Linda Dempsey
Vice President
International Economic Affairs

February 9, 2017

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-2016-0026

Dear Ms. Peterson:

The National Association of Manufacturers (NAM) welcomes the opportunity to provide these written comments for the 2017 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 more than three-quarters of private sector research and development. In total, manufacturing contributes nearly $2.2 trillion to the U.S. economy annually.

Innovation and intellectual property (IP) are the lifeblood of our economy, and the foundation for a competitive manufacturing base that can compete successfully around the world. Vigorous protection of IP rights at home and abroad against those who would steal our innovative ideas and products is a necessity. It spurs further innovation, creating greater certainty for manufacturers that their inventions will be safe and thus enabling them to build new industries and create sustainable, high-paying jobs. Strong IP protection and enforcement are also vital to promote broader U.S. interests, consumer health and safety.[1]

The United States has spent decades building a strong domestic legal framework to protect and enforce manufacturers' intellectual property and working towards a robust set of global rules and standards to strengthen the worldwide protection and enforcement of intellectual property rights. This framework includes not only the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), but also specific, enforceable provisions to boost IP protection in U.S. free trade agreements (FTAs). These agreements not only provide important standards, but also vitally important dispute settlement mechanisms, which, when actively and appropriately used, help ensure that manufacturers in the United States get the bargain of the agreements reached.

[1] White House Office of the Intellectual Property Enforcement Coordinator, "Supporting Innovation, Creativity & Enterprise: Charting a Path Ahead: U.S. Joint Strategic Plan on Intellectual Property Enforcement, FY 2017-2019," December 2016.

Despite those efforts, U.S. IP is a constant target for both foreign competitors who want to steal it, and for foreign governments who want to capture it to build competitive industries. Manufacturers in the United States face a wide variety of challenges to their IP, including growing attacks on the global IP frameworks that afford critical protection around the world for innovative manufacturers and common concerns in many markets such as rampant counterfeiting and piracy, the lack of effective trade secrets protection and efforts at the national level to restrict the granting and use of patents and trademarks. A 2013 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, harming U.S. businesses, jobs, and workers in the process.[2]

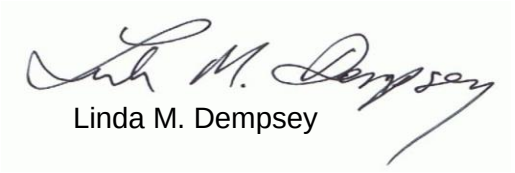
Manufacturers in the United States face particular problems in a number of specific foreign countries that flout international rules and seek to restrict or deny adequate and effective protection and enforcement of U.S. IP. Based on the impact of these foreign governments' market-distorting actions that harm innovative manufacturers, the NAM is recommending that the Office of the U.S. Trade Representative list and classify specific foreign countries in this year's Special 301 report, including:

- **Priority Watch List**: China, Colombia, India, Indonesia, Russia
- **Watch List**: Australia, Brazil, Canada, South Africa, Thailand
- **Out-of-Cycle Reviews**: Colombia, India

To address these challenges, the United States must use all available options, including full use of tools provided under past Special 301 reports such as out-of-cycle reviews; domestic trade enforcement tools such as action plans and enforcement authorities provided by the Trade Facilitation and Trade Enforcement Act of 2015; international trade enforcement tools provided by the WTO; bilateral, regional and global platforms and negotiations to push for vigorous and stronger IP protection and enforcement; and creative education, training and capacity building programs. Additionally, the NAM encourages the U.S. government to take active steps to strengthen interagency coordination to ensure that government agencies speak with one voice in support of robust IP protections that benefit U.S. interests, strengthen the economy, and protect and grow American jobs.

The NAM and its members welcome this opportunity to comment and look forward to working with USTR and other federal agencies to address and resolve the critical IP concerns outlined above and in the attached comments.

Sincerely,



Linda M. Dempsey

[2] Commission on the Theft of American Intellectual Property, "The IP Commission Report," (Washington: National Bureau of Asian Research), May 2013.

Chart: NAM Priority IP Issues by Country

This chart identifies illustrative examples of the types of intellectual property challenges NAM members face in key markets. An "x" indicates priority challenges in a given market.

		Priority Watch List					Watch List		
		China	Colombia	India	Indonesia	Russia	Australia	Austria	Brazil
Broad Policy	**Protectionist Industry, R&D, Localization Policies**	x		x	x	x	x		x
Enforcement	**Problematic Levels of Counterfeiting and Piracy**	x		x		x			
	Weak Channels to Fight IP Infringement	x	x	x		x	x	x	x
	IP-related Customs policies					x			
Patents	**Compulsory Licensing**		x	x	x	x			x
	Patentability Criteria and Patent Review Processes	x	x	x	x				x
	Long Backlogs			x					x
Trademarks	**Challenges to Legitimate Trademark Use**	x					x		x
	Geographical indications (GIs)	x			x				
	Long Backlogs for Trademarks			x					
Copyrights	**Enforcement of manufacturing-related copyrights**	x							
Trade Secrets	**Inadequate Protection of Trade Secrets**	x		x		x		x	
	Insufficient Protection of Business Confidential Information and Regulatory Data	x		x		x			
Other Issues	**Seeks to Erode IP in Multilateral Forums**			x					x
	Rules Governing IP Licensing	x			x				
	Incorporation and Treatment of IP in Standards Activities	x							

Chart: NAM Priority IP Issues by Country

This chart identifies illustrative examples of the types of intellectual property challenges NAM members face in key markets. An "x" indicates priority challenges in a given market.

		Watch List			Others				
		Canada	South Africa	Thailand	Argentina	Dominican Republic	Ecuador	European Union	Peru
Broad Policy	**Protectionist Industry, R&D and Localization Policies**		x						
Enforcement	**Problematic Levels of Counterfeiting and Piracy**	x		x		x	x		
	Weak Channels to Fight IP Infringement	x		x	x				x
	IP-related Customs policies								
Patents	**Compulsory Licensing**		x	x		x			x
	Patentability Criteria and Patent Review Processes	x	x		x				
	Long Backlogs			x		x			
Trademarks	**Challenges to Legitimate Trademark Use**	x		x					
	Geographical indications (GIs)	x						x	x
	Long Backlogs for Trademarks								
Copyrights	**Enforcement of manufacturing-related copyrights**	x							
Trade Secrets	**Inadequate Protection of Trade Secrets**								
	Insufficient Protection of Business Confidential Information and Regulatory Data	x			x		x		x
Other Issues	**Seeks to Erode IP in Multilateral Forums**		x						
	Rules Governing IP Licensing								
	Incorporation and Treatment of IP in Standards Activities								

National Association of Manufacturers
Detailed Comments for 2017 Special 301 Report

Innovation and intellectual property (IP) are the lifeblood of our economy, driving U.S. global leadership in manufacturing. The numbers are clear: the added value of patents, trademarks, copyrights and trade secrets to the U.S. economy is rising faster than ever before, reaching $6.6 trillion in 2015, or nearly 40 percent of total U.S. gross domestic product (GDP). That value continues to grow with nearly 2.8 percent of U.S. GDP devoted to R&D: a figure that makes up more than a quarter of all R&D conducted globally.[3] Such R&D contributes directly to the U.S. economy: a recent study showed that in countries such as the United States, a 1 percent increase in R&D expenditures can grow the economy by an average of 0.61 percent.[4] IP and other intangible assets account for a significant majority of the total market value of key manufacturing industries from information and communications technology to food and beverages, from pharmaceuticals to automobiles, from personal care products to advanced machinery.[5]

Strong IP protection provides powerful incentives for solutions to global challenges, allowing, for example, greater energy efficiency and the delivery of next-generation lifesaving medications. Where IP rights are protected and enforced, innovators thrive, creating and sustaining jobs and promoting international trade. According to a 2016 report by the Department of Commerce and U.S. Patent and Trademark Office, innovative industries accounted for more than 50 percent of all U.S. merchandise exports in 2014, and directly or indirectly support more than 45 million jobs across the country.[6]

With so much at stake, vigorous protection and enforcement of IP rights at home and abroad is critical for manufacturers. Strong IP protections and enforcement further innovation, creating greater certainty for manufacturers that their inventions will be safe and thus enabling them to build new industries and create sustainable, high-paying jobs. These protections are particularly important for small-and medium-sized manufacturers (SMMs), for whom the cost and complexity of protecting their IP rights around the world can be very high relative to their annual sales. The United States has spent decades building a strong domestic legal framework to protect and enforce manufacturers' intellectual property and working towards a robust set of global rules and standards to strengthen the worldwide protection and enforcement of intellectual property rights, such as the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and in more detail in U.S. free trade agreements (FTAs).

