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Ms. Susan F. Wilson
Director for Intellectual Property and Innovation
Office of the United States Trade Representative
600 17th Street, N.W.
Washington, DC 20503

Ref: Docket No.: USTR-2014-0025

Dear Ms. Wilson:

The National Association of Manufacturers (NAM) welcomes the opportunity to provide these written comments for the 2015 Special 301 Review. The NAM is the largest manufacturing association in the United States, representing businesses of all sizes in every industrial sector and in all 50 states. Manufacturing employs more than 12 million women and men across the country, accounting for two-thirds of private sector research and development and contributing over $2.08 trillion to the U.S. economy annually.

The NAM's comments highlight the growing importance of intellectual property rights (IPR) for manufacturing. They identify foreign countries that deny adequate and effective protection of intellectual property rights and note emerging cross-cutting concerns, including the lack of effective trade secrets protection and enforcement around the world and IPR erosion in a range of international fora. To address these challenges, the United States must use all available tools, including opportunities through global, regional and bilateral negotiations.

For the reasons explained further below, the NAM recommends that China, India and Russia remain on the Priority Watch List. The NAM further recommends that the Office of the U.S. Trade Representative (USTR) conduct an Out-of-Cycle Review (OCR) of India in 2015 to evaluate concrete progress toward and results achieved in addressing longstanding IPR challenges in that country. The NAM urges increased attention to new and continuing concerns with Canada's IPR protection and enforcement regime.

1. Importance of IPR for Manufacturing

Innovation drives and supports U.S. global leadership in manufacturing. The value of patents, trademarks, copyrights and trade secrets to the U.S. economy is rising faster than ever before, from $5.5 trillion in 2005 to more than $9 trillion in 2011. Intangible assets like these now account for at least 90 percent of the total market value of ten industries. Those industries include not only traditional science, IT and R&D intensive sectors like pharmaceuticals and telecommunications, but also food and beverages, personal care products, and automobiles.[1]

[1] Hassett, Kevin A. and Robert J. Shapiro, "What Ideas are Worth: The Value of Intellectual Capital and Intangible Assets in the American Economy," September 2011.

Strong IPR protection and enforcement provide powerful incentives for solutions to global challenges, including increasing energy efficiency and delivering the next generation of lifesaving medications. Where IPR is protected and enforced, innovators thrive – creating and sustaining jobs and promoting international trade. According to the Department of Commerce, innovative industries directly support more than 27 million jobs across the country. In 2010, they accounted for more than 60 percent of all U.S. merchandise exports.[2]

But today, intellectual property rights are under threat around the world. A report by the Commission on the Theft of Intellectual Property found that stolen ideas, brands and inventions drain more than $300 billion from the U.S. economy.[3] In fiscal year 2013, U.S. Customs and Border Protection seized counterfeit and pirated goods worth more than $1.74 billion at America's borders.[4] China remains the leading source of these products, which include medicines, auto parts, toys and other goods that could pose serious health and safety risks.

To help meet this challenge and stop unfair competition from the use of stolen intellectual property, the NAM has joined more than a dozen other business associations and some 275 manufacturers across the country to form the National Alliance for Jobs and Innovation (NAJI) (http://naji.org). By addressing the unfair cost advantage that results when foreign manufacturers use pirated software and other stolen intellectual property, NAJI hopes to increase awareness and ensure a level playing field for businesses in the United States.

2. Country-Specific IPR Threats

Manufacturers in the United States face serious obstacles to adequate and effective IPR protection in India, China, Canada and other large and emerging markets. The significance and rapid growth of these economies present great opportunities for industry, as well as critical challenges. While serious concerns remain, NAM members have seen progress with China and welcomed renewed dialogue with India over the last year. However, the IPR environment in Canada appears to be worsening and requires prompt attention.

a. India

USTR's *2014 Special 301 Report* kept India on the Priority Watch List, recognizing India's "weak IPR legal framework and enforcement system." USTR also noted "the critical role that meaningful, constructive, and effective engagement between India and the United States should play in resolving these concerns." Accordingly, an Out-of-Cycle Review (OCR) was announced, for the purpose of "commencing an assessment of the progress in that engagement."[5]

When the OCR was conducted, USTR cited "useful commitments in recent months, including to institutionalize high-level engagement on [intellectual property] issues, to pursue a specific work program and to deepen cooperation and information exchange with the United

[2] U.S. Department of Commerce (Economics and Statistics Administration and U.S. Patent and Trademark Office), "Intellectual Property and the U.S. Economy: Industries in Focus," April 2012.
[3] Commission on the Theft of American Intellectual Property, "The IP Commission Report," (Washington: National Bureau of Asian Research), May 2013.
[4] U.S. Customs and Border Protection, Office of International Trade, "Intellectual Property Rights: Fiscal Year 2013 Seizure Statistics," March 2014.
[5] Office of the United States Trade Representative, *2014 Special 301 Report*, April 2014.

