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ELECTRONIC SUBMISSION TO <http://regulations.gov>

Elizabeth L. Kendall
Acting Assistant U.S. Trade Representative for Innovation and Intellectual Property
Office of the United States Trade Representative
600 17th Street NW
Washington, DC 20508

Re: ACTION for Trade Comments on the 2018 Special 301 Review

Dear Ms. Kendall:

The American Creative Technology & Innovative Organizations Network for Trade (“ACTION for Trade”) is a coalition of like-minded business associations and companies that seeks to advance economic growth based on creativity and innovation through the protection of unique intellectual property (“IP”) in the U.S. trade agenda. By bringing creative and innovation-intensive companies together, we aim not only to address the collective concerns of creative and innovation industries, but also to advance an ecosystem in which our members can enhance the value of their creativity- and knowledge-based assets.

With the rise of the creativity- and knowledge-based economy, ACTION for Trade represents the vanguard of the U.S. economy in the global trading system. In these diverse industries—which span audiovisual, music, and literary content development, production, publication, and distribution; biopharmaceutical manufacturing; and technology and software development—companies rely on the strong protection of their IP around the world, new market access opportunities, and fair international trading rules to make their significant contributions to the American economy. Respect for creativity and innovation through the protection of intellectual property rights deserves to be a paramount trade priority given the scale and continued growth of the U.S. innovation economy. This is a premier front for American leadership.

Voters overwhelmingly recognize the importance of American-made innovation and creativity across sectors, especially related to job creation and economic growth. Nearly two-thirds of Americans say U.S. trading partners currently undervalue American innovation. Nearly nine-in-ten Americans agree that continued innovation is important to keep the United States competitive globally and that our economic future is dependent on ensuring the next generation of innovative products is made in America.¹

¹ Morning Consult, National online survey of 1,986 registered voters from January 11–14, 2018.

Overall, IP-intensive industries account for \$6.6 trillion in value added and more than 38 percent of the U.S. GDP. They grew at an aggregate annual rate of 4.81 percent from 2012 to 2015, compared with the average annual growth rate of 2.11 percent for the U.S. economy generally.² IP-intensive manufacturing—including in biopharmaceuticals, semiconductors, computers and electronics, aerospace and transportation—supports more than 57.6 million American jobs, including 20 million directly and another 37.6 million indirectly through robust supply chain activities.³

IP-based industries are also strong export drivers, providing a promising means to address trade imbalances through expanded U.S. exports. At \$88.2 billion, the use of IP accounted for the largest U.S. digital trade surplus of all services categories in 2014, and the second-largest export of such categories at \$130.3 billion, behind only travel services at \$177.7 billion.⁴ As one of the top exporters among U.S. IP-intensive industries, the biopharmaceutical industry's exports reached around \$52 billion as of June 2017.⁵ The U.S. filmed entertainment sector enjoyed a trade surplus of \$16.3 billion in 2014. Meanwhile, copyright-protected audiovisual and related products accounted for U.S. exports valued at \$19.4 billion, with a trade surplus of \$11.7 billion, in 2014.⁶ The ability to license music content also contributed to the U.S. digital services trade surplus, with music companies licensing over 40 million sound recordings to over 360 digital music services worldwide.⁷ Overall, the licensing of intellectual property has consistently contributed positively to the U.S. trade balance.

It is critical for the United States to encourage policies in our trading partners that support our global leadership in innovation. Protecting a healthy, legitimate, and sustainable digital marketplace through trade ensures that the United States maintains its edge in the industry. Failure to curb unfair actions by U.S. trading partners that undermine the time, resources, and efforts that make up the true value of IP could result in loss of U.S. leadership in the new economy. We call on the Trump Administration and on America's trade negotiators to ensure our global trading partners properly protect and reward the innovation and creativity that drive our economic future and foster development of tomorrow's inventions.

² Stephen Siwek, Copyright Industries in the U.S. Economy: The 2016 Report, Economists Incorporated, Prepared for the International Intellectual Property Alliance, 2016, at 2, available at: http://www.iipawebsite.com/copyright_us_economy.html.

