AmCham EU
SPEAKING FOR AMERICAN BUSINESS IN EUROPE

Consultation response

Protection and enforcement of intellectual property rights in third countries

AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and U.S. positions on business matters. Aggregate U.S. investment in Europe totalled more than €3 trillion in 2019, directly supports more than 4.8 million jobs in Europe, and generates billions of euros annually in income, trade and research and development.

American Chamber of Commerce to the European Union
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Introduction

The American Chamber of Commerce to the European Union (AmCham EU) welcomes the European Commission's ongoing efforts to advance strong and balanced intellectual property rights (IPR) globally. Together with the EU Counterfeit and Piracy Watch List, the biannual report on the protection and enforcement of IPR in third countries is an important tool in assessing the scale and scope of the challenges being faced, and in determining where to focus the EU's efforts.

US businesses invested in and committed to Europe often rely on the appropriate legal frameworks in third countries regarding IPR. These US companies invest and innovate in a range of critical sectors, including life sciences, digital, audiovisual and consumer goods. Such innovations bring benefits to citizens, patients and consumers, as well as the broader economy – not just in Europe or the US, but across the globe. As a reflection of our stake in this, European affiliates of US companies invested $33 billion in R&D in Europe; while ten of the top twenty export platform countries for US companies are in Europe, including Belgium, Germany and Ireland.[1] In the latter case, Irish affiliates of US companies export four times more globally than they do from China, and three times more than from Mexico.[2]

As two trading partners whose IP intensive industries are the most impacted by infringement in third countries[3], businesses in the EU and the US need focused support on reducing infringement that only government to government interaction can drive through trade and other contacts. Enforcement resources, prioritisation and the legal structures to support them in third countries are vital for both export-driven growth of Europe's domestic industries and in preventing importation or the placing on the European market of infringing goods or services. This protection of the level playing field then reduces burdens on domestic customs and enforcement agencies to act after the fact. The recent proposal to double the budget for the external border in the Customs Action Plan is one reminder that costs of compliance fall on the states as well as business.

Intellectual property (IP) violations manifest themselves in multiple ways, reflecting the diverse range of IP rules and incentives. This includes in the areas of patents, trademarks and copyright, as well as more specific mechanisms, such as regulatory data protection (RDP), which is critical for protecting clinical and other test data in certain highly-regulated sectors. Research consistently shows that the lack of appropriate rules, large scale infringements and poor enforcement cause significantly adverse impacts on right holders, licensees and legitimate businesses. They also undermine competitive advantages in innovation, while posing threats to consumer health and safety as well as to jobs and growth. To underline the potential impact of this on Europe's economy, the European Union Intellectual Property Office (EUIPO) notes that IPR-intensive industries account for about 90% of EU trade with the rest of the world.[4]

We call upon the European Commission to strengthen its focus on securing sustainable improvements to the IP environment in third counties. The Commission's work with third countries should include a focus on strengthening rules and technical capabilities of authorities, clear and measurable objectives in improving prosecution of bad actors, reduction of exported infringements and ease of resolving civil disputes between competitors. The mechanisms to support this may include further dialogue and engagement of third country governments and other stakeholders, technical programmes (eg, IP Key[5]), negotiating ambitious IP provisions in EU Free Trade Agreements (FTAs), and critically the Commission's new trade enforcement strategy, which

[1] 'The Transatlantic Economy 2020: Annual Survey of Jobs, Trade and Investment between the United States and Europe', https://transatlanticrelations.org/wp-content/uploads/2020/03/TE2020_Report_FINAL.pdf.

[2] Ibid.

[3] OECD-EUIPO (2019), 'Illicit Trade: Trends in Trade in Counterfeit and Pirated Goods', https://euipo.europa.eu/tunnel-web/secure/webdav/guest/document_library/observatory/documents/reports/trends_in_trade_in_counterfeit_and_pirated_goods/trends_in_trade_in_counterfeit_and_pirated_goods_en.pdf.

[4] European Union Intellectual Property Office (EUIPO) (2016), 'Intellectual property rights intensive industries and economic performance in the European Union', https://euipo.europa.eu/ohimportal/en/web/observatory/ip-contribution.

[5] European Commission's IP Key Programme in Latam, China and Southeast Asia: https://ipkey.eu/en.

strengthens the implementation and enforcement of EU trade policy, including for IP. In addition, we also encourage reinforcing existing collaborations, including with the US. AmCham EU stands ready to work with the European Commission in achieving those goals and in sharing insight on other countries and the IPR challenges faced by our companies globally.

Below we have listed some critical global markets and inputs about IP related challenges. The list compiled should not be considered exhaustive, but we hope it will help bring some clarity on some of the concerns when it comes to the protection and enforcement of IPR in third countries.

