NATIONAL ASSOCIATION OF Manufacturers

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Vice President
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February 7, 2019

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-2018-0037

Dear Mr. Chang:

The National Association of Manufacturers (NAM) welcomes the opportunity to provide these written comments for the 2019 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 12.7 million women and men across the country[1] and drives innovation more than any other sector with roughly 65 percent of private-sector research and development.[2] In total, manufacturing contributes $2.33 trillion to the U.S. economy, up from $1.7 trillion in 2009.[3]

Innovation and intellectual property (IP) remain the lifeblood of our economy and the foundation for a globally competitive manufacturing base here at home and U.S. global leadership in manufacturing abroad. The United States has long made vigorous protection of IP rights at home and abroad against those who seek to steal our innovative ideas and products a core component of national competitiveness strategies and trade policy. 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 direct bilateral negotiation, robust investigations such as the Special 301 process and a robust set of global IP 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 set standards for IP protection that all are supposed to follow, but are also vitally important dispute settlement mechanisms that, when actively and appropriately used, help ensure that manufacturers and their workers in the United States reap the benefits of these agreements through fair market access and opportunities for exports.

Despite those efforts, U.S. IP remains a constant target for foreign governments and businesses who, in some cases, wish to steal it to boost their own industries and businesses. As a result, manufacturers in the United States face a wide variety of IP threats, including

[1] Bureau of Labor Statistics, "Manufacturing: NAICS 31-33: Employment, Hours and Earnings from the Current Employment Statistics Survey (National)," last visited February 6, 2018.
[2] Bureau of Economic Analysis, "Activities of U.S. Multinational Enterprises: 2016,"v August 24, 2018.
[3] Bureau of Economic Analysis, "Gross Domestic Product by Industry: First Quarter 2018," July 20, 2018.

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.[4]

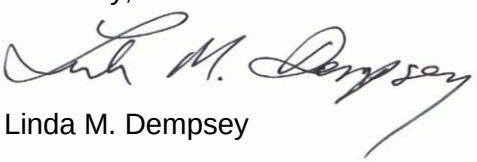
Though manufacturers in the United States face IP challenges in markets around the world, they confront particular challenges securing and protecting their intellectual property in a number of specific foreign countries. Based on the impact of these foreign governments' market-distorting actions that harm innovative manufacturers, the NAM is recommending that the Office of the U.S. Trade Representative focus on a series of foreign countries in this year's Special 301 report with specific classifications, including a **Priority Watch List designation for seven countries (Canada, Chile, China, Colombia, India, Indonesia and Russia)** and a **Watch List designation for six additional countries (Argentina, Australia, Brazil, Japan, Korea and South Africa).**

The United States must make strategic use of available options, working collaboratively across agencies, to address the IP challenges identified in this submission. This must include not only active use of Special 301-related tools such as country classifications, out-of-cycle reviews, results-oriented action plans and existing legislative authorities, but also efforts such as:

- Pushing for strong, enforceable IP protections in current and future trade agreement negotiations, including negotiations with the European Union, Japan, and the United Kingdom, and working to cement strong IP provisions in recently negotiated agreements such as the United States-Mexico-Canada Agreement (USMCA);
- Prioritizing IP protection as part of other bilateral talks, formal and informal, including ongoing trade negotiations with specific countries (such as China and India) and ongoing Trade and Investment Framework Agreement talks with countries such as Indonesia, Argentina, Ecuador, Ukraine and others;
- Leveraging international and regional organizations and platforms, including the WTO and the World Intellectual Property Organization (WIPO), to both pursue enforcement of IP rules and standards as well as to push for vigorous and stronger IP protection and enforcement and promote the development of new international best practices for IP protection; and
- Expanding creative education, training and capacity building programs with national IP authorities.

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

Sincerely,



Linda M. Dempsey

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

Chart 1: NAM Priority IP Issues by Country: Priority Watch List Recommendations

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

	Priority Watch List						
	Canada	Chile	China	Colombia	India	Indonesia	Russia
Broad Policy							
Discriminatory Industry, R&D, Localization Policies			x		x	x	x
Enforcement							
Problematic Levels of Counterfeiting and Piracy	x		x		x		x
Weak Channels to Fight IP Infringement	x	x	x	x	x		x
Improper IP-related Customs policies						x	x
Patents							
Compulsory Licensing		x		x	x	x	x
Patentability Criteria and Patent Review Processes	x	x	x	x	x	x	
Long Backlogs					x		
Other Policies that Undermine Value of Innovation	x						x
Trademarks							
Challenges to Legitimate Trademark Use	x	x	x				
Inappropriate Geographical indications (GIs)	x	x	x			x	
Long Backlogs for Trademarks					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 Fora					x		
Discriminatory Rules Governing IP Licensing			x			x	
Improper incorporation and Treatment of IP in Standards Activities			x				

Chart 2: NAM Priority IP Issues by Country: Watch List Recommendations

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

	Watch List					
	Argentina	Australia	Brazil	Japan	Korea	South Africa
Broad Policy						
Discriminatory Industry, R&D, Localization Policies		x	x			x
Enforcement						
Problematic Levels of Counterfeiting and Piracy	x					
Weak Channels to Fight IP Infringement	x	x	x			
Improper IP-related Customs policies						
Patents						
Compulsory Licensing	x					x
Patentability Criteria and Patent Review Processes	x		x			x
Long Backlogs	x		x			
Other Policies that Undermine Value of Innovation		x		x	x	
Trademarks						
Challenges to Legitimate Trademark Use		x	x			x
Inappropriate Geographical indications (GIs)	x			x	x	
Long Backlogs for Trademarks						
Trade Secrets						
Inadequate Protection of Trade Secrets						
Insufficient Protection of Business Confidential Information and Regulatory Data	x		x	x		
Other Issues						
Seeks to Erode IP in Multilateral Fora			x			x
Discriminatory Rules Governing IP Licensing						
Improper incorporation and Treatment of IP in Standards Activities						

National Association of Manufacturers
Detailed Comments for 2019 Special 301 Report
February 7, 2019

Innovation and intellectual property (IP) remain the lifeblood of our economy and the foundation for a globally competitive manufacturing base here at home and U.S. global leadership in manufacturing abroad. IP spurs further innovation, creating greater certainty for manufacturers to take innovative risks that enable them to build new industries, invest in advanced manufacturing facilities, create safer and healthier products for their customers, and create sustainable, well-paying jobs.[5] Such protections are important for manufacturers of all sizes, but 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 numbers are clear: patents, trademarks, copyrights and trade secrets contribute massively to the U.S. economy. In 2015, value-added from IP reached $6.6 trillion, or nearly 40 percent of total U.S. gross domestic product (GDP), an amount that has only grown since then.[6] As of 2017, the United States was responsible for more than one-quarter of all research and development (R&D) conducted globally, with nearly $19 billion in R&D (2.8 percent of U.S. GDP).[7] 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.[8]

Such R&D contributes directly to the U.S. economy. Recent literature clearly demonstrates a direct relationship between increasing R&D expenditures and increasing economic growth, as high as a one-to-one relationship, in both developed and developing countries.[9] 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, helping to support well-paying jobs in increasingly high-value manufacturing. Strong IP protection also provides powerful incentives for innovative solutions to global challenges that span from health to the environment, from energy to infrastructure. Where IP rights are protected and enforced, innovators thrive, creating and sustaining jobs and promoting international trade.

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[5] 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.
[6] Antonipillai, Justin and Michelle K. Lee, "Intellectual Property and the U.S. Economy: 2016 Update," September 2016.
[7] For R&D expenditures, see Industrial Research Institute and Research Technology Management, "2018 Global R&D Funding Forecast," R&D Magazine, March 12, 2018.
[8] Antonipillai and Lee.
[9] See, for example, Santacreu, Ana Maria and Heting Zhu, "Domestic Innovation and International Technology Diffusion as Sources of Comparative Advantage," Federal Reserve in St. Louis, 2018 Q4; Mohnen, Pierre, "The role of research and development in fostering economic performance. A survey of the macro-level literature and policy implications for Finland," Organisation for Economic Cooperation and Development, February 2018; Caesar, Ayamba Emmanuel, Haibo Chen, Thomas Bilaliib Udimal and Andrew Osei-Agyemang, "The Influence of R&D on Economic Development in the West African Sub-Region," Open Journal of Social Sciences, March 2018; Gumus, Erdal and Ferdi Celikay, "R&D Expenditure and Economic Growth: New Empirical Evidence," The Journal of Applied Economic Research, August 2015; and Inekwe, John, "The Contribution of R&D Expenditure to Economic Growth in Developing Economies," Social Indicators Research, November 2014.

