



November 5, 2021

The Honorable Katherine Tai  
United States Trade Representative  
600 17<sup>th</sup> St. NW  
Washington, D.C. 20508

Dear Ambassador Tai:

We, the undersigned organizations, write in support of your plans to strengthen the U.S.-India trading relationship, renewing the United States-India Trade Policy Forum this fall and “ensur[ing] our [India] trade policy strikes the right balance.” Your commitment here has been matched by commitments by your Indian counterparts, most recently Minister of Commerce Piyush Goyal, to work “with [the United States] on market access issues”<sup>1</sup> and grow annual bilateral trade volumes to \$500 billion, goals set when the TPF was last restarted in 2014 and still unrealized.<sup>2</sup> We urge you to ensure that the renewed TPF can deliver results for businesses and workers in the United States, realizing the potential in the U.S.-India trade relationship by resolving trade and market access barriers our businesses face in India.

As you and your team plan for this year’s TPF, we would like to highlight a range of sectoral and cross-sectoral barriers that limit the ability of businesses in the United States to operate in India, as well as specific outcomes needed to address them. The concerns affect products and services that Americans design, manufacture, grow, supply, and record, including many raised in previous TPFs that remain unresolved. For each issue in this letter, we also highlight specific outcomes that we believe progress can be made in this year’s TPF. Tangible progress on these issues can also create a pathway to restore India’s benefits under the Generalized System of Preferences program, and build a track record of success that could support broader trade negotiations commensurate with the strategic importance of close U.S.-India relations.

### **Intellectual Property**

Intellectual property protection remains a major challenge for many U.S. sectors due to India’s burdensome requirements to register and enforce a patent, high piracy rates, lax trade secret protections, and other challenges. Companies face a wide range of intellectual property issues in India, including longstanding, challenging issues that are well-documented in USTR’s Special 301 report. Intellectual property must remain a key component of this year’s forum, with a clear focus on charting real progress with respect to a series of concerns where progress is achievable,

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<sup>1</sup> Dhoot, Vikas, “U.S. Not Interested in Trade Pact: Piyush Goyal,” The Hindu, August 19, 2021, <https://www.thehindu.com/business/Economy/us-not-interested-in-trade-pact-piyush-goyal/article36001920.ece>.

<sup>2</sup> “PM’s US Visit: Narendra Modi, Barack Obama Target \$500 Billion India-US Trade,” The Economic Times, October 1, 2014, <https://economictimes.indiatimes.com/news/economy/foreign-trade/pms-us-visit-narendra-modi-barack-obama-target-500-billion-india-us-trade/articleshow/43974400.cms?from=mdr>.

many of which are laid out below, while also laying the groundwork for open dialogue on more challenging issues. Indeed, the U.S. and India have an opportunity to build upon efforts earlier this year to relaunch the joint Intellectual Property Task Force.

First, trade secrets remain a key concern.<sup>3</sup> India still lacks a unified law to protect information that qualifies as a “trade secret” under international law, as defined by Article 39.2 of the TRIPS Agreement, instead relying on a mix of court interpretations and statutory requirements for contracts. This forces companies to seek protection under contract law, an approach that provides inadequate protection for critical business confidential information. Trade secrets are an important facilitator for investment in IP-intensive sectors—and the lack of such protections in India has discouraged U.S. companies from investing in and bringing key technologies and products to the Indian market. USTR should work with India to enact a unified trade secrets law to afford full protection to trade secrets and business confidential information.

Second, biopharmaceutical innovators face challenges in India that compromise their interest and ability to invest in research and development in India, in turn undermining their ability to discover new medicines designed to meet the needs of Indian patients. For example, India does not provide mechanisms to notify innovators when follow-on manufacturers are seeking approval of generics or biosimilars during the patent term or to resolve patent disputes before a generic or biosimilar launches in the market. Such mechanisms improve the transparency and coordination of regulatory approvals in the pharmaceutical sector. The government of India should encourage the mandatory registration of new drug applications in a centralized, public database known as the “SUGAM Portal.”