China

From a pharmaceuticals viewpoint, China has made some encouraging steps to strengthen its IP protection and enforcement system. The amended Drug Administration Law and the Patent Law, along with multiple proposed implementation measures, would strengthen its regulatory and IP frameworks for innovative medicines to potentially at least partially address long-standing concerns about loss of patent term due to lengthy regulatory approval processes, ineffective patent enforcement and inconsistent patent examination guidelines. Nevertheless, the sector is still seriously concerned about the lack of effective RDP, and is eager to hear more about the planned legislation and detailed rules for newly-introduced mechanisms such as patent term extension and the early resolution of patent disputes. The pharmaceutical industry is also concerned with the human genetic resource (HGR) review requirement for all clinical studies sponsored by foreign entities. This creates huge and unnecessary burdens on drug development, notably including requirements for forced IP sharing between foreign and Chinese parties.

From a brand protection perspective, recent reforms are aimed at creating a more transparent and effective system regarding the IP protection and enforcement in China. The government has introduced broad changes to its agencies responsible for IP-related matters. China has also embarked on judicial system reforms as well as reviewed and/or amended its IP legislations including the e-commerce law. For example, the new e-commerce law introduced joint liability for e-commerce platforms and counterfeiters who fail to 'take the necessary measures' to prevent and stop sellers from infringing IPR. The practical impact of the recent changes remains to be seen. We note that China continues to be the leading source of counterfeit and pirated goods. The OECD reports that 80% of counterfeit and pirated goods that are seized worldwide originate from China.[6] China also continues to be listed in the US special 301 Report, issued by the Office of the United States Trade Representative (USTR), and Chinese brands continue to be present on the US report and review of the Notorious Markets List. Continuous efforts by China towards decreasing the counterfeit market are essential. This should include further facilitating IP holders to bring cases against counterfeiters before Chinese courts, improving criminal penalties for IP infringements, adopting as well enforcement measures to effectively discourage repeat infringers.

Despite new legislation being adopted over the past years, such as the establishment of courts specialised in dealing with IPR cases, there is generally a low level of IPR protection and lack of enforcement in the country by the authorities. The continual postponement of the new copyright law has left rights holders and judiciary alike in a state of limbo waiting for the new laws to come into force. Right holders who would otherwise take steps to enforce their rights in court face barriers including high costs, unnecessary delays and inconsistencies in jurisdiction, in particular for cases involving online content. It should be noted that before enforcement can even take place there is a heavy evidential burden put on rights holders to prove both copyright ownership and the infringement levels in the target physical and digital market. The high threshold of infringement required to trigger criminal enforcement action in physical markets (500 infringing titles/articles) is given a rather rigid and narrow interpretation for the digital market, which obligates rights holders to show ownership and infringement of 500 separate titles in order to trigger enforcement action. The most common route for rights holders to protect their work is to take criminal or administrative action rather than civil, which does not provide compensation for infringement. Increasing the range and scale of penalties available for criminal and

[6] OECD (2019), 'Trade in fake goods is now 3.3% of world trade and rising', https://www.oecd.org/newsroom/trade-in-fake-goods-is-now-33-of-world-trade-and-rising.htm.

administrative actions would be of use to significantly deter infringers. An increased compensation in litigation would help to deter infringements and strictly enforce the ruling regarding compensation. At the same time lowering the burden of proof of ownership and infringement will help encourage rights holders to instigate enforcement actions, which will in turn tackle the wider problem of cross-provincial organised crime networks.

Other sectors report that while the legal system and enforcement mechanisms in China with respect to IP have improved over the past five years, there are still a number of issues to highlight:

- Local protectionism – corruption is still entrenched particularly in many second, third and fourth tier cities. The heartland of counterfeit production, Guangdong province, still has many cities such as Shantou, Chaozhou, Foshan, Dongguan and even Guangzhou where high levels of protectionism persist. This makes it difficult to root out the foundations of sophisticated and entrenched counterfeiting networks. Criminal prosecutions and convictions continue to grow, however the finance and leadership behind large scale organised crime in counterfeiting remains largely unaffected.

- We are seeing the continuation in the trend away from the production and sale of direct counterfeit products to more instances of 'lookalike' products trading off legitimate businesses' packaging designs and shapes. The implications of this shift means that IP protection will become even more complex and cost intensive. Furthermore, the administrative and court system in China needs to be developed and provided greater knowledge and capability to effectively uphold the IP rights of brand owners in China.

- There has been an increase in the discovery of the use of trademarks, or variations, as signage on retail stores. Other than pursuing claims related to unfair competition, we see it as an opportunity to systematically urge the Market Surveillance Agency (MSA) to implement clear and transparent procedures and requirements for taking down such infringing signage. In particular, we would like to see consistency and clarity in their attitude towards protection of a brand owner's registration of a Class 35 mark related to retail and advertising.

