

Jan. 31, 2022

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

Ref. Docket No.: USTR-2021-0021: Request for Comments and Notice of a Public Hearing  
Regarding the 2022 Special 301 Review

Dear Mr. Ewerdt:

The National Association of Manufacturers welcomes the opportunity to provide written comments for the 2022 Special 301 Review. The NAM is the largest manufacturing association in the United States, representing nearly 14,000 manufacturers small and large, in every industrial sector and in all 50 states. Manufacturing employs 12.5 people across the country and drives innovation more than any other sector, contributing 58% of all private sector research and development in the United States. In total, manufacturing contributed \$2.52 trillion to the U.S. economy in the second quarter of 2021.<sup>1</sup>

Innovation, intellectual property and research and development are the foundation for globally competitive manufacturing operations and a skilled, educated workforce here at home and the basis of U.S. global manufacturing leadership. Innovation drives opportunity and creates well-paying jobs for millions of working Americans and their families, ushering in the so-called “fourth wave” of manufacturing that is creating new opportunities and new high-skilled jobs to remake our workforce.<sup>2</sup> Intellectual property protections provide the incentive and the certainty for manufacturers to take the necessary risk to create new industries and new jobs, invest in advanced manufacturing facilities, expand workforce development programs and create safer and healthier products for their customers. Intellectual property will be a critical driver of U.S. global technology leadership in emerging fields such as green technology, robotics and the digital economy. The continuing COVID-19 pandemic also underscores just how important these protections are right now: throughout the pandemic, manufacturers have worked day and night to create and produce the vaccines, therapeutics, diagnostics, personal protective equipment and the broader array of goods needed to help the United States fight this disease.

Strong support for IP has long been a bipartisan issue, with Democratic and Republican administrations alike making robust protection of IP rights a core component of their strategies to boost national competitiveness and trade opportunities that inclusively benefit businesses and workers. These strategies have long been built on two pillars: a strong domestic legal framework to protect and enforce manufacturers’ IP at home, and consistent efforts to fight for strong IP protection and enforcement abroad. These efforts include defending and expanding strong global IP rules (such as the World Trade Organization’s Agreement on Trade-Related Aspects of Intellectual Property Rights), building pro-IP provisions into bilateral and regional

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<sup>1</sup> National Association of Manufacturers, [“Facts about Manufacturing.”](#) last visited Jan. 13, 2022.

<sup>2</sup> Manufacturing Institute, [“Training to Win: Talent Solutions for the New Economy.”](#) March 2020.

agreements (including all types of trade and investment agreements) and partnering with foreign governments to strengthen their IP laws, regulations and enforcement. This strategy not only sets clear, consistent IP standards around the world, but also unlocks vitally important dispute settlement and domestic legal mechanisms that, when actively and appropriately used, can promote exports, market access and a level playing field for manufacturers and their workers in the United States.

Manufacturing competitiveness here in America continues to depend on these efforts, as our innovation remains a constant target for foreign governments and businesses who, in some cases, wish to steal their IP or undermine IP protections to boost their own industries and businesses. Manufacturers in the United States face a wide variety of IP threats, including both harmful actions taken by individual bad actors—such as counterfeiting, patent infringement and trade secret theft—and coordinated efforts by governments and others to weaken the global IP frameworks that protect manufacturers and workers in the United States and open doors to exports and market access for innovative products that support well-paying manufacturing jobs in the United States. 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 annually, harming U.S. businesses, jobs and workers in the process.<sup>3</sup>

Though manufacturers in the United States face IP challenges globally, they confront particular challenges securing and protecting their IP in specific markets. Based on the harmful impact of these foreign governments' market-distorting actions on 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 nine countries (Argentina, Canada, Chile, China, Colombia, India, Indonesia, Mexico and Russia)** and a **Watch List designation for seven additional countries (Australia, Brazil, Japan, Korea, Saudi Arabia, South Africa and Thailand)**.

The United States must take a “whole-of-government” approach to support innovative manufacturing businesses and workers, collaborating across agencies to address the IP challenges identified in this submission through specific, action-oriented work plans. This must include not only active use of Special 301-specific tools such as country classifications, out-of-cycle reviews, results-oriented action plans and existing legislative authorities, but also trade-related efforts such as:

- Negotiating and enforcing strong IP protections in current and future trade negotiations and frameworks, including robustly enforcing IP commitments in existing agreements (including formal free trade agreements such as the United States-**Mexico-Canada** Agreement, the **Korea**-United States Free Trade Agreement, and other agreements with **Australia, China, Chile** and **Colombia**) and leveraging new frameworks such as the Indo-Pacific Economic Framework, in future new trade agreements with markets such as the **United Kingdom, Kenya** and potentially elsewhere in Africa, or expanded bilateral agreements with markets such as **China** and **Japan** to bolster U.S. innovation and intellectual property;
- Prioritizing IP protection in bilateral trade dialogues, formal and informal, including Trade and Investment Framework Agreement talks (both those with individual countries such as **Indonesia** and **Argentina** and regional agreements with **Association of Southeast**

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<sup>3</sup> Commission on the Theft of American Intellectual Property, [“Update to the IP Commission Report,”](#) (Washington: National Bureau of Asian Research), February 2017.

**Asian Nations** countries) and other bilateral consultations (with individual countries such as **Brazil** and **India**);

- Leveraging international and regional organizations and platforms, including the WTO, the World Intellectual Property Organization and **APEC**, to pursue enforcement of IP rules and standards, promote the development of new global rules that expand and update critical IP protections and confront efforts by other countries to weaken those protections;
- Strengthening bilateral engagement with foreign governments on IP-related enforcement actions to ensure transparency and due process in administrative proceedings, fair, efficient treatment in judicial cases and effective enforcement of arbitration awards; and
- Expanding creative education, training and capacity building programs with national IP authorities.

Similarly, manufacturers urge the U.S. government to fully implement domestic tools and authorities to protect intellectual property here at home and tackle foreign bad actors. These activities include full implementation of important legislation such as the Trade Facilitation and Trade Enforcement Act of 2015 and the Synthetics Trafficking and Overdose Prevention Act of 2018, as well as other steps to address issues such as counterfeiting identified in previous government reports such as the Department of Homeland Security's January 2020 counterfeiting report.

The NAM and its members welcome this opportunity to comment and look forward to working with USTR and other agencies to address critical IP concerns facing manufacturers.

Sincerely,

A handwritten signature in black ink, appearing to read 'K. Monahan', written in a cursive style.

Ken Monahan

## **National Association of Manufacturers Detailed Comments for 2022 Special 301 Report**

Innovation, intellectual property and research and development remain critical foundations of a globally competitive manufacturing base and a skilled, educated workforce here at home and the basis of U.S. global manufacturing leadership. That innovation remains critical in driving opportunity and creating well-paying jobs for millions of working Americans and their families, ushering in the so-called “fourth wave” of manufacturing that is creating new opportunities, and new high-skilled jobs to remake our workforce.<sup>4</sup>

The numbers are clear: patents, trademarks, copyrights, trade secrets and other forms of intellectual property fuel the U.S. economy. As of 2019, the United States was responsible for just under 30% of all research and development conducted globally,<sup>5</sup> with nearly \$667 billion in total R&D (3.1% of U.S. GDP).<sup>6</sup> According to a 2016 report by the Department of Commerce and U.S. Patent and Trademark Office, innovative industries account for more than 50% of all U.S. merchandise exports and directly or indirectly support more than 45 million jobs across the country.<sup>7</sup>

Innovation and intellectual property support U.S. global manufacturing leadership, spurring the creation of businesses and industries that create new jobs, provide valuable goods and services for Americans and allow us to compete on a global scale. Strong IP protection also provides powerful incentives for innovative solutions to global challenges such as health, the environment, energy, infrastructure and more. Where IP rights are protected and enforced, innovators thrive, creating and sustaining jobs and promoting international trade.

Innovation and intellectual property also provide broad benefits for American workers, families and communities of all backgrounds. IP-intensive industries employ millions of U.S. workers, offering jobs with higher wages for all workers. For example, the 2016 DOC-USPTO study also showed that U.S. workers across IP-intensive industries earned an average weekly wage nearly 50% higher than their counterparts in non-IP-intensive industries.<sup>8</sup> Intellectual property also creates opportunities for entrepreneurs and inventors from all backgrounds to create products and technologies that reflect their knowledge, their experience and their diverse perspectives. Numerous studies have shown that expanded access to the tools of innovation and to intellectual property protection strengthens economic opportunity and broad U.S. economic growth that benefit all Americans.<sup>9</sup> Moreover, the positive impacts of innovation and intellectual property benefit countries at various levels of development: experts continue to find a clear,

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<sup>4</sup> Manufacturing Institute, [“Training to Win: Talent Solutions for the New Economy.”](#) March 2020.

<sup>5</sup> Congressional Research Service, [“The Global Research and Development Landscape and Implications for the Department of Defense.”](#) last updated June 28, 2021 and accessed Jan. 16, 2022.

<sup>6</sup> For statistics on total U.S. R&D, see Boroush, Mark, [“New Data on U.S. R&D: Summary Statistics from the 2019-20 Edition of National Patterns of R&D Resources.”](#) Dec. 27, 2021. Percentage of GDP is calculated directly using GDP figures from the U.S. Bureau of Economic Analysis: see BEA, [“Gross Domestic Product, \(Third Estimate\), GDP by Industry, and Corporate Profits, Fourth Quarter and Year 2020.”](#) Mar. 25, 2021.

<sup>7</sup> Statistics cited in the report date to 2014. See Antonipillai, Justin and Michelle K. Lee, [“Intellectual Property and the U.S. Economy: 2016 Update.”](#) September 2016.

<sup>8</sup> Antonipillai and Lee.

<sup>9</sup> For a discussion on many of these studies, see U.S. Patent and Trademark Office, [“Report to Congress pursuant to P.L. 115-273, the SUCCESS Act.”](#) October 2019.

direct relationship between a country's increasing R&D expenditures and its level of economic growth.<sup>10</sup>

The ongoing COVID-19 pandemic underscores just how important these protections are: during COVID-19, manufacturers have worked day and night to create and produce the vaccines, therapeutics, diagnostics, personal protective equipment and the broader array of goods needed to help the United States and the rest of the world fight this disease. Strong intellectual property protections have made this possible, catalyzing innovation and providing certainty for creative manufacturers to act in times of crisis. And the legal certainty provided by intellectual property rules has allowed innovative manufacturers to partner at an unprecedented speed and scale to accelerate the development, production and distribution of critical products such as vaccines, therapeutics, diagnostic kits and personal protective equipment.

Yet American IP remains a major target for foreign competitors who want to steal or undermine it, posing a threat not only to U.S. economic competitiveness and jobs 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 potentially dire impacts 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.<sup>11</sup> This includes theft of patented technology and trade secrets, counterfeiting of branded manufactured goods and piracy of industrial software that is important for manufacturers. Counterfeit products such as personal care products, medicines, and toys also threaten the health and safety of businesses and consumers in the United States that purchase and use these products.

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 its trade policy and national competitiveness. These strategies have long been built on two pillars: a strong domestic legal framework to protect and enforce manufacturers' IP at home, and consistent efforts to fight for strong IP protection and enforcement abroad.

To fully and consistently protect American intellectual property from global theft, the United States should:

- Fully enforce existing IP and innovation-related commitments under existing trade agreements, including agreements with **Australia, Canada, Mexico, China, Korea, Chile** and **Colombia**, making active use of bilateral consultations and, as appropriate, state-to-state dispute settlement to hold these parties accountable and ensure continued progress on IP protection.
- Include strong, enforceable, “best-in-class” IP protections in current and future trade negotiations and frameworks, including potential free trade agreement negotiations with

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<sup>10</sup> See, for example, German-Soto, Vicente, Mauro Soto Rubio and Luis Gutiérrez Flores, [“Innovación y crecimiento económico regional: evidencia para México \(Innovation and regional economic growth: evidence from Mexico\),”](#) *Problemas del Desarrollo (Problems of Development)* 52(205), August 2021; Cirera, Xavier, Andrew D. Mason, Francesca de Nicola, Smita Kuriakose, Davide S. Mare, Trang Thu Tran, [“The Innovation Imperative for Developing East Asia. World Bank East Asia and Pacific Regional Report,”](#) World Bank; Wilsdon, Tim, Artes Haderi, Zlatina Dobrova and Giuliano Ricciardi, [“The economic impact of changing the environment for innovation in Argentina,”](#) *Journal of World Intellectual Property* (2020), Issue 23; and Santacreu, Ana Maria and Makenzie Peake, [“Why Intellectual Property Rights Protection Matters for Economic Growth,”](#) Federal Reserve in St. Louis, Sept. 12, 2019.

<sup>11</sup> Commission on the Theft of American Intellectual Property, [“Update to the IP Commission Report,”](#) (Washington: National Bureau of Asian Research), February 2017.

markets such as the **United Kingdom** and **Kenya** and potentially elsewhere in Africa, expanded agreements with markets such as **Japan** and **China** and new, broader initiatives such as the Indo-Pacific Economic Framework. These provisions should ensure strong, specific, enforceable protections for all forms of IP that are critical to manufacturers, including (but not limited to) patents, trademarks, trade secrets, copyrights and industrial designs. These provisions, when actively and appropriately used, provide direct benefits to manufacturers and workers in the United States through fair market access and export opportunities, setting a high standard for others to emulate and clearly signaling to foreign partners that the United States continues to support innovation and IP as bedrocks of U.S. competitiveness.

- Prioritize IP protection in bilateral trade dialogues, formal and informal, including Trade and Investment Framework Agreement talks with countries (both those with individual countries such as **Indonesia** and **Argentina** and regional agreements with **Association of Southeast Asian Nations** countries) and other bilateral consultations with countries (such as **Brazil** and **India**).
- Leverage IP and trade-promoting international and regional organizations and platforms, including the WTO, G7, G20, Organization for Economic Cooperation and Development, **APEC** and the World Intellectual Property Organization, to promote the development of stronger rules and best practices for IP protection and enforcement, enforce existing IP rules and obligations and to push back actively against efforts by other countries to weaken IP protection through initiatives at these and other regional and multilateral organizations.
- Strengthen bilateral policy and technical engagement with foreign governments on IP-related enforcement actions to ensure transparency and due process in administrative proceedings, fair, efficient treatment in judicial cases and effective enforcement of arbitration awards.
- Work across relevant federal agencies to boost education, training and capacity-building programs with IP-relevant foreign government authorities, pooling resources and expertise strategically to expand existing programs and to develop new programs and 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, Customs and border authorities, law enforcement officials, judges and other judicial staff.

