



Linda Dempsey
Vice President
International Economic Affairs

February 8, 2018

Mr. Sung Chang
Director for Intellectual Property and Innovation
Office of the United States Trade Representative
600 17th Street NW
Washington, DC 20503

Ref. Docket No.: USTR-2017-0024

Dear Mr. Chang:

The National Association of Manufacturers (NAM) welcomes the opportunity to provide these written comments for the 2018 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 \$2.25 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 in order to sustain and boost good-paying jobs. Vigorous protection of IP rights at home and abroad against those who would steal our innovative ideas and products is a necessity. IP spurs further innovation, creating greater certainty for manufacturers that their inventions will be safe and thus enabling them to build new industries and provide 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 both building a strong domestic legal framework to protect and enforce manufacturers' IP and pushing for stronger global protection and enforcement of IP rights through both direct bilateral negotiation, robust investigations such as the Special 301 process and building a robust set of global rules and standards. 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). Such 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 reap the benefits of these agreements through fair market access and opportunities for exports.

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 remains a constant target for foreign competitors who want to steal it to boost their businesses, 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 2017 report by the Commission on the Theft of Intellectual Property found that stolen ideas, brands and inventions drain up to \$600 billion from the U.S. economy, harming U.S. businesses, jobs, and workers in the process – an estimate nearly double that of its previous report four years before.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:** Canada, China, Colombia, India, Indonesia, Russia
- **Watch List:** Australia, Brazil, South Africa, Thailand
- **Out-of-Cycle Reviews:** Colombia, India

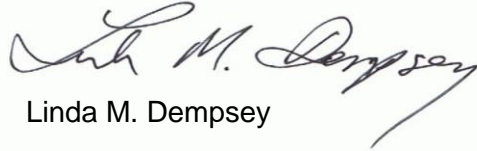
To address these challenges, the United States must use all available options. This includes making strong, enforceable IP protections a strategic priority in current and future trade negotiations, including talks to modernize the North American Free Trade Agreement (NAFTA) and the Korea-U.S. (KORUS) Free Trade Agreement (FTA). The U.S. government should also make active use of Special 301-related tools such as country classifications, out-of-cycle reviews, results-oriented action plans and enforcement authorities provided by the Trade Facilitation and Trade Enforcement Act of 2015.

Additionally, the U.S. government must leverage international trade enforcement tools provided by the World Trade Organization (WTO); bilateral, regional and global platforms and negotiations to push for vigorous and stronger IP protection and enforcement and promote the development of new international best practices for IP protection; and creative education, training and capacity building programs with national IP authorities. As well, 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, and design strategic remedies and negotiating tools to best do so.

² Commission on the Theft of American Intellectual Property, ["Update to the IP Commission Report,"](#) (Washington: National Bureau of Asian Research), February 2017.

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,

A handwritten signature in black ink, appearing to read "Linda M. Dempsey", is written over a light green rectangular background.

Linda M. Dempsey

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

National Association of Manufacturers Detailed Comments for 2018 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).³ That value continues to grow with approximately 2.8 percent of U.S. GDP devoted to R&D: a figure that makes up roughly a quarter of all R&D conducted globally.⁴ Such R&D contributes directly to the U.S. economy: recent literature clearly shows a direct relationship between increasing R&D expenditures and increasing economic growth, as high as a one-to-one relationship.⁵ 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.⁶

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.⁷

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 both building a strong domestic legal framework to protect and enforce manufacturers' IP and pushing for stronger global protection and enforcement of IP by building a robust set of global rules and standards. 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). Such agreements not only provide important standards, but also vitally important dispute settlement mechanisms, which, when actively and

³ Antonipillai, Justin and Michelle K. Lee, ["Intellectual Property and the U.S. Economy: 2016 Update."](#) September 2016.

⁴ For R&D expenditures, see Industrial Research Institute and Research Technology Management, ["2017 Global R&D Funding Forecast,"](#) R&D Magazine, Winter 2017. For GDP figures, see Federal Reserve Bank of St. Louis, [FRED Database.](#)

⁵ See, for example, Gumus, Erdal and Ferdi Celikay, ["R&D Expenditure and Economic Growth: New Empirical Evidence."](#) The Journal of Applied Economic Research, August 2015; and 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 International Congress on Economics II (EYC2015), November 5-6, 2015, Ankara, Turkey.

⁶ 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.

⁷ Antonipillai and Lee.

appropriately used, help ensure that manufacturers in the United States reap the benefits of these agreements through fair market access and opportunities for exports.

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 legitimate IP rights around the world remains a serious problem with a serious impact on the U.S. economy. A 2017 report by the Commission on the Theft of Intellectual Property found that stolen ideas, brands and inventions drain up to \$600 billion from the U.S. economy – an estimate nearly double that of its previous report four years before.⁸ This includes theft of patented technology and trade secrets, counterfeiting of branded manufactured goods, and piracy of industrial software that is important for manufacturers. Though fiscal year 2017 statistics have not yet been released, U.S. Customs and Border Protection in 2016 seized counterfeit and pirated goods worth more than \$1.38 billion.⁹ 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 (43 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 current and future trade negotiations such as talks to modernize the North American Free Trade Agreement (NAFTA) and improve implementation of the Korea-U.S. (KORUS) FTA. The U.S. government should make strong, enforceable IP protections a strategic priority in these and any future trade negotiations. New and updated trade agreements should ensure that parties join a common set of international IP treaties, protect inventors and their IP from unfair government actions, address issues related to patentability, patent protection, and patent terms, streamline trademark procedures and strengthen core trademark protections, secure strong protection for trade secrets and confidential business information. The NAM provided [direct comments on NAFTA priorities](#) in June 2017 that describe in greater detail on IP views.

