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May 5, 2023

Katherine M. Hiner
Acting Secretary to the Commission
U.S. International Trade Commission
500 E Street, S.W.
Washington, DC 20436

Re: *COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities*
ITC Investigation No. 332-596
Post-hearing Supplementary Written Submission

Dear Acting Secretary Hiner,

BIO appreciates the opportunity to provide comments responding to the U.S. International Trade Commission's (USITC, the Commission) request for public comments regarding the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement, the Agreement) following USITC's public hearing investigating whether to extend flexibilities and waive provisions of the TRIPS Agreement applying to COVID-19 diagnostics and therapeutic technologies.

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, for example, a TRIPS waiver will undermine American innovation and ultimately fail to meaningfully expand global supply and access.

Expansion of the existing TRIPS waiver will not achieve the intended goal of expanding supply and access to COVID-19 therapeutics because the IP protections as contained in TRIPS are not a binding constraint on supply and access. Rather regulatory barriers, trade restrictions, inadequate investment in health systems and lack of adequate infrastructure are limiting factors on supply and access to COVID treatments and vaccines. By removing the IP rights holders, who embody both the technical expertise and tacit organizational knowledge, from the collaborative process needed to establish capacity in lower- and middle-income countries and innovate new treatments and vaccines, the WTO risks creating barriers that frustrate the ability for WTO members' to rapidly respond to future public health emergencies.

Furthermore, a waiver of IP rights would significantly disrupt the existing investment and research landscape in the biotechnology sector – with a particularly acute impact on U.S. based SME biotech firms. Biotechnology innovators in the United States account for over 50 percent of the COVID-19 therapeutic research and development programs globally. In addition, 87 percent of the global COVID-19 therapeutic development programs in the U.S. originated from SME biotech firms. This assault on IP is detrimental to U.S. based innovation and the broader U.S. economy – especially as proponents of a COVID-19 IP waiver

also seek to expand the use of IP waivers to agriculture and green technology. BIO's members 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. Reduced investment, brought on by increased risk to underlying IP assets, will affect research and manufacturing jobs in the United States across biotech sectors – which amounts to a disservice to science and to the patients and people around the world waiting for the next generation of cures and breakthrough innovations.

As an alternative to the TRIPS waiver, the U.S. and other leading economies should encourage the WTO and international organizations to consider investments which directly support globally "building resilient health systems," such as those recommended by the World Health Organization.[1]

I. Intellectual Property & Innovation

Innovation and intellectual property go hand-in-hand. No company would invest significant sums of money developing inventions that could be used by competitors, just like no farmer would plant a field anyone could freely harvest.

Intellectual property is so essential to innovation that businesses will have to abandon potentially transformative inventions when denied the necessary intellectual property protections. For example, a study, updated in December 2019, identified 1,310 U.S. patent applications that were abandoned following eligibility rejections under the *Alice-Mayo* framework.[2] The study also concluded that almost half of the abandoned applications (618 of the 1,310) were directed to diagnosis or treatment of important diseases like heart failure, cancer, Alzheimer's disease, and diabetes.[3] Peter O'Neill, Executive Director of Cleveland Clinic Innovations, testified before the Senate Judiciary Committee and stated, "if an invention can't get intellectual property protection, usually that is a fatal flaw and the invention is abandoned at that point."[4]

As governments roll back public investments in pandemic mitigation, waiving intellectual property protections will also stymie private sector investment in COVID-19 therapeutics and diagnostics. Companies cannot get capital investment without intellectual property protections. Venture capital has a history of leaving entire sectors when intellectual property protections become uncertain.[5] In the aforementioned congressional testimony, Peter O'Neil credited the guarantee of their patent for enabling the success of the Cleveland HeartLab and its ability to raise the required investment funding.[6]

From a survey of 475 venture capital and private equity investors, 62 percent of investors "agreed that their firms are less likely to invest [in companies developing patent-ineligible technologies] given the unavailability of patents, while only 20 percent disagreed."[7] Furthermore, in the four years following the