Despite those efforts, U.S. IP is a major target for both foreign competitors who want to steal it, and for foreign governments who want to capture it to build competitive industries. The theft of

[3] Industrial Research Institute and Research Technology Management, "2016 Global R&D Funding Forecast," R&D Magazine, Winter 2016.
[4] Şahin, Begüm Erdil, "The Relationship Between R&D Expenditures and Economic Growth: Panel Data Analysis 1990-2013," Paper 207, Presented at Ekonomik Yaklasim Association's EY InternationalCongress on Economics II (EYC2015), November 5-6, 2015, Ankara, Turkey.
[5] As recently as 2009, intellectual property and other intangible assets accounted for more than 90 percent of the total market value of most of these sectors. See 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.
[6] Antonipillai, Justin and Michelle K. Lee, "Intellectual Property and the U.S. Economy: 2016 Update," September 2016.

legitimate intellectual property rights around the world remains a serious problem with a serious impact on the U.S. economy. A 2013 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.[7] This includes theft of patented technology and trade secrets, counterfeiting of branded manufactured goods, and piracy of industrial software that is important for manufacturers. In fiscal year 2016, U.S. Customs and Border Protection seized counterfeit and pirated goods worth more than $1.38 billion.[8] China remains by far the leading source of these products: in 2016, 88 percent of counterfeit goods by value seized at U.S. borders were from China (45 percent) or Hong Kong (44 percent). Major categories of counterfeit products included medicines, consumer electronics, toys, computer accessories, automotive products and other goods that could pose serious health and safety risks if fake.

Manufacturers in the United States face a wide variety of challenges to their IP, including growing attacks on the global IP frameworks that afford critical protection around the world for innovative manufacturers and common concerns in many markets such as rampant counterfeiting and piracy, the lack of effective trade secrets protection, and efforts at the national level to restrict the granting and use of patents and trademarks. Additionally, manufacturers in the United States face particular problems in a number of specific foreign countries that flout international rules and seek to restrict or deny adequate and effective protection and enforcement of U.S. IP, giving rise to specific NAM recommendations to categorize countries into specific categories that reflect the level of concern and impact for manufacturers in the United States.

To address these challenges, the United States must use all available options, including full use of tools provided under past Special 301 reports such as out-of-cycle reviews; domestic trade enforcement tools such as action plans and enforcement authorities provided by the Trade Facilitation and Trade Enforcement Act of 2015; international trade enforcement tools provided by the WTO; bilateral, regional and global platforms and negotiations to push for vigorous IP protection; and creative education, training and capacity building programs. Additionally, the NAM encourages the U.S. government to take active steps to strengthen interagency coordination to ensure that government agencies speak with one voice in support of robust IP protections that benefit U.S. interests, strengthen the economy, and protect and grow American jobs.

1. Cross-Cutting Concerns

As manufacturers in the United States work to protect their intellectual property rights in countries around the world, they encounter a series of common, cross-cutting concerns that deny or threaten to deny adequate and effective IP protection and enforcement for manufactured goods. Many of these concerns are growing, spreading from country to country and compounding the challenges faced by manufacturers. While many of these concerns are included in the NAM's analysis of specific countries, we also urge the Office of the U.S. Trade Representative and other U.S. government agencies to understand and address these concerns comprehensively and strategically, using all available tools and platforms to raise and address these concerns.

[7] Commission on the Theft of American Intellectual Property, "The IP Commission Report," (Washington: National Bureau of Asian Research), May 2013.
[8] Office of Trade, U.S. Customs and Border Protection, "Intellectual Property Rights Seizure Statistics: Fiscal Year 2016," January 2017.

IP Erosion in Multilateral Forums

The global framework of IP protections and enforcement, particularly for clean technology, energy, healthcare and other advanced manufacturing products, is being challenged in a range of international fora. Strong IP protection and enforcement is critical to achieving global energy and environment objectives. In international organizations such as the World Intellectual Property Organization (WIPO) and the World Health Organization (WHO), however, some countries continue to call for compulsory licensing of U.S.-held patents, a concern that requires strong U.S. pushback. Indeed, it has taken a concerted effort of the U.S. and key allies to fend off such an approach at the United Nations Framework Convention on Climate Change (UNFCCC), including discussions at COP21 in Paris (2015) and COP22 in Marrakesh (2016), and the debate over these issues even in that forum is likely to continue through COP23 in Bonn. Such a strong response was possible only through a strong and coordinated interagency approach to ensure common messaging and close work with like-minded countries and negotiators, efforts that must continue for this and other areas.

Those calls are similar to broader efforts across the United Nations (U.N.) system to position IP incorrectly as a barrier to public health, the development, dissemination and deployment of clean technologies, and access to entertainment and information products. Key initiatives include:

- Challenges to IP protection that have been tabled at WIPO's Standing Committee on Copyright and Related Rights[9], Standing Committee on the Law of Patents[10], and Standing Committee on the Law of Trademarks[11] through discussions on expanded use of exceptions and limitations for patents and copyrights and discussions of Europe's push for a separate system to manage geographical indications (GIs).
- Assertions without convincing evidence in reports such as the WHO's Global Action Plan for the Prevention and Control of Noncommunicable Diseases that IP could prevent countries and patients from accessing treatments unless countries make maximum possible use of trade-related patent flexibilities.[12]
- Initiatives such as the U.N. High-Level Panel on Access to Medicines,[13] whose final report in September 2016 showed deep flaws. Claiming to address a very real problem (lack of access to medicine) the panel instead targeted innovation, intellectual property, and manufacturing through multiple proposals to weaken key parts of the global IP framework and limit the ability of countries such as the United States to protect innovators. Although the U.S. government issued a strong response opposing the report and its findings, its supporters have sought broad visibility and support for the report in other forums, such as the U.N. Human Rights Council, WTO TRIPS Council, and WIPO. Additionally, as the panel reports and the issues it raises are playing out in multilateral

[9] See draft documents (including agenda) for November 14-18, 2016 meetings of WIPO's Standing Committee on Copyright and Related Rights, with prominent discussions on exceptions and limitations to copyrights for various uses.

[10] See draft agenda for December 12-15, 2016 meetings of WIPO's Standing Committee on the Law of Patents, with prominent discussions on challenges to use of health-realted patent flexibilities for promoting public health exceptions and more broadly on patent exceptions and limitations to address development.

[11] See draft agenda for October 17-19, 2016 meetings of WIPO's Standing Committee on the Law of Trademarks, Industrial Designs and Geographical Indications, with proposals from various European countries on geographical indications.

[12] World Health Organization, *Global Action Plan for the Prevention and Control of Noncommunicable Diseases, 2013-2020*.

[13] United Nations, "Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines: Promoting Innovation and Access to Health Technologies," September 2016.

forums, they are also being used to pressure national governments to take similar actions, such as Chile, Colombia, Ecuador, India, and Indonesia.

Such attacks on IP in multilateral forums are exacerbated by parallel efforts in some multilateral organizations to limit engagement with private industry. For example, the WHO in May 2016 released their Framework of Engagement with Non-State Actors, a set of rules that limits the organization's engagement with the private sector. Such efforts undermine the organization's ability to draw on innovators' expertise and experience developing and deploying targeted solutions in different markets, while also undercutting the legitimacy and fairness of policy recommendations that the organization releases.[14]

Growing Use of Compulsory Licensing

The NAM has also seen an uptick in the number of countries that have increased their legal flexibility or use of compulsory licensing of patented products, or are considering revisions to legal frameworks to give them that flexibility. Such provisions are often being touched in the name of public health. This includes countries such as Brazil, Colombia, Ecuador, India, Indonesia, Peru, Russia, South Africa, and Turkey but these efforts are being noticed, and often copied, by other countries. For example, NAM members report that the Dominican Republic may be considering revisions to its patent regime to increase use of compulsory licensing, in part due to influence from Colombia, and that Vietnam's Ministry of Health is drafting a circular on compulsory licensing for pharmaceutical patents that would grant broad and arbitrary powers to grant compulsory licenses.[15]

While compulsory licenses can be legitimate government tools to protect public health under certain circumstances, the NAM believes that their use must comply fully with international rules, and should be limited to exceptional circumstances. Decisions to issue compulsory licenses should be made on the facts of the individual case through transparent processes that involve close consultation with all stakeholders. Additionally, such decisions should be based narrowly on public health grounds, not as a tool to promote or protect local manufacturing.

To address these and other challenges to global IP 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 that TRIPS signatories should be held accountable for their compliance with the framework, while ensuring the United States and other countries have the tools at their disposal to address TRIPS-violating behaviors.

Increasing Challenges to Legitimate Trademark Use

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

[14] 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."
[15] "Vietnam: Draft Circular on Compulsory Licensing," Managing Intellectual Property, September 8, 2016.

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

Based on these fundamental tenets of trademark use, the NAM is concerned by, and opposes, increased efforts to block or limit the use of trademarks for certain types of products, particularly plain packaging legislation. Australia was the first country to pass and implement controversial legislation prohibiting the application of marks and instead mandating the plain packaging of tobacco products, even though their legislation has been challenged in the WTO by five countries. The United Kingdom, France, and Hungary have passed and begun implementing plain packaging legislation, and an additional group of more than countries – including Argentina, Brazil, Canada, Chile, Colombia, Ecuador, Finland, Ireland, Kenya, New Zealand, Norway, Singapore, Slovenia, Sweden, Thailand, Turkey, and Uruguay – are at various stages of working on legislation. While much of the immediate focus has been on tobacco, some plain packaging proponents have already called for similar approaches to be taken on other product areas, such as food and beverages. Other jurisdictions have considered and dropped such proposals, including Belgium, Mexico, Panama and the EU Parliament.