The United States should further make strategic use of Special 301-related tools such as country classifications, out-of-cycle reviews, and results-oriented, action plans and enforcement authorities provided by the Trade Facilitation and Trade Enforcement Act of 2015. Additionally, the U.S. government must leverage 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 promote the development of new international best practices

⁸ Commission on the Theft of American Intellectual Property, [“Update to the IP Commission Report,”](#) (Washington: National Bureau of Asian Research), February 2017.

⁹ Office of Trade, U.S. Customs and Border Protection, [“Intellectual Property Rights Seizure Statistics: Fiscal Year 2016,”](#) January 2017.

for IP protection; and creative education, training and capacity building programs with national IP authorities.

The NAM also strongly 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.

Cross-Cutting Concerns

As manufacturers in the United States work to protect their IP 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.

IP Erosion in Multilateral Forums

The global framework of IP protections and enforcement, particularly for health, clean technology, energy and other advanced manufacturing products, is being challenged in a range of international fora. Strong IP protection and enforcement are critical to achieving global energy and environment objectives. In international organizations such as the World Intellectual Property Organization (WIPO), World Health Organization (WHO), and WTO, 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), particularly discussions at COP21 in Paris (2015). Yet the debate over these issues has continued through subsequent conferences of parties, including COP22 (Marrakesh, 2016) and COP23 (Bonn, 2017) and is expected to arise again at COP24 in Katowice, Poland. The strong U.S. pushback during and since COP21 has been 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:

- Efforts at the WHO to undermine innovation by focusing on IP as the primary barrier preventing access to medicines and vaccines. This approach duplicates the problems that many stakeholders had with the strongly biased and deeply flawed 2016 report by the U.N. High-Level Panel on Access to Medicines.¹⁰ Despite clear evidence that many health system barriers stand between patients and the medicines they need in many parts of the world, the UNHLP improperly singled out IP as the sole cause of problems with access to medicines in developing countries, and drafted a report that was not developed transparently or by a balanced panel, and ignored the views of key

¹⁰ 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.

stakeholders (such as the U.S. government). Unsurprisingly, the report and its findings were highly flawed: a fact clearly recognized by the U.S. government in September 2016 with the release of a statement rejecting the panel's attacks on innovation and IP. Despite these facts, its supporters have sought broad visibility, support, and reference for the report in other forums, including in the WHO (with several high-profile agenda items at the January 2018 WHO Executive Board meeting)¹¹, the U.N. Human Rights Council, WTO TRIPS Council, WIPO, UNAIDS, and other forums. Even in forums that have not made explicit references to the UNHLP, these concepts have broadly influenced discussions even in traditionally high-standard, pro-growth organizations like the Organization for Economic Cooperation and Development (OECD).

- 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
- 2016 WHO guidance designed to curtail marketing of complementary food products for infants and young children up to three years of age, rules which restrict the use of trademarked brand names, logos, symbols and packaging on imported products while also increasing the risk that counterfeit products could enter the supply chain.
- Challenges to IP protection embodied in troublesome discussions at key WIPO committees such as agenda items on the expanded use of exceptions and limitations for patents and copyrights and creation of a separate system to manage geographical indications (GIs).

Such discussions in international forums are often the direct result of lobbying by specific member states, with **India, Brazil, Indonesia** and **South Africa** often playing a leading role. Reports, guidelines and action plans that result from these discussions are critical in shaping the agenda within these organizations in ways that are more hostile to innovation and IP. Equally disturbing, however, such reports have clear, direct impacts on policymaking at the national level, as they influence national governments to adopt policy recommendations into their own laws and regulations. International organizations themselves further distort these discussions by directly lobbying or offering technical assistance to national governments to revise their legal frameworks to undermine innovation and strong IP protections. Manufacturers have seen such activity in organizations such as the WHO and the U.N. Development Programme. Manufacturers have seen direct influence of these conversations, including in many cases direct citation of problematic reports such as the UNHLP, around the world, including markets such as **Chile, Colombia, Ecuador, Hong Kong, India, Indonesia, Malaysia, South Africa, and Thailand.**

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 (FENSA), a set of rules that limits the organization's engagement with the private sector, and has subsequently sought to encourage other U.N. agencies (through ECOSOC) to adopt similar restrictions. A FENSA-like framework directly undermines the ability of an international organization to draw on innovators' expertise and experience developing and deploying targeted solutions in different markets,

¹¹ These include [agenda items](#) such as the Director-General's current reports on addressing the global shortage of, and access to, medicines and vaccines (EB142/13) and the global strategy and plan of action on public health, innovation and intellectual property (EB142/14).

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

while also undermining the legitimacy and fairness of policy recommendations that the organization releases.¹³

Finally, IP and innovation are also a critical topic in broader multilateral discussions, including negotiations with countries seeking to join organizations like the OECD. Given the growing interest from countries to join the OECD and other bodies, it remains crucial for the United States to hold firm on the need for these countries to demonstrate that their laws are drafted and being implemented in line with those organization's high standards, including in the critical areas of innovation and IP. Allowing accession on anything less than those terms undermines the IP standards for the entire OECD community. These issues are currently a factor in **Colombia's** efforts to join the OECD but will be equally critical for other countries that have demonstrated interest in joining, including **Brazil** and **Argentina**.

