ACTION for Trade Position Paper

The American Creative Technologies & Innovative Organizations Network for Trade (“ACTION for Trade”) is a coalition of like-minded business associations and companies that seeks to advance content- and creativity-based growth and protect innovation and unique intellectual property (“IP”) in the U.S. trade agenda. Taking advantage of the U.S. position as the world leader in international trade, we seek also to influence the global trade regime, spearhead international standards, open new markets, ensure that innovation and creativity are rewarded, and protect the creative assets of our members in the United States and overseas.

ACTION for Trade was conceived because we believe respect for creative content and innovation deserves to be a paramount trade priority, particularly given the scale and continued growth of U.S. creative and innovative industries. Trade Promotion Authority contains important provisions directing that trade agreements include commitments on intellectual property, digital trade, and regulatory practices, but policy makers often struggle to reduce the economic impact of creative and innovative industries into quantifiable trade effects that they can easily conceptualize. That leads some to think of trade as only involving tangible goods, and to discount the utility of establishing rules to foster a pro-innovation environment that can lead to the creation of innumerable U.S. jobs. Recognizing the work that existing advocacy groups have done and continue to do to raise the profile of issues such as intellectual property (“IP”) rights, ACTION for Trade seeks to complement and supplement these efforts through a government outreach strategy that focuses on cross-cutting issues that affect the broader creative and innovative industries, while educating policy makers about the enormous impact these industries have on U.S. and global economic growth and job creation.

Through these efforts, we aim to enhance the Administration’s appreciation of the creative content and innovation economy as a premier front for American leadership. This, in turn, must translate into concrete trade policies that demand respect and protection for our creative and innovative assets and their owners.

I. CREATIVE AND INNOVATIVE INDUSTRIES IN THE 21ST CENTURY NEW ECONOMY

The trade environment is changing. While international trade has traditionally focused on market access and lowering tariffs for the exchange of goods and services, an increasing proportion of the global economy is taking the shape of intangible assets such as creative and innovative work product, intellectual property, and knowledge. Even with respect to manufactured goods, a large portion of the value-added is in the form of brand and character recognition, or technology, R&D, software, and other innovation embedded into the functionality of products. Digital trade has also become a critical feature of the U.S. economy, fueled by the creative and innovative industries. The development of a content- and knowledge-based
The economy has created cross-cutting issues that are not easily addressed through a traditional trade model that focuses solely on restrictive categories of commodity goods.

The value of creative content and innovation is nowhere better exemplified than in the United States, where innovation- and creativity-based industries are growing at a rapid pace, both in importance and prevalence in the U.S. economy. For example, in the United States, copyright-intensive industries contributed $1.2 trillion to the U.S. economy in 2015, and grew at an aggregate annual rate of 4.81 percent from 2012 to 2015, compared with average annual growth rate of 2.11 percent for the U.S. economy generally.¹

On a sector-specific basis, the U.S. biopharmaceutical sector produced over $1.3 trillion in economic output for the United States, and invested almost $65.5 billion in researching and developing new medicines in 2016 alone.² The U.S. film industry posted $10.3 billion in revenues in 2015, and in addition to the steady growth in traditional box office receipts, streaming of video content grew by 15 percent in 2015.³ Meanwhile, the U.S. recording industry continues to record growth, with revenues reaching $15 billion in 2015. In particular, music subscription streaming services have seen dramatic growth, with revenue (including ad-supported “freemium” revenue) growing 58.9 percent in 2015. It is estimated that in 2015, 68 million consumers around the world paid for music subscription services, up from 41 million in 2014, and eight million when data was first collected in 2010.⁴

Creative and innovative based industries are also the greatest job creators in the United States, including jobs in the manufacturing industry. IP-intensive manufacturing industries (including biopharmaceuticals, semiconductors, computers and electronics, aerospace and transportation) support more than 57.6 million American jobs – 20 million directly and another 37.6 million indirectly through robust supply chain activities.⁵ As of 2016, the U.S. technology industry employs more than 6.7 million people.⁶ The IP-intensive manufacturing industry is also recording faster job growth than any other industry. During the most recent economic recovery period, jobs in IP-intensive manufacturing industries grew more than in non-IP-intensive manufacturing industries, i.e., 7.2 percent compared to 6.7 percent. In 2015 alone, 200,000 jobs were added to the technology sector, representing the fifth consecutive years of growth in that industry.