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 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 foreign competitors who want to steal it, posing a threat not only to U.S. economic competitiveness but also to the health and safety of U.S. consumers. The theft of legitimate IP rights around the world remains a serious problem with a serious impact on the U.S. economy, manufacturers and workers. 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.[10] This includes theft of patented technology and trade secrets, counterfeiting of branded manufactured goods and piracy of industrial software that is important for manufacturers. Stolen technologies and fake products also threaten those businesses and consumers in the United States that would purchase and use these products. According to U.S. Customs and Border Protection statistics, major categories of counterfeit products included fake personal care products, medicines, consumer electronics, toys, computer accessories, automotive products and other goods that could pose serious health and safety risks.[11]

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 confront 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.

The United States must make strategic use of available options, working collaboratively across agencies, to address the IP challenges identified in this submission. This must include not only 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, but also additional efforts:

- Strong, enforceable IP protections should be a priority area for current and future trade agreement negotiations, including negotiations with the European Union, Japan and the United Kingdom and working to cement strong IP provisions in recently negotiated agreements such as the United States-Mexico-Canada Agreement (USMCA). New and updated trade agreements should ensure that parties join a common set of international

[10] Commission on the Theft of American Intellectual Property, "Update to the IP Commission Report," (Washington: National Bureau of Asian Research), February 2017.
[11] Office of Trade, U.S. Customs and Border Protection, "Intellectual Property Rights Seizure Statistics: Fiscal Year 2016," January 2017.

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. These obligations should be backed up by strong and neutral enforcement mechanisms.

- The United States must also prioritize IP protection as part of other bilateral trade talks, formal and informal, including ongoing trade negotiations with specific countries (such as China and India) and ongoing Trade and Investment Framework Agreement (TIFA) talks with countries such as Indonesia, Argentina, Ecuador, Ukraine and others. Where the U.S government has a TIFA framework in place with an IP-priority country but not active negotiations, the United States should work to restart those discussions.
- International and regional organizations and platforms, including the WTO and the World Intellectual Property Organization (WIPO), should be leveraged to pursue enforcement of IP rules and standards as well as to push for vigorous and stronger IP protection and enforcement and promote the development of new international best practices for IP protection; and
- Relevant federal agencies should work together to boost education, training and capacity-building programs with national IP authorities, pooling resources and expertise strategically to expand existing programs and to develop new programs and new models. These programs should take a broad view of relevant officials, including officials and agencies involved in setting IP-relevant policies or regulations impacting innovative industries, patent and trademark examiners, law enforcement officials, judges and other judicial staff.

Cross-Cutting Trends and Concerns

As manufacturers in the United States seek to obtain, use and enforce their IP rights in countries around the world, they encounter a range of challenges. Although the specific barriers differ from country to country, manufacturers see a number of cross-cutting, thematic issues that deny them adequate and effective IP protection and enforcement for manufactured goods. These include both longstanding and emerging issues, such as:

- IP erosion in multilateral fora,
- Growing foreign country pressure to undermine core IP protections for manufacturers,
- Growth and evolution of global counterfeiting,
- Inadequate infrastructure and political will to grant and enforce IP,
- Increasing technical barriers to obtaining patents,
- Inadequate protection of trade secrets and business confidential information, and
- Expansion of geographical indications.

Many of these concerns are growing, spreading from country to country and compounding the challenges faced by manufacturers. These issues appear as key themes in the analysis below of challenges in priority markets, but manufacturers also urge the U.S. government to approach these issues comprehensively and strategically given their cross-cutting nature.

IP Erosion in Multilateral Fora

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, environment, public health and other important objectives. In international organizations

and fora, some countries continue to call for compulsory licensing of U.S.-held patents. Strong U.S. pushback in these fora has been instrumental at defending critical IP but has only been possible through a strong and coordinated interagency approach to ensure common messaging and close work with likeminded countries and negotiators, efforts that must continue for this and other areas.

Those calls are similar to broader efforts across the United Nations (UN) system to claim that IP is inherently a barrier to public health, environmental protection, sustainable development or access to information and entertainment products, such as:

- Initiatives at the World Health Organization (WHO) and health advocates in other international fora to undermine innovation and intellectual property with false claims that IP is inherently a barrier to public health or to seek to limit use of IP in the name of public health.

    - Access to medicines has been one key front for this activity. There is clear evidence that many other barriers stand between patients around the world and the life-saving medicines they need and that effective solutions require a holistic, inclusive discussion of all such barriers. Despite this fact, the WHO continues to focus, improperly and narrowly, on IP as a main cause of problems with access to medicines. Ignoring and in some cases purposefully excluding the views of key member states and other stakeholders, the WHO continues to drive flawed policy recommendations, including unbounded expansion of trade-related patent flexibilities (known as "TRIPS flexibilities") that would hamper urgently-needed health innovation without solving the access issues they claim to address.

      While many of these problematic conversations have taken place at the WHO, they have also appeared in a range of other fora and reports in recent years. The most high-profile example of this in recent years was the deeply flawed UN High-Level Panel on Access to Medicines, which the U.S. government sharply and consistently criticized.[12] Yet its supporters have sought to reference this report, its recommendations, and the broader approach in multiple WHO workstreams (including its Global Action Plan for the Prevention and Control of Noncommunicable Diseases and several items on the January-February 2019 WHO Executive Board meeting agenda such as the road map on access to medicines and vaccines and a new report on cancer medicines).

    - Other health initiatives, such as the push to tackle non-communicable diseases such as obesity, have also sought to impinge upon the normal and appropriate exercise of IP rights. For example, 2016 WHO guidance designed to curtail marketing of complementary food products for infants and young children up to three years of age restricts 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.

  Moreover, supporters of these approaches have sought to export them to other international organizations, including UN General Assembly resolutions (such as the December 2018 Global Health and Foreign Policy Resolution), in the UN Human Rights

[12] 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.

Council, WTO TRIPS Council, WIPO, UNAIDS, and even in traditionally high-standard, pro-growth organizations like the Organization for Economic Cooperation and Development (OECD).

- Challenges in other international fora to the global framework of IP protections and enforcement, particularly for health, clean technology, energy and other advanced manufacturing products.

    - In international organizations such as WIPO and the WTO (in addition to the WHO as mentioned above), however, some countries continue to advocate for expanded flexibilities, exceptions and limitations on U.S.-held patents and other forms of IP, a concern that requires strong U.S. pushback. For example, it took a concerted effort of the United States 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 COP24 (Katowice, 2018). Similarly, troubling conversations have taken place at key WIPO committees, such as the Standing Committee on Patents.

    - Manufacturers are also watching growing calls to utilize competition law and policy as an additional area of TRIPS flexibilities, including a submission[13] sponsored by **China** and **South Africa** to the May 2018 WTO TRIPS Council to share national experience on "the use of competition law and policy" to improve public health by limiting intellectual property rights.

- Efforts to use international fora to legitimize the creation of alternate dialogues and frameworks for intellectual property, such as efforts to expand a trademark-alternative system to manage geographical indications (GIs) under the Lisbon Convention at WIPO.

Such discussions in international fora are often the direct result of lobbying by specific member states. On many of the patent issues, for example, **India**, **South Africa**, **Brazil**, **Ecuador** and **Indonesia** often play a leading role, while the **European Union** and key member states such as **France**, **Germany** and **Italy** lead the charge in support of GIs. Reports, guidelines and action plans that result from these discussions have an outsized impact on the agenda within these organizations in ways that are more hostile to U.S. IP and key industries.

Even more disturbing, these discussions create pressure for policymakers at the national level, influencing national governments to adopt flawed policy recommendations in their own laws and regulations that are having negative impact on manufacturers and their workers in the United States. International organizations increase that pressure by directly lobbying or offering technical assistance to national governments to revise their legal frameworks to undermine innovation and strong IP protections or by offering tailored grants to third-party stakeholders that have a vested interest in such changes. Manufacturers have seen such activity in organizations such as the WHO and the UN Development Programme, and by initiatives housed at these organizations, such as Unitaid. Manufacturers have seen direct influence of these conversations in policymaking around the world, including markets such as **Chile**, **Colombia**, **Ecuador**, **Hong Kong**, **Indonesia**, **Malaysia**, **Mongolia**, **South Africa**, **Thailand** and **Ukraine**.

[13] China and South Africa, "Intellectual Property and the Public Interest: Promoting Public Health through Competition Law and Policy," Document IP/C/W/643, May 24, 2018.

Such attacks on IP in multilateral fora 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 UN 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, while also undermining the legitimacy and fairness of policy recommendations that the organization releases.[14] Recent examples of problematic activity in this space, such as efforts to undermine R&D with the WHO's recent release of a draft report and data on cancer medicines, illustrate the problem, with WHO staff largely ignoring critical U.S. input while also directly excluding private sector voices.

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 will be critical in 2019 discussions about countries that have expressed a strong interest in joining, such as **Brazil** and **Argentina**.

Growing Foreign Country Pressure to Undermine Core IP Protections for Manufacturers
Innovative manufacturers in the United States also face increasing challenges from growing foreign country efforts to erode intellectual property in the name of other public policy prerogatives. Regulators and national authorities in multiple foreign countries are increasingly seeking to narrow the ability of manufacturers to obtain, use and protect patents, trademarks and other forms of intellectual property, claiming that such restrictions are being done in the name of areas such as public health or environmental protection.

