. Our technology platform, with continued research and development, has the potential to not only combat COVID but address other known and novel emerging biodefense threats.

An agreement to waive IP rights for COVID-19 therapeutics at the WTO would needlessly expose our company's IP assets protecting our platform technology which we are using to develop treatments for COVID and for other potential infectious diseases, immune and autoimmune disorders, and oncology. A waiver of IP rights could potentially allow our patents to be infringed and our technology platform deployed by competitors to develop COVID treatments or treatments for other diseases without meaningful legal recourse.

IP and Innovation: IP is the Currency Driving Investment in R&D

While some continue to argue that IP rights hindered the response to the COVID pandemic, in fact that legal architecture provided the basis for the successful R&D behind the vaccines, therapeutics, and diagnostics, and the partnerships that delivered millions of doses around the world with historically unprecedented speed.

As Seth Berkley, the former CEO of Gavi, the Vaccine Alliance, recently said the push for the vaccine IP waiver was a distraction: "You know, it was a challenge. Because here we were in the middle of this emergency, and there was a whole community that said, this is what we have to do, and focused on it and pushed on it, and it was irrelevant."[1]

Through the collective research efforts of the global innovative biotechnology community, there have been over 800 independent therapeutic R&D programs initiated since the beginning of the pandemic and hundreds of collaborative, voluntary research and manufacturing partnerships. The global IP framework has enabled this lifesaving innovation and provides a reliable legal foundation for companies to enhance research collaborations globally on a voluntary basis.

IP rights are the currency used by innovative biotech companies to encourage investment in new and emerging technologies with significant promise. Biotechnology research and development has a greater than

[1]Jenny Lei Ravelo, "TRIPS Waiver 'Did Nothing' for Vaccine Access, Gavi's Seth Berkley Says" Devex (March 8, 2023) (available at: devex.com/news/trips-waiver-did-nothing-for-vaccine-access-gavi-s-seth-berkley-says-105091).

90% failure rate, can take many years, and cost hundreds of millions of dollars. We cannot expect rational investors to fund this work if we cannot demonstrate that we have secure and enforceable rights to our technology. Investors scrutinize our patent portfolio as part of any due diligence. It can make or break a company long before we have our first approved product.

I'm happy to say that SAB has recently announced a private placement investment of over $100M in our company to advance a disease modulating immunotherapy SAB-142 to delay the onset and/or progression of Type 1 Diabetes and we just announced commencement of our Phase 1 clinical trial. If we would have had to disclose a waiver of our IP rights to our COVID-19 portfolio it would have put our company at serious risk of losing a major investment because the waiver would have also exposed all COVID-19 associated IP assets which would have included our novel platform used to develop many kinds of products not just the COVID-19 product.

This risk exposure brought on by the proposed TRIPS Waiver to our IP portfolio, and to the IP portfolios of other U.S. based biotech firms with technologies used to develop COVID treatments, significantly impacts how we entrepreneurs allocate capital to support future R&D efforts and how we approach the investor community to raise funds. The uncertainty around the ability to control and enforce our IP rights globally discourages investment in this space, especially from pre-revenue early-stage biopharmaceutical companies whose most important assets are their IP. The threat to the delicate balance of investment risk cannot be understated in an already highly competitive environment that could negatively impact companies the responded to the COVID-19 pandemic (and perhaps future global health emergencies) in good faith.

U.S.-based small and medium sized enterprises (SMEs) led the global R&D campaign to rapidly develop drug candidates to treat COVID-19 and account for over 75% of the projects in the biopharmaceutical global clinical pipeline. This is where most of the innovation in this field occurs. Many of these companies have yet to bring an approved product to market or have a revenue stream. They are entirely dependent on private capital markets to fund their research. A waiver of IP at the WTO would disrupt that vital funding to the detriment of science, public health, and to the U.S. based biotech companies that led the fight developing treatments against COVID-19.

