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February 5, 2016

Ms. Christine Peterson
Director for Intellectual Property and Innovation
Office of the United States Trade Representative
600 17th Street NW
Washington, DC 20503

Ref: Docket No.: USTR-2015-0022

Dear Ms. Peterson:

The National Association of Manufacturers (NAM) welcomes the opportunity to provide these written comments for the 2016 Special 301 Review. The NAM is the largest manufacturing association in the United States, representing more than 14,000 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 $2.17 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 also note emerging cross-cutting concerns that impact manufacturers in a number of markets, 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 global, regional and bilateral negotiations and enforcement tools.

For the reasons explained further below, the NAM recommends that **China**, **India** and **Russia** remain on the Priority Watch List, and that **Colombia** remain on the Watch List. The NAM further recommends that the Office of the U.S. Trade Representative (USTR) conduct three Out-of-Cycle Reviews in 2016 to determine placement and monitor IP progress:

- **India**, to evaluate concrete progress toward and results achieved in addressing longstanding IPR challenges in that country that have been the subject of numerous dialogues over the last 18 months;
- **Canada**, to reflect more accurately continued IPR concerns in areas such as its "promise doctrine," counterfeiting, and data protection and the tools needed to address them; and
- **Colombia**, to monitor ongoing IP developments, particularly related to the implementation of its National Development Plan.

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. That value continues to grow with 2.8 percent of U.S. GDP devoted to R&D, and each dollar of R&D in turn producing between $16 and $69 of additional economic output over the subsequent ten years.[1] Intellectual property and other intangible assets now account for at least 90 percent of the total market value of ten key manufacturing-related industries. Those industries include not only traditional science, information technology and R&D-intensive sectors like pharmaceuticals and telecommunications, but also food and beverages, personal care products, and automobiles.[2]

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.[3] A more recent report now indicates that IP supports over 57 million U.S. jobs.[4]

The theft of legitimate intellectual property rights around the world has, however, a significant impact on the U.S. economy. 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.[5] In fiscal year 2014, U.S. Customs and Border Protection seized counterfeit and pirated goods worth more than $1.23 billion at America's borders.[6] China remains by far the leading source of these products: in 2014, 63 percent of counterfeit goods by value seized at U.S. borders were from China, with another 25 percent from Hong Kong. Counterfeit products include medicines, auto parts, consumer electronics, 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 and enforcement in a number of markets, including both large emerging markets

[1] CREATe and PWC, "Economic Impact of Trade Secret Theft," February 2014.
[2] 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.
[3] 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.
[4] Global Intellectual Property Center, "Employing Innovation across America." Accessed January 26, 2016.
[5] Commission on the Theft of American Intellectual Property, "The IP Commission Report," (Washington: National Bureau of Asian Research), May 2013.
[6] U.S. Customs and Border Protection, Office of International Trade, "Intellectual Property Rights: Fiscal Year 2013 Seizure Statistics," April 2015.

such as India, China, and Russia, and developed markets, including Canada. The significance and rapid growth of these economies present great opportunities for industry, as well as critical challenges. The NAM has seen progress on some issues in these markets, including a focus on trade secret protection in China, active bilateral dialogue in India, and changes related to counterfeiting in Canada. Serious challenges remain, however, in each of these markets that need to be addressed through concerted bilateral dialogue that is focused on meaningful, tangible progress.

Additionally, NAM members have seen continued and emerging IPR issues in markets ranging from Brazil and Colombia to Austria and Australia. As well, the tolerance of illicit trade of smuggled and counterfeit goods and the failure to provide full IPR protections and enforcement is a problem that needs to be addressed in several of these markets. The NAM encourages USTR and other U.S. government agencies to take steps to raise these issues as well.

a. India

Previous Special 301 reports have consistently cited India's "weak IPR legal framework and enforcement system" and "the critical role that meaningful, constructive, and effective engagement between India and the United States should play in resolving these concerns."[7] Yet, despite a 2014 Out-of-Cycle Review[8] and significant new bilateral engagement on these issues, there has not been any substantial progress by India on the IPR issues of concern.