Growing Use of Compulsory Licensing

Innovative manufacturers have seen an uptick in the number of countries seeking to expand through policy, administrative action or judicial ruling the use of compulsory licensing or other flexibilities for patented products, generally in the name of public health. While compulsory licenses can be legitimate government tools to protect public health under certain circumstances, their use must comply fully with international rules, should be limited to exceptional circumstances, and through decisions made on the facts of the individual case through transparent processes that involve close consultation with all stakeholders. Above all, these decisions should be based firmly on public health grounds, not as a protectionist excuse to promote or protect local manufacturing. These efforts include not only high-profile government action in **Malaysia** to invoke the "right of government" to exploit a pharmaceutical patent in 2017, but also countries such as **Brazil, Colombia, Ecuador, India** and **Indonesia** that have issued compulsory licenses. Countries such as **Turkey** have passed legislation expanding the ability to issue compulsory licensing, and countries such as the **Dominican Republic** and **Vietnam** that are considering rules to broaden use of compulsory licensing.

In addition to compulsory licensing and other patent flexibilities, many countries are using direct price caps, broad transparency requirements, a lack of patent linkage, aggressive use of reference pricing, and reimbursement hurdles to drive down the price or limit market access for innovative products in ways that have a negative impact on IP protection and business incentives that drive future innovation. These countries include **Australia, Brazil, Canada, China, Colombia, Egypt, France, Germany, Greece, India, Japan, Jordan, Korea, Malaysia, Netherlands, New Zealand, Norway, Romania, Russia, Singapore, South Africa, Spain, Tunisia, Turkey**, the **United Kingdom**, and several Middle Eastern countries involved with the **Gulf Cooperation Council** such as **Saudi Arabia** and the **United Arab Emirates**. Countries also limit the ability of US manufacturers to benefit from IP through regulatory delays or localization barriers that prevent market access for innovative manufactured goods, including barriers in **Malaysia, Mexico** and **Turkey**. Recent troubling examples of policies that thus undermine IP include **Japan's** December 2017 launch of a new Price Maintenance Premium (PMP) program, **Canada's** proposed revisions to the Patented Medicines Pricing Review Board (PMPRB) pricing rules, and **China's** September 2017 notice on national price negotiations (currently suspended).

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-

¹³ 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."

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 – most recently at the December 2017 Ministerial Conference in Buenos Aires. The continued moratorium limits member state accountability to demonstrate that they are abiding by their international commitments to protect IP. 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. 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. These efforts include:

- The continued expansion of 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. Despite the ongoing WTO dispute settlement case, other countries have adopted or are considering similar rules. **France, Hungary, Ireland, Norway, the United Kingdom** have already begun full or partial implementation of plain packaging rules. **Georgia, New Zealand, Slovenia, and Thailand** have adopted but not yet implemented similar measures, and other countries from **Canada to Singapore, from South Africa to Chile** are considering similar rules for tobacco products. Similar plain packaging approaches have also begun to leak into other unrelated sectors, such the food and beverage sector restrictions faced in **Chile**.
- Draft laws that impact trademarks for infant formula products in several countries, including **Thailand, Indonesia** and **Hong Kong**, based on 2016 World Health Organization (WHO) guidance designed to curtail marketing of complementary food products for infants and young children up to three years of age. The WHO guidance and draft laws that copy its tenets raise serious IP concerns by restricting the use of trademarked brand names, logos, symbols and packaging on imported products that consumers depend on to identify safe, effective products, while also increasing the risk that counterfeit products could enter the supply chain.
- Regulations that limit use of trademarks related to health products, including a 2014 decree in **Ecuador** that limit or even prevent the use of trademarks for any medicine once the patent on that medicine has expired.

Insufficient 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.¹⁴ 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 **India**, **Korea**, and **Singapore** as leading hubs for counterfeit products in the United States and **Bangladesh**, **Canada**, **Pakistan**, **Taiwan**, the **United Arab Emirates** and the **United Kingdom** as other notable sources and transshipment points for counterfeits. NAM 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**, **Egypt**, **India**, **Korea**, **Malaysia**, **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.¹⁵

Such authorities must address all appropriate channels for counterfeit goods. For example, foreign counterfeiters have long shipped counterfeit goods into the United States 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 for U.S. Customs and Border Protection (CBP) screening before being transferred to the United States Postal Service (USPS) for delivery.¹⁶ In recent years, however, the volume of packages bringing counterfeit goods into the United States through this route has exploded. The reasons are complex, including the significant expansion of global e-commerce, counterfeiter practices to break up shipments into smaller packages to avoid detection, and subsidized shipping rates provided by USPS to foreign shippers under the Universal Postal Union (UPU)'s international terminal dues system. In fact, many of the counterfeit products now sold into the United States are *only* economically viable because of these subsidized shipping rates. The sheer volume of shipments makes it impossible for U.S. CBP 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.¹⁷

¹⁴ International Trademark Association and Business Action to Stop Counterfeiting and Piracy, "[The Economic Impacts of Counterfeiting and Piracy](#)," February 2016.

¹⁵ 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.

¹⁶ 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).