Similarly, the NAM has serious concerns about the trademark implications of new draft laws in several countries – including Thailand, Indonesia and Hong Kong – that expand existing infant formula restrictions in troubling ways. These draft laws, spurred by a controversial World Health Organization guidance document developed in 2016 addressing the marketing of complementary food products for infants and young children, generally seek to expand the age coverage for existing marketing bans to include formula and milk products for children up to three years of age. Moreover, these draft laws cover a much broader range of promotional, advertising, educational, labeling and branding activities involving these products. These draft laws raise serious IP concerns, as they restrict the use of trademarked brand names, logos, symbols and packaging that consumers depend on to identify safe, effective products, while also increasing the risk that counterfeit products could enter the supply chain. The draft law also has significant trade and health implications, as it targets only imported products (while exempting local products) and ignores readily available, less trade-restrictive, alternative policy measures to increase breastfeeding rates. It is more restrictive than relevant international standards, specifically the Codex Alimentarius Commission and the WHO Code of Marketing of Breast-Milk Substitutes.

Weak Efforts to Battle Counterfeiting, Piracy, and Patent Infringement

Many countries lack meaningful legal deterrents or suffer from insufficient enforcement mechanisms to address IP infringement, including patent infringement, counterfeiting and piracy, and limited capacity or political will to strengthen those enforcement mechanisms. A February 2016 study estimated that the global economic value of counterfeit and pirated products could reach $2.3 trillion by 2020, costing more than 5 million jobs around the world.[16] Such IP-infringing actions that continue to harm manufacturers of a wide variety of products, including agricultural chemicals, auto parts, consumer goods, machinery, pharmaceuticals, and software.

Counterfeiting and piracy impact countries around the world, but NAM members are highly concerned by the role of China (both directly and via Hong Kong) as the world's major hub for counterfeiting, with Canada, India, Korea, Russia, Singapore, Taiwan, Turkey and the United Arab Emirates as other problematic sources and transshipment points for counterfeits. NAM

[16] International Trademark Association and Business Action to Stop Counterfeiting and Piracy, "The Economic Impacts of Counterfeiting and Piracy," February 2016.

members are also concerned about weak patent enforcement, including a lack of timely and effective channels for early resolution of patent disputes, poor access to legal tools such as injunctions, and lack of access to evidence. These issues impact manufacturers in the United States in a variety of markets, including Algeria, Argentina, Australia, Brazil, Canada, China, Colombia, India, Korea, Mexico, Peru, Russia, Thailand, Turkey, and Vietnam.

The NAM believes customs officials abroad must have enforcement authority sufficient to combat the illicit trade in counterfeit and pirated goods, including the ability to monitor 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 inadvertently facilitates illicit trade to the detriment of brand owners, as 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 8 to 15 percent of global GDP.[17]

Such authorities must address all appropriate channels for counterfeit goods. For example, 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.[18] Overseas remote sellers often 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 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 and can be delivered 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.[19] 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.

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 zones are outside Customs territories (although still subject to Customs oversight) and the relaxed regulations that apply. This contributes to the problem of IP violations, but there are ways to address it laid out in leading reports published by industry and expert groups.[20]

Additionally, anti-counterfeiting efforts must tackle not only traditional physical counterfeiting markets and cross-border transit routes, but consider all means by which counterfeit products are circulating, including online auction sites in China such as Alibaba and Taobao. Some of

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[17] 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.
[18] 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).
[19] U.S. Postal Service, "Basic Eligibility Standards for Priority Mail," November 1, 2010.
[20] See, for example, 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.

these platforms have pledged actions, but have yet to address in a meaningful way all of the concerns for many brand-owners facing rampant counterfeiting via online platforms.

Inadequate Protection of Trade Secrets

Protecting trade secrets from increasingly sophisticated physical and electronic theft and ensuring adequate and effective enforcement presents a growing worldwide challenge, making them top priorities for manufacturers. Trade secrets form an increasingly important part of the IP portfolios for 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.[21] More recently, a 2016 U.S. International Trade Commission report cited surveys of U.S. firms noting that more than 62 percent of manufacturing firms of all sizes said that trade secrets are "very important" to their business, a number even higher than the level of concern for patents, trademarks, or copyrights.[22]

For a host of reasons, however, trade secret theft and misappropriation are growing challenges. A 2014 study estimated that the economic loss from trade secret theft is between 1 and 3 percent of U.S. GDP, translating to a loss between $180 billion and $500 billion.[23] Weak trade secret protection and enforcement puts industrial know-how and technology at risk, 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 low civil and criminal penalties, insufficient procedural remedies, failure to protect confidentiality during legal proceedings, and poor administrative enforcement.[24] Effective enforcement also depends, at least in part, on the availability of information and access to evidence. In many countries, enforcement is complicated by lack of judicially supported mechanisms of gathering evidence related to an alleged violation and the potential scope of damages. This is especially true for trade secrets (along with process patents), where a defendant can hide its illegal use of such IP within the four walls of its facility with impunity.

Trade secrets are a particular challenge in countries such as Austria, China, India and Russia. Last year's passage of the Defend Trade Secrets Act here in the United States, and of the new Trade Secrets Directive in the European Union, were important steps forward to strengthen the tools for companies and regulators to boost trade secrets protection. Broader adoption of these types of protections would greatly benefit manufacturers in the United States.

Restrictions on Patentability Criteria

Despite a clearly limited set of three criteria for patentability under TRIPS Article 27.1: that a potential patent must be new ("novelty"), non-obvious ("inventive step"), and useful ("industrial applicability"), the NAM and its members have noted a growing number of countries applying additional hurdles that inventors must jump over in order to obtain or defend patents. Such

[21] Forrester Consulting, "The Value of Corporate Secrets: How Compliance and Collaboration Affect Enterprise Perceptions of Risk," March 2010.
[22] Linton, Katherine, "The Importance of Trade Secrets: New Directions in International Trade Policy Making and Empirical Research," *Journal of International Commerce and Economics*, September 2016.
[23] PricewaterhouseCoopers and CREATe.org, "Economic Impact of Trade Secret Theft: A Framework for Companies to Safeguard Trade Secrets and Mitigate Potential Threats," February 2014.
[24] Brant J., Lohse S., Trade Secrets: Tools for Innovation and Collaboration (2014, published by International Chamber of Commerce, Paris.

unique limitations have popped up in markets such as Argentina, Canada, China, India, and Indonesia.

These additional criteria have taken a variety of forms, including higher-level requirements for a patent to demonstrate utility at the time of filing (Canada), specific restrictions on certain types of inventions such as specific uses for pharmaceutical products (Argentina, India, and Indonesia), and bans on filing of supplemental data to obtain or defend a patent (China, Canada). Regardless of their form, however, such additional criteria are inconsistent with these countries' TRIPS obligations. In the case of Canada, they also appear to violate its North American Free Trade Agreement (NAFTA) obligations.

Long Backlogs for Patents and Trademarks

In some countries around the world, long delays in obtaining intellectual property (particularly patents and trademarks) create significant challenges for companies seeking to register and legally use those IP rights. Delayed patent and trademark applications hinder both domestic and foreign investors across manufacturing sectors exporting to, or operating in, those markets. Such backlogs limit the speed at which companies can deploy products and technologies to these markets, making them less attractive as export and investment destinations, and limiting product choice for consumers in those markets.

While patent and trademark delays cause challenges in a variety of markets, NAM members note that the challenges are particularly high in markets such as Brazil, Egypt, India, and Thailand. In some cases, these delays can partially explained by the approval processes. In Brazil, for instance, patents in areas such as health are required to be reviewed by the health ministry (ANVISA) in addition to the IP office (INPI), causing delays. In other instances, delays are due to the lack of adequate capacity or full training for patent and trademark examiners. Resolving these processes must involve streamlining patent and trademark procedures (including both application and review processes) and building capacity among examiners. For patents, the NAM also encourages USTR to urge countries with long patent backlogs to consider patent-term adjustment procedures, which would allow a patent applicant to apply for an extended patent term to account for time lost through long patent application backlogs.

Insufficient Protection of Business Confidential Information and Regulatory Data

Protection of test data and other business confidential information provided to regulators of various industries, including pharmaceuticals, biotechnology products, and agricultural chemicals, remains a serious problem in a wide variety of markets. The lack of adequate protection of test data is a major concern in India and Russia, and is also a factor in markets such as Algeria, Argentina, Canada, Chile, Ecuador, Egypt, Jordan, Mexico, Morocco, Peru, Saudi Arabia, Tunisia, and Turkey. Protection of broader business confidential information is similarly a concern in a number of markets, including many of those listed above as well as China.

The failure to protect such data has a variety of implications for manufacturers in the United States. Protecting test data for the pharmaceutical and biotechnology sector, for example, provides critical incentives for investment in new products and future R&D activities. Clear rules to protect business' confidential information enable businesses to comply with foreign regulations without having to give up core technologies, and prevent foreign governments from sharing critical operational information to foreign competitors. The NAM urges USTR and other agencies to focus greater attention on protection of business-critical testing and operational data

by foreign regulators, encouraging them to set clear requirements to protect such data and specific ramifications for officials and agencies that fail to do so.

2. Country-Specific IP Challenges

Manufacturers in the United States face serious obstacles to adequate and effective IP protection and enforcement in both developed and developing markets. While the size, growth, and potential of these markets present great opportunities for manufacturers, discriminatory IP policies shelter domestic companies that create competitive challenges around the world and challenge the ability of manufacturers in the United States to export to these markets.

The NAM has seen progress in some markets, including dialogue on copyrights and trade secrets in India, greater attention to IP enforcement in China, and efforts to address patent backlogs in markets like Brazil and Thailand. Many countries, however, have seen little progress, and others are moving in the wrong direction. Overall, challenges faced by innovative manufacturers around the world that try to protect and use their IP are growing. These issues must be addressed through stronger trade enforcement and through concerted bilateral dialogue that is focused on meaningful, tangible progress.