Furthermore, India does not provide protection against the unfair commercial use of undisclosed test or other data submitted to obtain marketing approval for medicines, which hinders the ability of innovative biopharmaceutical companies to conduct clinical trials or launch medicines in India. Restrictive patentability criteria under the India Patents Act also create impermissible hurdles for patenting medicines. In addition, patent grant delays due to repeated filings of pre-grant oppositions and rampant post-grant opposition proceedings compromise the predictability and certainty provided by patents to invest in new treatments and cures. In recent years, countries like Thailand and Israel have taken steps to phase out pre-grant oppositions—reducing patient wait times for the most innovative products. India should take steps to restrict, or eliminate, pre-grant opposition proceedings, as it complements recent initiatives by the government to reduce bureaucracy for the examination and enforcement of patents.

Finally, we note our continued concerns regarding the Department for Promotion of Industry and Internal Trade’s proposed expansion of India’s statutory licensing scheme for television and radio broadcasts (Section 31D of India’s Copyright Act) to include internet transmissions. The proposed expansion of Section 31D would not only violate India’s international obligations—including Articles 10 and 14 of the WIPO Performances and Phonograms Treaty (WPPT)—it would harm the otherwise rapidly growing creative sector of India’s digital economy. It will also make India less competitive as compared to regional competitors like China, where nearly every

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<sup>3</sup> “India and United States Joint Statement on the Trade Policy Forum,” United States Trade Representative, October 20, 2016, <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2016/october/%E2%80%8BIndia-US-Joint-Statement-TPF>.

digital music service provider fairly negotiates and obtains licenses from rights owners. Rather than punish the creative content providers fueling rapid growth in India, DPIIT should retract the memo expanding the scope of Section 31D. We also encourage India to fully implement its obligations under the WIPO Copyright Treaty and WPPT, especially with respect to protection against unlawful circumvention of technological protection measures.

### **Health Industries**

As you know, a major focus of U.S.-India trade discussions since 2017 has been price controls by India on certain medical devices. We are encouraged that earlier this year the National Pharmaceutical Pricing Authority brought six COVID-19 related products (i.e. oxygen concentrators and pulse oximeters) under price regulation in June and July using the Trade Margin Rationalization (TMR) approach. Since the price controls on stents and knee implant systems in 2017, the U.S. medical device industry has advocated for the TMR pricing policy as an alternative to draconian price cuts that do not allow for product differentiation. The U.S. and India should agree to this approach and memorialize this in a joint TPF statement or communique. We would also ask for progress on two concerns that merit quick resolution.

First, India's preferential procurement policies are blocking innovative U.S. pharmaceuticals and medical devices out of the India market, thus harming businesses and workers in the United States, as well as patients in India. Revisions to India's Public Procurement Order 2017 increased local content requirements, forcing procuring authorities to seek exemptions for each product. The changes create preferential access for Indian companies by limiting access for products manufactured by American workers, which could reduce India's supply of emergency therapeutics and medical devices. Exports of health care products to India support many jobs in the United States. The United States and India should work through the TPF to develop procurement policies that ensure fair and mutually beneficial market access.

Second, new pharmaceuticals often face market entry challenges. India's Central Drugs Standard Control Organization (CDSCO) created Rule 101 to facilitate faster entry of life saving products to the Indian market and plug any access-related gaps.<sup>4</sup> Per Rule 101, CDSCO can exempt clinical trials of those products coming from regulated countries, but CDSCO has yet to create the list of such countries. Therefore, therapeutics developed in the United States still face the high cost of duplicative clinical trials before India will consider granting regulatory approval. India should issue such a list quickly to allow Rule 101 to operate properly. This step would not only promote the export of U.S. products to India, but also help India respond to the Covid-19 pandemic.

### **Digital Trade**

In recent years, India has imposed and proposed a series of digital protectionist policies that appear designed to benefit Indian industry at the expense of U.S. companies. This is an important missed opportunity for our bilateral relationship. A collaborative approach to digital trade among

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<sup>4</sup> "The Gazette of India," Government of India Ministry of Health and Family Welfare, March 19, 2019, [https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download\\_file\\_division.jsp?num\\_id=NDI2MQ==](https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NDI2MQ==).

the U.S. and India would expand opportunities for small businesses and entrepreneurs across sectors and in both countries to grow, add jobs, and participate in the global economy.