One of the biggest challenges in this area is the intersection of innovation, intellectual property and public health, with growing foreign government attempts to limit the effectiveness of innovative manufacturers in a range of sectors. Ignoring that global rules and standards for innovation and IP have fostered decades of U.S. manufacturing innovation, support millions of well-paying jobs, saved millions of lives, and expanded consumer choice for millions of people around the world, some foreign governments and their regulators argue that IP rights should be eliminated or abrogated based on the false premise that strong IP protections are an inherent barrier to public health. This push has impacted multiple forms of intellectual property, including efforts to expand TRIPS flexibilities to undermine patents and the expansion of plain packaging restrictions that violate core trademark protections.

1. *Patents: Compulsory Licensing and Other TRIPS Flexibilities*

Compulsory licensing – government actions to compel licensing of a patent under protection in the name of domestic interests – has seen a notable uptick in recent years, with a growing surge of countries seeking to force patentholders to license their technologies and products through policy, administrative action or judicial ruling. Compulsory licenses, as recognized by

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

the more than 160 WTO members that agreed to the international rules laid out in the TRIPS Agreement, and the subsidiary Doha Declaration on the TRIPS Agreement and Public Health, needs to be limited to exceptional circumstances so as not to undermine the substantial benefits that IP protection provides. That means that compulsory licenses should only be used when they meet the criteria laid out in those agreements and must constitute decisions clearly based on the facts of the individual case through transparent processes that involve close consultation with all stakeholders.

While compulsory licensing is not a new concern for manufacturers and their workers in the United States (with past actions in markets such as **Brazil**, **Colombia**, **Ecuador**, **India** and **Indonesia** still resonating), concerns continue to expand particularly in the face of **Malaysia**'s high-profile action to invoke the "right of government" to exploit a pharmaceutical patent for hepatitis C in 2017, an action which is clearly inconsistent with the very rules to which Malaysia had agreed to abide. Malaysia's action has also catalyzed additional pressure in other countries, particularly as the Malaysian government has actively sought to instruct other countries on its approach in hopes of inspiring similar actions.

Alongside Malaysia's action, countries such as **Russia** have courts that have granted compulsory licenses, while other countries such as **Saudi Arabia** and the **United Arab Emirates** are granting marketing authorizations to local manufacturers for patent-protected products. Additional countries, such as **Chile**, **Colombia**, **Ecuador**, and **Peru,** are all either considering or working toward compulsory licensing actions. Others have moved forward with legislative changes designed to make compulsory licensing actions easier: **Turkey** and **Ukraine** passed legislation expanding the ability to issue compulsory licenses, while the **Dominican Republic** and **El Salvador** are considering legislative changes that could broaden use of compulsory licensing. These actions have also prompted increased efforts to reject related patent applications or challenge existing patents, including government actions in **Argentina** and an ongoing dispute at the **European Union**'s European Patent Office.

In addition to compulsory licensing and other patent flexibilities, many countries are using other regulatory and legislative tools that undermine the value and incentives for innovation and threaten U.S. exports of innovative manufactured goods. The range of tools and countries engaging in these types of actions is broad, with particularly troublesome activity taking place in countries such as **Australia**, **Canada** and **Japan** and additional activity in **Brazil**, **China**, **Egypt**, **France**, **Germany**, **Greece**, **India**, **Jordan**, **Korea**, **Malaysia**, **Mexico**, **Netherlands**, **New Zealand**, **Norway**, **Romania**, **Serbia**, **Singapore**, **South Africa**, **Spain**, **Tunisia**, **Turkey** and the **United Kingdom**.

To address these and other challenges to global IP rules that support manufacturing jobs and innovation, manufacturers support USTR's efforts to end the moratorium on TRIPS-related "non-violation nullification and impairment" disputes. This moratorium originally was planned as short-term measure, but it continues to be extended in the WTO by unanimous consent, including 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.

2. Trademarks: Continued Expansion of Plain Packaging Approaches

In the meantime, manufacturers in a range of industries remain highly concerned with and oppose the expansion of so-called "plain packaging" approaches that undermine companies' ability to use longstanding and vital trademark rights. Trademarks enable the public to identify and recognize goods or services as originating from a particular company and being a particular known product. They are the most valuable assets owned by many manufacturers and are essential for fair and effective competition in the global marketplace. As a result, governments around the world have long agreed to binding international rules at the WTO and WIPO to protect trademarks, obligations on which manufacturers of all sizes have relied as they continue to make significant investments to develop, promote and protect their trademark rights.

Governmental acts restricting or prohibiting the use of trademarks, such as plain packaging that eliminates consumers' ability to distinguish readily between products has highly negative consequences, not just in severely impairing the value of trademarks for manufacturers and their workers in the United States, but also denying consumer information, undermining fair global commerce and promoting increases in harmful and sometimes dangerous counterfeiting.

Manufacturers remain highly concerned with the continued expansion of plain packaging approaches in numerous countries.

- **Australia** was the first country to pass and implement controversial legislation prohibiting the application of marks and instead mandating plain packaging as a tool to limit consumption of products in a targeted sector (tobacco products).[15] In the wake of those rules, other countries have adopted or are considering similar rules in this area. **France**, **Hungary**, **Ireland**, **New Zealand**, **Norway** and the **United Kingdom** have already begun full or partial implementation of plain packaging rules. **Georgia**, **Romania**, **Slovenia**, **Thailand** and **Uruguay** have adopted but not yet implemented similar measures, and other countries from **Canada** to **Singapore**, from **South Africa** to **Saudi Arabia**, from **Chile** to **Turkey** are considering or in the process of drafting similar rules for tobacco products.

- Manufacturers in a range of other sectors are concerned about growing calls to apply plain packaging and other IP-restrictive approaches to other sectors and increased regulatory momentum toward restrictions on marketing and advertising in these sectors that predated plain packaging in other industries. **Chile** was one of the first countries to expand the use of these approaches with the imposition of a number of trademark-restricting actions and "STOP-sign" warnings on food and beverage products and other countries (including **Canada** and **Mexico**) have considered similar measures. Similarly, countries and regions such as **Thailand**, **Mongolia** and **Hong Kong** have responded to WHO lobbying (as described above) with new or revised regulations to curtail advertising and marketing of complementary food products for infants and young children up to three years of age.

[15] Those rules were the subject of a WTO dispute settlement case filed by four countries (Cuba, Indonesia, Honduras and the Dominican Republic). The WTO's dispute settlement panel in June 2018 ruled that the packaging law was in line with WTO rules, but Honduras and the Dominican Republic filed a formal appeal that has not yet been decided.

- Other countries have imposed additional regulations to limit use of trademarks, including a 2014 decree in **Ecuador** to limit or even prevent the use of trademarks for many medicines once the patent on that medicine has expired.

Growth and Evolution of Global Counterfeiting

Many manufacturers are also grappling with the significant challenge of battling a tide of fake products sold in the United States. This is not a new problem, but it is a large one: a 2017 estimate by the Commission on the Theft of Intellectual Property showed that counterfeit and pirated goods cost the U.S. economy between $29 billion and $41 billion every year.[16] More broadly, a 2016 OECD report found that global trade in counterfeit and other fake goods exceeded $460 billion, or 2.5 percent of global trade, in 2013.[17] A February 2016 industry study reveals an even starker story, with estimates that the global economic value of counterfeit and pirated products could reach $2.3 trillion by 2020.[18] Counterfeiting harms manufacturers and their workers in a wide variety of sectors, including agricultural chemicals, auto parts, consumer goods, industrial machinery and pharmaceuticals. While these issues impact manufacturers large and small, counterfeiting is particularly harmful for SMMs.

Fake products hurt more than the economy and businesses. Organized criminal networks use counterfeiting as a way of generating income for their activities. Estimates of the worldwide scale of illicit trade range from $650 billion to more than $5 trillion, representing a significant share of global GDP.[19] Moreover, fake products pose a direct risk to public health and safety. Many of the most commonly counterfeited goods are those used directly by consumers (such as personal care products or apparel) or that pose a direct risk of serious injury (such as fake airbags or fake batteries used in electronics).

Counterfeit and pirated goods arrive in the United States from numerous countries around the world, but manufacturers are highly concerned by the role of **China** (both directly and via **Hong Kong**) as the world's major hub for counterfeiting and the source of more than three-quarters of all counterfeit goods by value seized at U.S. borders in the latest Customs and Border Protection statistics (2017)[20] **India**, **Korea** and **Singapore** also remain consistent sources for counterfeit products coming into the United States (ranking in the top 10 sources for seized counterfeit goods by value for each of the last five years), with **Bangladesh**, **Canada**, **Pakistan**, **Taiwan**, **Turkey** and **Vietnam** also making recent and repeat appearances as top sources for counterfeits.

