

Submission of the International AntiCounterfeiting Coalition to the United States Trade Representative

2021 Special 301 Review
Identification of Countries
Under Section 182 of the
Trade Act of 1974
Request for Public Comment
85 FR 81263 - 64 (December 15, 2020)

January 28, 2021

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INTRODUCTION

The International AntiCounterfeiting Coalition, Inc. ("IACC"), is pleased to submit these recommendations to the Office of the United States Trade Representative ("USTR"), pursuant to the request published in the Federal Register on December 15, 2020, seeking written comments from the public concerning the acts, policies, and practices of foreign countries relevant to the determination by the USTR, in cooperation with its interagency partners in the Special 301 review ("Special 301"), under Section 182 of the Omnibus Trade and Competitiveness Act of 1988, 19 USC § 2242, of countries that deny adequate and effective protection of intellectual property rights ("IPR") or deny fair and equitable market access to U.S. persons who rely on intellectual property protection.

The IACC is the world's oldest and largest organization dedicated exclusively to combating trademark counterfeiting and copyright piracy. Founded in 1979, and based in Washington, D.C., the IACC represents more than 200 corporations, trade associations, and professional firms, spanning a broad cross-section of industries. IACC members include many of the world's best-known brands in the apparel, automotive, electronics, entertainment, luxury goods, pharmaceutical, software, and other consumer product sectors.

Central to the IACC's mission is the education of both the general public and policy makers regarding the severity and scope of the harms caused by intellectual property crimes – not only to legitimate manufacturers and retailers, but also to consumers and governments worldwide. The IACC seeks to address these threats by promoting the adoption of legislative and regulatory regimes to effectively protect intellectual property rights, and to encourage the application of resources sufficient to implement and enforce those regimes.

To that end, the IACC worked with both foreign government officials and the private sector throughout the past year to identify, and to seek remedies to, legislative deficiencies and practical impediments to IP enforcement. The IACC has also led the development of voluntary collaborative programs on a global scale to address key priorities in the online space, including its RogueBlock and IACC MarketSafe programs. The role of governments in encouraging these types of collaborative approaches remains vital. Further, rights-holders continue to face concerns that require direct intervention by governments at home and abroad. These challenges continue to evolve, and we welcome the assistance of the U.S. government in resolving both the new concerns highlighted in this year's comments, and those which have been reported in past years' submissions.

Whether measured in terms of lost sales to legitimate manufacturers, tax revenues and duties that go unpaid to governments, decreased employment, or diminished investment in capital improvements and research and development; counterfeiting is a significant drain on the U.S. and global economy. Further, the production and distribution of goods manufactured in an entirely unregulated supply chain, where the makers have every incentive 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. We look forward to working with you to ensure the safety of consumers and the vitality of legitimate manufacturers and retailers impacted by the global trade in counterfeit and pirated goods.

As in past years, the comments submitted by the IACC are drawn from a variety of sources including surveys of member companies, interviews with local experts in the identified countries of concern, research of publicly-available sources, and data generated by the IACC through its own programs and direct engagement with foreign governments. It should be noted, however, that the countries and issues discussed herein are not an exhaustive list of rights-holders' concerns, but merely a snapshot of current and ongoing issues faced by rights-holders around the world, to which the IACC wishes to draw special attention. It is expected that the majority of the countries and issues raised in this filing will come as no surprise to USTR and the interagency team, as many of those highlighted by IACC members are long-standing concerns that have been raised in previous years' filings.

Our comments this year cover 35 countries and span five continents, underscoring the truly global scope of the problems faced by rights-holders. Twelve countries are recommended for inclusion at the Priority Watch List level, and an additional fifteen for the Watch List. While we make no formal recommendation for the placement of the remaining eight countries, it is hoped that those comments will serve to inform the interagency team's determinations when considered within the broader context of comments provided by other relevant parties.

At the outset, we also wish to acknowledge the impact that the ongoing COVID-19 pandemic has had on rights-holders' enforcement efforts, as well as those undertaken by government agencies, regulatory bodies, and judiciary operations around the world. Broadly speaking, most of the rights-holders providing input for the comments contained herein noted significant decreases in the trafficking of counterfeits via brick-and-mortar outlets, and concurrent increases in online sales, as consumers avoided traditional retail outlets (whether voluntarily, or due to restrictions on operations imposed by governments). In addition, rights-holders widely acknowledged the difficulties faced by their counterparts in law enforcement and customs agencies, and have taken into account those challenges in making their assessments of the present situation in each jurisdiction.

We thank you for the opportunity to share our experiences.

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¹ It is worth noting that seizures of counterfeit goods deemed to pose a heightened risk to consumers' health and safety now account for greater than 20% of U.S. Customs and Border Protection's total IPR-related seizures by volume, and greater than 11% by value. *See*, United States Customs and Border Protection, Intellectual Property Rights – Fiscal Year 2019 Seizure Statistics, available at https://www.cbp.gov/sites/default/files/assets/documents/2020-Sep/FY%202019%20IPR%20Statistics%20Book%20%28Final%29.pdf (last accessed Jan. 28, 2021).

PRIORITY WATCH LIST RECOMMENDATIONS

ASIA-PACIFIC REGION

CHINA

The People's Republic of China has, for many years, been the top priority for rights-holders small and large, across all product sectors. That continued to be the case during this year's consultations. China remains the single largest source for the production of counterfeit goods sold in the U.S. market and throughout the world. In its most recently published IPR seizure statistics, U.S. Customs and Border Protection reported that China (mainland and Hong Kong) accounts for 83% of its total seizures – more than 23,000 shipments – at U.S. ports.² In terms of value, those counterfeit shipments approached 92% of total seizures – over \$1.4 billion in Fiscal Year 2019.³ While those figures themselves are disconcerting, perhaps more so is the fact that those seizures represent only a fraction of the Chinese-manufactured counterfeits that reach U.S. consumers each year.

Many of the issues raised herein are well-known to USTR; rights-holders' perennial concerns about China's perceived over-reliance on administrative remedies, thresholds for criminal investigation and prosecution, policies related to product valuation, and continuing concerns related to bad faith trademark registrations have been discussed in numerous past submissions. Similarly, issues pertaining to online trafficking have been well-documented over the years, and remain a priority for brands across every product sector. The IP landscape in China remains extremely challenging even for well-resourced multi-nationals, and even more so for small- and medium-sized brands. Given the severity and scope of the challenges that rights-holders continue to face in the country, we strongly support China's retention on the Priority Watch List in 2021.

Relevant Legislation

China's statutory framework was described by respondents in generally positive terms – "fairly robust," "workable," "generally in-line with global norms." Nearly every brand that provided feedback though highlighted areas in which improvements or additional clarity were desirable, or noted that the legal regime remains a "work in progress." To its credit, China has continued to review, refine, and modernize its IP laws.

² See, U.S. Customs and Border Protection – IP Seizure Statistics for FY 2019, supra, note 1.

³ *Id*.

In December of last year, China's Standing Committee of the National People's Congress (NPCSC) passed a new amendment to the Criminal Law Amendment (XI) that is expected to take effect on March 1, 2021. The new law focuses on six areas that have been among the Chinese government's top priorities, by both adding new crimes and raising penalties for existing ones. Rights-holders were pleased to see that IP crime was one of the enumerated priorities; the new law contains two positive changes that have been sought for years: an expansion of the definition of criminal counterfeiting to include counterfeit services, and an increase in the maximum prison term for criminal counterfeiting from 7 to 10 years.

Respondents also expressed support for provisions of the Anti-Unfair Competition Law passed in recent years, which broadened the definition of unfair competition based on misuse of famous trademarks and established statutory damages of up to RMB250,000 where revenues are undetermined. It is hoped that this will aid authorities in assessing tougher penalties for such violations. Others however have identified challenges in their attempts to avail themselves of the AUCL's provisions, tied to some courts' narrow reading of the law. Additional guidance would be helpful to ensure proper application of the AUCL.

Brands in the pharmaceutical sector wish to draw attention to Article 121 of the New Drugs Administration Law of China, which requires a quality test report issued by the Institute for Drug Control to support the imposition of penalties related to offenses involving counterfeit or substandard drugs. This requirement makes taking action against counterfeit drugs more difficult, due to practical constraints on obtaining such a report. Respondents cite limited access to qualified labs, the length of time necessary to obtain such testing and analysis, and the unavailability of (or lack of ready accessibility to) necessary reference samples as obstacles to compliance. The end result is that law enforcement agencies may be discouraged from pursuing those charges.

Enforcement

The enforcement of IP rights remains challenging, even for the most well-resourced of the IACC's members, and that fact was borne out in the comments received during this year's consultations. As in past years, administrative enforcement is the default approach under the Chinese system, and brands have long taken issue with the high thresholds that must be overcome to allow for the involvement of criminal authorities. As documented in countless past submissions, counterfeiters have grown incredibly sophisticated in the management of their operations to evade the threat of criminal prosecution. Unfortunately, the fines imposed through the administrative enforcement process are generally seen as insufficient to create any true deterrence.

Despite rights-holders' frustrations with the administrative enforcement regime; respondent brands generally expressed satisfaction with their counterparts in the AICs, Market Supervision Bureaus, and other relevant administrative bodies, noting their

engagement and cooperation while also highlighting their successful handling of many cases brought to their attention. Rights-holders have, however, reported significant obstacles to these enforcement efforts. By way of example, some administrative authorities have been reluctant to pursue action against offenders who produced evidence (e.g., an invoice) that they'd obtained the relevant goods from a "legitimate source." Forged documents of this kind have been seen frequently during brands' investigations, but authorities are often inclined to accept them at face value, and simply direct the brand to pursue action against the purported supplier of the goods. Where the documents are valid, the supplier is often located across jurisdictional bounds, necessitating the IP owner's starting the enforcement process over from scratch with a new agency, and unnecessarily increasing costs to the rights-holder.

Rights-holders have also noted officials' tendency to strictly apply China's sub-class trademark system in a manner that effectively limits the scope of enforcement. For example, administrative authorities may refuse to seize products bearing identical trademarks that are outside of specific classes or sub-classes of a brand's Chinese trademark registrations. This has been a source of great aggravation where an individual has used marks identical to a trademark registered for a particular class of goods, in connection with names and signage for the sale of unrelated or unauthorized goods in that same class.

IACC members tended to speak highly of China's criminal enforcement bodies, with some singling out the Public Security Bureaus for their consistent support in raiding factories and large-scale distributors. Respondents also expressed their appreciation for criminal authorities' apparent growing appetite to collaborate on cross-border and multijurisdictional investigations. Others reported continuing cooperation in pursuing "online-to-offline" investigations in collaboration with major e-commerce platforms and criminal authorities, as was previously highlighted in last year's submission.

Rights-holders comments in connection with civil enforcement this year were largely unchanged from those heard in the recent past. A priority concern in this context is the need to strengthen provisions governing the preservation of defendants' assets to ensure the viability of judgments obtained in the courts. Historically, IP owners have reported little, and often only begrudging, cooperation from Chinese financial institutions in this regard.