³ NDP Analytics, "IP-Intensive Manufacturing Industries: Driving U.S. Economic Growth," Sept. 2017, available at <http://www.ndpanalytics.com/report-ipintensive-industries-drive-economic-growth-2017/>

⁴ CompTIA, "Cyberstates 2016: The definitive state-by-state analysis of the U.S. tech industry," Feb. 2016, at 1, available at: <https://www.comptia.org/docs/default-source/advocacydocs/cyberstates/comptia-cyberstates-2016-vfinal-v2.pdf?sfvrsn=2>.

⁵ PhRMA Comments Regarding Trade Agreement Violations and Abuses, citing PhRMA analysis of U.S. International Trade Commission data, using U.S. domestic exports for North American Industry Classification System (NAICS) Code 3254, as reported at <https://dataweb.usitc.gov> (accessed June 2017).

⁶ Alexis Grimm, "Trends in U.S. Trade in Information and Communications Technology (ICT) Services and in ICT-Enabled Services," Bureau of Economic Analysis, May 24, 2016, at 1, available at <http://www.esa.doc.gov/economic-briefings/new-bea-estimates-international-trade-digitally-enabled-services>.

⁷ International Federation of the Phonographic Industry (IFPI) and Worldwide Independent Network (WIN), "Investing in Music: The Value of Record Companies," 2016, at 14; available at: <https://www.riaa.com/wp-content/uploads/2017/01/ifpi-iim-report-2016.pdf>.

I. ISSUES OF CONCERN

Despite the contribution of innovative and creative content to the U.S. economy, trade priorities have not kept abreast of the evolving needs of the industry. ACTION for Trade's goal is to highlight these issues and ensure they take center stage in the Administration's trade priorities. Issues of critical concern for our members fall into three broad categories: (1) the continued lack of regulatory transparency and due process in our trading partners; (2) lack of sufficient enforcement efforts by other nations; and (3) acts, practices, and policies our trading partners design to discriminate against U.S. companies. We provide examples of these concerns with unfavorable policies in Canada, China, Japan, Korea, Malaysia, and Mexico.

a. Regulatory Transparency & Due Process

Many countries make significant changes to regulations affecting IP and the American creative and innovative industries without industry consultation. Approval and administrative processes may be delayed without explanation. And decisions are applied inconsistently in a non-transparent manner. The lack of predictability acts as a deterrent to U.S. businesses accessing foreign markets, cutting off significant market opportunities and depressing export-dependent U.S. job growth. Moreover, a failure of regulatory transparency and due process ultimately fails to value the innovative content inherent in our members' products.

Legislative and regulatory processes in our trading partners that impact trade should be transparent and provide opportunities for meaningful engagement with creative industries and other stakeholders, including through advanced notice of, and an opportunity to comment on, draft laws, regulations, standards and other measures affecting trade. The ability to appeal such regulations and the completion of the regulatory process in a timely manner are other due process features important to our members. Overall, regulatory processes that are transparent, efficient, and accountable foster greater private sector innovation and investment.

i. Patent Delays and Heightened Criteria

Long patent examination and approval backlogs harm domestic and overseas inventors in every economic sector. Backlogs undermine incentives to innovate, prevent timely patient access to valuable new treatments and cures, and impose huge societal costs. Because the term of a patent begins on the date an application is filed, unreasonable delays in obtaining patents can directly reduce the value of granted patents and undermine investment in future research. For biopharmaceutical companies, patent backlogs can postpone the introduction of new medicines. Backlogs create legal uncertainty for research-based and generic companies alike by increasing the time and cost associated with bringing a new treatment to market.

- Canada: In June 2017, the Canadian Supreme Court struck down the “promise doctrine,” a legal theory of product utility Canada alone had used for years to invalidate over 25 patents on innovative medicines.⁸ ACTION for Trade applauds this decision and encourages the USTR to monitor the implementation of that decision in the actions of lower Canadian courts. However, Canada has several other bureaucratic barriers that create delays between

⁸ See *AstraZeneca Canada v. Apotex*, 2017 SCC 36 (June 30, 2017).

the time an application is submitted and the ultimate availability of the product through public formularies. These barriers include unnecessary extra stages of review by the Patented Medicine Prices Review Board (“PMPRB”), the conduct of health technology assessments, price negotiations through the Pan-Canadian Pharmaceutical Alliance, and the negotiation of product listing agreements with individual public drug plans. These regulatory steps result in significant delays for Canadian patients to access innovative medicines and decrease the time available to innovative companies to recoup their investments.