The NAM's comments provide greater detail on a targeted list of priority countries that have been prioritized by members across the NAM's membership, including:

- Argentina
- Australia
- Austria
- Brazil
- Canada
- China
- Colombia
- Dominican Republic
- Ecuador
- European Union
- India
- Indonesia
- Peru
- Russia
- South Africa
- Thailand

Additionally, the NAM and its members also have flagged issues in a variety of other countries and regions that are highlighted in the cross-cutting issues, including issues in:

- Algeria
- Argentina
- Chile
- Egypt
- Finland
- Hong Kong
- Ireland
- Jordan
- Kenya
- Korea
- Mexico
- Morocco
- New Zealand
- Norway
- Saudi Arabia
- Singapore
- Slovenia
- Sweden
- Tunisia
- Turkey
- Uruguay
- Vietnam

India

India continues to be one of the most challenging markets for innovative manufacturers across the board: not only those concerned with patents, but also trade secrets, copyrights, and brand protection. Previous Special 301 reports have cited India’s “weak IP legal framework and

enforcement system"[25] and "longstanding challenges that represent significant IP regime deficiencies compared to other markets."[26]

Over the last year, India has taken some steps designed to alleviate concern about their IP regime. This includes greater public recognition, through the release of their National IP Policy and statements at key bilateral dialogues, of the value of intellectual property for its economic growth and development, and the launch of new campaigns to better educate Indian stakeholders of that value. Additionally, the Controller General of Patents, Designs and Trademarks has taken steps to address longstanding concerns about delays for patent and trademark applications by hiring more examiners, expanding electronic filing procedures, and meeting with public stakeholders to collect ideas for further improvements.

In parallel, the U.S. government has sought to engage their Indian counterparts on IP issues through channels such as the High-Level Working Group on Intellectual Property, cooperative workshops held in 2016 with India's Department of Industrial Policy and Promotion (DIPP) on copyright policies and trade secrets protections, and other engagement surrounding the Strategic & Commercial Dialogue (S&CD)[27] and Trade Policy Forum (TPF).[28] Such efforts have resulted in a handful of broad commitments such as India's recognition of the value of "robust and balanced IP protection," the role that IP and innovation play in enhancing access to health, and the importance of "transparency, predictability, speed, clarity, and streamlining" of patent procedures.

Despite such dialogues and broad commitments, the fundamental challenges facing manufacturers in the United States trying to protect their patents, trademarks, copyrights, and trade secrets remain unchanged. This is not a new problem: USTR's 2014 out-of-cycle review,[29] designed to assess tangible progress that stemmed from more U.S.-India engagement on IP showed that the United States had gained commitments to further boost dialogue, but had achieved few specific actions.

India's new National Intellectual Property Policy, released in May 2016, is a perfect example of this dichotomy.[30] The policy includes positive language that recognizes on the importance of IP for economic development and calls for stronger IP laws and enforcement, and includes a few other areas of progress, such as reorganizing and increasing capacity in India's IP agencies, process reforms to streamline and increase enforcement, and more campaigns to build public awareness of the value of IP. The policy itself, however, is lacking in concrete detail, and removes detail on areas such as legal reforms that was included in earlier drafts. Overall, the policy illustrates little real willingness by India to tackle some of the greatest concerns with its existing IP framework, including those related to patents and trade secrets flagged by the NAM and other industry groups in detailed comments. Specific concerns include continued goals to seek unfettered use of TRIPS flexibilities (while defending all aspects of India's current Indian policy and practice as fully TRIPS-compliant) and expanded language on IP licensing and technology transfer.

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[25] Office of the U.S. Trade Representative, "2014 Special 301 Report," April 2014.
[26] Office of the U.S. Trade Representative, "2016 Special 301 Report," April 2016.
[27] "Joint Statement on the Second India-U.S. Strategic and Commercial Dialogue," August 31, 2016.
[28] "India and United States Joint Statement on the Trade Policy Forum," October 20, 2016.
[29] 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.
[30] Department of Industrial Policy and Promotion, "National Intellectual Property Rights Policy," May 12, 2016.

Other broad Indian policies have also raised concerns with language that appears designed to benefit or promote domestic industries at the expense of innovative foreign manufacturers. For example, India released a National Manufacturing Policy in late 2011 that encourages compulsory licensing of green technology that is "not available at reasonable rates" or is not manufactured in India.[31] 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 2011 National Competition Policy requires IP owners to license all "essential facilities," a provision that appears to include a wide range of technologies.[32] The right to exclude is a key component of intellectual property that spurs innovation, and is critical to spur innovation; such a blanket curtailment of such rights harms India's image in ways that could discourage innovation and investment. All of these policies remain in place as of early 2017.

India continues to deny **patent protection** for inventions that meet internationally accepted criteria. Under the 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 2005 revised Patent Act, however, creates a fourth "enhanced efficacy" test that allows them to reject TRIPS-compliant patent applications. Moreover, the Patent Act does not provide clear guidance as to how patent examiners should interpret this criterion, leading examiners and courts to interpret it subjectively and inconsistently in patent proceedings. Using Section 3(d), India has rejected, invalidated, or otherwise revoked at least 25 products over the last five years, including products and therapies widely patented in other countries around the world. Despite repeated attempts by the U.S. government to engage on this issue, India has remained unwilling to consider changes to its Patent Act or Patent Examination Guidelines to address these concerns.

The lack of predictability around **compulsory licenses** in India, particularly for innovative pharmaceuticals, remains a serious challenge. By all accounts, the Indian government has generally taken a more careful approach to compulsory licensing cases over the last several months, including cases in which domestic applications for compulsory licenses were rejected. Such an approach, however, does not address the broader concerns with India's compulsory licensing regime. Documents such as the Department of Industrial Policy and Promotion (DIPP)'s 2011 discussion paper on compulsory licensing that stressed the value of compulsory licensing to promote domestic invention and domestic industry raise legitimate concerns about the intent and approach to compulsory licensing.[33]

More specifically, grounds for issuing a compulsory license under Sections 66 and 92 of the Patent Act remain are broad and vague, granting the Controller General of Patents, Designs and Trademarks broad authority to issue such licenses on broad grounds and often with little transparency or consultation. Additionally, the Ministry of Health (MOH) troublingly continues to recommend imposing compulsory licenses on certain anti-cancer medicines using special provisions under Section 92, and broad government statements continue to stress India's right

[31] Government of India, Ministry of Commerce and Industry, Department of Industrial Policy and Promotion, "National Manufacturing Policy," November 2011.
[32] Technologies listed in Section 5.1(vi) include at least "electricity, communications, gas pipelines, railway tracks, ports, IT equipment." See Competition Commission of India, "National Competition Policy 2011."
[33] Department of Industrial Planning and Promotion, "Discussion Paper: Compulsory Licensing," 2011.

to use compulsory licenses as broadly and freely as it chooses.[34] The NAM believes that while use of compulsory licenses should, as required by both the spirit and letter of TRIPS, in fact be much narrower in scope, limited to exceptional circumstances, based on a transparent assessment of the facts of the case, and narrowly constituted on public health grounds, and not as a tool to promote or protect local manufacturing.

India has also been **vocal in multilateral fora** challenging the value of IP property rules and seeking to broaden as much as possible the grounds and uses of TRIPS flexibilities. At the WTO TRIPS council, for example, Indian representatives have denied links between IP and innovation.[35] At WIPO, India has questioned and sought to redirect work on patent quality.[36] India was also a leading voice pushing for broad adoption of the September 2016 U.N. High-Level Panel on Access to Medicines, and a vocal advocate urging other forums to discuss the report and its findings. 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.

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 test data or other information generated to obtain marketing approval for pharmaceutical and agricultural chemical products. This lack of protection allows domestic companies to simply use test data paid for and generated for marketing approval abroad, providing a substantial cost advantage to domestic generic companies at the expense of both foreign companies and foreign regulators. Though an earlier draft of the National IP Policy had described protection of such data as an "important area of study and research for future policy development," that language was unfortunately removed from the final draft.

Counterfeiting and **piracy** are both challenges for many companies in India. Recent studies show that counterfeiting is particularly problematic in manufacturing sectors such as pharmaceuticals, packaged foods, mobile phones, and alcoholic beverages, and those sectors lost above $6.2 billion in 2014.[37] As in other markets, counterfeiting (and piracy) in India are increasingly operating through online channels, a fact exacerbated by India's underdeveloped legal and regulatory framework for e-commerce. Copyright piracy is similarly widespread across India, despite reforms passed in 2012. Though the rate of piracy has declined slowly over time, nearly 60 percent of all software is not properly licensed: that unlicensed software has a commercial value of $2.7 billion in a 2014 study.[38] According to an NAM study, global software piracy cost more than 42,000 U.S. manufacturing jobs over the last decade.[39] An April 2016 copyright workshop between USTR and DIPP and forward-looking statements at the October

[34] For example, the Ministry of Commerce and Industry in March 2016 issued a statement stating that "Under the Doha Declaration on the TRIPS Agreement Public Health, each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted… Even as Government of India is conscious of the need to spur innovation and protect individual rights, it retains the sovereign right to utilize the flexibilities provided in the international IP regime." Ministry of Commerce and Industry, "Clarification on Media Reports Regarding Compulsory Licence," March 22, 2016.
[35] TRIPS Council Meeting Minutes, June 11-12, 2014, IP/C/M/76/Add.1, paragraph 347.
[36] WIPO Standing Committee on Patents Minutes, July 27-31, 2015, SCP/22/7, paragraph 41.
[37] Federation of Independent Chambers of Commerce in India (FICCI), "Inadequate enforcement and lack of consumer awareness boost counterfeiting in India," Press Release, January 15, 2016.
[38] BSA, The Software Alliance, "Seizing Opportunity Through License Compliance - BSA Global Software Survey," May 2016.
[39] Kerr, William and Chad Moutray, "Economic Impact of Software Piracy for Manufacturers in the U.S.," National Association of Manufacturers, January 2014.