Bad Faith Trademarks

Notwithstanding recent amendments to China's Trademark Law, IACC members continue to report an unacceptably high number of bad faith trademark registrations in China. The filing of bad faith applications appears to have become a full-time job for some, as rights-holders have reported numerous encounters with individuals who have registered or have pending applications for hundreds of trademarks identical to those

belonging to legitimate brands. Others, meanwhile, appear to take a more targeted approach, filing smaller numbers of applications in China, while simultaneously filing applications in other jurisdictions. Proving bad faith under China's system remains extremely challenging; and whether the applicants' ultimate objective is to "ransom" the mark or to hijack the goodwill of well-known brands, the cost to legitimate manufacturers is immense, and growing.

Online Concerns

As noted in last year's submission, the past decade has seen a dramatic shift in the counterfeit distribution chain, with direct-to-consumer and fulfillment distribution models driven by the explosion in e-commerce displacing traditional brick-and-mortar distribution. Despite these changes, China's status as the primary source for counterfeit goods globally has been a constant, and intellectual property owners have taken considerable interest in the development of China's IP regime in the online context.

A primary focus of that interest has been China's implementation of the E-commerce Law. One concern that appeared consistently in the feedback received from rights-holders during this year's consultations involved the need for clear and detailed guidance on the proper scope, interpretation, and practical application of that law (including its interplay with other relevant Chinese law). As stated by one respondent, "Criminal counterfeiters will exploit any gaps or gray areas they can find ... Creating legal certainty is vital to protecting the interests of rights-holders, consumers, and legitimate e-commerce businesses."

In September of last year, the PRC government issued two documents relevant to rights-holders' concerns: Guiding Opinions of the Supreme People's Court on Deciding Intellectual Property Right Disputes that Involve ECommerce Platforms ("Guiding Opinions"); and Official Reply of the Supreme People's Court on Several Questions of the Application of Law on Disputes over Network Infringements on Intellectual Property Rights ("Official Reply"), offering additional guidance concerning the application and interpretation of the law. Additional questions remain unanswered, however.

Regarding the issue of contributory liability, one respondent noted that the E-commerce Law indicates that an intermediary "e-commerce platform operator" is liable for online infringing activity when it *knew or should have known* of infringing activity and failed to take appropriate action; this standard is repeated in the judicial guidance documents. The standard for making that determination remains unclear, however; rights-holders would encourage the provision of a clear standard that incentivizes platforms to take both proactive and reactive steps to combat infringement on their platforms.

Concerning the treatment of repeat offenders, judicial guidance appears to indicate that platforms may only terminate a merchant's account following multiple, intentional

infringements.⁴ That guidance would appear, unnecessarily, to require platforms to engage in extensive reviews of relevant facts before arriving at a subjective determination regarding the violator's state of mind or the willfulness of each violation. A "bright line" standard would be preferred.

Others have pointed to concerns about the rapid evolution of e-commerce (and counterfeiters') business models, and the potential for the law's strict definitions to become quickly outdated. As noted in last year's submissions, IP owners are already reporting that counterfeiters are migrating their operations away from traditional e-commerce platforms to social media and commerce outlets that may not fall squarely within the four corners of the law.

IACC members have likewise encouraged the consideration of more comprehensive "know your customer" requirements as a means to facilitating enforcement and preventing known bad actors from restarting or migrating their operations following disciplinary action (whether imposed by an e-commerce platform, or the government).

Consumer Health & Safety

We continue to hear troubling reports from rights-holders regarding the apparent increased trafficking of goods in a number of sectors with clear consumer health and safety implications. Among the impacted industries are pharmaceuticals and medical devices (including products such as personal protective equipment (PPE), medical testing kits, and the like, which saw a massive spike as counterfeiters moved to exploit the current pandemic); food & beverage; wine & spirits; and tobacco and electronic nicotine delivery systems (as highlighted in the "issue spotlight" at the conclusion of these comments). Generally speaking, each of these product categories is subject to more extensive testing and regulation, and for some categories, increased taxation by governments, translating into a higher final cost to the end consumer. As counterfeiters have no incentive to ensure that their products comply with the relevant regulations (nor to comply with taxation regimes), higher prices correlate directly with higher profit margins, making these product sectors increasingly attractive targets for illicit trafficking. USTR should urge the Chinese government to focus greater attention on the production, sale, and export of counterfeit goods in these high-risk categories. Further, both the Chinese and U.S. governments should take additional steps to educate consumers about the health risks associated with buying fakes, and encourage consumers to buy only from legitimate, trusted sources.

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⁴ Guiding Opinions, paragraph III.

In closing, we wish to highlight the comments of Chinese President Xi Jinping, made just last month, about the importance of strengthening IP protection in China and calling for the use of legal, administrative, economic, technological, and social governance means to achieve that goal. President Xi underscored the need for reform and innovation for IP litigation, implementation of punitive compensation systems, and the enactment of legislation to prevent IP registration abuse. This is the first time the highest government official in China has made such a detailed call for stronger IP protection, and the IACC welcomes these statements. Our members will undoubtedly be closely monitoring developments in China throughout the year; we sincerely hope that President Xi's words are matched with equally comprehensive action. At this time, however, we support China's retention on the Priority Watch List in 2021.

INDIA

India was retained on the USTR's Priority Watch List in 2020 due to inadequate levels of enforcement, and concurrent high levels of copyright piracy and trademark counterfeiting, a variety of patent-related concerns, and insufficient protection of trade secrets, among other concerns. The IACC concurred with India's retention at the Priority Watch List level due to a lack of progress on a number of long-standing issues including significant delays in the country's court system and trademark office. Despite some positive comments during this year's consultations, particularly with regard to rightsholders' interactions with enforcement authorities, we believe India should remain on the Priority Watch List in 2021.

IACC members have reported consistent improvement among Indian law enforcement over the past several years, noting both an increased interest and expertise among their counterparts. And while there remains some variation in the level of support received among various locales throughout the country, those disparities are less pronounced than in the past. As noted in prior submissions, respondents felt that the efforts of the police would benefit from a more strategic approach; too often enforcement actions seem to target "low-hanging fruit." Member brands also continued to express their desire for a more collaborative approach to enforcement, and cited overly-bureaucratic procedures and a lack of transparency as obstacles to more effective coordination with their law enforcement counterparts. Rights-holders described having to meet repeatedly with police in order to organize raids, and bemoaned the lack information often provided by police following successful enforcement actions, which was seen to preclude, or limit the effectiveness of, follow-up investigations or the pursuit of civil actions.

Respondents' comments concerning customs enforcement remained largely unchanged from those heard during last year's consultations. Overall, seizures are said to have increased in recent years, and brands have commented positively on Indian Customs' interest and participation in training events, though obviously such opportunities were largely impossible in 2020.

As has been the case for many years, IACC members' greatest criticisms of the Indian regime involved delays – both in the country's court system and in its Trademark Office. Each is seen to diminish the overall effectiveness of the country's IP regime. With cases continuing unresolved for years, and in some instances more than a decade, the threat of consequences for violations remains more conceptual than practical, and any disincentive to recidivism similarly meaningless. The duration of cases also correlates to their expense, leading many to view supporting criminal prosecutions or pursuing civil litigation as cost-prohibitive. Delays at the Trademark Office have likewise been a perennial complaint; rights-holders continued to cite India as among the most difficult jurisdictions in the world in which to obtain a trademark registration.

One final matter that we wish to highlight – the Indian government was expected to move forward with the adoption of a National E-Commerce Policy in 2020. While that has reportedly been delayed, rights-holders will be closely monitoring the issue, given the increasing (and increasingly important) online trade in India.

Perhaps the greatest frustration expressed by IACC members was that many of the issues raised in these comments have been highlighted for many years. They are not novel, and there are a number of actions that have been proposed to address the concerns. The development of a "fast-track" process for IP matters or a specialized IP court have been suggested in past submissions. Likewise, the development of procedures that would allow for an expedited disposition of seized counterfeits (as a means to decreasing costs typically borne by the rights-holder associated with storage) costs would be welcome. While the government has shown some signs of an increased political will to address long-standing concerns, efforts to improve the country's IP regime are still driven – and funded – largely by private industry. We are hopeful that further progress on these issues will materialize in 2021, but at this time support India's retention on the Special 301 Priority Watch List.

INDONESIA

In last year's report, USTR retained Indonesia on the Special 301 Priority Watch List, citing continuing challenges faced by rights-holders including "widespread piracy and counterfeiting," insufficient levels of enforcement, and the need for more deterrent penalties for violations in both the brick and mortar and online contexts. In our own comments to USTR, the IACC noted rights-holders' concerns related to the country's border enforcement regime, lack of prosecutions, and reported corruption, in addition to the above. To a large extent, the issues raised by IACC members during our Special 301 consultations echoed those heard in prior years' submissions; and so, we recommend Indonesia's continued retention on the Priority Watch List in 2021.

We received few complaints from rights-holders with regard to Indonesia's substantive legal framework; the consensus view however, is that the overall level of criminal enforcement is inadequate. The blunt assessment of one brand was, simply, "The criminal system is broken." And while some rights-holders have reported increased raids and seizures by the authorities, there is little apparent follow-through. Most respondents indicated that they've seen few, if any, criminal prosecutions pursued in connection with violations of their IP rights.

Corruption is seen as widespread, and as the greatest hindrance to enforcement. In some cases, this takes the form of protectionism; other rights-holders also report the solicitation of bribes by law enforcement when they've sought assistance. And while such acts allow the illicit trade to thrive, we've also received reports of law enforcement personnel interfering with legitimate business by, for example, holding up shipments due to purported "paperwork issues," and indicating that any problems "can be resolved" by paying the officer. We've seen no indication that the Indonesian government views these as priority concerns, and no reports of concrete steps to address them.

IACC members' pursuit of civil remedies has been similarly discouraging. Litigation is seen as costly, rulings inconsistent, and penalties viewed as insufficient to deter recidivism.

In the patent space, rights-holders noted their dismay that judiciary officials appear to lack sufficient expertise to handle matters independently; they're frequently required to rely upon assistance from the Patent Office for matters involving infringement and invalidation.

As was the case in many jurisdictions, rights-holders noted a shift in counterfeiting activity from physical to online marketplaces, attributed to COVID-19-related restrictions. IACC members expressed frustration at the lack of significant or sustained online enforcement efforts by Indonesian authorities.

Respondents also repeated concerns voiced in previous years' submissions related to the country's border enforcement regime.

In light of the feedback received during this year's consultations, we support Indonesia's retention on the Priority Watch List in 2021.
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EUROPE - MIDDLE EAST - AFRICA REGION

KUWAIT

Last year, the USTR moved Kuwait from the Priority Watch List to the Watch List, in recognition of steps taken to address a number of deficiencies in the country's copyright regime. Regrettably, the substance of comments received from our members during this year remained largely unchanged from last year's submission, when we recommended Kuwait's retention on the Priority Watch List. Rights-holders remain frustrated by a range of issues in the country, perhaps most notably with respect to the level (and effectiveness) of enforcement both at the border and within the local market.

As noted in last year's filing, Kuwait's anti-counterfeiting enforcement regime was described as "virtually nonexistent;" that same critique was offered this year. Rightsholders also continued to decry the perceived disinterest of law enforcement officials in pursuing complaints when initially filed, or in following cases through to resolution. Some brands have continued to report outright refusals of their offers of assistance to enforcement personnel – e.g., offers to aid in authentication of goods or verification of counterfeiters' "authorization" documents. Taken together, many IP owners have grown increasingly discouraged about working with law enforcement in the country.