- Korea: In the Korea-U.S. Free Trade Agreement (“KORUS”), Korea agreed to provide patent term extension to compensate for unreasonable delays experienced by companies when obtaining marketing approval for new drugs. Korea is in violation of this commitment since a recent court decision inexplicably held that patent term extension should apply only to the specific product approved, rather than to the full scope of the patent that protects that product. This decision effectively allows competitors to market variations of the product during the period of extension that would otherwise infringe the innovator’s patent.

ii. Compulsory Licensing

Compulsory licenses should be granted in accordance with international rules and only in exceptional circumstances as a last resort. Unfortunately, some governments have issued compulsory licenses that allow local companies to make, use, sell or import particular patented medicines without the consent of the patent holder, while others have adopted or are considering resolutions, laws and regulations that promote or provide broad discretion to issue such licenses. Studies have shown that compulsory licensing is not an effective way to improve access or achieve other public health objectives, especially in comparison to the many alternatives policy options available, such as drug donation and differential pricing programs, voluntary licensing, and non-assert declarations.⁹ The use of compulsory licenses must therefore be closely monitored and U.S. trading partners must be encouraged to make decisions on public health grounds through fair and transparent procedures that involve participation by all stakeholders.

- Malaysia: Through an opaque process late last year, the Malaysian government has approved and issued a compulsory license for a patented medicine used in state-owned hospitals. The government did not consult industry stakeholders on this unilateral action. Furthermore, the Ministry of Health continues to entertain recommendations from advocacy groups to impose compulsory licenses on additional treatments, which would allow local companies to import, manufacture, sell, and distribute generic versions of patented products. This issuance of the license has already harmed the U.S. manufacturer that was negotiating a voluntary license with the government at the time the compulsory license was issued. Malaysia is using this compulsory license as a means to coerce price reductions and achieve its public health policy on the back of U.S. drug manufacturers. Furthermore, this action carries significant risks of contagion to other markets in that region.

⁹ See, e.g. R.F. Beall et al, Compulsory licensing often did not produce lower prices for antiretrovirals compared to international procurement, Health Aff. 34(3) Health Aff. (Millwood) 493-501 (2015).

iii. Pricing Controls

The extensive upfront, high-risk investments in innovation made by companies in the creative and innovative sectors are enabled by their ability to commercialize the protected products. Appropriately valuing those products through market-based mechanisms, free from restrictions that artificially lower prices, ensures that future investments in new innovation will continue. Harmful policies like reference pricing and ad hoc price cuts are especially prevalent in government regulation of innovative medicines and treatments. For example, current initiatives to update pricing regulations, particularly by Canada to its PMPRB, will only serve to further undervalue innovative U.S. medicines.

When trade partners arbitrarily set prices of innovative medicines, or peg innovative products to older, previous generation products, the incentives for future innovation falter. These tactics, which artificially lower the prices paid for medicines developed in the United States, can be compounded by a lack of transparency and due process. In failing to properly value U.S. innovations, government price controls harm patients, hamper investment in research and development, and put American jobs at risk.

- Canada: Canada is one of the worst actors in this space. Canada's PMPRB seeks to expand its authority to interfere in private sector negotiations and to set Canadian prices by importing bad policies from poorer countries. In June 2017, Health Canada released a consultation document proposing to expand the mandate of the PMPRB from ensuring "non-excessive" prices to ensuring "affordable" prices for pharmaceuticals. Key proposals would amend the basket of reference countries such that prices of patented medicines would be set at the OECD median, introduce various new factors to determine whether a price is "excessive," and require manufacturers to report all indirect price reductions. These changes would have a serious negative impact on U.S. companies operating in Canada. In advance of mandated public consultations on the new draft regulations, PMPRB has already issued a hearing decision against a U.S. company.
- Korea: Korea also fails to properly value innovative medicines despite clear obligations in the KORUS free trade agreement to do so. In particular, the Korean government does not comply with its commitment to "recognize the value of [a] patented pharmaceutical product."¹⁰ The current government sets prices for new medicines based on the weighted average price within that medicine's therapeutic class, a category including off-patent products and generics. As a result, the government artificially depresses the prices of innovative medicines. Since 2010, the Ministry of Health has repeatedly changed its policies on pricing and reimbursement without considering the long-term implications for innovation and market predictability. These policy changes have occasionally targeted particular pharmaceutical companies. Nor does the Korean government comply with its commitment to allow pharmaceutical and medical-device manufacturers to request an independent review of its pricing and reimbursement methods. The Korean government has taken the position that its National Health Insurance Service does not make "determinations," which would be subject to review, rather it merely "negotiates." This interpretation clearly runs counter to the original purpose of independent review.