2016 Trade Policy Forum point in the right direction, but to date, little meaningful action has been taken.

India does not provide adequate and effective protection for **trade secrets** and **confidential business information**. India lacks a stand-alone trade secrets law, as is commonly used in other jurisdictions (including the United States and the European Union). Instead, businesses must rely primarily on contracts in order to protect their trade secrets, a narrow application that does not apply to many trade secrets breaches that impact businesses, including trade secret theft where there is not a direct contractual relationship between the trade secret owner and the infringer, and also offers only civil remedies (not criminal).[40] In practice, manufacturers in the United States may have little recourse against contract service providers in India that misappropriate trade secrets. India's 2016 National IP Policy does call for research and study on future policy development for trade secrets, but with little detail. In October 2016, USTR and India's Department of Industrial Policy and Promotion (DIPP) held a workshop that produced steps in the right direction, including a new study on legal approaches to trade secrets protection, development of a toolkit for industry on existing channels for trade secret protection, and potential judicial training on trade secrets issues. The NAM supports these efforts and further engagement on ways to improve India's trade secrets regime to provide effective protection.

Long **backlogs for patent and trademark reviews** continue to create challenges for manufacturers seeking to register and use their IP in India. In India, for example, the average patent grant takes nearly eight years from its application date, a number that has increased steadily in recent years.[41] As noted above, India has taken some steps over the past year to address pendency concerns by hiring more examiners, expanding electronic filing procedures, and meeting with public stakeholders to collect ideas for further improvements. Indian government statistics seem to indicate some improvement in this area, with upticks in the number of patents and trademarks reviewed and granted that could cut into the backlog. In contrast to these positive steps, the NAM is concerned about efforts to reduce patent and trademark backlogs that require localization or promote domestic industry. For example, the 2015 Patent Rule Amendments issued by the Ministry of Commerce and Industry that offer expedited patent examination for applicants that manufacture or commit to manufacture their inventions in India are discriminatory and do not align with international patent norms.

India's December 2015 **revised Model Bilateral Investment Treaty (BIT) text** was an improvement on some aspects of earlier drafts, including welcome coverage of IP ("copyrights, know-how, and IP 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. However, the draft continues to exclude compulsory licenses from any BIT obligations, and raised other investment concerns that are troubling to innovative manufacturers in the United States. 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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[40] As some have pointed out, Indian law does allow plaintiffs to use the common law tort of 'breach of confidence' in some cases, but in practice these cases can be challenging and rulings are not always consistent enough to provide clear confidence for investors. See Library of Congress, "Protection of Trade Secrets: India," June 2015; Chandni Raina, "Trade Protection in India: The Policy Debate," Working Paper, Indian Institute of Foreign Trade Centre for WTO Studies, September 2015.

[41] Schultz, Mark and Kevin Madigan, "The Long Wait for Innovation: The Global Patent Pendency Problem," George Mason University Center for the Protection of Intellectual Property, October 2016.

To address the challenges companies face in India's IP environment and other discriminatory policies to manufacturing and jobs in the United States, the NAM and 15 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 ensure a fair, robust, and reciprocal U.S.-India economic relationship and address ongoing challenges that have negatively impacted U.S. economic growth, exports, and jobs.

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 IP 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 thorough OCR of India in 2017 to assess the tangible results of robust bilateral engagement on intellectual property over the past three years and inform not only India's placement in future Special 301 reports but also future approaches to IP with India.

China

China's increased recognition of the value of innovation and intellectual property, as reflected in high-level documents such as the 13th Five-Year Plan, has fostered more attention on IP at home and progress on IP issues in bilateral dialogues such as the 2016 Strategic and Economic Dialogue (S&ED) and Joint Commission on Commerce and Trade (JCCT). In 2016, for example, that included commitments to eliminate persistent indigenous innovation requirements in government procurement policy, address security-related IP issues in information technology policies, and cooperation on technology licensing, and addressing IP infringement over e-commerce platforms.[42] The NAM supports these outcomes and USTR efforts to ensure robust implementation of Chinese commitments related to intellectual property.

Yet there is a clear reason why China has remained on the Priority Watch List of the Special 301 report year after year: manufacturers in the United States continue to face significant IP-related challenges that stem from Chinese government policies and practices. The United States must continue to urge China to do more to create a fair innovation environment. Such an environment would allow foreign companies to develop, register, and protect IP in China on a non-discriminatory basis, while not providing unfair advantages to domestic firms or requiring them to localize their R&D or technology in China. Examples of discriminatory or otherwise harmful IP policies include China's continued position as a hub for global counterfeiting and piracy, lack of effective trade secret protection and protection for confidential business information, continued weaknesses and implementation questions on core IP laws, and indigenous innovation and industry development policies that protect domestic IP-intensive industries, and structural barriers that hinder effective enforcement of IP rights.

Counterfeiting and **piracy** remain rampant in China, which continues to be the leading source of counterfeit and pirated goods traded around the world. In 2014, 87 percent of the $1.35 billion in counterfeit goods seized at U.S. borders were from China (52 percent) or Hong Kong (35 percent).[43] Major categories of counterfeit products included medicines, consumer electronics, toys, computer accessories and other goods that could pose serious health and safety risks. IP theft in China is a serious concern for manufacturers of all sizes, but can pose an

[42] Office of the U.S. Trade Representative, "U.S. Fact Sheet for the 27th U.S.-China Joint Commission on Commerce and Trade," November 2016.
[43] Office of Trade, U.S. Customs and Border Protection, "Intellectual Property Rights: Fiscal Year 2015 Seizure Statistics," April 2016.

insurmountable challenge for small businesses. These firms often do not have in-house IP experts or investigators. They do not have the resources to track down and prosecute counterfeiters and pirates, and are particularly reliant on government actions to stop international counterfeiting and piracy and trade in fakes.

In China, these problems are fueled by structural policy barriers, including insufficient coordination among different agencies and levels of government, insufficient political will by officials to tackle the problem, and inadequate resources and capacity to address IP infringement. Specific value thresholds prevent criminal prosecution for IP infringement in most cases, and low administrative fines and civil damages provide little deterrence as counterfeiters and pirates often see fines merely as a cost of doing business.

While U.S. federal agencies are taking important and meaningful steps to stop international counterfeiting and piracy, including new tools provided by the Trade Facilitation and Trade Enforcement Act of 2015, those officials face a huge challenge in trying to address counterfeiting and piracy in China. Chinese counterfeiting and piracy have a broad impact here in the United States: exposing U.S. consumers to illegal or even hazardous imported products and putting critical U.S.-developed technologies at risk. For some, that risk is just too high. Smaller NAM members, in particular, often are reluctant to or decide not to export to China for fear of losing their IP, thus cutting them out of one of the world's largest markets. The United States cannot afford to accept weak IP enforcement in China that prevents small businesses from exporting to one of the world's largest and fastest growing markets.

Fighting counterfeiting and piracy in China must not only tackle traditional physical counterfeiting markets and cross-border transit routes, but all means by which counterfeit products are circulating, including online auction sites in China such as Alibaba and Taobao that have pledged actions but have yet to address concerns for many brand-owners facing rampant counterfeiting via their platforms. Other means that must be tackled include transit of counterfeit products via inadequately policed free trade zones in markets around the world, and illegal use by overseas rogue sites and remote sellers of international mail services and airmail such as the China-based express mail service of the China Post.

Trade secret theft also remains a challenge in China, though companies have seen some positive steps, including a handful of trade secrets cases in which courts granted preliminary injunctions. 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, but remain limited in terms of their scope and jurisdiction. Current actions, however, 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 IP seriously.

Previous rounds of the Joint Commission on Commerce and Trade (JCCT) included Chinese commitments on these areas, including revisions to its Anti-Unfair Competition Law, issuance of issue model or guiding court cases, and clarification of rules on preliminary injunctions,

evidence preservation orders, and damages.[44] Indeed, China's State Administration of Industry and Commerce (SAIC) in February 2016 released a draft of the AUCL for public comment that included some positive changes, including increasing administrative fines for trade secret infringement and allowing a company bringing a trade secret case to shift the burden of proof to a defendant once they can establish that infringement has probably occurred. Yet the law did not fully address other challenging areas of trade secret protection, including high evidentiary burdens, low damage awards, and limited use of judicial tools such as preliminary injunctions, and is not yet final. The NAM encourages the U.S. government to work with China to meet its JCCT commitments related to trade secrets, and to continue encouraging China to move beyond those commitments to consider legal and judicial 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.

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. In the run-up to the 2016 JCCT, the State Council issued a formal document requiring local governments and agencies to eliminate provisions linking indigenous innovation to government procurement preferences, reaffirming a commitment made by former president Hu Jintao in 2011 and addressing one area of discriminatory treatment for innovative foreign products.[45] As with the 2011 commitment, full and robust implementation and monitoring will be key to address manufacturer concerns. Despite these developments, NAM members are monitoring closely to ensure that policies at the central and provincial level, such as the Made in China 2025 policy framework, do not unfairly protect domestic business at the expense of innovative foreign manufacturers.