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[1] Building health systems resilience for universal health coverage and health security during the COVID-19 pandemic and beyond: WHO position paper (October 2021). https://www.who.int/publications/i/item/WHO-UHL-PHC-SP-2021.01.
[2] See *Alice Corp.,* 573 U.S. at 217-18, 110 USPQ2d at 1981 (citing *Mayo*, 566 U.S. 66, 101 USPQ2d 1961); see also, USPTO Manual of Patent Examining Procedure, Chapter 2100, Section 2106, subsection III, https://www.uspto.gov/web/offices/pac/mpep/s2106.html
[3] Mossoff, A., & Madigan, K. (2018). The Value of Public Data: Update to "Turning Gold to Lead". George Mason University. https://cip2.gmu.edu/2018/06/28/the-value-of-public-data-update-to-turning-gold-to-lead/
[4] Testimony of Peter O'Neill, Executive Director of Cleveland Clinic Innovations, to the Subcommittee on Intellectual Property of the Senate Judiciary Committee. June 11, 2019. Pg. 4.
[5] Cortese, M. (2020, September 3). Changes in U.S. patent system linked to decrease in venture capital funding. Property Rights Alliance. https://www.propertyrightsalliance.org/news/changes-in-u-s-patent-system-linked-to-decrease-in-venture-capital-funding/
[6] Ibid. Pg. 5.
[7] Taylor, D. O. (2019). Patent eligibility and investment. SSRN Electronic Journal. https://doi.org/10.2139/ssrn.3340937

Mayo decision referenced above, venture capital "investment in disease diagnostic technologies was nearly $9.3 billion dollars lower than it [otherwise] would have been."[8] The direction of the effect is expected and intuitive: in biotech, IP is a necessary mechanism by which investment in risky ventures can be later remunerated. But the scale of the effect should caution policymakers intent on waiving IP rights assuming capital will continue to flow. Mr. Dennis Purcell, Founder of Aisling Capital, an investment firm focused on life sciences research, provided testimony to the USITC precisely on this point attesting to the importance of a robust and reliable global IP ecosystem to justify investments in the life sciences space.

Uncertainty around intellectual property protections is already affecting the therapeutics and diagnostic market. As BIO has pointed out in previous submissions, 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 COVID-19 related R&D (-55 percent) since February 2021.[9]

One explanation for this reaction from the capital markets is that an IP waiver cannot be limited strictly to the targeted medicine. Due in part to the complexity of formulations and production processes related to COVID-19 therapeutics, successful advancements in the development of medicines do not necessarily culminate in a discrete single patentable innovation. Rather, they are the result of iterative, interconnected, and interrelated innovations. An attempt to "draw a line around" a targeted COVID-19 therapeutic will invariably implicate dozens, even hundreds, of other medicines, technologies, methods of manufacture, and intermediate research tools currently under or actively seeking patent protection. In addition to compromising the IP of existing therapeutics that may treat COVID-19, as well as their methods of manufacture for instance, a waiver also jeopardizes IP rights for countless medicinal products still being researched and under development, as well as other R&D projects that may in the future result in products with potential applications against future pandemic diseases, including new COVID-19 variants.

Ultimately, due to this uncertainty and inherent risk brought on by the IP waiver, companies will receive less investment in a shrinking market, while having strong incentives to scale back research and development. Expanding the TRIPS waiver would disrupt innovation in mitigating COVID-19, when the virus continues to evolve and the world adjusts to perpetually managing its prevalence in a return to pre-pandemic normalcy.

II. Effect on Manufacturing Jobs for COVID-19 Diagnostics and Therapeutics

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. Before and during the COVID-19 pandemic, the U.S. biopharmaceutical industry has been an economic stalwart generating high-quality jobs in a range of fields from research to manufacturing and, with near continuous growth, the sector has acted as a key buffer during prior economic recessions. The ability of the biotech sector to weather economic downturns improves the lives of patients who rely on the production of breakthrough medicines and provides important stability for the regional economies and their workers in which those manufacturers operate.