¹⁰ U.S.-Korea Free Trade Agreement art. 5.2(b) (Mar. 15, 2012).

- Japan: In December 2017, Japan instituted new drug pricing policies which undermine innovation and attempt to skirt the costs of global R&D efforts which benefit Japanese citizens. Specifically, eligibility criteria for the new Price Maintenance Premium (“PMP”) program undervalue the most innovative American pharmaceutical products and treat American products differently from Japanese products. This policy was enacted suddenly and without adequate opportunity for stakeholder input, raising serious questions about the transparency and fairness of reforms.

b. Intellectual Property Right Protection & Enforcement

Protection of trademarks and copyrights are central to a strong innovation economy. To ensure the effectiveness of such protections, ACTION for Trade advocates for strong enforcement, including the availability of injunctive relief and civil and criminal sanctions for infringement of protections. We outline below some of the main issues faced by our members in achieving strong IPR protection and enforcement around the world.

i. Counterfeiting & Piracy

Counterfeiting and commercial piracy cause a significant drain on the U.S. economy, leading to lost sales for legitimate IP owners and lost tax revenues and duties to the U.S. government. This results in decreased U.S. employment and diminishes capital investments in research and development. For example, cyber-crime is projected to cost the global economy some \$2 trillion annually through consumer data breaches, financial breaches, market manipulation, and theft of IP.¹¹ Further, a 2016 OECD study found that international trade in counterfeit and pirated goods represented up to 2.5 percent of world trade, valued at \$461 billion in 2013.¹² In Fiscal Year 2016, U.S. Customs and Border Protection seized over 30,000 shipments—valued at nearly \$1.4 billion—teeming with counterfeit and pirated goods.¹³ This is only a small fraction of the overall volume of counterfeit and pirated goods entering the U.S. market. Counterfeiting and piracy now impact virtually every product and service industry, raising the stakes higher than ever before.

Today, counterfeiters are not only trading in fake luxury goods or unauthorized CDs and DVDs. They are also producing fake foods, beverages, pharmaceuticals, and even defense-related goods like airplane parts. Online piracy and counterfeiting of scientific, technical, and medical (“STM”) journal articles, academic textbooks and reference books is pervasive. The internet is riddled with sites that engage in “stream-ripping,” the unauthorized reproduction and distribution of popular copyrighted music that appears on music streaming services. With supply

¹¹ Juniper Research, “The Future of Cybercrime & Security: Financial and Corporate Threats & Mitigation,” Apr. 2017, available at: <https://www.juniperresearch.com/researchstore/innovation-disruption/cybercrime-security/enterprise-threats-mitigation>.

¹² Trade in Counterfeit and Pirated Goods: Mapping the Economic Impact; Organization for Economic Cooperation and Development and the European Union Intellectual Property Office; April 2016; p.5; available at: <http://www.oecd.org/gov/risk/trade-in-counterfeit-and-pirated-goods-9789264252653-en.htm>.

¹³ U.S. Bureau of Customs and Border Protection, “FY 2016 IPR Seizure Statistics,” Jan. 2017, at 6, available at: https://www.cbp.gov/sites/default/files/assets/documents/2018-Jan/FY2016%20IPR%20Seizure%20Statistics%20Book%20%28PDF%20Formatting%29_OT.pdf.

chains becoming ever more decentralized and with piracy technology developing at such a fast pace, it is important for regulations to catch up to illegal activity.