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 enjoy a high level of protection but often carry a low level of inventiveness. Though these patents may not have 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 companies and individuals. Since no substantive review of unexamined assets is required prior to their assertion, they can represent a significant business risk to innovation-driven U.S. and Chinese companies. The NAM believes China's patent system should be reformed to address these concerns. Possible reforms could include:

- Requiring the preparation of an evaluation report for utility model patents before issuing the patent;
- Encouraging the preparation of an evaluation report for utility model patents to accompany a cease and desist letter on a utility model patent, or requiring such an evaluation report prior to filing a complaint
- Requiring the patent applicant to pay the fee for a substantive examination, regardless of who requests the examination

[44] U.S. Department of Commerce Office of Public Affairs, "U.S. Fact Sheet: 26th U.S.-China Joint Commission on Commerce and Trade," November 2015; Office of the U.S. Trade Representative, "U.S. Fact Sheet for the 27th U.S.-China Joint Commission on Commerce and Trade," November 2016.
[45] US-China Business Council, Update: China's Innovation & Government Procurement Policies, May 2015

- Impose meaningful penalties for companies operating in bad faith by threatening competitors or customers with unexamined or rejected utility model patents.

Manufacturers in the United States are also closely watching the **ongoing revisions to key areas of the IP legal framework**, such as the Patent Law and the Copyright Law, which may impact the ability of manufacturers to register and protect their IP in China. With the Patent Law, for example, a number of outstanding questions remain related to administrative patent enforcement authority, the role of local patent authorities in enforcement, and vague language related to IP abuse that could pose challenges for companies to exercise their patent rights.

Other legal revisions already completed, such as the **Trademark Law** and its implementing regulations, 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. Other trademark issues facing manufacturers remain unaddressed by the latest revised law, including persistent issues of trademark squatting in China. This is a longstanding challenge for manufacturers, particularly SMMs, exacerbated by China's "first to file" system (which prevents consideration of prior unregistered use of a trademark) and a high standards for well-known trademarks (requiring the mark to be well-known to the average consumer across China) that often serves as a *de facto* bar for many foreign companies.

Manufacturers are also closely monitoring China's increasing incorporation of IP rules into other areas of regulation, sometimes in ways that raise significant concerns for manufacturers and questions about their consistency with WTO obligations. For example, China continues to give special, unwarranted attention to **IP in the context of competition**, with a number of outstanding guidelines designed to regulate "IP 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.[46] 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 IP does not equate to market power. In instances where competitive concerns may genuinely be raised by bad behavior, the appropriate remedy should be to address that behavior, not to curtail IP.

China's **IP-related 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 2013 with revised Regulatory Measures on National Standards Involving Patents 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

[46] These rules follow similar IP abuse rules already formulated and finalized by the State Administration of Industry and Commerce in April 2015.

competitors.[47] These gaps are particularly noticeable in areas of manufacturing such as information technology.

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. China at the 2016 JCCT stated that they are actively researching potential revisions to these regulations to address U.S. concerns, and plans to convene a joint seminar with the United States in the first quarter of 2017. The NAM encourages the U.S. government to hold China to that commitment.

Protection of sensitive business information is also a question for many NAM members operating in China. Similarly, companies report instances in which customs officials in **China** press importers of certain chemical formulations to supply proprietary information, including the name and percentage of each specific monomer as a condition of customs clearance.

China continues to draft a new regulation on "**service inventions**" that are created during an inventor's employment, though there have been no new updates in several months. If passed, the regulation could damage the ability of manufacturers to make commercial choices about how best to exploit IP 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.

The United States and China made important commitments at the December 2014 JCCT related to **geographical indications (GIs)**, an important area of IP protected as a trademark broadly around the world, including in the United States. Those pledges covered the importance of relationships between GIs and trademarks, recognition that generic terms are not eligible for GI protection, and the importance of GI opposition and cancellation proceedings, and a commitment to further dialogue on these issues. The United States and China should continue to engage actively on these issues both in bilateral discussions and as the two countries engage with other trading partners.

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 United States, Europe, Japan and Korea: meaning that patents accepted in these locations can experience problems in China. China's State Intellectual Property Office in 2016 issued draft Patent Examination Guidelines that would require examiners to consider post-filing experimental data – a shift that appears intended to implement its December 2013 U.S.-China Joint Commission on Commerce and Trade (JCCT) commitment to allow patent applicants to

[47] 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.

submit additional data after filing patent applications. The NAM hopes that the final guidelines, when released, reflect this change as well as other feedback received from industry groups.

Russia

Despite significant commitments made to improve its legal and enforcement framework, Russia has made little progress on IP issues over the last year. Russia continues to suffer from weak IP enforcement against **counterfeiting** and **piracy**, with existing problems not improving. Russia is both a producer of counterfeit products and a transshipment point for counterfeit products produced in other countries (such as China). Manufactured products affected include agricultural chemicals, auto parts, consumer goods, machinery, medicines, software and a wide array of other products. 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. Many have noted some uptick in action by Russian courts against online piracy, but the structural challenges remain in place. Patent enforcement also remains a problem, particularly in pharmaceutical products: innovative manufacturers in practice lack effective mechanisms to resolve patent disputes prior to the launch of generic products.

Trade secret protection is a particular problem in Russia, due to a variety of barriers created both by overly prescriptive requirements in the 2004 Federal Law on Commercial Secrecy that businesses must meet to bring a trade secrets case, judicial practices that apply limited penalties for trade secrets breaches despite a full set of legal options available under the Civil Code, and weak enforcement of trade secrets protection throughout the system. Changes both to legal provisions and court practice are needed to address these issues in full.

Additionally, the NAM has concerns about potential **compulsory licensing** issues in Russia. The Federal Anti-Monopoly Service (FAS) has developed legislation amending the Civil Code and Competition Law to enable compulsory licensing for medicines. In view of comments made by senior Russian officials alleging that some unnamed patent holders are abusing IP rights to gain a monopoly on the market and set high prices, the NAM is concerned that the government could promote compulsory licensing in certain circumstances to promote domestic generic medicines over imported innovative medicines. The legislation is still pending, but could be passed soon, based on statements from the head of FAS in December 2016.[48]

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 IP exhaustion and trademark protection. To date, Russia has not fully integrated its IP regime with the principles laid out by the EEU. This integration process should be monitored carefully to understand the regulatory environment impacting IP and IP-intensive industries.

Russia still does not effectively protect against **unfair commercial use of 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 in 2015 enacted amendments to its Law on Circulation of Medicines, which addresses protection of test

[48] "Russia's FAS designs mechanism for withdrawal of licenses on drugs production in Russia," The Pharma Letter, December 13, 2016.

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. A recent judicial interpretation of these rules has raised questions for policymakers how this may be interpreted and implemented going forward.

Canada

While Canada has made progress on some issues, the NAM has considerable concerns about a number of issues affecting our members broadly. On a positive note, the NAM supported Canada's efforts to strengthen customs authority to address counterfeiting, including the 2014 enactment of Bill C-8 (Combating Counterfeit Products Act) in December 2014 that granted customs authorities the power to seize imports of **counterfeit and pirated goods**. The NAM encourages continued work to fully implement these authorities, encouraging Canadian customs officials to work with their counterparts in the United States and other countries to prioritize enforcement actions and stop trade in infringing products. This work is critical in reversing a worrying trend of rising imports and transshipment of counterfeit and pirated goods into and through Canada.

Additionally, the Canadian government's 2015 passage of amended PM (NOC) Regulations were a positive step, addressing judicial rulings that had claimed 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 fixed 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, clarifying the rules for all inventors.

In other important areas, however, Canada's IP 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 manufacturers in the United States: though the doctrine has primarily been used for products in the pharmaceutical sector, it has been written, and in a few cases applied, in a way to catch products in other innovative sectors. Under TRIPS, an innovator generally must demonstrate the product is useful to receive a patent for a product. Canadian courts, however, have redefined that "utility" requirement in a way seen nowhere else around the world by requiring the applicant to submit 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 28 patents on innovative medicines since the doctrine was created in 2005. This invented "promise doctrine" poses an additional hurdle to patentability and, in some cases, has been wrongly conflated with effectiveness for regulatory approval. This has enabled companies seeking to make copies of innovative medicines to mount unjustifiable but successful patent challenges, and significantly dampened the flow of health innovation in Canada.

The application of this new doctrine has created a "Catch-22" for innovators. To obtain appropriate protection for patents that frequently have long approval timelines, medicine manufacturers apply for a patent before the marketing approval process in which safety and efficacy for use in relevant patient populations are demonstrated. This process is understood and incorporated into global patent office practice. 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.

Adding to these concerns, Canada does not permit post-filing evidence to support assertions of "utility," contrary to accepted practice in other countries. The "promise doctrine" has severely undermined patent protection for innovators in the United States and elsewhere and had the practical effect of essentially blocking innovative patents and products from reaching Canadian consumers. It appears to be inconsistent with Canada's international obligations, including TRIPS, NAFTA, and other 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 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.

NAM members have also raised issues related to **government protection of sensitive business information**. For example, under Canada's revised Workplace Hazardous Materials Information System, companies face a set of challenging options: they must provide the government with sensitive business information (either exact chemical concentrations or product-specific concentration ranges), or they must pay a per-product application fee for review and approval of the confidentiality of chemical concentrations, an option that quickly becomes expensive. These requirements do not align with both corresponding U.S. and European regulations.