⁵ [Forthcoming report on IP intensive industries and related manufacturing jobs.]
In addition to creating more jobs, workers in creative and innovative industries receive higher wages. Wages of workers in IP-intensive manufacturing industries, for example, are more than 45 percent higher than those in non-IP-intensive manufacturing industries, i.e., $67,378 compared to $46,248 per employee annually. Further, IP-intensive manufacturing industries contribute to the U.S. economy at higher rates than other industries, generating 1.4 times the output per employee as non-IP-intensive manufacturing industries, on average. And productivity is growing – output per employee in IP-intensive manufacturing industries grew more than two times faster than that of non-IP-intensive manufacturing industries between 2008 and 2015.

Creative and innovative based industries are also strong export drivers, providing a promising means to address trade imbalances through expanded U.S. exports. The use of IP rights accounted for the largest U.S. digital trade surplus of all services categories ($88.2 billion) in 2014, and the second-largest export of such categories ($130.3 billion), behind travel services (i.e., $177.7 billion). From 1999-2014, U.S. services exports with respect to the use of IP grew from $47.7 billion to $130.4 billion, which was among the largest increases of the information and communications technology ("ICT")-enabled services export categories over the course of this period. During the period from 2006-2014, services related to the use of IP rights experienced an annual growth rate of 6.7 percent.

As one of the top exporters among U.S. innovative industries, the biopharmaceutical industry’s exports reached around $52 billion as of June 2017. The U.S. filmed entertainment sector enjoyed a trade surplus of $16.3 billion in 2014. Meanwhile, the use of copyrights with respect to audio-visual and related products accounted for U.S. exports valued at $19.4 billion, with a trade surplus of $11.7 billion, in 2014. The ability to license music content also contribute to the U.S. digital services trade surplus, with music companies licensing over 40 million sound recordings to over 360 digital music services worldwide. Overall, the licensing of intellectual property has consistently contributed positively to the U.S. trade balance, including a surplus of $78 billion in 2016.

The innovation of American companies, across all product sectors, serves as a foundation for what has become one of many companies’ most valuable assets – their trademarks. In a recent report, American brands accounted for over half of the world’s 100 most valuable

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7 [Forthcoming report on IP intensive industries and related manufacturing jobs.]
8 CompTIA at 1.
9 CompTIA at 4, 6.
brands. The eight American brands ranking in the top ten, alone, are valued at over $625 billion.\textsuperscript{14} For consumers around the world, America brands are synonymous with high-quality products. It should come as no shock then that those same brands are under attack by copycats and fraudsters seeking to unfairly trade on that reputation by dumping cheap knock-offs on consumers around the world. It should also be readily apparent that our continued economic competitiveness is largely reliant on ensuring that the global trading system, and our partners in it, demonstrate a commitment to protecting and enforcing the intellectual property rights the fuel innovation both here and abroad.

II. OPPORTUNITIES

As demonstrated through these numbers, creative and innovative industries are the economic drivers of the future. They are the largest growing contributors to the U.S. economy, exports and trade surplus, jobs, and wages. Importantly, the United States has maintained a leadership position in this field.

The dominant position of the United States in these industries provides an opportunity for American leadership in the global economy. In particular, the ongoing NAFTA modernization talks offer a pivotal opportunity for United States to impact trade policy in a way that recognizes the importance of American creativity and innovation to long-term economic sustainability. The modernization talks cannot be more timely. More than ever, the creative and innovative economy is contributing to U.S. economic growth, the trade surplus, and the creation of American jobs. Now is an opportune time to educate decision-makers and working-level staff members so that they understand how to conceptualize the issues affecting our members and how to formulate a viable solution.