Kuwait was one of a number of jurisdictions highlighted in last year's comments which maintains a policy of allowing counterfeit goods to remain in the possession of offenders following raids but in advance of court proceedings. IACC members again expressed dismay over the application of this policy, for obvious reasons. Though governments have often adopted such an approach as a means to reducing the costs and logistical difficulties associated with large-scale storage of illicit goods, the potential adverse impact to evidentiary preservation is not a reasonable trade-off. Further, the increased harm to rights-holders and risks to consumers should those (often dangerous) goods continue to be sold in the interim, is unacceptable.

As discussed in last year's filings, brands' frustrations also extend to the judiciary; cases are described as slow-moving, processes as unnecessarily complicated, and legal and evidentiary standards applied inconsistently or without a reasonable foundation.

While we have heard promising reports of outreach by the Kuwaiti government seeking assistance to address some of these concerns, concrete improvements have not yet materialized.

Accordingly, we support Kuwait's return to the Priority Watch List in 2021, and would welcome the support of the U.S. Government in facilitating increased engagement between Kuwaiti authorities and the rights-holder community.

RUSSIA

In 2020, the IACC recommended Russia's placement on the Priority Watch List, as we have for more than a decade. Enforcement – both in the brick-and-mortar context and online – remains a significant concern for rights-holders across a broad range of product sectors, as does cross-border trafficking. Russia remains an important, albeit challenging, market for the protection of intellectual property; unfortunately, rights-holders reported no major developments over the past year that would justify the country's removal from the PWL in 2021.

During this year's consultations, the concerns most consistently heard from respondents involved the online trafficking of counterfeit and pirated goods. Brands highlighted the Russian legal regime's lack of any UDRP-type process for addressing domain disputes, the pervasiveness of illicit online sales via rogue websites, e-commerce markets, and increasingly through social media, as among the greatest challenges faced. A consensus view among brands was that the existing statutory framework has not kept pace with the development of the online market, and fails to provide the range of tools necessary to fully protect trademark and copyright owners. More broadly, members have expressed the view that the penalties available for counterfeiting offenses fail to provide sufficient deterrence. To that point, we were pleased with the Russian government's ongoing work to update the country's Administrative Offence Code. The revised provisions take effect in 2021 and should provide for the imposition of more substantial penalties for counterfeiting offenses.

IACC members were largely positive in their assessments of Russian law enforcement, complimenting both their engagement and professionalism. Results from those engagements varied among respondents though, with some noting a continued trend of increased raids and seizures in the market, while others blamed pandemic-related workforce reductions and other impacts of Covid as underlying reasons for reduced levels of enforcement during the past year.

Many brands have reported drastic increases in the volume of counterfeit trafficking online, largely attributed to the pandemic; and while some have described an increased responsiveness among internet intermediaries to rights-holders' takedown requests, online enforcement remains a considerable challenge (as discussed above). In the absence of laws specifically focused on online trafficking, some enforcement bodies – and prosecutors – have shown reluctance to pursue offenders even in clear-cut and large-scale cases. Even when offenders are pursued by enforcement agencies or intermediaries assist in the remediation of bad actors, however, those efforts are not seen to provide a lasting impact. Counterfeiters quickly and easily resume operations with a new virtual storefront.

As discussed in numerous past submissions, customs enforcement remains a key concern for rights-holders across all product sectors. China-sourced counterfeits continue to reach the Russian market, often via well-established overland routes via Kazakhstan, taking advantage of the minimal customs enforcement provided by the Eurasian Customs Union. Rights-holders also continue to report increased trafficking via small-packages.

In last year's comments, we noted increasing frustrations among IP owners related to Russian Customs' practice of simply returning small consignments to their point of origin, rather than seizing and disposing of those counterfeits, or leveraging data mining and analysis practices to improve targeting and interdiction against such small package trafficking. Those frustrations continued to be heard in this year's consultations.

Historically, the Russian government's commitment and political will to address long-standing deficiencies in the country's IP legal and enforcement regime has been called into question by rights-holders. This is perhaps not surprising, given the catalog of concerns that have kept Russia on the Special 301 Priority Watch List for countless years. We were understandably pleased though to hear reports this year regarding a number of "pro-" IP statements made in the country's Parliament during 2020, and increased support for tackling a number of rights-holders' priority concerns. We will, of course, continue to monitor the situation to ensure that those words are followed by concrete action. For now, though, we continue to recommend Russia's placement on the Priority Watch List in 2021.

SAUDI ARABIA

Despite some reports from brands regarding improvements seen in 2019, the IACC recommended Saudi Arabia's placement on the Priority Watch List in 2020, consistent with USTR's own final determination. USTR cited a variety of challenges faced by rightsholders in the country, perhaps most notably the exceedingly high levels of online copyright piracy facilitated by illicit streaming devices, failures to protect pharmaceutical data against disclosure, and broad concerns with the country's enforcement regime. In light of the feedback received from IACC members during this year's consultations, we support Saudi Arabia's continued retention on the Priority Watch List in 2021.

Enforcement remained the primary concern of IACC members polled during this year's consultations, with rights-holders from a variety of product sectors highlighting numerous challenges. While we do wish to recognize the efforts of the Ministry of Commerce – rights-holders singled out authorities in Riyadh and Dammam for praise – and positive engagement with the Anti-Counterfeiting and Fraud Division was highlighted by a number of IACC members; brands also continue to underscore the need for more meaningful and consistently-applied penalties. Recidivism remains problematic, and is seen as unlikely to decrease without the imposition of more severe punishments. Rights-holders bemoaned the too-common "enforcement" practice of simply seizing counterfeit goods and requiring an acknowledgment of the offense; it is not seen to offer true deterrence. The desire for greater transparency in the context of enforcement was also widely expressed, as it has been in past years' discussions. Members reported that they often receive little information regarding the ultimate resolution of cases following initial enforcement actions or any intelligence gathered during such actions that might facilitate further investigations by rights-holders.

Member reports regarding Saudi Customs' effectiveness ranged widely, with some brands offering praise for increasing seizures over the past two years, and others reporting no seizures at the border at all.

In contrast to past years, we've received reports of improved transparency with regard to the destruction and disposal of seized counterfeits; some respondents credited the SAIP for progress on that long-standing complaint.

We received troubling reports from the healthcare sector regarding a general lack of assistance received from the Ministry of Health and the Saudi FDA. Illicit trade in counterfeit pharmaceuticals and medical devices is seen as a growing problem, and these concerns are exacerbated by a perceived lack of controls on procurement in the Saudi healthcare system. Hospitals are said to frequently source goods on the basis of price alone, without essential safeguards in place to prevent the infiltration of the supply chain by counterfeits.

While IACC members noted some improvements in the country over the past year, and the government has demonstrated a greater commitment to continuing on that path, we support Saudi Arabia's retention on the Priority Watch List in 2021.

TURKEY

While USTR ultimately retained Turkey on the Special 301 Watch List last year, the IACC recommended its elevation to the Priority Watch List, largely due to increasing concerns about the country's judiciary. Those concerns remained pronounced in 2020, and we again encourage Turkey's elevation to the Priority Watch List.

The consensus view expressed by IACC members during this year's consultations is that Turkey has developed an adequate IPR regime, but the sufficiency of that regime is undermined by a lack of expertise on such matters, most notably within the judiciary and among the country's prosecutors. This is likely due to significant turnover in recent years, and is seen by many as a root cause of inconsistent rulings and procedures experienced by rights-holders. Respondents decried prosecutors' "ever-changing evidentiary requirements" when seeking search warrants, and their unwillingness to pursue prosecutions even where there was clear and ample evidence to support charges. Others described prosecutors as "openly hostile" to requests for assistance on IP-related matters. As in numerous other jurisdictions, criminal proceedings experienced significant disruptions connected with the pandemic during 2020; such disruptions were seen less in Turkey's IP Courts, which was reported to operate at or near normal capacity.

A lack of expertise is also pointed to as a contributing factor in Turkish courts' reliance on "expert" testimony. As noted by rights-holders on numerous occasions, these court-appointed experts often lack necessary training or relevant expertise to accurately make determinations about the authenticity of the goods at issue. The approach is all the more frustrating given the tendency of the courts to apply significantly greater weight to the testimony of those experts than is given to rights-holders' own analyses. Rights-holders also continue to report concerns involving courts' inconsistent decisions with regard to the issuance of search warrants. As ex officio action is generally limited to certain types of goods, e.g., tobacco and alcohol, the lack of certainty in dealings with the judiciary serves as a significant obstacle to effective enforcement.

In contrast to feedback offered on the judicial system, rights-holders were largely complimentary of Turkish law enforcement, particularly among the specialized IP units in major cities and the Anti-Smuggling Police. One member described Turkish police as having perhaps "the greatest level of commitment" they've witnessed across the EMEA region. Regrettably, those efforts by enforcement personnel too often go to waste, as a result of the above-described challenges experienced in pursuing prosecutions.

Turkey remains a major source of counterfeit goods entering the European Union, whether in terms of illicit products manufactured locally, or simply transiting Turkey en route to other European markets. In fact, one respondent during this year's consultations referred to Turkey as "the EU's 'China." Though some IACC members have reported greater levels of activity by Turkish Customs, targeting and interdiction of exports and transshipments must be made a higher priority. One brand noted that they'd seen a 300% increase in counterfeit seizures by Bulgarian Customs, arriving via ground transport from Turkey; they were unaware of any instance in which Turkish Customs had seized a shipment of counterfeit exports in 2020.

Reporting brands in the pharmaceutical and medical device sectors also cited the need for significantly greater controls and oversight to be implemented by the Turkish government in order to stem the flow of counterfeit, adulterated, diluted, mislabeled, or mishandled goods. Recent years have seen countless reports of such products, originating from Turkey, and reaching consumers in jurisdictions around the world. Such trafficking constitutes a major threat to patients' health and safety, and must be addressed urgently.

It is incumbent upon the Turkish government to demonstrate significantly greater political will in resolving the many issues raised herein. Until such time as concrete and sustained progress has been made in doing so, we recommend their placement at the Priority Watch List level.

UKRAINE

The IACC concurred with USTR's continued placement of Ukraine on the Priority Watch List during last year's Special 301 process, in light of the significant and long-standing challenges faced by intellectual property owners in the country. Given the political upheavals experienced in Ukraine during recent years, it is perhaps not surprising that intellectual property reforms have taken a backseat to other priorities; rights-holders remain frustrated however by the lack of progress seen on a host of concerns. We wish to stress that while those frustrations were heard across the entire spectrum of product sectors comprising the IACC's membership base during this year's process, we've heard increasing frustrations voiced by those in sectors with clear health and safety implications, including the consumer electronics, food and beverage, and crop protection sectors. Despite some notable developments over the past year, we again recommend Ukraine's retention on the Priority Watch List in 2021.

Rights-holders welcomed steps taken in 2020 by the Ukrainian government towards institutional reform of its IPR regime, and to align its legislative regime with EU laws. Among other provisions, Law No. 703-IX, established a National Intellectual Property Agency as a centralized governmental body for coordination on IP issues. The NIPA will replace the Ukrainian Intellectual Property Institute, and absorb certain functions of the Ministry for Development of Economy, Trade, and Agriculture. Respondents are hopeful that the reforms will streamline and shorten the IP registration process.