¹⁷ U.S. Postal Service, "[Basic Eligibility Standards for Priority Mail](#)," November 1, 2010.

NAM members believe that both systemic changes (such as major revisions to the international terminal dues system) and stronger enforcement efforts (including increased enforcement resources, process streamlining and smart 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 U.S. customs territories (although still subject to CBP 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.¹⁸

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 e-commerce sites in **China, India**, and other markets. Despite important actions pledged and taken by some of these platforms (such as Alibaba for its Taobao platform), significant numbers of counterfeit products are still being sold on the platforms. In addition, some concerns raised by manufacturers remain unaddressed or only partially addressed.

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. For example, 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.¹⁹

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 one and three percent of U.S. GDP, translating to a loss between \$180 billion and \$500 billion.²⁰ 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.²¹ Effective

¹⁸ 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.

¹⁹ 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.

²⁰ PricewaterhouseCoopers and CREATE.org, [“Economic Impact of Trade Secret Theft: A Framework for Companies to Safeguard Trade Secrets and Mitigate Potential Threats,”](#) February 2014.

²¹ Brant J., Lohse S., [Trade Secrets: Tools for Innovation and Collaboration](#) (2014, published by International Chamber of Commerce, Paris.

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 **China, India** and **Russia**. A wave of global trade secrets legislation in recent years, including the United States' Defend Trade Secrets Act, the **European Union's** Trade Secrets Directive, **Taiwan's** amended Trade Secret Act, and **Japan's** revised Unfair Competition Prevention Act, 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 unique limitations have popped up in markets such as **Argentina, Canada, China, Ecuador, India, Indonesia, and Korea**.

These additional criteria have taken a variety of forms, including targeted restrictions on patentability of certain types of inventions, such as specific formulations or uses for biopharmaceutical products (**Argentina, Ecuador, India, and Indonesia**), bans on filing of supplemental data to obtain or defend a patent (**China, Canada**), or limiting the scope of inventions eligible for patent term extensions (**Korea**). In **Canada**, the Supreme Court's June 2017 decision to strike down Canada's troubling "promise doctrine," which had imposed higher-level requirements for a patent to demonstrate utility at the time of filing, was a welcome decision, though manufacturers are closely watching next steps taken by Canadian agencies and judges to see whether heightened patentability criteria arise again. 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 NAFTA obligations.

Long Backlogs for Patents and Trademarks

In some countries around the world, long delays in obtaining IP (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** and **India**. In some cases, these delays can be 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.

Expansion of Geographical Indications

Manufacturers in a range of sectors, from processed food and beverages to textiles and apparel to consumer products, have long produced goods that utilize geographical indications (GI), product names or branding that reference a specific geographical origin as an indication of qualities or reputation associated with that place. In the United States and in many of its trading partners, GIs have been protected under the existing trademark system, allowing U.S.-manufactured products to utilize the existing IP system to export their products into overseas markets.

Despite these protections in place, the **European Union** continues to advocate heavily for stronger protection for its food and agricultural products by creating a new global system of protection for geographical indications (GIs), a push that would 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. This push has appeared in EU efforts to negotiate bilateral trade agreements with a variety of important U.S. trading partners, including agreements in force with critical markets such as **Canada, Colombia, Korea, and Peru**, and agreements still in negotiation with markets such as **Japan, Mexico, Argentina and Morocco**. It also has appeared at the WIPO, where European Union countries continue to push for WIPO funding to support the GI-centric Lisbon Agreement.

Country-Specific IP Challenges

Manufacturers in the United States face serious obstacles to adequate and effective IP protection and enforcement in a range of specific developed and developing countries. 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 increased efforts to promote public awareness of IP and bilateral dialogue on copyrights and trade secrets in India, key legal revisions and increased IP enforcement in China, and efforts to strengthen coordinated IP enforcement and cut patent backlogs in Thailand. Many countries, however, have seen insufficient 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 continue to grow. These issues must be addressed through strategic use of all available negotiating and enforcement tools.

Priority Watch List

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 has Canada's efforts in recent years 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.

The Canadian government's 2015 passage of amended Patented Medicines (Notice of Compliance) Regulations (PM(NOC)) included some positive developments dealing with **patentability**, addressing judicial rulings that had limited an innovator's ability to list a single-ingredient medicine patents on the Patent Register and providing important clarity for inventors. Those rules do, however, include several key deficiencies that weaken Canada's enforcement of patents, including the nature of patent dispute proceedings and rights of appeal for patent owners, excessive and windfall damage awards to generic litigants, and limitations and inequitable eligibility requirements on the listing of patents in the Patent Register. The Supreme Court of Canada's June 2017 decision to strike down Canada's troubling "promise doctrine," which had imposed higher-level requirements for a patent to demonstrate utility at the time of filing, was a welcome decision, though manufacturers are closely watching next steps taken by Canadian agencies and judges.

Canada has also exhibited highly troubling changes that limit **the value of innovative products**. For example, the Patented Medicines Pricing Review Board (PMPRB) has long set maximum prices for patented medicines in Canada that undermine the value of IP. Changes proposed in December 2017 would make this problem even worse, shifting the PMPRB mandate to ensuring "affordable" prices and requiring revised pricing regulations. Those regulations would exclude from the basket of comparable markets innovative markets like the United States to replace them with lower-cost countries, impose new reporting requirements on patent holders, and introduce new troublesome price regulation factors. These changes would have a directly harmful impact on U.S. innovation and exports. If left unchecked, these changes would go into effect in January 2019.