States on [intellectual property]-related issues under the U.S.-India Trade Policy Forum."[6] Beyond progress on engagement, the OCR did not identify any specific actions by India to address longstanding IPR concerns.

The NAM appreciates recent U.S. government efforts to improve engagement with India, including establishing a high-level working group on IPR as part of the U.S.-India Trade Policy Forum. India's recent commitment to stakeholder consultations on IPR policy matters, including on its Draft National IPR Policy, are also positive steps.[7] However, significant and growing challenges to securing and enforcing intellectual property rights remain. To address those challenges, improved engagement must lead to concrete progress and real results.

India continues to deny **patent protection** for inventions that would otherwise meet internationally accepted criteria. Since 2012, patents for at least 16 products have been invalidated, denied or revoked for various reasons. Under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), patents must be granted for inventions that are new, involve an inventive step and are capable of industrial application. But India's Patent Law, section 3(d), creates an impermissible fourth "enhanced efficacy" test.

On that basis, India denied patents for a therapy that is already patented in 40 other countries around the world. The *2014 Special 301 Report* noted "[t]he United States is concerned that section 3(d), as interpreted, may have the effect of limiting the patentability of potentially beneficial innovations."[8] However, India has taken no steps to bring its law into line with international rules and norms. Instead, manufacturers have seen a continued erosion of patent rights for innovative medicines in India.

India is promoting actions designed to benefit its own domestic industries at the expense of patent holders in the United States and elsewhere. In late 2011, India released a National Manufacturing Policy that encourages **compulsory licensing** of green technology that is "not available at reasonable rates" or is not manufactured in India.[9] This policy expands on a 2010 Department of Industrial Policy and Promotion discussion paper that encouraged compulsory licenses if, among other things, the patented invention is not being "worked" in India.

In a similar vein, India's National Competition Policy requires IPR owners to license all "essential facilities" which appear to include a wide range of technologies with correspondingly broad application.[10] The right to exclude is a key component of IPR, and the National Competition Policy's blanket curtailment of such rights may damage the incentives intellectual property is intended to create for advanced manufacturers in India and in many other countries around the world.

Data protection remains a serious problem in India. USTR's Special 301 Report consistently has highlighted India's failure to provide adequate and effective protection against unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data

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[6] Office of the United States Trade Representative, "Statement by the Office of the U.S. Trade Representative on the Out-of-Cycle Review of India," December 2014.
[7] The White House, "U.S.-India Joint Statement – 'Shared Effort; Progress for All,'" January 2015; and Government of India, Department of Industrial Policy and Promotion, "Press Release," December 2014.
[8] Office of the United States Trade Representative, *2014 Special 301 Report*, April 2014.
[9] Government of India, Ministry of Commerce and Industry, Department of Industrial Policy and Promotion, "National Manufacturing Policy," November 2011.
[10] National Competition Policy, Section 5.1(vi). Technologies include at least "electricity, communications, gas pipelines, railway tracks, ports, IT equipment."

generated to obtain marketing approval for pharmaceutical and agricultural chemical products. Such changes are needed to bring India's practices in line with TRIPS. However, India has yet to take action.

Copyright piracy is widespread across India, despite reforms passed in 2012. The country is a significant source of illegal film recordings. Nearly two-thirds of all software, valued at $2.9 billion, is not properly licensed.[11] According to a recent study, global software piracy cost more than 42,000 U.S. manufacturing jobs over the last decade.[12] In its *2014 Special 301 Report*, USTR called on India to take additional steps to combat physical and online piracy, signal theft, and circumvention of technological protection measures. No action was taken.

