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July 31, 2017

Edward Gresser
Chair of the Trade Policy Staff Committee
Office of the United States Trade Representative
600 17th Street, N.W.
Washington, DC 20508

Re: Comments in Response to Executive Order Regarding Trade Agreement Violations and Abuses

Dear Mr. Gresser,

Mylan welcomes the opportunity to submit written comments on the Administration's Reviews and Report to the President on Trade Agreement Violations and Abuses. Mylan appreciates the Administration's commitment to maximize exports while increasing competition in the pharmaceutical market to lower prices thus fostering patients' access to more affordable life-saving drugs.

Founded as a small company in West Virginia more than 55 years ago, Mylan today is one of the world's largest generic and specialty pharmaceutical companies with products in more than 165 countries and territories. We market a growing portfolio of more than 7,500 products around the world, including antiretroviral therapies on which approximately 50% of people being treated for HIV/AIDS in the developing world depend. In the U.S., one out of every 13 prescriptions dispensed, brand or generic, is a Mylan product. The growth of our company has also been reflected in the expansion of our labor force, as Mylan now has a workforce of more than 35,000. Nearly 80% of Mylan's products sold in America are manufactured at a Mylan U.S. site.

Critical Role of the Generic Drug Industry in the U.S.

Our significant growth has been propelled on the back of the Hatch Waxman Act of 1984 which created a carefully balanced legal and regulatory system designed to *both* promote innovation *and* spur competition from generic medicines. Prior to Hatch-Waxman, only 35% of top-selling drugs faced generic competition whereas today nearly 90% of prescriptions dispensed in the U.S. are generic.

The generic pharmaceutical industry plays a key role in providing critical savings to strained state and federal healthcare budgets. The Hatch-Waxman Act, and the wave of generic approvals it helped to facilitate, is one of the great legislative achievements of the past half-century. Since its approval in 1984, the Hatch-Waxman Act has resulted in the

approval and entry of over 10,000 lower cost generic drug products.[1] Generic drugs have been saving American consumers trillions of dollars, increasing from $8-10 billion of savings in 1994 alone[2] to $253 billion in 2016; in fact, from 2007 to 2016 generic drugs saved consumers $1.67 trillion.[3] Mylan is proud of its leading role in delivering generic savings to consumers and taxpayers in the U.S. Over the last decade, Mylan's average share of the generics prescriptions market was 11.2%, translating to approximately $187 billion in savings for U.S. patients and taxpayers.

The "2017 Generic Drug Access and Savings in the United States Report" conducted by IMS reiterates the important role generic companies play in providing patients access to high quality, affordable medicines, with generics representing 89% of prescriptions dispensed in the United States, but only 26% of total drug costs.[4] Generic drugs also generate substantial savings for government payors; for example, the U.S. Department of Health and Human Services found that in 2014 77.5% of Medicare Part D prescriptions were filled with generics while only accounting for 23% of spending.[5]

Key Trade Policy Considerations

Our company, like others in the generic industry, has experienced significant growth and transformation over the past 10 years as Mylan achieved global reach. Furthermore, Mylan invested approximately $4.2 billion in research and development ("R&D") between 2007 and 2016, and intends to continue making significant R&D investments in the future. Moreover, Mylan has more than 4,000 patents (granted and pending) for numerous investments we have made in science and innovation.

We understand the importance of rewarding the investment needed to innovate but believe such incentives should be carefully and meaningfully balanced against the need for competition and access. As one of the world's largest makers of generic and specialty medicines, Mylan is committed to supporting trade agreements negotiated by the U.S. that strike a balance between promoting innovation and ensuring the expedited launch of generic and biosimilar drugs. Like the Association for Accessible Medicines, Mylan strongly believes that U.S. trade policy provisions and efforts should 1) encourage trade and export provisions that will enhance the ability of generic and biosimilar

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[1] Interview by Tammie Lee Demler with Ralph G. Neas, President and CEO, GPhA (June 23, 2015), *available at* https://www.uspharmacist.com/article/interview-with-ralph-g-neas-president-and-ceo-gpha.

[2] Cong. Budget Office, 105th Cong., How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry (1998) at xi, *available at* https://www.cbo.gov/sites/default/files/105th-congress-1997-1998/reports/pharm.pdf.

[3] Association for Accessible Medicine, 2017 Annual Report *available at* http://accessiblemeds.org/wp-content/uploads/2017/02/AAM-Annual-Report-2017.pdf.

[4] "Generic Drug Access and Savings in the United States Report," IMS (2017).

