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COMMISSION STAFF WORKING DOCUMENT

**Report on the protection and enforcement of intellectual property rights in third
countries**

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1. INTRODUCTION

In accordance with the European Union's *Strategy for the Enforcement of Intellectual Property Rights in Third Countries*¹ and the European Commission's Communication on *A balanced IP enforcement system responding to today's societal challenges*², the Directorate-General for Trade of the European Commission (DG Trade), with the aid of the EU Observatory on Infringements of Intellectual Property Rights, has carried out a new survey of the protection and enforcement of intellectual property rights (IPR) outside the EU in 2016.

The main objective of this survey is to identify third countries in which the state of IPR protection and enforcement gives rise to the greatest level of concern and thereby to establish an updated list of so called "priority countries". This will help the European Commission focus its efforts and resources on those countries and on the specific areas of concern, with the aim of improving IPR protection and enforcement worldwide.

The results of this survey will also enable right holders, in particular small and medium-size enterprises, to gain awareness of potential risks to their IP when engaging in business activities in or with certain third countries and thus allow them to design business strategies and operations to protect their corporate value in intangibles. This report should also be useful for authorities in third countries as a source of information.

This report puts special emphasis on online counterfeiting and piracy, and the role free trade zones play in illicit trade.

A recently published study, commissioned by DG TRADE and undertaken by the OECD and the European Union Intellectual Property Office (EUIPO)³ provides empirical evidence on the scale of counterfeit and pirated trade worldwide and in the EU⁴, as well as on the latest trends in this area. The study shows that the share of small shipments, mostly by postal and by express services, containing counterfeits or pirated goods, keeps growing. This is due to shrinking costs of such modes of transport and the increasing importance of e-commerce in international trade. For traffickers, small shipments are also a way to avoid detection and minimise the risk of sanctions. This, in turn, raises the costs of checks and seizures for customs and presents additional challenges to enforcement authorities. Managing such a huge

¹ http://trade.ec.europa.eu/doclib/docs/2014/july/tradoc_152643.pdf

² <https://ec.europa.eu/transparency/regdoc/rep/1/2017/EN/COM-2017-707-F1-EN-MAIN-PART-1.PDF>

³ *Mapping the economic impact of trade in counterfeit and pirated goods – 2016* https://euiipo.europa.eu/tunnel-web/secure/webdav/guest/document_library/observatory/documents/Mapping_the_Economic_Impact_study/Mapping_the_Economic_Impact_en.pdf

⁴ According to the study, international trade in counterfeit and pirated products in 2013 represented up to 2.5% of world trade, or as much as EUR 338 billion. This was even higher in the EU context: 5% of imports or as much as EUR 85 billion.

volume of seizures, from processing to destruction in an environmentally friendly way, represents a significant burden on the operations of customs and significant cost to taxpayers.

The study⁵ also introduces new empirical data to show that trade routes in counterfeit and pirated goods are becoming increasingly complex. An analysis of counterfeit and pirated imports into the EU identified a set of important intermediary transit points. Some of these, such as Hong Kong and Singapore, are important hubs of international trade in general. Counterfeiters and pirates have the ability to quickly identify weak points and gaps and also to use free trade zones for repackaging and relabelling their products before entering the EU market (See Annex I).

The high exposure of geographical indications (GIs) to IP infringements⁶ made it necessary to dedicate, for the first time, a separate annex (See Annex II) to geographical indications. Many EU GI products were reported to confront abuses and usurpations also in third countries with important economic losses for EU producers.

The Commission uses the information collected for the preparation of this report to continue the cooperation with our important trading partners in the framework of IPR Dialogues and working groups. The IPR Dialogues and working groups enable both sides to exchange information on multilateral and bilateral IPR-related issues, on national IP legislation and practices, and to identify shortcomings and make proposals for improvement. The report will also be used by the Commission and the EUIPO in the framework of the four-year-long technical cooperation programmes IP Key⁷ China, Southeast Asia and Latin America, which were launched in September 2017.

2. METHODOLOGY

This Report is based on a variety of information and data, including the responses received to a questionnaire that sought specific information on IPR protection and enforcement, infringements that occur, measures undertaken, and reactions from national authorities to requests for enforcement or assistance. Invitations to take part in the survey were sent to right holders, consumer and industry associations, universities, EU Delegations and embassies of EU Member States.

More than 165 responses were received, covering 50 countries. Around a sixth of the replies were on China. The majority of the respondents were businesses (about 38 %) and associations representing right-holders, e.g. industry federations or collective management organisations (about 23 %). Individuals, public bodies, law firms and consumer associations also sent in contributions.

⁵ See footnote 3

⁶ According to the EUIPO's *Study on infringement of geographical indications for wine, spirits, agricultural products and foodstuffs in the European Union*, the value of GI infringing products in the EU was approximately €4.3 billion in 2014, which is approximately 9.0 % of the EU GI product market. https://euiipo.europa.eu/tunnel-web/secure/webdav/guest/document_library/observatory/documents/Geographical_indications_report/geographical_indications_report_en.pdf

⁷ <http://www.ipkey.org/en/>

The questionnaire indicated that information regarding the authors of the replies would remain confidential. Consequently, the respondents to the survey are not identified.

It should be highlighted that the survey is only one of the elements upon which the Commission services have based their identification of priority countries. The following additional sources also played a role in this assessment and prioritisation exercise:

- information received from EU Delegations and commercial representations,
- information received from DG TAXUD on customs enforcement of intellectual property rights by EU Member States,
- data on actions against IPR infringement published by various governments,
- reports and assessments made by other relevant bodies and organisations (e.g. the OECD),
- information made public through WTO's Trade Policy Reviews,
- assessments carried out by DG Trade's Market Access teams,
- assessments of IPR systems by the Commission services,
- judgments made by international bodies such as the WTO Dispute Settlement Body,
- the outcome of discussions Commission services have had with third countries in the context of IP Dialogues/Working Groups,
- measures taken and the political engagement shown by countries in the fight against piracy and counterfeiting.

This Report does not intend to provide an exhaustive analysis of IPR enforcement around the world. "Priority countries" may not be those where IPR protection and enforcement is the most problematic in absolute terms, but are rather those where such deficiencies are deemed to cause the greatest injury to EU interests, depending on their relevance in terms of trade.

3. RESULTS OF THE SURVEY

Summaries of the replies received in respect of those countries for which sufficient information was provided will be posted under the Enforcement section of DG Trade's IPR web site⁸. These summaries – with the exception of the section summarising the Commission's actions – will be based exclusively on the replies received. Such replies solely reflect the respondents' views. The survey included single answer questions as well as those which allowed for free text responses⁹.

⁸ <http://ec.europa.eu/trade/creating-opportunities/trade-topics/intellectual-property/enforcement/>

⁹ The single answer questions in relation to level of satisfaction consisted of five options:

- I agree fully
- I agree to some extent
- I neither agree nor disagree
- I disagree
- I strongly disagree

3.1 Global results

Almost 40% of the respondents either disagreed or strongly disagreed with the statement that current IPR protection and enforcement is satisfactory, whereas about 12% agreed fully and about 30% agreed to some extent that the situation is satisfactory.

Whereas just about 42% either agreed fully or to some extent that IPR protection and enforcement has improved in the last two years, 24% either disagreed or strongly disagreed with this statement.

Compared to previous years, the responses seem to indicate some improvement in IPR protection and enforcement in general.

3.2 Specific issues

This report identifies third countries where the **level of IPR protection and enforcement** has deteriorated over the past two years or where it remained unacceptably weak. It also identifies cross-cutting issues related to IPR protection and enforcement.

In general, problems with IP enforcement include the **lack of adequate infrastructure**, the **lack of resources**, the **lack of awareness** of the value of intellectual property and the lack of necessary civil enforcement measures and remedies.

A particularly serious problem in the area of enforcement is the **lack of the required grounds for the customs authorities** to take ex officio actions to detain, seize and destroy counterfeit and pirated goods **at the border** or **in free trade zones**. Indonesia, Turkey, Mexico and Canada, for instance, would be desirable to improve their border enforcement regimes substantially.

Copyright piracy, both online and offline, is a global problem, but it is identified as a particularly serious one in countries - such as China, Ukraine, Russia, Thailand, the Philippines and Mexico.

In the area of **patents**, Indonesia, India, Russia and Argentina, apply unduly **restrictive patentability criteria**, undermining innovation and research and preventing investment in these economies, while in Brazil, the interference of health authorities in the granting of patents in the pharmaceutical sector remains problematic.

In the area of **trademarks**, the traffic in pharmaceutical products and active pharmaceutical ingredients bearing counterfeit trademarks is a growing global problem, which can also endanger consumers' health and safety. The OECD-EUIPO study *Mapping the economic impact of trade in counterfeit and pirated goods*¹⁰ shows that India and China are the biggest producers of **counterfeit pharmaceuticals** and due to the boom of e-commerce these fake products are shipped all around the world, including Europe, also in small consignments.

¹⁰ See footnote 3

Problems affecting other specific forms of protection include the fact that **regulatory data protection for pharmaceuticals** and **plant protection products** is lacking or is not considered adequate or effective in countries such as China, Indonesia, India, Mexico and Argentina. Also, the **protection of undisclosed information** (trade secrets and know how) is not efficient in China and India and is very burdensome in Russia.

With respect to the **nature of the main infringements**, the respondents claimed that they were mainly linked to local production and local sales, followed by exports to other countries. Importation to the country concerned and exportation to the EU were also frequently mentioned.

More than 50% of the respondents considered that the infringement of their IPR resulted in **risks regarding the health or safety of customers** in the country concerned.

As regards **online infringements**, a quarter of the respondents agreed fully or to some extent that they were satisfied with the availability of legislative measures for combating online infringements (such as preliminary injunctions). Even if this remains a low level of satisfaction, it is nevertheless considerably higher than in the last report.

Only around 30% of the respondents were either fully or to some extent satisfied with the effectiveness of the **cooperation with** so called "**intermediaries**"¹¹ in combating infringements (e.g. responsiveness of ISPs to notice and takedown letters and blocking of websites, etc.). Even if the level of satisfaction is very low, it shows some improvement over the last two years. Almost half of the respondents were dissatisfied with the level of **engagement of the authorities on enforcement**.

More than 50% of the respondents consider that they experience **differences in treatment** between nationals and foreigners, which shows a significant increase over the last two years. Certain provisions of the national IP law of the countries concerned, such as a "local working" requirement, mandated technology transfer and abusive compulsory license schemes were considered to be detrimental to foreign right holders.

IP holders continue to face measures imposing "**local working**" **requirement** or **forced technology transfer** in countries such as Indonesia or China. These practices are as detrimental to the enforcement of IP as piracy and counterfeiting.

4. UPDATED LIST OF PRIORITY COUNTRIES

The updated list of priority countries remains, as in the previous survey, split into three categories:

¹¹ The concept of intermediaries is clarified in the Guidance on certain aspects of Directive 2014/48/EC on the enforcement of intellectual property rights, which was published in November 2017. <https://ec.europa.eu/docsroom/documents/26582>

Priority 1: China

Priority 2: Argentina, India, Indonesia, Russia, Turkey and Ukraine

Priority 3: Brazil, Ecuador, Malaysia, Mexico, Philippines, Thailand and the United States

The Commission also identified a separate category of countries, where IP enforcement gives rise to concern and where developments need to be closely monitored. This category of countries includes Israel, Kuwait, Paraguay, South Africa, United Arab Emirates and Uruguay.

In addition, this year there is a new section listing countries that have undertaken bilateral IPR commitments vis-à-vis the EU through trade agreements and where particular attention to the implementation of such commitments is required. The Commission continues monitoring closely the implementation of the IPR commitments in free trade agreements.

China continues to be a Priority 1 country for the EU, because longstanding problems in the area of IPR protection and enforcement persist. Both the Commission's annual *Report on EU Customs Enforcement of IPR*¹² and the OECD-EUIPO study *Mapping the economic impact of trade in counterfeit and pirated goods*¹³ show that China emerges as the origin of most counterfeit and pirated goods arriving in the European Union. More than 80% of the seizures of counterfeit and pirated goods come from China or Hong Kong.

It should be noted that Ukraine has been moved from Priority 3 to 2, because of the high level of counterfeiting and piracy reported and because of its lack of implementation of the EU-Ukraine Deep and Comprehensive Free Trade Agreement. The situation of collective rights management is also critical and causes irreparable harm to thousands of local and international right holders.

Indonesia has also been placed in the list of Priority 2 countries because of the lack of adequate and effective civil and border enforcement measures. Furthermore, the new patent law of Indonesia introduced measures, such as a local manufacturing requirement and additional patentability criteria, which limits the patentable subject matter.

¹²https://ec.europa.eu/taxation_customs/sites/taxation/files/report_on_eu_customs_enforcement_of_ipr_at_the_order_2017.pdf

¹³ See footnote 3

5. SUMMARY OF THE ASSESSMENT OF THE SITUATION BY COUNTRY

5.1. Priority 1

China

Progress

China has clear objectives and a long term strategy in the field of IPR with the overall ambition to become an innovation economy by 2020. The National IP Strategy (NIPS)¹⁴, adopted in June 2008, remains the main reference point, and it has been complemented by the 12th Five-Year Plan¹⁵ in 2010 setting the objective of developing China into an innovative country. The 13th Five-Year Plan¹⁶ and in particular the “Made in China 2025” program¹⁷ of 2015 confirmed and further developed this strategic vision of IPR as a key component in China’s industrial policy.

The increasingly positive attitude of the Chinese administration towards IP at central level is illustrated by the decisions to establish in 2014 three specialised IP Courts in Beijing, Shanghai and Guangzhou and in 2017 four additional IP tribunals (attached to ordinary courts) in Chengdu, Nanjing, Suzhou and Wuhan. The extension of IP tribunals to other provinces is under discussion. This development is laudable, since it increases the efficiency and coherence of court decisions, including at local level.

Furthermore, over the last years, China has made continued efforts to review and update its IP legislation and, in that context, has given external stakeholders, such as the EU, the possibility to comment on draft legislation during public consultations. China has launched several legislative amendments, in particular in the areas of patents, service inventions, copyright, unfair competition and e-commerce law. However, with the exception of the trademarks law of 2014¹⁸, none of these reviews, including the long awaited amendments of the patent and copyright laws, have been completed.

The measures taken by the Chinese government, in particular the creation in 2012 of a "national leading group" and various special "sword campaigns" against counterfeiting activities, while commendable, do not seem to have kept pace with new technologies and the scale of infringements. Online counterfeiting and piracy have substantially aggravated the scope and dimension of China's enforcement problem.