India does not provide adequate and effective protection for **trade secrets**. The failure to protect trade secrets is particularly concerning considering the relationships many overseas firms have with the country's service sector. Businesses abroad may have little recourse against contract service providers in India that misappropriate trade secrets. While India recognized the need to improve its trade secrets regime in its 2012 and 2014 drafts of a National IPR Policy, the country needs to take concrete steps to strengthen its laws and enforcement.

India's policies and practices are already harming India's global image as an investment climate for advanced manufacturing. Indeed, India tumbled 11 places in the World Economic Forum's latest Global Competitiveness Index, falling from 60th to 71st place, and ranks a disappointing 76th out of 143 on the Global Innovation Index. There is a risk that, if not corrected, India's weak IPR policies will serve as a model for other emerging economies. Some have already started to follow India's lead by proposing changes to their own national laws.

To address the threat of India's deteriorating intellectual property environment and other discriminatory policies to manufacturing and jobs in the United States, the NAM and 16 other leading business associations representing nearly every sector of the U.S. economy have united to form the Alliance for Fair Trade with India (AFTI) (http://aftindia.org). AFTI is working with Congress, the Administration and partners around the world to end India's unfair policies and to ensure they are not repeated in the future.

The NAM and its AFTI partners support further bilateral engagement on IP matters. However, in light of serious and unresolved deficiencies in India's IPR system, the NAM recommends India remain on the Priority Watch List for 2015. To evaluate progress and solutions resulting from improved engagement, the NAM urges USTR to conduct a rigorous and thorough OCR of India in 2015 that is based on verifiable actions. A meaningful review can inform 2016 discussion of India's placement in future Special 301 Reports.

b. China

Further action is needed for China to achieve an open and fair innovation environment that does not discriminate against overseas companies or accord unfair advantages to firms that develop intellectual property in China. Examples of discriminatory or otherwise harmful IPR policies include China's high rates of counterfeiting and piracy, indigenous innovation accreditation, continued lack of effective trade secret protection, discriminatory standard-setting

[11] BSA, The Software Alliance, "The Compliance Gap - BSA Global Software Survey," June 2014.
[12] Kerr, William and Chad Moutray, "Economic Impact of Software Piracy for Manufacturers in the U.S.," National Association of Manufacturers, January 2014.

and licensing policies and a range of systemic challenges that dramatically increase costs and risks for rights holders.

Counterfeiting and piracy are rampant in China, and the country remains the leading source of counterfeit and pirated goods traded around the world. IPR theft in China is a serious concern for manufacturers of all sizes, but can pose an insurmountable challenge for small businesses. These firms often do not have in-house IPR experts or investigators. They do not have the resources to track down and prosecute counterfeiters and pirates. They are particularly reliant on government actions to stop international counterfeiting and piracy and trade in fakes.

While federal agencies are taking important and meaningful steps to stop international counterfeiting and piracy, those actions have failed to deliver the results necessary to address the challenge and threat of counterfeiting and piracy in China. Smaller NAM members, in particular, often are reluctant to or decide not to export to China for fear of losing their IPR. The United States cannot afford to accept weak IPR enforcement in China that prevents small businesses from exporting to one of the world's largest and fastest growing markets.

Over the course of the past year, China has placed greater priority on protecting **trade secrets**. This increased emphasis on trade secret protection is appreciated by innovators and companies around the world that want to invest in China. These steps include naming trade secrets protection as one of MOFCOM's top three priorities in 2014, launching specialized IP courts in Beijing, Shanghai and Guangzhou, and developing an online platform where judicial decisions regarding intellectual property cases will be published.

In addition, China made several commitments on trade secrets in the Strategic & Economic Dialogue (SED) and the Joint Commission on Commerce and Trade, including limiting disclosure of trade secrets during the administrative licensing process, limiting information required from companies only to information reasonably necessary, stipulating that any requirements for government agencies to publicly disclose information appropriately allow for the withholding of trade secrets, strengthening confidentiality protection measures and holding relevant government officials accountable for unlawful disclosure. USTR must work to ensure China follows through on its SED commitments in this and other related areas.

If fully implemented, these commitments would provide a substantial framework for protecting trade secrets – providing important assurances for investors and helping China achieve its goal of attracting new technology and becoming a more innovative economy. However, it is imperative that both China and the U.S. follow through on ensuring these commitments are put in place as they were intended. Without successful implementation, the potential opportunity these commitments provide will be lost.