- Another issue is that of the reluctance of the MSA to transfer cases that meet the criminal threshold to the Public Security Bureau (PSB) due to subtle differences or variations between the counterfeit and genuine products. We urge the MSA to strictly comply with the laws and to transfer cases like this to the police for criminal prosecution.

India

From a patent viewpoint, India is highly unpredictable. Its legal and regulatory systems pose procedural and substantive barriers at every step, including patentability criteria, onerous application disclosure criteria and a lack of enforcement. Regarding RDP, India continues to fail to ensure that there is no unfair commercial use of the clinical test data submitted by another party when securing marketing approval for a medicine in India or in a third country.

From a brand protection perspective, India is one of the most challenging regions for IPR protection and enforcement. Brand owners continue to report sales of counterfeit and pirated goods, mainly in physical markets. The procedures at customs lack transparency and bureaucracy levels are high. Lack of a modernised infrastructure at many ports makes the seizures less efficient and does not allow for quick identification of counterfeit goods and infringers. Legal proceedings are also too lengthy.

Indonesia

Amendments to Indonesia's Patent Law in 2016 preclude patents on new uses, and establish criteria of 'increased meaningful benefit'. This latter point conflicts with international obligations by imposing additional patentability criteria that discriminates against particular classes of technology, notably pharmaceuticals. Changes to the Patent Law would impose patent disclosure requirements about genetic resources. These would introduce uncertainties into the patent system, inhibiting innovation in relevant technologies and undermining the potential of benefit-sharing.

In addition, Indonesia is one of the countries with the highest number of online take down requests in recent years. Several factors are responsible for this worrying trend. Firstly, the large numbers of counterfeit products present on various national and international e-commerce platforms such as Lazada, Shopee, Bukalapak or Tokopedia, whose clear counterfeit nature make them relatively easy to find and company monitoring systems return huge numbers of counterfeit listings on these platforms. This is also due to the insufficient seller vetting and pro-active controls by the platforms. Furthermore, even if these fraudulent listings are taken down, they often reappear very quickly, resulting in the 'whack-a-mole' effect and high take down numbers and costs. These e-commerce platforms are often less mature than larger players or their parent companies (eg, Alibaba) and their IP protection measures do not provide sufficient 'stay-down' options. Considering this confirmed trend of large numbers of online counterfeits on Indonesian platforms, we believe that more political pressure should be applied to force them to take effective measures to protect IPR holders and consumers from online counterfeiting.

Southeast Asian Nations

Trade flows in counterfeits into, from and intra the Association of Southeast Asian Nations (ASEAN) seem to be increasing. Gradual shifts in the location of the production of counterfeits from China to Vietnam and Cambodia are occurring, and border flows of counterfeits from China to Vietnam, Laos and Myanmar seem to also be increasing. Organised criminal networks can plot trade routes between Vietnam, Laos, Cambodia and Thailand avoiding enforcement hotspots. These trends, in addition to the online issues in Indonesia, Thailand and Malaysia, indicate that the demand and supply of counterfeits is growing as incomes and brand awareness continue to grow within ASEAN.

When compared with the greater political complexity of dealing with China, EU international IP policy engagement with ASEAN may be more impactful in terms of highlighting, advocating and supporting accelerated improvements in IP laws and enforcement capabilities. Certainly, pre-COVID-19, consumer demand has been strengthening for needed products and on the back of the growing popularity of online marketplaces. The ASEAN will need more support in terms of training and capacity building from the EU to assist them in developing stronger IP enforcement regimes to keep up with the challenges posed by regional counterfeit networks and expanding trade via poorly regulated e-Commerce.

Morocco

Counterfeited products have been growing for years in Morocco and have become a significant economic factor. Morocco's free trade zones and touristic sectors are important drivers for this. While Morocco appears to have all of the necessary laws and regulations in place, we find that in practice anti-counterfeiting measures are often complex and expensive. Consequently, raid actions and seizures are often not taking place as IPR holders are forced to file civil cases instead of using simplified criminal procedures. These are frustrating difficulties to encounter in anti-counterfeiting operations, and such procedures should be simplified for IPR holders with more proactive measures to be implemented by the authorities.