[5] Dep't of Health & Human Servs., Report to Congress: Prescription Drugs: Innovation, Spending, and Patient Access (Dec. 7, 2016), *available at* http://apps.who.int/medicinedocs/documents/s23128en/s23128en.pdf.

manufacturers to access markets globally, and 2) spur greater generic and biosimilar competition to drive even greater prescription drug savings to U.S. patients and taxpayers.

Our company, like the others in the generic industry, is proud of our contribution to increasing access to affordable drugs. Our growth also has a significant positive impact on the creation of jobs and exports as we continue to expand into foreign markets. Moreover, while today countries like the U.S. are important mature pharmaceutical markets, the biggest growth rates are in foreign markets including the so-called "pharmerging" markets. Since these markets are so critical to the future of Mylan and our mission of expanding access to medicine globally, it is essential that future trade agreements or the renegotiation of existing ones have balanced intellectual property ("IP") and regulatory provisions. If IP standards continue to be ratcheted up globally, they could become barriers to entry for generic and biosimilar products like ours, thus negatively impacting our ability to grow and the creation of new jobs here in the U.S.

For the most part, the trade agreements of the last few decades have had a negative impact on the generic/biosimilar industry. As the Administration considers reviewing some of the existing trade agreements and moves forward with the negotiation of new ones, it is essential that U.S. trade policies fully account for the evolved landscape of the U.S. pharmaceutical industry and the global marketplace. It is also necessary that these agreements represent the interests of the generic pharmaceutical industry in addition to the interests of the originator pharmaceutical industry. Trade agreements must strike a better balance between promoting innovation and ensuring patients' expedited access to affordable drugs. If balance is not restored, or worse, if the imbalance continues to be deepened, it would put at risk the future of the generic/biosimilar industry, and therefore impact consumers and strained health care budgets in the U.S. as well.

Nearly thirty years ago, an effort was launched to ensure that countries throughout the world were contributing to the cost of research and development for new drugs. At the time, few nations had intellectual property laws granting protection to pharmaceuticals. That changed dramatically with the adoption of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), part of the Uruguay Round of GATT (General Agreement on Tariffs and Trade), which set the global standard for the protection of IP rights. While originator pharmaceutical companies have always argued that TRIPS set the floor, the protection granted is actually high. For instance, TRIPS grants patent terms that are longer than those that were in force at the time in the U.S. Until then the patent term was 17 years from the date of granting of a patent, and TRIPS mandated a minimum term of 20 years from the date of filing of the patent.

The implementation of this new standard had a profound impact on the U.S. generic pharmaceutical industry, consumers and health care expenditures. In the case of Mylan, we had to delay the launch of drugs that were in the pipeline and about to enter the market, which had a direct and immediate impact on our business. This provision alone continues to affect every single drug that has associated patents. To achieve the goals of the Administration in promoting greater competition in the U.S. pharmaceutical market

as a means of addressing high drug costs, it will be critical to ensure that any trade agreements the U.S. is involved with do not further increase and broaden protections for originator pharmaceutical companies to the detriment of timely access to generic medicine.

As stated above, Mylan has significant investments in R&D, so we understand the need to require that countries contribute to the costs of researching and developing new drugs. The data show that this was achieved with the adoption and implementation of the TRIPS Agreement.[6] It is very problematic that, since then, the originator pharmaceutical industry has sought to ratchet up IP protection in other markets, particularly through the negotiation of trade agreements. Apart from the 2007 bipartisan New Trade Policy (May 10th Agreement) that was reflected in the bilateral trade deals with Colombia, Panama and Peru, these agreements have systematically failed to strike a balance, granting originator pharmaceutical companies broader and longer monopolies at the expense of generic/biosimilar companies and consumers. Unfortunately, the Trans-Pacific Partnership (TPP) deviated from the New Trade Policy.

Unlike with other industries, the international trade of pharmaceuticals with most countries with which the U.S. has concluded agreements in the last 20 years has resulted in a healthy surplus for our economy. In contrast to other sectors where there has been a consistent deficit, global trade in pharmaceuticals has experienced the opposite.[7] This is yet another reason why it is not necessary to continue to pursue ever increasing levels of intellectual property protection.

Restoring balance to IP negotiations to maximize U.S. exports of pharmaceuticals

As mentioned above, Mylan believes that the New Trade Policy, the bipartisan agreement negotiated under President Bush, should be the template for future trade agreements. Although it has TRIPS Plus provisions, it strikes an effective balance between fostering innovation and competition.