As counterfeiters continue to develop new ways to manufacture and sell fake products, manufacturers must keep up to protect their intellectual property. For example, counterfeiters often use free trade zones (FTZs) to transship counterfeit products. Though the roughly 3,500 FTZs worldwide contribute positively to global free trade, criminals take advantage of the fact that these zones are outside of their host countries' customs territory and thus often fall under more lax regulations or inspections. A recent study by the OECD and the European Union IP Observatory (EUIPO) estimated that each FTZ is associated with a nearly six percent increase

[16] Commission on the Theft of American Intellectual Property, "Update to the IP Commission Report," (Washington: National Bureau of Asian Research), February 2017.
[17] OECD, "Trade in Counterfeit and Pirated Goods: Mapping the Economic Impact," April 2016.
[18] International Trademark Association and Business Action to Stop Counterfeiting and Piracy, "The Economic Impacts of Counterfeiting and Piracy," February 2016.
[19] 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.
[20] Office of Trade, U.S. Customs and Border Protection, "Intellectual Property Rights Seizure Statistics: Fiscal Year 2017," February 26, 2018.

in the value of counterfeit exports from that FTZ's economy.[21] This contributes to the problem of IP violations, but leading reports published by industry and expert groups suggest a number of tools to tackle the issue, including tailored civil and criminal remedies and regimes to allow better tracking and tracing for products entering or leaving FTZs.[22]

While manufacturers have long battled fake products sold in physical markets, they face new challenges due to the explosion of fake products are being sold online, particularly through e-commerce platforms that link buyers and sellers such as eBay, Amazon and Alibaba's Taobao. A January 2018 report by the Government Accountability Office highlighted this change, a "shift in the sale of counterfeit goods from 'underground' or secondary markets, such as flea markets or sidewalk vendors, to primary markets, including e-commerce websites, corporate and government supply chains, and traditional retail stores, where consumers typically believe they are purchasing authentic goods."[23] Despite important actions pledged and taken by several of these platforms, significant numbers of counterfeit products are still being sold on the platforms. In addition, some manufacturers continue to raise concerns that platforms are not undertaking proactive enough activity to stem the growing tide of fake products and that complaints remain unaddressed or only partially addressed.

These challenges are exacerbated by structural challenges that allow counterfeiters to take advantage of postal infrastructure and low rates to subsidize their business. For example, foreign counterfeiters have long shipped counterfeit goods into the United States using international mail services and airmail. In recent years, however, the volume of packages bringing counterfeit goods into the United States through this route has exploded, partly due to counterfeiter practices to break up shipments into smaller packages to avoid detection and partly due to subsidized shipping rates provided by U.S. Postal Service (USPS) to foreign shippers under the Universal Postal Union (UPU)'s international terminal dues system. The sheer volume of shipments makes it impossible for Customs and Border Protection (CBP) agents to screen all incoming mail to detect such shipments. Once admitted and undetected, these shipments then enter the USPS 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 has long been complicated by rules that close materials shipped domestically by first-class, priority or express mail to inspection without probable cause.[24] President Donald Trump's October 2018 announcement of plans to seek significant changes in the UPU's "terminal dues" system, combined with the increased enforcement capabilities enabled by the *STOP Act* (S. 372/H.R 1057), are welcome steps for manufacturers struggling to push back against the growing menace of counterfeit goods.

Manufacturers believe that battling counterfeiters requires a range of strategies and priorities, including boosting the authority and political will of customs officials in key markets to seize and destroy counterfeit products, both those that originate within their customs territory and those that flow through FTZs. Global markets must also boost the ability to enforce their intellectual property rights and take down infringing product listings and websites that host infringing

[21] Stryszowski, Piotr and Bill Below, "Free Trade Zones: A Free Ride for Counterfeiters?", OECD On the Level, March 14, 2018; OECD and EUIPO, "Trade in Counterfeit Goods and Free Trade Zones: Evidence from Recent Trends," OECD Publishing, Paris.
[22] 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.
[23] U.S. Government Accountability Office, "Report to the Chairman, Committee on Finance, U.S. Senate: Intellectual Property: Agencies Can Improve Efforts to Address Risks Posed by Changing Counterfeits Market," January 2018.
[24] U.S. Postal Service, "Basic Eligibility Standards for Priority Mail," November 1, 2010.

content, a problem in markets such as **China**, **Russia** and **Ukraine**. The U.S. government should also expand its direct and collaborative enforcement efforts, including increased enforcement resources, streamlined procedures to detect, inspect, seize and destroy counterfeit products shipped by mail and smart engagement with overseas law enforcement officials. CBP and other agencies must robustly implement new authorities and deeper engagement with rightsholders provided under recently implemented laws such as the Trade Facilitation and *Trade Enforcement Act of 2015* and *STOP Act of 2017*.

Inadequate Infrastructure and Political Will to Grant and Enforce IP

Manufacturers seeking to obtain and enforce their intellectual property in foreign markets also frequently face a variety of structural barriers in seeking to do so. These barriers vary considerably, but can often include:

- Weak political will on the part of government officials to tackle IP infringement;
- Inadequate numbers of qualified and trained staff to handle review and grant of IP applications;
- Insufficient staff, training, resources or authority for law enforcement to detect, seize and destroy IP infringing products;
- Lack of timely, effective and neutral channels for rights-holders resolve IP disputes in areas such as patents; and
- Insufficient clarity surrounding, or inadequate access to, legal and judicial tools (such as preliminary injunctions) to properly enforce IP.

These barriers can manifest themselves in various ways. For example, inadequate numbers of trained patent and trademark examiners can result not only in inconsistent patent and trademark office decisions but also in long delays in obtaining IP. Such delays 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, manufacturers note that patent pendency is particularly high in markets such as **Brazil**, **India**, **Vietnam** and **Thailand**, with **Brazil** and **Vietnam** also singled out for long delays for trademarks as well.[25] 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. While several of these markets (notably **India**, **Thailand** and to a lesser extent **Brazil**) have taken steps in recent years to cut into their backlogs, further work remains. Fully resolving these processes must involve streamlining patent and trademark procedures (including both application and review processes) and building capacity among examiners. For patents, the manufacturers also encourage USTR to urge countries with long patent backlogs to consider patent-term adjustment procedures, which allow a patent applicant to apply for an extended patent term to account for time lost through long patent application backlogs.

In the patent area, many manufacturers 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**,

[25] WIPO, "World Intellectual Property Indictors, 2018," December 3, 2018.

Australia, **Brazil**, **Canada**, **China**, **Colombia**, **Egypt**, **India**, **Korea**, **Malaysia**, **Mexico**, **Peru**, **Russia**, **Thailand**, **Turkey** and **Vietnam**.

Increasing Technical Barriers to Obtaining Patents

Manufacturers also face policy challenges with the ability to obtain patents in the first place. For example, 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"), manufacturers 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**), strict limitations or *de facto* 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 and in the case of Canada, with the recently signed USMCA.

Additionally, many countries fail to protect adequately the test data used by regulators to grant appropriate market approvals for innovative products that serve as another key market access checkpoint alongside the issuance of a patent. These challenges impact various industries, including pharmaceuticals, biotechnology products and agricultural chemicals, and remain 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**, **Australia**, **Brazil**, **Canada**, **Chile**, **Ecuador**, **Egypt**, **Jordan**, **Mexico**, **Morocco**, **Peru**, **Saudi Arabia**, **Tunisia** and **Turkey**.

The failure to protect such data has a variety of implications for manufacturers and their workers 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. Manufacturers urge USTR and other agencies to focus greater attention on ensuring the 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.

Inadequate Protection of Trade Secrets and Business Confidential Information

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.[26]

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.[27] 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.[28] Effective enforcement also depends, at least in part, on the availability of information and access to evidence. In many countries, enforcement is complicated by lack of judicially supported mechanisms for 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.

Weak protections for trade secrets and other business confidential information remain 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.

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 established protections, 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 GIs, a push that would undermine the ability of the United States 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 now in force with **Canada**, **Colombia**, **Japan**, **Korea** and **Peru**, recently revised agreements with markets such as **Singapore**, pending agreements with markets such

[26] 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.
[27] PricewaterhouseCoopers and CREATe.org, "Economic Impact of Trade Secret Theft: A Framework for Companies to Safeguard Trade Secrets and Mitigate Potential Threats," February 2014.
[28] Brant J., Lohse S., Trade Secrets: Tools for Innovation and Collaboration (2014, published by International Chamber of Commerce, Paris.

as **Vietnam**, and agreements being negotiated or revised with markets such as **Australia**, **Chile**, **Indonesia**, **Mexico**, **New Zealand and the MERCOSUR markets of Brazil and Argentina.** EU member states also continue to push these issues on the multilateral stage, with several European countries actively pushing for WIPO funding to support the GI-centric Lisbon Agreement.

Country-Specific IP Challenges

Manufacturers and their workers 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 unfairly limit U.S. manufactured goods exports, shelter domestic companies, create competitive challenges around the world and challenge the ability of manufacturers in the United States to export to these and third-country markets.