Manufacturers strongly support the strategic use of Special 301-related enforcement tools—including country classifications, out-of-cycle reviews and results-oriented action plans and—to foster improvements in global intellectual property protection. Across U.S. government agencies, manufacturers also specific steps to fully implement important legislation such as the Trade Facilitation and Trade Enforcement Act of 2015 and the Synthetics Trafficking and Overdose Prevention Act of 2018, as well as steps to tackle counterfeiting identified in the Department of Homeland Security’s January 2020 counterfeiting report.

Beyond these specific actions, however, manufacturers urge broader, deeper, quicker action to strengthen IP at home, defend against efforts to weaken global IP rules abroad and tackle cross-border issues like counterfeiting.<sup>12</sup> Manufacturers encourage the Office of the U.S. Trade Representative to play a leading role in interagency efforts to develop and implement robust strategies to advance IP globally, as well as to make concrete, measurable progress in priority markets to promote market access and U.S. manufacturing competitiveness abroad.

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<sup>12</sup> National Association of Manufacturers, [“Countering Counterfeits: The Real Threat of Fake Products.”](#) July 2020.

## I. 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,
- Growth and evolution of global counterfeiting,
- Growing foreign country pressure to undermine core IP protections for manufacturers,
- 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 the European approach to 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.

### A. IP Erosion in Multilateral Fora

Strong IP protection and enforcement are critical to achieving global objectives in areas like health, climate and the digital economy. These protections incentivize investment and technology development in those areas, drive the creation of emerging technologies to tackle these global challenges and enable the spread of these technologies across the globe. Around the world, such protections are rooted in a strong, global framework of IP protections and enforcement built over decades by the United States and like-minded countries that wanted to harness the power of IP to drive global trade, investment and development.

Yet in multilateral fora such as the World Health Organization and WTO, some countries and activist groups continue to push to dismantle these protections, claiming falsely that IP is inherently a barrier to public health, environmental protection, sustainable development or access to information and ignoring the critical role that IP plays in driving solutions to these very problems. These efforts are often driven by these countries' own commercial interests and by agendas that seek to undermine IP protections. Such attacks on IP in multilateral fora are exacerbated by parallel efforts in some multilateral organizations to limit engagement with private industry, ignore private sector input or delegitimize pro-IP voices.

Strong U.S. advocacy in these fora has been instrumental in defending critical IP and has only been possible through a strong and coordinated interagency approach to ensure common messaging and close work with likeminded countries and negotiators. Those efforts must continue to address issues such as:

- Ongoing discussions at the WTO and other organizations leveraging the COVID-19 pandemic to propose a broad waiver or elimination of critical IP protections. As noted, manufacturers believe strongly that governments, private sector entities, civil society and others must work together to end the COVID-19 pandemic to save lives and livelihoods. The urgency of the pandemic demands that stakeholders work together to advance

practical, effective initiatives that most effectively confront the pandemic's health and economic challenges, including efforts to accelerate the creation, manufacture and distribution of critical products needed in the global COVID-19 response. This must include efforts to leverage our trade and investment capabilities to fight the pandemic. Trade policy can, and must, address core bottlenecks to manufacturing and distribution of COVID-19 products, promote critical global innovation and support manufacturers and workers in the United States in efforts to produce and export vaccines and other U.S.-made COVID-19-related products.

USTR and its fellow agencies should work with like-minded countries ahead of the WTO's rescheduled 12th Ministerial Conference to drive global consensus for such initiatives, which include the Trade in Health Initiative; an expanded "zero-for-zero initiative"; and robust efforts to tackle key trade bottlenecks identified by the WTO<sup>13</sup>, promote stronger regulatory cooperation, and strengthen national health systems to handle distribution of vaccines received. These efforts can tackle issues such as removing export restrictions, streamlining customs procedures, reducing tariffs and increasing transparency to facilitate trade of COVID-19 products.

These constructive proposals stand in contrast to a controversial WTO proposal from **India** and **South Africa** to waive global protections for all IP related to a wide range of COVID-19 products. That proposed waiver would not solve the critical manufacturing and supply chain challenges or the most pressing vaccine distribution challenges impacting the developing world, and the focus on the waiver is distracting attention away from solving these critical challenges. The proposed waiver would, however, undermine the growing body of voluntary licensing agreements<sup>14</sup>, both in effect and under negotiation, that are [accelerating manufacturing production to meet the world's needs](#). The waiver would also undermine U.S. technology leadership and jobs against global competitors such as China, and it would dampen domestic investment in innovation in ways that could harm future pandemic responses and U.S. health security.

The proposal at the WTO prompted highly contentious debate among member states that is still ongoing after multiple meetings in WTO fora, but the debate has not been limited to the WTO. Shortly after the proposal was announced, WHO Director-General Tedros Adhanom Ghebreyesus asserted that the WHO "welcomes" the proposal "to ease international and intellectual property agreements" for COVID-19 products, without sufficient consultation with WHO member states or time for members to reach a conclusion through the WHO process. Manufacturers urge the U.S. government to drive constructive conversations at the WTO on the pandemic response that strengthen, not weaken, the very innovation and intellectual property needed to fight the pandemic. The United States should also guard against efforts by member states to leverage organizations like the WHO, and upcoming processes like the negotiation of a potential global instrument on pandemic response, as alternative fora to broadly weaken U.S. competitiveness and the WTO's mandate over these issues.

- Initiatives and resolutions at other international organizations, such as the World Health Organization, that undermine innovation and intellectual property. Manufacturers see

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<sup>13</sup> World Trade Organization, "[Indicative List of Trade-Related Bottlenecks and Trade-Facilitating Measures on Critical Products to Combat COVID-19](#)," updated Oct. 8, 2021.

<sup>14</sup> For examples of manufacturers' efforts to partner across industry, with governments and with other entities, see [here](#), [here](#) and [here](#).



these issues across multiple workstreams at the WHO, including those aimed at improving access to medicines. There is clear evidence that many barriers stand between patients around the world and the life-saving medicines they need. Effective solutions require a holistic, inclusive discussion of all such barriers. Despite this fact, the leaders of these initiatives—often at the WHO—continue to focus, improperly and narrowly, on IP and paint it as the main cause of problems with access to medicines. Ignoring and at times excluding the views of key member states and other stakeholders, the WHO continues to drive flawed policy recommendations, including the unfettered expansion of trade-related patent flexibilities (known as “TRIPS flexibilities”) and calls to delink R&D costs from the prices of health products. Such initiatives would have a perverse effect, hampering urgently needed health innovation without solving the access issues they claim to address. Moreover, WHO leadership has increasingly sought to step beyond its bounds to influence the actions of other international organizations on these issues.

The WHO’s narrow view of intellectual property also colors its broader work on health, as reflected broadly through multiple reports and initiatives in recent years. These include not only work related to medicines referenced above, but approaches related to other health issues that have implications for the normal and appropriate exercise of trademarks. Reports for the January 2022 WHO Executive Board meeting are illustrative, with reports on intellectual property and trade (such as the report on implementation of its [global strategy and plan of action on public health, innovation and intellectual property](#) and of the [political declaration on the prevention and control of non-communicable diseases](#)), both of which containing language exceeding carefully negotiated member state consensus on issues impacting health and intellectual property.

- Advocacy in international organizations for expanded exceptions, limitations, and flexibilities for patents and other forms of IP in areas outside of health. For example, the United States and allies have worked to fend off such approaches at meetings of the United Nations Framework Convention on Climate Change that would have undermined critical U.S. environmental technologies. Such discussions have not been limited to UNFCCC, however, but have also arisen at core IP-focused agencies such as the WIPO Standing Committee on Patents and the WTO TRIPS Council.
- Continued efforts to use international fora to legitimize the creation of alternate IP dialogues and frameworks. Examples include ongoing efforts to expand a trademark-alternative system to manage geographical indications under the Lisbon Convention at WIPO and to secure WIPO funding for that initiative, despite the fact that it is contrary to the interests of the United States and other WIPO member states.

Such discussions in international fora are often the direct result of lobbying by specific member states to undermine IP in the name of their own commercial interests. For example, **India**, **South Africa** and **Indonesia** are among those leading efforts on key patent issues raised above; **Australia**, **Chile** and **Thailand** are among the countries leading efforts on trademark and branding issues; while the **European Union** (and specific EU 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.

Importantly, 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 can have a direct, 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 U.N. 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, Mexico, Mongolia, South Africa, Thailand and Ukraine.**

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 organizations' 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 future OECD accession negotiations, including for countries such as **Argentina, Brazil and Peru** for which the OECD announced the start of talks in January 2022.<sup>15</sup>

Manufacturers encourage the U.S. government to take steps to support and engage leadership of international organizations to support constructive discussions and a pro-innovation agenda in line with their jurisdictions. Manufacturers also encourage the United States to leverage IP and trade-promoting international and regional organizations and platforms, including the WTO and WIPO, to promote pro-IP workstreams that strengthen—not weaken—innovation and intellectual property protection and combat misguided narratives that ignore the constructive role that IP plays in promoting global goals such as health, environmental protection and development.

### *B. Growth and Evolution of Global Counterfeiting*

During the COVID-19 crisis, manufacturers have stepped up to deliver day-to-day necessities, lifesaving medical innovations and products to help Americans fight the pandemic. Yet manufacturers have also highlighted the significant threat of counterfeit products that put lives and livelihoods at risk. Counterfeiting is not a new problem, but it is a growing threat. The NAM has significantly increased efforts to fight fake and counterfeit goods, issuing in July 2020 a critical white paper that details the direct harm to businesses, workers and consumers. Our paper details a clear set of innovative policy solutions to address these issues once and for all to the benefit of manufacturers and their families in America.<sup>16</sup>

A June 2021 report by the OECD and the EU Intellectual Property Office, for example, shows the growth of global trade in counterfeit and pirated goods has exploded in recent years, reaching \$464 billion in 2019 (or 2.5% of all global trade).<sup>17</sup> Yet even this number likely fails to capture the full scope of the problem, as many counterfeit products evade detection and thus

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<sup>15</sup> Ayres, Marcela and Lisandra Paraguassu, [“OECD Begins Membership Talks with Brazil, Argentina, Peru and More.”](#) *Reuters*, Jan. 25, 2022.

<sup>16</sup> NAM, [“Countering Counterfeits.”](#)

<sup>17</sup> OECD and EUIPO, [“Global Trade in Fakes: A Worrying Threat.”](#) June 2021.

would not be captured in these calculations. A 2017 estimate by the Commission on the Theft of Intellectual Property estimated that authorities in the United States catch less than 2.3% of the total volume of counterfeit goods.<sup>18</sup> The NAM's July 2020 white paper showed the staggering losses for the U.S. economy stemming from fake and counterfeit products. Counterfeiting is estimated to have cost the U.S. economy nearly \$131 billion in 2019, reflecting direct, indirect and induced economic impacts. That means \$22.3 billion of lost labor income, 325,542 fewer jobs, \$5.6 billion of lost federal tax revenues and nearly \$4 billion less in state and local tax collections.<sup>19</sup>

Counterfeiters have gained strength due to a variety of factors, of which the most important has been the growth of online channels (including e-commerce marketplaces and social media platforms) that have transformed how companies connect with customers. E-commerce sales now make up more than 13% of all U.S. retail spending, up from 4.8% of total sales in 2011.<sup>20</sup> Those figures show that e-commerce sales in the United States reached \$759.5 billion in 2020, more than double the volume from just five years before.

While these platforms have created opportunities for manufacturers to sell their products and provided new conveniences for consumers, they have also created a pipeline directly to customers that bad actors can exploit. The online environment in which these sales take place is easier for counterfeiters to exploit by:

- Hiding their identity or other business details in ways that make it more difficult to enforce penalties when counterfeit products are discovered;
- Misrepresenting products online by, for example, posting authentic pictures while shipping fake products directly to consumers or posting fake reviews to promote the impression that their products are legitimate;
- Deflecting suspicion by maintaining a small stock of legitimate products to fulfill orders placed by law enforcement officials or brand representatives; and
- Fulfilling product orders through postal channels to avoid customs entry and import processes that would otherwise subject packages to government monitoring and inspection.

Online platforms present unique challenges for manufacturers – particularly small- and medium-sized manufacturers – that must devote ever-increasing resources and time to monitoring search engine results, e-commerce channels, social media postings, payment providers and others that may all play a role in driving online traffic to counterfeit products. The COVID-19 pandemic has added an extra challenge, providing an opportunity for counterfeiters to expand their reach by taking advantage of consumers' increased anxiety and fear, the high demand for certain goods and the substantial increase in e-commerce necessitated by social distancing measures.

The significant volume of counterfeit goods sold on e-commerce platforms necessitates stronger mechanisms to address instances of this unlawful activity and more work to hold these platforms liable for their role in the rise of counterfeits. This must include efforts to ensure that e-commerce providers prevent counterfeiters from abusing their platforms by exercising stronger

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<sup>18</sup> Commission on the Theft of American Intellectual Property, ["Update to the IP Commission Report."](#)

<sup>19</sup> NAM, ["Countering Counterfeits."](#)

<sup>20</sup> This figure matches the most recently statistics as of the third quarter of 2021: see U.S. Census Bureau, ["Quarterly Retail E-Commerce Sales: 3<sup>rd</sup> Quarter 2021,"](#) Nov. 18, 2021. For 2011 statistics, see U.S. Census Bureau, ["Quarterly Retail E-Commerce Sales: Time Series, Adjusted Sales,"](#) last accessed Jan. 16, 2022.

oversight. Manufacturers also urge stronger transparency requirements for providers to require users to provide verifiable contact and other information to platforms and consumers. This approach would help to limit the ability of counterfeiters to remain anonymous and circumvent applicable intellectual property laws.

Counterfeiters are also taking advantage of third-party operated fulfillment centers based in the United States, including those run by the very same e-commerce platforms, as a means to shorten shipping times and obscure the origins of these products. Such facilities receive inventories of products either directly from counterfeiters or through in-country intermediaries, then fulfill final orders from consumers. This approach obscures the counterfeiter's identity and creates an additional obstacle to manufacturers seeking legal redress, as these third-party fulfillment centers may disclaim responsibility for the products that they ship.