ACTION for Trade advocates for measures such as protection for encryption technologies through the full implementation of the WIPO Internet Treaties. Moreover, injunctive relief, employed today in over 40 countries, allows countries to disable access to primarily infringing sites and is a critical tool and emerging best practice in Europe and the Asia Pacific region.

- Canada: Canada is home to many intermediaries and facilitators of piracy by third parties, such as domain name registrars, privacy services, and reverse proxy services. For example, Easy DNS is a large Canadian registrar offering services to numerous pirate sites. Stream-ripping sites whose domain names are registered in Canada are also well-trafficked and inflict considerable damage on music producers. Zippyshare.com, a leading source of illicit recorded music, is a major cyberlocker service whose domain name is registered by a Canadian company to a Canadian proxy registration service. The site is ad-supported and has been in operation for more than a decade. The site responds to take-down notifications, but the same infringing content is regularly re-uploaded to the site. The distribution of permanent free downloads from sites like zippyshare.com deprives artists and record companies of streaming revenue by eliminating the need for users to return to licensed services every time they listen to the music. At the same time, these services damage pay-for-download sites like the U.S.-based iTunes, Google Play, and Amazon by offering the tracks for free. The overall popularity of these sites and the staggering volume of traffic they attract is evidence of the enormous damage being inflicted on the U.S. recording industry.
- China:
 - China is a hub for the manufacture and distribution of illicit streaming devices (“ISDs”), media boxes, set-top boxes, and other devices that allow users to stream or download unauthorized content from the internet. These devices and corresponding software programs are fast becoming a significant means through which consumers around the globe access pirated motion picture and television in their homes.
 - Piracy of academic content such as journal articles and textbooks is also a significant problem in China. Several entities continue to host and provide wide scale unauthorized access to scholarly content. These sites rarely act on infringement notifications and the Chinese government has made no improvements to its inadequate online enforcement regime.
 - China has made some positive strides on music piracy since the Sword Net Action in 2015 and subsequent crackdowns on unlicensed platforms and content by the National Copyright Administration of China. In fact, the resulting uptake of licenses by major music services led to 60% growth in music industry revenues in China during 2015-2016. But music piracy has not disappeared and remains dominated by illegal downloads on P2P/file-sharing sites, cyberlockers, and an ecosystem of piracy apps on mobile devices and televisions. Previously pirated content also remains available. While the Sword Net Action had positive benefits, there is little

transparency into ongoing actions. For example, the music industry regularly submits evidence of infringing websites, but there is often no feedback to rights holders about the process.

- Mexico:

- High levels of online piracy continue in Mexico. A large proportion of producers' digital revenue stream has been co-opted by pirate services. According to a 2017 study by the Coalition for the Legal Access to Culture, more than 37 million people consumed pirated music in Mexico in 2016. In 2017, 81 Motion Picture Association of America member films were illicitly recorded in Mexican theaters, placing Mexico as the second largest foreign market for illicit camcording. Satellite and signal piracy also remain concerns in Mexico, along with the use of ISDs. The Mexican government has not adopted any policy or attempted official action against the plethora of locally operated websites, stream ripping sites, P2P sites, or the importation of ISDs. To combat the issue, the Mexican government should adopt measures consistent with the size and urgency of the problem. The appointment of a central authority to coordinate the national response to piracy or the creation of an anti-piracy commission with public and private sector resources would be welcome first steps.
- Mexico also has the highest reach of user-uploaded content platforms for music (i.e., 99 percent of users surveyed), and the largest increase in stream-ripping piracy (predominantly from a single user-uploaded content platform) of any country (i.e., 66 percent growth from 2015 of users surveyed). While Mexico has the highest percentage of music pirate site users of any country (i.e., 71 percent of users surveyed), users in Mexico are among the most likely to turn to user-uploaded content platforms when pirate sites are unavailable. Users in Mexico are also the most likely to turn to stream ripping from a single user-uploaded platform when pirate sites are unavailable.¹⁴

- ii. Traditional Enforcement

Even the strongest protective measures are not effective without the political will and the legal authority to enforce those measures. In many countries, seizures of counterfeit goods at the border remain unacceptably low, and there is often a lack of political will to pursue criminal prosecution of infringers, even in countries with criminal sanctions in place. In other cases, customs authorities simply do not have adequate resources or authority to take effective action against infringing goods. In addition, new challenges brought about by the global economy have made detection and enforcement even more difficult.