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.

The NAM is also concerned about efforts to advance **plain packaging** requirements for tobacco products as a major problem for legitimate trademark protection. In mid-2016, the Canadian government conducted a round of public consultation on draft regulations to introduce plain packaging.²² 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)²³, which went into force provisionally in September 2017, 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 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.

²² Health Canada, "[Regulatory Initiative: Regulations on Plain and Standardized Packaging for Tobacco Products - Forward Regulatory Plan 2017-2019](#)," May 2016.

²³ Government of Canada, "[Canada-European Union Trade Agreement Final Text](#)."

To address these challenges, the United States must use all available options, including current and future trade negotiations such as talks to modernize the North American Free Trade Agreement (NAFTA) and improve implementation of the Korea-U.S. (KORUS) FTA.

The U.S. government should make strong, enforceable IP protections a strategic priority in ongoing talks to modernize the North American Free Trade Agreement (NAFTA). Manufacturers are seeking high-standard, ambitious IP outcomes from a revised NAFTA that protect the hard-won innovation of manufacturers throughout their production processes, including patents, trademarks, trade secrets, and copyrights. The adoption of such outcomes can ensure that the agreement benefits manufacturers and the high-paying jobs they support. Key changes to achieve these outcomes are provided in [direct comments on NAFTA priorities](#) submitted by the NAM in June 2017.

China

China in recent years has increasingly recognized the value of innovation and IP to grow its economy, fostering more attention on IP at home and progress on IP issues in bilateral engagement. In recent years, that has translated into a greater focus on IP protection in high-level documents (such as the 13th Five-Year Plan), revisions to its core IP laws and policies (most recently the Anti-Unfair Competition Law), an expanding legal framework that better recognizes the value and role of IP (such as efforts to improve patent linkage and regulatory data protection rules), and proliferation of specialized IP courts (which now include tribunals in Beijing, Shanghai, Guangzhou, Nanjing, Suzhou, Chengdu, Wuhan, and Shenzhen). All of these have translated to booming registrations of patents, trademarks and other forms of IP in China that have made China's State Intellectual Property Office (SIPO) the busiest in the world, and growing recognition among Chinese government officials and businesses of the importance of IP.

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.

Administration efforts to push for fair, robust protection of American IP rights in China through various channels, including the ongoing Section 301 investigation, present a real opportunity to address these longstanding concerns in ways that will address concretely the issues that manufacturers face. Efforts that identify specific policies and documentable practices directly impacting manufacturers in the United States, and that strategically target changes in those policies that can be monitored and enforced are best suited to yield concrete solutions that will directly impact manufacturers in the United States. 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 2016, 88 percent of the more than

\$1.38 billion in counterfeit goods seized at U.S. borders were from China (45 percent) or Hong Kong (43 percent).²⁴ 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. IP theft in China is a serious concern for manufacturers of all sizes but can pose an insurmountable challenge for small and medium-sized manufacturers (SMMs). These firms often do not have in-house IP experts or investigators or the resources to track down and prosecute counterfeiters and pirates. As such, SMMs, 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. This must include online auction sites in China such as Alibaba's Taobao platform that have pledged and taken some actions but have not yet stemmed the tide of counterfeit products being sold on 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. China's revised Anti-Unfair Competition Law (AUCL), a broad law designed to address a wide variety of unfair market practices that impact consumers and businesses, came into effect in January 2018 with a number of important changes for trade secrets, including expanded fines and damages, in administrative and civil cases, revised trade secrets definitions that bring China's rules more in line with international definitions, and stronger requirements for government officials to protect of trade secrets.

²⁴ Office of Trade, U.S. Customs and Border Protection, "[Intellectual Property Rights: Fiscal Year 2015 Seizure Statistics](#)," April 2016.

While these steps are welcome, China must take further steps to boost practical 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.

Moreover, **protection of confidential business information** is also an issue for many NAM members operating in China. China's system for regulatory data protection, for example, has long been a challenge for many innovative health companies. In May 2017, the China Food and Drug Administration issued drafts of a series of circulars related to innovation in approval processes for pharmaceuticals and medical devices, including a newly proposed structure for regulatory data exclusivity that could address manufacturer concerns. Conversely, however, many manufacturers 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.

Chinese policies to promote economic development through **indigenous innovation**, which is often interpreted as innovation by Chinese firms in China at the expense of foreign companies, products and technologies, have also raised significant concerns. The United States and other national governments have pushed back repeatedly to halt or force revisions to discriminatory innovation policies, including incentives provided under China's Strategic and Emerging Industries (SEIs) program and efforts to create a national catalogue of indigenous innovation products that would be eligible for various government incentives.

While the NAM welcomes past Chinese commitments to address these concerns, such as eliminating discriminatory catalogues of Chinese indigenous innovation products and clarify that foreign companies are eligible to participate in innovation-related government programs, manufacturers in the United States continue to face problematic indigenous innovation policies, including language in policies such as Made in China 2025, the Cybersecurity Law, and others, and persistent local programs to recognize and boost indigenous innovation products that largely exclude foreign products.

