Biotechnology Innovation Organization

Docket # USTR-2018-0034

Edward Gresser
Chair of the Trade Policy Staff Committee
Office of the United States Trade Representative

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to respond to the U.S. Trade Representative's (USTR) request for comments on negotiating objectives for a United States – Japan Trade Agreement.

BIO is a non-profit organization with a membership of more than 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in almost all 50 States and a number of foreign countries. BIO's members research and develop health care, agricultural, industrial, and environmental biotechnology products. The vast majority of BIO members are small to medium sized pre-commercial companies.

Advances in biotechnology innovation have had a transformative impact on many sectors of the economy — from advances in healthcare to improved plants that are key to feeding the world to industrial biotechnology applications that are leading to bio-based fuels, chemicals and products that can protect our environment and herald a new age of sustainable development.

Bioscience industries employed 1.7 million people in 2014 across more than 77,000 U.S. business establishments. The broader employment impact of the U.S. biosciences is the creation an additional 7.5 million jobs throughout the economy. Taken together, these direct, indirect, and induced bioscience jobs account for a total employment impact of 9.3 million jobs.[1]

The industry continues to pay high wages, reflecting the high skills and education requirements of an innovative workforce, with the average U.S. bioscience worker earning nearly $95,000 per year, or 85% greater than the private sector average. Since 2001, bioscience wages have grown substantially faster than overall private sector wages.[2] The bioscience industry is also well distributed geographically in the United States: 32 states and Puerto Rico have an employment specialization in at least one bioscience subsector, and 222 of 381 U.S. metropolitan areas, have employment in at least one biotechnology sector.[3]

BIO supports the U.S. government entering negotiations with the Government of Japan as an opportunity to grow U.S. exports and create U.S. jobs. We would strongly urge the U.S. government to build on the recent U.S.-Mexico-Canada agreement and that the agreement

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[1] "**The Value of Bioscience Innovation in Growing Jobs and Improving Quality of Life 2016**", **https://www.bio.org/sites/default/files/BIO%202016_Report_FINAL_DIGITAL.pdf at 2.**

[2] *Id.*
[3] *Id.*

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comprehensively addresses the biotechnology sector as an engine for growth for both economies.

BIO Priorities for a US-Japan Trade Agreement

Agricultural Innovation

Japan is an important market for U.S. exports of food and agricultural products, accounting for $13.5 billion in 2017, therefore, maintaining long-term access to the Japanese market is critical for the sustainability of rural communities. Concurrently, advances in agricultural innovation hold great promise for solving or mitigating significant human and animal health and welfare, food security, and environmental challenges important to U.S. farmers and the consuming public. To fully realize the benefits of agricultural innovation, technology developers must be able to integrate the products of these technologies into global supply chains. The cost and uncertainty in the global regulatory environment create significant barriers to entry and limits the utilization of these technologies for the public good. A U.S.-Japan trade agreement is an opportunity for two leading countries to improve the global policy environment to enable innovation to meet society's greatest needs.

Because Japan is an important export market for U.S. agricultural commodities, achieving biotechnology approvals and ensuring uninterrupted trade between the U.S. and Japan is critical to ensuring the sustained growth of the U.S. agricultural economy. BIO appreciates the willingness of Japanese authorities to participate in technical exchanges that have allowed the two governments to resolve challenges over the years in a timely and practical manner.

BIO welcomes the potential for a US-Japan trade agreement to strengthen this relationship to ensure regulation is science-based, transparent and predictable. BIO seeks to continue to build upon the improvements to the global policy environment for agricultural biotechnology achieved in the U.S.-Mexico-Canada Agreement (USMCA), as well as seek gains in the policy environment for veterinary medicines. Predictable, science and risk based regulation is critical to enabling innovation and attracting investment especially small and medium enterprises (SME). BIO encourages the U.S. and Japan to utilize this opportunity to improve the global policy environment and better enable SMEs to operate in this space. BIO welcomes the opportunity to work with the Administration in achieving these objectives.

BIO Pharmaceuticals

BIO welcomes progress made in recent U.S. bilateral trade agreements, in particular with Australia and Korea, to require transparency and accountability of foreign government pricing and reimbursement of biopharmaceuticals, to ensure market access and reward for innovation. BIO believes that to ensure that U.S. trading partners are allowing fair, non-discriminatory access to new medicines, and shouldering a fair share of the costs of innovation, that any modern trade agreement, including a U.S-Japan agreement should build on these provisions.

Cross-border collaboration in the biopharma sector has intensified in recent years between the United States and Japan, in part because of important progress and reform within Japan's drug regulatory system that now approves products on a similar time frame as the U.S. Advances in scientific research in both countries have also increased the opportunities for collaboration. However, a variety of aspects of Japan's system for pricing and reimbursing new drugs now threatens to hinder innovation in Japan, and with it, opportunities that small, medium-sized

and large biopharma companies in the United States have to develop and launch new drugs in Japan. Some of these developments in fact particularly make it difficult for small companies to consider developing and launching in Japan. BIO has gone on the record in past years as to a number of these issues, and reiterates them here:

- **Anti-innovation changes to the Price Maintenance Premium (PMP) system**. Recent changes to PMP are discriminatory to U.S biotechnology companies and make it harder for new therapies to become eligible for full benefits. BIO is particularly concerned about criteria related to the number of drugs launched and trials held in Japan, which obviously discriminate against small non-Japanese companies, no matter how significant their innovations may be.