For example, with the movement away from brick-and-mortar supply chains towards “direct-to-customer” distribution models, express delivery and international mail have seen considerable growth as a vector for the trafficking of counterfeit goods into the United States. In

¹⁴ IPSOS Connect and IFPI, Music Consumer Insight Report 2017, available at <http://www.ifpi.org/downloads/Music-Consumer-Insight-Report-2016.pdf>

the past, the predominance of large scale cargo shipments meant that a single seizure could serve as a significant deterrent to a counterfeiter. In today's economy, however, small parcel shipping has not only increased the strain on customs enforcement resources, it has also minimized the impact to the counterfeiter. Loss of inventory in small shipments is nominal and unlikely to provide substantial insight into the ultimate scope of the illicit trafficking in which the sender is involved. Because no customs agency has the resources to investigate all small parcels, a system of promoting collaboration between officials and their private-sector counterparts will be essential to identifying and enforcing IP protections at the border.

Another trend deterring detection and interdiction of illicit goods is the use of transshipment to mask the origins of counterfeit products. It is widely understood that production of counterfeit goods is dominated by a handful of countries. In order to avoid the higher level of scrutiny that will inevitably be applied to shipments from those countries, manufacturers will often route shipments through low-risk countries less likely to draw attention from customs authorities. Customs agencies in the countries of transshipment are less likely to take action against illicit goods-in-transit because they are unwilling to take on the costs associated with the storage and destruction of illicit goods that are not intended to enter into commerce in their own territories. However, the nature and complexity of the counterfeit distribution chain demands that countries share the costs associated with illicit traffic and take available opportunities to remove counterfeits from the distribution chain.

The music industry places particular importance on the availability of statutory damages because it is often difficult to prove the number of infringements and to obtain financial records from infringers. Other enforcement priorities for the recorded music industry include the presumption of ownership, a right of information against all intermediaries, and the absence of burdensome requirements to submit evidence into courts, such as notary reports.

- Mexico: It is exceedingly difficult to initiate criminal cases related to copyright infringement in Mexico. Lack of resources and staffing inconsistencies at the public prosecutor's office have made it difficult for copyright holders to enforce their rights. Moreover, though copyright registration is not legally required, the Mexican Attorney General's Office and Mexican courts have adopted practices requiring rights-holders to undertake a time-consuming process to obtain registration certificates before commencing criminal or civil investigations. Further, Mexico's Copyright Law provides that there is no infringement of producers' rights where "no direct economic benefit is sought."¹⁵ Judges have interpreted this provision to mean that there is no violation when the infringer is not selling any product or service to the public, such as on P2P websites, creating a large loophole for infringing parties.
- Japan: ACTION for Trade applauds Japan's efforts to address counterfeiting issues generally, but remains concerned about the scope of Japan's "personal use" exception for the importation of counterfeit goods. As applied in Japan, there is no clear delineation of the volume or value of goods which may be claimed for personal use under this exemption and no limit on the number of times the exception may be invoked. Further, rather than seizing goods, our members are aware of cases in which Japanese Customs released infringing goods

¹⁵ Mex. Copyright Law ch. III, art 151(I).

to the importers after allowing them to remove or mark over counterfeit marks on goods and packaging.

- Malaysia: Inadequate border controls and enforcement remain concerning in Malaysia. Enforcement is generally hampered by the lack of an effective trademark recordation system, lack of adequate staffing, and lack of coordination between Malaysian Customs and the Ministry of Domestic Trade Cooperative and Consumerism (“MDTCC”). When Customs identifies a suspicious consignment of products being imported into the country, they should contact the MDTCC, but this rarely occurs in practice. Even when enforcement actions are taken, prosecutors rarely follow up with appropriate legal action. These policies create a permissive environment in which counterfeiting and piracy can flourish.

iii. Online Enforcement

With the growth of the digital market, online enforcement has emerged both as a growing concern and a significant challenge for rights-holders, particularly in the copyright industries. In many countries, legislation against the sale of illicit goods through the internet lags behind the prominence of the online marketplace. As a result, law enforcement agencies are often reluctant or unable to devote the necessary time and resources to IP-related crimes. It is estimated, for instance, that: there were over 137.3 billion visits globally to websites dedicated to music piracy in 2016; the commercial value of digital piracy in film in 2015 was \$160 billion; and digital piracy in the music industry in 2015 was \$29 billion.¹⁶ There is a critical need to push U.S. trading partners to develop mechanisms to effectively monitor and enforce laws against illicit online activity.