The NAM has seen progress in some markets, including continued efforts to promote public awareness of IP and legislative moves related to innovative medicines in India, efforts to reduce patent and trademark backlogs in Thailand and Brazil and expansion of judicial channels to enforce IP in China. More progress, however, is needed in these and other long-troublesome markets, as well as other markets that are moving in the wrong direction. Overall, challenges faced by innovative manufacturers in the United States continue to grow globally. These issues must be addressed through strategic use of effective negotiating and enforcement tools.

Priority Watch List

Canada

Canada has made progress on IP in recent years, but manufacturers in the United States still have considerable concerns about a number of IP-related issues that impact their businesses. The recently signed USMCA modernizes IP provisions with Canada, including strong language on patents, trade secrets, copyright and regulatory data protection that will be beneficial for a broad range of innovative manufacturers. Notable changes in the USMCA include the expansion of the data protection period for biologics to 10 years; required civil and criminal procedures and penalties to enforce trade secrets; authorization for enforcement and presumption of damages against counterfeit goods that are in transit; restoration or adjustment of patent terms due to delays in patent reviews at the Canadian Intellectual Property Office (CIPO) or time spent for regulatory reviews and approvals; and stronger processes to allow stakeholder inputs and opposition as countries are consider recognizing potential GIs.

Surrounding these changes, Canada has also made a number of changes to its core IP laws, including revisions to its Industrial Design Act (in effect as of November 5, 2018) and Trademark Law (in effect as of June 17, 2019), and is in the process of revising its Patent Rules as well (with the latest draft published by CIPO in December 2018). Additionally, the Canadian government in October 2018 tabled a budget implementation bill that proposed additional changes to its core IP rules. Manufacturers will be looking to ensure that Canada fully implements the USMCA provisions. Manufacturers also have noted Canada's efforts in recent years to strengthen customs authority to address counterfeiting in line with the implementation of the December 2014 enactment of Bill C-8 (Combating Counterfeit Products Act)

Manufacturers continue to closely watch **patent-related administrative and judicial challenges** in Canada that are relevant to innovative products. Canada's Patented Medicines

(Notice of Compliance) Regulations (PM(NOC)) continues to raise questions about Patent Register listings, patent dispute proceedings, damages that impact innovative products versus their generic counterparts. 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. More recent decisions in Canadian courts indicate more circumspect approach, rejecting several attempts to revive the promise doctrine under other guises, but manufacturers continue to monitor closely actions taken by CIPO, the Patent Appeal Board or the courts. In other areas, innovative manufacturers remain highly concerned about potential changes. For example, Canada's Patented Medicines Pricing Review Board (PMPRB) continues to work on proposed changes to its guidelines that could impose new reporting requirements on patent holders, introduce new troublesome regulatory factors, and limit available input to narrowly selected market data. These approaches will not only hamper PMPRB's ability to develop smart policies but will also have a directly harmful impact on U.S. innovation and exports. PMPRB's Technical Working Group is currently working on a final report, and further action could proceed quickly.

The new USMCA contains important new language on protection of undisclosed test data for multiple categories of manufactured products that will be impactful if properly implemented. Despite those protections, manufacturers continue 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. The 2014 Protecting Canadians from Unsafe Drugs Act (bill C-17) provided the Health Minister wide discretion to share test data without safeguards to protect against unfair commercial use. The broad restrictions imposed by Canada on the scope of data protection in this respect are not supported by the text of either Article 39.3 of TRIPS, Article 1711 of the NAFTA, much less Article 20.48 of the USMCA. 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.

Manufacturers have also raised issues related to **government protection of sensitive business information**. Article 20.78 of the new USMCA could provide important new protections for businesses by prohibiting government officials from unauthorized disclosure of trade secrets outside of the scope of their official duties. It remains to be seen, however, how this will impact government practices, and manufacturers remain watchful of regulations that require them to provide significant amounts of sensitive 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 either corresponding U.S. and European regulations.

Manufacturers are also concerned about legislative efforts to advance **plain packaging** requirements for tobacco products as a major problem for legitimate trademark protection. As discussed above, manufacturers have taken a strong stance against the elimination of trademarks through plain packaging programs, as envision by this draft regulation, and would be similarly concerned if this legislation moved forward.

Additionally, manufacturers remain concerned about the implementation of IP-relevant chapters of the Canada-European Union Trade Agreement (CETA)[29], particularly measures that provide stronger protection for European **GIs** outside of trademark-provided protections food and agricultural products. USMCA contains stronger language to ensure transparent registration and opposition procedures for potential GIs, but those already covered as *sui generis* GIs under the CETA agreement undermine the ability of the United States 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.

Chile

Manufacturers note that not only has Chile failed to meet fully all of its IP-related commitments required under the U.S.-Chile FTA, but that the country has moved backwards on multiple IP-related fronts over the last year, with disturbing trends related to patents and trademarks that the United States should look to address through appropriate means, including consultations on implementation of the U.S.-Chile FTA and other bilateral trade discussions. Given that trajectory, the NAM is recommending adding Chile to the Priority Watch List for 2019.

Chile, like several of its Latin American neighbors, has increasingly considered **compulsory licensing** in recent years, starting with a January 2017 resolution passed by the Chilean Chamber of Deputies calling on the Minister of Health to use compulsory licensing authorities. That same body in January 2018 approved a second resolution asserting that a compulsory license was warranted in the case of certain drug products, prompting former Health Minister Carmen Castillo Taucher to issue a separate resolution (Resolution 399) declaring that such compulsory licensing would be justifiable based on public health grounds. Despite a transition in the Chilean government, current Health Minister Emilio Santelices Cuevas in August 2018 reaffirmed that resolution, raising serious risk that a compulsory license will be issued for these products, and that others could be petitioned. As noted previously, compulsory licensing should be limited to exceptional circumstances of clear health emergencies and must constitute decisions clearly based on the facts of the individual case through transparent processes that involve close consultation with all stakeholders. Manufacturers are concerned that Chile's actions may not meet these stringent criteria and may thus represent an inappropriate use of the Chilean government's compulsory licensing authority.

Moreover, Chile's efforts to curb IP in the name of other prerogatives is not limited to patents. This includes efforts to promote **plain packaging** approaches for various sectors. Additionally, Chile was a first mover in applying labelling, marketing and advertising restrictions seen as a precursor to plain packaging to other sectors. For example, Chile has imposed a number of trademark-restricting actions and "STOP-sign" warnings on food and beverage products, setting a negative example in the region that is already being considered in other markets such as **Brazil**, **Canada** and **Mexico**.

In addition, Chile has yet to satisfy commitments made under the U.S.-Chile FTA to establish a robust mechanism to enable effective **patent enforcement** before marketing approval decisions are made and implemented. FTA provisions had required Chile to notify a patent owner of the identity of any third-party seeking marketing approval while a patent is still in force and deny such approval until the patent is expired unless the patent owner gives explicit consent. In

[29] CETA went into force provisionally in September 2017, though final implementation is still pending passage by EU member states. See Government of Canada, Canada-European Union Trade Agreement Final Text.

practice, however, innovative manufacturers that hold such patents report that those notices are not taking place consistently, adding to the monitoring burden for companies and increasing the risk of inappropriate approvals being granted.

Finally, manufacturers are closely monitoring ongoing negotiations between Chile and the European Union on a potential modernization of the existing EU-Chile FTA, particularly measures that provide stronger protection for European **GIs** outside of trademark-provided protections food and agricultural products. Such measures undermine protections under the existing U.S.-Chile FTA and the ability of the United States 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.

China

In recent years, China 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. This recognition has expanded both opportunities and challenges for U.S. companies in China. Over the past year, members have reported important positive developments related to intellectual property in China, including the launch of a new national-level appeals court for intellectual property disputes, critical IP improvements for key innovative sectors such as pharmaceuticals, a proposed system for patent term restoration, new policy frameworks and legal revisions to boost punishments for companies that steal intellectual property and draft revisions to its Foreign Investment Law that would explicitly ban mandatory technology transfers from foreign companies.

Yet there is a clear reason why China has remained on the Priority Watch List of the Special 301 report year after year: manufacturers have continued to see the proliferation of industrial policies and other policies to promote domestic champions in key innovative industries and resistance to tackling long-standing structural issues that prevent effective enforcement of U.S. intellectual property rights.

Manufacturers in the United States continue to face problematic and discriminatory approaches to innovation that relate to **broad industrial policies**, including central policies such as Made in China 2025 and local programs that inappropriately promote local firms and technologies at the expense of fair market opportunities for manufacturers in the United States. Moreover, China's Cybersecurity Law and related laws and regulations (such as the National Security Law, Counterterrorism Law and Personal Information Security Specification) have imposed extensive **data localization** requirements and restrictions on cross-border data flows that harm a broad range of manufacturers using advanced technologies such as cloud computing or big data analytics.

China remains the leading source of **counterfeit and pirated goods** traded around the world, with 78 percent of the more than $1.2 billion in counterfeit goods seized at U.S. borders in 2017 coming from either China (46 percent) or Hong Kong (32 percent).[30] These problems are fueled by structural barriers, including value thresholds and low fines and damages that prevent effective criminal prosecution, weak coordination among different agencies and levels of government, insufficient political will by officials to tackle the problem, inadequate resources and

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

capacity to address IP infringement and the growth of online auction sites in China that are hubs for counterfeit products.