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

- 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 standard 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, last release for public comment in March 2017.²⁵ 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

²⁵ These rules follow similar IP abuse rules already formulated and finalized by the State Administration of Industry and Commerce in April 2015.

competitors.²⁶ 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 continues to draft a new regulation on "**service inventions**" that are created during an inventor's employment, though the drafting process has been quiet since 2016. 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 could 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 SIPO 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. New Patent Examination Guidelines from the SIPO that took effect in April 2017 have not fully clarified whether supplemental data is acceptable in practice.

The NAM has submitted regular comments to USTR on China related to various policy issues, including other issues such as **cybersecurity**, **cross-border data flows**, and **policies that spur technology transfer**. For more on these policies, see the NAM's September 2017 [submission on China's compliance with its WTO commitments](#), September 2017 [submission for the Section 301 investigation on IP and technology transfer](#), and its October 2017 [submission for the National Trade Estimate report](#).

²⁶ 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.

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 in Colombia's National Development Plan 2014-2018 (NDP), **compulsory licensing** actions that appear to violate Colombia's IP-related commitments made in the U.S.-Colombia Trade Promotion Agreement (TPA), and **market access challenges for innovative manufactured products** due to regulatory barriers such as Colombia's "third pathway" for biologics.

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, 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."²⁷ 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."²⁸

In addition, the NAM is concerned about the increased use of declarations of public interest (DPIs) to drive compulsory licenses or to devalue innovation for innovative manufactured products. Due in part to high levels of concerns from the U.S. government and industry groups surrounding a June 2016 DPI decision, Colombia committed to revising its DPI process. Yet despite Colombian government claims that it has revised the DPI process to address questions, the National Pricing Commission's November 22, 2016 Circular 3 sets out a general pricing methodology that will apply to all medicines subjected to a DPI. Such broad use of DPIs and

²⁷ Article 31(b), [World Trade Organization Trade-Related Aspects of Intellectual Property Rights Agreement](#).

²⁸ Organisation of Economic Cooperation and Development, "[Recommendation of the Council on Regulatory Policy and Governance](#)," Conference Paper, OECD Regulatory Policy Conference, 2010.

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.

India

India continues to be a priority market for innovative manufacturers across the board: not only those concerned with patents, but also trade secrets, copyrights, and brand protection. Prime Minister Narendra Modi and other senior level officials have made positive statements about the importance of innovation and IP protection, and these statements have fostered some progress on IP. For example, India's new National Intellectual Property Policy, released in May 2016, included positive language that recognizes the importance of IP for economic development, calls for an IP public awareness campaign (now being implemented by the Cell for IPR Promotion and Management) and promotes capacity building programs among IP personnel. India's Department of Industrial Policy and Promotion (DIPP) have taken steps to expedite patent approval process and increase examiner capacity to reduce longstanding delays in patent and trademark examinations, and to offer new training resources for local enforcement officials. Some states, in turn, have created specialized structures to coordinate IP enforcement or increased campaign efforts.

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 over the past two years with India's Department of Industrial Policy and Promotion (DIPP) on copyright policies and trade secrets protections, and other engagement surrounding the Commercial Dialogue (CD) and Trade Policy Forum (TPF). 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. Cooperative dialogue on IP must be a foundation for the relationship but cannot be the benchmark – and positive rhetoric must translate into concrete progress. India's National Intellectual Property Policy, released in May 2016, is a perfect example of this dichotomy.²⁹ As noted above, the policy includes positive language that recognizes on the importance of IP for economic development and calls for stronger IP laws and enforcement, and marks progress in areas 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, includes scant detail and few benchmarks on how India would 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. In addition, the policy's strong statements that India's current IP policies are fully TRIPS-compliant and should continue to seek unfettered use of TRIPS flexibilities raise significant red flags for manufacturers in the United States.

²⁹ 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.³⁰ 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.³¹ The right to exclude is a key component of IP 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 this submission.

India continues to deny **patent protection** for inventions that meet internationally accepted criteria, and makes regular use of mechanisms designed to make it easier to invalidate patents. 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 and provides a standing basis to issue compulsory licenses. 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 since 2012, 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 legislative or administrative changes to address these concerns. Innovative companies also face other burdens, including requirements under Section 8 of the Patents Act that require patent-holders to notify when filing patents for “the same or substantially same invention” outside of India or face invalidation of their patents and authority for state-level authorities to grant marketing approval for a generic version of patented medicines without having to verify whether the patent is still in force. Each of these requirements not only place burdensome administrative requirements on innovative manufacturers operating in India but also undermine the value of patent protection and ultimately confidence in India’s innovative patent system.

The lack of predictability around **compulsory licenses** in India, particularly for innovative pharmaceuticals, remains a challenge. India has taken a welcome pause in compulsory license decisions in recent years and positive decisions in a handful of cases. As long as these criteria remain on the books and part of the active public discussion, however, government and judicial officials have the power to use compulsory licensing to shield India’s domestic industries at the expense of U.S. innovation and IP. 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.³² More specifically, grounds for issuing a compulsory license under Sections 66 and 92 of the Patent Act remain broad and vague, granting the Controller General of Patents, Designs and Trademarks broad authority

³⁰ Government of India, Ministry of Commerce and Industry, Department of Industrial Policy and Promotion, [“National Manufacturing Policy,”](#) November 2011.

³¹ 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.”](#)

³² Department of Industrial Planning and Promotion, [“Discussion Paper: Compulsory Licensing,”](#) 2011.