USTR's *2015 Special 301 Report* further detailed steps taken by the Government of India, such as the "establishment of a domestic IPR-focused experts group, commitment to technical engagement on specific issues of concern, and the issuance of encouraging domestic policy pronouncements."[9] It also acknowledged that "recent positive developments on engagement should translate into substantive and measurable action."[10]

Such engagement, including at the 2015 Strategic & Commercial Dialogue and Trade Policy Forum, however, demonstrates more of a focus on process and dialogue rather than actual results. While the NAM recognizes the fundamental value of candid exchanges on IPR issues, these steps have yet to result in meaningful progress on priority issues facing U.S. manufacturers. The fact that the Indian Government's willingness simply to engage in such discussions is taken as measurable progress speaks volumes about how dire the situation was before the dialogues that began in 2014. As USTR looks forward to 2016 engagement with India, it must emphasize both internally and externally that bilateral engagement on IP issues must produce tangible results to improve IPR protection and enforcement in India to be effective. In other words, process is not the end, it is merely a means to progress.

As reviewed by the U.S. International Trade Commission in its September 2015 report:

> The Modi government introduced no new IPR laws during May 2014-July 2015 to address barriers to the protection of trade secrets, regulatory test data, patents, trademarks, and copyrights. Nevertheless, U.S. industry and government representatives noted the willingness of Modi government officials to engage in

[7] Office of the U.S. Trade Representative, "2014 Special 301 Report," April 2014.
[8] Office of the U.S. Trade Representative, "Statement by the Office of the U.S. Trade Representative on the Out-of-Cycle Review of India," December 2014.
[9] Office of the United States Trade Representative, 2015 Special 301 Report, April 2015.
[10] Id.

discussions with the United States on IPR issues, particularly in the context of the December 2014 Draft National IPR Policy.[11]

Such concrete progress and changes are needed on a range of issues. India continues to deny **patent protection** for inventions that would otherwise meet internationally accepted criteria. Since 2012, patents for at least 25 products have been undermined through rejection, invalidation, or other revocation. 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. Section 3(d) of India's Patent Law, however, creates an impermissible fourth "enhanced efficacy" test.

On that basis, India has denied patents for a range of widely accepted products, such as 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."[12] While India is considering IPR reform, it has not made concrete legal changes to address the continued erosion of patent rights for innovative medicines, as found as well by the U.S. International Trade Commission. These actions have raised concerns for many companies.

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.[13] 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, and continues in force into 2016. Internationally, India worked to promote compulsory licensing of green technologies in international negotiations related to greenhouse gas emissions.

In a similar vein, India's National Competition Policy requires IPR owners to license all "essential facilities," a provision that appears to include a wide range of technologies with correspondingly broad application.[14] 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. Previous Special 301 Reports have consistently 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 generated to obtain marketing approval for pharmaceutical and agricultural chemical products. Such changes are needed to bring India's practices in line with TRIPS, but India has yet to take action.

[11] U.S. International Trade Commission, Trade and Investment Policies in India, 2014-2015, USITC Pub. 4566, September 2015.
[12] Office of the United States Trade Representative, 2014 Special 301 Report, April 2014.
[13] Government of India, Ministry of Commerce and Industry, Department of Industrial Policy and Promotion, "National Manufacturing Policy," November 2011.
[14] Technologies listed in Section 5.1(vi) include at least "electricity, communications, gas pipelines, railway tracks, ports, IT equipment." See National Competition Policy.

Copyright piracy is widespread across India, despite reforms passed in 2012. Nearly two-thirds of all software, valued at $2.9 billion in a 2014 study, is not properly licensed.[15] According to a NAM study, global software piracy cost more than 42,000 U.S. manufacturing jobs over the last decade.[16] 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 meaningful action has been taken since then to improve this situation.

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 – and that policy has not yet been finalized.