Concerns and areas for improvement and action

According to the OECD-EUIPO study *Mapping the economic impact of trade in counterfeit and pirated goods*¹⁹, China is the world's main producer of counterfeit goods. Around 61.8%

¹⁴ http://www.gov.cn/english/2008-06/21/content_1023471.htm

¹⁵ http://www.china.org.cn/china/NPC_CPPCC_2011/2011-03/15/content_22143099_2.htm

¹⁶ <http://en.ndrc.gov.cn/newsrelease/201612/P020161207645765233498.pdf>

¹⁷ <http://english.gov.cn/2016special/madeinchina2025/>

¹⁸ <http://www.wipo.int/wipolex/en/details.jsp?id=13198>

¹⁹ See footnote 3

of all counterfeit goods come from China (together with Hong Kong, this number is higher than 80%). *The Report on EU customs enforcement of intellectual property rights in 2016*²⁰ shows that around 80% of the seized counterfeit goods by article came from China, which by value constituted around 72%. The digital environment has aggravated the situation in recent years, since the proliferation of online trading platforms provides wider and easier access to Chinese counterfeit and pirated products at global level.

The important shortcomings of IPR enforcement in China are partially due to the significant differences between its various provinces and cities. In provinces or cities like Beijing or Shanghai, standards of administrations and courts are reported as being, in general, satisfactory and expected to improve further, whereas lack of expertise and corruption continue to be pointed out as serious problems in the remainder of China.

One of the specific problems identified by stakeholders is that all documents submitted in administrative or judicial litigation need to go through a cumbersome notarisation and legalisation process when originating from a foreign country.

Stakeholders also point to deficient cooperation between different administrative and police entities competent to address IPR infringements.

Another recurrent concern relates to the difficulty to obtain interim injunctions, despite their paramount importance for effective IPR protection and enforcement. Additionally, stakeholders indicate that the amount of damages awarded for IPR infringements neither compensates for losses nor deters future infringements.

As for trademarks, EU stakeholders report that the main concern in China continues to be the registration of bad-faith applications. China's trademark law of 2014 explicitly refers to this issue for the first time, however, the protection afforded against this recurrent practice is considered limited compared to international standards. There are also important loopholes in the protection of trademark owners against the use of their signs as company names.

As for copyright, the pending amendment of China's copyright law introducing a right of remuneration for performers and producers for public performance and broadcasting of phonograms published for commercial purposes is still pending.

The Chinese patent system (with invention patents, utility models and industrial designs) is growing very fast in terms of numbers of applications. There are, however, serious concerns about the quality of the granted invention patents, mainly linked to the search of prior art and treatment of very simple technical solutions. Another problem highlighted is the frequent use of invalidation proceedings against patents of foreign companies which have sought legal protection against Chinese infringers on the basis of those patents. Furthermore, the wide use of utility models leads to dense groups of IP rights in certain fields of technology ("patent-thickets"), hindering the patentability and commercialisation of new inventions. A key policy issue in this context has been the "quantity-based" incentives set by the Chinese government

²⁰ See footnote 12

in its drive to become an innovative country. It will be important to monitor which concrete effects China's new patent commercialization strategy, set out in the 2014-2020 IP Strategy²¹, will produce.

In the ICT sector, EU companies hold a number of important patents for technologies that are essential for the functioning of certain standards (standard essential patents). EU stakeholders report that Chinese companies widely use these technologies without paying adequate royalties. Furthermore, there is continued uncertainty about the future use of competition law by Chinese authorities in this regard, e.g. in the form of imposing heavy fines to holders of SEPs or setting very low royalty rates. The publication of various draft regulations, guidelines and rules by different IP agencies has incremented the already existing worries and uncertainty.

Regarding regulatory data protection for chemical entities, EU stakeholders complain that China provides for different registration categories which define chemical entities as "new" only when they have never been marketed in any country. This practice would discriminate against foreign products and raises concerns as to its compatibility with Article 39(3) of the TRIPS Agreement.

As regards trade secrets, EU stakeholders complain about the various proceedings requiring the disclosure of business information when trying to enter the Chinese market (procurement, standard setting, company registration, joint ventures, etc.). This is coupled with the difficulties to get effective and efficient protection before the administration and courts against unfair commercial use and unauthorised disclosure of such data.

Another important identified concern relates to China's objective to take over foreign technology and make it Chinese, particularly in key technological areas defined by the State. The means employed to reach this objective are manifold. An example is the high and new technology enterprises law (HNTE law)²², which foresees that the tax rate is reduced if 60% of the R&D expenditure is carried out in China and the Chinese company owns the IPR or has an exclusive license. In parallel, the law on scientific and technological progress²³ indicates the receipt of research funds from the Chinese government as the one acquiring ownership of the technology resulting from the research. Moreover, stakeholders report that many Chinese procurement proceedings require technology transfers or know-how disclosure from foreign companies.

China has not yet ratified the Geneva Act of the Hague Agreement Concerning the International Registration of Industrial Designs.

²¹ <https://chinaipr.com/2014/12/30/action-plan-for-further-implementation-of-the-national-ip-strategy-2014-2020-approved/>

²² Administrative Measures for Recognition of High and New Technology Enterprises, Guo Ke Fa Huo 2016 No. 32

²³ Law of the People's Republic of China on Progress of Science and Technology, Order No. 82 of the President of the People's Republic of China

EU action

The need for improved IPR protection and enforcement is a message constantly conveyed by the European Commission to Chinese authorities at all levels of government, including at the highest level during the EU-China Summits, as well as to key local administrations.

The EU-China Dialogue Mechanism has been in place for twelve years. This mechanism allows both sides to exchange information and opinions regularly on a wide range of IPR issues. It comprises two components: the EU-China IP Dialogue at strategic level, taking place once a year and the EU-China IP Working Group at technical level, taking place twice a year.

The IP Dialogue Mechanism is highly valued by the EU and China and provides a platform for a constructive and open discussion. Both sides are also engaged in building up judicial and academic networks. However, despite these positive developments, significant progress on priority issues is still needed especially regarding IPR enforcement.

Online counterfeiting is one of the priority issues and dedicated conferences on this subject took place in Beijing in 2016 and 2017, with a focus on discussing matters such as notice-and-take-down. The Chinese company Alibaba has recently become more involved in the fight against counterfeiting and piracy by joining the Memorandum of Understanding on the sale of counterfeit goods via the internet concluded in 2016 between IP right owners, internet platforms and associations²⁴, and facilitated by the Commission.

The EU-China Joint Customs Cooperation Committee is another important pillar of cooperation on IPR. It was established in 2009 and is in charge of the strategic framework for customs cooperation and for the EU-China Customs IPR action plans²⁵. These plans foresee the exchange of general risk information and trends, the creation of networks of sea- and airports to target high risk consignments, strengthening cooperation with other law enforcement agencies and the development of partnerships between business communities and customs authorities in China and the EU.

The EU-China customs network has led to improvements in collaboration between customs authorities from both sides at the associated air- and seaports and has resulted in a number of concrete detentions and cases. Overall, the EU is reasonably satisfied with the implementation of the action plans although there remains much room for improvement. Since many detained goods suspected of infringing IPR come from Hong Kong, the Commission has established an action plan on cooperation in customs enforcement of IPR also with Hong Kong²⁶.

The EU has a long experience with carrying out technical cooperation programmes dedicated to IP in China. First, it launched the programmes IPR1 in 1999-2004 and IPR2 in 2007-2011

²⁴ <http://ec.europa.eu/DocsRoom/documents/10468/attachments/1/translations/>

²⁵ https://ec.europa.eu/taxation_customs/sites/taxation/files/docs/body/action_plan_eu_china_ipr_2014_2017.pdf

²⁶ Action Plan on Cooperation in Customs Enforcement of Intellectual Property Rights in the European Union and Hong Kong (China)

and then, as from 2013, the cooperation programme IP Key²⁷, which is implemented by the European Union Intellectual Property Office. A new IP Key China programme started in September 2017 and will run for four years.

The Commission has an IPR SME Helpdesk in China²⁸, which aims to support the EU's small and medium sized enterprises in protecting and enforcing their IPR in China through the provision of free information and services. The rendered services include a free-of-charge helpline, trainings, and web-based materials. The term of the China IPR SME Helpdesk was extended for another three years at the beginning of 2015.

5.2. Priority 2

Argentina

Progress

The second half of 2016 seems to have brought a change of attitude from the government and the National Institute of Industrial Property (INPI) towards the protection of IPR in Argentina. Argentina has introduced a number of legislative proposals to improve IPR protection and enforcement. These proposals include a bill to improve trademark law by increasing penalties for counterfeiting²⁹ and a bill to strengthen the protection of industrial designs³⁰. EU stakeholders report that other legislative initiatives concerning collective rights management and the sanctioning of the circumvention of technological protection measures are being considered.

These legislative drafts have triggered cautious optimism on the part of some EU stakeholders but it is too early to assess whether they will deliver. EU stakeholders report that INPI has stepped up efforts to reduce its patent examination backlog. INPI has also introduced a fast-track procedure for patent applicants who have already been granted a patent in other jurisdictions. Argentina is also devoting more resources to patent examinations and has started to work on a more efficient online management system.

Concerns and areas for improvement and action

Right holders continue to suffer from the local production and sale of counterfeit products notably at "La Salada" Market which has been in existence for many years and where the sale of infringing goods is carried out openly and on a large scale. La Salada is the largest open-air market selling counterfeit and pirated goods in Latin America.

²⁷ See footnote 7

²⁸ <http://www.china-iprhelpdesk.eu/frontpage>

²⁹ File N° 1591-D-2017 from the Chamber of Representatives and File N° 1315-S-2016 from Senate

³⁰ File N° 4294-D-2017 from the Chamber of Representatives

Stakeholders also report widespread online piracy despite the increase in legal offer and enforcement against online piracy is described as inefficient. EU stakeholders reportedly face difficulties in enforcing their rights because the judicial and administrative proceedings are slow and unreasonably complex. Particular problems seem to exist as regards urgent or provisional court measures. Furthermore, sanctions and sentences actually imposed appear not to be deterrent enough to prevent further infringements.

EU stakeholders are also concerned about a draft law currently going through the legislative process which could prove counterproductive to combat online piracy, since it would introduce an overly broad liability exception for online intermediaries³¹.

EU stakeholders also complain about opaque patentability criteria. Very slow registration procedures combined with a considerable patent backlog penalise innovative business. The situation seems to have deteriorated further especially for pharmaceutical patents. Moreover, there is a problem of marketing authorisations being granted to products which may infringe patents. This would point to insufficient coordination between INPI and the national agency for medicines, food and medical technology (ANMAT).

EU stakeholders report that the lack of regulatory data protection leads to the unauthorized disclosure of test or other data generated to obtain marketing approval for pharmaceutical and agricultural chemical products.

EU stakeholders also claim that a compulsory mediation in trademark opposition procedures seems to slow down the process considerably.

Argentina has not yet ratified the Madrid Agreement Concerning the International Registration of Marks, the Madrid Protocol, the Geneva Act of the Hague Agreement Concerning the International Registration of Industrial Designs and the 1991 Act of the International Convention for the Protection of New Varieties of Plants (UPOV 1991).

EU action

EU-Mercosur negotiations were resumed in October 2016. They include a chapter on IPR where the EU is seeking to improve its protection and enforcement.

The resumption of the IPR Dialogue (which is planned for 2019 at the earliest) initiated in 2008 should enable both sides to exchange information on multilateral and bilateral IPR-related issues, on national IP legislation and practices, and to identify shortcomings and proposals for improvement.

The Commission has also initiated the technical cooperation programme IP Key³² Latin America in September 2017. It is foreseen that one of the two technical teams implementing this programme will be located in Buenos Aires. This programme should contribute to the raising of the level of IPR protection and enforcement in Argentina. Additionally, the IPR

³¹ File N° 0942-S-2016 from Senate - Draft bill on liability of Internet providers

³² See footnote 7

SME Helpdesk in Latin America³³ will continue to provide free assistance and information to SMEs for a better understanding of the IPR environment in Argentina.

India

Progress

Some improvements can be noted in India's IPR legislation. In March 2017, India's new Trademark Rules³⁴ entered into force. The main changes include the following: (i) the number of trademark application forms has been reduced from 74 to 8; (ii) the overall fees have been rationalized by reducing the number of fee categories from 88 to 23; (iii) the modalities for determination of well-known trademarks have been laid down for the first time; (iv) the procedures relating to registration as registered user of trademarks have been simplified; (v) the use of electronic means of communication has been incentivised; and (vi) the number of adjournments in opposition proceedings has been restricted to a maximum of two by each party.

EU stakeholders have reported some positive developments regarding patent protection, notably the hiring of additional examiners, the introduction of online transparency measures (e.g. the application tracking tools) and the involvement of stakeholders in the development of new guidelines.

India seems to be focusing its efforts now on administrative improvements, awareness raising and capacity building with a view to improving the efficiency of its IPR system. The Ministry of Commerce has created a cell for IPR Promotion and Management (CIPAM)³⁵, which aims to supervise and support these efforts. However, much remains to be done.

Concerns and areas for improvement and action

Several constraints on patent protection remain detrimental to EU companies. Restrictive patentability criteria combined with difficulties to enforce patents granted, as well as very broad criteria being applied for granting compulsory licenses or for revoking patents, make effective patent protection in India very difficult, notably for pharmaceuticals and chemicals but also for other sectors where local innovation is being promoted. Even if some positive measures have been undertaken by the Indian Patent Office to improve registration efficiency, there is still a worryingly large patent backlog.

Another area of continued concern reported by right holders is the absence of an effective system for protecting undisclosed test and other data generated to obtain marketing approval for pharmaceutical and agrochemical products against unfair commercial use, as well as their unauthorized disclosure. To date, there seems to be no statute that specifically addresses regulatory data protection for pharmaceuticals and for the protection of trade secrets.

³³ <http://www.latinamerica-ipr-helpdesk.eu/test-home>

³⁴ <http://www.ipindia.nic.in/acts-rules-tm.htm>

³⁵ <http://cipam.gov.in/>

Further progress remains necessary regarding enforcement, including through a stronger commitment of relevant authorities to fight IPR infringements and through sanctions against infringers that would have a deterrent effect. While EU stakeholders' experience with the enforcement of trademark rights has been more positive, they remain concerned about patent enforcement which is still characterized by backlogs in the Courts that hear them. It remains to be seen to what extent the High Courts Act³⁶, will improve the enforcement situation: to this date, Commercial divisions have been set up in a handful of high courts, including Delhi and Mumbai, but not in Kolkata, Chennai and other major economic centres.

EU stakeholders report that the implementation of IPR enforcement mechanisms needs further strengthening, in particular outside of Delhi. While stakeholders consider that there is cooperation with customs authorities as regards the recording of trademark rights in order to suspend the release of infringing goods at the borders, they also stress the difficulty to identify potential patent infringers, as authorities responsible for the granting of pharmaceutical manufacturing licenses appear to be reluctant at times to provide (sufficient) information on actual or potential licensees.