The renewed TPF should dedicate special attention to the raft of digital protectionist policies imposed or under consideration by the Indian government. Deepening engagement on these issues would build on previous TPF joint statements that have emphasized the importance of digital trade and “promote[d] the digital economy through a free and open internet,”<sup>5</sup> while also aligning with your commitment during your confirmation process to use “a wide range of trade tools to address discriminatory practices that hinder U.S. workers and firms, including practices that discriminate against U.S. digital and technology exports.”

India has promulgated a series of measures that re-emphasize its intentions to impose data localization requirements on foreign companies. mandate the local storage and/or processing of data. India has taken several approaches to mandating local storage and processing requirements through the draft Personal Data Protection Bill, the Non-Personal Data Governance Framework, the draft E-Commerce Policy, and the Reserve Bank of India’s Guidelines on data localization, which explicitly discriminate against foreign companies. In sum, these measures complicate the ability of businesses in the United States representing a variety of sectors to do business in India, increasing the costs and legal complexities of operating in India and negatively impacting the range of services U.S. companies are able to offer in the Indian market.

The TPF provides a venue for a concrete outcome on electronic payment services (EPS), one that commits India to maintain a level playing field and equal treatment for U.S. providers. Notably e-payments were the first sector to be subject to India’s data localization policies when in 2018 the Reserve Bank of India issued guidelines requiring on-shore storage on payments data. Since then, as detailed below, we have seen an expansion of these onshoring requirements across sectors. An outcome on EPS would serve as an early trust-building measure on digital trade, facilitate digital inclusion for small businesses and citizens, and achieve a meaningful market access outcome for American services exporters.

The Telecom Regulatory Authority of India (TRAI) has proposed, and the Department of Telecommunications (DoT) will soon consider, proposed recommendations on a proposed Regulatory Framework for cloud services providers (CSPs), including a proposal for all CSPs to register with a government-controlled trade association or else the provider will be disallowed from providing services. TRAI has recommended that the government oversee this body, including the ability to issue directions, rules and standards, and to cancel registrations of “errant” CSPs. These proposals would create unnecessary and arbitrary restrictions on CSPs’ operations and create the risk of nationalizing CSPs by granting them “critical infrastructure” status.

For digital hardware, India continues to expand barriers, such as indigenous standards, local testing requirements and World Trade Organization (WTO) non-compliant tariffs that discriminate against U.S.-developed and manufactured ICT products. These overlapping barriers appear designed to boost domestic industries and discourage the purchase and use of imported

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<sup>5</sup> “India and United States Joint Statement on the Trade Policy Forum,” United States Trade Representative, October 20, 2016, <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2016/october/%E2%80%8BIndia-US-Joint-Statement-TPF>.

products, reflecting active calls in India to cut imports of ICT equipment to create a neutral trade balance in the category.<sup>6</sup> For example, India is promoting a domestic Indian version of 5G, called “5Gi,” a problematic approach that would limit market access for foreign products but could ultimately serve to isolate India from the larger information and communications technology ecosystem. Other indigenous standards create significant compliance burdens, such as certification under its Trusted Electronics Value Chain (TEVC) scheme, rather than the internationally developed Open Trust Technology Provider Standard. The certification and auditing process under TEVC is both highly burdensome and diverges from international standards.

India also requires that a range of telecommunications and IT products undergo mandatory testing and certification under its Mandatory Testing and Certification of Telecom Equipment (MTCTE) scheme, which is similar to the screening process already required by the Bureau of Indian Standards (BIS). BIS screening is unpredictable and opaque, with procedures that lack defined timelines and often produce costly delays.

Given the national security importance of telecommunications technology, we ask that USTR use the TPF to engage India to address each of the concerns above, and to create a dedicated dialogue to address digital issues. These steps should include eliminating tariffs that do not comply with India’s WTO commitments, resolving concerns related to data localization requirements, restrictions on cloud services providers, working to align domestic standards with international standards, and eliminating problematic local testing requirements. These steps would support businesses and workers in the United States, while also boosting bilateral trade in ICT services and products and boosting the security of our telecommunications networks.

## **Tariffs**

In previous TPFs, India failed to adequately address ongoing concerns with its approach to tariffs. India has long maintained high applied tariffs on a broad range of products, including automobiles, textiles, distilled spirits, pharmaceuticals and rubber and a wide range of agricultural products such as apples, vegetable oils and fruit juices. These high tariffs are particularly problematic in the agriculture sector, where India maintains the highest average agriculture tariffs in the world (averaging 113 percent). Moreover, India regularly uses, and adjusts, tariffs as an industrial policy tool to protect domestic companies in selected industries, such as information technology products, pharmaceuticals and medical devices. It frequently changes tariff duty rates without sufficient interagency or public consultation, harming U.S. exports to the country.