- China: Baidu is the largest search engine in China, with a market share of over 75%. According to IPSOS data, 73% of Baidu users used the search engine to search for free music. Rights holders in the music industry regularly send Baidu a high number of delist requests. Even when Baidu reacts, notified content reappears quickly or immediately. Baidu is becoming prevalent in other markets outside China (e.g. Brazil), thereby expanding the reach of the problem. The recording industry believes Baidu can do more to prevent search results to infringing content and promote licensed content.

iv. Safe Harbor

When safe harbors from liability for copyright infringement were first introduced in the United States and the European Union, they were intended to apply to passive intermediaries such as Internet Service Providers, not to platforms actively engaged in distributing content. ACTION for Trade supports safe harbors as they were originally intended and applied as limited to these passive, neutral intermediaries. However, too many of our trading partners have begun to misapply safe harbor immunities and copyright liability rules far beyond that original intent, thereby harming copyright-intensive industries and the ecosystem for creative content. Such rules have increasingly been used to shield non-passive businesses with safe harbor immunity,

¹⁶ Frontier Economics; The Economic Impacts of Counterfeiting and Piracy, A Report Prepared for BASCAP and INTA; February 2017; pp. 23-39, available at: <http://www.inta.org/Communications/Pages/ImpactStudies.asp>.

putting other digital partners at a massive competitive disadvantage and undermining the stability of the online marketplace.

The misapplication of safe harbor rules has denied copyright holders for music, television, film, and written works the ability to protect their work from infringing activities online. Misapplication also promotes theft of American creative content overseas and fundamentally undermines the ability of U.S. owners of intellectual property to use and profit from their IP rights. Weak copyright protections compound this dynamic. Strong and effective protection and enforcement of copyright is critical to combat the theft of American creativity and to prevent unfair competition from those seeking to profit unjustly at the expense of American creators.

Of utmost concern in this regard are flawed rules that perpetuate the misuse of copyright safe harbors. These rules effectively immunize certain global internet platforms from liability for copyright theft. As a result, the rules of the digital road do not apply to them. Under such safe harbor rules, user uploaded content (“UUC”) platforms have been able to claim that they are not liable for copyright infringing content that they profit from and actively make available to the public. Further, these platforms claim that they are exempt from any requirements to commercially license such content as uploaded to their service by users. This abuse of safe harbor rules results in a structural barrier denying rights-holders the ability to license their material with the largest and most-used UUC services. Moreover, fully-licensed digital services and new market entrants face unfair competition in the marketplace from UUC platforms that have access to music at below-market rates, stifling growth, innovation, competition, and consumer choice.

- Canada: Canadian law conspicuously lacks even a takedown obligation, instead implementing a weaker “notice and notice” system. The absence of a takedown obligation when services are notified or become aware of infringing content gives these services free rein to proliferate on the back of unauthorized content made by American producers. Under this regime, Internet Service Providers have no obligation to track notices and no obligation to escalate enforcement. Canadian law is also a serious obstacle to addressing piracy because infringing content simply remains online. Canada’s steadfast refusal to adopt any legal requirements as a condition for limiting the liability of hosting providers leave it an outlier in the global environment, and substantially diminishes the interests of rights-owners.
- China: The Chinese Regulations regarding the Protection of the Right to Network Dissemination of Information Enforcement provide overbroad safe harbors from liability for copyright infringement. As the result of the apparent abuse of those safe harbor provisions, the streaming of infringing music video content on unlicensed user-uploaded content services has increased dramatically. Reform of such provisions is a top priority for the music industry. In this regard, it has become increasingly critical to amend such provisions to ensure only neutral intermediaries that do not contribute to infringing activities are eligible for such safe harbors.
- Mexico: Mexico lacks key aspects of a strong and effective legal system to combat online piracy, including clear secondary copyright liability rules. Secondary liability provides a critical incentive for online platforms to address infringement and to effectively takedown

infringing content. Moreover, Mexican law does not provide penalties for non-compliance with such notices, even when infringing content is enumerated. Meaningful reform of the Copyright Law (and related laws), especially on digital enforcement issues, has long been stalled.