Additionally, counterfeiters continue to exploit additional loopholes that allow them to sell and send their products to customers. For example, counterfeiters continue to ship counterfeit goods through the international postal system to take advantage of the U.S. Postal Service's weak-to-nonexistent detection and compliance infrastructure. In recent years, the volume of packages carrying counterfeit goods into the United States through this route has accelerated due to several factors. First, shipping subsidies provided by the USPS to foreign shippers under the Universal Postal Union's international terminal dues system pad profit margins for counterfeiters.<sup>21</sup> Second, USPS has been slow to collect reliable advanced electronic data to aid CBP in package screening, despite a clear mandate in U.S. law such as the Synthetics Trafficking and Overdose Prevention Act of 2018 (Public Law No. 115-271). Third, if these counterfeit shipments avoid detection and are admitted, they then enter the USPS postal mail stream where they generally may not be inspected without probable cause.<sup>22</sup> The U.S. government responded to these concerns by pushing for structural reforms to the UPU's terminal dues system, resulting in negotiated changes announced in September 2019 to allow countries like the United States to impose "self-declared rates" for distributing foreign mail.<sup>23</sup> These were welcome changes but need to be consistently enforced, with strict monitoring of the global implementation of the new UPU agreement. Moreover, the U.S. government can address ongoing concerns about the lack of data through accelerated steps to ensure full implementation and enforcement of the STOP Act.

Finally, manufacturers also face a steadily growing flow of counterfeit products being sold or transshipped through free trade zones. Though the more than 4,000 estimated FTZs worldwide contribute positively to global free trade,<sup>24</sup> criminals often take advantage of the fact that these zones are outside of their host countries' customs' territory and are thus subject to significantly less rigorous regulations or inspections, which further facilitates counterfeiting and other illicit activity. A 2018 study by the OECD and the EU IP Observatory estimated that each FTZ is

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<sup>21</sup> See Memorandum from President Donald Trump to Sec. of State, Sec. of Treasury, Sec. of Homeland Security, *et al.*, "[Modernizing the Monetary Reimbursement Model for the Delivery of Goods Through the International Postal System and Enhancing the Security and Safety of International Mail.](#)" 83 FR 47791, 47792 (August 23, 2018).

<sup>22</sup> U.S. Postal Service, "[Basic Eligibility Standards for Priority Mail.](#)" November 1, 2010.

<sup>23</sup> Harris, Laurie Beth, "[Universal Postal Union Changes Deliver Win for Manufacturers.](#)" NAM, Sept. 25, 2019.

<sup>24</sup> Though statistical updates on the number of FTZs are not regular, the Economist estimated the number as above 4,000 as of 2015, with earlier estimates from the International Labor Organization of roughly 3,500 in 2006. For more, see Prichard, Taylor, "[Top Free Zones 2017.](#)" Site Selection, November 2017; "[Political priority, economic gamble.](#)" *The Economist*, 4 April 2015; Singa Boyenge, Jean-Pierre, "[ILO database on export processing zones \(revised\).](#)" ILO Sectoral Activities Programme Working Paper, April 2007.

associated with a nearly 6% increase in the value of counterfeit exports from that FTZ's economy.<sup>25</sup>

Counterfeits can often be a significant challenge for manufacturers beyond their country of origin. For example, manufacturers have increasingly seen counterfeit products from key hubs (such as China) unfairly targeting third-country markets (such as markets throughout Southeast Asia and Africa) with counterfeit, poorly regulated and potentially unhealthy counterfeit products. The United States must work with trading partners to address more directly third-country counterfeiting issues through enforcement, capacity building and joint advocacy. 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 83% of all counterfeit goods by value seized at U.S. borders in the latest available CBP statistics (2020).<sup>26</sup> **India, Korea, Turkey, Vietnam** are consistent sources for counterfeit products coming into the United States, with **Canada, Singapore, the Netherlands, Pakistan** and **Taiwan** also appearing regularly and recently as problematic shipment points.<sup>27</sup>

To address global counterfeiting concerns, the U.S. government should work more closely with their foreign counterparts and private sector actors to take a series of key actions, including working with foreign policymakers to strengthen penalties for counterfeiters, closer engagement with foreign law enforcement officials to tackle counterfeit shipments and improved capacity building with international counterparts to boost authority, expertise and resources to address these issues. For a more detailed list of recommendations to address both the domestic and international dimensions of counterfeiting, see the NAM's July 2020 report, "[Countering Counterfeits: The Real Threat of Fake Products.](#)"

### *C. 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 IP, purportedly to address other public policy prerogatives. Ignoring the fact that global rules and standards for innovation and IP have fostered decades of U.S. manufacturing innovation, support millions of well-paying jobs, save millions of lives and expand 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.

Regulators and national authorities in multiple foreign countries increasingly seek to narrow the ability of manufacturers to obtain, use and protect patents, trademarks and other forms of IP, claiming that such restrictions are being adopted to address policy areas such as public health or environmental protection, despite the clear evidence that existing IP rules are not an impediment to such protection. They also erect numerous market access barriers for innovative

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<sup>25</sup> 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.](#)" May 2018.

<sup>26</sup> Office of Trade, U.S. Customs and Border Protection, "[Intellectual Property Rights Seizure Statistics: Fiscal Year 2020.](#)" September 2021.

<sup>27</sup> India, Korea, Turkey and Vietnam have ranked among the top 10 sources for seized counterfeit goods by value of counterfeit seizures value for each of the last four years. Canada, Singapore, Pakistan and Taiwan have also appeared at least three times, including at least once in the last two years. The Netherlands has now also ranked in the top ten countries for each of the last two years. For more, see CBP Office of Trade's annual IPR seizure statistics for FY2016 through FY2020, available at CBP, "[IPR Annual Seizure Statistics.](#)" last accessed Jan. 16, 2022.

products that negate the effectiveness of the products' IP protection. This push has impacted multiple forms of IP, 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*

Broad use of compulsory licensing—government actions to compel licensing of a patent under protection in the name of domestic interests—has seen an uptick in recent years, with a 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 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, must operate under specific guidelines, including strict limitation to exceptional circumstances so as not to undermine the substantial benefits that IP protection provides. Compulsory licenses should only be granted and 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. Such international consensus around compulsory licenses, and the clear processes, are critical to protecting both public health and intellectual property.

Manufacturers have long been concerned with the expanded use of compulsory licensing actions that do not meet the carefully crafted criteria in the Doha Declaration, but this issue has become increasingly problematic as stakeholders that have long pressured for greater licensing to undermine global intellectual property rules have grown louder. The ongoing COVID-19 pandemic underscores just how important IP protections are to create the public health products that the world needs, and that it is more important than ever to adhere to these carefully negotiated processes to avoid undermining those protections.

With past compulsory licensing decisions in markets such as **Colombia, Ecuador, India, Indonesia and Malaysia** still in place, moves in recent years by countries such as **Hungary, Israel and Russia** to grant compulsory licenses and decisions by countries such as **Saudi Arabia** and the **United Arab Emirates** to grant marketing authorizations to local manufacturers for patent-protected products raise significant questions for innovative manufacturers. In addition to the recent moves above, manufacturers are closely monitoring an array of legislative changes passed during the pandemic designed to make compulsory licensing actions easier. **Australia, Brazil, Canada, Colombia, Germany, Hungary, Indonesia and Russia** passed legislation or issued formal decrees expanding the ability to issue compulsory licenses, while **Chile, the Dominican Republic, Ecuador, El Salvador** and the **Netherlands** are considering similar legislative changes. Countries such as **Canada, Colombia** and the **Dominican Republic** are all weighing potential compulsory licensing petitions.

More broadly, key stakeholders who have long advocated weakened IP protections and expanded compulsory licensing have used the COVID-19 pandemic as a reason to advance their agenda, including stakeholders pushing at the national level in markets such as **Brazil and Chile** and member states (led by **India and South Africa** but with support from countries such as **Argentina, Egypt, Indonesia, Kenya, Pakistan** and others) working at the multilateral level to suspend IP related to COVID-19 products.

In addition to IP-related policies such as compulsory licensing and patent flexibilities, many countries are increasingly using policies and regulations in areas such as procurement, standards, competition, pricing and reimbursement that negatively impact innovative manufacturers or raise questions about whether they are sufficiently fair, reasonable, non-discriminatory or based on market-based approaches that appropriately recognize the value of innovation. Manufacturers note particularly troublesome activity taking place in countries such as **Australia, Canada, China, Korea, Japan, Mexico** and **Turkey**.

To address these and other challenges to global IP rules that undermine manufacturing jobs and innovation (such as the rising challenge posed by China's inadequate protection of intellectual property), manufacturers urge USTR to continue its longstanding efforts to end the moratorium on TRIPS-related "non-violation nullification and impairment" disputes. This moratorium originally was planned as a short-term measure, but it continues to be extended in the WTO by unanimous consent—and will come up again at the next WTO Ministerial Conference. The continued moratorium limits the ability of member states 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 opposed to 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). In the wake of those rules, other countries have adopted or are considering similar rules in this area. **Belgium, Canada, France, Hungary, Ireland, Israel, the Netherlands, New Zealand, Norway, Saudi Arabia, Singapore, Slovenia, Thailand, Turkey, the United Kingdom** and **Uruguay** have already begun full or partial implementation of plain packaging rules for these products. **Armenia, Denmark** and **Georgia** have adopted but not yet fully

implemented similar measures, and other countries, including **Chile, Costa Rica, Finland, Mauritius, South Africa** and **Sri Lanka** are drafting or actively considering similar rules.

- Manufacturers in a range of other sectors are concerned about growing calls to apply plain packaging and other IP-restrictive approaches to other sectors, which in some cases have prompted specific regulatory proposals. **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. It is also discussing a plain packaging-style policy to apply to pharmaceuticals, including a prohibition on brand-name prescription. Other countries have followed Chile’s lead, most notably **Mexico**, which has issued a series of actions over the last year to curtail trademark use and intellectual property related to food and beverage products. Similar actions appear well underway in markets such as **Brazil, Colombia, Ecuador, Israel, Peru, Saudi Arabia** and **Uruguay** (and regional groupings such as the **Gulf Cooperation Council**). Manufacturers see the same signals in proposals underway or being considered in additional markets such as **Argentina, Canada, Poland, Romania, South Africa**, the **United Kingdom** and **Vietnam**. Similarly, countries and regions such as **Thailand, Mongolia** and **Bangladesh** 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.

#### *D. Inadequate Infrastructure and Political Will to Grant and Enforce IP*

Manufacturers seeking to obtain and enforce their IP 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 the review and granting 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 to 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 pendency remains high for patents in **Brazil**, and well-above average in markets such



as **Argentina, Ecuador, India and Thailand**.<sup>28</sup> Similarly, pendency remains high for trademarks in countries such as **Brazil, Canada, Ukraine and Vietnam**.<sup>29</sup> In some cases, these delays can be partially explained by bureaucratic delays in countries' approval processes. In **Brazil**, for instance, patents in areas such as health are required to be reviewed by the Agência Nacional de Vigilância Sanitária (Brazil's health authority) in addition to the Instituto Nacional da Propriedade Industrial (Brazil's IP office), causing delays. In other instances, delays are due to the lack of adequate capacity or sufficient training for patent and trademark examiners. Importantly, a number of important markets have made important strides in recent years to cut into their backlogs since 2019, including countries like **Brazil** (which cut patent pendency from 7.2 years to 5.2 years and trademark pendency from 2.5 years to 2.0 years) and **India** (which cut patent pendency from 4.3 years to 3.5 years and trademark pendency from 210 days to just 40 days).<sup>30</sup> Yet in other markets, such as **Saudi Arabia and Thailand** for patents and **Canada** for trademarks, pendency has clearly gotten worse.

Fully resolving these processes must involve streamlining patent and trademark procedures (including both application and review processes), building capacity among examiners. For patents, manufacturers also encourage USTR to urge countries with long patent backlogs to implement patent-term restoration adjustment procedures, which allow a patent applicant to apply for an extended patent term to account for time lost through long patent application backlogs. USTR should also address legislative efforts that could undermine existing patent-term restoration procedures (as with the **EU's** revisions to its supplementary protection certificate regime, and a similar regime proposed in **Israel**). The U.S. government (particularly the U.S. Patent and Trademark Office) should also consider signing work-sharing arrangements, or patent prosecution highway agreements, with such countries that would allow more work-sharing for patent reviews to supplement limited examiner capacity and reduce patent and trademark pendency, as they have done in the past two years with **Brazil's** National Institute of Industrial Property and **Saudi Arabia's** Saudi Authority for Intellectual Property.

Many manufacturers are also concerned about weak patent enforcement, including a lack of timely channels for early resolution of patent disputes, poor access to legal tools such as injunctions, lack of access to evidence, and the absence of effective patent linkage systems that prevent the approval of products that are under patent. Some markets (such as **China and Taiwan**) have announced important steps in recent years to implement patent linkage systems, while other countries (such as **Chile**) have signaled intentions to introduce legislation or regulations to improve patent enforcement. Manufacturers need to see these efforts fully realized to ensure effective enforcement of patents. Additionally, longstanding challenges remain in a variety of markets, including **Algeria, Argentina, Australia, Canada, Colombia, Egypt, India, Japan, Korea, Malaysia, Mexico, the Philippines, Russia, Turkey and Vietnam**.

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<sup>28</sup> For more on these and other countries, see figure A.45 ("Average pendency times for first office action and final decision at selected offices") from WIPO's [2020](#) and [2021](#) editions of the World Intellectual Property Indicators, as well as the WIPO IP Statistics Data Center, "[Patents: 12 – Average pendency from request for examination to the first office action \(days\)](#)," last accessed Jan. 22, 2022.

<sup>29</sup> WIPO IP Statistics Data Center, "[Trademarks: 10 – Average pendency time \(days\)](#)," last accessed Jan. 16, 2022.

<sup>30</sup> See figure A.45 ("Average pendency times for first office action and final decision at selected offices") and B.43/B.44 ("Duration of trademark examination for selected offices") from WIPO's [2019](#) and [2021](#) editions of the World Intellectual Property Indicators.

#### *E. Increasing Technical Barriers to Obtaining Patents*

Manufacturers also face policy challenges to their ability to obtain patents in the first place. In some cases, these challenges result because countries (such as **Argentina**) have not joined important international IP systems, such as the Patent Cooperation Treaty. In other cases, these stem from policy barriers that limit the ability of innovative manufacturers to seek patents. 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 over which inventors must jump in order to obtain or defend patents. 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, Indonesia and Ukraine**).

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—whether due to an inadequate period of time for such protection or to other regulatory measures that permit government officials to share undisclosed test data—remains a concern in **Algeria, Argentina, Brazil, Chile, China, India, Israel, Japan, Malaysia, Mexico, Peru, Russia, Saudi Arabia, Thailand, Turkey and Vietnam**.

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.

#### *F. 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% 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.<sup>31</sup>

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<sup>31</sup> 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.

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 represents 1-3% of U.S. GDP, translating to a loss between \$180 billion and \$500 billion.<sup>32</sup> 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.<sup>33</sup> 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. The U.S. government must strengthen bilateral engagement on trade secrets enforcement to ensure fair, efficient treatment in judicial cases and effective enforcement of arbitration awards.