Respondent brands also wished to highlight two orders – No. 281 and 282 – issued by the Ministry of Finance in June of last year, and pertaining to customs measures. Among other things, the orders provide for the rights-holder's responsibility for costs associated with the detention of infringing goods by Customs, while also including a right to reimbursement from the owner of the infringing goods. In addition, they established a new procedure for the destruction of small consignments of counterfeit goods, without contacting the rights-holder. We will be closely monitoring implementation of this process, which based on initial reports, appears comparable to the "voluntary abandonment" approach that has been adopted in recent years by U.S. Customs & Border Protection. As we've expressed to CBP, we believe that capturing information related to such shipments and making the same available to rights-holders is a vital component to combating the trafficking of counterfeits via international mail and express consignment shipments. We encourage Ukrainian Customs to take a similar approach.

The Ukrainian government is keen to secure membership to the European Union, and for the past several of years has been seeking input and guidance from the EU and the private sector from outside of Ukraine on improvements that should be made to improve their IPR regime.

Like Turkey in the south, Ukraine continues to be viewed with concern by right-holders as a key transit point for the trafficking of counterfeit goods into the EU market; this is particularly so in sectors such as agribusiness. The lack of a clear enforcement framework, as well as longstanding concerns about transparency were frequently cited by respondents as contributing to these problems. IACC members continue to report

difficulties with regard to border enforcement, despite a recent restructuring of Customs and the implementation of new rules and procedures intended to aid IP enforcement. As noted above, there is great interest in the implementation of Ukraine's newly adopted approach to handling small consignments of counterfeits. We are pleased, however, to learn that Customs appears to have abandoned its "return to sender" policy for counterfeits interdicted in the small consignment context. That practice has been highlighted in recent years' submissions as a point of frustration for IP owners. A sizeable portion of respondents continue to report very few seizure notifications though, and the consensus view is that Ukrainian Customs' interdiction efforts are still in need of significant improvement (as evidenced by the overall volume of counterfeits that continue to be seen in the local market, and neighboring markets).

Rights-holders' assessments of law enforcement in Ukraine have, historically, been less than complimentary. Given that background, we were pleased to hear more positive comments during this year's consultations regarding increased engagement by police with rights-holders, and growing enthusiasm for tackling long-standing IP concerns. Respondents from the pharmaceutical sector expressed their pleasure with the pursuit and handling of a wide-ranging investigation into a major counterfeit manufacturing and distribution operation – perhaps the largest in the country's history. Other members noted, however, that enforcement too often focuses on "low-hanging fruit," and would encourage a more strategic approach to identify and dismantle large-scale operations that continue to thrive in the illicit market. Increased transparency and involvement of rights-holders both in the early stages of investigations, and as those investigations progress, could lead to significantly improved outcomes.

It will surely come as no surprise that online issues remain a key concern for both trademark and copyright owners. In last year's Special 301 report, USTR underscored persistent concerns related to the administration of collective management organizations, government use of unlicensed software, and the need for more effective means to combat online infringement: each of these remained priorities during the past year.

Rights-holders also continue to call for improvements in the court system, with numerous respondents raising concerns about the level of expertise demonstrated by both prosecutors and judges in IP matters, as well as the overall efficiency of proceedings. These matters are compounded by issues raised in past filings including failures to impose deterrent penalties and a lack of transparency in the disposition of counterfeit goods subsequent to court proceedings.

While we are hopeful that the actions taken by the Ukrainian government during the past year to realize structural reforms to its IP system are an indicator of increased political will to address long-standing deficiencies, we recommend the country's retention on the Priority Watch List in 2021, and until such time as more concrete progress has materialized.

AMERICAS REGION

BRAZIL

Though the IACC recommended its elevation to the Priority Watch List in 2020, Brazil was retained at the Watch List level on last year's Special 301 Report. Brazil remains among IACC members' greatest priorities in the Western Hemisphere, and among the most challenging jurisdictions in which to protect their IP rights. In light of the feedback we've received from members during this year's consultations, we again recommend Brazil's elevation to the Priority Watch List in 2021.

Respondents described Brazil's statutory regime as "largely in-line with international norms," but highlighted a number of obstacles to effective protection and enforcement. Perhaps chief among rights-holders' concerns are the penalties authorized for IP violations, which are seen as far too low to create any effective deterrent. This is particularly the case when one takes into account the effect of Act 9099. That provision deems offenses involving industrial property as "minor offenses;" as a result, IP violations rarely lead to custodial sentences – probation remains the norm. Member brands have also expressed support for the adoption of specific statutes for the protection of trade dress and to deal with the growing problem of online trafficking of counterfeit goods.

While a number of IACC members commented positively regarding the efforts of their counterparts in law enforcement, the protection of IPR is said to be greatly inhibited by two factors: corruption and the inefficiency of the Brazilian court system. We've devoted significant attention to the former issue in past submissions, describing raids that have been derailed due to internal leaks, protectionism benefiting politically-connected counterfeiters, and even police agencies' need, at times, to obtain assistance from law enforcement personnel from outside of the region in order to successfully execute raids. Even well-known outlets for the trafficking of counterfeit goods often appear to be entirely insulated from enforcement activity.

That is not to say that criminal raids do not take place; on the contrary, numerous IACC members have noted a great deal of police activity, and increasing engagement by Customs as well over the past two years, leading to many large-scale seizures. Last October, for example, the specialized IP Police unit in Sao Paulo seized one-and-a-half tons of counterfeit merchandise; and earlier this month, Customs intercepted shipments of counterfeit apparel with an estimated value of 23 million Reals. Despite regular seizures however, counterfeit goods of all types remain widely available in the local market. As described by one respondent, "Law enforcement repeatedly raids the same large markets, seizing tens of thousands of counterfeits each time, often shutting the markets for significant periods of time, only to have them open back up and resume counterfeit sales. There is no lasting impact from the enforcement actions." Rightsholders lay much of the blame for this situation at the feet of the Brazilian judiciary.

In describing the Brazilian courts, member responses typically included one or more of the following words: "slow," "inefficient," or "lenient." Court actions are seen as unnecessarily protracted; civil cases are estimated to run in excess of five years, criminal cases more than four. One brand offered the example of a recent case that required more than seven years to conclude. Unfortunately, the ultimate pay-off for that seven-year investment of time and resources was the assessment of a rather modest fine to the defendant. Comparable scenarios remain frequent in the civil context as well, where defendants often receive what amounts to a slap on the wrist. The lack of deterrence resulting from such penalties is seen clearly in the amount of recidivism experienced by rights-holders. IP owners would strongly support the adoption of a statutory damages regime, or the availability of treble damages for serious, willful, or repeat offenses.

It is incumbent upon the Brazilian government to apply significantly greater political priority to address the long-standing deficiencies in the country's IP regime, if there is to be any optimism for improvement in the Brazilian market. We are aware that a public consultation was opened by the government last year to inform the country's National IP Strategy (ENPI), and we're hopeful that the government will take into account the feedback provided in these, and past years', comments. We would also welcome further efforts by the government geared towards raising consumer awareness about the harms caused by the counterfeit trade, and the benefits provided by strong intellectual property protections. Given the lack of progress on these issues over the course of the past year, and the severity of the challenges faced by rights-holders there, we recommend Brazil's elevation to the Priority Watch List this year.

CANADA

Canada has appeared on the Special 301 Watch List in each of the past two years, following an appearance on the Priority Watch List in 2018. The IACC has consistently advocated for the country's elevation to the PWL absent significant improvements in the country's enforcement regime. We reiterate our support for its an elevation again this year.

The lack of enforcement against the trafficking of counterfeit goods, both at the border and within the domestic market, has been a sore spot for rights-holders for many years. Despite the adoption of legislation in recent years intended to remedy some of these longstanding issues, including the enactment of new criminal provisions and expansion of authority to permit Canada Border Services Agency personnel to act ex officio: IACC members continue to report that the overall level of enforcement remains insufficient. As highlighted in a prior submission, even years after the enactment of the Combating Counterfeit Products Act, CBSA's annual IP-related seizures totaled approximately 1/1000th of the seizures effected by U.S. Customs and Border Protection. While Canadian authorities would, on occasion, undertake intensified enforcement campaigns - for example, in response to USTR's inclusion of the Pacific Mall in the 2017 list of Notorious Markets - such actions tend to be short-lived and provide little long-term benefit to IP owners. The consensus view among respondents in this year's consultations was that most law enforcement agencies have little interest in pursuing IP offenses; and those that do receive little support from the policymakers who establish the agencies' priorities. As a result, police and prosecutors often encourage brands to simply pursue civil remedies for violations of their rights; civil enforcement remains impractical in many cases however, given the unavailability of statutory or treble damages.

Some respondents have noted modest increases in the number of customs seizures during the past 18 months, but totals remain far below the numbers expected for a market the size of Canada. One brand stated that it has seen no border seizures by CBSA during the past 5 years. IACC members also reiterated past concerns regarding the cost and procedural burdens imposed by the Canadian regime. The lack of an expedited, administrative process to deal with counterfeit shipments unnecessarily increases the cost to rights-holders, discourages action against smaller shipments (which are increasingly becoming the norm due to shifting sales and distribution models), and results in practical limitations on the overall level of enforcement.

One final consideration raised during this year's consultations concerns the standards applied by the Canadian Intellectual Property Office in analyzing distinctiveness and descriptiveness in determining the registrability of marks. Despite one affected brand's registration of its mark in nearly 150 jurisdictions around the world, Canadian examiners have refused to allow registration. The rights-holder points to the enactment in 2019 of amendments to the Trademark Act as the source of the problem. Prior to 2019, foreign trademark applicants were able to rely on foreign registrations to support a Canadian application by showing that their foreign-registered trademark was "not without distinctive character." The 2019 amendments removed that article, resulting in a higher standard that must be satisfied by foreign applicants to demonstrate distinctiveness. As

applied, this creates an unreasonably high threshold of distinctiveness for foreign trademarks, and in turn creates an opportunity for infringers in Canada to exploit the lack of protection, in contrast to that enjoyed in nearly every other global jurisdiction. We would welcome USTR's investigation of this issue, which adversely impacts a number of brands.

In light of the feedback we've received during this year's consultations, and of the overall lack of progress on a number of issues raised in past years' submissions, we would support Canada's elevation to the Priority Watch List in 2021.

CHILE

The IACC concurred with USTR's decision to retain Chile on the Special 301 Priority Watch List in 2020; and despite some positive reports heard during this year's consultations, we believe its retention on the PWL remains justified in 2021.

IACC members have historically focused their critiques of the Chilean IP regime on matters related to enforcement – particularly border enforcement measures. As such, we've been pleased to hear positive comments concerning increased activity by the National Customs Service. Chile's ports however remain an attractive entry point for the South American market, and they continue to be targeted by counterfeiters based in China and elsewhere in Asia. Rights-holders also highlight a need for the adoption more efficient and streamlined procedures to address increased trafficking via small packages – a growing problem in Chile, and countless other jurisdictions. Brand representatives were generally complimentary of their counterparts in Customs, describing them as engaged and helpful, though also noting the continued significant volume of cross-border counterfeiting traffic between Chile and other countries in the region including Peru and Bolivia.