The large number of locally produced infringing goods remains a source of serious concern, in particular as regards patents and trademarks.

According to the OECD-EUIPO study *Mapping the Real Routes of Trade in Fake Goods*³⁷, India is the main producer of counterfeit pharmaceuticals in the world. India is also identified among the main producers of counterfeit foodstuffs, cosmetics and perfumery, clothing and textile fabrics, optical, photographic and medical equipment, electronics and electrical equipment, footwear as well as toys and games.

Detentions of suspect goods with Indian origin by EU customs are increasing, notably for medicines. The latest report on *EU customs enforcement of intellectual property rights*³⁸ showed that India represented more than 62% of all articles detained in 2016 in that sector, which shows an increase of almost 6 percentage points compared to the figures in 2015. In terms of the number of articles detained in postal traffic into the EU, more than 16% were medicines in 2016. The fact that IPR-infringing medicines are often sent in small consignments continues to be challenging for customs to take action.

According to the *World Customs Organization's Illicit Trade Report 2015*³⁹, India is at the origin of around 2% of the reported cases, but ranks fifth when it comes to the number of pieces of goods (7,237,228 pieces) detained. Although considerable progress has been made as compared to the WCO's report of 2013, there is scope for further improvement. The latest

³⁶ No. 4 of 2016 Act on the Commercial Courts, Commercial Division and Commercial Appellate Division of High Courts

³⁷ https://euiipo.europa.eu/tunnel-web/secure/webdav/guest/document_library/observatory/documents/reports/Mapping_the_Real_Routes_of_Trade_in_Fake_Goods_en.pdf

³⁸ See footnote 12

³⁹ <http://www.wcoomd.org/-/media/wco/public/global/pdf/topics/enforcement-and-compliance/activities-and-programmes/illicit-trade-report/itr-2015-en.pdf?db=web>

EU customs enforcement of intellectual property rights report also shows that more than 7% of the seized articles at the EU border transported by post came from India in 2016. Overall, according to that report, India remains in the top 7 countries of provenance of goods suspected of infringing IPR.

India has not yet ratified the WIPO Copyright Treaty, the WIPO Performances and Phonograms Treaty, the Geneva Act of the Hague Agreement Concerning the International Registration of Industrial Designs, and the 1991 Act of the International Convention for the Protection of New Varieties of Plants (UPOV 1991).

EU action

The EU continues its attempts to engage with India, but so far progress has remained limited. The IP Dialogue, which was agreed with India in 2005, was never implemented due to reticence on the Indian side, even if such a mechanism has demonstrated its utility with several other key trading partners as a means to informally and rapidly discuss emerging IPR problems.

The EU-India IP cooperation project, financed under the EU Programme Capacity Building Initiative for Trade Development (CITD)⁴⁰ and managed by the EUIPO, has made a positive contribution in the period 2015-2017. In this context, the EUIPO is cooperating with the Indian Ministry of Commerce in various areas of IP administration (e.g. simplification of workflows and forms, user-friendliness, electronic communication, e-filing, link to TMclass, well-known trademarks). One of the main achievements has been the reduction of the examination time for trademarks, notwithstanding an increase in trademark filings by 35% between 2015 and 2016.

Indonesia

Progress

There have been a number of positive developments in the area of intellectual property in Indonesia over the last two years.

Indonesia ratified the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks. Indonesia passed a new law on trademarks,⁴¹ which strengthens considerably the current levels of protection. The new law includes elements that enable the faster and cheaper registration of trademarks and the recognition of non-traditional trademarks. It also establishes the pillars of a new GI system which is compatible with the EU regime.

⁴⁰ <http://citd-standards.com/>

⁴¹ Law N° 20 of 2016 on Trademarks and Geographical Indications

The Indonesian government introduced implementing regulations for the Copyright Act adopted in 2014⁴² creating an online notification system for right holders to request action against allegedly infringing websites.

Indonesia also passed a law on IPR border measures in 2017⁴³, which brings its legislation closer to the EU *acquis* and has the potential to make the customs procedures more efficient. Pursuant to the new law, customs authorities use risk analysis to identify goods suspected of infringing an IP right and customs authorities decide about the granting or recording of the application within a reasonable time period from its submission.

Concerns, areas for improvement and action

According to the OECD-EUIPO joint study *Mapping the real routes of trade in fake goods*⁴⁴, between 2011-2013 Indonesia was one of the main producers of fake foodstuffs, leather articles and handbags, jewellery as well as optical, photographic and medical equipment.

EU stakeholders report that significant challenges still remain in terms of the enforcement of IP laws, with overly lengthy judicial proceedings. It has been deemed necessary for courts to enhance the application of provisional and precautionary measures to prevent imminent infringements of an intellectual property right. Further improvement of the law in terms of civil proceedings are needed in order to ensure that the competent judicial authorities may order the destruction or at least the definitive removal from the channels of commerce of goods that they have found to infringe an IP right or materials predominantly used for the creation or manufacture of those goods.

EU stakeholders also report that enforcement cooperation among relevant agencies, including the National Inter-Ministerial IPR Task Force, Directorate General for Intellectual Property, Creative Economy Agency, National Agency for Drug and Food Control and Attorney General's Office need to be improved.

IP laws are not properly enforced at the border due to the lack of efficient IPR border measures. EU stakeholders report on the need to tackle legal uncertainty through ensuring enhanced consistency across Indonesia in the implementation of customs legislation. The infringing goods seized by the customs authorities are not destroyed or removed from the channels of commerce, which reportedly causes serious harm to the right holders. Although there is an enforcement division (Directorate of Investigation within the Directorate General

⁴² Law N° 28 of 2014 on Copyright and Joint Regulations of the Ministry of Law and Human Rights No. 14 of 2015 and the Ministry of Communication and Information Technology No. 26 of 2015 on the Implementation of Closure of Content and/or Access Rights for Users of Copyright and Related Rights Infringement in the Electronic System

⁴³ Government Regulation N° 20 of 2017 on Control of Import and Export of Goods Resulting from Intellectual Property Infringement, effective since 2 August 2017, to implement measures stipulated under the Law No. 17 of 2006 on Customs

⁴⁴ See footnote 37

of Intellectual Property Rights), their impact is described by right-holders thus far as minimal because of limited manpower and resources.

The new Patent Law⁴⁵ introduced a "local working" requirement. This creates unpredictability for businesses in sectors heavily relying on patent protection and impedes the dissemination of technical information, which is indispensable for the development of new products including pharmaceuticals. The contested provisions set out that the patent holder is obliged to manufacture the patented product or use the patented process in Indonesia, and that non-compliance with the requirement triggers the possibility to issue a compulsory license. Moreover, the absence of local manufacturing of the patented product or of the use of the patented process may lead to the abolishment of the patent. These rules clearly discriminate imported patented products against domestically produced goods under patent protection.

Certain patentability requirements in Indonesia do not seem to meet international standards. Notably the requirement to prove the "enhanced efficacy" of the pharmaceutical product when applying for secondary patent protection, limits unduly the patentable subject matter as the information on "enhanced efficacy" is generated in the course of the clinical trials which are usually ran only after the patent is granted.

EU stakeholders consider that the Patent Law creates significant uncertainty for pharmaceutical innovators by discouraging voluntary licensing and promoting compulsory licensing on grounds that need to be more precise and consistent with Indonesia's international obligations.

EU stakeholders report that the alleged shortcomings in terms of regulatory data protection leads to unauthorized disclosures of test or other data generated to obtain marketing approval for pharmaceutical and agricultural chemical products.

Furthermore, EU stakeholders report that bad faith registration by local companies infringing foreign trademarks is a common problem with the consequence that the right-holder has to undertake lengthy and expensive proceedings in the commercial court to cancel them.

Indonesia has not yet ratified the Geneva Act of the Hague Agreement Concerning the International Registration of Industrial Designs and the 1991 Act of the International Convention for the Protection of New Varieties of Plants (UPOV 1991).

EU action

The EU and Indonesia launched negotiations in 2016 with the objective to conclude a comprehensive economic and partnership agreement. One of the areas under negotiation concerns the protection and enforcement of intellectual property rights.

Beyond this, the EU continues to deliver IP-related messages to the Indonesian authorities in different fora. The European Commission engaged with like-minded countries to raise

⁴⁵ Law N° 3 of 2016 on Patents

concerns about the Patent Law and the "local working" requirement to the Indonesian authorities.

The EU-ASEAN Project on the Protection of Intellectual Property Rights (ECAP III)⁴⁶ continued until February 2017. It aimed at supporting ASEAN regional integration and at further harmonising the systems for IP creation, protection, administration and enforcement in the ASEAN region, including Indonesia. Among its achievements, the project led to an integration of ASEAN member states into the ASEAN TMview, TMclass and DesignView databases. An ASEAN-specific portal for each of the databases has been set up providing easily accessible trademark and design data.

Further technical assistance will be granted to Indonesia under the ASEAN Regional Integration Support from the EU (ARISE Plus) programme⁴⁷ which aims to support greater economic integration in ASEAN countries inter alia by improving IPR protection and enforcement. Under the IPR component of ARISE Plus, the EU will continue supporting the legal and regulatory IP frameworks to enable ASEAN countries like Indonesia to participate in global protection systems, to develop regional platforms and to strengthen the network of ASEAN IP Offices with a view to improving their capacity to deliver timely and quality services. Activities will include enhancing IP awareness in society and the IP capacity of the productive sector. The specific objective of this component is to support ASEAN regional integration and further upgrade and improve the systems for IP creation, protection, utilization, administration and enforcement in the region.

The EU launched a four-year-long technical cooperation programme (IP Key⁴⁸) in September 2017 covering also South East Asia, including Indonesia. This programme aims to further contribute to the raising of the level of IP protection and enforcement in Indonesia.

Finally, the ASEAN IPR SME Helpdesk⁴⁹, which was set up in 2013, provides SMEs with free-of-charge assistance, trainings and useful materials for foreign businesses to help them understand the IP environment in Indonesia.

Russia

Progress

A number of improvements have taken place over the last two years, for instance, the extension of the scope of the online piracy regulation and the introduction of ex officio powers for customs authorities.

In 2015, new amendments were enacted that expanded the applicability of online piracy measures to a broader set of copyright protected material. Since 2015, one of Russia's largest social networking websites, VK is reported to be taking steps to address piracy. VK has

⁴⁶ <http://www.ecap3.org/>

⁴⁷ https://ec.europa.eu/europeaid/projects/asean-regional-integration-support-eu-arise_en

⁴⁸ See footnote 7

⁴⁹ <http://www.southeastasia-iprhelpdesk.eu/en/frontpage>

concluded licensing agreements with major record companies and has taken steps to prevent third party applications dedicated to download infringing content from the site. Despite these changes, copyright piracy is a persisting concern for stakeholders in Russia.

Concerns and areas for improvement and action

EU stakeholders report that copyright infringements continue to be a serious problem, including, but not limited to, online piracy, in spite of the improvement of the toolbox of the Russian enforcement authorities to tackle IP infringements. Several online pirate sites are still hosted in Russia and the enforcement measures are not efficient enough to tackle the problem. EU stakeholders report significant levels of piracy of music, films, books and television programmes.

According to the OECD-EUIPO study *Mapping the real routes of trade in fake goods*⁵⁰, between 2011-2013, Russia was one of the top provenance economies of counterfeit foodstuff imported to the EU. EU stakeholders report that the trafficking in counterfeit goods online is still widespread, including pharmaceutical products, footwear, sporting goods and electronic devices.

In the area of trademarks, the biggest concern for European business is that there is no opposition procedure in place in Russia.

There are also worrying developments in the area of parallel imports, because in April 2016, a Eurasian Intergovernmental Council's Resolution⁵¹ paved the way to establish exceptions to the application of the regional exhaustion principle to the Eurasian Trademark with regard to some categories of goods.

EU stakeholders report also that the protection of trade secrets is burdensome and overly costly in Russia, because it is too formalistic and overregulated with unreasonable requirements⁵².

EU stakeholders also report that the regulatory data protection system for pharmaceuticals is not efficient in Russia. In June 2016, the Russian Supreme Court invalidated the regulatory data protection for an innovative biopharmaceutical product, stating that the regulatory data protection regime is not applicable to clinical and other data published or available in the public domain. This interpretation is followed by the marketing authorities and creates the potential for marketing authorization of generic medicines during the regulatory data

⁵⁰ See footnote 37

⁵¹ Resolution N° 6, of 13 April 2016

⁵² The following requirements were reported to be overly burdensome for the business: the companies have to prepare a comprehensive list of information that is to be treated as a trade secret, the enterprises have to put in place measures to restrict access to trade secrets via an internal regulation procedure for handling the relevant information, the enterprises have to keep an up-to-date record of people who are allowed access to the trade secrets and to whom the relevant information has been disclosed and the enterprises have to use written confidentiality clauses in employment agreements and all documents and other media containing secret information must be recoded and marked as such.

protection term of the originator medicine. This interpretation seems to be inconsistent with standard international practice.

EU stakeholders report that in the case of patents, preliminary injunctions remain difficult to obtain and the delays in court can lead to the approval and marketing of generic medicines, despite the existence of a valid patent.

Russia is meant to provide patent term extensions for up to five years. However, EU stakeholders report that it is very difficult for an applicant to prove the entitlement for such an extension which is therefore rarely granted in practice.

EU stakeholders report that patentability requirements often do not appear to meet international standards, e.g. the requirement to prove the "enhanced efficacy" of the pharmaceutical product when applying for secondary patent protection seriously limits the patentable subject matter, as the information on "enhanced efficacy" is generated in the course of the clinical trials which are usually run only after the patent is granted.

Russia has not ratified the Geneva Act of the Hague Agreement Concerning the International Registration of Industrial Designs; hence it is impossible for foreign right holders to protect their industrial designs without registering them locally. EU stakeholders report that bad faith registration of foreign industrial designs by some local producers, especially in the furniture sector, is widespread.

EU action

Due to the current political situation, the IPR Dialogue has been suspended. Nevertheless, the European Commission through the EU Delegation in Moscow regularly conveys IP related messages to the Russian authorities to improve the standards of protection and enforcement.

The European Commission also facilitates and supports voluntary stakeholder initiatives, dialogues between European and Russian stakeholders in Russia in the area of counterfeiting and piracy or other issues of particular relevance related to IPR for the European business in Russia.

Turkey

Progress

Positive developments have been noted over the last two years. Turkey has established specialized IP courts and specialized police departments for IP infringements and has adopted a new Industrial Property Code⁵³. The new Industrial Property Code, adopted in January 2017, aims at streamlining and modernising the current Turkish industrial property regime by increasing the efficiency of administrative processes, providing new enforcement tools for right holders and improving transparency. The reform has brought the Turkish industrial property law closer to the EU acquis.