China has also signaled over the past year that it is exploring options for either improving existing laws for protecting trade secrets or creating a new law. Enhancements to the legal structures supporting trade secrets would augment these other efforts to improve trade secret protection in China by strengthening the foundation for these reforms. Further progress is essential because other obstacles to sufficient trade secret protection remain in China's enforcement system.

Historically, damage awards have not adequately compensated trade secret owners against losses. However, China's new and specialized IP courts were created to facilitate better management of complex IP matters, including providing consistent, streamlined opportunities for IP litigants. Furthermore, China Premier Li Keqiang announced that China is going to impose

"a large sum" of damages against IP infringers, and it is anticipated that the new IP courts will be the vehicle for this activity. A strong enforcement system is critical to deterring trade secret misappropriation and demonstrating to innovators that China takes protecting their intellectual property seriously.

The NAM also welcomed recent efforts by China to limit the use of indigenous innovation policies in government procurement, to liberalize foreign company access to government projects, and to delink innovation policies from government procurement preferences.

Despite these positive developments, NAM members continue to face innovation policy-related difficulties in China, particularly at the sub-national level. For example, China's Indigenous Innovation Product Accreditation systems impose onerous and discriminatory requirements on businesses seeking to sell into China's government procurement market. Similarly, Draft IP Abuse Rules extend the essential facilities doctrine to intellectual property rights, requiring IPR to be licensed by those in a dominant market position.

China's **standard-setting practices** continue to cause significant concern. As part of its National Intellectual Property Strategy, China has focused on improving its standards-related policies. China moved in that direction in 2012 with revised draft Disposal Rules for Involving of Patents in National Standards that removed some problematic language. However, manufacturers based abroad still can only participate in China's standard setting processes by invitation, putting them at a significant disadvantage relative to their Chinese competitors.[13]

In a move clearly aimed at encouraging businesses to develop technology locally, China's Technology Import-Export Administrative Regulations impose greater risks and liabilities on overseas technology licensors than on domestic licensors. For example, unlike a domestic licensor, an overseas licensor is liable for infringing a third party's rights due to the licensee's use of the licensed technology and also could not own the improved technology made by the licensee. This puts manufacturers based abroad at a significant competitive disadvantage.

China is considering a new regulation on "**service inventions**" that are created during an inventor's employment. If passed, the regulation could damage the ability of manufacturers to make commercial choices about how best to exploit intellectual property derived from inventions in China and increase legal and financial risks. It may require employers to decide how best to protect an asset before that asset has been fully developed by the inventor. The draft rules also apply to technical secrets, which would be both administratively challenging and likely to lead to disputes that put such innovation at risk.[14]

China's **trademark law amendments**, which went into force in May 2014, increase the risk that brand owners will be held hostage to pirates registering marks in bad faith. For example, if an existing trademark owner opposes preliminary approval of a mark registered by another party and loses, the mark is deemed valid until and unless a special review board invalidates it. As a result, a bad-faith registrant may not only freely use a mark for years while waiting for a review board without infringing the brand owner's rights, but also take enforcement

[13] This is particularly significant as the draft Rules limit the ways patents that relate to standards can be used, regardless of participating in the relevant standard body. See State Administration of Industry and Commerce of China, Regulations on the Prohibition of Abuse of Intellectual Property Rights to Eliminate and Restrict Competition (IP Abuse Rules), June 2014.

[14] If an inventor of subject matter covered by the regulations is unhappy with the proposed compensation, it may be disputed with an administrative agency. This likely would result in disclosure of trade secrets to the relevant body without any protection to prevent its further dissemination.

action against the brand owner. When disputes inevitably arise between employees and employers, valuable trade secrets may be put at risk.

China's patent system includes the issuance of IP assets, including utility models and design rights, without substantive examination. The quality of these unexamined assets is unknown, regularly resulting in the granting of "**junk patents**," that ought not to have been granted. However, because of the absence of substantive examination, such patents often are granted, providing the recipients with a basis to further abuse the legal process by asserting these junk patents against genuine innovators. The vast majority of unexamined rights are held by Chinese domestic companies and individuals. Since no substantive review of unexamined assets is required prior to their assertion, they represent a significant business risk to innovation-driven U.S. and Chinese companies.