IACC members noted significant increases in "finishing" operations (encompassing the trafficking of counterfeit components, labels, and packaging materials) and an apparent increase in domestic production of counterfeits, both of which are greatly troubling.

As noted in past submissions, some rights-holders have faced challenges in their dealings with public prosecutors, often tied to inconsistent criteria established for pursuing a case, which are said to vary from city to city. Some have also raised concerns about prosecutors' and courts' over-reliance on "technical experts" who typically lack the knowledge and training of rights-holders' representatives, while discounting (or precluding entirely) the testimony or analyses provided by those rights-holders. And while most respondents tended to view the judiciary in Chile as competent, and demonstrating sufficient understanding of IP matters, the verdicts in criminal cases generally fail to show that IP crimes are viewed as serious offenses, or that deterrence is a priority. Counterfeiting charges rarely result in jail time, and guilty parties are typically only ordered to pay a fine.

We would welcome greater efforts from the Chilean government in prioritizing IP enforcement, particularly by ensuring that the Customs Service is provided with sufficient personnel and resourcing to carry out its IP enforcement mission. We would also encourage the government to take a leadership role in facilitating increased collaboration with neighboring countries to combat the cross-border trafficking that continues to thrive in the region. In light of the feedback received this year, we support Chile's retention on the Priority Watch List in 2020.

MEXICO

In 2020, the IACC recommended Mexico's placement on the Priority Watch List, citing a variety of long-standing concerns faced by rights-holders. While acknowledging the need for additional progress in the country, USTR noted Mexico's agreement to important IP provisions in the U.S.-Mexico-Canada Agreement, and progress toward implementation of the same; it was retained on the Watch List last year.

IACC members are closely monitoring the implementation of Mexico's new Federal Law for Industrial Property, and are hopeful that it will bring about long-awaited progress on a number of priority issues that have been raised in recent years' filings. In addition to increased fines for IP violations and greater availability of damages to victims, the new law offers tools to enforce against counterfeit goods in-transit or transshipped through Mexico. Rights-holders also welcomed the inclusion of provisions focused on online offenses, and an expansion of IMPI's authority that should allow the agency to collect fines assessed for violations, which it is hoped will provide enforcement actions with more teeth than in years past.

Regrettably, the new law fails to provide Mexican Customs with ex officio authority to seize counterfeit goods at the border. Despite rights-holders' urging for several years, such actions will still require a trademark owner to file a case with IMPI or to pursue a criminal complaint with prosecutors. Further, the newly enacted provisions failed to expand the scope of information that Customs may disclose to an injured intellectual property owner following a seizure, limiting their abilities to undertake further investigations of the illicit trafficking.

A point that was stressed by numerous respondents though was that the enactment of improved statutes alone is meaningless. The enforcement of those laws, and perhaps more to the point – the government's actions to prioritize enforcement of IP, and the provision of adequate resources to the agencies tasked with that enforcement – are vital to bringing about an improved environment for rights-holders in Mexico. Each of these has been severely lacking in recent years, and it remains to be seen whether the Mexican government is serious about improving the situation.

IACC members continued to report a reluctance on the part of federal prosecutors to accept intellectual property cases during 2020, unless they were deemed sufficiently large – a de facto threshold on criminal prosecution. And while respondents generally reported positive interactions with their counterparts in law enforcement, corruption remains a concern in some areas and is said to have contributed to difficulties in pursuing targets of investigation. Rights-holders also continue to bemoan the limited number of cases that result in prosecution, and the nominal penalties that are frequently imposed by Mexican courts for IP offenses.

One final matter that we wish to highlight involves growing concerns with the manufacturing, sale, and use of counterfeit, unregistered, and untested crop protection chemicals including fertilizers, pesticides, herbicides, and the like. IACC members have reported a number of instances involving illicit agricultural products, including examples

with a nexus to Mexican food exports to the United States. Given the potential health hazards involved, the relevant enforcement and regulatory agencies must prioritize investigations and prosecutions of such activity when it is identified, and take steps to ensure necessary oversight that will prevent similar incidents in the future.

We will continue to monitor Mexico's implementation of the new Industrial Property Law throughout 2021; but until such time as concrete progress has been demonstrated in the areas discussed herein, and in past submissions, we continue to recommend Mexico's placement on the Priority Watch List.

WATCH LIST RECOMMENDATIONS

ASIA-PACIFIC REGION

BANGLADESH

IACC members — most notably in the apparel sector — registered severe concerns in Bangladesh over the past year, and urge USTR to look into what appears to be a rapid deterioration in the environment for IP protection. While rights-holders have exhibited some level of concern about Bangladesh in past years, 2020 reportedly saw a drastic increase in manufacturing and exports of counterfeit apparel, confirmed by seizures in a number of global markets.

The country's existing infrastructure for the production of apparel and accessories is said to be increasingly leveraged for the production of illicit goods. Law enforcement and Customs personnel — cognizant of the large number of jobs supplied by garment manufacturing and wary of the potential for unrest that may result if action is taken against those factories — have reportedly turned a blind eye to the illegal activity. The significant downturn in orders from the legitimate apparel industry that has resulted from the pandemic has left a vacuum that is now being filled by counterfeiters eager to take advantage of the country's inexpensive and skilled labor force. According to one respondent, approximately 30-35% of the counterfeit apparel they've seized globally during the past year has a nexus to Bangladesh.

We welcome USTR's attention to these urgent concerns, and support the placement of Bangladesh on the Special 301 Watch List for 2021.

CAMBODIA

IACC members' comments concerning Cambodia largely mirrored those heard with respect to Bangladesh, though more localized – i.e., the counterfeit apparel manufactured in Cambodia has been discovered in a number of markets within Southeast Asia, but further afield, have been seen less frequently.

Many of the same factors mentioned above appear to be contributing to the present situation, namely the excess capacity for production among a skilled and low-cost workforce. And as in the case in Bangladesh, there's little apparent political will from the higher levels of government or among the rank and file within the country's enforcement infrastructure to crack down on the illicit production and exports.

Given the severity of the concerns reported, and the rapid deterioration of the situation during the past year, we recommend Cambodia's placement on the Watch List in 2021.

HONG KONG

In recent years, the IACC has highlighted several issues in Hong Kong said to adversely impact the protection and enforcement of our members' IP rights. To our dismay, we've seen little to no progress on each of these issues since they were first enumerated. Also troubling is the recent adoption of a policy by the Hong Kong Department of Justice that would require the disclosure of incredibly sensitive information during the enforcement process, and could result in significant harm to IP owners. These issues are each discussed in turn below. While we've made no recommendations regarding Hong Kong's placement in past years, given the lack of improvement, and indeed, the worsening situation for rights-holders; we recommend that Hong Kong be added to the Special 301 Watch List in 2021.

As detailed in past submissions, Hong Kong is a major transit hub for the shipment of counterfeit goods from mainland China to the United States and numerous other markets around the world. During Fiscal Year 2019, U.S. Customs and Border Protection seized nearly 10,000 shipments, valued at just under \$400 million, arriving at U.S. ports from Hong Kong.⁵ This represents 35% of CBP's total seizure by volume, and 26% by total value in terms of MSRP.

These shipments are comprised overwhelmingly of counterfeit goods produced in mainland China, which simply make use of Hong Kong's well-developed port infrastructure. The level of enforcement against such shipments has, to date, failed to significantly reduce the volume of counterfeits flowing through Hong Kong. Rightsholders also continue to express frustration over the lack of information made available by Hong Kong Customs & Excise, and the failure to adopt meaningful "Know Your Customer" regulations that might encourage the type of oversight and compliance efforts that should reasonably be expected from freight forwarders and other shipping intermediaries. Respondents also note that a considerable portion of these transshipments are sent via express consignment companies; we'd encourage HKC&E to work more closely with those providers and rights-holders to execute "mail blitzes" that could significantly increase seizures.

Another issue highlighted in prior submissions involves HKC&E's existing policy requiring rights-holders to verify the inauthenticity of each item in a seized shipment. This mandate is viewed as needlessly resource-intensive, particularly in the case of large-scale seizures. An alternative approach permitting the examination and authentication of a representative sample of the goods included in such shipments should be sufficient, and would allow for a more efficient allocation of resources.

A new issue brought to our attention during this year's consultations involves the adoption of new guidelines in early 2020 by the Hong Kong Department of Justice. The revised requirements for expert witness statements provided by IP owners in support of

⁵ FY 2019 IP Seizure Statistics, *supra* note 1.

criminal cases seek far more detailed and sensitive information than was previously required. Based on the reports received from members during this year's consultations, this may include confidential corporate information, as well as proprietary information related to product identification and authentication. Such documents may be made publicly available, and the disclosure of the detailed information required could result in substantial harm to the relevant rights-holder, while also providing counterfeiters with a roadmap to produce more convincing fakes and evade detection and enforcement. These expanded requirements should be rescinded.

In consideration of the above, we would support Hong Kong's addition to the Special 301 Watch List in 2021.

MALAYSIA

The IACC supported USTR's decision to retain Malaysia on the Special 301 Watch List last year, citing the persistent and widespread sales of counterfeit goods in the domestic market, long-standing issues related to customs enforcement, and a reported lack of prosecutions related to IP offenses. Each of these concerns remained throughout the past year, and we've received a significant volume of complaints alleging corruption within Malaysia's enforcement bodies. Accordingly, we support Malaysia's retention on the Watch List again in 2021.

In past years' submissions, IACC members have highlighted the need for more consistent and effective cooperation between Malaysian Customs and the Ministry of Domestic Trade, Cooperatives, and Consumerism; such cooperation is necessitated by limitations on Customs' authority to directly enforce against counterfeits. When confronted with illicit shipments, customs personnel are expected to contact the MDTCC to effect a seizure; in practice, however, this often fails to occur. Rights-holders view this ineffective collaboration and Malaysia's lack of an effective trademark recordation system as the most significant obstacles to border enforcement in the country. That latter concern, along with the overall lack of customs seizures, has also frequently been highlighted in past submissions.

With regard to enforcement in the domestic market, rights-holders were generally pleased with the frequency of raids, and the volume of seizures effected by Malaysian enforcement personnel. Those efforts are undermined, however, by a number of long-standing concerns. Among these is an over-reliance on administrative remedies; offenders typically face little real threat of a custodial sentence, and non-deterrent fines are said to be the norm. This is further exacerbated by the lack of effective prosecutions – one brand commented that despite seeing regular seizures of counterfeits, they have not seen a case proceed to prosecution in more than a decade. Others noted that even where cases have moved forward, the penalties imposed have been nominal. Greater training for both prosecutors and the judiciary is urged.

Rights-holders also continue to cite corruption as a significant contributor to the challenges experienced in Malaysia. As in past years, respondents pointed to raids organized by the MDTCC that were frustrated by tip-offs to offenders, as well as instances where officers unnecessarily and inexplicably delayed carrying out raids, allowing counterfeiters time to remove illicit goods from the targeted premises. In the context of customs enforcement, one brand discussed receiving inquiries as to the availability of "bounties" or "rewards" for large seizures. All of these situations are cause for great concern, and should be addressed by the Malaysian government. Whether the political will exists to do so remains an open question.