Canada passed its Copyright Modernization Act nearly five 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 and are not yet resolved. 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.

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,"[49] and a reference in Prime Minister Justin Trudeau's mandate letter to Minister of Health Jane Philpott that stressed introduction of plain packaging rules as a top priority.[50] 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 IP in other markets, such as Australia (see below), and would be similarly concerned if this legislation moved forward.

Additionally, the Canada-European Union Trade Agreement (CETA)[51], agreed upon by both sides but still going through final ratification, raises various IP-related questions for NAM members. The U.S. government work to make sure that CETA is implemented in a manner that protects and respects innovation and IP in both countries and provides clear legal channels for

[49] Galloway, Gloria, "Liberal Pledge to Demand Plain Cigarette Packaging Draws Cheers," The Globe and Mail, October 30, 2015.
[50] Letter from Prime Minister Justin Trudeau to Minister of Health Jane Philpott, November 13, 2015.
[51] Government of Canada, Canada-European Union Trade Agreement Final Text.

innovative manufacturers to protect their rights. Additionally, the agreement includes measures that provide stronger protection for European **GIs** outside of trademark-provided protections food and agricultural products. Such measures undermine the ability of the U.S. and other countries to protect existing trademarks in these products as well as to ensure fair treatment for those making products on terms already treated as generic.

Colombia

Colombia has increasingly moved away from a pro-IP environment in recent years with a series of legislative and enforcement actions. Over the last year, however, Colombia has taken a number of additional actions putting IP at risk in ways that are not fully consistent with Colombia's international commitments, harm manufacturers in the United States, and risk long-term damage to Colombia's business climate. These include concerns with **patent processes** under provisions Colombia's National Development Plan 2014-2018 (NDP) and **compulsory licensing** actions that appear to violate Colombia's IP-related commitments made in the U.S.-Colombia Trade Promotion Agreement (TPA).

Colombia has increasingly used the NDP to justify actions to curb IP protection for innovative medicines, and includes a number of problematic provisions:

- Article 70 grants authority to the Ministry of Health and Social Protection (MHSP) to issue nonbinding opinions to Colombia's patent office on the patentability of medical products undergoing patent review. This authority is inconsistent with global best practices on patentability and introduces subjectivity into patent reviews, and will have the practical effect of delaying patent review, slowing innovation across the board.
- Articles 69 and 70 allow MHSP to review health technology patents to consider potential compulsory licensing on protectionist economic grounds such as a shortage in domestic manufacturing. Such provisions run contrary to Colombia's international IP commitments in the TRIPS and the TPA that require "national emergency," "circumstances of extreme urgency," or "cases of public non-commercial use" before a country can unilaterally impose a compulsory license without negotiating authorization from the patent holder on reasonable commercial terms."[52] These provisions are also inconsistent with the standards of the Organization for Economic Cooperation and Development (OECD), to which Colombia is seeking to accede.
- Article 72 requires the MHSP to issue a price determination as part of the sanitary registration process for medicines and medical devices, and also allows the National Institute of Food and Drug Supervision (INVIMA) to add indications (specific usage circumstances such as treatment of a specific disease) to a pharmaceutical product based on a subjective review of evidence, sometimes in reliance on evidence submitted in other jurisdictions. The delay and unpredictability created by these regulatory hurdles impede market access and depart from Colombia's international commitments and OECD standards urging countries to "eliminate unnecessary regulatory barriers to trade and investment" and seek "harmonisation towards international standards."[53]

In line with these concerning provisions, MHSP in June 2016 issued a Declaration of Public Interest (DPI) in June 2016 with respect to an innovative pharmaceutical product,[54] and

[52] Article 31(b), World Trade Organization Trade-Related Aspects of Intellectual Property Rights Agreement.
[53] Organisation of Economic Cooperation and Development, "Recommendation of the Council on Regulatory Policy and Governance," Conference Paper, OECD Regulatory Policy Conference, 2010.
[54] Ministry of Health and Social Protection, "Resolución 2475 de 2016: Por medio de la cual se adelanta una declaratoria de existencia de razones de interés público," June 14, 2016.

announced in December 2016 a corresponding price cut of 44 percent.[55] These actions unilaterally set a lower price for sales of the product, even though its prices is already regulated in Colombia, the product is on the national formulary, and generic versions are already available on the market. MHSP's price cut brings the price down to levels as if the patent on the product did not exist.

While this DPI did not result in a compulsory license for this particular proprietary pharmaceutical product, the NAM is highly concerned that increased use of DPIs could result in inappropriate compulsory licensing in the future or attempts to achieve the same result through forced price reductions. For example, the NAM notes with concern the National Pricing Commission's November 22, 2016 Circular 3, which sets out a general pricing methodology that will apply to all medicines subjected to a DPI. Such broad use of DPIs and compulsory licensing unnecessarily and harmfully revokes basic, internationally accepted property rights, and run contrary to Colombia's international commitments in this area, including its TRIPS obligations. More broadly, such actions undermine the TPA and the U.S.-Colombia commercial relationship, signaling that investments and technologies made under the TPA could be at risk.

Indonesia

Indonesia is an increasing concern for manufacturers in the United States due to a growing number of problems, and an approach to IP that increasingly resembles other troublesome countries in the region. Within the last year, Indonesia has revised both its Patent Law and its Trademark and Geographical Indications Law. The **Patent Law** contains a number of concerning provisions that will weaken, rather than strengthen, Indonesia's IP system, and harm U.S. jobs that depend on strong IP protection and enforcement in overseas markets. In particular, the NAM is very concerned about implementation of measures that would narrow the scope of patentable subject matter, require disclosure of the origin of genetic resources or traditional knowledge, discourage voluntary licensing of technology, and provide for compulsory licensing on vague and arbitrary grounds that are inconsistent with Indonesia's international obligations. In addition, the process of developing implementing rules for the new law remains opaque, with little room for stakeholder input.

Compulsory licensing is also a growing issue in Indonesia, particularly in pharmaceutical products. In recent years, Indonesia issued compulsory licenses (CLs) on nine patented pharmaceutical products, often without attempts to consult with the affected companies to find sustainable, long-term solutions. Indonesia also does not offer any mechanism to appeal the compulsory license directly or to undergo a judicial review, as should be required under TRIPS. Concerns about compulsory licenses are exacerbated by language in the new Patent Law that discourages voluntary licensing agreements between private parties.

Indonesia also maintains **localization requirements** that impact innovative manufacturers. For example, the government bans foreign biopharmaceutical companies from importing medicines unless it partners with an Indonesian firm and transfers relevant technology so that those medicines can be domestically produced within five years. Such discriminatory moves to promote local manufacturing must be robustly addressed.

Finally, a series of Indonesian regulations related to food products raise IP concerns. The NAM has serious concerns about the **trademark implications** of Indonesia's draft revisions to its Law

[55] Cobb, Julia Symmes and Luis Jaime Acosta, "Colombia cuts price of Novartis cancer drug by 44 percent," Reuters, December 21, 2016.

on Food that would restrict the marketing of pediatric nutrition for older infants and young children. These draft revisions not only expand the age coverage to include formula and milk products for children up to three years of age, but also would cover a much broader range of promotional, advertising, educational, labeling and branding activities involving these products. The draft revisions raises serious intellectual property concerns, as they may restrict the use of trademarked brand names, logos, symbols and packaging that consumers depend on to identify safe, effective products, while also increasing the risk that counterfeit products could enter the supply chain. The draft revisions also have significant trade and health implications, as they target only imported products and ignore readily available, less trade-restrictive, alternative policy measures to increase breastfeeding rates. It is more restrictive than relevant international standards, specifically the Codex Alimentarius Commission and the World Health Organization Code of Marketing of Breast-Milk Substitutes.

Additionally, Indonesia's new mandatory Law on Halal Product Assurance, enacted in September 2014, also raises IP concerns, as it requires companies in affected industries – including chemicals, cosmetics, food and beverages and pharmaceuticals – to **disclose sensitive business confidential information** to the Halal Product Assurance Organizing Agency (BPJPH) and the Indonesian Ulama Council in order to obtain Halal certification. While these requirements are being implemented in different ways for impacted industries, the broader concerns about requirements and protection of such confidential information are a common concern for many NAM members.

Other countries of concern

Argentina has continued to take steps in recent years to limit the patentability of innovative pharmaceuticals, including a 2012 joint resolution that significantly narrowed the scope of chemical compounds and compositions that can be patented and an October 2015 resolution seeking to limit patents on biologics with specific exclusion of a long list of areas. These resolutions, issued by Argentina's Ministry of Health and Industry and the National IP Institute (INPI), narrowed the scope of patentable drug inventions in Argentina and created burdens for those areas left open, while also contradicting other Argentinian laws and, as they apply additional patentability criteria, appear to violate both Argentina's TRIPS obligations and its bilateral investment treaty with the United States. These and other concerns must be addressed in the context of ongoing bilateral dialogues and requests from Argentina to boost access to the U.S. market

Australia has become an increasing concern for NAM members on IP protection and enforcement due both to questions about the broad direction of its IP regime and specific issues impacting various sectors. In December 2016, Australia's Productivity Commission released a detailed review of Australia's IP system with a number of recommended changes to policy and practice that raise significant concern to innovative manufacturers in the United States. The final report indicates active consideration of steps to weaken IP protection in a number of areas, including patents and copyrights, with specific focus on innovative industries such as pharmaceuticals and semiconductors. If implemented, these proposals could reduce the value of IP for American innovation and constrain U.S. export opportunities in a number of sectors. The NAM urges the U.S. government to engage actively with Australia to address concerns with the final report and engage on follow-up policy changes, as the report is available for broad public consultation through mid-February 2017.

