



Joseph Damond
Senior Vice President, International Affairs
Biotechnology Industry Organization
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Good afternoon. My name is Joseph Damond. I am Senior Vice President for International Affairs at the Biotechnology Industry Organization, or BIO. BIO represents nearly 1000 small, medium-sized and large companies engaged in biotechnology research and development in the healthcare, industrial, environmental and agricultural areas, accounting for more than 1.6 million high-tech, well-paying jobs across the country.

Currently, there are more than 250 biotechnology health care cures, treatments, and vaccines available to patients, many for previously untreatable diseases, with nearly a thousand more under active development. More than 18 million farmers around the world use agricultural biotechnology to increase yields, prevent damage from insects and pests and reduce farming's impact on the environment. And more than 50 biorefineries are being built across North America to test and refine technologies to produce biofuels and chemicals from renewable biomass, which can help reduce greenhouse gas emissions.

Today, I am here primarily to represent the interests of BIO's several hundred members engaged in research and development into new medicines. These members have been deeply interested in the TPP negotiation since its inception because their future depends upon it. The medicines BIO members develop are intended to treat patients around the world, but if TPP falls short,



they will have neither the resources nor the incentive to bring those new medicines to many patients in need.

BIO's general position with respect to TPP has been simple: the Administration should follow the guidelines set by Congress earlier this year when it enacted Trade Promotion Authority. With respect to intellectual property, TPA directs the Administration to seek protections similar to those enshrined in U.S. law. The most important and fundamental protection for BIO members is the term of data protection for biologic products. Biologics are drugs synthesized by living cell lines, rather than using the traditional method of chemical synthesis. The data protection period is the period during which no other company can rely on the clinical trial data, which an innovator company has typically spent hundreds of millions of dollars or more to develop, to obtain regulatory approval to sell a similar competing product.

The U.S. standard of data protection for biologics was set at 12 years in the Affordable Care Act in 2010. This period in fact was approved by strong bipartisan majorities in the Committees of jurisdiction after robust debate. Before 2010, companies seeking approval for imitator biologics similar to those already approved had to submit a full dossier of clinical trial data to the FDA, as if these biosimilars were brand new medicines. To encourage competition, the ACA established a new regulatory "pathway" for biosimilar products that allowed competing companies to, in effect, rely on the clinical trial data developed by an innovator company to abbreviate their own development program.

Congress recognized, however, the importance of maintaining incentives for innovator companies to research new medicines. Accordingly, after a rigorous analysis of the average period of patent protection on traditional chemical medicines that remains after FDA approval under the successful Hatch-Waxman Act, Congress sought to mirror that experience and set the period of data protection for biologics at 12 years.



One may then ask, why can't biosimilar medicines simply rely on the patent protection they too have? The reason is that, whereas chemical generics are exact copies of the original medicines, biosimilars are, by definition, similar, not identical, to the original molecule patented. That means that for biologic medicines – which are far more complex and often far more difficult to develop and manufacture – patents may provide less certain protection against biosimilars than they do against true generic competitors.

Moreover, biologics often are said to represent the future of personalized, genomic-based medicine. This is where the technology and the science are taking us. All the 12 year protection period does is create a level playing field for biologics when compared to the 20-year period of patent protection that we have long had for chemical medicines, and to which all TPP countries committed when the World Trade Organization was created in 1995.

Coming back to TPP, allowing other countries to adopt a period of protection shorter than 12 years means two things. First, it will upset the balance that has worked so well for chemical medicines between incentivizing the development of new biologic medicines and creating biosimilar competition. And second, it will allow foreign competitors to appropriate U.S. technology more quickly, effectively free-riding on U.S. research and development costs. That will be especially harmful if TPP becomes the global standard the Administration hopes it will.

Some parties have expressed concern that a 12-year period in TPP could limit access to these new biologic medicines. To this, I would respond in several ways. First, again, this level of protection essentially replicates the level of patent protection adopted by TPP members over 20 years ago when the World Trade Organization was created. Since that time, the market for both generic *and* innovative chemical medicines has grown at an explosive pace, and by virtually any measure, access to both new and older chemical medicines around the world is much greater. There is every reason to believe that



adopting the U.S. standard for biologics data protection would have a similar effect for biologic medicines.

Second, BIO members are working with developing country governments every day to arrive at deals that permit new medicines to be introduced to their populations in a sustainable manner. BIO and its member companies are committed to finding ways to improve access to new medicines, including through increasing the technical capacity of regulatory agencies to efficiently assess and approve new medicines and through creative contracting and distribution mechanisms.

Finally, it is our industry's hope to find partners in developing and other countries that can help us find solutions to unmet medical needs. But for this to happen, universities and researchers in these countries will need the economic incentives to engage and partner in such research. They will need a level of intellectual property protection akin to the one that has created the world's leading biotechnology industry here in the United States.

We believe that these are viable, proven solutions to the problem of access that do not involve the forfeit of good American jobs or the uncontrolled expropriation of U.S. technology.

Thank you.