Protection of **trade secrets and confidential business information** in China remains a concern, although manufacturers have seen some improvements on formal trade secret protection with the revised Anti-Unfair Competition Law, the continued expansion of specialized IP courts and decisions in a handful of trade secrets cases to grant preliminary injunctions. Yet manufacturers in the United States also urge China to take additional steps to boost practical trade secrets enforcement, addressing evidentiary burdens, allowing meaningful access to judicial tools, such as preliminary injunctions, and boosting damage awards to serve as a meaningful deterrent to trade secret theft. Additionally, manufacturers have also long faced concerns with inadequate protection of confidential business information provided as a part of regulatory and judicial processes. Some industries, such as the pharmaceutical and medical device industries, have seen improvements on regulatory data exclusivity, but other manufacturers report challenges with requests from Chinese customs officials and other agencies for sensitive business data such as chemical formulations.

Despite helpful steps in the patent and associated regulatory space for some innovative manufacturing sectors (such as pharmaceuticals), manufacturers continue to face a number of patent-related issues in China. China still suffers from longstanding issues with **patent quality**, due to the lack of substantive examination for utility model and design patents that can fuel the granting of "junk patents" that enjoy a high level of protection but often carry a low level of inventiveness.[31] Finally, patent filers in the pharmaceutical industry continue to face patentability and patent invalidation issues related to inconsistent interpretation of new rules requiring examiners to consider submitting **supplemental data**. Despite a 2016 revision to rules by China National Intellectual Property Administration (CNIPA, formerly the State Intellectual Property Office) to require examiners to consider data generated after a patent is filed during patent prosecution to describe inventions or satisfy inventive step requirements, its implementation has not been consistent. Such a lack of consistent implementation deviates from the world's other busiest patent offices, including patent offices in the United States, Europe, Japan and Korea, resulting in problems in China even for patents granted widely in those other jurisdictions.

Inadequate trademark procedures also make manufacturers more vulnerable to pirates registering marks in bad faith or to other parties infringing upon their legitimate trademarks. For example, under the current Trademark Law, if a trademark owner opposes a bad-faith third-party application to register a mark and loses, the registration is granted without appeal, forcing the trademark owner to go through another timely and costly proceeding to seek invalidation of that mark (and may even have to halt the use of its mark in the meantime if it is similar to the bad-faith mark). Trademark squatting issues also remain a problem and not one covered well under existing law.

Manufacturers are also closely monitoring the evolution of rules and enforcement practices in IP-related areas such as:

- **Competition**, where China continues a strong focus on IP in the context of antitrust with a number of outstanding guidelines and a series of regulations from the State Council Anti-Monopoly Commission and others that have raised concerns about how Chinese

[31] For more on these issues and areas for patent reform that could address them, see reports such as Thomas T. Moga, "China's Utility Model Patent System: Innovation Driver or Deterrent," U.S. Chamber of Commerce, November 2012.

regulators may treat the legitimate exercise of IP in consideration of competition concerns.

- **Standards**, where China's IP-related standard-setting practices continue to cause significant concern, with a growing number of court cases involving standard-essential patents (SEPs), China's ongoing reforms to its standards system and longstanding questions about the ability of manufacturer participation in standard-setting activities.
- **IP licensing** due to challenges manufacturers face licensing technology into China even to their own subsidiaries. China's 2001 Technology Import-Export Administrative Regulations and its March 2018 State Council Trial Measures on External Transfer of Intellectual Property Rights impose clear risks for companies seeking to leverage technology between their domestic and China-based operations and increase the risk of IP loss.

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, Colombia has continued to take actions putting IP at risk in ways that are not fully consistent with Colombia's international commitments, harm manufacturers and their workers 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), continued **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."[32] These provisions are also inconsistent with OECD standards of which Colombia is the newest member.
- 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

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

OECD standards urging countries to "eliminate unnecessary regulatory barriers to trade and investment" and seek "harmonisation towards international standards."[33]

In addition, manufacturers in the United States are concerned about the increased use of declarations of public interest (DPIs) to drive compulsory licenses or to devalue innovation for innovative manufactured products.[34] 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. Despite Colombian government claims that it has revised the DPI process to address questions, the National Pricing Commission's November 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 compulsory licensing unnecessarily and harmfully revokes basic, internationally accepted property rights and runs 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. Over the past several years, Prime Minister Narendra Modi and other senior level officials have released statements and broad policies about the importance of innovation and IP protection (such as the 2016 National Intellectual Property Policy), prompting tangible steps such as IP training and public awareness campaigns, steps to expedite patent approval process and increase examiner capacity, and efforts by selected states to create new IP enforcement teams. In the weeks leading up to this submission, manufacturers saw a handful of small but positive developments, including Ministry of Pharmaceutical-announced amendments to the Drugs Prices Control Order to allow equal exemption treatment for U.S.-developed innovative products, a Supreme Court decision overturning a lower court ruling that invalidated patents for an innovative agricultural product and publication of draft revisions to the Patent Rules that lowered some patent fees. In parallel, the U.S. government has sought to engage their Indian counterparts on IP issues through channels such as the Commercial Dialogue (CD) and Trade Policy Forum (TPF) and through related dialogues and cooperative workshops with India's Department of Industrial Policy and Promotion (DIPP) on topics such as trade secrets and copyrights.

Despite these broad statements, more tangible action is needed: better rhetoric has all too often failed to translate into robust deliverables that would tangibly improve the IP environment for manufacturers. India's National Intellectual Property Policy, released in May 2016, is a perfect example of this dichotomy.[35] The policy includes important broad language that recognizes on the importance of IP for economic development and calls for stronger IP laws and enforcement and calls for progress in areas such as capacity building, agency streamlines and building public awareness of the value of IP. The policy itself, however, includes scant detail on how India would improve its policy framework or address concerns related to patents and trade secrets flagged by industry stakeholders. In addition, the policy claims that India's current IP policies are

[33] Organisation of Economic Cooperation and Development, "Recommendation of the Council on Regulatory Policy and Governance," Conference Paper, OECD Regulatory Policy Conference, 2010.
[34] The most recent example of a DPI came from the Ministry of Health's Resolution 5246 (December 2017) to initiate an administrative process to assess whether a DPI is required to ensure access to a specific hepatitis C treatment.
[35] Department of Industrial Policy and Promotion, "National Intellectual Property Rights Policy," May 12, 2016.

fully TRIPS-compliant in line with "national needs and international commitments," and that the country could continue its use of TRIPS and other treaty flexibilities. Combined with other longstanding industrial policies such as the 2011 National Manufacturing Policy and 2011 National Competition Policy that promote domestic policy and IP flexibilities at the expense of manufacturers in the United States, such policies raise significant red flags for manufacturers in the United States.

India continues to deny **patent protection**, or invalidate existing patents, for inventions that meet internationally accepted criteria. Under the TRIPS, patents must be granted for inventions that are new, involve an inventive step and are capable of industrial application. Section 3 of India's 2005 revised Patent Act, however, creates a fourth "enhanced efficacy" test for a number of categories of inventions that allows them to reject TRIPS-compliant patent applications, and the Indian Patent Office has not provided clear guidance as to how patent examiners should interpret this criterion, leading examiners and courts to interpret it subjectively and inconsistently in patent proceedings. Under Section 3, action using Section 3(d) (pharmaceuticals) is the most common, but Section 3 contains similar restrictions that have been used to deny other patentable manufacturing-relevant technologies.[36] Using Section 3(d), India has rejected, invalidated or otherwise revoked patents on at least 25 products since 2012, including products and therapies widely patented in other countries around the world. Other burdensome policy challenges, such as Section 8 requirements to notify when filing outside of India upon threat of invalidation of their Indian patents and the continued authority for state-level authorities to grant marketing approval for a generic version of patented medicines without verifying whether there is a related patent, undermine the value of patent protection and ultimately confidence in India's innovative patent system.

Compulsory licensing also remains a key challenge. While India has issued fewer compulsory licenses in recent years, it continues to insist on its unfettered right to issue compulsory licenses. The continued presence of vague legal criteria that permit their broad use (such as under Sections 66 and 92 of the Patent Act) without clear process or transparency requirements mean that Indian 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 and a continued flow of patent challenges in India's courts. Despite repeated attempts by the U.S. government to engage on this issue, India has remained unwilling to consider any steps, large or small, to address these concerns. Pressure for compulsory licensing has also arisen in other areas, such as environmental technologies and "essential facilities."

Long **backlogs for patent and trademark reviews** continue to create challenges for manufacturers seeking to register and use their IP in India. As noted above, India has taken some steps in recent years 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 point to some improvement in this area, which is a welcome development for manufacturers. The NAM remains vigilant in monitoring 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.