Russia

The Russian government is pursuing draft legislation that may improperly limit certain types of patents for innovative medicines and create vague and arbitrary criteria for compulsory licensing (CL) of patented medicines. Beyond this, Russian courts in two cases have granted compulsory licenses (CLs) to generic companies for innovative foreign medicines based on an extremely low evidence test and standard of proof. In addition, the Russian Federal Anti-Monopoly Service (FAS) and other services continue to push expanded use of CLs, and to amend laws in a way that would undermine IPR in Russia, going beyond established international commitments under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Russia's RDP regime is also highly problematic. The six-year period is fundamentally undermined by the fact that competitors may apply for marketing approval of generic medicines as early as four years after marketing authorisation for a reference chemical drug, and three years for a biological medicine.

Online counterfeiting and piracy are rife in Russia, and while it is possible to shut down rogue websites, sellers of counterfeits and distributors of infringing content are able to easily and quickly restore their website using a slightly modified URL or using a different ISP. Enforcement remains a challenge as a lack of UDRP process and general unwillingness of intermediaries like ISPs to act means that civil court actions are one of the only options to tackle online infringement and counterfeiting, even in the most clear-cut cases. Even in cases following a successful court judgement, the infringements often continue in largely the same form under supposedly new ownership, making these civil actions largely futile. Under the current court practice, the extent of the court's authority is limited to imposing sanctions against the specific defendants and websites detailed in the case.

A major concern is also the hosting of piracy websites and cyberlockers and the difficulties in prosecuting them. Piracy is rampant for both physical and digital editions. Despite changes to the law in recent years to make it less challenging for rights owners to address online piracy by Russian sites the relevant law only directs the blocking of sites to the Russian market, it remains challenging to get action taken against a site based in Russia that is being accessed by visitors from outside Russia.

Saudi Arabia

Although Saudi Arabia's legal regime explicitly provides for a five-year pharmaceutical RDP following marketing approval of the product for which the data was submitted. Since 2016 the Saudi Food and Drug Authority (SFDA) has repeatedly approved generic versions of innovative products in breach of their ongoing RDP term. There are also concerns that Saudi Arabia may be planning changes that would further weaken RDP, eg, linking the start of protection period to the first marketing approval globally, containing overly broad exceptions, and continuing to not have the necessary enforcement mechanisms.

Whilst historical IPR protection and enforcement for brand protection in Saudi Arabia has been very problematic, some recent positive developments can be linked to the government's plans to attract more foreign investment. However, Saudi Arabia still has little to no enforcement against piracy and counterfeiters. Penalties imposed are still light and offer limited deterrent. There is also limited transparency regarding the destruction and disposal process of seized counterfeit goods.

Turkey

In Turkey, we notice important regional differences in anti-counterfeiting operations. This, together with the lack of co-operation between different law enforcement authorities makes it difficult to prosecute larger cases, involving various offenders in different locations. Turkey often acts as a door to Europe for all sorts of counterfeit products coming from Asia and other places. In addition, it is also notable that Turkey has its own growing counterfeit production industry, notably for perfumes and textiles. Given that Turkey has an important strategic position within the counterfeit supply chain as well as its own counterfeit production capacity, it is even more important for IPR holders to have the necessary tools to combat counterfeiting. This is currently not satisfactory, as the lack of a country wide coordination, stark regional differences and the lack of simplified procedures make it difficult for IPR holders to defend their rights.

Turkey's RDP regime also has a number of deficiencies, including the scope of protection and, notably, linking the start date of the protection period to the first Marketing Authorisation (MA) in the EU, rather than the MA start date in Turkey. Given the MA is usually much later in Turkey than in the EU, linking to the earlier EU start date significantly reduces the RDP protection period for innovative medicines in Turkey, putting companies at a disadvantage.

United Arab Emirates

The United Arab Emirates (UAE) and the city of Dubai in particular play an important role in the counterfeit supply chain and due to its large free trade zones, including ports and airports. The UAE lacks efficient IP protection and enforcement measures as it suffers from the shortage of enforcement particularly in the free trade zones, as well as scarce transparency and efficiencies in procedures, including for the destruction of

counterfeit goods as well as criminal referrals. The new IP Law signed by the UAE President in December 2016 allowed for significantly greater penalties for counterfeiting offenses, but has still not been implemented by the authorities. Experiences with the local custom authorities is also mixed and at times unsatisfactory, especially in cases when the authorities do not act despite clear and precise information being provided to them. In just one example, detailed information about a large shipment of confirmed counterfeit goods was passed on to the authorities in Dubai, which despite repeated reminders, did not take any steps to control and seize the counterfeited products in question. Consequently, the ship left the port for Iraq, where it is even more difficult to seize counterfeit products and a simple opportunity to stop counterfeits was lost. We believe that increased pressure should be applied to the UAE to ensure that they recognise counterfeit as a serious offence and to provide sufficient resources against it, and in particular to control the free trade zones.

Furthermore, while welcoming some potential reforms, the life sciences industry also has concerns about effective patent enforcement and RDP in the UAE.