Statement for the Record by

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Using Trade Rules to Level the Playing Field for
U.S. Companies and Workers

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Chairman Wyden, Ranking Member Hatch, Honorable Members of the Finance Committee, ladies and gentlemen. I greatly appreciate the opportunity to testify before you today on a matter of great importance to my company, Eli Lilly and Company, our industry, and all U.S. businesses involved either directly or indirectly in trade.

My name is Bart Peterson, and I am the Senior Vice President of Corporate Affairs at Lilly. Since our founding by Col. Eli Lilly in 1876, we have been committed to discovering solutions to the world's most pressing health challenges. More than a century later, we remain true to our founding family's vision and values – to create high-quality medicines that make life better for people here and around the world with integrity, excellence, and respect for people.

Trade is essential for our success. A fair and transparent set of trade rules across the globe is fundamental to our ability to bring medicines to people who need them. Those rules must be enforced, and the U.S. Government must have the tools and resources necessary to enforce them.

We rely on U.S. trade policy not only to open new markets, but also to enforce existing obligations with our trading partners – whether through bilateral or multilateral trade agreements. Where enforcement is weak, slow, or does not exist, we struggle to level the playing field against state-owned enterprises, unfair domestic competition, and outright theft of our intellectual property.

While Congress has granted U.S. trade agencies and the Administration a number of tools to help enforce trade agreements and protect the rights of U.S. companies abroad, we welcome the Committee's efforts to measure and modernize those tools. We are concerned that the market access provisions of Special 301 in particular are not given as much weight as the IP provisions. We feel strongly that a lack of market access diminishes our IP rights, and Special 301 should reflect that reality. We also hope that the Committee will continue to consider how to make the enforcement of Special 301 more robust. We have the utmost respect for the work of the staff of USTR, handling numerous complex and challenging issues with professionalism and considerable skill. Some of the concerns related to enforcement relate to limited resources at USTR and other agencies, but overall, in complicated sectors such as ours and other IP-intensive industries, we could use better tools to address the market access, counterfeiting, and IP

challenges we face.

While enforcing compliance with the provisions of existing trade agreements is fundamental, it is equally important to have the highest standards enshrined in new agreements. We also encourage the Committee to work diligently to pass Trade Promotion Authority. We respect the Chairman's goal to build consensus around TPA language before it moves forward, but we hope that Congressional leaders will bear in mind that the world is watching. Not having TPA hurts the ability of our negotiators to get the best deal possible in TPP and TTIP. The bi-partisan TPA bill introduced earlier this year addressed a number of important issues for our sector, including new enforcement tools, strong language on IP, a commitment to ensuring fair processes regarding pricing and reimbursement of our medicines, and safeguards against forced localization and protectionist policies. We hope that any future versions of TPA legislation will be equally strong on these important provisions, and we look forward to working with the Committee and Senate leadership on getting TPA passed as soon as possible.

Intellectual property is the lifeblood of the pharmaceutical sector, and its protection is one of our most pressing trade issues. We welcome Chairman Hatch's proposal to create the position of Chief IP Negotiator at USTR. Nowhere is the need for strong language to protect IP more important than in the Trans-Pacific Partnership (TPP). To achieve the negotiating objective of having a high-standard, 21st-century agreement, it is critical that the final TPP has pharmaceutical IP provisions equal to KORUS and U.S. law, including 12 years of data exclusivity for biologics. We commend USTR for pressing for these standards, as well as Japan for its support for them. Whether or not China and India ever become TPP members, it is clear that the standards that are set in TPP will be the new global ceiling. With this in mind, it is critical that we work closely together on both sides of the Pacific to ensure that the final TPP has the highest pharmaceutical IP standards, including 12 years of data exclusivity for biologics. On TTIP, we strongly favor an ambitious, comprehensive, and high-standard trade and investment agreement. Lilly and the pharmaceutical industry believe that TTIP represents a unique opportunity to promote the highest standards of intellectual property protection, market access, and regulatory coherence. For the IP-driven sectors in which the EU and U.S. enjoy a global advantage, in particular, we believe the two governments should use TTIP to work together to maintain and strengthen that advantage.

We are not naïve to the politics and controversy regarding our industry and trade. I spend a lot of time in Geneva dealing with stakeholders, including many critics of our industry, and I am very familiar with their arguments in the area of intellectual property. As a company, we believe firmly that IP is not an impediment to access to medicines in emerging economies or the developing world. The good work of many global groups to provide access to medicines in LDCs, often with the support of companies like Lilly, must be accompanied by commitments by governments in these nations, civil society, and the private sector to address fundamental gaps in basic care, diagnosis, technology, trained medical staff, and healthcare infrastructure. We hope that negotiations on issues such as data exclusivity in TPP will be on their own merits and not confused with the very real issues at play in global health. We believe that innovation and new medicines are part of the solution to these problems and have demonstrated our willingness to be long-term partners around the world in this area.

From an international business perspective, I wanted to take the opportunity to briefly describe a diverse set of examples of why trade enforcement is so important to us. But I wanted to begin with describing what trade means to my company and my state. While we are a global company, our headquarters, and one might say our soul, is in Indiana. In that state alone, thousands of small- and medium-sized businesses depend on the financial health of Lilly. It is sometimes said, “When Lilly catches a cold, the State of Indiana gets ill."