India has also been vocal in multilateral fora challenging the value of IP systems. At the WTO's TRIPS council, for examples, Indian representatives have denied links between IP and innovation.[17] At WIPO, India has been a vocal opponent of work on patent quality. NAM members are concerned about India's positions and the impact they could have in shaping international opinion, considering that country's coordinating role amongst BRICS countries in international fora.[18]

India's policies and practices are already impacting India's global image as an investment climate for innovation and advanced manufacturing. In 2015, India fell five places in the Global Innovation Index, ranking 81st out of 143 countries. The report noted that India's attempts to temper intellectual property rights has "resulted in a relatively weaker IPR regime and a lower propensity to filing patents in India."[19] India's ranking in the Global Competitiveness Index fell for five consecutive years before ticking upwards in 2015, but ultimately still ranks only 55th overall – and even amidst the overall improvement, still saw a drop in its ranking for the country's capacity to innovate. 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 in areas like compulsory licensing and trade secrets.

The NAM welcomed India's review of its **Model Bilateral Investment Treaty (BIT)**, completed in December 2015, and appreciated the opportunity to offer comments on its March 2015 draft. There were many aspects of that revised text, however, that deviated substantially from the U.S. model BIT. While the final text does cover intellectual property ("copyrights, know-how, and IPR such as patents, trademarks, industrial designs and trade names, to the extent they are recognized under the law of a Party") under the scope of investment, it continues to exclude compulsory licenses from any BIT obligations. Exemptions for compulsory licenses should be limited to those issued in accordance with TRIPS. A blanket exemption for any compulsory license would undermine the goal of any BIT to help attract high-quality, innovation-based investment.

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[15] BSA, The Software Alliance, "The Compliance Gap - BSA Global Software Survey," June 2014.
[16] Kerr, William and Chad Moutray, "Economic Impact of Software Piracy for Manufacturers in the U.S.," National Association of Manufacturers, January 2014.
[17] TRIPS Council Meeting Minutes, June 11-12, 2014, IP/C/M/76/Add.1, paragraph 347.
[18] BRICS Intellectual Property Offices Cooperation Roadmap, Magaliesburg. May 2013
[19] Dutta, Soumitra, Bruno Lanvin, and Sacha Wunsch-Vincent, "The Global Innovation Index 2015 Effective Innovation Policies for Development," September 2015.

The NAM supports Prime Minister Modi's stated goal of making India a better place to do business – yet ongoing problems with India's IP system and troubling provisions of the Model BIT do not serve that goal. Those factors, and others like them, contribute to India's low standing on the World Bank's *Ease of Doing Business* index, on which India has moved only a modest four spots, remaining at 130th out of 189 economies.[20]

To address the challenges companies face in India's 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 to produce progress on IP matters. In light of serious and unresolved deficiencies in India's IPR system, the NAM recommends India remain on the Priority Watch List for 2016. To evaluate progress and solutions resulting from improved engagement, the NAM urges USTR to conduct a rigorous and thorough OCR of India in 2016 based on verifiable actions. A meaningful review can inform 2017 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 continued position as a hub for global counterfeiting and piracy, lack of effective trade secret protection, discriminatory standard-setting and patent licensing policies, policies to support indigenous innovation and domestic IP-intensive industries, and a range of systemic challenges that dramatically increase costs and risks for rights holders.

Counterfeiting and piracy remain 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.

Progress in China on protecting **trade secrets** has been slow despite some positive statements. The outcomes of the 2015 Joint Commission on Commerce and Trade (JCCT) included a commitment to provide strong trade secrets protection, and noted that China is in the process of

[20] World Bank, "Doing Business 2016: Measuring Regulatory Quality and Efficiency," January 2016.

amending its Anti-Unfair Competition Law. China also committed to issue model or guiding court cases, clarify rules on preliminary injunctions, evidence preservation orders, and damages.[21]

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. It is imperative that both China and the U.S. follow through on ensuring these commitments are put in place as they were intended. China should also be open to moving beyond the letter of such commitments to find approaches that may be more effective, including legal reforms that extend beyond the confines of the Anti-Unfair Competition Law – which contains only a portion of the relevant legal provisions dealing with trade secrets issues.

Trade secret enforcement also remains a significant challenge, though companies have seen some positive steps, including two high-profile cases in Shanghai in which courts granted preliminary injunctions in trade secrets cases. 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.