Even aside from the broader trade impacts that stem from updated trade relations among the North American countries, the new NAFTA will set the benchmark for all future trade agreements that will be negotiated and renegotiated under this Administration. Therefore, it is imperative that the United States take advantage of this opportunity to embed the principles of respecting creativity and innovation and protecting the fair value of IP into all U.S. trade agreements.

With the most robust creative and innovative industries in the world, protecting a healthy, legitimate, and sustainable marketplace through trade agreements ensures that the United States maintains its global lead in these industries. On the other hand, losing out on this opportunity can have grave effects for these industries. While U.S. dominance in this field is presently unchallenged, failure to curb unfair actions by U.S. trading partners that undermine the time, resources, and efforts that make up the true value of creativity and innovation could result in loss of U.S. leadership in the new economy.

III. ISSUES AFFECTING CREATIVE AND INNOVATIVE INDUSTRIES

As the economy changes, the issues facing the economy also change. Despite the contribution of innovation and creative content to the U.S. economy, trade priorities have not

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\textsuperscript{14} Id.
kept pace with the evolving needs of these industries. ACTION for Trade’s goal is to highlight these issues and ensure that they take center stage in the Administration’s trade priorities.

A. CROSS-INDUSTRY ISSUES

1. Regulatory Transparency and Due Process

   In many countries, regulations affecting innovation and creative content are significantly changed without the benefit of consultations with the affected industries, approval and administrative processes are often delayed without explanation, and government decisions are applied inconsistently in a non-transparent manner in ways that impacts the prices of innovators’ products. 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 allow innovators to obtain the full value of the innovative content inherent in our members’ products.

   Transparency and the rule of law are inextricably linked, and this is no different in the digital environment. Legislative and regulatory processes of our trading partners that impact digital trade should be transparent and provide opportunities for meaningful engagement with creative and innovative industries and other stakeholders, including through advanced notice of, and an opportunity to comment on, draft laws, regulations, standards and other measures affecting digital trade.

2. Localization Requirements

   Creative and innovative industries are particularly susceptible to acts, policies and practices abroad that are designed to benefit local producers at the expense of manufacturers and employees in the United States and elsewhere around the world. These 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, in-country medicine trial requirements, technology transfer requirements, local testing and certification requirements, and de facto bans on imports, such as licensing requirements that virtually prevent market entry.

3. Properly Valuing Innovation

   Foreign governments deploy a number of tactics to artificially lower the prices paid for medicines developed in the United States rather than allowing markets to determine their value. These practices are often 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 good American jobs at risk. Congress recognized this threat in the most recent Trade Promotion Authority text, calling for U.S. negotiators to tackle the problem. In Canada, for example, the Patented Medicine Prices Review Board seeks to expand its authority to interfere in private sector negotiations and to set Canadian prices by importing bad policies from poorer countries. NAFTA negotiations will provide a critical opportunity to address this dynamic. In addition, Korea fails to properly value innovative medicines despite a
clear FTA obligation to do so. We must seek to enforce these hard-fought rules with our trading partners to ensure a level playing field.

Another 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. In essence, foreign governments are using antitrust as a price control mechanism. These investigations, which are particularly prevalent in 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.

4. IPR Protection and Enforcement

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

- **Counterfeiting and Piracy.** Counterfeiting causes a significant drain on the U.S. and global economy, leading to lost sales to legitimate manufacturers, tax revenues and duties that go unpaid to governments, decreased U.S. employment, and diminished investment in capital improvements and research and development. In Fiscal Year 2016, U.S. Customs and Border Protection seized over 30,000 shipments, valued at nearly $1.4 billion, of counterfeit and pirated goods entering the country. Such seizures are widely regarded though as accounting for only a small fraction of the overall volume of counterfeit and pirated goods entering the domestic 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, but are producing fake foods and beverages, pharmaceuticals, and even defense-related goods like airplane parts. The production and distribution of goods produced in an entirely unregulated supply chain, where the makers

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are incentivized to cut corners by using cheap, substandard components, and no incentive to abide by accepted standards of consumer health and safety, presents a clear threat to the health and well-being of consumers, and to the integrity of our national security infrastructure.