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 to use compulsory licenses as broadly and freely as it chooses.³³ The NAM believes that use of compulsory licenses, as required by both the spirit and letter of TRIPS, should 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 protectionist 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.³⁴ At WIPO, India has questioned and sought to redirect work on patent quality.³⁵ 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. In November 2017, India hosted a global conference on access to medical products and international laws for trade and health, a platform to push for broad adoption of the UNHLP's findings. NAM members are concerned about India's positions and the impact they could have in shaping international opinion in a manner hostile to innovation and IP.

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 2014.³⁶ 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.³⁷ According to an NAM study, global software piracy cost more than 42,000 U.S. manufacturing jobs over the last decade.³⁸ An April 2016 copyright workshop between USTR and DIPP and forward-looking statements at the October 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, confidential business information, or regulatory test data**. India lacks a stand-alone trade secrets law, as is commonly used in other jurisdictions (including the United States and the European Union).

³³ 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.

³⁴ [TRIPS Council Meeting Minutes](#), June 11-12, 2014, IP/C/M/76/Add.1, paragraph 347.

³⁵ [WIPO Standing Committee on Patents Minutes](#), July 27-31, 2015, SCP/22/7, paragraph 41.

³⁶ 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.

³⁷ BSA, The Software Alliance, "[Seizing Opportunity Through License Compliance - BSA Global Software Survey](#)," May 2016.

³⁸ Kerr, William and Chad Moutray, "[Economic Impact of Software Piracy for Manufacturers in the U.S.](#)," National Association of Manufacturers, January 2014.

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).³⁹ In practice, manufacturers in the United States may have little recourse against contract service providers in India that misappropriate trade secrets. Moreover, India does not 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. On broader trade secrets, the 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. Recent studies show that the average patent grant in India occurs nearly eight years after its application date, a number that has increased steadily in recent years.⁴⁰ 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 revised text continues to exclude compulsory licenses from any BIT obligations and raises 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

³⁹ 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.

⁴⁰ 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.

TRIPS. A blanket exemption for any compulsory license would undermine the goal of any BIT to help attract high-quality, innovation-based investment.

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 17 other leading business associations representing nearly every sector of the U.S. economy work with Congress, the Administration and partners around the world through the [Alliance for Fair Trade with India \(AFTI\)](#) to ensure a robust, reciprocal U.S.-India economic relationship and address ongoing challenges that negatively impact U.S. economic growth, exports, and jobs.

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. In 2016, Indonesia has revised both its Patent Law and its Trademark and Geographical Indications Law. While the latter included some language to improve trademark process and expand the scope of eligible trademarks, the **Patent Law** contains a number of concerning provisions that weakened Indonesia's IP system and harmed innovative manufacturers in the United States. In particular, the NAM remains very concerned about implementation of measures that 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. Article 20 mandates local production of patented products, creating major challenges for innovative manufacturers. Indonesia's Directorate General of Intellectual Property had been working on draft implementing rules to implement Article 20. In a welcome move, however, a draft of implementing regulations sent to the Ministry of State Secretariat was rejected due to its negative impact on investment and sent back to the Ministry of Law and Human Rights for revisions in dialogue with industry.⁴¹

Compulsory licensing remains a concern issue in Indonesia, particularly in pharmaceutical products. In 2013, Indonesia issued compulsory licenses (CLs) on nine patented pharmaceutical products⁴² without following proper procedures, including 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 on Food that would restrict the marketing of pediatric nutrition for older infants and young

⁴¹ American Chamber of Commerce in Indonesia, "[Government to Work on a New Presidential Decree Draft on Patent Law Implementation,](#)" December 18, 2017.

⁴² Government of Indonesia, "[Special 301 USTR Submission,](#)" February 20, 2013.

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 raise serious IP 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.

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 that impact enforcement of all types of IP in the courts remain in place. For example, Russian courts typically do not grant preliminary injunctions or permanent injunctions at the end of a successful litigation. 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, including direct compulsory licensing and weak patent policies (such as a lack of patent linkage, weak patent enforcement, and use of government tendering to boost local manufacturing). 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. That legislation is still pending.⁴³

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 data, NAM members are concerned that 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 2016 judicial interpretation of these rules has raised questions for policymakers how this may be interpreted and implemented going forward.

Watch List

Australia

Australia has become an increasing concern for NAM members on IP protection and enforcement due to concerns that its IP regime is becoming less friendly to innovative manufacturers. 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 patents and copyrights, with a specific focus on innovative industries such as pharmaceuticals and semiconductors. In August 2017, the Australian government released its response to the final report, signaling support for several of the Productivity Commission's recommendations such as abolishing the so-called "innovation patent" system, tightening patentability criteria and criteria for applicants, and reforming patent renewal fees so that they increase each year at an increasing rate. Many of those recommendations were then incorporated into draft legislation circulated for public comment in October 2017 that would effectively weaken IP protection in Australia. The NAM urges the U.S. government to engage actively with Australia to address concerns with the final report and draft legislation.

Additionally, Australia maintains a unique policy enabling the Department of Health to seek **damages from patent holders** that litigate legitimate patent claims and are granted preliminary

⁴³ "[Russia's FAS designs mechanism for withdrawal of licenses on drugs production in Russia](#)," The Pharma Letter, December 13, 2016; Horodisk & Partners, "[Legal Protection of Selection Inventions in Russia](#)," No. 118, September 2017.

injunctive relief but ultimately are unsuccessful in their litigation. This has created a significant hurdle for companies seeking to defend their legitimate patent rights. Those damages are allegedly 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 seven cases against innovative pharmaceutical companies with large claims (in one case, above \$300 million). 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: permitting the same government that examined and granted a patent to seek damages if that patent is later ruled invalid or not infringed as a part of proceedings that the innovator has the right to initiate to enforce that patent. 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. While news reports in May 2017⁴⁴ indicated that the case had been decided in favor of Australia, no final decision has been released as of the date of this submission.