Despite some positive feedback from rights-holders, greater efforts are necessary to address these long-standing concerns, and others highlighted by the IACC in past years. Accordingly, we continue to recommend Malaysia's placement on the Watch List in 2021.

PHILIPPINES

IACC members continued to report largely positive interactions with the National Bureau of Investigation and the Intellectual Property Office of the Philippines in 2020. Regrettably, these positive views did not extend to the country's judicial system. The overwhelming consensus among respondent brands during this year's discussions, as in many past years, was that the judiciary's ineffectiveness and inefficiency was the greatest obstacle to the protection of their IP rights in the Philippines. In light of these continuing concerns, we recommend that USTR place the Philippines on the Special 301 Watch List in 2021.

During our consultations regarding enforcement in the Philippines this year, one participant stated, rather bluntly, that they couldn't really comment on the effectiveness of law enforcement's efforts. When asked to elaborate, the brand's representative stated that they had largely abandoned enforcement in the country. In their view, at present, no matter the effort and resources applied by the NBI or IPO-PHL to clean up the local market, "ultimately, the case is going to move the Philippines' broken court system." That same brand noted that it currently has cases in the courts that have been pending for more than a decade.

Reports from other respondents failed to offer a significantly rosier view; the consensus opinion was that prosecutors appear largely uninterested in pursuing IP cases, and typically pressure rights-holders to settle with offenders. Where cases do move forward, brands report the need to constantly monitor their progress, lest the cases (and counterfeiters) simply disappear. One brand discussed adopting a strategy of filing a private prosecution to run in tandem with the public prosecutor's case. The slow-moving processes, the need to file concurrent private actions, and related factors significantly, and unnecessarily, increase the costs associated with enforcement. In the view of some rights-holders, those costs greatly outweigh the benefits of policing their rights in the Philippines, particularly when the ultimate pay-off for a decade-worth of effort is the imposition of rather modest penalties by the court.

Border enforcement in the Philippines also remained a significant concern for IACC members in 2020. Despite some reports of increased seizures during the past year, many continue to view the country's border control measures as insufficient, and encouraged the provision of greater resources by the government to combat illicit trafficking.

In light of these issues, and the reported lack of progress on additional concerns raised in last year's filing; we continue to support the Philippines' return to the Watch List this year.

THAILAND

The IACC recommends Thailand's placement on the Special 301 Watch List in 2021, in light of rights-holders' continuing concerns related to widespread availability of counterfeit goods in local markets and online, significant delays in obtaining registrations, and the need for greater priority within the government to address long-standing obstacles to effective IP protection.

While the Thai legal regime was widely regarded as "reasonably robust" by respondents during this year's consultations, a number of challenges highlighted in past years' submissions were reiterated by IACC members. One such obstacle is tied to rights-acquisition; brands continue to experience significant delays in obtaining trademark registrations. The inability to obtain registrations within a reasonable timeframe presents a major hurdle to enforcement, for obvious reasons. Last year's submission referenced comments from a member who had had numerous applications pending in excess of five years; that same brand confirmed that many of those applications still have not proceeded to registration.

Rights-holders' comments with respect to enforcement personnel varied widely this year. Some spoke highly of their engagement with the Thai Customs, the Royal Thai Police, and the Economic Crime Suppression Division, describing them as willing and enthusiastic partners in IP enforcement. Those respondents point to successful raids that have been carried out during the past few years, as well as well-attended IP training programs held for Customs and other enforcement personnel. Other respondents, however, stated that they've witnessed a consistent and noticeable decrease in the level of enforcement during the past 4 years, highlighting decreased seizures at the border, pervasive retail sales in well-known hotspots, and a lack of meaningful enforcement online. One brand noted that they did not see a single case initiated involving the enforcement of their rights – whether by law enforcement or Customs – during 2020. Even among those brands who have seen cases proceed, there is a view that the penalties imposed by Thailand's courts lack sufficient deterrence. As noted last year, these cases also too often focus on lower-level offenders; greater emphasis should be placed on pursuing higher-level distributors and manufacturers.

Given the continued need for improvement across a range of issues, we recommend Thailand's retention on the Special 301 Watch List in 2021.

VIETNAM

Vietnam has made annual appearances in the IACC's submissions to USTR for countless years, and remains an important, if challenging, jurisdiction for rights-holders. Comments received from IACC members during this year's consultations were largely unchanged from those detailed during last year's process. The continued reliance, or over-reliance, upon administrative remedies by Vietnamese authorities has been a perennial subject of criticism by IACC members; the failure of that approach to bring widespread counterfeiting and piracy under control was highlighted in USTR's final report in 2020.

While a number of brands have expressed pleasure with the progress that Vietnam has made throughout the past decade, more remains to be done. The past decade has also brought about a burgeoning online trade, one that is being monitored with great concern by rights-holders. With regard to that issue, the Ministry of Science and Technology continues to receive plaudits for its responsiveness to complaints about rogue websites engaged in IP offenses. Reports from rights-holders indicate that MoST typically disables websites upon conclusive evidence of counterfeit sales; respondents note that sales through both standalone sites and e-commerce marketplaces are a growing concern. Some brands have described a notable shift to online trafficking, presumably as a result of the COVID-19 pandemic and resulting stay-at-home orders and travel restrictions. We would encourage the Vietnamese government to significantly step-up its online enforcement efforts to address this illicit activity.

In light of these increasing concerns related to online trafficking, and the need for additional progress on those issues highlighted in last year's submission, we support Vietnam's retention on the Special 301 Watch List in 2021.

EUROPE - MIDDLE EAST - AFRICA REGION

EGYPT

IACC members' feedback regarding their experiences in Egypt remained almost entirely unchanged from comments provided in prior submissions. Overwhelmingly, respondents' input focused on continuing challenges related to enforcement. As in past years, these assessments were roundly negative, with brands noting the need for more, and more well-trained, enforcement personnel to enforce the country's IP laws. Raids were said to be hindered frequently by delays on the part of law enforcement, limited intelligence gathering, and a reluctance to work collaboratively with rights-holders. As also discussed in past submissions, the "seizure" of counterfeit goods often amounts to notifying the offender that the goods in question are not to be sold or moved, as opposed to physically taking custody of the goods and removing them to a secure storage facility. This approach raises obvious concerns with regard to the preservation of evidence and the effective removal of illicit goods from the market.

Border enforcement likewise remains a priority concern, with most respondents citing few, if any, seizures at the border.

The lack of deterrent-level penalties for IP offenses – highlighted by USTR in last year's Special 301 Report – also remains a source of frustration.

Accordingly, we support the retention of Egypt on the Special 301 Watch List in 2021.

NIGERIA

IACC members highlighted a variety of challenges to the protection and enforcement of their rights in Nigeria during this year's consultations, ranging from a relatively week statutory regime, insufficient border controls, a need for a more coordinated approach to enforcement, and an inefficient court system. In combination, these factors create a difficult environment for rights-holders; accordingly, we recommend Nigeria's placement on the Special 301 Watch List this year.

Trademark enforcement in Nigeria is generally undertaken pursuant to the infringement provisions of the Trademarks Act or criminal trademark forgery provisions of the Merchandising Marks Act. While both statutes permit police to conduct searches, raids, and seizures of counterfeit goods, the authorized penalties for such offenses are relatively low; rights-holders note that offenses are typically met with modest fines.

Despite those structural obstacles to effective enforcement, respondents were generally complimentary of their counterparts in law enforcement. A representative assessment of the Nigerian Police describes them as "working hard to combat counterfeiting, cooperative, and readily engaging with trademark owners." The efforts of the police are said to be hindered by a need for greater resourcing however, and the non-deterrent penalties that are often imposed by the courts for IP offenses diminishes the effectiveness of those efforts.

Rights-holders' views of Nigerian Customs were less flattering, with some respondents noting incidents of corruption, and some reporting a general reluctance among agency personnel to meet with rights-holders or to participate in training events.

As referenced above, those rights-holders who have seen enforcement actions carried through to trial have been frustrated by the level of penalties assessed – both in the civil and criminal context. While this is due in part to statutory concerns, judges are also seen as not appreciating the gravity of IP offenses. Cases are further said to progress very slowly, in some instances taking years to conclude, contributing to the loss of evidence and the availability of witnesses. One respondent stated that they had not seen a case involving their IP rights concluded during the past four years.

IACC members urge the Nigerian government to increase the priority of IP protection, and in doing so, to ensure both the proper resourcing and coordination of enforcement agencies. We would also welcome a review of the existing legislative framework with an eye towards addressing deficiencies and practical obstacles to the protection and enforcement of IP rights.

Given the feedback received from rights-holders during this year's consultations, we support Nigeria's addition to the Special 301 Watch List in 2021.

UNITED ARAB EMIRATES

IACC members have raised a number of concerns about the Emirates' IP regime – most frequently in connection with ineffective customs enforcement (including within the UAE's free trade zones) – for many years. Given the lack of meaningful progress reported by rights-holders during this year's consultations, we urge the USTR to retain the United Arab Emirates on the Watch List in 2021.

Rights-holders were hopeful that the enactment of the UAE's new IP law in 2016 signaled a growing recognition of the importance of IP protection and enforcement. Over four years later, any optimism in that regard appears to have been misplaced. The law remains largely unimplemented, and welcomed provisions such as significantly increased penalties have yet to materialize. Recidivism attributed to the UAE's non-deterrent penalties has remained a point of frustration for rights-holders.

On a somewhat positive note, respondents in the healthcare sector expressed support for a requirement introduced by the Emirates' Ministry of Health, mandating hospitals' procurement of medical devices from authorized distributors only. That simple step has been seen to decrease the prevalence of counterfeit medical devices in the hospital setting, and correlating to enhanced patient safety. And, while less frequent, those incidents do continue to materialize; respondents underscore the need for greater cooperation and transparency in remedying such issues.

Rights-holders' concerns with regard to enforcement have been discussed in detail in numerous past submissions, and feedback provided during this year's consultations remained largely unchanged from that heard in previous years. To wit, most participants spoke in roundly positive terms when discussing their work with the Police and the Departments of Economic Development throughout the Emirates; their harshest criticism was reserved for Customs. Customs officials in the UAE are described as, "at best, reluctant partners."

In light of these issues, and numerous outstanding issues raised in past submissions – most notably the lack of enforcement in the UAE's many Free Trade Zones and its continued policy of re-exporting counterfeit shipments (often without providing any relevant information that would enable follow-up investigations by a rights-holder) – we ask USTR to retain the United Arab Emirates on the Special 301 Watch List in 2021.

AMERICAS REGION

COLOMBIA

The IACC concurred with USTR's placement of Colombia on the Watch List in 2020; we support the country's retention on the Watch List in 2021 as well.

Respondents spoke in generally positive terms regarding their engagement with Colombian enforcement agencies, an improvement over last year's assessment which described enforcement as "uneven." Several members singled out Colombia's tax and customs police (PolFA) for praise, describing them as "diligent," "responsive," and "professional" in their work and in interactions with rights-holders. Enforcement agencies are seen as under-resourced however, a contributing factor to the persistent retail market for counterfeits (including several well-known and notorious markets).