Weak protections for trade secrets and other business confidential information have long been a particular challenge in countries such as **China, India and Russia**. A wave of global trade secrets legislation in recent years in the United States, **EU, Taiwan, Japan and China** have each marked an important step forward to strengthen the tools for companies and regulators to boost trade secrets protection. Broader adoption of these types of protections through domestic legal changes and through trade agreement negotiations would greatly benefit manufacturers in the United States.

#### *G. 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 GIs, the 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 **EU** continues to advocate stronger protection for its food and agricultural products by creating a new global system of protection for GIs, a push that undermines 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 at least provisionally in force with **Canada, Colombia, Ecuador, Japan, Korea, Peru, Singapore and Vietnam**, pending agreements with markets such as **Mexico** and the **MERCOSUR** markets of **Argentina, Brazil, Paraguay and Uruguay**, and agreements being negotiated or revised with markets such as **Australia, Indonesia, New Zealand and East African Community** countries such as

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<sup>32</sup> PricewaterhouseCoopers and CREATE.org, "[Economic Impact of Trade Secret Theft: A Framework for Companies to Safeguard Trade Secrets and Mitigate Potential Threats](#)," February 2014.

<sup>33</sup> Brant, Jennifer and Sebastian Lohse, [Trade Secrets: Tools for Innovation and Collaboration](#) (2014), published by International Chamber of Commerce, Paris.

**Kenya.** The EU has also negotiated GI-specific agreements with markets such as **China**. EU member states also continue to push these issues on the multilateral stage, with several member states actively pushing for WIPO funding to support the GI-centric Lisbon Agreement. The EU-led expansion of these provisions has a negative impact on American jobs and workers supported by exports to critical global markets.

## II. 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 and workers, 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 some implementation of IP-related commitments by **China** as part of the Phase One U.S.-China trade deal, sustained efforts in **Brazil** and **India** to reduce patent and trademark backlogs, **Indonesia**'s revisions to its Patent Law to remove problematic localization requirements and revisions in **Canada** of multiple core IP laws in line with commitments under the United States-Mexico-Canada Agreement. More progress, however, is needed to build on these moves and to reverse negative trends in these and other markets. 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.

### A. Priority Watch List

#### *Argentina*

Although the United States and Argentina have had increased interaction in the last few years on areas of trade and investment<sup>34</sup>, Argentina remains challenging on a wide range of IP issues. Argentina's IP legal framework lacks protections in key areas that are required under the country's WTO TRIPS obligations, while also maintaining a number of specifically problematic elements, particularly for patents. Given the continued nature of these challenges and the lack of concrete progress on these issues over the last year, we recommend that the United States highlight intellectual property challenges in U.S.-Argentina Trade and Investment Framework Agreement discussions and that Argentina remain on the Priority Watch List in 2022.

The country continues to lack meaningful protection for **regulatory test data**, as is required by Argentina's international commitments under Article 39.3 of the WTO TRIPS agreement. Argentina instead has longstanding legal provisions (Law No. 24,766<sup>35</sup> as well as Decree

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<sup>34</sup> These include October 2018 meetings of the U.S.-Argentina Council on Trade and Investment under the existing Trade and Investment Framework Agreement, as well as the November 2020 Innovation and Creativity Forum for Economic Development, both cited in USTR's [2021 Trade Policy Agenda and 2020 Annual Report](#).

<sup>35</sup> See Law No. 24,766, "[Ley de Confidencialidad Sobre Informacion y Productos Que Esten Legitimamente Bajo Control de Una Persona y Se Divulgue Indebidamente de Manera Contraria a Los Usos Comerciales Honestos](#)," promulgated Dec. 20, 1996.

150/92<sup>36</sup>) allowing competitors to submit data provided by innovative manufacturers to authorities in other markets as a basis for authorizations to market similar products in Argentina.

At the same time, Argentina's Instituto Nacional de la Propiedad Industrial, Ministry of Health, and Ministry of Industry have instituted a series of standing guidelines, including the 2012 Guidelines for Examination, that **restrict patentability** in ways that are not in line with its TRIPS obligations or the 1994 U.S.-Argentina Bilateral Investment Treaty. Argentina in more recent years has continued to narrow the scope of patentability, including a 2015 resolution focused on biotechnology products. Together, these provisions limit the scope of inventions that are eligible for patents. 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.

**Patent backlogs** remain a significant issue, with some industry estimates of a backlog of approximately 21,000 applications<sup>37</sup>—more than six times above the 3,492 new applications received in 2020.<sup>38</sup> WIPO statistics for 2020 showed that Argentina had the world's longest delay between a patent filing and a first office action (4.9 years)<sup>39</sup>, with the time to a final decision stretching even longer. Although the INPI implemented a Patent Prosecution Highway mechanism in 2016, it was narrowly restricted to specific categories of patented products. INPI must do significantly more to begin tackling the existing backlog. Delays in reviewing manufacturer-critical patents not only represent extra time and costs 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.

Argentina maintains **problematic government policies** that fail to value innovation and that harm market access for innovative products. In August 2021, Argentina's Executive Branch proposed an amendment to increase preference programs for local manufacturers in procurement and reimbursement and to expand its programs to cover a broader mix of government actions. Such policies provide undue preferences for domestic products through government programs and policies such as reimbursement. Such policies also appear inconsistent with Argentina's international obligations and international best practices, while also undermining investment in innovation and R&D in the country.

Like other countries in Latin America, Argentina has moved to implement regulatory policies impacting manufacturers' **use of trademarks**, specifically updating food and beverage regulations to include front-of-pack warning labels and advertising. In November 2021, following passage of the Health Food Promotion Law in the Chamber of Deputies, Argentina issued Decree 782/2021<sup>40</sup> that included STOP-sign-type labels as well as prohibitions on advertising, promotion and sponsorship of a wide range of food and beverage products. Such moves raise continued IP concerns by restricting the use of trademarked brand names, logos, symbols and

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<sup>36</sup> See Decree 150/92, "[Normas para el registro, elaboración, fraccionamiento, prescripción, expendio, comercialización, exportación e importación de medicamentos. Ambito de aplicación. Disposiciones generales.](#)" promulgated Jan. 20, 1992.

<sup>37</sup> Pharmaceutical Research and Manufacturers of America, "[2021 National Trade Estimate Report on Foreign Trade Barriers: Submitted by PhRMA.](#)" Oct. 30, 2020.

<sup>38</sup> WIPO IP Statistics Data Center, "[Patents: 12 – Average pendency from request for examination to the first office action \(days\).](#)"

<sup>39</sup> *Id.*

<sup>40</sup> See Decree 782/2021, "[Promoción de la Alimentación Saludable.](#)" promulgated Nov. 12, 2021.

packaging that consumers depend on to identify safe, effective products. Manufacturers strongly encourage USTR to continue actively raising concerns with these developments through bilateral consultations with Argentina.

Manufacturers continue to report challenges with **IP enforcement** in Argentina. Although Argentina's record on enforcement is better than other markets in the region, counterfeit goods are widely available through both physical markets and increasing online sales 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, and manufacturers report significant challenges accessing tools such as preliminary injunctions that are available under law to protect IP. Manufacturers also report specific challenges related to registration and enforcement of trademarks. The costs and requirements of registering trademarks with the Argentine Customs Authority are higher and more burdensome than the rest of the region and are limited only to word-based trademarks (not logos or designs). Similarly, manufacturers report government structures such as the Argentine Tax Authority's Customs Alert System that allow right holders to record trademark registration with effective for surveillance of infringing products.

Argentina also has yet to ratify a set of key **international treaties** on intellectual property protection that could benefit both U.S. and Argentine manufacturers. Most notably is the Patent Cooperation Treaty (Argentina is the second-largest economy that is not a member), and Argentina has also not acceded to the Madrid Protocol to cover trademarks. Finally, given the OECD's January 2022 announcement that it had started membership discussions with Argentina manufacturers urge the U.S. government to make a strong push for improvements in Argentina's IP environment as a part of that process.

Finally, **Argentina** (as part of **MERCOSUR**) remains also engaged in negotiations with the **EU** for a potential free trade agreement. Manufacturers are watching these negotiations closely, including any discussions that would provide stronger protection for **EU GIs** in the Argentine market outside of trademark-provided protections for food and agricultural products. As in other markets, such measures would undermine the ability of the United States and other countries to protect existing trademarks for these products in Argentina, developments that would have a negative impact on American jobs and workers supported by exports to that country.

### *Canada*

In recent years, Canada has worked with the United States under the new USMCA and other channels to improve core areas of IP law and practice. Yet despite that progress, innovative manufacturers have also seen contrasting trends in Canada, and still have considerable concerns about a number of IP-related issues that impact their businesses. Manufacturers urge USTR and its interagency counterparts to prioritize intellectual property and market access concerns for innovative manufacturers through all appropriate forums, including USMCA discussions and other bilateral dialogues. Broadly and based on the concerns below, the NAM continues to recommend that Canada be included in the Priority Watch List in 2022.

Importantly, Canada has taken positive legislative steps to improve its IP legal framework and better promote innovation. These include strong Canadian commitments under the USMCA that benefit manufacturers across the range of IP that matters for our industry, including patents, trademarks, trade secrets, industrial designs, copyrights and geographical indications. Canada has also worked in recent years to update and improve its core IP laws, including revisions to its

Industrial Design Act (in effect as of Nov. 5, 2018), Trademark Law (in effect as of Jun. 17, 2019), and the Patent Act (in effect as of Oct. 30, 2019) along with similarly revised Patent Rules and new guidelines on patentable subject-matter under the Patent Act. Additionally, the Canadian government in June 2019 implemented a range of updates to its core IP laws and strategies included in the 2018 Budget Implementation Act.<sup>41</sup> Globally, Canada is often a key partner with the United States in raising concerns about global attempts to undermine intellectual property rules, including as an allied voice raising concerns about the October 2019 proposal to suspend countries' obligations to protect intellectual property related to COVID-19.

Even so, manufacturers still have concerns regarding Canadian policies. 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)) continue to raise significant questions about Patent Register listings, patent dispute proceedings and damages that disproportionately 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. Decisions since that point have continued to reflect a more circumspect approach, rejecting several attempts to revive the promise doctrine under other guises, but manufacturers continue to watch the judicial docket closely for efforts to undermine the Supreme Court's decision.
- In other areas, innovative manufacturers remain highly concerned about potential changes. For example, Canada's Patented Medicines Pricing Review Board (PMPRB) in August 2019 published final regulations that impose new reporting requirements on patent holders, introduce new troublesome regulatory factors, adjust PMPRB's basket of reference countries to exclude comparable markets like the United States and limit available input to narrowly selected market data. Although a December 2020 decision by the Federal Court of Canada ruled that provisions requiring manufacturers to report all indirect price reductions are invalid, other provisions were allowed to move forward. Those provisions were scheduled to come into effect in July 2021 but have now been delayed twice to a proposed implementation date of July 1, 2022.<sup>42</sup> Those provisions have been appealed by industry. More broadly, however, innovative manufacturers remain concerned about PMPRB's policy direction, which 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. Manufacturers urge the Canadian government to use this additional window of time to engage with stakeholders to address outstanding concerns.

Canada's actions related to **patent term restoration** have also raised concerns. Despite commitments that Canada made under both the USMCA (Article 20.44) and the Canada-EU Comprehensive Economic and Trade Agreement (Article 20.27) to compensate manufacturers for regulatory delays associated with patent and market approval, Canada's Ministry of Health is interpreting these commitments narrowly under its 2017 Certificate of Supplemental Protection Regulations, with eligibility and process barriers that limit access to this relief for innovators. Manufacturers believe that Canada should work to ensure that its patent term restoration

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<sup>41</sup> See [Budget Implementation Act, No. 2 \(S.C. 2018, c. 27\)](#).

<sup>42</sup> For the most recent postponement, see the [Dec. 23, 2021 statement](#) by Canadian Minister of Health Jean-Yves Duclos.

system works as intended to address the negative impact of lengthy IP approval and regulatory processes.

Manufacturers have also raised issues related to **government protection of sensitive business information**. Manufacturers remain watchful of regulations that require them to provide significant amounts of sensitive information.

- The 2014 Protecting Canadians from Unsafe Drugs Act (bill C-17) provided the Minister of Health wide discretion to share test data without safeguards to protect against unfair commercial use, and a more recent court decision ordering the release of clinical trial data exacerbates manufacturer concerns.<sup>43</sup> Canada's obligation to protect data pursuant to these agreements' provisions is not in any way lessened simply because an approved medicine or vaccine is not marketed in Canada.
- Additionally, Canada's revised Workplace Hazardous Materials Information System forces companies into 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. or European regulations.

Manufacturers are also concerned about regulatory **measures that curtail the legitimate use of trademarks**, such as plain packaging for a range of products, that have advanced in Canada.<sup>44</sup> As discussed above, manufacturers have taken a strong stance against the elimination of trademarks through plain packaging programs, as envisioned by this draft regulation, and would be similarly concerned if this legislation moved forward. Manufacturers have also carefully monitored the trademark implications of Canada's amended Food and Drug Regulations, which were originally scheduled to fully come into effect in December 2021. Manufacturers appreciate that the Canadian Food Inspection Agency worked with industry during the COVID-19 pandemic to delay their full implementation until Dec. 14, 2022,<sup>45</sup> but will continue to watch this closely as well as the results of a joint public consultation from CFIA and Health Canada on future changes to food labelling requirements that ran in the spring of 2021.<sup>46</sup>

Canada has made important legal progress to better strengthen customs authority to address **counterfeiting**, both with provisions in the December 2014 enactment of Bill C-8 (Combating Counterfeit Products Act) and commitments in the USMCA (Article 20.83). Manufacturers report, however, that despite these stated authorities, Canada Border Services Agency (CBSA) activity against counterfeit remains scant (previously reported at less than 20 seizures per year).<sup>47</sup> That number seems inappropriate, particularly given U.S. Customs and Border Protection reports about the number of seizures from Canada (nearly 600 shipments in 2019).<sup>48</sup>

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<sup>43</sup> The Federal Court of Canada in a Jul. 9, 2018 ruling ordered Health Canada to release significant amounts of data from pharmaceutical clinical trials to a researcher; Health Canada did not appeal the ruling. See [Doshi v. Canada \(Attorney General\)](#), 2018 FC 710.

<sup>44</sup> See [Tobacco Products Regulations \(Plain and Standardized Appearance\)](#) and [Regulations Amending the Food and Drug Regulations - Healthy Eating Provisions including Front-of-Pack Labelling, Other Labelling Provisions, Industrially Produced Trans Fats and Vitamin D](#).