⁵³ Act N° 6769 on Industrial Property

The Turkish Patent and Trademark Institution has improved its online application and call centre services, especially with regard to trademarks.

Turkey has stepped up efforts to reduce the trade in counterfeit goods which can pose health and safety risks by introducing enhanced measures and remedies against the manufacturing and selling of counterfeit pharmaceuticals. In the area of border enforcement, the customs registration system has resulted in an increased number of seizures.

Concerns and areas for improvement and action

According to the OECD-EUIPO study *Mapping the Real Routes of Trade in Fake Goods*⁵⁴ Turkey appears to be an important producer of counterfeit goods in some sectors, such as leather goods, clothing and textile fabrics, perfumes, footwear, foodstuff and cosmetics, toys, games and sport equipment with road trafficking being the main shipping mode for these goods to the EU. Turkey also seems to be a regional producer exporting counterfeit perfumery and optical, photographic and medical apparatus almost exclusively to the EU. The latest report on EU customs enforcement of intellectual property rights⁵⁵ places Turkey among the "top 3" countries of provenance by value of the detained counterfeit goods. Turkey also plays a role as a transit point for fake electronics and toys being shipped to the EU. Counterfeit and pirated goods are widely available for sale not only in tourist sites but also in Ankara and other major cities.

The setting up of further specialised courts, especially in industrial cities such as Bursa, Gaziantep, Konya and Izmir would be indispensable for efficient IP enforcement. As regards customs enforcement, the online services of the customs dealing with the complaints of the right holders have improved remarkably. However, risk analysis techniques are not applied for the detection of counterfeit goods and customs do not take action against goods in transit.

EU stakeholders report that in the area of copyright, the Turkish collective rights management system does not apply minimum transparency, accountability and good governance standards. The tariff-setting of the collective management organizations does not seem to be transparent. Many collective management organizations do not distribute royalties to right holders and some of them do not have the necessary mandate to represent them.

Furthermore, the membership criteria in the Turkish collective management organisations appear to discriminate between national and foreign entities and do not allow the latter to get a full membership.

In Turkey, the Trademark Decree-Law⁵⁶, the Turkish Civil Code⁵⁷ and the Court of Appeal's precedents set the framework to address bad faith registrations. However, EU stakeholders report that this legal framework does not work in practice and bad faith registrations are still

⁵⁴ See footnote 37

⁵⁵ See footnote 12

⁵⁶ Decree-Law N° 556 on the Protection of Trademarks

⁵⁷ Law N° 4721 on Turkish Civil Code

widespread in Turkey. Although the specialized IP Courts' decisions are more satisfactory in this area, there remains room for improvement.

EU stakeholders report that the decisions of the Turkish trademark office to refuse a trademark application are not duly reasoned. The identity or similarity of the signs or the designated goods or services are regulated in the Turkish trademark law as an absolute ground for refusal, but the implementation of this provision in the judicial or administrative proceedings remains problematic.

EU stakeholders also report difficulties in getting search and seizure orders, especially by first instance courts. One of the reasons it is difficult to get a search or seizure order is the lack of IP knowledge of certain courts, in particular the Turkish first instance courts. Another obstacle is the high degree of evidence the right holders are required to provide.

EU action

The EU and Turkey continue to hold annual intellectual property working group meetings. In this framework the EU and Turkey aim at discussing ongoing legislative developments, exchanging experience on enforcement by the customs and enforcement authorities and the administrative and judicial bodies.

The EU is committed to assist Turkey in aligning its IP laws with the EU acquis, therefore, the EU remains in close contact with the Turkish side.

Finally, in the framework of the modernization of the EU-Turkey Customs Union, the IPR regime should be updated to address the existing challenges.

Ukraine

Progress

The EU-Ukraine Association Agreement (DCFTA) entered into force on 1 January 2016. The DCFTA includes an ambitious IPR chapter aiming at regulatory approximation with the EU acquis and enforcement practices.

Ukraine has recently passed a Law on Cinematography⁵⁸, which includes provisions to reduce the level of online piracy. This is a positive development, as for many years Ukraine has had a very poor record of hosting illegal websites. The new law lays down clear measures to tackle online piracy and clarifies the liability of intermediary service providers. It also clarifies the availability of remedies for online piracy.

The Ukrainian Cybercrime Unit of the Police has participated in training sessions against online IP infringements, expanded its manpower and established cooperation with the right

⁵⁸ Law on State support to the cinematography industry dated 23 March 2017 N° 1977

holders to fight jointly against online piracy. This has already resulted in some successful operations against illegal websites.

The pending trademark applications database has become searchable and accessible free of charge for right holders which make it easier and faster for users to register trademarks and avoid trademark infringements in Ukraine.

On September 29 2017 a decree was issued on the establishment of the High Court for Intellectual Property Matters⁵⁹, which will be based in Kyiv.

Ukraine presented an IP reform package in the second half of 2017. The EU will closely monitor the subsequent legislative process to ensure the proper implementation of the DCFTA commitments.

Concerns and areas for improvement and action

The level of IP protection and enforcement remains weak. According to the OECD-EUIPO joint study *Mapping the real routes of trade in fake goods*⁶⁰, Ukraine was one of the four main transit points for fake goods to the EU's market.

Notwithstanding the new anti-piracy law's potential to reduce the availability of illegal content online, EU stakeholders report that online piracy remains a significant problem because Ukraine has not implemented effective means to combat such practices.

EU stakeholders also report that there are still major problems with the efficiency of the customs authorities. There are no adequate facilities to destroy certain types of counterfeit products (e.g. pesticides) and even the simplified customs procedure is time-consuming, complicated and expensive. EU stakeholders also complain about corruption within the customs system (leading for instance, to the disappearance or the re-entry of confiscated infringing goods into channels of trade). In general, there seems to be a lack of effective procedures and legal norms governing the destruction of seized counterfeit products and equipment used for their manufacture.

EU stakeholders report that regulatory data protection is not effective in Ukraine as the status of the reference medicine is not checked during the registration of a generic medicine, since the State Expert Committee (SEC) is not responsible for reviewing the regulatory data protection status. The information on the medicines under marketing authorization procedure is not available publicly which undermines transparency and the adequate enforcement of regulatory data protection.

⁵⁹ <http://www.president.gov.ua/documents/2992017-22722>

⁶⁰ See footnote 37

EU stakeholders also report that in the area of patents there are no clear criteria defining circumstances under which the government can consider and issue compulsory licenses which leads to legal uncertainty.

The long-standing situation regarding collective rights management causes irreparable damage to the legitimate interests of thousands of local and international right holders, especially in the music sector. The legislative framework remains the main problem, as it allows the operation of numerous collective management organizations which lack the required mandates from right holders and the necessary human and financial resources for carrying out collective rights management. These organisations reportedly collect royalties without distributing them to the legitimate right holders.

EU stakeholders report that state broadcasting organisations do not pay royalties to performers and phonogram producers for the broadcasting and communication to the public of their performances and phonograms despite the legal obligation in the Ukrainian copyright law.

In the area of trademarks there is no provision in Ukrainian law that would allow for the refusal or invalidation of a trademark on the grounds of bad faith. The reasoning of the trademark office of a trademark registration refusal is usually quite general and not always complete. EU stakeholders report that there is no information available indicating whether or not an application has already been examined. Therefore, it is difficult for third parties to establish whether they can still file oppositions against a certain application. Such system gives too much discretion to the trademark examiners to accept or reject an opposition and thus does not provide legal certainty. The new draft law on industrial property⁶¹ has the potential to improve the situation.

EU action

The EU-Ukraine Association Agreement contains provisions requiring an enhanced level of IP protection and enforcement in Ukraine. The DCFTA represents a major regulatory approximation of the Ukrainian IP law with the EU acquis in the area of copyright, trademarks, designs, topographies of semiconductors, patents, plant varieties and civil and border enforcement.

The EU has provided funding for a Twinning Project to assist Ukraine in the implementation of the DCFTA. A number of draft laws in the area of copyright, industrial property, enforcement and e-commerce were prepared by the Twinning Project in 2015, but regrettably none of them passed the Ukrainian Parliament.

The IPR Dialogue forms part of the broader cooperation between the EU and Ukraine in the context of the European Neighbourhood Policy⁶². The IPR Dialogues enable both sides to

⁶¹ Draft Law amending certain legislative acts of Ukraine to improve legal protection of intellectual (commercial) property (Registration N° 5699)

⁶² https://ec.europa.eu/neighbourhood-enlargement/neighbourhood/overview_en

exchange information on multilateral and bilateral IPR-related issues, on national IP legislation and practices and to identify shortcomings and proposals for improvement.

The EU is committed to an effective implementation of the DCFTA and remains in close contact with the Ukrainian side in this regard as well as on issues going beyond the DCFTA.

5.3. Priority 3

Brazil

Progress

The Brazilian IP office (INPI) has continued to recruit patent and trademark examiners to address the considerable registration backlog but since there has been an increase in the number of applications also via the Patent Cooperation Treaty, no concrete reduction in the patent backlog has been witnessed so far. As concerns trademarks, there is a slight improvement and it appears that the backlog is finally shrinking a bit. The National Council to Combat Piracy (CNCP) has stepped up its efforts to tackle the widespread counterfeiting and piracy especially in the period preceding and during the Olympic Games.

In 2017 the National Sanitary Regulatory Agency (ANVISA) and INPI concluded an agreement in order to speed up the examination of medicinal patent applications and to change the role ANVISA plays in the process, which has been a key concern for EU right holders for a number of years. It remains to be seen how the new role of ANVISA will influence the examination of patent applications.

New rules limit INPI's involvement in technology transfer contracts to the registration process and do not affect taxation and royalties related to technology transfer contracts as in the past.

Concerns and areas for improvement and action

The Brazilian IPR system still features important shortcomings. EU stakeholders report that IPR protection and enforcement in Brazil has not improved over the last two years. Local production and importation of counterfeit products sold in various known "fake" markets is still considerable and digital piracy (including illegal downloading, illegal streaming and peer to peer file sharing) is not efficiently addressed. No significant progress has been made in the long-announced reform of the copyright law.

Another continued grave concern for the EU stakeholders is the scrutiny of ANVISA in pharmaceutical patent applications before they have been examined by INPI, although steps have been taken to supposedly realign the procedures with international standards.

EU stakeholders report that in the judicial system, IP enforcement procedures are complex, not fully transparent and can go on for up to 8 or 10 years. Despite the efforts made by the competent authorities, long delays still persist in the examination of both patent and

trademark applications, although slightly quicker, are still beyond the limits imposed by international standards.

EU stakeholders report that the lack of regulatory data protection for medicines leads to the unauthorized disclosure of test or other data generated to obtain marketing approval for medicines.

The treatment of IPR-related contracts involving domestic and foreign companies has also been a cause of concern for many years (i.e. capping of royalties sent abroad by foreign companies and interference with technology transfer contracts) and it is hoped that recent developments at INPI in this context will alleviate the situation.

Brazil has not yet ratified the Madrid Agreement Concerning the International Registration of Marks, the Madrid Protocol, the WIPO Copyright Treaty, the WIPO Performances and Phonograms Treaty and the Geneva Act of the Hague Agreement Concerning the International Registration of Industrial Designs.

EU action

After a break of four years the EU-Mercosur negotiations were resumed in October 2016, including the discussion of an IPR chapter. The annual IPR Dialogues enable both sides to exchange information on multilateral and bilateral IPR-related issues, on national IP legislation and practices, and to identify shortcomings and proposals for improvement. IPR is also discussed in the context of the EU-Brazil Joint Committee meetings.

In September 2017 the Commission launched the technical cooperation programme IP Key⁶³ Latin America. This programme should contribute to raising the level of IPR protection and enforcement also in Brazil.

The IPR SME Helpdesk in Latin America⁶⁴ will continue to provide free assistance and information to SMEs for a better understanding of the IPR environment also in Brazil.

Ecuador

Progress

Positive developments have been noted over the last two years, including the reduction of patent fees and the final adoption in December 2016 of the new IP code⁶⁵. However, a partial Presidential veto on the new IP Code introduced a number of last-minute amendments to the text, before its final approval by the Ecuadorian Parliament. The amendments raise concerns

⁶³ See footnote 7

⁶⁴ See footnote 33

⁶⁵ Organic Code of Social Economy of Knowledge, Creativity and Innovation, Official Journal Supplement No. 899 of 9 December 2016

in terms of compliance with Ecuador's international commitments, including obligations under the EU-Columbia, Peru, Ecuador Trade Agreement.

Some provisions of the IP Code have been welcomed by EU stakeholders, in particular the protection of undisclosed information, including regulatory test data or other information submitted to obtain marketing approval for pharmaceutical products.

Concerns and areas for improvement and action

EU stakeholders report that IP enforcement remains a serious concern due to the widespread availability of counterfeit and pirated goods (including online and physical markets such as La Bahia Market in Guayaquil).

The Ecuadorian IP system features also other shortcomings. On patents, the IP Code appears to include a "local working" requirement that raises concerns in view of Ecuador's international obligations. EU stakeholders report that it undermines patent protection and thus the marketing of certain innovative products. The contested provisions would oblige the patent holder to manufacture the patented product or use the patented process domestically and that non-compliance with the requirement may trigger the possibility of issuing a compulsory license. These rules would clearly discriminate between imported patented products and domestically produced goods under patent protection.

The IP Code raises other concerns in terms of potential incompatibilities with international obligations regarding patentability criteria and revocation of patents. Contrary to what appears to be foreseen under the IP Code – a patent cannot be rejected on the basis of any additional criteria than those existing in the TRIPS Agreement. The more so, where such additional criteria are applied retroactively for revocation.

In the area of pharmaceuticals, the amendment of Decree 522 on the labelling of generic medicines (upon patent expiry)⁶⁶, now distinguishes between generics and reference products, which raises concerns of compatibility with Article 20 of the TRIPS Agreement. Ecuador has not yet provided clarifications through implementing regulations that the use of the trademark of the reference medicine will not be unjustifiably encumbered by special requirements.

EU stakeholders report that the protection of plant varieties raises concerns, since the new IP Code would allow the exchange of propagation material between farmers, rather than limiting such use for their own exploitation on their own land, which appears to be contrary to Ecuador's international obligations.

EU stakeholders report that the new IP Code introduced overly broad exceptions and limitations to copyright and related rights, despite the reference to the three steps test. This is notably the case for the exceptions to public performance rights, which seems to be contrary

⁶⁶ The Executive Decree 1159 amends Executive 522: Modification to the Rule for the Application of the Law of Production, Imports, Commercialization and Dispensing of Generic Medicines for Human Use, Official Journal: First Supplement No. 843 of 19 September 2016

to international obligations and the commitments under EU-Columbia, Peru, Ecuador Trade Agreement.