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[8] A. Sasha Hoyt, *The Impact of Uncertainty Regarding Patent Eligible Subject Matter for Investment in U.S. Medical Diagnostic Technologies*, 79 Wash. & Lee L. Rev. 397 (2022). https://scholarlycommons.law.wlu.edu/wlulr/vol79/iss1/8.

[9] Based on period from Feb. 3, 2021 – Dec. 2, 2022 (Source: https://statista.com/statistics/1104278/weekly-performance-of-djia-index/)

An expansion of the TRIPS waiver could lead to the loss of American-based research and manufacturing jobs during a critical time, as the U.S. continues to recover economically from the COVID-19 pandemic. These domestic job losses would have far-reaching consequences. Currently, the biosciences sector collectively provides many stable, high quality jobs to over 2.14 million people in the United States and contributes to approximately 10.3 million additional jobs resulting in a $2.9 trillion impact to the U.S. economy.[10] In 2020, the U.S. had over 1,500 facilities across the country manufacturing FDA-approved human-use products under Good Manufacturing Practice (GMP) regulations, a gold-standard level of manufacturing not required in most other countries.[11] These biopharmaceutical manufacturing operations span across 47 States, the District of Columbia, and Puerto Rico.[12] There are currently 40 States which have 5 or more manufacturing facilities producing FDA-approved medicines; New Jersey, California, and Pennsylvania have 180, 174, and 104 registered manufacturing facilities, respectively.[13]

An expansion of the TRIPS waiver puts domestic manufacturing jobs at risk, a position contrary to the Biden Administration's ongoing goal to "revitalize [the United States'] manufacturing base, strengthen critical supply chains, and position U.S. workers and businesses to compete and lead globally in the 21st century."[14] In 2020 alone, the U.S. biopharmaceutical industry generated more than $131 billion in employee income, averaging more than $145,000 in annual compensation per worker, which is directly invested back into the U.S. economy.[15] The U.S. biopharmaceutical manufacturing industry has a significantly higher-than-average productivity measure, exceeding $380,000 in value added per worker per year (compared to a $163,000 for other non-pharmaceutical U.S. manufacturing jobs).[16] For every 1 biopharmaceutical job, the industry supports an additional 3.92 jobs in the U.S. economy.[17] In total, the biopharmaceutical industry provided $359 billion in wages and benefits to Americans in 2020.[18]

It is important for the Biden Administration to support its goals of shoring up additional domestic manufacturing jobs, and an expansion of the TRIPS waiver would do the opposite. There have been years in which the biotechnology industry has contributed more than $400 billion into the domestic economy, equal to over 2 percent of the U.S. gross domestic product (GDP).[19] There have been other studies which estimate the biotechnology industry contributes between 5 to 7 percent of the U.S. GDP.[20] In terms of scale, the size of the U.S. biotechnology industry is approximately equal to the worldwide semiconductor industry.[21]

An expansion of the TRIPS waiver would not only hurt the U.S. economy and its domestic manufacturing workforce, but the TRIPS waiver opens the U.S. to increased national security risks from adversarial countries. Numerous reports and former U.S. officials have warned "for decades" about foreign

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[10] *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

[11] The Economic Impact of the U.S. Biopharmaceutical Industry:. (2022). TEConomy, PhRMA. https://qa-phrma.mrmdigital.com/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/0-9/2020-Biopharma-Jobs-ImpactsMarch-2022-Release.pdf

[12] *Id*

[13] *Id*

[14] The Biden-Harris Plan to Revitalize American Manufacturing and Secure Critical Supply Chains in 2022. February 24, 2022. https://www.whitehouse.gov/briefing-room/statements-releases/2022/02/24/the-biden-harris-plan-to-revitalize-american-manufacturing-and-secure-critical-supply-chains-in-2022/