Additionally, 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. 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 Australia's IP commitments in the WTO and in the U.S.-Australia FTA. NAM members are concerned about these policies not only in Australia, but also for the precedent they set for other markets.

In addition, Australia was the first country to pass and implement controversial legislation prohibiting the application of marks and instead mandating the plain packaging of tobacco products, even though their legislation has been challenged in the WTO by five countries. These requirements continue to lack a clear, compelling evidentiary basis and do not reflect regulatory best practice considerations. As noted in the section on cross-cutting concerns, 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: all reasons why Australia's plain packaging rules have been challenged in the WTO.

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 that omit areas such as marketing insights and financial models commonly protected as trade secrets, 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 2015, there were only eight convictions for trade secrets crimes under Sections 11 and 12 UWG, and only 13 convictions under Sections 122 to 124 of the Criminal Code. Civil cases remain the most effective way to address trade secrets breaches in Austria.

Manufacturers also continue to face significant challenges in **Brazil**, including significant delays in securing IP, patentability review by non-intellectual property agencies and discriminatory application of data protection. A 2013 study on patent reform by the Center for Strategic Studies and Debates underneath the Brazilian Chamber of Deputies raises serious concerns about the future direction of Brazil's IP policy. Among other things, this study recommends new limitations on patent terms and proposes expanding the use of compulsory licensing to promote local production.[56]

Brazil is advancing such proposals in domestic legislation and also pushing similar ideas in international fora. For example, Brazilian representatives in Geneva have pushed for WIPO to

[56] Center for Strategic Studies and Debates, Brazil's Patent Reform: Innovation towards National Competitiveness, July 2013.

develop a manual on patent exemptions and limitations to encourage developing countries to limit intellectual property rights to promote local manufacturing at the expense of manufacturing in the United States, and frustrated WIPO engagement on improving the effectiveness of patent systems.[57]

While Brazil's IP office, the National Institute of Intellectual Property (INPI), has taken steps to reduce approval delays, Brazil still boasts some of the longest wait time for patents in the world, with the average patent grant takes taking more than 11 years from its application date. This number has worsened in recent years, and is true across the board: pendency averages more than 14 years for mobile technology, more than 12 years for life sciences, and more than 10 years for other forms of technology.[58] Trademarks in Brazil also face long delays. These delays may undermine otherwise valid patent rights and incentives for companies to bring innovative products to Brazil.

Brazil's health regulatory agency, the National Sanitary Surveillance 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's 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, and contributes significantly to Brazil's long patent backlogs.

Technology licensing and transfer is also a particular challenge in Brazil. INPI's statutory role in approving all IP licensing and technology transfer agreements – and the authority to modify them to protect local industry – can impinge on the freedom of companies to contract freely for goods and services and may result in the destruction of trade secrets.[59]

Additionally, Brazil does not provide regulatory data protection to all sectors. Although Brazil has enacted federal laws to ensure adequate data protection for veterinary and crop products (Law 10.603/02), it still does not provide for adequate regulatory data protection for pharmaceuticals and allows marketing approval for pharmaceuticals to competitors relying on test and other data submitted by innovators to prove the safety and efficacy of their products.

Manufacturers also face challenges in the **Dominican Republic**, including the widespread availability of pirated and counterfeit products, satellite signal piracy, and administrative denials of patent term adjustments. Despite continued work by the Public Ministry and the National Police to execute raids on counterfeit food and drug products, close illegitimate pharmacies and food retailers, and make arrests, broad IP enforcement has still remains weak.

NAM members have noted that patent pendency has decreased in recent years as a result of efforts by the Dominican National IP Office (ONAPI), resulting in a decrease in the large backlog of pending patent applications. The NAM welcomes ONAPI's continued efforts to digitize patents 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

[57] See, for example, Proposal from Brazil to the World Intellectual Property Organization, Standing Committee on the Law of Patents, Fourteenth Session, January 2010.
[58] Schultz and Madigan.
[59] 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.

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 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.

Finally, the Presidential Commission for the National Pharmaceutical Policy (COPPFAN) announced in December that they are in the final stages of drafting bills to regulate the pharmaceutical market that will include policies and strategies to promote generic medicines and set rules for market authorizations.[60] Such policies could have important implications for innovative companies in the industry, but it remains to be seen what these policies might look like, and which models in the region could be used as reference points. The NAM encourages the U.S. government to engage with their Dominican counterparts to get more information on these plans.

Ecuador has taken some positive steps over the last year to slow what had been a concerning trend towards actions to weaken its poor IP protection and enforcement regime. In August 2016, the Ecuadorian Patent Office reduced its patent fees to be more in line with international fees, cancelling moves in 2012 to hike patent maintenance fees to unacceptable levels, charging up to 11 times than similar fees in the United States. Ecuador also recently revoked ten compulsory licenses for medicines issued since 2010 that had raised significant concerns for innovative manufacturers. Both are positive trends, though questions remain about the actual implementation of these fee reductions.

Yet problems still remain in Ecuador. 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 IP violations – removing essential tools to protect against a wide range of counterfeit and pirated goods.

In 2014, Ecuador also issued a decree (Decree 522) that 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 IP protection that is critical to ensure innovator companies can distinguish their products from others. Trademarks help physicians and their patients identify that quality, safety and effectiveness of medicines – critical reputational capital that manufacturers strive to build over time.

Finally, innovative manufacturers operating in Ecuador continue to contend with restrictive patentability criteria, including decisions to follow Andean Court of Justice opinions to refuse to recognize second medical uses (SMUs) of patents, and insufficient protection of regulatory test data.

The **European Union** continues to advocate heavily for stronger protection for its food and agricultural products by creating a new global system of protection as geographical indications (GIs), a push that would undermine the ability of the U.S. and other countries to protect existing

[60] Morel, María Teresa Morel, "Busca regular el mercado medicinas," El Caribe, December 21, 2016.

trademarks in these products as well as to ensure fair treatment for those making products on terms already treated as generic. This push has appeared in EU efforts to negotiate bilateral trade agreements with a variety of important U.S. trading partners, including Korea, Vietnam, Canada, Peru, and Morocco.

Since January 2014, **Peru**'s Ministry of Health (MOH) has been reviewing a petition for a compulsory license on an innovative medicine. However, the process has suffered from a lack of transparency and due process: neither the manufacturer nor the local innovative pharmaceutical industry association have been permitted to participate in the MOH's review, including any ability to provide data and information for the ministry's technical analysis, and have ignored outreach attempts from the manufacturer and local innovative pharmaceutical industry association to engage. These steps are major red flags for innovation in Peru, and risk undermining the U.S.-Peru commercial relationship.

Additionally, Peru's 2010 free trade agreement with the European Union includes measures that provide stronger protection for European GIs outside of trademark-provided protections food and agricultural products. Such measures undermine the ability of the U.S. and other countries to protect existing trademarks in these products as well as to ensure fair treatment for those making products on terms already treated as generic.

South Africa has been actively working on a draft Intellectual Property Consultative Framework, releasing their most recent draft for public comment in July 2016.[61] While manufacturers welcome many positive positions expressed in the draft framework, including language recognizing the value of IP as a means of promoting innovation and economic growth and new mechanisms to boost interagency cooperation, the NAM is very concerned by language calling for South Africa to "balance" IP policy with objectives to promote local manufacturing, increase broad use of TRIPS flexibilities, set unique patentability requirements, and use patent disclosure to facilitate technology transfer. These provisions 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.

South Africa, like Brazil and India, has also been vocal in multilateral fora challenging the value of IP rules and seeking to broaden as much as possible the grounds and uses of TRIPS flexibilities. NAM members are concerned about South Africa's positions on these issues given their impact in shaping international opinion, particularly in the developing world.

Although delays in granting patents have been decreasing in **Thailand** since 2011, patent pendency remains a challenge for innovative manufacturers. It still takes nearly 10 years from the original application date to receive a patent. The problem is particularly challenging for life-sciences patents, where that rate is more than 14 years (and has gotten worse in the last three years).[62]

The NAM has serious concerns about the trademark implications of a new draft law in Thailand to expand existing infant formula restrictions in troubling ways. The draft law not only expands the age coverage to include formula and milk products for children up to three years of age, but also would cover a much broader range of promotional, advertising, educational, labeling and

[61] South Africa International Trade and Economic Development, "Intellectual Property Consultative Framework," July 6, 2016.
[62] Schultz and Madigan.

branding activities involving these products. The draft law raises serious IP concerns, as it restricts the use of trademarked brand names, logos, symbols and packaging that consumers depend on to identify safe, effective products, while also increasing the risk that counterfeit products could enter the supply chain. The draft law also has significant trade and health implications, as it targets only imported products (while exempting local products) and ignores readily available, less trade-restrictive, alternative policy measures to increase breastfeeding rates. It is more restrictive than relevant international standards, specifically the Codex Alimentarius Commission and the WHO Code of Marketing of Breast-Milk Substitutes, and has generated concerns by leading medical societies in Thailand, including the Royal College of Pediatricians.