Ecuador has not yet ratified the Madrid Agreement Concerning the International Registration of Marks, the Madrid Protocol, the Geneva Act of the Hague Agreement Concerning the International Registration of Industrial Designs and the 1991 Act of the International Convention for the Protection of New Varieties of Plants (UPOV 1991).

EU action

Ecuador's accession to the EU-Colombia and Peru Trade Agreement (Trade Agreement), which entered into force on 1 January 2017, should contribute to improving its environment for IPR protection and enforcement.

In the run-up to the conclusion of the negotiations and currently in the context of implementation of IPR commitments under the Trade Agreement, the EU urged Ecuador to rectify the abovementioned problematic issues. The EU will continue to monitor the developments and take actions in the context of the Trade Agreement to ensure effective implementation of Ecuador's obligations. IPR is also discussed in the context of the annual meetings of the IP Sub-Committee.

In addition, the Commission launched in September 2017 the technical cooperation programme IP Key⁶⁷ Latin America, which also covers Ecuador.

The IPR SME Helpdesk in Latin America⁶⁸ will continue to provide free assistance and information to SMEs for a better understanding of the IPR environment in Ecuador.

Malaysia

Progress

IPR protection and enforcement in Malaysia have improved over the last two years. EU stakeholders report an increased engagement by the Malaysian authorities' in raising IPR awareness and other positive developments following the establishment of the specialised IP Court, which has accelerated judicial proceedings. Malaysia is in the process of reviewing its IP legislation in order to introduce changes required by commitments stemming from free trade agreements recently concluded by Malaysia.

Concerns and areas for improvement and action

According to the OECD-EUIPO study *Mapping the real routes of trade in fake goods*⁶⁹, Malaysia figures amongst the top provenance economies for counterfeit products in several categories of goods, including leather articles and footwear also destined for Europe. In the

⁶⁷ See footnote 7

⁶⁸ See footnote 33

⁶⁹ See footnote 37

Commission's annual *Report on EU Customs Enforcement of IPR*⁷⁰ in 2015, Malaysia was in the "top 7" countries of origin of suspected IPR infringing goods detained and seized at the EU borders. EU stakeholders also report on the need to ensure more effective coordination between enforcement authorities and that customs officers do not act ex officio to seize goods suspected of infringing an IPR.

Despite the current review of the IP legislation and the enhanced efforts of the government, IPR enforcement remains a concern, in particular at the border. There is widespread availability of IPR-infringing goods in Malaysia, both on physical and online markets. EU stakeholders report the widespread availability of IPR-infringing goods on physical markets like Batu Ferringhi Night Market (Penang), Petaling Street (Kuala Lumpur) and Low Yat Plaza (Kuala Lumpur).

Regarding pharmaceutical and agrochemical products, there have been no changes as regards Malaysia's regulatory data protection system, where protection is not granted if a marketing authorisation is not applied for in Malaysia within eighteen months from the granting of the first marketing authorisation anywhere in the world.

EU stakeholders report that there have been developments as regards collective rights management (CRM) in Malaysia. A new collective management organisation (CMO), called Music Rights Malaysia (MRM) was established in 2017, replacing the former four independent CMOs, to represent all categories of music rights holders (authors, performers and producers). Despite this reform, EU stakeholders still perceive that there is margin for improvement in terms of the new governance rules, including the allocation of revenues and the involvement of government officials in the management. The new governance rules seem not to be in line with the minimum transparency, accountability and good governance standards.

EU stakeholders report that the administrative opposition proceedings for trademarks are overly slow in Malaysia.

According to the OECD-EUIPO study *Mapping the Real Routes of Trade in Fake Goods*⁷¹ Malaysia appears to be an important producer of fake jewellery, clothing and textile fabrics, leather articles, footwear, perfumes as well as optical, photographic and medical equipment.

Malaysia has not yet ratified the Madrid Agreement Concerning the International Registration of Marks, the Madrid Protocol, the Geneva Act of the Hague Agreement Concerning the International Registration of Industrial Designs and the 1991 Act of the International Convention for the Protection of New Varieties of Plants (UPOV 1991).

⁷⁰ https://ec.europa.eu/taxation_customs/sites/taxation/files/2016_ipr_statistics.pdf

⁷¹ See footnote 37

EU action

A Partnership and Cooperation Agreement (PCA) was concluded with Malaysia in 2016. The negotiations of a Free Trade Agreement (FTA) are currently on hold. A possible resumption is being considered. Any future agreement would include an extensive chapter dedicated to IPR protection and enforcement, including enhanced civil and border enforcement.

The EU-ASEAN Project on the Protection of Intellectual Property Rights (ECAP III)⁷² continued until February 2017. It aimed at supporting ASEAN regional integration and at further harmonising the systems for IP creation, protection, administration and enforcement in the ASEAN region, including Malaysia. Among its achievements, the project led to an integration of ASEAN member states into the ASEAN TMview, TMclass and DesignView databases. An ASEAN-specific portal for each of the databases has been set up, providing easily accessible trademark and design data.

Further technical assistance will be granted to Malaysia under the ASEAN Regional Integration Support from the EU (ARISE Plus) programme⁷³ which aims to support greater economic integration in ASEAN countries inter alia by improving IPR protection and enforcement. Under the IPR component of ARISE Plus, the EU will continue supporting the legal and regulatory IP frameworks to enable ASEAN countries like Malaysia to participate in global protection systems, to develop ASEAN regional platforms and to strengthen the network of ASEAN IP Offices with a view to improving their capacity to deliver timely and quality services. Activities will include enhancing IP awareness in society and IP capacity of the productive sector. The specific objective of this component is to support ASEAN regional integration and further upgrade and improve the systems for IP creation, protection, utilization, administration and enforcement in the ASEAN region.

The Commission launched in September 2017 a technical cooperation programme, IP Key⁷⁴ South East Asia, covering also Malaysia, which will be implemented over the next four years, with special focus on the support of negotiations and implementation of IPR provisions in FTAs.

In addition, the EU funded ASEAN IPR SME Helpdesk⁷⁵ will continue to support SMEs with free-of-charge assistance and relevant information on IPR protection and enforcement in Malaysia.

Mexico

Progress

Mexico intended to launch a general reform process of its IP laws in view of the IP standards agreed upon during the Trans-Pacific Partnership (TPP) negotiations. Though this general

⁷² See footnote 46

⁷³ See footnote 47

⁷⁴ See footnote 7

⁷⁵ See footnote 49

reform process was not continued after the halt of the TPP ratification, Mexico is still working on a limited reform.

Mexico introduced in 2016 an opposition procedure against trademark applications, which is expected to increase transparency in the trademark registration process and filter out also bad faith applications. The procedure is not of adversarial nature, and it is at the mere discretion of the examiner in charge to decide whether or not he takes the opposition into account.

The Public Procurement Office (PGR) has stepped up its efforts in the fight against online counterfeiting and piracy by creating a sub-unit dedicated to fight against IP infringements.

Concerns and areas for improvement and action

IPR enforcement remains the main issue of concern in Mexico. EU stakeholders complain that judiciary proceedings are very slow, with the exception of copyright related cases. Applicants are not allowed to file an action directly before the civil courts claiming damages. It is first necessary to establish before the administrative instances that an infringement has occurred. The whole process for obtaining damages may therefore include multiple instances and take between eight and ten years, during which time the plaintiff even has to bear the costs of the storage of the seized goods.

EU stakeholders report that obtaining preliminary injunctions is unreasonably difficult and, when granted, they can be lifted by the alleged infringer by paying a counter-bond. Investigations in general focus on the seizure of products and not on dismantling the responsible criminal organisations.

EU stakeholders report that Mexico's legal framework and efforts are insufficient to fight effectively counterfeiting and piracy, mainly because the coordination among federal and sub-federal officials is weak and because there are not enough resources devoted to IP enforcement or deterrent penalties against infringers. A crucial shortcoming is the lack of a clear mandate and ex officio powers for Mexico's customs authorities. EU stakeholders also report that both counterfeit and pirated goods are widely available in physical markets around the country, notably in Tepito (Mexico City) and San Juan de Dios (Guadalajara), and that online counterfeiting and piracy are serious concerns.

Despite Article 39(3) of the TRIPS Agreement, Mexico does not have legal provisions on the protection of regulatory data protection for pharmaceutical and agrochemical products. There are only guidelines for the authority in charge of marketing authorisation (COFEPRIS), and their application and enforcement in concrete cases remain an ongoing concern. The situation is aggravated because Mexico's patent law does not seem to foresee any compensation for undue delays in the marketing authorisation proceedings.

EU stakeholders also report that there are no provisions on the liability of Internet Service Providers (ISPs), leading to legal uncertainties in this regard for ISPs and right holders.

Mexico has not yet ratified the Geneva Act of the Hague Agreement Concerning the International Registration of Industrial Designs.

EU action

Since 2016, the EU and Mexico have been engaged in regular bilateral exchanges during the EU-Mexico FTA modernisation negotiations. It is foreseen to re-establish annual meetings through an IP Sub-Committee.

The Commission has recently carried out training activities on customs issues with officials from Mexico and other Central American countries and on opposition proceedings against applications for trademarks and GIs.

The Commission launched in September 2017 the technical cooperation programme IP Key⁷⁶ Latin America. It is foreseen that one of the two technical teams implementing this programme will be located in Mexico City.

The IPR SME Helpdesk in Latin America⁷⁷ will continue to provide free assistance and information to SMEs for a better understanding of the IPR environment in Mexico.

The Philippines

Progress

The Philippines has taken some significant steps to improve the IPR environment over the past two years. These steps included a new law with amendments to the Intellectual Property Code⁷⁸, such as the introduction of the landlords' liability for the sale of IPR-infringing goods in their premises and the granting of IPR enforcement functions to the Philippines IP Office (IPOP HL). The Philippines continues to be at the forefront of IP discussions within ASEAN with committed staff at the IPOP HL. In 2017, the Philippines IP Office launched a consultation process towards an enhanced national IP strategy.

Concerns and areas for improvement and action

EU stakeholders report that court procedures are overly long and unreasonably complex and the penalties and fines prescribed by the IP Code are not sufficiently deterrent. Despite the progress, counterfeiting and piracy are a serious problem, particularly in the digital environment and on copyright related matters.

EU stakeholders report that another area of concern is the absence of an effective system to protect undisclosed test and other data generated to obtain marketing approval for

⁷⁶ See footnote 7

⁷⁷ See footnote 33

⁷⁸ Republic Act N° 10372 - An Act Amending Certain Provisions of Republic Act No. 8293 (Intellectual Property Code of the Philippines)

pharmaceutical and agrochemical products against unfair commercial use, as well as unauthorized disclosure. There seems to be no law that specifically addresses regulatory data protection for pharmaceuticals and the protection of trade secrets.

EU stakeholders also claim that patentability requirements do not seem to meet international standards, because the requirement to prove the "enhanced efficacy" of the pharmaceutical product when applying for patent protection, seriously limits the patentable subject matter. The information on "enhanced efficacy" is generated in the course of the clinical trials which are usually run only after the patent is granted.

According to the OECD-EUIPO study *Mapping the Real Routes of Trade in Fake Goods*⁷⁹ the Philippines appears to be an important producer of counterfeit footwear as well as leather articles and handbags.

The Philippines has not yet ratified the Geneva Act of the Hague Agreement Concerning the International Registration of Industrial Designs and the 1991 Act of the International Convention for the Protection of New Varieties of Plants (UPOV 1991).

EU action

The EU and the Philippines launched negotiations in 2016 with the intention to conclude a free trade agreement. The negotiations cover all intellectual property rights and also civil and border enforcement. The IPR chapter aims at complementing the efforts of the IPOPHL to further increase the level of IPR protection and enforcement in the Philippines in line with international norms and standards.

The EU-ASEAN Project on the Protection of Intellectual Property Rights (ECAP III)⁸⁰ continued until February 2017. It aims at supporting ASEAN regional integration and at further harmonising the systems for IP creation, protection, administration and enforcement in the ASEAN region, including the Philippines. Among its achievements, the project led to an integration of ASEAN member states into the ASEAN TMview, TMclass and DesignView databases. An ASEAN-specific portal for each of the databases has been set up, providing easily accessible trademark and design data.

Further technical assistance will be granted to the Philippines under the ASEAN Regional Integration Support from the EU (ARISE Plus) programme⁸¹ which aims to support greater economic integration in ASEAN countries inter alia by improving IPR protection and enforcement. Under the IPR component of ARISE Plus, the EU will continue supporting the legal and regulatory IP frameworks to enable ASEAN countries like the Philippines to participate in global protection systems, to develop ASEAN regional platforms and to strengthen the network of ASEAN IP Offices with a view to improving their capacity to deliver timely and quality services. Activities will include enhancing IP awareness in society and the IP capacity of the productive sector. The specific objective of this component is to

⁷⁹ See footnote 37

⁸⁰ See footnote 46

⁸¹ See footnote 47

support ASEAN regional integration and further upgrade and improve the systems for IP creation, protection, utilization, administration and enforcement in the ASEAN region.

The Commission launched in September 2017 a technical cooperation programme IP Key⁸² South East Asia, also covering the Philippines, which will be implemented over the next four years, with special focus on the support of negotiations and implementation of IPR provisions in FTAs.

The ASEAN IPR SME Helpdesk⁸³ provides free assistance and information to SMEs for a better understanding of the IPR environment in the Philippines.

Thailand

Progress

Thailand, notably the Department of Intellectual Property of the Ministry of Commerce, has made efforts to reinforce IPR protection and enforcement. Thailand has also rolled out in 2016 a 20-year-long IP Roadmap⁸⁴ which intends to review the IP laws in support of the economic transformation of the country. Besides, Thailand has started the implementation of the ASEAN Working Group on IPR Cooperation (AWGIPC)⁸⁵ and the IPR Action Plan 2016-2025⁸⁶.

Thailand has established the National Committee on Intellectual Property Policy and a subcommittee on enforcement against IP infringements, which has improved the coordination on enforcement in the Thai administration.

Thailand ratified the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks in 2017.

The IP Roadmap with the reported aim of reforming the country's entire IP system will be carried out in the framework of the government's Thailand 4.0 Policy to Transform the Thai Economy⁸⁷ that aims to transform Thailand into a more innovation and creativity driven higher value-added economy. The roadmap consists of six areas, four of which are in the context of the intellectual property value chain (creation, protection, commercialisation and enforcement).