[15] Supra fn. 11

[16] *Id*

[17] *Id*

[18] *Id*

[19] Carlson, R., Sbragia C., & Sixt, K (2021). Beyond Biological Defense: Maintaining The U.S. Biotechnology Advantage. https://warontherocks.com/2021/09/beyond-biological-defense-maintaining-the-u-s-biotechnology-advantage/

[20] *Id*

[21] *Id*

efforts to illegally acquire IP from American entities, and the U.S. Federal Bureau of Investigation (FBI) has recently warned of the serious national security risks related to "increased espionage" of COVID-19 research and related IP.[22] Weakening the international protections for IP will make efforts to steal COVID-19 related IP all the easier.

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

There is no credible evidence that IP protections have acted as a constraint on patient access to COVID-19 vaccines, diagnostics, or therapeutics.[23] To the contrary, the U.S. pharmaceutical industry swiftly invested billions of dollars to develop many effective COVID-19 diagnostics, vaccines, and treatments and by the time of the initial waiver decision, more than 14 billion COVID-19 vaccine doses had been produced, with enough pharmaceutical capacity to vaccinate the world in the face of new variants. In fact, significant numbers of vaccine doses have gone unused and required disposal because of expiration and improper storage[24], or simply a lack of demand,[25] with one analysis from around the time of the initial waiver decision estimating "the number of COVID-19 vaccine [doses] which are likely to have been wasted…to be 1.1 billion."[26]

COVID-19 treatments subsequently led to significant improvements in patient care during the COVID-19 pandemic, especially for individuals who were unvaccinated. To date, over 70 million courses of COVID-19 antivirals have been produced, which far exceeds all estimated patient demand. In 2022 alone, 5.5 million people received antibody treatments for COVID-19.[27]

IV. Difficulties Associated with Biopharmaceutical Development and Production

Biotech Production is Costly and Complicated

Biotech manufacturing is a complex process and knowing how to properly manufacture, dose, fill, and finish syringes or other specialty devices is itself a technical process often done by specialty manufacturers. If this part of the process could be provided as a turnkey outsource solution, then this would not present a problem. However, even successful contract development and manufacturing organization (CDMO) relationships are predicated on months or years of fine-tuning, and continuous improvement to correctly execute a manufacturing contract for complex products.

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[22] Dilanian & Kosnar, (2022) "Chinese Attempts to Hack Health Care, Drug Firms"; FBI, "Targeting of COVID-19 Research Organizations"; and Sanger and Perlroth, "U.S. to Accuse China of Trying to Hack Vaccine Data." https://www.jhuapl.edu/sites/default/files/2022-12/Carlson_Wehbring-Biotech.pdf

[23] Michael Rosen, "Confronting Joe Biden's Proposed TRIPS Waiver for COVID-19 Vaccines and Treatments: Highlights from an Expert Panel Discussion," *AEIdeas*, American Enterprise Institute, July 2, 2021, https://www.aei.org/technology-and-innovation/confronting-joe-bidens-proposed-trips-waiver-for-covid-19-vaccines-and-treatments-highlights-from-an-expert-panel-discussion/. (Quoting former US Patent and Trademark Office Director Andrei Iancu: "There is no evidence that IP has actually been a problem. In fact, all the evidence is to the other side….within 12 months or less of the discovery of [the COVID] sequence, there were not one but multiple vaccines – not just created, but also approved and already being delivered into people's arms.")