[36] Examples of potential risk include 3(h) for agricultural products, 3(i) for diagnostic and treatment processes and 3(o) for integrated circuits.

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, forcing businesses to rely on contracts in order to protect their trade secrets. In practice, this approach guarantees a narrow application of trade secrets that fails to cover key challenges such as trade secret theft where there is not a direct contractual relationship between the trade secret owner and the infringer. This contract-law-based approach allows only civil remedies, not criminal remedies.[37] Moreover, India does not offer 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. Despite intermittent positive signals of progress on these issues, including broad language calling for research on future trade secret policies in the National IP Policy and a 2016 workshop between USTR and India's Department of Industrial Policy and Promotion (DIPP), there has been no real change in this area to improve trade secrets protection in the country.

India continues to create challenges through **investment restrictions or regulatory hurdles for some IP-intensive industries**. These can include a variety of policy barriers, such as high tariffs on technology-intensive sectors like information technology and medical devices, price controls on medical device products and localization barriers in industries from energy to information technology. India also maintains, and has proposed, investment restrictions related to use of intellectual property, such as a 2016 DIPP proposed ban on investment "in technology collaboration, licensing for franchise, trademark, brand name and management contracts" for the tobacco sector. Such restrictions limit the market space for innovative manufacturing sector while also undermining India's investment and business climate.

In addition to the challenges that manufacturers continue to face in India itself, India's desire to be a **vocal challenger of intellectual property in multilateral fora** has prompted major concerns among manufacturers. At the WTO TRIPS Council, at WIPO, and at the WHO, India has sought to undermine international rules and standards to promote strong IP protections, denying links between IP and innovation and advocating robustly for maximum use of TRIPS flexibilities. India was also a major supporter of the flawed UN High-Level Panel on Access to Medicines and a fierce advocate urging other fora to discuss the report and its findings. Manufacturers are concerned about India's positions and the impact they could have in shaping international opinion in a manner hostile to innovation and IP.

Indonesia

Indonesia is an increasing concern for manufacturers in the United States due to a growing number of problematic legal and policy changes. The NAM does note positive steps to improve enforcement against counterfeit and pirated goods, including the establishment of new procedures for businesses to record their IP with customs and increased seizures of fake products. Yet many aspects of Indonesia's approach to IP, particularly for patents and trade secrets, increasingly reflect those in other troublesome countries in the region.

Indonesia's 2016 revisions to its Patent Law contained a number of concerning provisions that undermine Indonesia's IP system. Members' biggest concern remains Article 20, which mandates **local production of patented products** and allows any "party representing the

[37] 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.

national interest" to challenge patents under the rule. The Ministry of Law and Human Rights in July 2018 finalized implementing regulations for Article 20 that allows patent holders to postpone compliance with the local manufacturing requirement by applying for a five-year, extendable delay, but cementing the underlying local working requirement and providing few details as to the timing and processes for companies to apply for waivers.[38] More broadly, Indonesia maintains other **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 and unfair moves to promote local manufacturing must be robustly addressed.

The revised law also revived concerns about compulsory licensing, given that it provides for **compulsory licensing** on vague and arbitrary grounds that are inconsistent with Indonesia's international obligations. Indonesia's 2013 decision to issue compulsory licenses on nine patented pharmaceutical products[39] without following proper procedures (including attempts to consult with the affected companies to find sustainable, long-term solutions or any appeal or judicial review process) still echoes for innovative manufacturers concerned about their ability to protect their IP in Indonesia. In December 2018, the Ministry of Law and Human Rights issued troubling new regulations (Regulations No. 39/2018) on implementation of compulsory licensing raising the specter of expanded use of compulsory licenses, particularly granted to local manufacturers. These rules lack clarity in terms of scope, process and technical guidance. In addition, clauses in the new rules allowing compulsory licenses if a patent holder does not meet its local manufacturing obligation would seem to conflict with the five-year delay granted to foreign manufacturers under the July 2018 rules mentioned above.

The NAM also remains concerned with implementation of other changes in the law, including measures that narrow the scope of patentable subject matter, require disclosure of the origin of genetic resources or traditional knowledge and discourage voluntary licensing of technology.

Finally, a series of Indonesian regulations related to food products raise IP concerns. The NAM has serious concerns about the **trademark implications** of potential revisions to Indonesia's Law on Food or Regulations on Food Labelling and Advertising to expand limitations on marketing of pediatric nutrition products to include not only a broader population (by expanding the age coverage to include formula and milk products for children up to three years of age) but also a broader range of promotional, advertising, educational, labeling and branding activities involving these products. Additionally, Indonesia's mandatory Law on Halal Product Assurance, enacted in September 2014, 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 manufacturers in the United States.

[38] Indonesian Ministry of Law and Human Rights, "Implementation of Patent by Patent Holder," No. 883, 2018; July 11, 2018.
[39] Government of Indonesia, "Special 301 USTR Submission," February 20, 2013.

Russia

Russia has made little progress on IP issues over the last year and has taken some troubling steps backwards. Manufacturers have long been concerned about potential **compulsory licensing** issues in Russia, with increasing legislative steps and statements from senior Russian officials pointing to rising concern about either direct compulsory licensing or indirect expropriation of the value of innovation through weak patent policies (such as a lack of patent linkage, weak patent enforcement, and use of government tendering to boost local manufacturing). These steps include efforts by the Federal Anti-Monopoly Service (FAS) and other agencies to advance legislative changes to enable compulsory licensing for medicines, for which FAS has already submitted drafts to the Russian government. Of additional concern, the Moscow Arbitration Court in July 2018 granted a compulsory license for a cancer medicine developed in the United States. This decision could set a problematic precedent, influencing other judges and cases to issue further such decisions.

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). Impacted manufacturing sectors include agricultural chemicals, auto parts, consumer goods, machinery, medicines, software and a wide array of other products. Yet despite the scope of the challenge, enforcement remains challenging, with a long backlog to seek criminal action and major challenges getting police to tackle counterfeiting issues robustly. Online counterfeiting continues to plague the Russian market, and the government has not established an effective enforcement strategy to combat websites and online platforms that feature infringing content or feature fake goods. In addition, broad 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 tenders of products such as pharmaceuticals: innovative manufacturers in practice lack effective mechanisms to resolve patent disputes prior to the launch of generic products and are unable to obtain preliminary injunctions.

Trade secret protection remains a challenge 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. Russia also 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. Despite 2015 amendments to its Law on Circulation of Medicines and a 2016 judicial interpretation, concerns remain that they contain mechanisms that are contrary to, or do not effectively implement, regulatory data protection consistent with Russia's international obligations.

Russia in 2015 launched the **Eurasian Economic Union (EEU)**, a regional organization that now has five members (Armenia, Belarus, Kazakhstan, Kyrgyzstan and Russia) that have pledged to integrate their 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, though it has plans to implement various steps (such as the creation of a common EEU trademark and a

single customs register for IP rights) that should be monitored carefully to understand the regulatory environment impacting IP and IP-intensive industries.

Watch List

Argentina

Argentina is a troublesome market for a wide range of IP challenges, with the most significant issues related to patents and enforcement. Argentina's IP legal framework lacks key protections that are required under the country's WTO TRIPS obligations, while also maintaining a number of specifically problematic elements. For example, Argentina lacks meaningful protection for regulatory test data, as is required by Argentina's international commitments in the WTO TRIPS agreement, and instead has a domestic law allowing officials to use innovator data to approve marketing authorizations for competitors to make similar products. At the same time, Argentina's Instituto Nacional de la Propriedad Industrial (INPI), Ministry of Health, and Ministry of Industry have standing guidelines to limit the scope of inventions that are eligible for patents, with the most notable restrictions on pharmaceutical innovations. This narrowed scope does not align with other jurisdictions, meaning that INPI rejects patents that have been granted by other patent offices. This longstanding issue made headlines in December 2017, when INPI rejected a pharmaceutical patent under these restrictive criteria, thereby opening the door for domestic production at the expense of U.S. innovative manufacturing, U.S. workers and U.S. exports.

Additionally, while Argentina is not as challenging as others in the region, **patent backlogs** remain a significant issue, with some estimates placing the backlog of patents waiting to be adjudicated above 20,000 across sectors. Delays in reviewing manufacturer-critical patents not only represent extra time and cost for those companies, but also directly cut into the period of protection, given that Argentina does not permit adjustments to patent terms to account for patent office delays.

Finally, Argentina maintains **discriminatory government policies that harm market access for innovative products**, with a preference for domestic products. Such policies in the reimbursement space fail to recognize the value of innovation while also undermining investment in innovation and R&D in the country.

Members also report challenges with **IP enforcement** in Argentina, with counterfeit goods widely available and inadequate government action (such as through raids and prosecutions) to tackle these issues. Punishments and remedies (including fines and damages) are often too low to disincentivize counterfeiters.