Current actions are not doing enough to help companies protect critical know-how. China must take steps to boost trade secrets enforcement, addressing evidentiary burdens and other practical barriers – such as the difficulty of using judicial tools such as preliminary injunctions – that in practice prevent companies from enforcing their trade secrets through China's courts. Additionally, damage awards have not adequately compensated trade secret owners against losses. 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 welcomes efforts by China to address foreign company concerns about **indigenous innovation initiatives**, including steps to limit the use of indigenous innovation policies in government procurement, to clarify that foreign companies are eligible to participate in innovation-related government such as its semiconductor development plan. Despite these developments, NAM members continue to face innovation policy-related difficulties in China, particularly at the sub-national level. For example, although China rolled back a national-level indigenous innovation product accreditation program and required local governments to break links between innovation and procurement in 2011, provincial catalogues of indigenous innovation products continue to raise questions about treatment for innovative foreign products.[22]

China continues to give special, unwarranted attention to IPR in the context of **competition**, with a flurry of recent draft regulations designed to regulate "IPR abuse" – including draft Anti-Monopoly Guidelines on Abuse of IP Rights released by the State Council Anti-Monopoly Commission and the National Development and Reform Commission. These policies raise concerns about how Chinese regulators may treat the legitimate exercise of IP in consideration of competition concerns. These regulations should align with international best practices and with specific Chinese commitments made in bilateral dialogues to ensure that competition enforcement is "fair, objective, transparent, and non-discriminatory." China should explicitly recognize that the existence of IPRs does not equate to market power. In instances where

[21] U.S. Department of Commerce Office of Public Affairs, "U.S. Fact Sheet: 26th U.S.-China Joint Commission on Commerce and Trade," November 2011.
[22] US-China Business Council, Update: China's Innovation & Government Procurement Policies, May 2015

competitive concerns may genuinely be raised by bad behavior, the appropriate remedy should be to address that behavior, not to curtail IPRs.

China's **standard-setting practices** continue to cause significant concern as it relates to IPR. 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 related to the handling of IP in standard-setting processes. Participation in standard-setting activities, however, remains a question for some companies: manufacturers still can only participate in China's standard setting processes by invitation, putting them at a disadvantage relative to their Chinese competitors.[23]

IP licensing also remains an issue for many companies, due to challenges they face licensing technology into China even to their own subsidiaries. In a move clearly aimed at encouraging businesses to develop technology locally, China's 2001 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 technology improvements developed by the licensee. This puts manufacturers based abroad at a significant competitive disadvantage. Although the United States and China have discussed this issue, China's Ministry of Commerce has not undertaken any serious efforts to revise these regulations.

China is drafting 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 not only legal and financial risks but the cost of research and development operations in China, making China a less attractive location for manufacturing R&D. Progress was made last year, however, with revisions that mean the regulations would no longer apply to technical secrets.

China's amended **Trademark Law** and its implementing regulations, most recently amended in 2013-2014, continue to increase the risk that brand owners will be held hostage to pirates registering marks in bad faith or to other parties infringing upon their legitimate trademarks. For example, if a trademark owner opposes a third-party application to register a mark and loses, they cannot appeal that decision under the new Trademark Law, and the registration is granted. The trademark owner must then go through another timely and costly proceeding to seek invalidation of that mark, and if the registered mark is identical to the trademark owner's prior yet unregistered mark, the owner must either halt its use of the mark or risk an enforcement action.

China's patent system also has issues with **patent quality**, due to the lack of substantive examination for utility model and design patents. The quality of these unexamined assets is largely unknown, regularly resulting in the granting of "junk patents" that ought not to have been granted. Though these patents would not have necessarily been granted if fully examined, they still carry full patent rights, allowing those who hold them to assert these junk patents against genuine innovators. The vast majority of these unexamined rights are held by Chinese domestic

[23] 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.

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. The NAM believes China's patent system should be reformed to (1) ensure that patent applications based on unexamined rights cannot proceed until the validity of the model or design involved has been determined and (2) allow for recourse to civil litigation for patent infringement to the exclusion of often politically influenced administrative enforcement remedies.

