



Docket # USTR-2017-0006

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 to modernize the North American Free Trade Agreement (NAFTA).

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 modernization of NAFTA as an opportunity to grow U.S. exports and create U.S. jobs. We would strongly prefer that the U.S. build upon, rather than renegotiate NAFTA, to improve the agreement for U.S. farmers, workers, and businesses. Further, all three national economies should ensure that NAFTA continues to evolve overtime without the need to re-open or modernize periodically. This is particularly true for regulating the biotechnology

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.*

industry – as advances in science continuously lead to new breakthrough therapies and cures and biological tools for farmers and industry.

BIO Priorities for the Modernization of NAFTA

Agriculture

The U.S. agricultural community has benefited enormously from the implementation of NAFTA commitments. Canada and Mexico, respectively, are the United States' second and third largest trading partners. Since 1994, U.S. exports to Canada and Mexico have grown from \$10 billion to over \$38 billion in 2016. For the biotechnology industry, the modernization of NAFTA presents an opportunity to partner with Canada and Mexico to create a model trade agreement to address modern agricultural biotechnology for both plant and animals.

Combined, the U.S. and Canada cultivate over 200 million acres of biotechnology crops. Regulatory authorities in the three countries review essentially the same data for each product application and each time arrive at the same regulatory decision – crops derived from modern biotechnology are as safe as their conventional counterparts. After 20 years of experience assessing crop biotechnology products, the three countries should approach NAFTA as an opportunity to streamline the process and costs of assessing food and feed safety. For example, since the inception of the industry, the three countries have collectively reviewed and approved 660 products.

With the Uruguay Round Agreement on the Application of Sanitary and Phytosanitary Measures as the basis, and advances made within the negotiations of the Trans-Pacific Partnership (TPP) related to agricultural biotechnology, the three countries should establish an ambitious negotiating agenda to provide for regulatory convergence and relief for agricultural biotechnology, particularly with respect to food and feed safety. Specifically BIO recommends the three countries establish mutual recognition of food and feed safety assessments. Further, as a block, the three countries should establish a common approach to managing Low-Level Presence (LLP), particularly as it relates to products authorized in a non-NAFTA country and a food and feed safety assessment has been completed.

Addressing asynchronous approvals remains a high level priority for the U.S. government. NAFTA presents a unique opportunity to partner with Canada to set the global standard for how trading partners should work together to streamline regulatory processes, align regulatory timelines, manage LLP and address future agricultural technology innovation.

Further, innovation in plant and animal breeding is based on increased understanding of plant and animal genomes and advances in the discovery of new desirable traits. Future innovation depends on sound, risk-based policies. Therefore the three countries should aim to achieve consistent policies to support agricultural innovation, and in particular, plant and animal breeding methods such as genome editing. The three countries should identify common objectives in this space and apply the necessary flexibilities as innovation evolves.

With regard to seed movement within North America, BIO encourages that each party follow the International Standard for Phytosanitary Measures for Seed (ISPM 38) which was ratified in April 2017 by the International Plant Protection Convention.

Intellectual Property

In general terms, the text of the TPP offers a good starting point for a modernized NAFTA IP chapter, but fell short in a number of areas of key importance to the biotechnology industry.

First, and most importantly, the TPP did not reach the **U.S. standards of data protection for biologic products (12 years)**. This remains one of BIO's top objectives in any future trade agreement. Any NAFTA modernization needs to align data protection in North America around the U.S. standard of 12 years, in accordance with Trade Promotion Authority Act requiring the U.S. government to leverage trade agreements to bring our trade partners in line with U.S. standards for intellectual property rights.

Second, the TPP failed to establish full patent subject matter eligibility for biotechnology innovations. For example, the TPP did not ensure patent eligibility for plant and animal innovations, and provided only limited success with respect to new process technologies. Our members are at the forefront of these fields of technology, and are entitled to secure patent protection for the full scope of their innovations.

Third, the TPP placed a number of inappropriate constraints on the ability of patent owners to secure a full term of effective patent exclusivity for their innovations. For example, it placed constraints on patent term adjustments for delays securing patents, and for patent term restoration for products subject to regulatory approval periods that reduce the effective term of patent rights.