Australia

Australia has become an increasing concern for manufacturers in the United States on IP protection and enforcement due to concerns that its IP regime is becoming less friendly to innovation. 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. That review has prompted a detailed process of legislative changes, including a first round of

changes that was passed in August 2018,[40] and a second round of proposed changes that has been through multiple rounds of consultation.[41] The first round of changes included areas that could harm innovative manufacturers doing business in Australia, including trademark changes that could boost parallel imports and a reduction in procedural requirements for pharmaceutical patent innovations. The second round of proposed changes, however, includes broader items that meet APC recommendations such as abolishing the so-called "innovation patent" system. Although IP Australia has recently indicated that it would not include changes to raise the criteria for "inventive step" of a potential patent pending further consultation, those changes remain under consideration. Manufacturers urge the U.S. government to engage actively with Australia to address concerns with potential legislative changes to ensure they do not undermine innovative manufacturers.

Additionally, Australia maintains a unique policy enabling the Department of Health to seek **damages from patent holders** that litigate granted patent claims and are granted preliminary injunctive relief but ultimately are unsuccessful in their litigation. This has created a significant hurdle for companies seeking to enforce or defend their legitimate patent rights. Since 2012, this policy has resulted in at least seven cases against innovative companies with large claims (in one case, above $300 million). Such efforts create uncertainty for businesses, undermining R&D, innovation and investment, while also unfairly penalizing inventors who have sought to defend their legitimate patent rights. These actions appear inconsistent with Australia's IP commitments in the WTO and in the U.S.-Australia FTA and set a bad precedent for other markets.

Manufacturers also report challenges with **regulatory data protection** in Australia, with no provisions in law to provide such protection to data provided in registering products such as health and therapeutic goods other than a five-year period for new chemical entities. This failure to protect these data continues despite obligations under the Australia-U.S. FTA that required parties to provide at least three years of regulatory data protection from the date of marketing approval if new clinical information is required.

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, a move that has significant negative impact for trademarks. 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 remain under appeal at the WTO.[42]

Brazil

Manufacturers continue to face significant challenges in Brazil, including continued discussions about **compulsory licenses, patent rejections and other forms of TRIPS flexibilities**. Brazilian industrial policies and strategies continue to include references to the value of compulsory licenses and patent limitations to promote local production. While Brazil has not

[40] IP Australia, "Intellectual Property Laws Amendment (Productivity Commission Response Part 1 and Other Measures) Act 2018."
[41] IP Australia, "Consultation on the Intellectual Property Laws Amendment Bill 2018."
[42] As noted above, The WTO's dispute settlement panel in June 2018 ruled that the Australia's packaging rules did not violate WTO rules, but Honduras and the Dominican Republic filed a formal appeal that has not yet been decided.

issued new compulsory licenses in recent years, a May 2018 court decision to suspend a patent granted widely in other jurisdictions has revived those concerns. Brazil's rhetoric in international fora also spurs this concern, as Brazil continues to push or support **anti-innovation proposals in international fora**, such as efforts to introduce UNHLP recommendations as international organization workstreams or language in reports.

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 sciences, and more than 10 years for other forms of technology.[43] INPI in 2017 announced efforts to address the backlog by expediting review of certain types of patents, but that announcement concerningly excluded a key innovative sector important to the U.S. economy (pharmaceutical patents), raising questions about the announcement's WTO compliance. Trademarks in Brazil also continue to 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 has long required **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. For many years, ANVISA did not limit its role to review of potential sanitary risks but also reviews patentability requirements. INPI and ANVISA in April 2017 released a joint statement (Joint Ordinance No. 1/2017) clarifying the roles of the two agencies and limiting ANVISA's role to the public health perspective, leaving INPI to handle all questions of patentability. While this is an important step, ANVISA's continued role in the process prompts concern.

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.[44]

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.

Japan

After years of important reforms in critical policy areas and government systems to support greater market entry for innovative products into Japan, Japan has moved backwards over the

[43] Schultz and Madigan.
[44] 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.

last two years with policy steps that undermine the country's pro-innovation environment, leading the NAM to add them to our recommended Watch List for this year.

These steps have raised increasing doubts about **discriminatory government policies that harm market access for innovative products**. For example, in 2017, Japan launched a series of reforms to a critical program (known as the Price Maintenance Premium System (PMP)) that was established in 2010 to lower practical barriers that had slowed market access and entry for innovative health manufacturers into Japan. These reforms introduced changes to criteria, process and timing that undermine confidence for these manufacturers in their ability to invest in R&D of advanced medical devices and innovative pharmaceuticals, and in Japan's commitment to the type of R&D needed to create and bring new products such as innovative pharmaceuticals to the market. Moreover, these rules appear to be crafted in a tiered way that favors domestic companies at the expense of manufacturers in the United States, particularly SMMs. In addition to concerns about process, the Japanese government's stated intention to move from its biennial revisions to an annual revision to the program has created considerable uncertainty and has undermined investment and R&D.

Manufacturers note other areas where improvements to the Japanese **patent regime** are also needed, including improvements to patent term adjustments to cover unreasonable delays in issuance of patents and reforms to extend and clarify regulatory data protection for key innovative sectors.

Additionally, manufacturers are closely monitoring the pending implementation of IP-relevant chapters of the European Union-Japan Economic Partnership Agreement, including measures that provide stronger protection for European **GIs** outside of trademark-provided protections food and agricultural products. Such measures undermine the ability of the United States 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.

Given soon-to-be launched U.S.-Japan bilateral trade agreement negotiations, manufacturers continue to urge that these issues remain a top focus of U.S. negotiations.

Korea

Korea continues to suffer from important weaknesses related to market access for innovative products, with policies that not only discriminate against foreign innovative manufacturers but also violate key commitments made under the U.S.-Korea Free Trade Agreement (KORUS) related to pricing. Given these challenges and the urgent need to fulfill pledges made by Korea during the KORUS update, the NAM is suggesting that Korea be placed on the Watch List in 2019

These weaknesses include **discriminatory government policies that harm market access for innovative products**. For example, Korea's 2016 Drug Expenditure Rationalization Plan (DERP) requires a multi-step process for setting government prices with specific criteria that effectively discriminate against patented products and do not reflect the value of innovation. Follow-up policies, such as the 2016 Plan of Improving the Drug Pricing System, deepened the market access problems facing innovative manufacturers. The system also suffers from transparency and due process concerns by not providing an independent mechanism for innovators to appeal government determinations of specific prices. This, coupled with other regulatory actions that similarly undercut innovative manufacturers, have slowed market access

and entry for critical products and have undermined confidence for Korea's commitment to supporting the R&D needed to create the next generation of innovative manufactured products.

In March 2018, bilateral renegotiation of key provisions of KORUS included a Korean commitment to amend key pricing and reimbursement policies to be consistent with language in the agreement. In particular, Chapter 5 of that agreement includes language in which both sides committed to recognize the value of innovative products and ensure that all rules are fair, reasonable and non-discriminatory. Those amendments have yet to be fully passed and implemented in Korea, raising continued concerns for manufacturers and their workers in the United States.

More broadly, manufacturers have also raised concerns about the implications of a recent Korean court decision that undermines critical patent term restoration protections by seeking to narrow protections sharply to the product approved, but not the underlying patented invention. This practice spurs competitors to seek approval for variations on the product (that would be blocked under the un-restored patent), as well as continued challenges related to patent reform.

As with other markets, members are also monitoring ongoing implementation of the European Union-South Korea Free Trade Agreement, including any efforts to expand protections for European **GIs** that could block effective market access for food and agricultural products in the United States. Such measures undermine the ability of the United States and other countries to protect existing trademarks in these products as well as to ensure fair treatment for those making products on terms already treated as generic.

South Africa

South Africa has taken steps to revise its **national IP strategies**. Following nine months of drafting and consultation work led by South Africa's Department of Trade and Industry (DTI), the South African cabinet in May 2018 approved a follow-up IP Policy that included many of the positive and negative aspects of its predecessor (the 2018 IP Consultative Framework). This included positive language recognizing the value of IP as a means of promoting innovation and economic growth and new mechanisms to boost interagency cooperation. Yet it 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. The policy also includes provisions that subject patent applications to heightened scrutiny (including potential changes to patentability criteria), implement lower-quality utility model patents, and foster increasing use of TRIPS flexibilities (including compulsory licensing and competition law restrictions) to balance IP protection with other social goals. 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. Manufacturers urge the U.S. government to work with the South African counterparts to ensure that implementation of the policy is conducted in a way that does not undercut innovative manufacturing in the United States.

South Africa has also joined other countries to challenge trademarks by advancing **plain packaging** requirements for tobacco products as a major problem for legitimate trademark protection. In May 2018, South Africa's Department of Health released for a three-month public comment period the draft Control of Tobacco Products and Electronic Delivery Systems Bill of

2018, which included language proposing plain packaging rules. This bill, like its counterparts in other countries, raises serious questions about its implications for trademark rights broadly.

South Africa 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. Manufacturers are concerned about South Africa's positions on these issues given their impact in shaping international opinion, particularly in the developing world.

Appendix: Index of Countries/Territories in NAM Submission to 2019 Special 301 Report