- **Supply Chain Management.** The growth of sophisticated logistics networks and information sharing through data networks and the internet has increased the number and role of intermediaries in the supply chain. These trends have created significant challenges for rights-holders in managing and protecting against infringements that could occur anywhere within their complicated supply chains. It is therefore important to establish practices and principles to enable both policymakers and rights holders to identify the intermediaries involved in the supply chain, understand how these supply chains can be infiltrated, document steps being taken to prevent infiltration, and develop steps to curb abuse of intermediaries through effective enforcement.

- **New Challenges in Enforcement Efforts.** Even the strongest protective measures are not effective without the political will and the legal authority to enforce these protections. 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 the countries where criminal sanctions are in place. In other cases, customs authorities simply do not have adequate 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 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, shipping via small parcels has not only increased the strain on customs enforcement resources, but also minimizes the impact to the counterfeiter because any loss of inventory is nominal and unlikely to provide substantial insight into the ultimate scope of volume of the illicit trafficking in which the sender is involved. No customs agency has the resources to investigate all small parcels, and a system of promoting collaboration between officials and their counterparts in the private sector will be essential to identifying and enforcing IP protections at the border.

Another trend that is 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 the shipments through low-risk countries that are less likely to draw attention from customs authorities. Customs agencies in the countries of transshipment are often less likely to take action against illicit goods-in-transit simply 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. The nature and complexity of the counterfeit distribution chain demands that
countries that are serious about addressing the problem share the burdens associated with that illicit traffic, and that they take necessary steps to remove counterfeits from the distribution chain when the opportunity presents itself.

- **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. In many countries, legislation against the sale of illicit goods through the internet lags behind the prominence of the online marketplace, and as a result, law enforcement agencies are often reluctant or unable to devote the necessary time and resources to IP-related matters. Therefore, there is a critical need to push trading partners to develop mechanisms to effectively monitor and enforce actions against illicit online activity.

5. **Market Access**

Market access barriers can impose significant negative impacts on digital trade. U.S. trade policy must be updated to focus on market access opportunities and challenges in creative and innovative based industries. These market access issues 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. Innovative industries face forced localization requirements which seek to hand U.S. innovative content to local competitors as well as regulatory delays and barriers which effectively prevent market access and diminish the value of U.S. IP.

6. **Security Concerns**

Where the Internet is not secure, digital trade cannot thrive. Protecting the digital environment against cybercrime should remain a key priority, including ensuring that the policies and measures of our trading partners provide security that safeguards privacy, promotes trust, and fosters creativity. Such disciplines should include prohibitions against circumventing access controls (i.e., technological protections measures, or “TPMs”), and manufacturing, importing, offering to the public, providing, or otherwise trafficking in such TPM circumvention devices.

**B. FILM INDUSTRY**

The U.S. motion picture and television industry is a major U.S. employer that supported two million American jobs and $134 billion in total wages in 2015. The industry is comprised of a nationwide network of small businesses, with nearly 88,000 businesses in total located in every state. While some of these businesses may not directly conduct business internationally, with 70 percent of global box office and a growing share of TV revenues coming from overseas markets, their success relies on a healthy and fair global marketplace. We highlight below the main unfair practices that are depriving the film industry of the full value of its creative content and IP.
1. **Online Piracy**

Piracy remains a persistent and growing threat to the media and entertainment industry. It is the most significant impediment to the ability of U.S. media and entertainment businesses to fully tap the potential of the U.S. and global marketplace. With piracy technology developing at a fast pace, it is important for regulations to catch up to such illegal activity. Therefore, ACTION for Trade advocates for measures such as protection for encryption technologies through the full implementation of the WIPO Internet treaties, to help ensure a hospitable legal framework for the technologies that enable diverse online offerings to consumers. 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 Asia Pacific. Such laws and regulations are imperative to facilitating the growth of the legitimate online marketplace.