The NAFTA modernization should rectify these shortcomings of the TPP standards, and implement within the NAFTA new standards that reflect the practical needs of biotechnology innovators.

In addition, BIO again draws attention to some important intellectual property issues in Canada and Mexico identified earlier this year in its 2017 "Special 301," which BIO now believes should be addressed and resolved as part of the NAFTA.

Canada-Patent Utility

Canada's approach to the so-called utility requirement of patentability is an anomaly in international patent law. It discriminates against biopharmaceutical inventions, creates significant uncertainty in the patenting process, and is generally inconsistent with Canada's international obligations.

The Canadian requirement that a patent demonstrate or disclose the basis of a sound prediction for the subjectively-construed "promise" of utility in the application at the time of filing is out of step with the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), NAFTA and the Patent Cooperation Treaty (PCT). Canada's utility requirements also stand in sharp contrast to practice in the United States. U.S. law requires that a patent specification disclose a specific, substantial and credible utility. For pharmaceutical inventions, in practice this standard is met by disclosing technical information supporting the specific, and scientifically plausible usefulness for the invention, which may be framed as identifying a particular a disease or illness that can be treated, or by identifying a biologically relevant mechanism that can be exploited using the invention for doing so.

Since 2005, Canada's onerous utility requirements, which are unique to Canada, have caused approximately 25 patents for plainly useful pharmaceuticals to be invalidated for lack of utility.⁴ Canada's burdensome utility test imposes substantial uncertainty as to how much work must be performed and disclosed when a patent application is filed. Further, it is nearly impossible to predict how a court will interpret the "promise" of the patent in litigation that occurs many years after the filing of an application and the grant of the initial patent.

Canada's practices cannot be reconciled with the existing NAFTA standards, which require the patent applicant to only identify a utility for the invention. The NAFTA renegotiation exercise should clarify the utility standard to foreclose use of unreasonable and uncertain standards for measuring utility of an invention

Canada-Right of Appeal in PM(NOC) Proceedings

The Patented Medicines (Notice of Compliance) regulations create a process and a forum to resolve patent infringement issues and validity between generic and brand companies as part of the early working regulatory exception to patent infringement in the Patent Act (Section 55.2). However, the regulations at a very practical level provide unequal appeal rights in favor of the generic company. A generic company can appeal the decision in a Notice of Compliance proceeding, but an innovator cannot. Any changes to rules surrounding PM(NOC) proceedings must acknowledge that even with a patent infringement action under the current procedure, complete redress remains illusory. This imbalance should be rectified through appropriate changes to the data protection standards and/or the provisions governing judicial and administrative procedures.

Canada-Injunctive Relief

Canadian jurisprudence takes the view that monetary damages are sufficient compensation in patent infringement cases – making injunctive relief rarely if ever available. Interlocutory injunctions to prevent market entry are rarely granted. Even if the biopharmaceutical patentee prevails, there is a significant loss of reasonable opportunities to enjoy the full benefits of the patent. BIO urges Canada to revisit the remedies available to innovators and make injunctive relief pending the outcome of litigation more readily available.

Canada-Patent Term Restoration and Regulatory Data Protection

Canada lacks patent term restoration which restores the loss to patent term caused by lengthy clinical trials and the regulatory approval process. USTR should also insist that any implementation of PTR that does not confer full patent rights, e.g., that would provide an exception for "manufacturing for export" or other infringing activities, should not be allowed as this would not be consistent with the fundamental purpose of restoring patent term lost due to marketing approval delays. Likewise, there exists in Canada no meaningful ability to mitigate the effects of wrongful generic entry on the basis of a court's application of incorrect principles

4

http://www.canadianpatentutility.org/sites/default/files/uploads/canadian_federal_court_decisions_revoking_pharmaceutical_patents_based_on_inutility_5.2.16.pdf.)

of law. Damages or profits are often poor compensation for the loss of the innovator's market position following generic entry.

Canada should also provide for three years of Regulatory Data Protection for new clinical information submitted to secure marketing approval of a previously approved pharmaceutical product covering a new indication, new formulation or new method of administration.