Finally, patent filers in the pharmaceutical industry continue to face patentability and patent invalidation issues related to ongoing restrictions on submitting **supplemental data**. China's State Intellectual Property Office does not consistently accept data generated after a patent is filed during patent prosecution to describe inventions or satisfy inventive step requirements. Such a practice deviates from the world's other busiest patent offices – including patent offices in the US, Europe, Japan and Korea – meaning that patents accepted in these locations can experience problems in China. China continues to prohibit post-filing data, citing Articles 26.3 and 22.3 of its Patent Law, in spite of a December 2013 JCCT commitment to allow patent applicants to submit such supplemental data, and has yet to resolve a number of ongoing lawsuits involving foreign pharmaceutical patents.

c. Russia

Russia continues to illustrate **weak IP enforcement**, meaning that manufacturers of agricultural chemicals, auto parts, consumer goods, machinery, medicines, software and a wide array of other products face ongoing challenges in basic enforcement of IPR. This includes the persistent threat of counterfeiting and piracy due to the effective lack of trademark enforcement, both from Russian-made counterfeit products as well as counterfeit products produced in other countries (such as China) that are transshipped or sold in Russia. 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. Although the Russian Duma in 2014 adopted legislation that criminalized pharmaceutical counterfeiting, problems with counterfeiting and piracy in that sector continue.

Additionally, in relation to patent infringement for pharmaceuticals, there are no effective mechanisms for innovators to resolve patent disputes prior to the launch of a generic product, and **practical barriers to using legal protections**. The Russian Arbitration Procedural Court rarely – if ever -- grants preliminary injunctions, frustrating company efforts to resolve potential patent issues before potentially infringing pharmaceutical products are launched on the market.

Russia, along with Belarus and Kazakhstan, launched the **Eurasian Economic Union (EEU)** on January 1, 2015, with a goal of integrating the three former Soviet countries' economies with rules to promote free trade, broad financial interaction and labor migration. This follows earlier announcements of plans to modify rules in the previous Customs Union, including those related to IPR exhaustion and trademark protection. This integration process should be monitored carefully to understand the regulatory environment impacting IPR and IP-intensive industries.

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, despite relevant commitments made in its WTO Working Party Report. 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.

d. Canada

While Canada has made progress on some issues, the NAM has considerable concerns about several areas impacting our members. On the positive side, the Canadian government recently amended PM (NOC) Regulations to address judicial rulings holding that an innovator could not list a patent claiming a single medicinal ingredient of a Fixed Dose Combination (FDC) product on the Patent Register. This amendment addressed a contradiction between these rulings and Health Canada's longstanding policy, as set out in the Health Canada Guidance Document, which explicitly allows for such a practice.

In other important areas, however, Canada's IPR protection and enforcement regime has fallen behind the standards maintained in the rest of the developed world. Canada's **"promise doctrine" for patents** is a major issue facing companies in the pharmaceutical sector. To receive a patent for a product, an innovator generally must demonstrate the product is useful. Canadian courts, however, 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 24 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. The "promise doctrine," however, 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.

The NAM continues to have serious concerns about the potential loss of data protection under Canadian laws and regulations, particularly if an innovative medicine or vaccine is not being marketed in Canada. 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. In addition, the 2014 Protecting Canadians from Unsafe Drugs Act (bill C-17) provided the Health Minister broad discretion to share undisclosed test data without safeguards to protect against unfair

commercial use. 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 transshipment 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 three years ago, but U.S. rights-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.

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 were disappointed that Canada was not been a more positive force in TPP IPR discussions. As the U.S. and other TPP signatories work to pass and then implement the TPP, the NAM encourages Canada to be more of a positive force to address outstanding IPR-related issues in the TPP such as inadequate data protection for biologics.

We also note with concern a campaign pledge made by the Liberal Party that it "will introduce plain packaging requirements for tobacco products, similar to those in Australia and the United Kingdom." [24] The NAM has taken a strong stance against the elimination of trademarks through plain packaging for all consumer products as a violation of internationally recognized IPR in other markets, such as Australia (see below), and would be similarly concerned if this legislation moved forward.

e. Other countries of concern

Australia has become an increasing concern for NAM members on IPR protection and enforcement due to several issues impacting various sectors.