Of particular concern, every year since 2014 India has increased duties on many ICT products, in contravention of its commitments to provide duty-free treatment for many of these products under the Information Technology Agreement (ITA). India now imposes duties of 20 percent on telecommunications switches and base stations, a 20 percent tariff on mobile phones, a 10 percent tariff on certain parts for telecommunications equipment, and a 7.5 percent tariff on parts

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<sup>6</sup> Rathee, Kiran, “India Should Aim for Net Zero Imports of Telecom Equipment by 2022: Trai,” Business Standard, August 3, 2018, [https://www.business-standard.com/article/economy-policy/india-should-aim-for-net-zero-imports-of-telecom-equipment-by-2022-tra-118080400044\\_1.html](https://www.business-standard.com/article/economy-policy/india-should-aim-for-net-zero-imports-of-telecom-equipment-by-2022-tra-118080400044_1.html).

and accessories of test equipment. This year, India increased tariffs on printed circuit board assemblies, camera modules, connectors, and other ICT inputs. These costly and frequently changing tariffs have inhibited the ability of companies in the United States to operate in India. We ask that India commit to reduce these tariffs that harm companies in the United States.

India continues to accelerate its use of tariffs to protect domestic industry and retaliate against other countries. Since 2017, India has increased tariffs on leading U.S. agricultural exports that together total around \$900 million, including almonds, walnuts, cashews, apples, chickpeas, wheat, and peas.<sup>7</sup>In 2020, Prime Minister Narendra Modi announced the “Self-Reliant India” campaign during the country’s Covid-19 lockdown to support business and employment in India. That campaign has spurred a series of actions by different Indian ministries that discriminate against businesses in the United States, including a May 2020 government-wide ban of foreign companies competing for procurement orders under \$27 million<sup>8</sup>and an August 2020 Ministry of Defense announcement that listed 101 items that are prohibited from importation as part of the “self-reliance” movement, creating tariffs on motorcycles, automobiles, and alcoholic beverages of above 50 and as high at 150 percent.

### **Non-Tariff Barriers and Technical Barriers to Trade**

We are also seeing a worrying trend of regulatory processes that lead to preference for companies of Indian origin across multiple sectors, including chemicals, technology, personal care products, medical device, apparel and footwear. Indian government rulemaking often lacks predictability and stability and can lead to approaches that penalize American products. This dynamic has worsened since the start of the global pandemic. India's increasing use of TBTs and lack of GRP suggest an industrial policy based on import substitution that discriminates against U.S. exports and investments and negatively impacts market opportunities for companies and workers in the United States. Additionally, these approaches harm India’s own development, its long-term prospects for domestic manufacturing, and undermines its goals to attract foreign direct investment (FDI) and create jobs. The TPF should focus on the need to minimize technical barriers to trade (TBT) and promote Good Regulatory Practices (GRP). The United States and India should create a framework to bring stability, predictability, and transparency to regulatory procedures across India’s government, with standards across government agencies that enable American engagement, emphasize minimizing trade impact, and incorporate international best practices.

Since the last TPF, The Government of India enacted various quality control orders that have effectively limited imports of U.S.-designed products in sectors such as toys and footwear. For example, the Toys Quality Control Order 2020 requires in-person factory inspections of foreign factories. Since the global pandemic began, India has refused to send inspectors or consider

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<sup>7</sup> Anita Regmi, “Retaliatory Tariffs and U.S. Agriculture,” Congressional Research Service, September 13, 2019, <https://sgp.fas.org/crs/misc/R45903.pdf>

<sup>8</sup> “Businesses including Small and Medium Enterprises,” Government of India, May 13, 2020, <https://cdnbbsr.s3waas.gov.in/s3850af92f8d9903e7a4e0559a98ecc857/uploads/2020/05/2020051717.pdf>; “Govt Notifies Changes in Rules Disallowing Global Tender for Procurement up to Rs 200 cr,” The Economic Times, May 21, 2020, and <https://economictimes.indiatimes.com/news/economy/policy/govt-notifies-changes-in-rules-disallowing-global-tender-for-procurement-up-to-rs-200-cr/articleshow/75867265.cms?from=mdr>.

virtual options or differentiated conformity assessment procedures and has yet to resolve this issue. In combination, these steps have left many businesses in the United States with no way to meet India's conformity assessment requirements, and thus no way to get key products into the market. India should either postpone implementation of these orders until they can resume sending inspectors or permit virtual factory audits, differentiated conformity assessment procedure or third-party audits as an interim solution until physical audits can commence.