Mexico-Patent Term Restoration

Mexico does not have provisions in domestic law providing for patent term extensions or supplementary term certificates to compensate lost patent term due to delays from the regulatory authority in approving drugs covered by patents. Consequently, innovative biopharmaceutical companies are unjustly deprived of their patent term and exclusivity period for their innovative product in violation of NAFTA Article 1709.

Mexico-Patent Infringement Adjudication

Furthermore, when faced with generic entry in Mexico, extensive periods of time pass before patent infringement cases are decided. Member companies report that IP enforcement cases proceed in two stages before the Mexican Patent Office that can last 4-5 years. Two additional appeal stages then follow before a final decision is made in the case. This problem is particularly acute as the possibility to recover damages is delayed until after all appeals are exhausted. Even then, innovators are not allowed to receive damages in court and must initiate a second proceeding before a civil court to receive a damage award. While some may argue that injunctions prevent this problem, the infringer can post bond without providing evidence of non-infringement and have the injunction lifted and allow the infringing products to remain on the market. This causes extensive delay that can last up to 10-12 years between initiation of proceedings and recovery of damages. This process which effectively makes patents unenforceable is extremely costly and inequitable to innovative companies, and particularly harmful to small companies.

Mexico-Patent Linkage

Linkage between the regulatory agency and the patent office only covers patents that claim a pharmaceutical active ingredient per se. Several court decisions have ordered the publication of formulation and use patents to satisfy linkage requirements but the patent office refuses to publish these patents without litigation and the regulatory agency has shown reluctance to observe these patents. Normally, patents are only included in the linkage gazette when the patentee requests it. The linkage system provides a process in which COFEPRIS (Mexican Sanitary Regulatory Agency) consults IMPI on whether a specific generic infringes on an existing patent.

Mexico-UPOV 1991

Mexico is not a signatory to the International Union for the Protection of New Varieties of Plants (UPOV)'s 1991 convention. UPOV establishes guidelines for intellectual property protection for new plant varieties. Considering Mexico plays an important role in the production of seed, IP protection is essential to ensure companies can protect inventions.

Therefore, BIO strongly recommends that the U.S. government encourage Mexico to accede to UPOV 1991, in line with all U.S. free trade agreements since NAFTA.

Market access for bio-pharmaceuticals

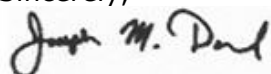
BIO welcomes progress made in recent U.S. bilateral trade agreements, in particular with Australia and Korea, to require transparency and accountability of foreign government pricing and reimbursement of biopharmaceuticals, to ensure market access and reward for innovation. BIO believes that to ensure 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 NAFTA modernization should build on these provisions. Such provisions should include clear timetables for pricing and reimbursement decisions, clear justifications given for government decisions, the right to appeal decisions to an independent body, and provisions that ensure fair reward for innovative products.

With respect to Mexico, BIO members find that upon obtaining marketing authorization from the Mexican regulatory authority, Cofepris, for a new drug, the drug does not automatically get listed on the national formulary list. The Mexican social security agencies, the Ministry of Health and state agencies must purchase drugs from the national formulary. Committees that update the national formulary have delayed inclusion of innovative drugs. For example, additional information on safety and efficacy of drugs has been requested, ultimately amounting to a de novo marketing authorization regulatory review. Given that these drugs had already been reviewed by Cofepris, this amounts to nothing more than a tactic to prevent innovative biotherapeutics from being listed on the national formulary and, ultimately, to prevent these drugs from being purchased. Thus, patient health is compromised by not allowing for access to the most innovative biotherapeutics at the expense of economic policies. This sort of market distortion of the biopharmaceutical sector in Mexico is yet another example of an area where modernization of NAFTA will help to create a stronger North-American economy and public health system.

Conclusion

Modernization of the NAFTA offers the United States a unique opportunity to build upon the success of NAFTA, particularly in agriculture, and update critical provisions, such as Intellectual Property to establish a model 21st century trade agreement. BIO appreciates the opportunity to comment and commits to working with the United States government and partner associations in the United States as well as Canada and Mexico to expand on these comments as the process to modernize NAFTA evolves.

Sincerely,



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