[24] Eaton, J. (2022, June 6). The U.S. has discarded over 82 million Covid vaccine doses, led by CVS and Walmart. NBC News. https://www.nbcnews.com/news/us-news/covid-vaccine-doses-wasted-rcna31399

[25] See, P. R. Sanjai, "Serum Institute halts COVID-19 vaccine production amid global supply glut," *Business Standard (India)*, April 22,2022, https://www.business-standard.com/article/current-affairs/serum-institute-halts-covid-19-vaccine-production-amid-global-supply-glut-122042200692_1.html; and Paul Adepoju, "Lack of orders could halt COVID-19 vaccine production in South Africa," *Devex*, April 14, 2022, https://www.devex.com/news/lack-of-orders-could-halt-covid-19-vaccine-production-in-south-africa-103052.

[26] Airfinity, "Global wastage of COVID-19 vaccines could be 1.1 billion doses" [Press release], July 10, 2022, https://www.airfinity.com/articles/global-wastage-of-covid-19-vaccines-could-be-1-1-billion-doses.

[27] Airfinity (science.airfinity.com).

Collaborative approaches to enhance and increase global manufacturing footprint maximizes the likelihood of successful, indeed productive, licensor/licensee relationships. Much of the knowledge gained in developing and producing effective therapeutics is continually gathered, developed, and refined, by the innovator. Only through voluntary, collaborative approaches, can innovators share this knowledge with manufacturing partners. International bodies should encourage and facilitate this needed collaboration – an expansion of the TRIPS vaccine waiver to therapeutics and diagnostics would do the opposite and instead erect additional hurdles and barriers to this type of collaboration.

Successfully replicating production of biotherapeutics is not a matter of simply following a "recipe." For instance, with respect to complex biologics and other biopharmaceuticals the formulation is only a part of the breakthrough innovation: "with a variable end product, *the process* has to become the regulated and tested entity, and this brings a new approach to quality assurance,"[28] an aspect of the innovation bundle that is not effectively transferred when granted blanket access to underlying IP—especially where the IP rights holder cannot count upon a reliable IP system, without the threat of IP waivers, that permits and facilitates voluntary collaboration.

Expanding Access to IP Does Not Increase Supply of Inputs

During the height of the COVID-19 pandemic, "many materials required for biopharma manufacturing [saw] delays of six to 12 months, as well as having a higher cost due to increased demand.," according to the head of a prominent contract biologics manufacturer.[29] In the U.S. alone, stresses from the pandemic "exhausted existing inventories of drug products and raw materials," many of which are sourced or finished in "Europe, India, and China, including active pharmaceutical ingredients (APIs)."[30] Increased demand, especially unforeseen spikes, does not induce a concomitant increase in supply of ingredients, equipment, or finished drugs in the near term. The most plausible way to meet increased needs in the fastest way possible is to deploy additional capital and labor in existing productive capacity. Moreover sourcing ingredients and skilled labor with specialized knowledge is easiest along existing relationships.

Expanding Access to IP Does Not Expand Productive Capacity

Countries that lack pre-existing manufacturing infrastructure were unable to take advantage of the existing TRIPS waiver. As Patrick Tippo, executive director of the African Vaccine Manufacturing Initiative, highlighted, "There are shortfalls in infrastructure and supply chains, as well as the experts needed to make both work. Key regulatory agencies are missing. Then there is an even bigger deficiency on a continent where most vaccines are provided by UNICEF with the support of Gavi, the Vaccine Alliance."[31]

Lack of access to vaccines, other medical products, and critical technology during the COVID-19 pandemic was caused by a shortage of raw materials, delivery and logistical challenges and deficiencies in

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[28] "The challenges of manufacturing biologics compared with traditional molecules," *Manufacturing Chemist*, March 2021 (emphasis added) https://www.manufacturingchemist.com/news/article_page/The_challenges_of_manufacturing_biologics_compared_with_traditional_molecules/175188.

[29] *Key challenges for bio/pharmaceutical manufacturing 2022*. (2022, April 4). European Pharmaceutical Review. https://www.europeanpharmaceuticalreview.com/article/167733/key-challenges-for-bio-pharmaceutical-manufacturing-2022/.