2. **Pay-Television Piracy**

The unauthorized broadcast, cablecast or satellite delivery of films and television content, including the unauthorized retransmission of broadcast signals over the Internet, is a significant impediment to the legitimate pay-television market. Related problems include operators who take cable and satellite signals by unauthorized means, such as hacked set top boxes, decoding or decrypting signals, or stealing “overspill” signals from neighboring countries, and sell them to consumers without paying for any of the content. The latter remains a severe problem in several countries in the Caribbean and Central and South America, as well as in Egypt, UAE, Indonesia, and India.

ACTION for Trade believes that regulations and enforcement should focus on prohibiting the trafficking in pay-TV or signal theft devices or technologies, the unlawful decryption of encrypted cable or satellite signals, and the onward use of the signals already decrypted – whether lawfully or not – without the authorization of the rights holders of the content or of the signal. Such laws can help foster licensing of broadcasters and cablecasters and weed out unlicensed television distributors.

3. **Illicit Streaming Devices**

Illicit streaming devices (“ISDs”) are media boxes, set-top boxes or other devices that allow users to stream or download unauthorized content from the internet. These devices and corresponding software programs take many forms but have common features, and they are fast becoming a significant means through which pirated motion picture and television content is accessed in consumers’ homes in markets around the world. China is a hub for the manufacture of these devices, which are not only distributed domestically but also exported overseas. ISDs have proliferated worldwide.

4. **Unauthorized Camcording**

Approximately 90 percent of newly released movies that are pirated can be traced to the unauthorized use of a digital recording device in a movie theater to record the film, whether image, sound or both). One digital copy uploaded to the internet impacts the lifecycle of a film, including
the pay-TV and over-the-top segments, and can undermine global markets and the huge investments needed to produce and distribute a feature film.

A multifaceted approach is needed to tackle this problem, including enacting and enforcing anti-camcording legislation to outlaw the use or attempted use of an audiovisual recording device in a theater to make or transmit a copy of all or part of a motion picture, educating the public about how unauthorized camcording hurts both consumers, employees, and businesses, and working with the private sector to identify and prevent unauthorized camcording in cinemas. This strategy has been implemented with good results in many foreign markets, including Canada, Japan, and Korea.

5. Censorship

In some territories around the world, such as China, censorship regimes remain opaque, unpredictable and slow, often resulting in de facto discrimination against foreign content. ACTION for Trade seeks to encourage countries utilizing censorship regimes to shift to industry self-regulation and classification in line with international best practices. Barring that, countries should ensure that their content regulation regimes are transparent, consistent, and expeditious, and ensure equal treatment of all content, regardless of origin.

6. Quotas

Content quotas are imposed by governments on different segments of a film’s lifecycle and on television programs. Examples include screen quotas in the theatrical window and broadcasting and video-on-demand quotas in the television window. Governments are also exploring quotas for the online marketplace. Screen quotas, regardless of form, ignore market demands and stifle development of a country’s theatrical market.

7. Advertising restrictions

Advertising restrictions manifest as either limitations or bans on advertising minutes, as “made-in” mandates, or both. For example, Indonesia’s 2005 Broadcasting law includes a “Made-in-Indonesia” requirement for advertising, including for pay-TV. The Indonesian government is currently considering how to implement those rules. In Russia, legislation enacted in January 2015 bans advertising on pay and scrambled signal channels, significantly impacting cable and on-demand services, including those operated by U.S. companies. Argentina, Korea and Mexico also impose restrictions on advertising. Such restrictions curb growth of the pay-TV sector by creating barriers to new channels wishing to enter the market resulting in higher fees for pay-TV consumers because of the decrease in broadcasters' advertising income.