Australia maintains a unique policy enabling the Department of Health to seek damages from patent holders that pursue unsuccessful patent claims, creating a significant hurdle for companies seeking to defend their legitimate patent rights. Those damages are designed to compensate Australia's pharmaceutical reimbursement scheme (PBS) for any higher price paid for a patented medicine during the period of a provisional enforcement measure. Since 2012, this policy has resulted in at least three cases against innovative pharmaceutical companies. Such efforts create uncertainty for businesses, undermining R&D, innovation, and investment. They also unfairly penalize inventors who have sought to defend their legitimate patent rights.

[24] Galloway, Gloria, "Liberal Pledge to Demand Plain Cigarette Packaging Draws Cheers," The Globe and Mail, October 30, 2015.

Additionally, the policy creates a conflict of interest by permitting the same government that examined and granted a patent to seek damages if that patent is later ruled invalid or not infringed. They appear to be inconsistent with WTO intellectual property rules, including with respect to provisional measures. NAM members are concerned about these policies in Australia, but also for the precedent they set for other markets.

In addition, Australia remains the only country that has implemented legislation prohibiting the application of trademarks and instead has implemented plain packaging of tobacco products. This requirement lacks an evidentiary basis and does not reflect regulatory best practice considerations. Additionally, these rules essentially eliminate internationally respected trademark rights and set a precedent that can apply to a wide range of other products, including food and beverages. 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 enable the public to identify and recognize goods or services as originating from a particular company and being a particular known product. As part of the source-identifying function, trademarks also help to protect against counterfeiting. Perhaps most importantly, 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. For these reasons and others (see cross-cutting issues), five countries have already challenged Australia's plain packaging rules in the WTO. Australia's actions have also been followed in other markets ranging from Ireland and France to Singapore and New Zealand, as have been discussed with respect to other industries as well. For all of these reasons, the NAM opposes Australia's plain packaging requirements.

Trade secret legislation and enforcement in **Austria** continues to suffer from key gaps and weaknesses that prevent companies from adequately protecting trade secrets through criminal prosecution, an important tool to prevent trade secret misappropriation. Austria's Act Against Unfair Competition ("UWG") and the Austrian Criminal Code impose numerous hurdles to a showing of criminal liability, including narrow definitions of trade secrets subject to criminal liability, limitations to criminal liability for employees or third-party competitors for some trade secret misappropriation, low criminal sanctions for trade secret violations, insufficient authority for public prosecutors to bring trade secrets cases. Additionally, criminal trade secret proceedings in Austria are heard not by specialized judges with the sophisticated knowledge needed to address complex trade secrets cases, but by district courts that generally handle low-value criminal matters. For all of these reasons, criminal prosecutions are largely disfavored in Austria; between 2000 and 2014, there were only six convictions for trade secrets crimes under Sections 11 and 12 UWG, and only 12 convictions under Sections 122 to 124 of the Criminal Code.

Manufacturers also 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, is authorized under Article 229-C of the 1999 Brazilian Patent Law to review and approve all patent applications for medicines. Their review is in addition to and given equal weight as INPI examination. ANVISA, however, 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.[25] 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.[26] Brazil is advancing such proposals in domestic legislation and international fora. For years, it has blocked discussions on patent quality and pushed WIPO to create a manual on how to use patent exceptions and limitations.[27]

Colombia has undertaken several negative actions impacting intellectual property for innovative medicines, including issues of patentability and compulsory licensing. For example, Article 70 of Colombia's recently enacted National Development Plan 2014-2018 (NDP) grants authority to the Ministry of Health and Social Services (MHSS) to issue nonbinding opinions to Colombia's patent office on the patentability of medical products undergoing patent review. This process would likely delay and introduce subjectivity into patent reviews.

Additionally, Articles 69 and 70 broaden authority and discretion to review patents related only to health technologies for potential compulsory licensing. These two provisions allow MHSS to seek compulsory licenses for patents on improper economic grounds, such as a shortage in domestic manufacturing, resulting in interference with intellectual property rights for medicines and medical devices. Both provisions deviate from international standards, including standards of the Organization for Economic Cooperation and Development (OECD), are inconsistent with international agreements such as the WTO TRIPS agreement, and raise questions about Colombia's full compliance with the Colombia-U.S. Free Trade Agreement.