c. Localization & Discriminatory Treatment

ACTION for Trade’s creative and innovative industries also see the detrimental effects of market access barriers, local content requirements, and other discriminatory treatment that encourages the transfer of U.S. IP to local competitors. Innovative and creative industries are particularly susceptible to acts, practices, and policies abroad that are designed to benefit local producers at the expense of manufacturers and employees in the United States. Localization barriers have become so pervasive that they are now a routine part of many transactions between businesses and governments—from securing patents, regulatory approval, and market entry to the most minor administrative formalities. Localization barriers include market participation or other benefits conditioned on local manufacturing, technology transfer requirements, local testing and certification requirements, and de facto bans on imports, such as licensing requirements that virtually prevent market entry.

Innovative industries often face forced localization requirements that seek to hand U.S. innovative content to local competitors, as well as regulatory delays and barriers that effectively prevent market access and diminish the value of U.S. IP. Market access issues faced by our members typically include duties on, and discriminatory treatment of, digital products; combatting data flow restrictions and server localization while preventing piracy across borders; promoting incentives for creativity, innovation, and legitimate digital growth, including with respect to streaming; ensuring freedom of contract; tackling investment and cross-border services limitations, including ensuring market access for cultural industries; advancing digital security and development of online payment systems; and promoting transparency and meaningful engagement with stakeholders in government processes.

- China:
 - China has several data localization policies that promote or force technology transfers to local competitors. For example, the Online Publishing Service Management Rules require that all servers used for online publishing in China be located within China. The Cyber Security Law contains broad requirements for local processing and storage of “important data.” And the Technology Import and Export Regulations incentivize the transfer of IP to local competitors with significant restrictions on the freedom of contract and remedies for breach.
 - When China joined the WTO, it agreed to provide a six-year period of regulatory data protection for undisclosed test or other data submitted to obtain approval for pharmaceuticals. While China’s Drug Administration Law does establish such a six-year period, in practice, the law is ambiguous and inconsistently applied. As a result, China’s regulatory environment allows local producers to make unfair use of safety and efficacy data generated by U.S. companies.

- Japan: Several elements of Japan's new PMP policy appear biased towards local companies. For example, the criteria for selecting companies who can benefit from full price stability include factors such as participation in clinical trials in Japan and how many products a company launches in Japan.

- Antitrust Investigations as a Technology Transfer Tool

A worrisome trend is the use of antitrust investigations by governments in an effort to undermine the rights of U.S. patent holders by transferring U.S. patented technology to domestic companies, to insulate domestic companies from competition from U.S. businesses, or to lower the prices U.S. companies can command to license their inventions. These investigations, which are particularly prevalent in the United States' Asian trading partners, are all the more problematic as they often lack due process protections and procedural fairness, sometimes resulting in discriminatory and extraterritorial remedies. Defending against foreign enforcement action is also extremely disruptive to businesses, hampering the ability of defendants in such investigations to conduct businesses overseas freely.

These investigations not only undermine U.S. patent rights, suppress innovation, and put U.S. competitiveness at risk, but they also potentially violate the terms of certain U.S. trade agreements. It is imperative that the United States fully utilize trade and investment negotiations and strongly enforce international remedies as provided under its trade laws to protect U.S. companies from discriminatory practices in the guise of legitimate regulatory authority.

In conclusion, ACTION for Trade seeks to work with the Office of the U.S. Trade Representative to address these critical concerns of the U.S. innovative and creative industries. We look forward to USTR action on the continued lack of regulatory transparency and due process in our trading partners, the lack of sufficient enforcement efforts by other nations, and acts, practices, and policies our trading partners design to discriminate against U.S. companies. We encourage USTR to focus efforts on Canada, China, Japan, Korea, Malaysia, and Mexico. Such actions will ensure continued U.S. leadership in creativity and innovation, contribute to trade surpluses, and support the growth of U.S. jobs and the U.S. economy.