<sup>45</sup> Health Canada, "COVID-19 Food Labelling Support Measures," last accessed Jan. 17, 2022.

<sup>46</sup> Health Canada and Canadian Food Inspection Agency, "Consultation on Proposed Joint Policy Statement on Food Labelling Coordination," last accessed Jan. 17, 2022.

<sup>47</sup> Tellingly, CBSA does not even report counterfeits as a category of products it seizes in its [annual statistics](#). See Beeby, Dean, "[Canada seizing few shipments of fake goods despite law targeting counterfeits](#)," Canadian Broadcasting Company, Mar. 22, 2018.

<sup>48</sup> CBP Office of Trade, "[Intellectual Property Rights Seizure Statistics: Fiscal Year 2020](#)."



This discrepancy matters, as Canada has regularly appeared among the top ten sources of counterfeit goods coming into the United States, a listing that can include those originating in Canada and those transshipped through the country. Manufacturers report that they have sought to engage CBSA with training, with limited interest in engaging with industry to boost enforcement. During COVID-19, CBSA has been somewhat more active tackling some types of fake and counterfeit products,<sup>49</sup> but manufacturers urge USTR and its fellow U.S. government agencies to encourage CBSA to increase its efforts and work more closely with industry to tackle counterfeit products originating in and transiting through Canada.

Finally, manufacturers remain concerned about the implementation of IP-relevant chapters of Canada's trade agreement with the EU<sup>50</sup>, particularly measures that provide stronger protection for European **GIs** outside of trademark-provided protections for food and agricultural products. The USMCA contains stronger language to ensure transparent registration and opposition procedures for potential GIs, but those already covered as *sui generis* GIs under the 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. It is important to ensure strong implementation of these USMCA commitments in order to avoid the negative impact on American jobs and workers supported by exports to Canada.

### *Chile*

Despite key IP commitments under the U.S.-Chile FTA, Chile has in recent years sent mixed signals on IP matters, passing an important update to its Law for Intellectual Property and showing progress in areas related to trademark enforcement while moving backwards on domestic policy areas related to patents and trademark use that raise direct concerns for a range of manufacturing sectors. The United States should engage more closely with Chile through the consultation frameworks under the U.S.-Chile FTA and other bilateral trade discussions. Given the trends in each of these areas, the NAM recommends that USTR again designate Chile for its Priority Watch List in 2022.

Chile has made significant changes to its **core IP laws**, approving in April 2021 a significant revision to its Law of Industrial Property, with a range of new statutes that matter directly for manufacturers in both constructive and concerning ways. Changes in the new law include provisions that strengthen the definition, as well as penalties and damages, for trademark counterfeiting; overhaul the registration process and term of protection for industrial designs; broaden the scope of registrable trademarks to include three-dimensional, smell and tactile marks; set exceptions to patent rights; and apply the Bolar exception for agricultural products. The new law will require Chile's IP authority, the Instituto Nacional de Propiedad Industrial, to issue follow-up regulations that manufacturers will be monitoring closely.

Chile, like several other countries in Latin America, has increasingly considered **compulsory licensing** in recent years, with repeated pressure from the Chilean Congress to use compulsory licenses and Ministry of Health Resolutions affirming that such compulsory licensing could be

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<sup>49</sup> CBPA, "[Combating unauthorized and counterfeit goods during the COVID-19 pandemic: the CBSA, Health Canada and RCMP announce the results of Project Purify.](#)" News Release, Nov. 5, 2020.

<sup>50</sup> 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](#).

justifiable on public health grounds.<sup>51</sup> The Chilean Congress continues to debate new legislation (Boletín 9914-11, known as *Medicines II*) that includes problematic measures, such as expanding the grounds for compulsory licensing in ways that appear inconsistent with the letter and spirit of both Chile's FTA commitments as well as WTO TRIPS rules. The full bill is now being considered by a Senate Joint Commission, though the commission has already approved an article to allow the government to issue compulsory licenses on broad grounds. President Sebastián Piñera has publicly urged the passage of *Medicines II* legislation as part of a broader series of proposals that reflect concerning attitudes towards IP and innovation<sup>52</sup>, and has pressed for faster action in January 2022.<sup>53</sup> Manufacturers across a range of sectors are watching these actions closely and are concerned that this broadening of compulsory licensing procedures may not meet the criteria needed to invoke them, including a clear health emergency and grounds for decisions clearly based on the facts of the individual case through transparent processes that involve close consultation with all stakeholders. In the meantime, Chile's Chamber of Deputies in March 2020 passed a resolution that would permit compulsory licensing for any vaccines or therapies used to fight COVID-19.<sup>54</sup>

In addition, Chile has yet to satisfy commitments made under the U.S.-Chile FTA (Article 17.10.2) to establish a robust mechanism to enable effective **patent enforcement** before marketing approval decisions are made and implemented. U.S.-Chile FTA provisions require 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 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.

Chile has shown mixed signals on the **protection of trademarks**. In addition to the changes noted in Chile's revised Law of Industrial Property, the Chilean Congress in May 2021 formally approved legislation for Chile to accede to the Madrid Protocol, which is now formally expected in 2022.<sup>55</sup> Manufacturers also report positive activity on trademark enforcement, where the Chilean Customs Administration has been more proactive in seizing counterfeit and other IP-infringing goods at the border and has taken other measures to combat fake and counterfeit products. At the same time, Chile has also been a regional leader in promoting plain packaging approaches for multiple 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"

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<sup>51</sup> These included a January 2017 resolution passed by the Chilean Chamber of Deputies calling on the Minister of Health to "use the compulsory licensing mechanism" for medicines, a January 2018 Chilean Chamber of Deputies resolution asserting that a compulsory license was warranted in the case of certain drug products. Those actions prompted 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, a resolution reaffirmed in August 2018 by her successor, former Health Minister Emilio Santelices Cuevas.

<sup>52</sup> ["President Piñera launches project to lower the cost of medications."](#) Government of Chile News Release, May 7, 2018.

<sup>53</sup> Latorre, Rocío, ["Ejecutivo ingresa indicaciones para regular precios de remedios que permitirá destrabar Ley de Fármacos II,"](#) *La Tercera*, Jan. 11, 2022.

<sup>54</sup> Silverman, Ed, ["Chilean lawmakers support compulsory licensing for coronavirus medicines and vaccines,"](#) STAT News, Mar. 18, 2020.

<sup>55</sup> Instituto Nacional de Propiedad Industrial, ["Sala del Senado aprueba Protocolo de Madrid relativo al registro de marcas,"](#) May 19, 2021; Chilean Chamber of Deputies, ["Boletín 13929-10: Proyecto de Acuerdo que aprueba el Protocolo concerniente al Arreglo de Madrid relativo al Registro Internacional de Marcas, adoptado en Madrid el 27 de junio de 1989, modificado el 3 de octubre de 2006 y el 12 de noviembre de 2007,"](#) last accessed Jan. 17, 2022.

warnings on food and beverage products, setting a negative example in the region that is already being considered in other markets such as **Argentina, Brazil, Canada and Mexico**. The *Medicines II* legislation also includes a proposal to introduce limitations on trademarks on packaging of pharmaceutical products by limiting the size and use of trademarks and brand names.

Finally, manufacturers are closely monitoring negotiations between Chile and the **EU** on a potential modernization of the existing EU-Chile FTA. Although those negotiations appear to be on hold as of 2019, manufacturers are closely watching discussion of any measures that provide stronger protection for European **GIs** outside of trademark-provided protections for food and agricultural products, given the EU's recent negotiating history. 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. These measures would have a negative impact on American jobs and workers supported by exports to Chile.

### *China*

China remains a broadly challenging market for a wide array of manufacturers on innovation and intellectual property issues, with manufacturers large and small facing significant, longstanding, structural challenges with IP. China has made important steps forward in key areas of law and policy in recent years, including changes to its IP framework that reflect both a growing domestic sense of the value of IP as well as implementation of key commitments in trade agreements such as the U.S.-China Phase One agreement. Despite this, manufacturers have seen little change in many of the longstanding structural issues that prevent effective enforcement of U.S. IP rights and face IP-related challenges with the proliferation of industrial policies and other discriminatory steps. In line with U.S. Trade Representative Katherine Tai's [October 2021 announcement](#) laying out a trade strategy for China, USTR must engage with China to ensure that China not only fully meets its commitments under the U.S.-China Economic and Trade Agreement (known as the "Phase One deal"), but also addresses additional IP concerns raised by U.S. stakeholders. Given the importance of these issues, the NAM recommends that China remain on the Priority Watch List in 2022.

In recent years, China has increasingly recognized the value of innovation and IP to grow its economy, fostering more attention on IP at home through high-level plans such as the October 2021 [14th Five-Year Plan on IP Protection and Utilization](#) as well as a series of regulatory changes. This recognition has expanded both opportunities and challenges for U.S. companies in China. In recent years, NAM members have reported important positive developments related to IP in China, particularly revisions to key Chinese laws and regulations such as the new Foreign Investment Law and revisions to its Patent, Trademark, Copyright and Anti-Unfair Competition Laws as well as Technology Import-Export Regulations. These changes have been matched by other operational developments in China's IP system, including expanded judicial channels such as China's new national-level appeals court for IP disputes.

The Phase One Deal signed in January 2020 also represents important progress across multiple areas of IP issues, including trade secrets, patents, trademarks and enforcement, cementing and providing new dispute resolution mechanisms for many of the legal changes listed above as well as securing Chinese commitments for additional legal changes. Manufacturers view these commitments as critical measures that, if fully implemented in a commercially meaningful way, would directly improve the IP environment in China for

manufacturers. The NAM urges USTR to ensure full, timely implementation of these commitments while also quickly and actively negotiating with its Chinese counterparts to secure additional IP reforms.

Despite these positive steps, 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. (The NAM detailed many of these policies, as well as other areas of broad market concern, in its [September 2021 submission to USTR on China's compliance with its WTO commitments](#).) China's Cybersecurity Law and other privacy and security-related regulations (such as the National Security Law, Counterterrorism Law, Personal Information Security Specifications, Human Genetic Resources Regulations and, most recently, Regulations on the Security and Protection of Critical Information Infrastructure) have imposed extensive **data localization** requirements and restrictions on cross-border data flows that harm a broad range of innovative 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 more than \$1 billion in counterfeit goods seized at U.S. borders in 2020 coming from either China (\$660.8 million, or just over half of the overall total) or **Hong Kong** (\$429.0 million, or 32% of the total).<sup>56</sup> Manufacturers welcome steps taken by Chinese courts over the last year to increase penalties for IP infringements, including December 2020 revisions to China's Criminal Law to increase maximum sentences and fines for some types of IP crime and the March 2021 Supreme People's Court guidance to more clearly define punitive damage in civil cases related to IP infringement. Yet deeper structural barriers remain to effective enforcement against both counterfeits and other types of IP infringement, including insufficient coordination among different agencies and levels of government and insufficient resources and implementation to address IP infringement. Specific value thresholds prevent criminal prosecution for IP infringement in most cases, and low administrative fines and civil damages provide little deterrence as counterfeiters and pirates often see fines merely as a cost of doing business. Local protectionism is also a frequent issue, with local government officials unable or unwilling to enforce IP.

Protection of **trade secrets and confidential business information** in China remains a concern. Manufacturers have seen clear 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. Other manufacturers report challenges with requests from Chinese agencies for sensitive business data, such as chemical formulations, manufacturing process information and batch records, that go beyond what other international regulators generally request.

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<sup>56</sup> CBP Office of Trade, ["Intellectual Property Rights Seizure Statistics: Fiscal Year 2020."](#)

Despite helpful steps in the patent and associated regulatory space for some innovative manufacturing sectors, 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 and government subsidies that can fuel high numbers of “junk patents” that enjoy a high level of protection but often carry a low level of inventiveness.<sup>57</sup> Steps in early 2021 by the China National Intellectual Property Administration to cancel government subsidies for patent applications and increase penalties against junk patent filers are welcome, though only if fully and consistently enforced at the national and provincial level. In the meantime, broader Chinese government encouragement for companies to file more patents at home and abroad, and use of raw patent numbers as a core benchmark, may continue to feed these challenges.
- Patent filers in the pharmaceutical industry have long faced patentability and patent invalidation issues related to inconsistent interpretation of new rules requiring examiners to consider submitting **supplemental data**, a practice that deviates from international best practices—including best practices followed by patent offices in the United States, the **EU, Japan** and **Korea**—and has resulted in challenges for patents in China easily granted in those other jurisdictions. China committed to accept supplemental data under the Phase One deal, and on Jan. 15, 2021, began implementing revised Patent Examination Guidelines that allowed the China National Intellectual Property Administration to conditionally accept supplemental data to demonstrate that the patent meets the “inventive step” criterion. Manufacturers will continue to monitor whether Chinese patent examiners consistently accept such data.
- China has also long suffered from an ineffective system for **regulatory data protection**, despite commitments made as part of its 2001 WTO accession process to provide a six-year period of protection. The National Medical Products Administration’s April 2018 draft measures (*Implementation of Drug Clinical Trial Data Protection*) provided an important pointer in the right direction, though with some questions about how broadly they may apply. Those rules, however, have yet to be finalized. Regulatory data protection commitments were not included in the Phase One deal.
- China’s longstanding lack of a robust **patent linkage** system has been a key concern for manufacturers. A functioning patent linkage system is critical to ensuring early resolution of patent disputes and preventing potentially infringing products from entering the market inappropriately. China’s revised Patent Law, which went into effect in June 2021, established a patent linkage framework. China has also moved forward on key regulations needed to implement a patent linkage system, including issuance of July 2021 interim measures to set up new information and enforcement mechanisms to prevent marketing approval of patent-infringing products, as well as February 2021 draft measures for an early resolution system for patent disputes. Yet manufacturers have outstanding concerns with the proposed linkage system, including the still-limited scope of patents for which notice is provided and the inadequate stay period. Manufacturers want to see speedy implementation of an effective patent linkage system, operating in line with international best practices, that addresses outstanding concern with both current practice and the proposed system.

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<sup>57</sup> 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.

**Inadequate trademark procedures** also make manufacturers more vulnerable to pirates registering marks in bad faith or to other parties infringing upon their legitimate trademarks. 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—areas generally not covered by recent legal changes or the U.S.-China trade deal—such as:

- **Antitrust**, where China continues a strong focus on IP in the context of competition law with a number of outstanding guidelines and a series of regulations from key regulators that have raised concerns about how they may treat the legitimate exercise of IP in consideration of competition concerns. Coupled with clear government signals of efforts to expand antitrust enforcement under the new Antimonopoly Bureau, manufacturers remain strongly concerned about these issues.
- **Standards**, where China’s IP-related standard-setting practices continue to cause significant concerns, 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. 2018 revisions to the Technology Import-Export Administrative Regulations to remove measures limiting the ability of foreign companies to include contract clauses to protect their IP were a key step, but manufacturers remain watchful for other measures in this space.