Patent law amendments China issued in August 2012 would make this problem far worse by enabling junk patent holders to assert their rights more effectively and disrupt foreign-owned patents. The NAM believes China's patent system should be reformed to ensure litigation based on unexamined rights cannot proceed until the validity of the model or design involved has been determined and to allow for recourse to civil litigation for patent infringement to the exclusion of often political administrative enforcement remedies.

c. Canada

Canada's IPR protection and enforcement regime has fallen well behind the standards maintained in the rest of the developed world. Deep flaws in that regime are harming or threatening to harm a range of industries. USTR should carefully examine Canada's proper placement in the *2015 Special 301 Report*. It should increase engagement with relevant Canadian authorities in the coming year and consider using other tools at its disposal to address continuing and emerging concerns.

To receive a **patent** for a product, an innovator generally must demonstrate the product is useful. However, Canadian courts have redefined that "utility" requirement as a new, and impermissible, element of patentability through the application of a "promise doctrine" found nowhere else in the world. For a patent application to succeed, that doctrine requires heightened evidence that demonstrates "or soundly predicts" a subjectively construed "promise of the patent," which may go well beyond the usefulness of the invention at hand.

This doctrine has been applied to invalidate a stunning 20 patents on innovative medicines. That an invention must have "utility," meaning capable of industrial application, is unremarkable. In Canada, however, the "promise doctrine" poses an additional hurdle to patentability and, in some cases, has been wrongly conflated with effectiveness for health regulatory approval. This has enabled companies seeking to make copies of innovative medicines to mount unjustifiable but successful patent challenges.

Conflating "utility" and effectiveness for regulatory approval has created a "Catch-22" for innovators. To obtain appropriate patent protection, medicines manufacturers apply for a patent before the marketing approval process in which safety and efficacy for use in relevant patient populations later will be demonstrated. But the "promise doctrine" demands that evidence well beyond the usefulness of the invention be shown in the patent application and long before this information is available.

These concerns are multiplied by the fact that, contrary to accepted practice in other countries, Canada does not permit post-filing evidence to support assertions of "utility." The "promise doctrine" has severely undermined patent protection for innovators in the United States and elsewhere and had the practical effect of rendering medical innovation all but unpatentable in Canada. It appears to be inconsistent with Canada's international obligations, including TRIPS and applicable bilateral and regional trade agreements.

Article 39.3 of TRIPS and NAFTA Articles 1711(5) and (6) require Canadian regulatory authorities to provide effective protection to prevent the unfair commercial use of clinical trial and other data submitted by innovative companies for market approval of their products. In October 2006, Canada published regulations implementing eight years of **data protection** to prevent unauthorized parties from gaining unfair commercial benefit during the protection period through reliance on the clinical dossier.

However, the NAM has serious concerns about the potential loss of data protection under the October 2006 regulations if an innovative medicine or vaccine is not being marketed in Canada. The restrictions imposed by Canada on the scope of data protection in this respect find no basis in the text of either Article 39.3 of TRIPS or Article 1711 of the NAFTA. Canada's obligation to protect data pursuant to these agreement provisions is not in any way lessened simply because an approved medicine or vaccine is not marketed in Canada.

The NAM was encouraged that Canada enacted bill C-8 in December 2014, granting customs authorities the power to seize imports of **counterfeit and pirated goods**. This was a long-awaited and important step in the right direction. To reverse a worrying trend of rising imports and trans-shipment of counterfeit and pirated goods into and through Canada, customs authorities now must work with their counterparts in the United States and other countries and use this new power to prioritize enforcement actions and stop trade in infringing products.

Canada passed its Copyright Modernization Act more than two years ago. However, U.S. right holders continue to face challenges protecting and enforcing their **copyrights** in Canada. The law contains broad exceptions, which have been exacerbated by unfortunate court decisions. Similarly, Canadian courts have placed a high burden on copyright owners to establish liability in the online context. Canada's choice of a purely informational notice, rather than a notice and takedown system, has contributed to continued problems with online piracy.

Following passage of the Copyright Modernization Act, the NAM supported Canada's entry into the Trans-Pacific Partnership (TPP) negotiations and hoped their participation would contribute to work toward high-standard IPR commitments. Manufacturers are very disappointed that Canada has not been a more positive force in TPP IPR discussions. On the contrary, Canada appears to be proposing and implicitly or explicitly supporting weaker standards that are inconsistent the goal of making the TPP a truly 21st Century agreement.

d. Other countries of concern

Manufacturers continue to face significant challenges in **Brazil**, including significant patent backlogs, patentability review by non-intellectual property agencies and discriminatory application of data protection. Brazil's patent office, INPI, has taken steps to reduce patent approval delays, but additional resources and actions are needed. Delays in excess of ten years still exist and may undermine otherwise valid patent rights and incentives for companies to bring innovative products to Brazil.