C. MUSIC INDUSTRY

With its platform moving from physical mediums to a digital marketplace, protecting the value of original content and IP has become critically important to the music industry. However, several trade barriers impede the ability of the music industry to unlock the full potential of the global digital economy. We identify below the key barriers that significantly impede digital trade for the music industry.
1. Copyright Protection and Enforcement

As stated above, IP protection and enforcement, including copyright protection and enforcement, is a vital common issue to most, if not all, IP-intensive and creative industries. The music industry in particular relies on copyright protection for sound recordings, including as digital products, to be licensed as a digital service. Several rights are critical for the continued growth and viability of the global digital music market. These rights include full exclusive communication to the public and broadcasting rights rather than remuneration rights, exclusive “making available” rights, and strong protection against circumvention of TPMs that are used to protect access to copyrighted sound recordings.

Strong copyright protection must be accompanied by robust enforcement, particularly in the digital environment. First, a strong copyright enforcement framework is predicated upon clear legal basis for liability, including both primary and secondary liability. Second, remedies for copyright infringement should include injunctions and damages, covering foreign infringing websites. The music industry places particular importance on the availability of statutory damages given the difficulties in proving numbers of infringements or obtaining 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, e.g., no notary reports required.

2. Overbroad Internet Service Provider (ISP) Safe Harbors with respect to Copyright Infringement

Overbroad ISP safe harbors for copyright infringement impose a monumental impediment on the digital music economy, both in the United States and as exported into U.S. trading partners. Such overbroad safe harbors exempt a dominant incumbent video streaming service from requirements to commercially license the music uploaded by users to that service. This exemption results in a massive structural barrier to global digital music trade by denying right holders the ability to commercially license their copyrights with the largest and most-used global music services. Abuse of safe harbor rules result in an unfair negotiating situation that allows services to take an “act first, negotiate later” approach, fundamentally distorting copyright licensing. This leaves copyright holders to rely on an ineffective “notice and takedown” system. Moreover, the availability of music generates substantial value for large technology companies that do not translate to fair reward to copyright holders for their work. Finally, fully licensed digital services and new market entrants face unfair competition in the marketplace from services that have access to music at below-market rates, stifling growth, innovation, competition, and consumer choice.

3. Overbroad Application of Copyright Exceptions and Limitations

Copyright exceptions and limitations must be premised on strong copyright protections and limited application, as well as a well-established intellectual property rights system, and a strong mechanism for the enforcement of such rights. Frequently, however, these exceptions threaten to swallow the rule – in terms of the law and practice of some U.S. trading partners – to the detriment not only of the U.S. music industry and creative industries, generally, but also of creators in those economies. In turn, these developments impose profound and negative
systemic impacts on the digital potential of that country to drive economic growth and development as well as on the legitimacy and sustainability of global digital trade as a whole.

This makes efforts to export exceptions and limitations that exist under U.S. law, such as the American fair use exception, particularly troubling. To protect against such harms, the United States should defend the “three step process” that has long been established as a bedrock principle of copyright protection and is consistent with U.S. law, and oppose over-broad exceptions by trading partners.

4. Copyright Piracy and Illegal TPM Circumvention

Online copyright piracy continues to impose a massive distortive impact on legitimate and sustainable digital commerce. Combating piracy is both critical to protecting the digitally-intensive U.S. creative sector as well as vital to securing the long-term viability of the global digital economy.

A major development in the music copyright infringement world has been the emergence of sites that engage in the unauthorized reproduction and distribution of the popular copyrighted music that appears on music streaming services. These illegal sites violate the terms of use of these services and circumvent the technological protection measures that such services employ to prevent copying and distribution of music streamed through their service. These stream-ripping sites allow free downloads of music files copied from streaming services and monetize their infringing activity through advertising.

The distribution of permanent downloads of files from streaming services 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 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.

D. BIOPHARMACEUTICAL INDUSTRY

The United States has the most innovative biopharmaceutical industry in the world. However, unfair practices by trading partners stifle innovation by depriving U.S. businesses of the full value of their efforts. We highlight below unfair practices that undermine biopharmaceutical innovation.