- **Non-transparent Nature of Pricing and Reimbursement (P&R) Policy Making.** BIO has long been concerned with the non-transparent, and non-inclusive nature of policy making with respect to P&R for new drugs. In particular, we find the Chuikyo process seriously flawed with regard to its provision of advance notice of issues to stakeholders, and its limited opportunities for such stakeholders to engage. We believe it is unfair for one of the world's largest markets for new medicines to do such a poor job of reaching out to the U.S. biotech community – which originates a large number of all new medicines globally – for its input. Outreach to large U.S. companies located in Japan is also deficient, but even that does not include any input by our SME members, which are the backbone of this industry.

- **Systemic Discrimination Against Innovative Medicines in the Budgeting Process – Undervaluation of Innovation.** BIO recognizes that the Japanese health care system faces fiscal constraints. But time and again, we find that health care budgets and government policies repeatedly and disproportionately limit spending on new innovative medicines (e.g., the percentage of budgetary cuts far exceed our percentage of health care expenditures) compared to other health care services and products, despite the fact that many new medicines create significant health care savings in the longer run. Bluntly put, new medicines which are predominantly developed abroad (mostly in the U.S.) face much deeper cuts than Japanese constituents in the health care system such as doctors and hospitals. This is not only unfair and discriminatory, it systemically works to undervalue new medicines and therapies, undermines IP, and stunts incentives for biopharma innovation within Japan.

- **A Rigid Health Technology Assessment (HTA) in Japan Could Exacerbate the Trend of Anti-Innovation**. BIO is concerned that existing plans to develop a rigid cost-effectiveness-based HTA system, potentially inclusive of the pricing and also the reimbursement decision for new medicines will be constructed in ways that further disincentivizes innovation in Japan, add to costs (particularly burdensome for small companies) and potentially delay patient access to new medicines. In addition, the methodology used by the Government of Japan in its HTA pilot, on which the HTA system will be based, was not developed in a transparent process and deviates from standard methodologies aligned with the latest available science. The process and methodology should be revised in a transparent manner prior to establishment of HTA in Japan. Any future HTA system needs to encourage innovation, not be unduly

burdensome, incorporate a broad set of benefits in the value framework, and not simply be used a tool for rationing care to Japanese patients.

Proposals to Ensure that the U.S.-Japan FTA Process Truly Advances Biopharma Innovation

Fortunately, the U.S. and Japan have been engaged in intensive bilateral trade talks involving this sector for over 30 years – the advent of "MOSS talks" in 1986. This means there is a rich record of discussion, agreements and achievements upon which to build in any new FTA. BIO proposes the following four part plan for such achieving a successful outcome in the new negotiating process:

- **Apply existing "standstill" commitments to this sector**. BIO notes that the parties have already agreed not to impose new measures that would worsen market access or improve their negotiating positions. This should be applied to any new measures not already in effect that would reduce access to new medicines, including proposals for annual price revisions in April 2019, six months ahead of the scheduled consumption tax hike, and annual price revisions starting in 2021 for innovative products in Japan.

- **Capture and Formalize Key Past Agreements as part of any new "Early Achievements" in the Process**. The fact that there are longstanding agreements in key areas makes them natural and easy targets for early achievement, in particular, commitments made in 1986 to ensure that new products are listed for reimbursement 60 and not more than 90 days after regulatory approval.

- **Address More Complicated P&R Issues (as noted above) in the main body of the trade agreements.** Over thirty years of negotiating experience demonstrates that critical P&R issues affecting innovative medicines *can* be addressed bilaterally between the United States and Japan. Such agreements should build on the transparency provisions contained in the KORUS agreement, and include substantive changes to the process and content of the Japanese system. They should also include broad general commitments and a series of specified steps by which to carry them out.

- **Establish an Ongoing System of Compliance.** The long experience of this sector is that the Japanese health care system as it pertains to new drugs changes constantly – at least every two years, and that the issues of today will not be the issues of tomorrow. To ensure that pro-innovation principles are adhered to, the U.S.-Japan agreement, like the U.S.-Australia and U.S.-Korea agreements needs to establish a regular, (at least annual) system of consultation on these issues, in effect supplanting the last three decades of MOSS talks, but now in a more enforceable setting.

Intellectual Property

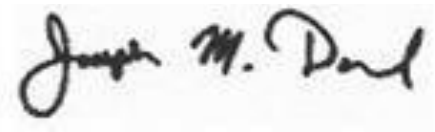
In accordance with the Trade Promotion Authority Act requiring the U.S. government to leverage trade agreements to bring our trading partners in line with U.S. standards for

intellectual property rights, BIO strongly believes the U.S. standards of data protection for biologic products (12 years) remains the gold standard and should be the basis for negotiations with Japan. The recently concluded US-Mexico-Canada Agreement presents a strong foundation from which to build and achieves a standard closer that U.S. law. In addition, BIO would welcome a strong patent enforcement mechanism, including patent term restoration to address patent examination delays.

Conclusion

Biotechnology is a powerful set of tools with applications to address an incredibly broad range of global challenges affecting human, animal, plant and environmental health. It is also a sector with a diverse and healthy ecosystem that is becoming increasingly global. BIO strongly supports a U.S.-Japan Trade Agreement with an ambitious and comprehensive agenda and looks forward to engaging both the U.S. and Japanese government as the negotiations begin to take shape.

Sincerely,



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