### *Colombia*

Colombian government actions have raised concerns in recent years about their commitment to a pro-IP environment, despite repeated USTR engagement with the Colombian government on a range of core issues. Additionally, Colombia has introduced new actions that curb the use of intellectual property, negatively impacting key trademark-using sectors. Given these trends, the NAM continues to recommend that Colombia be included on USTR’s Priority Watch List in 2022.

Colombia has taken a series of actions that put 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 statements and actions related to **compulsory licensing** processes 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 and subjective application of regulations related to innovation incentives.

Colombia continues to use 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."<sup>58</sup> 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 OECD standards urging countries to "eliminate unnecessary regulatory barriers to trade and investment" and seek "harmonisation towards international standards."<sup>59</sup>

In addition, manufacturers in the United States are concerned with **compulsory licensing** issues. In recent years, manufacturers have seen the increased use of declarations of public interest (DPIs) to drive compulsory licensing reviews or to devalue innovation for innovative manufactured products in Colombia.<sup>60</sup> 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. Moreover, the Colombian Congress is still considering a new bill on pharmaceutical safety, introduced in 2020, that includes provisions to expand broadly the use of compulsory licenses beyond international best practices through broad definitions of public interest and through forced disclosure of company technical data. 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.

Colombia is actively pursuing a significant update of its front-of-pack labelling regulations that may have important implications for **trademark use**. In February 2020, Colombian Minister of Health Fernando Ruiz Gómez announced plans to introduce new front-of-pack labelling

<sup>58</sup> Article 31(b), [World Trade Organization Trade-Related Aspects of Intellectual Property Rights Agreement](#).

<sup>59</sup> Organisation of Economic Cooperation and Development, "[Recommendation of the Council on Regulatory Policy and Governance](#)," Conference Paper, OECD Regulatory Policy Conference, 2010.

<sup>60</sup> 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.

proposals that include actions that aim to restrict use of trademarks as part of expanded warning label proposals.<sup>61</sup> In July 2020, Minister Ruiz issued a draft resolution that further detailed the new proposals,<sup>62</sup> with a public comment period through August. The Ministry of Health in June 2021 published a final resolution ([Resolution 810 of 2021](#)) establishing new rules related to front-of-pack labelling, including new warning labels, with rules scheduled to go into effect in December 2022 (eighteen months from the resolution). These steps, which reflect and give further momentum to troubling regional trends to curtail IP use, have raised trademark and intellectual property concerns that should be addressed through bilateral and regional consultations with Colombia.

### *India*

India continues to be a priority market for innovative manufacturers across the board: not only for those concerned with patents, but also for those focused on trade secrets, copyrights and brand protection. Manufacturers note a series of positive steps that the Indian government has taken to improve IP protection in the last few years, including steps to reduce long backlogs for patent and trademark approvals and efforts to boost state-level enforcement and increased engagement with the U.S. government on intellectual property issues. Yet longstanding structural barriers for innovation, and the widely prevalent anti-IP attitude among policymakers, remain. As such, the NAM continues to recommend that India be designated on the Priority Watch List in 2022.

Over the past several years, India has made some important steps reflecting a stronger recognition of the value of innovation and intellectual property for the Indian economy. In December 2020, India's Department for Promotion of Industry and Internal Trade signed a new memorandum of understanding with the U.S. Patent and Trademark Office to cooperate on IP examination and protection for the next ten years, representing an important mechanism for IP improvement if fully implemented.<sup>63</sup> Similarly, USTR and the Ministry of Commerce and Industry have relaunched an IP-focused working group under the reinvigorated U.S.-India Trade Policy Forum.

Similarly, 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), with 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. The Delhi High Court in July 2021 launched a new Intellectual Property Division to assume key responsibilities from the Intellectual Property Appellate Board, and issued new rules for the division that were released for comment in November 2021.<sup>64</sup> India has made significant improvements in its efforts to reduce times for patent procedures approvals, reducing patent pendency for a first

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<sup>61</sup> Ministry of Health and Social Welfare, "[Colombia tendrá etiquetado nutricional en los alimentos envasados.](#)" Feb. 26, 2020.

<sup>62</sup> Federación Nacional de Comerciantes, "[MinSalud establecerá reglamento técnico sobre requisitos de etiquetado nutricional y frontal de alimentos envasados para consumo humano.](#)" Jul. 31, 2020.

<sup>63</sup> USPTO, "[USPTO and India's central IP department agree to cooperate on IP examination and protection.](#)" Dec. 2, 2020.

<sup>64</sup> Delhi High Court, "[Creation of Intellectual Property Division in the Delhi High Court.](#)" Jul. 6, 2021; Delhi High Court, "[Delhi High Court Intellectual Property Rights Division Rules, 2021.](#)" Nov. 10, 2021.



office action from 6.0 years in 2016 to 1.5 years in 2020.<sup>65</sup> The Indian government has also taken some small but positive steps to create opportunity for innovative manufacturers, including 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 published draft revisions to the Patent Rules that lowered patent fees.

Beyond these high-level steps, however, manufacturers urge India to translate broad rhetoric into more robust action to tangibly improve the IP environment for manufacturers. India's National Intellectual Property Policy, released in May 2016, remains the best example of this challenge.<sup>66</sup> The policy includes important broad language that recognizes the importance of IP for economic development, calls for stronger IP laws and enforcement and promotes progress in areas such as capacity building, agency streamlines and building public awareness of the value of IP. The policy itself, however, included scant detail on how India would improve its policy framework or address concerns related to patents and trade secrets flagged by industry stakeholders. No further details have been provided in the years since the policy was released, and the generally positive tone has seemingly had little impact on India's appetite for any change to longstanding structural barriers to IP. Moreover, Indian domestic rhetoric to insist that its actions are fully TRIPS-compliant and its efforts on the multilateral stage to weaken global IP rules directly undermine the credibility of pro-innovation and investment rhetoric from senior leaders and dampen the prospects for real, robust U.S.-India engagement on these issues.

India continues to deny **patent protection**, or invalidate existing patents, for inventions that meet internationally accepted criteria. Under 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.<sup>67</sup> Using Section 3(d), India over the last decade has rejected, invalidated or otherwise revoked dozens of patents for innovative products, including products and therapies widely patented in other countries around the world. Other burdensome policy challenges, such as problematic evidentiary standards for pre-grant opposition proceedings, Section 8 requirements to notify when filing outside of India upon threat of invalidation of their Indian patents and the continued ability of state-level authorities to grant marketing approval for a generic version of patented medicines without verifying whether there is a related patent, all 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 not formally issued any compulsory licenses since 2012, Indian officials keep the threat alive with continued insistence on their unfettered right to issue them. 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

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<sup>65</sup> See WIPO, "[World Intellectual Property Indicators 2017](#)," Dec. 6, 2017; WIPO IP Statistics Data Center, "[Patents: 12 – Average pendency from request for examination to the first office action \(days\)](#)."

<sup>66</sup> Department of Industrial Policy and Promotion, "[National Intellectual Property Rights Policy](#)," May 12, 2016.

<sup>67</sup> Examples of potential risk include 3(h) for agricultural products, 3(i) for diagnostic and treatment processes and 3(o) for integrated circuits.

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."

India has taken significant steps to reduce backlogs for **patent and trademark reviews** in recent years, which is a welcome step. As noted above, these reductions have been prompted by concrete reforms by India's Office of the Controller General of Patents, Designs & Trademarks, such as hiring more examiners, expanding electronic filing procedures and meeting with public stakeholders to collect ideas for further improvements. India has made significant progress on patent pendency, as noted above, and on trademarks, India has sharply slashed the pendency period for a final action down to a mere 40 days.<sup>68</sup> Patent pendency continues to cause challenges for manufacturers, as do other issues related to continued "bad faith" registrations. The NAM remains vigilant in monitoring India's IP review processes, as well as raising concerns about any efforts to reduce patent and trademark backlogs that inappropriately require localization or promote domestic industry. For example, the 2015 Patent Rule Amendments issued by the Ministry of Commerce and Industry that offer expedited patent examination for applicants that manufacture or commit to manufacture their inventions in India are discriminatory and do not align with international patent norms.

India 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.<sup>69</sup> 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, 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 IP, such as a 2016 DIPP proposed ban on investment "in technology collaboration, licensing for franchise, trademark, brand name and management contracts" for the tobacco

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<sup>68</sup> WIPO IP Statistics Data Center, "[Trademarks: 10 – Average pendency time \(days\).](#)"

<sup>69</sup> 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.

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 IP in multilateral fora** has prompted major concerns among manufacturers. At the WTO TRIPS Council, at WIPO and at the WHO, India has championed efforts to undermine international rules and standards to promote strong IP protections, denying links between IP and innovation and robustly advocating maximum use of TRIPS flexibilities. Manufacturers remain concerned about India's positions and the impact they could have in shaping international opinion in a way that prevents open, constructive discussion about innovation and IP, as well as the reflection they provide of India's true domestic views on these topics.

### *Indonesia*

Indonesia remains a significant concern for manufacturers in the United States due to a growing number of problematic legal and policy changes. Indonesia has worked with USTR and other agencies to improve aspects of its IP system, including the notable deletion in October 2020 of local manufacturing requirements for patents. Yet many aspects of Indonesia's current approach to IP, particularly for patents and trade secrets, continue to be highly problematic. As such, the NAM recommends that USTR continue to designate Indonesia on its Priority Watch List in 2022.

Manufacturers recognize that Indonesia has taken some important steps forward in recent years, most notably Indonesia's deletion of problematic provisions from its Patent Law that required local manufacturing as a part of the Omnibus Bill on Job Creation passed by Indonesia's House of Representatives in October 2020. In August 2021, Indonesia's Directorate General of Intellectual Property proposed draft revisions to the Patent Law that broadens the scope of patentable products and technologies, allows patent licensing and takes other steps that signal a stronger commitment to intellectual property. Finally, Indonesia has also taken some 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.

While recognizing key progress on the local manufacturing requirements for patents, Indonesia's Patent Law (revised in 2016) still contains a number of concerning provisions, particularly provisions that authorize **compulsory licensing** on vague and arbitrary grounds, narrow the scope of patentable subject matter, require disclosure of the origin of genetic resources and discourage voluntary licensing of technology. The follow-up Regulation No. 39/2018 (implementation of compulsory licensing) had raised further concerns among patent holders, though Indonesia's MLHR and the Directorate General of IP worked with stakeholders to reissue them (as Regulation No. 30/2019) in December 2019 with revisions that provided much better clarity on the processes and criteria for a compulsory licensing provision with critical references to TRIPS requirements. Yet in July 2020, President Joko Widodo issued Presidential Regulation 77/2020 that detailed the government's right to issue a compulsory license broadly for patents related to national defense, security or the vague circumstance of "very urgent need in the public interest," raising significant concerns for manufacturers in a wide range of sectors. In November 2021, President Widodo invoked that regulation to issue compulsory licenses on two key COVID-19 treatments, even though imports of those products

were sufficient.<sup>70</sup> Similarly, DGIP’s proposed Patent Law revisions include a problematic provision enabling government use of patents for imported pharmaceutical products.

Although the provision regarding local manufacturing for patentability has been deleted from the Patent Law, Indonesia maintains other **localization requirements** that impact innovative manufacturers. For example, Indonesia maintains market access barriers related to domestic manufacturing and technology transfer in multiple sectors. Such discriminatory and unfair moves to promote local manufacturing must be robustly addressed.

Finally, a series of Indonesian regulations related to food products raise IP concerns. The NAM has serious concerns about the **trademark implications** of potential revisions to Indonesia’s Law on Food and 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, recent changes to Indonesian law (in 2014, 2019 and most recently, February 2021) require companies in affected industries—including chemicals, cosmetics, food and beverages and pharmaceuticals—to **disclose sensitive business confidential information** to Indonesian government agencies in order to obtain required 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.

Manufacturers also note continued challenges in **IP enforcement** in Indonesia, particularly in manufacturing-relevant copyrights. Enforcement against fake and counterfeit products remains weak, reflecting a lack of political will as well as insufficient government coordination to tackle IP enforcement. Manufacturers also report a series of practical challenges, including requirements that trademark owners must have a local office in order to register (and protect) their trademarks with Indonesia’s Directorate General of Customs and Excise, and no channel to add registered copyrights. Additionally, manufacturers who frequently register artwork used on packaging as copyrights in other markets continue to have challenges registering those copyrights with Indonesia’s Directorate General of Intellectual Property Rights.

### *Mexico*

Mexico agreed to a number of critical commitments under the USMCA to improve core areas of IP law and practice, commitments that if implemented fully and consistently will have significant benefits for manufacturers across sectors. Yet despite those commitments, manufacturers report both longstanding issues in Mexico, particularly related to enforcement, as well as new policy developments that will negatively impact innovative manufacturing in the country. Due to these issues and the increasing need for stronger efforts to ensure that Mexico meets its USMCA commitments, the NAM recommends that USTR add Mexico to its Priority Watch List in 2022.

The USMCA marked an important step forward on IP issues in Mexico, as the government made important commitments in areas such as patent protection, trade secrets, GIs, and

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<sup>70</sup> These included presidential decrees allowing government exploitation of patents for remdesivir and favipiravir. See [“Presidential Decree 100/2021: Tentang Pelaksanaan Paten Oleh Pemerintah Terhadap Obat Remdesivir,”](#) Nov. 10, 2021; and [“Presidential Decree 101/2021: Tentang Pelaksanaan Paten Oleh Pemerintah Terhadap Obat Favipiravir,”](#) Nov. 10, 2021.

enforcement against fake and counterfeit products. The Mexican Congress passed the new Federal Law for the Protection of Industrial Property (or LFPPI) in early July as part of a package of five bills to implement key provisions in the USMCA, though not without a last-minute push for revisions to undermine critical IP protections. To date, the Instituto Mexicano de la Propiedad Industrial has been slow to work on follow-up regulations that would provide critical detail on the implementation of key LFPPI provisions in areas such as patent term adjustment, patent linkage and other areas. Manufacturers encourage USTR to engage IMPI on the timing and process for releasing these follow-up regulations, and to work with U.S. stakeholders to address areas of priority.