[30] *The Pandemic and the Supply Chain*, Johns Hopkins Bloomberg School of Public Health (November 2020), https://www.jhsph.edu/research/affiliated-programs/johns-hopkins-drug-access-and-affordability-initiative/publications/Pandemic_Supply_Chain.pdf.

[31] Green, A. (2021, October 7). Where are we on COVID-19 after a year of TRIPS waiver negotiations? DevEx. https://www.devex.com/news/where-are-we-on-covid-19-after-a-year-of-trips-waiver-negotiations-101795

public health infrastructure.[32] Collaborative, as opposed to coercive, public and private sector cooperation has scaled up manufacturing and led to mass distribution of the necessary medical products. Intellectual property rights have not been a hurdle in that collective effort; "even Doctors Without Borders' Roz Scourse acknowledged in a BBC interview that suspending patent rights 'wouldn't produce millions of more vaccines.'"[33]

V. Conclusion

As the U.S. Government declares the end of the COVID-19 public health emergency on May 11, 2023 and with global supply of therapeutics far exceeding demand, a waiver is wholly unnecessary and only succeeds in emboldening U.S. competitors, undermining U.S. leadership, and jeopardizing future pandemic preparedness efforts.

Furthermore, on May 5, 2023, the World Health Organization declared an end to the COVID-19 pandemic emergency.[34] The Director-General concurring with the advice offered by the International Health Regulations (2005) (IHR) Emergency Committee regarding the ongoing COVID-19 pandemic and determined that COVID-19 is now an established and ongoing health issues which no longer constitutes a public health emergency of international concern (PHEIC).

As innovative therapeutics have become available, breakdowns in health system infrastructure around the world impeding the efficient delivery of COVID-19 therapeutics have become more apparent. Nevertheless, proponents of an IP waiver myopically point to IP rights as the barrier to access while ignoring genuine public health challenges that frustrate the distribution of therapeutics. Modernizing health system infrastructure, eliminating trade barriers, improving regulatory frameworks, and ensuring robust testing and therapeutic procurement initiatives are measures that can promote global public health without undermining the IP rights system.

Proponents' incessant pursuit and prioritization of the waiver demonstrates a lack of concern with improving public health bottlenecks affecting the distribution of existing therapeutics. Rather, proponents are keen on leveraging the pandemic to achieve a goal that has been decades in the making – the radical undermining of the existing global IP rights system.

U.S. support of a policy which points to IP rights as a barrier to the access of COVID-19 therapeutics around the world would undermine the American biotech sector and compromise U.S. leadership in the life sciences. This would be a disservice to science and the ecosystem that enables cutting-edge R&D around the world. It also has significant ramifications to the U.S. economy and workers.

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[32] Yu, P. K. (2022). A critical appraisal of the COVID-19 TRIPS waiver. INTELLECTUAL PROPERTY RIGHTS IN THE POST PANDEMIC WORLD: AN INTEGRATED FRAMEWORK OF SUSTAINABILITY, INNOVATION AND GLOBAL JUSTICE, Taina E. Pihlajarinne, Jukka Mähönen and Pratyush Upreti, eds., Edward Elgar Publishing, Pg. 8.

[33] Ezell, S. (2021, April 9). Ten reasons why a COVID-19 trips IP waiver is unwarranted. Information Technology and Innovation Foundation | ITIF. https://itif.org/publications/2021/04/09/ten-reasons-why-covid-19-trips-ip-waiver-unwarranted/

[34] Statement on the fifteenth meeting of the International Health Regulations (2005) Emergency Committee regarding the coronavirus disease (COVID-19) pandemic, May 5, 2023 - https://www.who.int/news/item/05-05-2023-statement-on-the-fifteenth-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-coronavirus-disease-(covid-19)-pandemic#:~:text=The%20WHO%20Director%2DGeneral%20concurs,of%20international%20concern%20(PHEIC).

Thank you for the opportunity to submit comments and participate in the USITC consultation process.

Sincerely,

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BIO