The IP Roadmap comprises both short- and long-term action plans. Short-term actions include an increase in staff, improving database systems and information technology, and making registration procedures for the different industrial property rights more efficient. It also includes further developing the Thai IP laws towards international standards and amending

⁸² See footnote 7

⁸³ See footnote 49

⁸⁴ http://thailand.prd.go.th/mobile_detail.php?cid=4&nid=3737

⁸⁵ <https://www.aseanip.org/About>

⁸⁶ <https://www.aseanip.org/Statistics-Resources/ASEAN-IPR-Action-Plan-2016>

⁸⁷ http://thailand.prd.go.th/mobile_detail.php?cid=4&nid=3784

the Patent Act. Ambitious initiatives aiming to decrease the patent backlog are also welcomed.

Concerns and areas for improvement and action

EU stakeholders report that serious concerns persist regarding the widespread availability of counterfeit and pirated goods, both in physical and online markets, as well as the lack of effective and deterrent enforcement measures. The lack of sustained, coordinated enforcement and prosecution continues to be a problem.

EU stakeholders also report that civil proceedings are overly long and expensive, provisional measures and injunctions are rarely ordered by the courts, criminal sanctions seem not to be deterrent enough, search warrants are difficult to obtain, undermining the preservation of evidence and customs procedures are available only against trademarks and copyright. No landlords have yet been prosecuted for IPR infringements of their tenants. The inclusion of landlord liability in Thailand's copyright and trademark legislation would complement existing procedures under the Criminal Code, which, so far seem to have been ineffective for this purpose.

EU stakeholders report that Thailand's patent office lacks resources to keep up with the volume of applications, resulting in a worrying patent backlog. It remains to be seen whether the recently announced measures to reduce the backlog will be effective to address the concerns.

EU stakeholders also report that the lack of adequate tools against the circumvention of technological protection measures and the unauthorized alteration or removal of rights management information causes them considerable harm. The Copyright Act⁸⁸ provides legal protection against the circumvention of technological protection measures, but includes a list of exceptions to this protection which are overly broad and pre-empts the protection.

EU stakeholders also indicate that in the absence of an effective "notice and take down" procedure, illegal content can only be removed upon a court order, which the court system in Thailand is usually perceived to experience difficulties in delivering promptly, making the procedure less efficient in practice. A more effective "notice and take down" system to enforce copyright online would be necessary.

According to the OECD-EUIPO study *Mapping the Real Routes of Trade in Fake Goods*⁸⁹ Thailand appears to be an important producer of perfumes, footwear, leather articles and handbags, jewellery, clothes and textile fabrics, optical, photographic and medical equipment as well as electronics and electrical equipment.

Thailand has not yet ratified the WIPO Copyright Treaty, the WIPO Performances and Phonograms Treaty, the Geneva Act of the Hague Agreement Concerning the International

⁸⁸ Copyright Act (N° 2) B.E. 2558 (2015)

⁸⁹ See footnote 37

Registration of Industrial Designs and the 1991 Act of the International Convention for the Protection of New Varieties of Plants (UPOV 1991).

EU action

In March 2013, the EU and Thailand launched negotiations for a Free Trade Agreement, with the aim to include rules to ensure effective and adequate IPR protection and enforcement in Thailand. Among other goals, the agreement aims at addressing deficiencies in the registration of industrial property rights and urging Thailand to adhere to the relevant multilateral agreements and conventions in the area of IP. However, due to the political situation, the negotiations have been suspended.

The EU and Thailand have launched an annual IPR Dialogue to discuss ongoing legislative developments, exchanging experience on enforcement by the customs and enforcement authorities and the administrative and judicial bodies. In addition, the EU Delegation has participated in the biannual consultations between government agencies and business convened by the Department of Intellectual Property.

The EU-ASEAN Project on the Protection of Intellectual Property Rights (ECAP III)⁹⁰ continued until February 2017. It aimed at supporting ASEAN regional integration, and at further harmonising the systems for IP creation, protection, administration and enforcement in the ASEAN region, including Thailand. Among its achievements, the project led to an integration of ASEAN member states into the ASEAN TMview, TMclass and DesignView databases. An ASEAN-specific portal for each of the databases has been set up, providing easily accessible trademark and design data.

Further technical assistance will be granted to Thailand under the ASEAN Regional Integration Support from the EU (ARISE Plus) programme⁹¹ which aims to support greater economic integration in ASEAN countries inter alia by improving IPR protection and enforcement. Under the IPR component of ARISE Plus, the EU will continue supporting the legal and regulatory IP frameworks to enable ASEAN countries like Thailand to participate in global protection systems, to develop ASEAN regional platforms and to strengthen the network of ASEAN IP Offices with a view to improving their capacity to deliver timely and quality services. Activities will include enhancing IP awareness in society and the IP capacity of the productive sector. The specific objective of this component is to support ASEAN regional integration and further upgrade and improve the systems for IP creation, protection, utilization, administration and enforcement in the ASEAN region.

The Commission launched in September 2017 a technical cooperation programme IP Key⁹² South East Asia, also covering Thailand, which will be implemented over the next four years, with special focus on the support of negotiations and implementation of IPR provisions in FTAs.

⁹⁰ See footnote 46

⁹¹ See footnote 47

⁹² See footnote 7

The ASEAN IPR SME Helpdesk⁹³ will continue to provide free assistance and information to SMEs for a better understanding of the IPR environment in Thailand.

United States

Progress

The US has well developed laws and procedures for IPR protection and enforcement. A recent development is the entry into force of the Defend Trade Secrets Act of 2016 (DTSA)⁹⁴, which provides for new federal civil cause of action for misappropriation of trade secrets. This law supplements the federal criminal law and state law protections against trade secrets theft. Also, the new patent litigation pleading standards⁹⁵ are seen as having a positive effect. In addition, the EU and the United States continue to enjoy good cooperation on IP issues, which allows for discussion of common IPR enforcement challenges in third countries.

One big change in 2016 was that the US administration decided to grant a licence for the renewal of the Havana Club trademark in the US. This is a positive development as it could lead to compliance with the WTO dispute settlement decision⁹⁶ that found Section 211 of the US Omnibus Appropriations Act of 1998 as contrary to the US' obligations under the TRIPS Agreement.

Concerns and areas for improvement and action

The Commission notes the lack of progress in implementing the WTO panel decision on Irish Music⁹⁷. Section 110(5)(B) of the US Copyright Act was found to be incompatible with the TRIPS Agreement and constitutes a copyright infringement. Disrespecting WTO dispute settlement decisions on IPR establishes a negative precedent and undermines the credibility of WTO members such as the EU and the US who share a common interest in promoting effective IPR protection and enforcement, notably in emerging economies.

EU stakeholders report that patent trolls remain a cause for concern as they constitute an obstacle for business development.

⁹³ See footnote 49

⁹⁴ Public Law 114-153 – May, 11, 2016. Defend Trade Secrets Act of 2016

⁹⁵ Following Supreme Court decisions in *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007); and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), the US abrogated Form 18, as authorized by former Federal Rule of Civil Procedure 84. Form 18 provided a simple way to plead direct patent infringements. It required a party to provide little more than the asserted patent number and a general statement that a class of the defendant's products embodied the patented invention. With the rise of patent monetization entities and so-called patent troll litigation over the past 10 years, the form made it possible to easily mass-produce patent infringement complaints; arguably often without including sufficient detail for accused infringers to discern how their products allegedly infringed the patents. In the absence of Form 18, it is widely accepted that patent infringement complaints are now governed by the plausibility standard. However, given the apparent subjectivity built into the standard — and the lack of appellate guidance on what it requires in patent cases — a consensus on pleading standards has been slow to emerge from district courts.

⁹⁶ WTO DS176: United States – Section 211 Omnibus Appropriations Act of 1998

⁹⁷ WTO DS160: United States – Section 110(5) of US Copyright Act

EU action

The European Commission continues the long-established tradition of Transatlantic IPR Working Group with the US. The Transatlantic IPR Working Group is seen as a very valuable instrument by both sides – mostly for coordinating the cooperation vis-à-vis third countries and multilateral organisations and exchanging best practices and providing information on the recent domestic developments. Cooperation between the EU and the US is taking place also in multilateral fora, notably at the WTO and at the OECD.

6. MONITORING OF THE IMPLEMENTATION OF FREE TRADE AGREEMENTS

IPR is a key interest to the EU in the context of international trade. The overall objective of the IPR Chapter in the EU's trade agreements, building upon EU *acquis*, is to ensure that right holders enjoy a high level of protection of IPR, and that they have at their disposal adequate measures to enforce these rights.

The IPR chapters in the EU's free trade agreements as far as possible offer similar levels of IPR protection to those existing in the EU, while taking into account the level of development of the trading partners. In other words, the TRIPS Agreement provides the minimum standard for every WTO member and the EU aims to bring the IP law of the trading partners as close as possible to the EU *acquis*. The EU also seeks to fill gaps in the TRIPS Agreement, notably those resulting from the passage of time (it has been over 20 years since the TRIPS Agreement has been adopted). Most notably, we aim to address issues arising from the need to protect IPR in the digital environment.

The standard IPR Chapter of the EU's free trade agreements as much as possible follows the structure of the TRIPS agreement, since it includes a couple of general provisions (scope, exhaustion, national treatment, etc.), sections dealing with the substantive protection of each IPR (copyright, trademarks, designs, GIs, patents, undisclosed information and plant varieties), and a general enforcement section that applies to all IP rights (including civil and customs enforcement).

The EU concluded free trade agreements with a number of third countries, including Canada, South Korea, Singapore and Vietnam. The monitoring of the IP legislation of these countries is essential to ensure that they properly implement the free trade agreements.

Canada

Progress

Positive developments have been noted recently. Canada is in the process of addressing further issues under the Comprehensive Economic Trade Agreement (CETA) with the EU. On 19 July 2015, Canada ratified the 1991 Act of the International Convention for the Protection of New Varieties of Plants. Improvements were also made regarding IPR enforcement.

New provisions on IPR border measures, which entered into force on 1 January 2015⁹⁸, provide Canadian customs authorities with the (ex officio) power to detain suspected counterfeit or pirated products at the border and to exchange information with right holders in order to confirm the infringing nature of the products. These provisions, which aim to support the civil enforcement of copyright or trademark rights by giving the right holders the information and assistance necessary to pursue a remedy in court, were part of the Combating Counterfeit Products Act, which became law on 9 December, 2014⁹⁹.

The Budget Implementation Act 2015¹⁰⁰, which entered into force in January 2016, extended the term of copyright protection for sound recordings to 50 years after the end of the calendar year in which the first fixation of the sound recording was made.

In May 2017, the Canada-EU CETA Implementation Act¹⁰¹ received Royal Assent. The new legislation introduces important changes to Canada's Patent Act¹⁰². Canada introduces a system of supplementary protection certificates (CSPs) for pharmaceutical products for a maximum period of two years after the end of a patent term in order to compensate patentees for delays in the marketing approval process and also provides for a right of appeal related to decisions thereto.

Concerns and areas for improvement and action

The Canadian IPR system still features shortcomings. Despite recent positive developments, a number of issues remain to be addressed, in particular weaknesses in enforcement mechanisms including adequate authority for customs officials to seize and destroy counterfeit and pirated goods at the border and in the sharing of information between Canadian IPR enforcement authorities and right holders. There still appears to be a low prioritization of tackling IPR infringements by law enforcement, prosecutors and courts and a lack of resources. Moreover, the way broad exceptions in copyright law are applied may be detrimental to right holders.

EU stakeholders report that recent Canadian jurisprudence evaluates an invention's utility under the Canadian Patent Act¹⁰³ not just by assessing whether it is useful, but also against the "promise of the patent" in the patent application at the time of filing. This heightened standard for patent utility, which raises serious doubts of compatibility with the TRIPS Agreement, presents an area of serious concern as it has resulted in the invalidation or unenforceability of numerous patents over the past decade, in particular as regards pharmaceutical innovations.

EU stakeholders also report that Canada remains a host to illegitimate pharmacy websites, i.e. online pharmacies which originate from other countries without mandatory physical presence

⁹⁸ Combating Counterfeit Products Act, S.C. 2014, c. 32

⁹⁹ See footnote 98

¹⁰⁰ Economic Action Plan 2015 Act, No. 1, S.C. 2015, c. 36

¹⁰¹ Canada–European Union Comprehensive Economic and Trade Agreement Implementation Act, S.C. 2017, c. 6

¹⁰² Patent Act, R.S.C., 1985, c. P-4, <http://laws-lois.justice.gc.ca/PDF/P-4.pdf>

¹⁰³ See footnote 102

in Canada and which escape Health Canada's regulatory control. Some of these online pharmacies replace brand-name medication with other drugs that are reported as generics, but which may not have been approved by Health Canada, while others may be substandard or counterfeit. EU stakeholders are also concerned about the Minister of Health's margin of discretion in disclosing confidential business information without notifying the person to whose business or affairs the information relates or obtaining their consent.

Furthermore, EU stakeholders report that Canada has become a host to services enabling anonymous registration of website domains and hiding the identity of the real service operator by using reverse proxies. While the enablement cause of action in Section 27(2.3) of the Copyright Modernisation Act 2013¹⁰⁴ has improved the legal means of right holders, it appears insufficient in the aforementioned cases where the identity of the service operator is unknown. Right holders seem not to be in a position to apply for an injunction aimed at preventing a continuation of a copyright infringement (e.g. website blocking).

The "notice and notice" regime for Internet copyright infringements, which came into effect in January 2015, still needs to be supplemented by a "notice and take down" requirement, as well as by other measures to encourage all players to address online infringement in an effective way. There is currently no requirement for the internet service provider (ISP) or the user to take down infringing material and the only way to enforce a takedown is via the courts.

Canada has not yet ratified the Madrid Agreement Concerning the International Registration of Marks or the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks. Once Canada joins the Madrid Protocol, this will considerably facilitate the access of European industry to extended trademark protection.

EU action

The bilateral "CETA" trade agreement, which entered into force provisionally on 21 September 2017, resulted in important enhanced IPR protection in Canada. It addressed the key element of IPR protection for pharmaceuticals by providing for an additional period of patent protection as compensation for delays in the marketing authorisation procedure, a right of appeal for patent holders in marketing procedures, and protection of clinical test data for a period of eight years. Moreover, CETA gives EU copyright and trademarks a similar level of protection in Canada as they enjoy in Europe. In particular, Canada will align its copyright protection to international standards. This will protect the intellectual property of the EU's creative industries (artworks, publications, music or software) including its dissemination through new technologies and communication systems such as the internet.

The EU is committed to a smooth and effective implementation of CETA and remains in close contact with the Canadians in this regard as well as on issues going beyond CETA.

¹⁰⁴ http://laws-lois.justice.gc.ca/PDF/2012_20.pdf

South Korea

Progress

Positive developments have been noted over the last two years in South Korea. The overall level of protection and enforcement of IPR in Korea has considerably improved. There have been increased and successful efforts to combat counterfeit products on street markets, notably in the Seoul area.