Mexico has issued a series of policies to update its front-of-pack labelling regulations that will have a significant negative impact on manufacturers and their **use of trademarks**. Mexico first announced plans in October 2019 to implement a new front-of-pack labelling scheme for a wide range of pre-packaged, non-alcoholic food and beverage products sold in Mexico, with use of black-and-white “stop sign” labels; follow-up regulations banned advertising for products. Such moves raise serious IP concerns by restricting the use of trademarked brand names, logos, symbols and packaging that consumers depend on to identify safe, effective products, and create concern both due to the importance of the Mexican market and due to Mexico’s position as a regional leader. Manufacturers strongly encourage USTR to continue actively raising concerns with these regulations, as well as follow-up regulations and sales bans, through bilateral and regional consultations with Mexico.

Manufacturers are also concerned about Mexican efforts to **enforce intellectual property**. Fake and counterfeit goods continue to be widespread in Mexico, particularly due to the continued prevalence of counterfeit markets. Yet the Servicio de Administración Tributaria (Mexico’s customs service) still initiates a relatively small number of cases, and key IP enforcement agencies are not sufficiently resourced or coordinated in their activity. Manufacturers encourage USTR and its fellow agencies to urge Mexico to strengthen interagency coordination and devote more time and resources to battling IP infringement. Patent enforcement is also an issue, as manufacturers also report little to no notice that a potentially patent infringing product is entering the market and face ongoing challenges with securing effective preliminary injunctions or final decisions on cases regarding IP infringement within a reasonable time. Even when injunctions are granted based on evidence of infringement and likely irreparable harm and supported by payment of bonds, it remains easy for an alleged infringer to submit a motion to the court to lift the injunction and allow the challenged product to enter the market at any point during lengthy infringement proceedings. Manufacturers subsequently have difficulties collecting adequate damages, requiring further proceedings that take additional time and resources.

Manufacturers are also closely watching issues impacting **market access for innovative industries** in Mexico in the wake of the USMCA. For example, the Federal Commission for Protection against Health Risks (COFEPRIS) has significantly delayed approval processes for key innovative manufacturing industries, including biopharmaceutical and agriculture biotechnology products, despite USMCA provisions on product approvals in these areas.<sup>71</sup> Moreover, the Mexican government has taken steps in the area of procurement that have negatively impacted fair market access in these products. These include August 2020 revisions to the Federal Procurement Law to bypass the public bidding process envisioned in the USMCA in favor of procurement from international organizations such as the Pan American Health

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<sup>71</sup> See, for example, USMCA provisions on regulatory approvals for agricultural biotechnology products (Chapter 3) and for biopharmaceutical products (Annex 12-F).

Organization and the United Nations Office for Project Services for health products. Since then, manufacturers have seen significant operational challenges with the new process, including a lack of transparency or meaningful engagement with participating stakeholders, a lack of coordination between UNOPS and Mexican government agencies, and ongoing logistical barriers that are limiting users' ability to accept procured goods. These issues are not only disrupting the flow of these products to Mexican patients but are also causing payment challenges for some manufacturers. Mexico has also proposed further revisions to key laws that impact procurement of IP-intensive manufactured products (specifically, the Ley de Adquisiciones, Arrendamientos y Servicios del Sector Público) to alter procurement practices that could discriminate against U.S.-based innovative manufacturers and undermine fair bidding processes.

The USMCA included important provisions to ensure that the protection of **GIs**, including those negotiated through FTAs, may only be granted after a fair and transparent examination and opposition process. Yet in April 2020, Mexico reached an "agreement in principle" on an updated FTA with the **EU**, which included agreements to strengthen protection for European **GIs** outside of trademark-provided protections for food and agricultural products. Those provisions 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. Both issues would have a negative impact on American jobs and workers supported by exports to Mexico.

### *Russia*

Russia has made little progress on IP issues over the last year and has taken some troubling steps backwards. Manufacturers note some signals by Russian government agencies, including the Ministry of Economic Development and the Russian Patent Office to engage industry on weaknesses in the country's IP system for key innovative sectors. Yet they still face longstanding and emerging challenges in Russia across a range of types of IP. As such, the NAM recommends that Russia remain on the Priority Watch List in 2022.

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 and other agencies to advance legislative changes to enable compulsory licensing for medicines. These include legislation to expand governmental discretion to issue a compulsory license on broad criteria (approved in April 2021)<sup>72</sup> and to allow exports of medicines produced in Russia under compulsory licenses (approved in June 2021).<sup>73</sup> Even while these pieces of legislation were still going through the approval process, and while the Federal Antimonopoly Service is working on implementing regulations, the Russian government in December 2020 issued its first compulsory license for a COVID-19 treatment.<sup>74</sup> These actions were mirrored by compulsory licensing activity in Russian

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<sup>72</sup> ["Federal Law No. 107-FZ: On Amendments to Article 1360 of the Civil Code of the Russian Federation,"](#) approved Apr. 30, 2021.

<sup>73</sup> ["Federal Law No. 212-FZ: On Amendments to Part IV of the Civil Code of the Russian Federation,"](#) approved June 11, 2021.

<sup>74</sup> Russian Prime Minister Mikhail Mishustin on Dec. 31, 2020 signed and issued [Decree No. 3718-r](#) to grant a local generic company a one-year compulsory license for the patented product remdesivir and to allow procurement, citing national security.

courts: the Moscow Arbitration Court over the past two years has granted compulsory licenses (based on dependent patents held by a local manufacturer) against two innovative medicines developed outside of Russia. Although the dependent patent in the first case was later annulled (leading to the dismissal of that case), the second decision was upheld by the Russian Supreme Court. These cases represent a troubling trend and could set a highly problematic judicial precedent.

Innovative manufacturers also remain concerned with new and ongoing challenges related to weak **patent enforcement** in Russia. This includes the lack of an effective mechanism to allow patent holders the opportunity to resolve patent disputes before the launch of off-patent products, circumstances that spur continued patent infringement in the country. Moreover, the Ministry of Economic Development in August 2021 released a draft federal law that would create a national register of certain patents for biopharmaceutical inventions but omitted necessary provisions for creating a patent linkage system necessary to prevent undue infringement by domestic producers.

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.

**Trade secret protection** remains a challenge in Russia due to a variety of barriers created 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 (EAEU)**, 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 intra-EAEU 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 EAEU, though it has plans to implement various steps (such as the creation of a common EAEU trademark and a single customs register for IP rights) that will have implications for IP protection

in Russia and the other EAU countries. These developments should be monitored carefully to understand the regulatory environment impacting IP and IP-intensive industries.

Manufacturers are also monitoring implementation of a new law officially recognizing **GIs** as a new type of IP right (separate from trademarks) that was signed into law in July 2019. This law could have immediate and long-term negative implications for manufacturers in several sectors.

### Watch List

#### *Australia*

Australia remains a concern for manufacturers in the United States on IP protection and enforcement. Manufacturers are encouraged by ongoing consultations between the two governments to potentially reconvene key IP-related mechanisms under the U.S.-Australia FTA, such as the Medicines Working Group (dormant since 2008), that provide valuable forums to discuss key IP issues. More broadly, the U.S. and Australian governments should use the FTA more broadly as a mechanism to engage on innovation and IP issues. Yet given the ongoing challenges related to Australian valuation of innovation outcomes, we again recommend that Australia be added to USTR's Watch List in 2022.

In December 2016, Australia's Productivity Commission released a **detailed review of Australia's IP system** with several 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 and received royal assent in August 2018<sup>75</sup> and a second round of proposed changes that received royal assent in February 2020.<sup>76</sup> The first round of changes included some 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 makes deeper structural changes such as abolishing the so-called "innovation patent" system, decreasing patentability by raising the criteria for "inventive step" of a potential patent, and amending rules on compulsory licensing to broaden their scope and application. Manufacturers remain highly concerned with these changes and urge the U.S. government to engage actively with Australia directly and under the framework of the U.S.-Australia FTA to address these concerns and ensure continued opportunities for innovative manufacturers in that market.

Manufacturers also note issues related to **patent enforcement**. Australia maintains, and has used several times since 2012, 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. Similarly, Australia does not implement a patent notification system for pharmaceutical products that would provide patent holders with reasonable notice of the entry of a generic competitor. These policies have created significant hurdles for companies seeking to enforce or defend their legitimate patent rights, as well as uncertainty for businesses, undermining R&D, innovation and investment, while also

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<sup>75</sup> IP Australia, "[Intellectual Property Laws Amendment \(Productivity Commission Response Part 1 and Other Measures\) Act 2018.](#)"

<sup>76</sup> Parliament of Australia, "[Intellectual Property Laws Amendment \(Productivity Commission Response Part 2 and Other Measures\) Bill 2019.](#)"



unfairly penalizing inventors who have sought to defend their legitimate patent rights. These actions appear inconsistent with Australia's WTO commitments under TRIPS<sup>77</sup> and set a troubling precedent for other markets.

Manufacturers also report challenges with **regulatory data protection** in Australia. Australia has 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 and biologic entities, figures that are far lower than those in advanced trading partners like the United States and Europe. This failure to protect these data creates a significant obstacle for Australian innovation and inbound investment in innovative industries. Yet it continues despite obligations under Article 17-10 of the U.S.-Australia FTA required parties to provide at least regulatory data protection for a range of undisclosed test data.

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 the legitimate use of trademarks around the world. As noted in the section on cross-cutting concerns, these rules essentially eliminate internationally respected trademark rights and set a precedent that has increasingly been explored for other products, including food and beverages.

Manufacturers are also monitoring ongoing negotiations between Australia and the **EU**, given the potential risk of concessions on **GIs** outside of trademark-provided protections for food and agricultural products. As with other trading partners, such concessions could 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. These measures would also have a negative impact on American jobs and workers supported by exports to Australia.

### *Brazil*

The Brazilian government has taken important steps forward to improve its IP system in key areas and to signal openness to foreign trade and investment in manufacturing. These efforts include Brazil's ratification of the Madrid Protocol on trademarks, and concrete steps to address its backlog of patents and trademarks. Additionally, Brazil has shifted its tone at the multilateral level, shifting from a frequent critic of IP protection to a more nuanced voice that is willing to partner with the United States on innovation issues. Yet Brazil remains a challenging market for innovative and IP-intensive manufacturing sectors, with issues in registering, utilizing and enforcing their intellectual property. Moreover, longstanding protectionist and anti-IP threads in Brazilian policy remain, manifesting themselves over the last year with a series of troubling anti-intellectual property developments. For these reasons, we recommend that Brazil remain on USTR's Watch List in 2022.

Brazil's IP office, the National Institute of Intellectual Property (INPI), has taken concrete steps designed to accelerate reviews and tackle Brazil's notoriously long **patent and trademark backlogs**, and to ensure that these backlogs do not meaningfully diminish the value and protection of intellectual property in Brazil. Steps to reduce these backlogs include include INPI's agreement with the U.S. Patent and Trademark Office to expand its Patent Prosecution

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<sup>77</sup> See TRIPS Article 41, which provides for the practical availability of enforcement proceedings that "permit effective action" against IP infringement, including expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements."

Highway (PPH) agreement to allow both an expanded scope and a higher quota of applications that could qualify for expedited patent applications. INPI has also taken other important steps, such as increasing its pool of patent examiners (up 60% between 2016 and 2018) and publishing multiple plans to address patent issues (including a June 2019 resolution and a July 2019 plan to reduce the patent backlog by 80% within two years and to increase the efficiency of patent prosecution) and trademarks (including new January 2018 rules to expedite trademark applications and reduce backlogs). Additionally, Brazil acceded to the Madrid system for global trademarks in July 2019, with applications beginning in October 2019. These commitments are paying off, as Brazil cut its patent pendency by two years and its trademark pendency by six months between 2018 and 2020.<sup>78</sup> Although Brazil's patent processes are still long (with a pendency of 5.2 years as of the end of 2020), this progress is notable and highly welcome.

At the same time, given Brazil's longstanding challenges with patent pendency and patent backlogs, **patent term adjustment** provisions under Article 40 of the Patent Law of 1996 that ensured that an invention patent had a term of protection of no less than 10 years from the grant date was a critical backstop to restore a portion of the patent term for unreasonable delays during examination of a patent application. Manufacturers remain concerned about the broad impact of the Brazilian Supreme Court's May 2021 decision to rule that language unconstitutional across patents, and to apply it retroactively to key sectors such as pharmaceutical and medical products, as it leaves innovative manufacturers across a broad range of sectors with no reasonable recourse for such delays that have been a challenge in Brazil in years past.

Brazil's Congress has also actively moved to expand authorities for **compulsory licensing**, passing in August 2021 new legislation to broadly expand compulsory licensing provisions in ways that raise significant concerns. The bill, as passed by the Congress, gave the Brazilian executive and legislative branches of government broad powers to issue compulsory licenses based on vague and ambiguous grounds (by declaration of "public health emergency," in instances of "public calamity," or even with a broader determination that granting such a license would be of "national or international interest"). Additionally, the bill requires the executive branch to prepare a broad list of targeted patents on which compulsory licenses could be issued, and in the event of a compulsory license also requires patent owners to share necessary trade secrets, technical information and know-how to exercise or face the full loss of their patent. Although President Jair Bolsonaro vetoed some of the most problematic portions of the legislation in early September, including provisions requiring transfer of technology and trade secrets, the remainder of the legislation was issued as Law No. 14.200. As of this submission, the Brazilian Congress has yet to finish evaluating the new version of the law and determining whether to override the president's veto.

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. In August 2021, President

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<sup>78</sup> See figure A.45 ("Average pendency times for first office action and final decision at selected offices") and B.43/B.44 ("Duration of trademark examination for selected offices") from WIPO's [2019](#) and [2021](#) editions of the World Intellectual Property Indicators.

Bolsonaro issued Law No. 14,195/2021 to revoke Article 229-C, thus eliminating requirements for ANVISA to review patent applications and accelerating Brazil's patent review process.

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.

Brazil also creates extra hurdles for manufacturers in **trademark registration and enforcement**. INPI has set a very high bar for 3D trademark registrations, with the level of descriptiveness set at levels much higher than other jurisdictions. Manufacturers continue to report challenges in IP enforcement in Brazil, with customs surveillance against counterfeits an ongoing challenge. Bureaucratic challenges with the Brazil's Central Coordination of Customs Affairs (known as COANA) mean that companies seeking to file inspection requests to halt the flow of counterfeit goods often must file inspection requests in specific Brazilian ports of entry when aware of a potential shipment of counterfeit goods. This adds significant time and burden for rightsholders, and also depends on their awareness of a pending counterfeit shipment. Different Brazilian ports also have different procedures and requirements to trigger suspension and seizure procedures, making the system very challenging to navigate and use effectively.