Manufacturers also face significant challenges in the **Dominican Republic**, including the widespread availability of pirated and counterfeit products, satellite signal piracy, and administrative denials of patent term adjustments. While the government has taken some steps to improve IPR enforcement – including continued work by the Public Ministry and the National Police to execute raids on counterfeit food and drug products, to close illegitimate pharmacies and food retailers, and to make arrests – IPR enforcement has not improved in other areas.

Manufacturers have noted that patent issuance has improved over the past year as a result of efforts by the Dominican patent office (ONAPI), resulting in a decrease in the large backlog of pending patent applications. The NAM welcomes ONAPI's continued efforts to digitize patents

[25] The 1970s-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.
[26] Center for Strategic Studies and Debates, Brazil's Patent Reform: Innovation towards National Competitiveness, July 2013.
[27] See, for example, Proposal from Brazil to the World Intellectual Property Organization, Standing Committee on the Law of Patents, Fourteenth Session, January 2010.

and create an online application and retrieval system, and urges continued work to expand these efforts. One area to address is patent term adjustments: applications for adjustment of previously granted patents to account for patent application backlogs continue to be denied at the administrative level.

Manufacturers also face challenges on the lack of transparency in processes and predictability in the protection of undisclosed test data and other information generated to obtain marketing approval for pharmaceutical products against unfair commercial use and unauthorized disclosure. The NAM encourages the Dominican Republic to develop regulations to improve the process and protection of biotechnology products in ways consistent with international safety and efficacy standards.

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. Rather than take the steps necessary to address that problem, Ecuador amended its laws in 2014 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 denies 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. Those fees, however, do not secure protection for innovators. The Ecuadoran Intellectual Property Institute has granted ten compulsory licenses for innovative medicines since 2010, with another 11 applications still pending. More than a third of these petitions have been filed by one public pharmaceutical firm, Enfarma. Compulsory licenses should be granted only based on clearly demonstrated need and in compliance with international obligations.

In **South Africa**, the Ministry of Trade and Industry has published a draft National Policy on Intellectual Property.[28] While manufacturers welcome many positive positions expressed in the draft Policy, the NAM is very concerned by provisions that challenge IPR in certain fields and suggest goals that could undermine the importance and value of innovation and intellectual property. The NAM is hopeful that comments from IP creators will be solicited and heeded and that the problematic elements can be removed.

[28] Ministry of Trade and Industry, Draft National Policy on Intellectual Property 2013, (Republic of South Africa Government Gazette), September 2013.

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 next steps on the TPP agreement, ongoing trade negotiations with Europe, 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.[29]

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 billion.[30] 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. Across countries, legal frameworks are characterized by non-deterrent civil and criminal penalties, insufficient remedies, failure to protect confidentiality during legal proceedings, and poor enforcement.[31] In the European Union ("EU"), for example, the fragmented approach to trade secret protection is out of step with today's cross-border business environment. As a result, trade secret theft often goes unpunished and U.S. firms have been forced to dedicate increasing resources to protect trade secrets, resources that could otherwise be dedicated to R&D. The EU is considering a new Directive that would harmonize and upgrade protection for trade secrets.[32] The NAM welcomes new provisions in the TPP addressing some aspects of trade secret theft and urges USTR to work for even stronger provisions in negotiations with the EU.

IPR erosion remains a serious concern, particularly in the multilateral context. The global framework of IPR protections, particularly for clean technology, energy, healthcare and other advanced manufacturing products, is being challenged in a range of international fora. Strong IPR protection and enforcement is critical to achieving global energy and environment objectives. In the World Intellectual Property Organization (WIPO), the World Health Organization (WHO) and elsewhere, however, some foreign countries continue to call for compulsory licensing of clean technologies. Indeed, it took a concerted effort to fend off such an approach at the United Nations Framework Convention on Climate Change (UNFCCC) COP21

[29] Forrester Consulting, "The Value of Corporate Secrets: How Compliance and Collaboration Affect Enterprise Perceptions of Risk," March 2010.
[30] Office of the National Counterintelligence Executive, "Foreign Spies Stealing U.S. Economic Secrets In Cyberspace," October 2011.
[31] Brant J., Lohse S., Trade Secrets: Tools for Innovation and Collaboration (2014, published by International Chamber of Commerce, Paris.
[32] "Trade Secrets," European Commission, last accessed February 2, 2016.

conference in Paris late last year, and the debate over these issues even in that forum is not likely to be concluded.