The Ministry of Culture, Sport and Tourism (MCST) has proposed an amended presidential decree with the aim of increasing the number of venues that will pay royalties for the communication to the public of copyright protected music. The decree¹⁰⁵ entered into force on 23 August 2017. However, this is only a partial and very limited solution to the problem of lack of remuneration for public performance.

Due to the inclusion of a 1-year grace period however, the Recording Industry Association of Korea (RIAK), the Korea Music Copyright Association (KOMCA), the Korean Society of Composers, Authors and Publishers (KOSCAP) and the Federation of Korean Music Performers (FKMP) will only start collecting fees from 23 August 2018.

The Korean National Assembly has recently approved several amendments to the Korean Trademark Act¹⁰⁶, which came into effect on September 1, 2016, further improving the trademark environment. While a number of smaller amendments have been implemented over the years, this is the first comprehensive amendment to the Trademark Act in many years.

Concerns and areas for improvement and action

Concerns remain in respect of the patent filing system, in particular in the pharmaceutical sector and concerning limited patent scope. EU stakeholders also expressed concerns in relation to the adequate protection of patent rights in the context of standard essential patents (SEPs) in Korea.

One of the remaining systemic deficiencies pointed out by right holders in the area of enforcement has to do with the level of sanctioning, which is considered insufficient to ensure adequate deterrence against IP infringements with regard to counterfeit and pirated goods. The fight against the sale of counterfeit goods on physical markets has intensified, but continued actions are still needed. Online IP infringement should get more attention by authorities.

¹⁰⁵ The Ministry of Culture, Sports and Tourism has decided to revise Presidential Decree No. 27970 to expand the list of businesses which are not exempted by Article 29(2) of the Act. A draft was published on 2 May 2017 and the Cabinet Council of the Republic of Korea approved the revision of the Presidential Decree of Copyright Act on 16th August 2017, to slightly widen the positive list of venues where rightholders can claim remuneration for public performance. On 23 August 2017, the Ministry of Culture, Sports and Tourism published the law, making it effective from the date of the publication.

¹⁰⁶ Act No. 14033, February 29, 2016

One of the most pressing problems is in the area of copyright and related rights. The legislation governing the single equitable remuneration for performers and phonogram producers has not progressed over the last two years and overly broad exceptions limit the applicability of these rights. South Korea has not yet brought its law in compliance with international commitments.

EU stakeholders report that there is differential treatment between South Korean companies and foreign companies, both in administrative and judicial procedures.

According to the OECD-EUIPO study *Mapping the Real Routes of Trade in Fake Goods*¹⁰⁷ South Korea appears to be an important source country of counterfeit electronics and electrical equipment.

EU action

The EU and South Korea have been working together to ensure the smooth and effective implementation of the EU-Korea Free Trade Agreement which entered into force in 2011. The IPR Dialogue, established by the FTA, has met regularly on a yearly basis to discuss ongoing legislative developments, exchanging experience on enforcement by the customs and enforcement authorities as well as by the administrative and judicial bodies. The Commission participated in the public consultation on the amendment of the presidential decree on public performance rights.

Singapore

Progress

The intellectual property regime of Singapore reflects high standards and Singapore is a member of the most important international agreements in the IP area.

The EU and Singapore completed the negotiations for a free trade agreement (FTA) on 17 October 2014. The ratification is expected in the course of 2018. The FTA includes a comprehensive IPR chapter, with specific provisions on IPR protection and enforcement including enhanced border measures. The implementation of the FTA should contribute to improving IPR protection and enforcement in Singapore. It is also worth mentioning that Singapore has undertaken the commitment to provide equitable remuneration to performers and phonogram producers within two years from the entry into force of the FTA.

Concerns and areas for improvement and action

The latest results of the joint OECD-EUIPO study *Mapping the real routes of trade in fake goods*¹⁰⁸ singles out Singapore as a major transit hub of counterfeit goods. Singapore needs to step up efforts against counterfeiting and piracy with respect to goods under customs control (including import, export, transshipment, etc.) and empower its customs authorities to seize or

¹⁰⁷ See footnote 37

¹⁰⁸ See footnote 37

suspend the release of goods suspected of infringing an IP right. The customs authorities should have the authority to take action on the request of the right holder and also ex officio. In the OECD-EUIPO study Singapore is mentioned also among the producers of counterfeit perfumes, cosmetics, electronics and electrical equipment.

EU action

The EU-ASEAN Project on the Protection of Intellectual Property Rights (ECAP III)¹⁰⁹ continued until February 2017. It aimed at supporting ASEAN regional integration, and at further harmonising the systems for IP creation, protection, administration and enforcement in the ASEAN region, including Singapore. Among its achievements, the project led to an integration of ASEAN member states into the ASEAN TMview, TMclass and DesignView databases. An ASEAN-specific portal for each of the databases has been set up, providing easily accessible trademark and design data.

Further technical assistance will be granted to Singapore under the ASEAN Regional Integration Support from the EU (ARISE Plus) programme¹¹⁰ which aims to support greater economic integration in ASEAN countries inter alia by improving IPR protection and enforcement. Under the IPR component of ARISE Plus, the EU will continue supporting the legal and regulatory IP frameworks to enable ASEAN countries like Singapore to participate in global protection systems, to develop ASEAN regional platforms and to strengthen the network of ASEAN IP Offices with a view to improving their capacity to deliver timely and quality services. Activities will include enhancing IP awareness in society and IP capacity of the productive sector. The specific objective of this component is to support ASEAN regional integration and further upgrade and improve the systems for IP creation, protection, utilization, administration and enforcement in the ASEAN region.

The EU will closely monitor developments in Singapore as regards the implementation of IPR obligations under the FTA, in particular in view of the recent data provided by the joint OECD-EUIPO study¹¹¹.

Vietnam

Progress

Negotiations for an FTA between the EU and Vietnam were concluded in December 2015. Ratification is expected by the end of 2018. Vietnam has continued to make progress on its legislation, including the adoption of a Circular defining inspection, supervision and temporary suspension of customs procedures¹¹² for exported and imported goods that are subject to IPR as well as control of IPR infringing goods. The government has continued to

¹⁰⁹ See footnote 46

¹¹⁰ See footnote 47

¹¹¹ See footnote 37

¹¹² Circular No. 13/2015/TT-BTC of January 30, 2015, of the Ministry of Finance, defining Inspection, Supervision, Temporary Suspension of Customs Procedures for Exported and Imported Goods that are Subjects of Intellectual Property Rights; Control of Counterfeit Goods and Goods Infringing Intellectual Property Rights

encourage training for its officials and to carry out awareness raising campaigns.

In July 2016, the new Vietnam Criminal Code 2015¹¹³ entered into force. Among other things, the new code introduces a number of important IP related changes such as criminal liability of juridical persons for manufacturing and trading IPR infringing goods. Criminal sanctions applicable to juridical persons include monetary fines, the suspension of business and a prohibition on doing business or raising capital.

Concerns and areas for improvement and action

Trade in counterfeit products is still a concern in Vietnam. According to the OECD-EUIPO study *Mapping the Real Routes of Trade in Fake Goods*¹¹⁴ Vietnam appears to be an important producer of counterfeit jewellery, clothing and textile fabrics, footwear, foodstuffs, as well as optical, photographic and medical equipment.

EU stakeholders are also concerned about the length of IP registration processes for trademarks and slow opposition procedures. While EU stakeholders' experience with authorities at national level has been positive, weaknesses were noted at local level. Further progress remains necessary regarding IPR enforcement. EU stakeholders report that IPR infringements remain prevalent across the country, especially in street markets and commercial areas. Concerns have been raised that sanctions against infringers have an insufficient deterrent effect and that there is still a lack of trained IP officials, including in the customs authorities. In the Commission's annual Report on EU Customs Enforcement of IPR in 2016¹¹⁵, Vietnam remains in the "top 7" countries of origin of suspected IPR infringing goods detained and seized at the EU borders. More generally, Vietnam's enforcement system has remained highly complex which makes it challenging also for right holders to take effective and efficient action against IPR infringements.

Vietnam has not yet ratified the WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty.

EU action

The negotiations of an EU-Vietnam Free Trade Agreement were concluded in December 2015. The FTA, which is currently subject to legal revision, is expected to enter into force by the end of 2018. The FTA includes a substantial IPR chapter in which Vietnam has committed to a high level of protection, going beyond the standards of the TRIPS Agreement.

With this agreement, EU innovations, artworks and brands will be better protected against being unlawfully copied, including through stronger enforcement provisions. Among other things, the EU pharmaceutical sector will benefit from improved data protection and of the possibility to get an extension of the patent term of up to two years if there are delays in the marketing authorization process.

¹¹³ Criminal Code No. 100/2015/QH13 of November 27, 2015

¹¹⁴ See footnote 37

¹¹⁵ See footnote 12

Vietnam continued to receive significant technical assistance in the field of IP from the EU. The European Trade Policy and Investment Support Project (MUTRAP)¹¹⁶, which is ongoing until the end of 2017, has benefited the Vietnamese IP Office (NOIP), other authorities, judges, business community, and legal practitioners. Its key objectives among others have been to assist the NOIP to improve the capacities of enforcement authorities on IPR and to increase the awareness and use of IP as a tool for economic integration. The EU funded ASEAN IPR SME Helpdesk¹¹⁷ supports SMEs also in relation to Vietnam.

The EU-ASEAN Project on the Protection of Intellectual Property Rights (ECAP III)¹¹⁸ continued until February 2017. It aimed at supporting ASEAN regional integration, and at further harmonising the systems for IP creation, protection, administration and enforcement in the ASEAN region. Among its achievements, the project led to an integration of ASEAN member states into the ASEAN TMview, TMclass and DesignView databases. An ASEAN-specific portal for each of the databases has been set up, providing easily accessible trademark and design data (available also in Vietnamese). For the period 2017-2020, ECAP III will be replaced by the new technical IP cooperation programme IP Key¹¹⁹ ASEAN. This project was launched in the second half of 2017.

Further technical assistance will be granted to Vietnam under the ASEAN Regional Integration Support from the EU (ARISE Plus) programme¹²⁰ which aims to support greater economic integration in ASEAN countries inter alia by improving IPR protection and enforcement. Under the IPR component of ARISE Plus, the EU will continue supporting the legal and regulatory IP frameworks to enable ASEAN countries like Vietnam to participate in global protection systems, to develop ASEAN regional platforms and to strengthen the network of ASEAN IP Offices with a view to improving their capacity to deliver timely and quality services. Activities aimed at private stakeholders will include enhancing IP awareness in society and IP capacity of the productive sector. The specific objective of this component is to support ASEAN regional integration and further upgrade and improve the systems for IP creation, protection, utilization, administration and enforcement in the ASEAN region.

¹¹⁶ <http://mutrap.org.vn/index.php/en/about-eu-mutrap-2>

¹¹⁷ See footnote 49

¹¹⁸ See footnote 46

¹¹⁹ See footnote 7

¹²⁰ See footnote 47

ANNEX I

1. TRANSIT HUBS AND FREE TRADE ZONES

1.1. Transit hubs

The OECD-EUIPO study *Mapping the real routes of trade in fake goods*¹²¹ classifies the countries of origin of counterfeit goods either as producing or transit countries. Counterfeit goods are transported to their final destination through different trade routes and may transit via several countries. Counterfeiters tend to ship their goods through complex trade routes in order to cleanse the documents, disguise the producing country and establish distribution centres for the fake goods in free trade zones where they can repackage and relabel these goods before forwarding them to their final destination in small parcels.

For the counterfeiters, the choice of transit country or free trade zones can be manifold. The geographical location, the low effectiveness of the enforcement and customs authorities, the relaxed regulations and oversight in free trade zones, the weak procedures and infrastructure for inspections or the lack of mechanisms to prevent money laundering are key components for counterfeiters when choosing their trade routes.

Hong Kong, the United Arab Emirates and Singapore are the main hubs for trade in counterfeit goods in all the product categories. These countries are also important transshipment centres where fake goods arrive in big quantities in containers and are forwarded in small parcels by courier services or via post to their final destination. There are also some important regional transit countries, such as the United Arab Emirates and Saudi Arabia as well as war-torn zones in the Middle East. Albania, Morocco and Ukraine were also identified for shipments of fake goods to the EU.

The OECD-EUIPO study¹²² and EU stakeholders' reports identify the following main transit points for counterfeit products in global trade:

- Foodstuffs: Saudi Arabia;
- Pharmaceuticals: Hong Kong, the United Arab Emirates and Iran;
- Perfumes and cosmetics: Hong Kong, the United Arab Emirates, Kuwait, Ukraine and Albania;
- Leather articles and bags: Hong Kong, Singapore, Kuwait, Egypt, Morocco, Albania and Bosnia and Herzegovina;
- Clothing and textile fabrics: Hong Kong, Singapore, the United Arab Emirates, Ukraine and Azerbaijan;
- Footwear: Hong Kong and Singapore, and also the United Arab Emirates, Iran, Morocco, Armenia, Panama and Senegal;
- Jewellery: Hong Kong and Singapore, and also the United Arab Emirates, Saudi Arabia, Morocco, Panama, Turkey and Ukraine;

¹²¹ See footnote 3

¹²² See footnote 3

- Electronics and electronic equipment: Hong Kong, Singapore, the United Arab Emirates and also Egypt, Turkey, Belize, Guatemala and Panama as well as Nigeria, Ghana and Cameroon;
- Optical, photographic and medical equipment: Hong Kong, Singapore, Kuwait, , Morocco, Algeria, Albania, Dominican Republic and Uruguay.
- Toys, games, and sports equipment: Hong Kong, Singapore, Macau, Saudi Arabia, the United Arab Emirates, Morocco, Paraguay and Mexico.

1.2. Free trade zones

The European Commission's increased attention to free trade zones builds on the latest empirical data collected by the OECD and the EUIPO¹²³. The new data shows that free trade zones play an essential role in counterfeiting because criminal networks engaged in counterfeiting tend to establish trading hubs and transshipment points in these zones exploiting the low-regulatory environment.

Free trade zones provide good opportunities and privileges for legitimate businesses and play a crucial role in international trade. Countries which offer relaxed regulations and oversight and tax exemptions in free trade zones can generate inward investment for their economy, contribute to economic growth and facilitate increased international trade.

According to the WCO's Revised Kyoto Convention Specific Annex D¹²⁴, a "Free Zone" means "a part of the territory of a Contracting Party where any goods introduced are generally regarded, insofar as import duties and taxes are concerned, as being outside the Customs territory". They are also known as free processing areas, free zones, enterprise zones, foreign trade zones, free ports and special economic zones.