Brazil's health regulatory agency, ANVISA, currently is authorized to review and approve all patent applications for medicines. Their review is in addition to and given equal weight as INPI examination. However, ANVISA does not limit its role to review of potential sanitary risks but also reviews patentability requirements. ANVISA and INPI also do not apply the same patentability review standards. This "dual examination" creates considerable uncertainty and appears to be incompatible with Brazil's TRIPS obligations.

INPI's role in approving all IPR licensing and technology transfer agreements potentially impinges on the freedom of companies to contract freely for goods and services and may result in the destruction of trade secrets.[15] Brazil does not provide data protection to all sectors. Although Brazil has enacted federal laws to ensure adequate data protection for veterinary and crop products, it still does not provide for adequate regulatory data protection for pharmaceuticals.

A study by the Center for Strategic Studies and Debates of the Brazilian Chamber of Deputies raises serious concerns about the future direction of Brazil's IPR policy. Among other things, it recommends new limitations on patent terms and proposes expanding the use of compulsory licensing to promote local production.[16] Brazil is advancing such proposals in domestic legislation and international forums. For years, it has blocked discussions on patent quality and pushed WIPO to create a manual on how to use patent exceptions and limitations.[17]

Ecuador has taken a range of actions over the last few years that are further weakening that country's already poor IPR protection and enforcement regime. The country has one of the highest rates of counterfeiting and piracy in Latin America. But rather than take the steps necessary to address that problem, Ecuador amended its laws last year to eliminate enforcement and sanctions provisions for IPR violations – removing essential tools to protect against a wide range of counterfeit and pirated goods.

In 2014, Ecuador also issued a decree (Decree 522), which appears to limit or even prevent the use of trademarks for any medicine once the patent on that medicine has expired. This measure would deny an important form of IPR protection that is critical to ensure innovator companies can distinguish their products from others. Trademarks helps physicians and their patients identify that quality, safety and effectiveness of medicines – critical reputational capital that manufacturers strive to build over time.

Ecuador charges excessive fees for patent maintenance that can range as high as $140,000, compared with just $12,600 in the United States. But those fees apparently do not secure protection for innovators. The Ecuadoran Intellectual Property Institute has granted nine compulsory licenses for innovative medicines since 2010, including six in the last year. Applications for a dozen other products are pending. Compulsory licenses should be granted only based on clearly demonstrated need and in compliance with international obligations.

As a result of **Russia**'s continued weak IPR enforcement, manufacturers of agricultural chemicals, auto parts, consumer goods, machinery, medicines, software and a wide array of

[15] The 1970's-era law that established INPI (Law 5648/70) also granted authority to approve licensing and technology transfer agreements. That authority was eliminated in 1996, but INPI continues to interfere.
[16] Center for Strategic Studies and Debates, Brazil's Patent Reform: Innovation towards National Competitiveness, July 2013.
[17] See, for example, Proposal from Brazil to the World Intellectual Property Organization, Standing Committee on the Law of Patents, Fourteenth Session, January 2010.

other products continue to face challenges in basic enforcement of IPR and the persistent threat of counterfeiting and piracy in and from that country. Online piracy continues to plague the Russian market, and the government has not established an effective enforcement strategy to combat the growing array of pirate web sites located in the country.

Russian authorities have announced plans to change the legislative framework and possibly respective rules in the Customs Union between Russia, Belarus and Kazakhstan on the issue of IPR exhaustion, with trademark protection in focus. The right to block parallel imports of branded products reportedly would be retained by way of a legal exception, but only for trademark owners/users which have set up, or will in the future set up, manufacturing of like branded products in Russia.

Russia still does not effectively protect against unfair commercial use of undisclosed test and other data generated to obtain marketing approval for pharmaceutical and agrochemical products. Although Russia has enacted amendments to its Law on Circulation of Medicines, which addresses protection of undisclosed test data, NAM members are concerned this law and applicable regulations contain mechanisms that are contrary to, or do not effectively implement, regulatory data protection consistent with Russia's international obligations.