In 2019, the Indian Department of Chemicals and Petrochemicals proposed the drafting of mandatory BIS standards for certain chemicals and petrochemicals. A major impact of the proposed change would be a requirement for an annual facility inspection. If made final, the requirement would create administrative hurdles, increase impounding costs and prompt procedural delays, affecting U.S. producers and Indian customers alike. It would also create substantial resource burdens on Indian government bodies, given the uncertainty of travel based on pandemic conditions as well as processing of hundreds of applications every single year. The Government of India should amend the proposal to align with international standards, allow for a "temporary" certification for imports during application period due to likely administrative and resource delays, and extend the certification validity from one year to five years.

U.S. chemical manufacturers are also concerned that the India's proposed chemicals management regime is largely inconsistent and incompatible with U.S. approaches, including a risk-based regulatory approach, and would impose higher upfront compliance costs on both domestic manufacturers and U.S. chemical manufacturers seeking to export to India. We recommend that India conduct a regulatory impact analysis, as recommended by the OECD and World Bank, on proposed chemical regulations before they are finalized. Such an RIA would identify potential unintended consequences, trade-offs, and "surprise" adverse impacts of regulations that must be addressed, and also ensure that proposed regulations will actually achieve their desired objectives. An RIA would both provide the Indian government a more complete perspective on the full extent of the impacts of the draft chemical management rules – including on Indian businesses and consumers -- and make the regulatory process open, transparent, and collaborative. The Indian government should also ensure full alignment with India's international agreements on mutual acceptance of data, as well as an adequate transition period for any such rules to allow industry adequate time to come into compliance. Finally, it should notify proposed rules to the WTO Technical Barriers to Trade Committee, with sufficient time for member states to comment and adequate consideration of those comments. also ensure an adequate transition time

In India, 60 percent edible oil consumed is imported and this year consumers have seen a steep increase in the rates of cooking oils due to price increases globally. Since June 8, 2021, the Food Safety and Standards Authority of India has banned the blending of mustard oil for production of multi-sourced edible vegetable oils. The ban will likely increase consumer prices further and may lead to blending that is unregulated and unlawful manner. The FSSAI should issue guidance that provides for a blending percentage on par with global standards, rather than ban blending overall.

Lastly, we are concerned with the Cosmetics Rules 2020, specifically Chapter III, Rule 17, regarding parallel imports. To ascertain the safety and efficacy of their products, brand owners ensure that their entire supply chain, from the raw ingredients to the point of sale, supports

product safety. These practices include, but are not limited, to good manufacturing practices, good practices for transportation and good practices for storage. Consistent with Indian legal precedent and the Trademark Act of 1999, CDSCO should amend the rule to require that the secondary importer assume responsibility for the products that they place on the market, require information on the product package denoting the product as a parallel import, and subject primary and parallel (or secondary) importers to the same registration requirements

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Thank you for your consideration of these concerns as you prepare for the TPF. We look forward to working with you to support economic opportunity for U.S. workers and companies in India.

Sincerely,

Advanced Medical Technology Association  
(AdvaMed)  
ACT | The App Association  
Biotechnology Innovation Organization (BIO)  
Coalition of Services Industries (CSI)  
Motion Picture Association (MPA)  
National Association of Manufacturers  
(NAM)  
The National Foreign Trade Council (NFTC)  
Pharmaceutical Research and Manufacturers  
of America (PhRMA)  
The Recording Industry Association of  
America (RIAA)

Small Business & Entrepreneurship Council  
(SBE Council)  
The Software and Information Industry  
Association (SIIA)  
The Telecommunications Industry  
Association (TIA)  
United States Chamber of Commerce Global  
Innovation Policy Center (GIPC)  
United States Council for International  
Business (USCIB)