The impact of PolFA and other enforcement bodies' efforts are, unfortunately, said to be limited though by sometimes inefficient prosecutions; rights-holders would encourage the expansion of the specialized IP enforcement unit that has been established by the Prosecutor's Office. There was also a strong consensus among respondents concerning the need for more substantial penalties; while the Colombian criminal code allows for substantial custodial sentences for IP offenses, in practice these are rarely imposed. Several IACC members expressed support for a greater emphasis on financial penalties to target counterfeiters' business, including the forfeiture of instrumentalities used to facilitate the criminal activity as well as any profits earned through their illicit sales.

While IACC members' feedback this year suggests that things are moving in the right direction, we support Colombia's retention on the Special 301 Watch List in 2021.

ECUADOR

USTR retained Ecuador on the Special 301 Watch List in 2020, citing a range of issues impacting trademark and copyright owners, in addition to the need for significant improvements to the country's border enforcement regime. Unfortunately, IACC members reported no significant improvements in the situation in Ecuador over the past year; accordingly, we support its retention on the Watch List again in 2021.

As discussed in prior years' submissions, Ecuador's border enforcement regime has been a point of significant frustration for rights-holders since the adoption of the current framework in 2016. In the words of one respondent, "Customs has been gutted." The high threshold established, in terms of the range and specificity of information required in order to pursue seizures has been incredibly discouraging to rights-holders, and even more so when they see counterfeit versions of their products sold widely in the local market.

We welcome USTR's continued focus of attention on the issues raised by the IACC and other organizations in recent years, and support Ecuador's continued placement on the Watch List this year.

GUATEMALA

USTR retained Guatemala on the Special 301 Watch List last year, citing a range of concerns including poor coordination among law enforcement and a lack of political will that has contributed to widespread copyright piracy and commercial-scale sales of counterfeit goods. Among the industries impacted by this activity are the computer software sector, television and other audiovisual content producers, as well as the pharmaceutical industry. During this year's consultations, we've also received troubling reports from rights-holders in the apparel sector detailing the significant worsening of concerns first reported two years ago.

Guatemala is now seen as a major production center for counterfeit apparel. The manufacturing appears to be centered in San Francisco El Alto, where the counterfeiting operations are subject to protectionism due to their significant contributions to the local employment base. Efforts to obtain assistance from law enforcement have been largely unsuccessful, partly the result of political opposition and concerns of the potential for civil unrest.

Some rights-holders, likewise, note considerable difficulty in obtaining assistance from Guatemalan Customs. That difficulty is exacerbated by the lack of an effective recordation system for intellectual property rights.

In light of the numerous issues highlighted in last year's Special 301 Report, Guatemala should, at minimum, be retained on the Watch List this year. Given the reports we've received concerning the increasing severity of the problems experienced by the apparel sector over the past two years however, we would also encourage USTR to consider elevating Guatemala to the Priority Watch List.

PARAGUAY

Paraguay has made consistent appearances in the IACC's annual Special 301 submissions over the past two decades. A one-time Priority Foreign Country, Paraguay continues to present a variety of challenges for IP owners. The range of issues involved, and the severity of those concerns faced by rights-holders across a number of product sectors is greatly troubling. We support Paraguay's retention on the Special 301 Watch List this year, while noting that there is increasing support among the IACC members we spoke with during this year's consultations to elevate the country to the Priority Watch List level.

IACC members highlighted a number of concerns in Paraguay including the country's statutory framework, the efficiency of its judicial processes, insufficient border controls, and non-deterrent penalties, among others.

One respondent described Paraguay's legal framework as, "sufficient on paper, but not in practice;" noting that the principal statute for the protection of IP is over twenty years old, and would benefit from modernization. Some brands, in more highly-regulated industry sectors, have found limited success in pursuing enforcement under statutes unrelated to intellectual property.

Rights-holders' comments concerning Paraguayan enforcement bodies were mixed, though generally positive. The Economic Crimes Unit of the National Police, e.g., was well-regarded, though many respondents opined that the group was chronically under-resourced, which limits its overall capacity to pursue IP offenses. The National Directorate for Intellectual Property (DINAPI) was also typically described as supportive of rights-holders, but constrained by its lack of enforcement authority and consequent reliance on the police and prosecutors.

Even where rights-holders' complaints are pursued however, many report little optimism regarding the ultimate resolution of those cases. Prosecutors are said to frequently show disinterest in pursuing IP-related offenses, and penalties are described as far too lenient to result in deterrence.

Customs enforcement in Paraguay also remains challenging. While some respondents reported positive interactions with Customs; many, when asked to gauge the effectiveness of Paraguay's border enforcement regime, simply pointed to the volume of counterfeits seen flowing through Paraguay en route to Brazil, Argentina, and Chile.

Perhaps most troubling, every respondent who provided input for our comments on Paraguay during this year's process cited corruption as a significant concern. It is viewed as endemic, and impacting nearly every aspect of IP protection and enforcement in the country. It is incumbent upon the Paraguayan government to identify and root out such activity if there is to be any expectation of an improved situation in the country.

Given the range and persistence of the concerns heard by IACC members this year, we recommend Paraguay's retention on the Watch List in 2021.

PERU

IACC members continued to report a variety of challenges in their efforts to protect their IP rights in Peru during the past year. Among the issues identified by respondents were widespread retail and wholesale distribution, as well as manufacturing of counterfeit goods; a lack of pro-active enforcement; insufficient resourcing, and the need for a more coordinated approach to IP enforcement.

Despite these and other difficulties, rights-holders commented positively on their interactions with the National Police of Peru, describing them as "diligent," "professional," and "willing to assist." Unfortunately, as noted above, the police are also chronically under-resourced, and often lack the manpower and materiel support that might enable them to be even more active. Respondents have also noted that enforcement personnel have at times appeared discouraged in pursuing IP offenses, as the impact of their work is seen to be limited by ineffective prosecutions and a court system that frequently imposes only nominal punishments for such crimes.

With regard to prosecutions, some brands expressed support for the development of a formal training curriculum for both prosecutors and the judiciary – it's thought that both groups lack the necessary expertise to effectively handle intellectual property matters. A number of brands provided feedback concerning the inconsistent application of legal standards, leading to unpredictable results in their cases. These concerns may be due, in part, to the fact that the court system, too, is consistently under-resourced, and burdened with heavy caseloads. Another frequently heard concern with regard to the judiciary involves the level of penalties imposed by the courts. While significant penalties are authorized for IP offenses, in practice, sentences rarely rise to a level that would be considered a significant deterrent.

In light of all of the above, it should come as no surprise that the Peruvian government's commitment to IP has been questioned by many rights-holders. Some members have expressed optimism though, in light of the recently issued Administrative Resolution No. 362-2020, for the creation of 45 new IP criminal courts. Those brands are hopeful that this action will help to alleviate some of the challenges discussed above. Further action to facilitate coordination among the Trademark Office, Customs Authority, National Police, IP prosecutors, and – importantly – the rights-holder community is viewed as essential to realizing significant progress on the many long-standing concerns highlighted in this and past Special 301 filings.

In light of the comments received from rights-holders during this year's consultations, the IACC supports Peru's retention on the Special 301 Watch List in 2021.

OTHER OBSERVATIONS

ASIA-PACIFIC REGION

SOUTH KOREA

IACC members registered concerns during this year's consultations regarding South Korea's departure from global analytical standards for determining the distinctiveness and descriptiveness of trademarks. As detailed in our comments pertaining to Canada herein, South Korea's approach has constituted an absolute bar to some IP owners' abilities to obtain registration (and in turn, effective protection of rights that are widely recognized in over 100 global jurisdictions).

These determinations by the South Korean Trademark Office have opened the door for counterfeiters to manufacture and distribute a variety of goods, while trading on the goodwill of well-known brands, to the detriment of both legitimate manufacturers and consumers in the Korean market.

SINGAPORE

The IACC recommended Singapore's inclusion on the Special 301 Watch List last year, citing rights-holders' continuing concerns with the country's border enforcement regime – described as both overly burdensome and as a significant impediment to enforcement. Singapore is viewed as a major hub for the transshipment of counterfeit goods.

During this year's consultations, rights-holders reiterated those concerns raised in each of the past two years. Both in terms of the expense involved and the procedural constraints imposed, border enforcement in Singapore remains largely unworkable for even large, well-resourced brands. Previous filings have noted the stringent timelines imposed on the enforcement process; in the absence of a court order, shipments may be detained for no more than two days. This burden is compounded by the costs associated with obtaining the bond required, not to mention those associated with litigating any disputes by the adverse party.

Rights-holders also urge greater coordination between the Police IPR Branch and their counterparts at Customs, which is seen as necessary to facilitate investigations into illicit trafficking.

We would welcome USTR's attention to these long-standing concerns in 2021.

EUROPE - MIDDLE EAST - AFRICA REGION

ANGOLA DEMOCRATIC REPUBLIC OF THE CONGO

While we make no recommendation for the placement of either Angola or neighboring Democratic Republic of the Congo on the Special 301 Watch List this year, we wish to draw USTR's attention to increasing reports received from rights-holders regarding the need for holistic improvement of both countries' IPR regimes.

At present, Angola's statutory framework is viewed as insufficient to address the growing counterfeit market in the country. Respondents suggest that training opportunities for law enforcement and the judiciary would be beneficial. Public awareness of the harms associated with the counterfeit trade is also said to remain relatively low, particularly with regard to product sectors presenting high risks to consumers' health and safety, e.g., food and beverage, pharmaceuticals, and electronics.

Similar issues were raised by rights-holders in connection with the DRC; there appears to be an increasing prevalence of counterfeits in the local market that has resulted in growing concerns among respondents. As noted in past years' submissions, border control challenges throughout the Sub-Saharan region have contributed to increased trafficking in a number of jurisdictions. We have been in contact with U.S. Government representatives, including the Department of Justice ICHIP based in Abuja, Nigeria, and HSI attaché in Pretoria, and we believe there may be opportunities for government and industry-led engagement efforts that could lead to progress on rights-holders' concerns.

ITALY

IACC members wish to draw USTR's attention to rising concerns related to the enforcement of their rights in Italy.

Perhaps chief among these concerns involves the approach taken by the Italian IP Office in examining trademark applications. Because the Office does not examine trademark applications based on relative grounds, criminals have taken advantage of this perfunctory examination process to register marks confusingly similar to well-known global brands. As a result, legitimate brands are forced, unnecessarily, to dedicate time and resources to challenging registrations that should never have issued in the first place. This problem is compounded by Italy's status as an EU Member State, and serves as a prime example of the type complications resulting from the EU's partially-integrated system.

Brands also sought to highlight Italy's role as a major hub for the importation of counterfeit goods into the European Union. That illicit traffic is fostered by inconsistent support from law enforcement – particularly in key regions, such as Puglia – and by the lack of (and lacking enforcement of) deterrent sentences against offenders. Significantly greater political will is required to address these issues.

QATAR

Rights-holders in the pharmaceutical and medical device sector reported significant challenges in Qatar during 2020, related to illicit distribution of counterfeit, diverted, and adulterated medicines, as well as sales of counterfeit medical devices. Respondents cited numerous incidents of such products being purchased by hospitals and medical offices through unauthorized channels, and described a lack of responsiveness from the Ministry of Health and Hamad Medical Corporation in regard to their complaints.