In **South Africa**, the Ministry of Trade and Industry has published a draft National Policy on Intellectual Property.[18] While manufacturers welcome many positive positions expressed in the draft Policy, the NAM is very concerned by provisions that would weaken IPR in certain fields and suggestions that weak IPR protections can be an effective part of the country's industrial policy. We are hopeful that comments from IP creators will be solicited and heeded and that the problematic elements can be removed.

3. Cross-Cutting Concerns

In addition to country-specific challenges, manufacturers urge USTR and other federal agencies to confront the following cross-cutting concerns that are denying or threaten to deny adequate and effective IPR protection for manufactured goods around the world. These concerns should be addressed comprehensively and strategically, using all available tools – including ongoing trade negotiations with Europe and Pacific Rim nations, engagement in global fora and education, training and capacity building.

Protecting **trade secrets** from increasingly sophisticated physical and electronic theft and ensuring adequate and effective enforcement is a growing worldwide challenge and a top priority for manufacturers. Trade secrets form an increasingly important part of the intellectual property portfolios of manufacturers small and large. A 2010 study found trade secrets account for some two-thirds of the value of a typical firm's information portfolio. In knowledge-intensive sectors, the rate increases to as much as 70 to 80 percent.[19]

However, trade secret theft and misappropriation are a growing challenge. One U.S. government estimate valued losses from economic espionage between $2 billion and $400

[18] Ministry of Trade and Industry, Draft National Policy on Intellectual Property 2013, (Republic of South Africa Government Gazette), September 2013.
[19] Forrester Consulting, "The Value of Corporate Secrets: How Compliance and Collaboration Affect Enterprise Perceptions of Risk," March 2010.

billion.[20] Trade secret protection and enforcement is still inadequate or non-existent in many countries and regions, putting industrial know-how and technology at risk and making it harder for U.S. companies to trade, do business and collaborate with local partners and suppliers in countries around the world.

Many countries do not yet provide for adequate and effective protection of trade secrets through their laws, policies and enforcement actions. In others, trade secrets are under threat by court decisions, such as the October 2013 European Court of Justice decision in the case of *Stichting Greenpeace and Pesticide Action Network Europe v. European Commission*, which would contravene the treatment of trade secrets under TRIPS Article 39.2, unless overturned on appeal.

The threat of **IPR erosion** remains a serious concern. The global framework of IPR protections, particularly for clean technology, energy, medicines and other advanced manufacturing products, is being challenged in a range of international forums. For example, strong IPR protection and enforcement is critical to achieving global energy and environment objectives. But in the United Nations (UN) Framework Convention on Climate Change, the World Intellectual Property Organization (WIPO), the World Health Organization (WHO) and elsewhere, several countries continue to call for compulsory licensing of clean technologies.

Those calls are consistent with broader efforts across the UN system to position IPR as a barrier to the treatment of disease and the development, dissemination and deployment of clean technologies. The UN Global Strategy for the Prevention and Control of Noncommunicable Diseases suggests IPR could prevent countries and patients from accessing treatments, despite a complete lack of evidence. WIPO has undertaken work streams to study patent exceptions and limitations. At the WHO, a recent proposal[21] is likely to be aimed at increasing IP flexibilities or exceptions from strong IPR protections. Similar proposals are being made in the context of the UN's Post-2015 Development Agenda.

To address these and other challenges to global IPR rules that support manufacturing jobs and innovation, the NAM supports USTR's efforts to end the moratorium on TRIPS-related "non-violation nullification and impairment" disputes. This moratorium originally was planned as short-term measure, but it continues to be extended in the WTO by unanimous consent. Lifting it would send a strong and timely signal, while ensuring the United States and other countries have the tools at their disposal to ensure global IPR rules are respected.

Illicit trade remains a significant concern for NAM members. Customs authorities in many countries do not have sufficient authority to seize counterfeit and pirated goods and other illicit products in transit or in Free Trade Zones. Organized criminals identify and exploit such loopholes to the detriment of manufacturers in the United States and elsewhere. Estimates of the worldwide scale of illicit trade range from $650 billion to as much as eight to 15 percent of global GDP.[22]

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[20] Office of the National Counterintelligence Executive, "Foreign Spies Stealing U.S. Economic Secrets In Cyberspace," October 2011.
[21] World Health Organization, "Global strategy and plan of action on public health, innovation and intellectual property," EB136/CONF./7, January 2015.
[22] Luna, David M., "Why Combatting Corruption and Illicit Trade is Critical to Market Prosperity, Economic Growth and Sustainable Futures," U.S. Department of State, September 2013.