1. Restrictive Patentability Criteria

To bring valuable new medicines to patients, biopharmaceutical innovators must be able to secure patents on all inventions that are new, involve an inventive step, and are capable of industrial application, as World Trade Organization rules require. National laws, regulations, or judicial decisions that prohibit patents on certain types of biopharmaceutical inventions or impose additional or heightened patentability criteria restrict patient access to valuable new medicines and undermine investment in future treatments and cures. These restrictions prevent innovators from building on prior knowledge to develop valuable new and improved treatments.
that can improve health outcomes and reduce costs by making it easier for patients to take medicines and by improving patient adherence to prescribed therapies.

2. **Patent Backlogs**

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 getting a patent 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. They create legal uncertainty for research-based and generic companies alike, and can increase the time and cost associated with bringing a new treatment to market.

3. **Localization Barriers**

Like businesses in many other sectors of the U.S. economy, the innovative biopharmaceutical industry is witnessing a proliferation of acts, policies, and practices abroad that are designed to benefit local producers at the expense of manufacturers and their employees in the United States and elsewhere around the world. These practices include conditioning market access on local manufacturing or other anticompetitive practices, importation rules that require transfer of sensitive intellectual property to domestic competitors, and exploitation of manufacturing licensing requirements that result in *de facto* bans on imports from biopharmaceutical innovators in the U.S.

4. **Weak Patent Enforcement**

To continue to invest in the research and development of new medicines, biopharmaceutical innovators must be able to effectively enforce patents. Mechanisms such as patent linkage that provide for the early resolution of patent disputes before potentially infringing follow-on products enter a market are essential for effective enforcement. The premature launch of a product that is later found to infringe a patent may disrupt patient treatment and require governments to adjust and re-adjust national formularies and reimbursement policies. For biopharmaceutical innovators, it may cause commercial damage that is impossible to repair later.

At a minimum, effective early resolution mechanisms would: (1) require governments to notify the holder of a patent on a biopharmaceutical product if another party applies for marketing approval for a generic or biosimilar versions of that product; (2) enable the holder of a patent on a biopharmaceutical product to seek provisional enforcement measures, such as a stay, preliminary injunction, or interlocutory injunction, to prevent the marketing of a potentially infringing generic or biosimilar version of that product; and (3) provide for the timely resolution of patent disputes before marketing approval is granted for a generic or biosimilar medicine.

5. **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. In particular, 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. 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.

6. Regulatory Data Protection Failures

Regulatory data protection (“RDP”) complements patents on innovative medicines. By providing temporary protection for the comprehensive package of information biopharmaceutical innovators must submit to regulatory authorities to demonstrate the safety and efficacy of a medicine for marketing approval, RDP provides critical incentives for investment in new treatments and cures.

RDP is particularly critical for biologic medicines, which may not be adequately protected by patents alone. Made using living organisms, biologics are so complex that it is possible for others to produce a version – or “biosimilar” – of a medicine that may not be covered within the scope of the innovator’s patent. For this reason and others, U.S. law provides twelve years of RDP for biologics. This was not an arbitrary number, but rather the result of careful consideration and considerable research on the incentives necessary to ensure biopharmaceutical innovators and the associated global scientific ecosystem are able to sustainably pursue groundbreaking biomedical research.

Unfortunately, many U.S. trading partners do not provide RDP. This is contrary to WTO rules, which require parties to protect regulatory test data submitted as a condition of obtaining marketing approval against both disclosure and unfair commercial use.

IV. CONCLUSION

The United States is unmatched as the world leader in creative and innovative industries, but U.S. exporters in these industries face a variety of trade barriers in the form of rules, regulations, and official government action that reduce their exports and hinder their ability to create jobs here at home. ACTION for Trade stands ready to represent its members in seeking strong progressive trade policies that protect the value of their original content, innovation, and IP in markets around the world.