Those calls are similar to broader efforts across the UN system to position IPR as a barrier to the treatment of disease, the development, dissemination and deployment of clean technologies, and to access to entertainment and information products. A number of such initiatives have been tabled at WIPO within both the Standing Committee on Copyright and Related Rights[33] and also the Standing Committee on Patents.[34] The UN Global Strategy for the Prevention and Control of Noncommunicable Diseases suggests without any evidentiary basis, IPR could prevent countries and patients from accessing treatments, despite a complete lack of evidence. In addition, the WHO has recently sought to limit substantially its engagement with the private sector, which would undermine further the organization's ability to draw on innovator's expertise and experience developing and deploying targeted solutions in different markets.[35] The NAM encourages the U.S. interagency team to build on their successful efforts at the UNFCCC COP21 conference last year, maintaining a strong and coordinated interagency approach to ensure common messaging and working closely with like-minded countries and negotiators to secure a final text that will safeguard IP and innovation while facilitating continued investments by U.S. manufacturers in clean technology.

Additionally, the NAM notes that a number of countries have either revised their policy frameworks in recent years to allow greater flexibility for compulsory licensing in the name of health. This includes Indonesia in addition to the countries named above (India, Colombia, and Ecuador), but is also an area to closely monitor for similar efforts in other markets. 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.[36]

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.

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[33] Various proposals for setting norms to promote global adoption of E/L to copyrights at WIPO's Standing Committee on Copyright and Related Rights (SCCR). For example, see SCCR, Draft Agenda for Thirtieth Session, June 29 to July 3, 2015.

[34] Future work program agreed during the July 27-31, 2015 meeting of WIPO's Standing Committee on the Law of Patents (SCP), held July 2015.

[35] *See* http://www.who.int/about/collaborations/non-state-actors/en/ for documents relating to discussions about WHO engagement with firms and other "non-state actors."

[36] 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.

Trademarks enable the public to identify and recognize goods or services as originating from a particular company and being a particular known product. Trademarks are also frequently 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.

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. Where elements of different trademarks appear similar, the distinguishing function is eroded. As part of the source-identifying function, trademarks also help to protect against counterfeiting.

As noted above, Australia has already implemented legislation prohibiting the application of marks and instead mandating the **plain packaging** of tobacco products – legislation that have been challenged in the WTO by five countries. The United Kingdom and Ireland have adopted but not yet implemented similar proposals, New Zealand, Chile, and France are in the later stages of adoption, while Canada, Uruguay, Thailand, Norway, Hungary, Brazil, and Singapore are seriously considering adoption. These would destroy trademark rights for tobacco and in some cases a wide range of other products, including food and beverages. Other jurisdictions have considered and dropped such proposals, including Belgium, Panama, Mexico, Argentina, and the EU Parliament.

Trademarks by their very nature are 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 is concerned with and opposes such plain packaging rules in global markets.

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.[37] Overseas remote sellers often mistakenly declare 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 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.[38]

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,

[37] 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).
[38] U.S. Postal Service, "Basic Eligibility Standards for Priority Mail," November 1, 2010.

seize and destroy counterfeit goods shipped by mail. A similar approach could be adopted in the United States.

Greater attention also needs to be paid to how Free Trade Zones, while contributing to global freer trade, also are a source of significant counterfeit and illicit trade. Criminals take advantage of the fact that these are outside Customs territories (although still subject to Customs oversight) and the relaxed regulations that apply. Enforcement of IPR and other protections is lax. This contributes to the problem of IPR violations, but there are ways to address it.[39]

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

[39] Business Action to Stop Counterfeiting and Piracy (BASCAP) Report, "Controlling the Zone: Balancing Facilitation and Control to Combat Illicit Trade in the World's Free Trade Zones," May 2013.