The NAM believes customs officials abroad must have enforcement authority sufficient to combat the illicit trade in counterfeit and pirated goods, including for goods in transit or in Free Trade Zones. Laws are needed to ensure counterfeit goods under customs supervision can be intercepted and prevented from further transit. Without such authorities and protections, the global trading system risks inadvertently facilitating illicit trade to the detriment of brand owners.

Trademarks enable the public to identify and recognize goods or services as originating from a particular company and being a particular known product. Through trademarks, companies associate their reputations with their products and promise a consistent level of quality. This widespread brand-based competition allows consumers to know that certain products are produced by recognized companies at a consistently high quality. As part of the source-identifying function, trademarks also help to protect against counterfeiting.

Trademarks are often the most valuable asset a manufacturer possesses and are at the center of the global economy. Given the importance of these assets and manufacturers' reliance on global, regional and bilateral obligations governments around the world have undertaken to protect them, companies of all sizes make significant investments to develop, promote and protect their rights.

Regrettably, Australia has implemented legislation prohibiting the application of marks and instead mandating the **plain packaging** of tobacco products. This requirement lacks an evidentiary basis and does not reflect regulatory best practice considerations. For these reasons and others, five countries have already challenged Australia's plain packaging rules in the WTO. However, other countries are considering similar proposals that would destroy trademark rights for tobacco and a wide range of other products, including food and beverages. Proposals that would undermine trademark rights in tobacco products are most advanced in Ireland and the United Kingdom. They are under consideration in Brazil, Chile, France, Finland, India, Israel, New Zealand, Panama, South Africa, Turkey and Thailand.

A governmental act restricting or prohibiting the use of trademarks impairs one of their essential functions – to ensure fair and effective competition for the benefit of producers and consumers. Trademarks hold manufacturers accountable to competitive market forces and represent a promise to consumers that the qualities associated with a product will in fact be present or absent, as appropriate. Where elements of different trademarks appear similar, the distinguishing function is eroded.

A trademark by its very nature is intended to be used in commerce. It makes little sense to provide registration and protection for a trademark and then to prohibit its use on a lawfully available product or its retail packaging, especially where such use is necessary to serve the core functions of trademarks. For these reasons, the NAM remains concerned with and opposed to plain packaging requirements.

Overseas rogue sites and remote sellers ship counterfeit goods into the United States primarily using **international mail services** and airmail, such as the China-based express mail service of the China Post. These shipments arrive at international mail facilities and are inspected for entry by U.S. Customs before being transferred to the postal service for delivery.[23]

[23] Mailing Standards of the United States Postal Service, International Mail Manual, § 711, August 2011, (incorporated by reference in the Code of Federal Regulations, 39 C.F.R. § 20.1).

Overseas remote sellers often misdeclare small individual mailings or break up shipments into smaller packages to avoid detection.

The sheer volume of small shipments makes it impossible for U.S. Customs agents to vigorously screen or x-ray all incoming mail to detect such shipments. Once admitted and undetected, these shipments then enter the U.S. postal mail stream from international mail facilities for delivery to U.S. consumers. The ability of the postal service to detect and inspect these packages is complicated by the fact that materials shipped domestically by first-class, priority, or express mail are closed to inspection without probable cause.[24]

NAM members believe increased enforcement, process streamlining and engagement with overseas law enforcement officials are necessary to combat this serious and growing threat. The United Kingdom's customs and revenue agency has demonstrated that effective enforcement is attainable through enhanced procedures designed to detect, detain, inspect, seize and destroy counterfeit goods shipped by mail. A similar approach could be adopted in the United States.

Finally, more education and engagement is needed urgently to better **enable smaller manufacturers to protect their intellectual property globally**. For these firms, the cost and complexity of protecting their rights around the world can be very high relative to their annual sales. While the Patent Cooperation Treaty and similar agreements have helped, there is much more work to do to ensure the global intellectual property system enables small businesses to effectively protect their ideas, brands and inventions.

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The NAM welcomes this opportunity to comment and looks forward to working with USTR and other federal agencies to address and resolve the critical IPR concerns outlined above.

Sincerely,

Linda M. Dempsey

[24] U.S. Postal Service, "Basic Eligibility Standards for Priority Mail," November 1, 2010.