While many of these businesses, from our lawn care providers, to our caterers, to our suppliers of sundry goods, as well as high-tech lab equipment, are not large enough on their own to trade with the world; make no mistake that the success of our global business helps support them. Every lost dollar of revenue due to unfair competition, questionable legal decisions, protectionism, or counterfeiting has an effect on the local economy. This is why trade enforcement and high-standard agreements are so fundamentally important.

Here are some prime examples of the need for strong enforcement with which many of the Committee members may be familiar. They run the gamut from developed to emerging economies, and they all massively impact our business:

CANADA:

Since 2005, Canadian courts have struck down 20 pharmaceutical patents, including three Lilly patents, for lack of “utility" or usefulness. This has resulted in more than one billion dollars in estimated lost revenue to our industry. Domestic generic companies in Canada have then been allowed to copy these clearly useful drugs.

Canada is the only country in the world using this heightened utility standard, which we believe is in violation of their trade obligations under both NAFTA and TRIPS. Enforcing Canada’s international obligations in this area should be a priority.

INDIA:

As this Committee well knows, in recent years the innovative biopharmaceutical industry has faced significant challenges in India in protecting the intellectual property that supports our industry’s innovations. Indian administrative and judicial decisions have undermined intellectual property in ways that are inconsistent with India’s WTO commitments. Since 2012, at least 15 new medicines have had their patent rights violated. This includes the use of a compulsory license, patent denials under Section 3(d), unwarranted pre- and post-grant oppositions, revocations and infringements of patents, and lack of regulatory data protection. We greatly appreciate the efforts of the U.S. Congress and Administration to raise these issues at the highest levels, as well as constructive plans to continue doing so with the new Indian Government. Secure IP protections, consistently enforced, are aligned with Prime Minister Modi’s goals of bringing growth to India through research, innovation, and manufacturing. There is a strong, positive, and well-recognized correlation between foreign direct investment inflows and reliable IP regimes. For these reasons, we are hopeful that the innovative industry and the U.S. Government will be able to engage in a renewed dialogue with the Indian Government on these issues and work productively toward solutions that will improve patient access to lifesaving medicines and healthcare overall without weakening the IP protections that incentivize their discovery. We urge the U.S. Government to encourage the new Indian Government to use this

opportunity to demonstrate respect for, and fair enforcement of, global IP rules.

CHINA:
When China joined the WTO, it committed to provide six years of protection against "unfair commercial use" of data submitted to the regulatory agency in the approval of new chemical entities. However, China defines "new" as "new to the world." This unique interpretation nullifies the data protection because it allows non-innovators to rely on an innovator's approval outside of China in the approval of un-authorized copies in China. As a result, commercially significant products face unfair competition from un-authorized copies, sometimes even before the innovator is able to enter the Chinese market. To further undermine its commitment, China does not consider biologically synthesized drugs within the scope of new chemical entities. This is not only inconsistent with common international practices, but it also stands to undermine the protection of the next generation of important medicines.

KOREA:
In the Korea-US Free Trade Agreement (KORUS), Korea agreed to "recognize the value of patented pharmaceuticals." However, certain Korean Government pricing practices fundamentally conflict with this commitment. Under Korea's universal healthcare system, the government sets the prices for new, patented pharmaceuticals by referencing the prices of similar products on the market – including the prices of generics and off-patent originators. Referencing the prices of such old products fails to recognize the value of the significant investment it takes to develop and bring new patented medicines to market.

CHILE:
Chile has so far reneged on implementation of its pharmaceutical IP commitments as part of the US-Chile Free Trade Agreement. This lack of commitment to implementing agreed-upon policies is worrisome and should be of great concern to USTR and this Committee as it pertains to high standards in trade agreements.

This may seem like a laundry list, but because our sector often bridges the gap between the public and private portions of most healthcare systems, we are unusually susceptible to increases in protectionism, the power of state-owned enterprises, a lack of transparency in decision making, and "creative" interpretations of IP standards. For innovation to thrive and for the U.S. to maintain its competitive advantage in innovative sectors, we need robust enforcement of trade obligations, as well as new trade agreements to open markets and create a high standard for rules related to trade.

ANTI-COUNTERFEITING
Without a doubt, counterfeiting is the most serious form of trademark infringement impacting both consumers and private companies like Lilly. Moreover, counterfeiters steal jobs from legitimate workers and avoid paying needed revenue amounting to approximately $30 billion annually. Most importantly, counterfeit medicines can be deadly. Counterfeit medicines have not been approved by the Food and Drug Administration for safety or efficacy and are a hazard to the health and safety of the nation. Unfortunately, the current laws have had limited effect in stopping this counterfeit trade, and Lilly supports stronger enforcement measures to better combat this problem. One positive example of international cooperation is Operation Pangea – a

collaboration between law enforcement, customs, and regulatory authorities from 111 countries to identify the makers and distributors of illegal drug products and medical devices. This collaboration has successfully targeted internet sales and worked to remove these dangerous products from the supply chain. More needs to be done because the problem is massive – there are approximately 35,000 rogue online pharmacies worldwide. Lilly supports U.S. Government efforts to expand international cooperation in this important area.

In closing, Mr. Chairman, I would like to compliment the work that your Committee and staff have done with the White House and USTR to continue to put advancing trade and enforcing the rights of U.S. companies front and center. Lilly looks forward to working with you on improvements to U.S. trade policy and enforcement to the benefit of our economy and our citizens.

Thank you.