**Technology licensing and transfer** also remain 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.<sup>79</sup>

Brazil has in recent years started to move away from its traditionally strong support for **multilateral efforts to undermine global IP protections**, including expansion of unfettered TRIPS flexibilities such as compulsory licenses, limited patentability criteria and increased patent challenges. For example, Brazil has worked with the United States and other pro-innovation economies to oppose the proposal by **India** and **South Africa** at the WTO TRIPS Council to suspend countries' obligations to protect intellectual property related to COVID-19. Manufacturers are strongly encouraged by Brazil's shifting approach on these issues and its willingness to work more closely with the United States in this space and encourage USTR and other U.S. government agencies to continue to support this evolution.

Brazil (as part of MERCOSUR) is also engaged in negotiations with the **EU** for a potential FTA. Manufacturers are watching these negotiations closely, including any discussions that would provide stronger protection for European **GIs** outside of trademark-provided protections for food and agricultural products. As in other markets, such measures would undermine the ability of the United States and other countries to protect existing trademarks for these products in Brazil, developments that would have a negative impact on American jobs and workers supported by exports to Brazil.

Given the OECD's January 2022 announcement that it had started membership discussions with Brazil, and U.S. government signals of support for that application, it is critically important for the United States to engage with Brazil on intellectual property. The United States must hold firm on the need for Brazil to demonstrate its commitment to the high IP standards to which the

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<sup>79</sup> 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.

OECD community ascribes by making changes to both law and practice to meet to those standards.

### *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 last several years with policy steps that undermine the country's pro-innovation environment. Given the importance of the U.S.-Japan relationship and USTR's November 2021 announcement of a new U.S.-Japan Partnership on Trade, manufacturers urge USTR to ensure that IP is a core priority in any and all negotiations with the Japanese government. Given the ongoing need and opportunities for progress on critical IP issues in Japan in the coming months, the NAM recommends that Japan be added to USTR's Watch List in 2022.

Japan's recent backward steps, particularly **discriminatory government policies that harm market access for innovative products and undermine patent protection**, raise questions about Japan's long-term commitment to valuing, and promoting, innovation. 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 and timing for processes that had long ensured access to innovative products. In parallel, the Japanese government in April 2019 revised a critical regulatory system to determining cost-effectiveness of innovative products (health technology assessments), with changes that could undermine critical innovation incentives. Despite the COVID-19 pandemic and the ongoing uncertainty to medical supply chains, the Japanese government in December 2020 issued a new rule that shifted to an annual price review process that included an automatic price cut for certain types of medicines beginning in April 2021. These rules are highly problematic for innovative manufacturers, and also appear to be crafted in a tiered way that favors domestic companies at the expense of manufacturers in the United States, particularly small and medium-sized manufacturers.

In addition, manufacturers are concerned about patent enforcement, given implementation issues with Japan's patent linkage system illustrated in recent government decisions. In late 2020, Japan's Ministry of Health, Labor and Welfare ignored findings of the Japanese Patent Office by issuing multiple generic versions of an on-patent product even though the JPO had upheld two of the four claims on the underlying method of use patent. Despite current litigation in Japanese courts against the approved generics, MHLW permitted those products to enter the market in December 2020, before the ruling on critical injunctive relief. These actions have created significant uncertainty for innovative and generic manufacturers. These actions sent damaging signals about Japan's commitment to innovation and about its commitment to effective, well-functioning patent enforcement systems. Each of these developments undermines confidence in Japan's commitment to innovation and R&D needed to create and bring new innovative products to market, as well as the effectiveness of its patent enforcement systems.

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 the issuance of patents and reforms to extend and clarify regulatory data protection for key innovative sectors. Manufacturers have raised concerns about current JPO procedures in considering patent term restoration for subsequent pharmaceutical product approvals. Currently,

JPO provides an extension period based only on what is considered “necessary testing” for the subsequent approval. This practice often means uneven extensions, with initial approval periods being longer than subsequent extensions. In practice, this approach can act as a disincentive to conduct research on additional medical uses and indications, including new formulations for an approved pharmaceutical product, and thus weakens Japan’s innovation ecosystem. Further, Japan has failed to implement legislation establishing a regulatory data protection system. While Japan’s system generally provides eight years of regulatory data protection, it has yet to formally establish such protection through legislation that would create more certainty and predictability for innovators and support investment in innovative manufacturing sectors.

Additionally, manufacturers are closely monitoring the ongoing implementation of IP-relevant chapters of Japan’s Economic Partnership Agreement with the **EU**, including measures that provide stronger protection for European **GIs** outside of trademark-provided protections for food and agricultural products. As in other markets, such measures would undermine the ability of the United States and other countries to protect existing trademarks for these products in Japan, developments that would have a negative impact on American jobs and workers supported by exports to Japan.

### *Korea*

Korea continues to suffer from strategic 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 FTA related to pricing. Although the U.S. government secured a March 2018 commitment to revise key policies that had undermined innovation as part of amendments and modifications to KORUS, Korea’s implementation has continued to be problematic. Given these challenges and the urgent need to ensure that Korea meets its commitments under KORUS and its update, the NAM suggests that Korea stay on the Watch List in 2022.

Manufacturer challenges in Korea include **discriminatory government policies that harm market access for innovative products**. For example, Korea’s 2016 Drug Expenditure Rationalization Plan 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. Under its 2018 commitments, Korea’s Health Insurance Review & Assessment Service (HIRA) was to revise the problematic policies. Although revised rules came into effect in January 2019, the new criteria remain so strict as to serve as a continued market access barrier for innovative manufacturers, and a September 2021 HIRA

announcement that it would use past results as opposed to updating their methods further illustrates this challenge. HIRA has also announced plans to adjust its approach to pricing for procurement of key innovative products in ways that would undervalue the innovation inherent in those products. These developments together have created significant uncertainty for innovative manufacturers. Manufacturers urge further engagement with industry, increased transparency in decision-making and efforts to ensure that these rules and practices meet both the letter and the spirit of Korea's commitments and provide meaningful market access for manufacturers.

As with other markets, members are also monitoring ongoing implementation of South Korea's free trade agreement with the **EU**, 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. Both developments would have a negative impact on American jobs and workers supported by exports to Korea.

### *Saudi Arabia*

Manufacturers continue to see opportunity and significant challenge related to IP in Saudi Arabia, with Saudi Arabia's broad "Vision 2030" plan flagging the importance of developing key innovative industries and the 2017 launch of the new Saudi Authority for Intellectual Property. However, manufacturers have watched with growing concern troubling developments related to IP in Saudi Arabia over the past few years, particularly in the patent and enforcement spaces. Due to those ongoing IP challenges and Saudi Arabia's importance as a first mover in the region, the NAM recommends that Saudi Arabia be included on the Watch List in 2022.

Saudi Arabia's broad "Vision 2030" framework, issued in 2016 by Crown Prince Mohammad bin Salman with implementation tasked to the Council of Economic and Development Affairs as part of plans to diversify the economy, includes positive signals about the importance of investment and innovation. The country's launch in 2017 of the SAIP as part of that implementation, and the Saudi government's efforts to consolidate authority and **implement a coherent national system for IP protection**, continue to create opportunities for the U.S. government and industry stakeholders to engage and partner on capacity building. The U.S. government has taken advantage of that in key areas, such as signing a PPH agreement with SAIP in December 2019.<sup>80</sup>

Yet despite these positive steps, Saudi Arabia remains a challenge for manufacturers in several key areas of IP. Saudi Arabia continues to pose problems related to **regulatory data protection**. While regulatory data protection is provided under Saudi law, it is often not effectively enforced. The Saudi Food and Drug Administration in recent years has granted marketing approvals to a local manufacturer to produce generic versions of two foreign innovative products, even though both products should have been able to benefit from protections under Saudi law (in one case, the original product was still under its term of patent protection; in another case, the original product's data should have been covered by the regulatory data protection period provided under Saudi law) Both products were then procured by the Saudi Ministry of Health, ensuring that they were sold and distributed even during the initial period of protection. These actions appear specifically designed to help domestic

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<sup>80</sup> ["Patent Prosecution Highway Pilot Program Between the United States Patent and Trademark Office and the Saudi Authority for Intellectual Property of the Kingdom of Saudi Arabia,"](#) December 6, 2019.

manufacturing at the expense of U.S. innovative manufacturers, an action that would appear to violate Saudi Arabia's WTO commitments. These challenges appear to be getting worse, not better, as reflected in a troubling September 2020 SAIP draft of proposed regulations on the protection of confidential business information that further weaken regulatory data protection and a continued push by SFDA to encourage manufacturers to seek approvals for generic versions of innovative products that are still covered by IP protections.

Manufacturers are also concerned with other standards and technical requirements that appear to require companies to provide intellectual property and **confidential business information** beyond international norms. New technical requirements for a wide range of electrical and electronic equipment (known informally, due to their similarity to **EU** regulations, as "Saudi RoHS") issued by the Saudi Standards, Metrology and Quality Organization are one such example, as they appear to require companies to provide a range of confidential business information such as source code or confidential manufacturing know-how, beyond requirements in other markets and without sufficient guarantees for how that information will be treated.

Saudi Arabia has also issued new, problematic regulations focused on **compulsory licensing** that have raised significant concerns. In April 2020, SAIP issued final regulations that include broad, vague criteria that could allow SAIP to issue licenses three years after they were granted, and without appropriate notice to the patent holder. These broad regulations do not align with longstanding best practices that compulsory licenses should be granted only under exceptional circumstances, that governments must follow internationally agreed-upon rules for their use, and that processes to consider licenses must follow transparent, rule-of-law based processes. These rules send highly troubling signals about Saudi Arabia's commitment to innovation that could damage Saudi Arabia's efforts to promote innovation and economic growth.

Saudi Arabia also continues to suffer from **counterfeiting and piracy** challenges, as manufacturers face continued challenges with enforcement and transparency. Saudi Arabia not only suffers from high levels of domestic counterfeiting, but also serves as a transit point for fake goods. While Saudi Arabia appears to be making efforts in this space with higher levels of seizures and enforcement and more information sharing, structural issues such as the lack of consistent seizure and destruction of counterfeit goods creates challenges for manufacturers large and small.

### *South Africa*

South Africa has taken steps to update its national IP policies and practices in recent years, addressing some longstanding areas of concern for manufacturers but raising new issues, particularly given South Africa's continued skepticism of innovation and IP. Moreover, South Africa continues to be highly vocal in international forums to undermine critical global intellectual property rules. For these reasons, the NAM continues to recommend that South Africa be placed on USTR's Watch List in 2022.

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 that provide

opportunities for U.S. government engagement with their South African partners. 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.

The South African government has continued work to translate provisions in the IP strategy into an update of South Africa’s IP laws, though key follow-up work on patents, trademarks and copyrights have not seen measurable progress since November 2020 statements from DTI that they planned to submit drafts of a Patent Amendment Bill and a Designs Amendment Bill to the cabinet for approval and were working on a Copyright Amendment Bill and potential accession to the Madrid Protocol on trademarks.<sup>81</sup> 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 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, seeking to broaden as much as possible the grounds and uses of TRIPS flexibilities<sup>82</sup> and the scope of these flexibilities to encompass other areas of law (such as competition law) beyond the scope of TRIPS.<sup>83</sup> South Africa has championed efforts at the WTO and other multilateral organizations 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. Manufacturers remain concerned about South Africa’s positions and the impact they could have in shaping international opinion on these topics, given its regional influence.

### *Thailand*

Thailand has worked more actively with the U.S. government in recent years to address manufacturers’ concerns related to IP, including ongoing work to amend its Patent Act and

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<sup>81</sup> Makoko, Maureen. [“Update: Phase 1 of South Africa’s IP Policy,”](#) Adams & Adams, Nov. 3, 2020.

<sup>82</sup> South Africa’s October 2019 communication to the WTO TRIPS Council is a perfect example, stating that WTO members “must commit to the full use” of TRIPS flexibilities, criticizing the “current model of medical innovation” and the “monopolist positions” of innovative manufacturing, and citing the controversial U.N. High-Level Panel on Access to Medicines as justification. See, for example, South Africa, [“Intellectual Property and the Public Interest: R&D Costs and Pricing of Medicines and Health Technologies,”](#) Document IP/C/W/659, October 4, 2019.

<sup>83</sup> See 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.



proactive steps to reduce the patent backlog through greater hiring of patent examiners. While manufacturers welcome each of these steps, they remain concerned about key areas of IP policy and practice in Thailand, including discriminatory innovation policies, continued issues with patent approvals and challenges in trademark enforcement. For these reasons, the NAM requests that Thailand be included on the Watch List in 2022.

Manufacturers are monitoring the **revisions to Thailand's Patent Act**, for which a draft was most recently published by the Department of Intellectual Property in September 2020. The latest draft covers both patents and industrial designs, including changes such as a shorter timeline for patent examination and easier rules for the recordation of patent licenses. The law, however, also includes new authorizations for compulsory licensing that raise concerns for innovative manufacturers.

Despite Thailand's efforts to streamline patent processes, **patent pendency and patent backlogs** remain an issue in Thailand. Overall statistics show that patent applications in Thailand have gotten considerably longer in recent years (now up to five years), with even longer pendency for certain sectors (such as biopharmaceuticals). These challenges are exacerbated by the lack of patent term adjustments in Thailand that could compensate for unreasonable delays in the patent approval process.

**Counterfeiting** is also a significant challenge for manufacturers in Thailand, with CBP statistics on seizures showing a significant jump in the value of counterfeits from Thailand in 2020 alone (up to \$12.6 million).<sup>84</sup> Manufacturers across sectors also report a significant increase of counterfeit products sold in Thailand, with counterfeit sales expanding nationwide through both online and offline sales channels. The sophistication of these counterfeit products has also improved, making them much more difficult for manufacturers and government enforcement officials to detect. Manufacturers urge the U.S. government to work with its Thai counterparts to strengthen enforcement at the border as well as to expand domestic enforcement to include online channels and physical channels beyond just the retail level.

**IP enforcement** continues to be a challenge for manufacturers in a range of sectors, with frequent manufacturers reporting that enforcement officials demand compensation in order to enforce existing IP law and the release (or leakage) of seized counterfeit goods back into the marketplace. The Thai Customs Department also does not allow manufacturers to register copyrights to aid enforcement, and officials often do not proactively seize shipments, instead requiring stakeholders to report incoming shipments of infringing goods.

Manufacturers urge USTR to work with Thai officials under the bilateral U.S.-Thailand Trade and Investment Framework Agreement, including the relevant subcommittee on IP enforcement.

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<sup>84</sup> CBP Office of Trade, ["Intellectual Property Rights Seizure Statistics: Fiscal Year 2020."](#)

**Appendix: Index of Countries, Territories and Regional Organizations  
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