Brazil

Manufacturers also continue to face significant challenges in Brazil, including **continued discussions about IP limitations and compulsory licenses**. 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.⁴⁵ Brazil is advancing such proposals in domestic legislation and also pushing **anti-innovation proposals in international fora**. For example, Brazilian representatives in Geneva have pushed for WIPO to develop a manual on patent exemptions and limitations to encourage developing countries to limit IP 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.⁴⁶

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 **patent and trademark backlogs** in the world. The average patent grant, for example, 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

⁴⁴ Tom Miles and Martinne Geller, "[Australia wins landmark WTO tobacco packaging case – Bloomberg](#)," May 4, 2017.

⁴⁵ Center for Strategic Studies and Debates, [Brazil's Patent Reform: Innovation towards National Competitiveness](#), July 2013.

⁴⁶ See, for example, [Proposal from Brazil](#) to the World Intellectual Property Organization, Standing Committee on the Law of Patents, Fourteenth Session, January 2010.

sciences, and more than 10 years for other forms of technology.⁴⁷ Despite an announcement to address the backlog by expediting review of patents, manufacturers are concerned about the implementation. Moreover, the announcement explicitly excludes a particular innovative sector important to the U.S. economy (pharmaceutical patents), raising questions about the announcement's WTO compliance. 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. Although new Brazilian Trademark Office rules went into place in January 2018 designed to expedite trademark applications and reduce backlogs, manufacturers will be watching to see whether it is implemented fully.

Brazil also requires **health oversight of its patent system**, as its 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, 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 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.⁴⁸

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.

South Africa

South Africa has taken steps to revise its **national IP strategies**. In 2016, South Africa's Cabinet approved a new Intellectual Property Consultative Framework, which includes many positive positions, including language recognizing the value of IP as a means of promoting innovation and economic growth and new mechanisms to boost interagency cooperation. However, that framework also incorporated troublesome themes such as a "flexible" approach to patents, compulsory licensing, and localization, including 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 undermine the importance and value of innovation and IP, and do not resolve longstanding questions for innovators in South Africa such as use of compulsory licensing, patentability, and regulatory data protection.

In August 2017, South Africa's Department of Trade and Industry (DTI) published for public comment a follow-up draft IP policy that mirrors both the positive and negative aspects of the Framework. The policy proposes changes such as subjecting patent applications to heightened

⁴⁷ Schultz and Madigan.

⁴⁸ 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.

scrutiny (including potential changes to patentability criteria), implementation of lower-quality utility model patents, and increasing use of TRIPS flexibilities to balance IP protection with other social goals. 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.

Thailand

Thailand has taken steps over the last year to improve IP in areas that have an impact for manufacturers in the United States, including stronger structures and mechanisms to coordinate enforcement activities and increased transparency and engagement with industry in revisions to key laws and regulations.⁴⁹ Thailand has also made progress in recent years tackling patent and trademark delays – with patent delays decreasing steadily since 2011.⁵⁰

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 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.

⁴⁹ Many of these changes were incorporated in to the Office of the U.S. Trade Representative's press release about the results of its 2017 Out-of-Cycle Review for Thailand, available [here](#).

⁵⁰ Schultz and Madigan.

Appendix: Index of Countries/Territories in NAM Submission to 2018 Special 301 Report

Country	Page
Algeria	11, 14
Argentina	9, 11, 13, 14
Australia.....	9, 10, 11, 29-30
Bangladesh.....	11
Brazil.....	8, 9, 11, 13, 30-31
Canada	9, 10, 11, 13, 14, 15-17
Chile	8, 10, 14
China	9, 11, 12, 13, 17-21
Colombia.....	8, 9, 11, 14, 21-22
Dominican Republic	9
Ecuador	8, 9, 10, 13, 14
Egypt	9, 11, 14
European Union	13, 14
France	9, 10
Georgia.....	10
Germany.....	9
Greece.....	9
Gulf Cooperation Council	9
Hong Kong.....	8, 10, 11
Hungary	10
India.....	8, 9, 11, 12, 13, 14, 22-27
Indonesia	8, 9, 10, 13, 27-28
Ireland.....	10
Japan.....	9, 13, 14
Jordan.....	9, 14
Korea	9, 11, 13, 14
Malaysia.....	8, 9, 11
Mexico	9, 11, 14
Morocco.....	14
Netherlands	9
New Zealand.....	9, 10
Norway	9, 10
Pakistan.....	11
Peru.....	11, 14
Romania	9
Russia.....	9, 11, 13, 14, 28-29
Saudi Arabia	9, 14
Singapore	9, 10, 11
Slovenia	10
South Africa	8, 9, 10, 31-32
Spain	9
Taiwan	11, 13
Thailand.....	10, 11, 32
Tunisia.....	9, 14
Turkey.....	9, 11, 14
United Arab Emirates.....	9, 11
United Kingdom	9, 10, 11, 12
Vietnam.....	9, 11