The innovative U.S. biotech sector, spanning early-stage startup biotech firms, pre-commercial SMEs and larger multinational biotechnology companies not only make incredible contributions to humankind through their scientific research efforts but also contribute to economic growth in the United States, directly employing 2.14 million people and contributing 10.3 million additional jobs resulting in a $2.9 trillion impact to the U.S. economy.[2] Reduced investment, brought on by increased risk to underlying IP assets, will affect research and manufacturing jobs in the United States and undermine our ability to harness the innovative potential of the U.S. private sector to timely and robustly respond to future global public health challenges.

The current debate about a potential extension of an IP waiver to include COVID-19 related therapeutics and diagnostics has already influenced how companies like mine are allocating resources to response to future pandemics. As BIO has pointed out in submissions to the USITC, the stock prices of SME biotech firms that have invested in COVID-19 related R&D have on average suffered more (-73 percent) than the average stock in the U.S. (-5.4 percent) and more than the average SME biotech company not working on

[2] *The Bioscience Economy: Propelling Life Saving Treatments, Supporting State and Local Communities 2020*, TEConomy/BIO, https://www.bio.org/value-bioscience-innovation-growing-jobs-and-improving-quality-life

COVID-19 related R&D (-55 percent) since February 2021.[3] This capital flight has real world consequences for the advancement of cutting edge science.

Reduced investments in the biotech sector and decisions to scale back certain research and development expenditures in response to a high-risk environment for IP rights brought on by the proposed expansion of the TRIPS waiver disrupts the economics of the U.S. biotech ecosystem and this has broader ramifications to the overall health and resilience of the U.S. economy.

Congress recognized the importance of a strong global IP system when it enacted the Omnibus Trade and Competitiveness Act of 1988, stating "Improved protection and market access for U.S. intellectual property goes to the very essence of economic competitiveness for the United States. The problems of piracy, counterfeiting, and market access for U.S. intellectual property affect the U.S. economy as a whole. Effective action against these problems is important to sectors ranging from high technology to basic industries, and from manufacturers of goods to U.S. service businesses."[4] That understanding has always guided U.S. policy and we court disaster if we abandon it now.

COVID-19 Vaccine, Diagnostic, and Therapeutic Supply Has Outstripped Demand

The facts and data clearly establish that protection of intellectual property (IP) rights has been essential to realize significant improvements to patient care and introduction of new medical breakthroughs, including effective medical countermeasure responses to COVID-19. To this end, any effort to circumvent critical IP protections through a TRIPS waiver will undermine American innovation, American leadership in the life sciences, and ultimately fail to meaningfully expand global supply and access.

There is no credible evidence that IP protections have limited patient access to COVID-19 therapeutics. Rather regulatory barriers, trade restrictions, inadequate investment in health systems and lack of adequate infrastructure are limiting factors on supply and access to COVID therapeutics. Accordingly, an IP waiver at the WTO would solve no legitimate issue of public interest. By compromising the legal certainty surrounding COVID-19 related IP, the WTO risks creating genuine barriers that frustrate the ability for biotech companies around the world to rapidly respond to future public health emergencies.

Conclusion

With news of the WHO declaring the end of the COVID-19 public health emergency on May 5, 2023, and with global supply of therapeutics far exceeding demand, a waiver is wholly unnecessary. The persistent pursuit and prioritization of an IP waiver at the WTO demonstrates a lack of concern from this multilateral organization with improving genuine public health bottlenecks affecting the distribution of existing therapeutics. Rather, the debate suggests that proponents of the waiver are keen on leveraging the COVID pandemic to achieve a goal that has been decades in the making – the radical undermining of the existing global IP rights system.

If we want to ensure U.S. companies are at the forefront of delivering innovative countermeasures in response to potential future pandemics and if we want to preserve U.S. leadership in the life sciences, then the U.S. Government must not hesitate in unequivocally expressing its opposition to the proposed

[3] Based on period from Feb. 3, 2021 – Dec. 2, 2022 (Source: https://statista.com/statistics/1104278/weekly-performance-of-djia-index/)
[4] S. Rep. 100-71 at 75 (1987).

expansion of the TRIPS Waiver for COVID-19 therapeutics at the upcoming WTO 13th Ministerial Conference.

Thank you for the opportunity to share my perspective on this important issue. I would be pleased to answer any questions you may have.