Furthermore, bearing in mind the President's goal of fostering the affordability of life saving drugs, where competition plays a critical role, Mylan would like to put forward some suggestions that would complement the New Trade Policy to achieve such a goal:

[6] A 2016 Report released by the U.S. International Trade Commission shows the increasing contribution of countries that implemented the TRIPS Agreement. For instance, the estimated increase in 2010 U.S. IP receipts due to increases in patent protection (1995-2010) is quite significant: India 140.1%, China 106.6%, Brazil 96.7%, Philippines 58.3%, Argentina 54.3%, Indonesia 52.1% just to mention a few. In other words, members of the WTO that have implemented the TRIPS Agreement are not free riders but are contributing to R&D. Therefore, the renegotiation of old agreements and/or the negotiation of new ones should not seek to ratchet up IP protection standards. Economic Impact of Trade Agreements Implemented Under Trade Authorities Procedures, 2016 Report (June 2016), at 132.
https://www.usitc.gov/publications/332/pub4614.pdf.

[7] Imports and exports data. https://www.census.gov/foreign-trade/statistics/product/enduse/index.html.

- *Incentives:* Inclusion of incentives for those that successfully challenge the validity or enforceability of a patent. While patents are important to promote innovation, they must reward real innovation. Companies sometimes engage in evergreening strategies to extend their monopolies and delay competition so it is essential that future trade agreements provide incentives for others to challenge the validity or enforceability of patents.

- *Bolar-type provision*: Inclusion of a mandatory and robust Bolar provision to allow the generic and biosimilar industry to work on the development of their drugs during the term of a patent for regulatory registration purposes. Failure to do so would delay generic/biosimilar competition.

- *Biologics*: The U.S. should not be locked into long exclusivity periods for biologic drugs. These are the newest and most expensive drugs in the market with some of them costing several hundred thousand dollars per patient per year, which prevents patient access and further strains healthcare budgets. For instance, the Medicare spending on just five biologics – Avastin, Herceptin, Neulasta, Remicade, and Rituxan – was a total of $5.47 billion in 2014.[8] It is crucial that the Administration seek provisions that ensure the development of both originator biologics and biosimilar drugs to address the high prices of biologics. While the U.S. Congress adopted a 12-year period of exclusivity for biologic drugs, the Federal Trade Commission has indicated that such exclusivity is not necessary.[9] Because this industry is new, it is still too early for anyone to fully predict how it will develop. Thus, Mylan believes that it would not be in the interest of the U.S. to enshrine in a trade agreement a long period of exclusivity that may restrict competition for these extremely expensive drugs and potentially disincentivize the costly development of biosimilars. The U.S. should preserve its ability to adjust the exclusivity period if necessary in the future.

- *"Best Mode"*: The disclosure of the "best mode" known to an inventor should be mandatory for the patentability of an invention as well as a ground for challenging the validity of a patent. This provision, which is in U.S. law, is very important, particularly for the development of biosimilar drugs.

- *Misuse of Patent Rights:* As there are penalties for those that infringe a patent, there should be penalties for those who misuse their rights simply to delay competition, i.e., with frivolous litigation or other evergreening practices.

- *Streamlining regulations*. In addition, it would be important that any revision of trade agreements or the negotiation of new ones seek to streamline regulatory

[8]Can Biosimilar Drugs Lower Medicare Part B Drug Spending (January 2017), at 3-4. http://www.pewtrusts.org/~/media/assets/2017/01/leveraging-biosimilars-to-lower-medicare-part-b.pdf.
[9] Emerging Health Care Issues: Follow-on Biologic Drug Competition (June 2009), at vi-vii. https://www.ftc.gov/sites/default/files/documents/reports/emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commission-report/p083901biologicsreport.pdf.

provisions for pharmaceuticals to prevent delays in the approval of drugs, much as the Administration is working to do in this country.

In conclusion, Mylan appreciates the opportunity to provide comments on this important topic. Mylan strongly believes that the Office of the USTR should adjust U.S. trade policies to maximize U.S. exports of pharmaceutical drugs and avoid the adoption of provisions that will serve as a barrier to entry for generic/biosimilar products. This is needed to ensure the sustainability of the generic/biosimilar industry which is key to ensure safe, effective, and affordable drugs in the U.S.

Mylan looks forward to working closely with the USTR and the Administration on fair and balanced trade policies that protect U.S. interests both here and abroad. If we can provide additional information on any of the matters raised within, please do not hesitate to contact us.

Sincerely,

Marcie E. McClintic Coates
Head of Global Policy