UNITED KINGDOM

Rights-holders continue to report frustrations related to the enforcement of their rights in the UK, particularly in the context of the country's border enforcement efforts. Respondent brands reported receiving relatively few seizure notices from Customs, despite the widespread availability of counterfeits in the British market. As the UK is not viewed as a significant source of counterfeit production, the logical conclusion is that counterfeit goods across every product sector are being imported from abroad on a massive scale.

The difficulties faced by rights-holders can be tied to a number of factors, including the insufficient resources allocated to border enforcement, and the increased focus of border enforcement personnel on immigration and counterterrorism priorities, as well as revenue collection. Some brands also described decreased cooperation from Customs officers when seizures or detentions have taken place. By way of example, some respondents complained of difficulties in obtaining samples of seized products, or being required to appear in-person to examine relevant samples. This would be challenging under normal circumstances, given the tight windows for intervention; it has been even more so during the pandemic. We've received additional reports regarding inconsistent and disparate treatment as well. As described by one brand, Customs tends to demonstrate more lenience or flexibility in its application of rules (e.g., timelines for providing information / evidence) in the case of importers, while strictly enforcing the same against rights-holders.

The transition period for the UK's exit from the EU ended on 31 December 2020, resulting in the creation of new UK specific IPRs and a new process for applying for an "Application for Action" (AFA) to request that Customs seize infringing goods entering the UK. Unfortunately, the transition has not been without difficulties. One brand highlighted that guidance for the new framework to take effect on January 1, 2021 was not published until December 4, 2020. As a result, rights-holders had lead-time of less than one month to implement necessary operational changes, such as the filing of new AFAs.

On a more positive note, IACC members offered more positive views with regard to the Police Intellectual Property Crimes Unit (PIPCU), citing its commitment and efforts throughout the country. PIPCU sits within the City of London Police Force and has a national remit for investigating complex IP crime, and so there is enormous potential for the agency to do more.

Given the above-discussed difficulties in dealing with UK Customs, rights-holders frequently seek assistance from UK Trading Standards to pursue counterfeiting matters. As detailed in prior years' submissions though, these agencies are chronically underresourced and IP offenses constitute only a small portion of their enforcement remit.

We're hopeful that USTR will highlight the need for significant improvement on each of these issues in the context of the ongoing U.S. – U.K. Free Trade Agreement negotiations.

AMERICAS REGION

PANAMA

Not long ago, Panama was viewed by many as the "gold standard" for customs enforcement in Latin America. Regular, large-scale seizures were frequently reported by rights-holders, who complimented enforcement personnel for their diligence, engagement, and collaborative approach. The high-level of enforcement seen in Panama was, to a large extent, credited by rights-holders for the increased traffic seen in other jurisdictions – i.e., it appeared counterfeiters were actively seeking alternate routes to move their wares into Central and South American markets due to the perceived risk of having their illicit shipments seized by Panamanian Customs.

We've been troubled, however, to hear a number of reports during this year's consultations regarding apparent significant decreases in the level of enforcement from that seen in the past. Seizures of counterfeits entering or transiting the country are said to have greatly diminished in recent years, with one major brand noting that it has not seen a single seizure by Panamanian Customs during the past five years.

Panama remains a vital hub for the distribution of both legitimate and illicit trade in the region; we call upon the Panamanian government to significantly increase the priority of IP enforcement, and welcome USTR's assistance in drawing attention to the need for improvements in this regard.

<u>ISSUE SPOTLIGHT</u> TRAFFICKING OF ELECTRONIC NICOTINE DELIVERY SYSTEMS

In our comments to USTR last year, the IACC highlighted growing concerns related to the emerging black market for electronic nicotine delivery systems (ENDS) and the negative impacts those products posed to consumer safety. Multiple, large-scale seizures by U.S. Customs and Border Protection (CBP), enforcement actions from the U.S. Food and Drug Administration (FDA), as well as actions taken by Chinese law enforcement against producers and distributors of these illicit goods, and enforcement campaigns undertaken directly by rights-holders in the sector during the past year have only served to underscore those concerns raised a year ago. ⁶

China remains a major source of illicit tobacco and nicotine products – including more technologically-advanced, reduced-risk products, like ENDS – seized at U.S. ports, en route to American consumers. While authentic ENDS products are appropriately regulated by FDA, illicit suppliers and distributors continue to circumvent federal laws and regulations by importing these infringing products into the United States via traditional cargo shipments (for retail sale in brick-and-mortar locations) and directly to consumers in small consignments (typically sourced via e-commerce sites).

In addition to infringing on the intellectual-property rights of U.S. companies, counterfeit and other illicit ENDS products present additional health and safety risks for U.S. adult consumers. These products may contain harmful chemicals that are not present in authentic, regulated products and are produced outside of generally accepted manufacturing practices with unknown and untested ingredients and defective components (e.g., batteries; heating mechanisms). The 2019 outbreak of vaping-related lung injuries (known as "EVALI") is an unfortunate, but real, example of the negative public-health consequences that result from illicit, unregulated black-market products. As FDA and the Centers for Disease Control and Prevention (CDC) have now affirmed, national and state data from patient reports and product sample testing reflect that illicit, THC-containing vapor products, particularly from informal sources, were linked to most EVALI cases.⁷ In total, at least 68 Americans died and over 2,800 were hospitalized as a

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⁶ See, e.g., CBP, FDA Seize Unapproved E-Cigarettes worth \$719,453, available at https://www.cbp.gov/newsroom/local-media-release/cbp-fda-seize-unapproved-e-cigarettes-worth-71945 (last accessed Jan. 28, 2021); and see, Noah Manskar, Counterfeit Juul E-Cigarette Manufacturer Busted in China, available at https://nypost.com/2020/10/30/counterfeit-juul-e-cigarette-manufacturer-busted-in-china (last accessed Jan. 28, 2021), detailing the prosecution of a large-scale manufacturer of counterfeit ENDS.

⁷ See, e.g., FDA, Lung Injuries Associated with Use of Vaping Products, available at https://www.fda.gov/news-events/public-health-focus/lung-injuries-associated-use-vaping-products (last accessed Dec. 23, 2020); CDC, Press Release, Most EVALI Patients Used THC-Containing Products as New Cases Continue to Decline (Jan. 17, 2020), available at https://www.cdc.gov/media/releases/2020/p0117-evali-cases-decline.html (last accessed Dec. 23, 2020); see also Lena H. Sun, CDC: Most People Who Died From Vaping-Linked Disease Used Products Containing THC, Washington Post (Oct. 25, 2019) ("Many sick patients said they bought THC vape products on the black market, and those have come under increased scrutiny.").

result of EVALI. Both FDA and CDC determined that the most likely root cause of EVALI was the use of black-market vapor products, largely from informal sources, with the ingredient vitamin E acetate. The lack of active and aggressive enforcement against counterfeit and other illicit products can only leave open the possibility that another public-health crisis like EVALI could occur.

A growing public-health, economic, and security issue, the emerging illicit trade of blackmarket ENDS products mirrors similar experiences with other tobacco and nicotine products. Illicit ENDS products generally fall into three product types: (i) counterfeit; (ii) compatible; (iii) diverted. 8 Similar to the illicit trade for other products, these illicit ENDS products reduce sources of government revenue through tax evasion; facilitate broader criminal activity and threaten national security; undercut the rule of law, legal and regulatory frameworks, and public-health policies; and violate the intellectual-property rights and impact brand integrity for U.S. companies. Critically, particularly for counterfeit and compatible ENDS products, they also present additional health and safety risks for U.S. adult consumers (given the inadequate manufacturing and quality controls and lack of product and ingredient testing) and facilitate underage access (given how they are often sold through non-traditional retail channels). While the global illicit trade for these products is growing, the predominant source continues to be China. Since 2019, U.S. Customs and Border Protection (CBP) has publicly confirmed at least ten seizures of illegally marketed or illicit ENDS products imported from China or Hong Kong. This includes over 379,000 devices and 4,300 e-liquid pods valued over \$3.5M.

Recently, ENDS products in the United States have undergone a significant shift to a more regulated, more transparent marketplace. As of September 2020, manufacturers of ENDS products that have been on the market as of August 8, 2016 — when FDA first asserted jurisdiction over ENDS and other deemed tobacco products — were required to submit premarket tobacco product applications (PMTAs) to FDA. Now, these regulated products are subject to FDA's science-based review process to determine whether they are appropriate for the protection of public health.

Moreover, FDA has taken direct policy actions to address underage use of ENDS products. For example, in January 2020, FDA issued guidance that outlined its enforcement priorities for ENDS products, which in part cleared the market of non-tobacco and non-menthol flavored, cartridge-based ENDS products without marketing authorization⁹. FDA noted the risk of an illicit trade or black market in ENDS products given its policy action, but maintained that it had the regulatory tools and enforcement authorities to address such products.

⁸ Counterfeit ENDS products are designed and marketed to mimic authentic ENDS products but are made and distributed by unauthorized manufacturers and violate the intellectual property rights of authentic

brands. Compatible ENDS products are third-party products designed, manufactured, and marketed to be used with authentic ENDS products and similarly violate the intellectual property rights of authentic brands. Diverted ENDS products are authentic products that are intended for and sold in non-U.S. markets but have been imported into the U.S. without the manufacturer's authorization.

⁹ FDA, Guidance for Industry: Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised) (April 2020).

Black-market ENDS products, in addition to being marketed illegally and in violation of various federal statutes, may pose additional health and safety risks for adult consumers beyond those of authentic, regulated products. According to FDA, "[a]dditional risks posed by these products include the potential that they contain harmful chemicals or constituents that are not present in other products, that they are manufactured using comparatively poor quality controls, and that they are designed in ways that facilitate modifications by distributors or users — all of which increase the risk of adverse events." FDA also has noted that the availability of black-market ENDS products undermine tobacco-control measures to address underage use to the extent they are sold through non-traditional retail channels, such as social sourcing or online commercial marketplaces that lack age-verification requirements.

Recognizing the importance of addressing this emerging black market and its impact across U.S. businesses and communities, the National Intellectual Property Rights Coordination Center (IPR Center) and the National Crime Prevention Council (NCPC) recently launched a public-private partnership to combat counterfeit and other illicit vapor products. This targeted campaign seeks to raise awareness on the public-health consequences of illicit vapor products and provide resources to law enforcement and adult community leaders to support enforcement against these illicit activities.¹¹

Like other illicit trades, collaboration across stakeholder groups is critical to address the illicit trafficking of ENDS products. Given the international implications, sourcing from abroad, and violations of U.S.-owned intellectual-property rights, we believe that USTR is well-positioned to facilitate action against counterfeit and other illicit ENDS products. Accordingly, we encourage enhanced enforcement efforts – including joint enforcement operations to leverage the collaborative efforts of U.S.- and China-based enforcement agencies – targeting the manufacturers, distributors, and retailers of these illicit products that increasingly jeopardize the health and safety of U.S. consumers.

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¹⁰ See id. at 28.

¹¹ See, e.g., Press Release, IPR Center, National Crime Prevention Council Launch Nationwide Campaign to Raise Awareness on Illicit Vapor Products (Oct. 21, 2020), available at https://www.ice.gov/news/releases/ipr-center-national-crime-prevention-council-launch-nationwide-campaign-raise (last accessed Dec. 23, 2020).