In practice, the purpose of the free trade zones is to establish a special status for the operations and goods in these zones with respect to customs and tax controls. Free trade zones tend to provide incentives for undertakings, facilitate export through alleviating or removing certain customs or other regulations in order to attract investments and the undertakings get special incentives to develop their businesses in these zones when providing import or export services. Even though the Revised Kyoto Convention lays down that goods in free trade zones are not exempt from customs inspection for non-duty related matters, the proper enforcement in the zones is usually lacking.

Free trade zones often offer zero taxation and foreign ownership advantages which makes them very attractive for foreign counterfeiters. Most free trade zones do not have stringent requirements related to company incorporation unlike companies based onshore that require a physical office to be established with a valid commercial license. This allows a lot of foreign companies to be able to hide ownership structures. Such companies easily rent warehouses in

¹²³ See footnote 3

¹²⁴ http://www.wcoomd.org/en/topics/facilitation/instrument-and-tools/conventions/pf_revised_kyoto_conv/kyoto_new/spand.aspx

free trade zones which would be difficult outside of the zone, where they have to provide commercial license details. Further, free trade zones also serve as operational hubs for logistics companies so counterfeiters use the services of these third parties making it difficult to trace the real owners of any counterfeit goods found during enforcement actions.

Infringing activities that often take place in free trade zones include manufacturing, storing, assembling, exporting, re-exporting, relabelling and repackaging of fake goods in order to disguise the country of origin or to complete the infringement by affixing the counterfeit trademark to the good.

Asia

In Singapore, the Port of Singapore, in Malaysia, Port Klang and in Indonesia, Port of Batam Island are reported to be trans-shipment and storage points for counterfeit goods destined for other Asian markets and are used as transit points for counterfeit products from China. In Malaysia, the Royal Malaysian Customs has jurisdiction to take action against counterfeiters and request information from the operators of free trade zones, even if the zones operate under specific zone rules. The main problem in Malaysia is that the customs authority does not perform physical and documentary controls in free zones allowing criminals to use the zones for storing and moving counterfeit goods.

Hong Kong, SAR has been declared a free port and separate customs territory from China, where the free movement of goods is assured. The main reason that this port is frequently used by counterfeiters lies in Section 12 of Hong Kong's Trade Description Ordinance (CAP362)¹²⁵ which prohibits and penalizes imports and exports of counterfeit trademarks but excludes transit goods from its application. This exemption allows counterfeiters to evade detection by customs authorities when transshipping products through this free trade zone in order to conceal or alter the shipment's history.

In the Philippines, Subic Bay Port is reportedly used as a transit and storage point for contraband goods and is frequently used as a 'fast boat' transit point for goods to re-enter into China.

Middle East

The United Arab Emirates is often shown as one of the main countries of provenance for counterfeit goods. According to the stakeholders, counterfeiters use the following free trade zones in the UAE to manufacture, store and especially transship counterfeit goods: Ajman Free Zone Area, Jebel Ali Port, Fujairah Port, Port Saqr, Shariah Port and Ras Al Khaimah Free Zone Area. Among these, Jebel Ali Port poses reportedly the highest risk of counterfeiting. Since the UAE is a federal country, each of its seven Emirates has their own separate and autonomous customs regime. As free trade zones operate autonomously with their own governing authorities and regulations this makes the law enforcement more complicated. The

¹²⁵ <https://www.elegislation.gov.hk/hk/cap362>

listed free trade zones in the ports are also reported to be used for logistical support, transshipments and repackaging activities of counterfeit products. Generally, brand owners report that the UAE serves as a commercial gateway for movement of goods coming from China and then onwards into the GCC or the European market. Reportedly, 97% of the goods arriving at these ports are in transit to a foreign final destination instead of for onshore distribution. The right holders cannot liaise directly with the port and it takes a long time for a suspect container to be inspected. Consignments in transit or re-exports are never detained and inspected and post-action intelligence is non-existent despite the customs' investigation department. Dubai is reported to be another frequently used transit point for counterfeiters. Allegedly, a lot of goods travelling through this zone come from China destined for Europe and the UAE and enter into East Africa. Brand owners cite a notable increase in goods being imported from India in the past 12-18 months. The customs never act ex-officio and the warehouses are also protected from random Economic Development Department (EDD) inspection searches as the EDD Inspectors have limited powers and they cannot enter free zone premises for inspections without obtaining search warrants from the Public Prosecutor. The only way to carry out raid actions in free trade zones is in coordination with the Dubai Police Authorities.

In Jordan, the Port of Aqaba has been identified by brand owners as receiving counterfeit and contraband goods from the UAE and China for onward transit to Iraq.

Latin America

In Latin America the stakeholders reported that there were a series of high-risk free trade zones which are frequently used by counterfeiters. In Belize, the Corozal Free Zone is reported to be the central place for storing and commercializing counterfeit goods in Central America. The Corozal Free Zone is a well-known distribution centre of counterfeit goods to Guatemala and Mexico due to weak border control. Containers mainly from Asia enter this free trade zone directly or via Panama and are then illegally diverted through blind spots or even through customs border controls mainly to Mexico and Guatemala.

In Colombia at least half of the free trade zones can be considered high risk in terms of counterfeiting and illicit trade. The following zones are reportedly the most notorious: Rionegro, Cucuta, Cartagena, La Tebaida, San Andres, Buenaventura and Sobo. Corruption in these zones has a direct effect on the implementation of the regulations on border controls.

In Panama, the Port of Colon reportedly plays an important role in the trade of counterfeit goods. This port is reported to be a manufacturing area, and used as an illicit trade destination for South and Central America, mainly Colombia and Chile and then further into Central America.

In Paraguay, the two free trade zones in Ciudad del Este (Trade SA and Global del Paraguay SA) are reported to be high risk free trade zones, often used by counterfeiters.

Africa

The projected growth of the Tanger Med Free Trade Zone in Morocco, only 15 km from the EU, is popular among criminal networks to export larger amounts of counterfeit goods to the EU. In North Africa the following free zones are considered to be the highest risk: Free zone of export of Tangier (north) (Morocco), Free zone of Tangier Med Ksar el Maiaz Mellousa 1 and 2 (north) (Morocco), Oil storage free zone of Kebdana and Nador (northeast) in Morocco, and Free zone of Dakhla and Laayoune (south) (Western Sahara). Brand owners are not aware of any sanctions or inspections in these free trade zones for IP-infringing activities. The main problems are in trans-shipment of containers destined for other African countries and transit via Mauritania for re-entry on land via the south.

In South Africa, reportedly, the following free trade zones play an important role in IP infringements: Coega, Richard Bay, East London, Saldanha Bay, Dube Port (30 km North of Durban).

ANNEX II

1. GEOGRAPHICAL INDICATIONS

1.1. General assessment

The protection of EU GIs at the international level is a key-element of EU Trade policy. Many EU GI products of significant economic importance are confronted with abuses and usurpations in third countries with important economic losses for EU producers. The problem is particularly present for agricultural products and foodstuffs (such as cheeses and meat products) but some EU wines and spirits GIs are also experiencing problems in third country markets.

The option of collective or certification trademarks is sometimes the only viable alternative for the protection of GI names in third countries, in the absence of a specific GI system. However, the protection granted is often insufficient to prevent misuse, imitation or evocation; in many cases non-legitimate GI users have already registered trademarks using EU GI names and GI producer groups are required to enforce their trademark rights themselves which is beyond their means in many cases.

The EU attaches high importance to better protection and effective enforcement of GIs on the international scene, both on the multilateral and bilateral level. Ambitious provisions on GIs are crucial for EU stakeholders. However, this is not just in the EU interest since consumers and producers in the third country can also benefit. In bilateral agreements the EU seeks direct protection through the agreement for a list of GIs at a high level of protection similar to that offered under EU legislation on GIs, accompanied by an effective administrative protection (allowing EU exporters to expect faster and less costly remedies to their cases), as well as co-existence of GIs with prior trademarks that were registered in good faith. This is combined in our bilateral deals with the creation of a cooperation mechanism, in particular for the enforcement of the GI protection.

Many bilateral agreements including GI provisions are already in force (for instance with Canada, South Korea, Switzerland, Ukraine, Moldova, Georgia, Serbia, Montenegro, Albania, Bosnia and Herzegovina, the former Yugoslav republic of Macedonia, Kosovo¹²⁶) or are close to be finalised (Singapore, Vietnam, Japan). Several are being negotiated (e.g. China, Mercosur, Mexico, Indonesia and Azerbaijan); and some negotiations are expected to be launched soon (Chile, Australia, New Zealand).

Nowadays, GIs are not an EU-only concern. They have become a global phenomenon, with countries in Asia, Africa and Latin America embracing and protecting GIs. The EU's system is seen as a reference, and recognition and protection of many commercially important EU GIs in key trade partners' markets is improving.

¹²⁶ This designation is without prejudice to positions on status, and is in line with UNSCR 1244/99 and the ICJ Opinion on the Kosovo declaration of independence.

One particular problem faced by EU stakeholders seeking protection of EU GIs in third countries is allegations that the name is considered to be generic, i.e. is a customary name. It is therefore of the utmost importance that competent authorities in third countries assess any such claims on the basis of compelling evidence in that territory (including case law or other legally conclusive acts) rather than on mere allegations or limited examples of commercial use of the name, often outside the territory concerned. According to Article 24(6) of the TRIPS Agreement, a WTO Member is constrained to only assess whether a name is the common name for goods "in the territory of that Member". Accordingly, the EU accepts that a name that is protected as a GI in its territory could also, in principle, be considered as generic in another territory.

EU GIs are sometimes depicted as common names in third countries while used in association with symbols (flags, symbols, etc.) that re-link those products to the names' place of origin. This is strong evidence that those names are not common names as companies using the name feel the need to convey to consumers an image that evokes a (false) origin.

It is worth mentioning that GIs are not different from other intellectual property rights. Protecting GIs is about guaranteeing a fair treatment for unique products. GIs guarantee consumers that a product is authentic while protecting the producer from those who want to exploit their reputation and know-how required to develop an original, high-quality product. When trade counterparts plead for stronger IPR protection in their contacts, GIs should not be an exception.

As regards enforcement, the EU and Member State legislation counters infringements of GIs in Europe, through civil enforcement, border measures and criminal enforcement (through national legislation in several EU Member States). A product falsely marked by a GI, faces the risk of being seized and destroyed by customs, police or food safety inspection authorities. This explains why the EU seeks commitments from its trade counterparts to the highest standards of protection and enforcement of GIs in their respective countries.

The appropriate implementation of bilateral agreements already in force, allows the EU to raise specific concerns on GIs to be solved in the framework of the Agreement, in full respect of commitments undertaken on the enforcement of the protection of EU names. Furthermore, the Commission reaches out to enforcement authorities in the framework of EU funded cooperation programmes (including training and capacity building projects) to improve their stance for protection in their respective markets.

The Commission also engages constructively with counterparts on GIs through more informal mechanisms like the dialogues on intellectual property rights with prioritised third countries, which allow for regular exchanges of information on legislative developments or to raise specific problems affecting EU GIs in third countries.

At the multilateral level, the EU is one of the major supporters of GI negotiations at WTO and seeks to improve GI protection through the extension to other goods of the higher level of

protection already granted to wine and spirits GIs (Art. 23 of TRIPS Agreement) and through the setup of a multilateral GI register.

The EU has actively contributed to the successful revision of the WIPO Lisbon Agreement on appellations of origin and now also GIs in May 2015 (through the adoption of the Geneva Act). The result will be an up-to-date agreement that works more smoothly and is fully compliant with the TRIPS Agreement and compatible with the level of protection for GIs in the EU (including coexistence with prior trademarks and assessment of genericness). It allows now for accession of intergovernmental organisations, such as the EU, which will make the revised Agreement more attractive to a wider membership and therefore increase the geographical coverage of GI protection.

On 21 December 2017 the Commission published a Roadmap on EU accession to the Geneva Act¹²⁷ setting out the factual and legal context of a prospective EU membership. The feedback received within the deadline (18 January 2018) was largely positive. Against this background, the Commission is now preparing proposals to the Council regarding the legal acts needed for EU membership and implementation.

1.2. Assessment of the situation by country

Canada

Since 2003, EU GI wine and spirit names have been eligible for recognition under Canadian trademark law as the result of a bilateral agreement (Canada-European Community Wine and Spirits Agreement). The Comprehensive Economic and Trade Agreement (CETA) expands Canadian recognition of EU GI products from the previous bilateral agreement. Under CETA, 143 EU GI products are recognized and granted the highest level of protection in Canada and additional GIs can be added in the future. However, protection will apply in a different way to different categories of products, with some types of EU GI products having phase-out periods for producers in Canada or different specifications for use of qualifiers such as “like” or “type”, as long as the origin is clearly indicated.

The EU must ensure that GI protection is fully enforced by Canada. The EU is closely monitoring the situation in Canada regarding effective GI enforcement based on domestic legislation (IPR law, customs and border enforcement law, consumer labelling law).

EU stakeholders report that the process of entering an indication on Canada’s list of protected wine and spirits GIs is unreasonably slow. Normally it should take about 6 months. However EU exporters are facing considerably longer delays, in some cases up to almost 4 years. The slowness of the administrative procedure diminishes the benefits which should accrue to EU exporters from CETA on trade in wines and spirits.

¹²⁷ https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-6308027_en

With the updated Trade Marks Act¹²⁸ and the publication of the list of GIs protected in CETA on the Canadian Intellectual Property Office website, relevant EU right holders have the following avenues to request action a) against violating manufacturers inside Canada, from the Canadian Food Inspection Agency (CFIA) and b) at the border (for imported goods falsely using relevant protected names or GIs) by the Canada Border Services Agency (CBSA).

Concerning border enforcement, as agreed under CETA Articles 20.43-20.48, Canada has added counterfeit GIs to the scope of the Intellectual Property Rights Program administered by the Canada Border Services Agency (CBSA), which was previously limited to trademarks and copyright.

Central America

Since the entry into force of the Trade Pillar (Part IV) of the EU-Central America Association Agreement in 2013, almost all the EU GI names to be protected in the 6 Central American countries have completed the national registration process out of a list of 114 EU GI names.

Besides the complexity of the GI registration process in Central America, areas of particular concern regard a number of legal proceedings and litigations, in particular in Guatemala. A further issue of concern is the publication by Honduras of a list of alleged generic terms, some of them conflicting with EU GI names protected via the Agreement.

The EU is seeking to address these issues via the institutions under the Agreement, in particular the sub-committee on Intellectual Property Rights (IPR).

Some cases of apparent usurpation of EU GI names have been detected in Costa Rica but also in El Salvador, Honduras and Panama.

China

The EU and China are making progress with the negotiation of an EU – China bilateral agreement on GIs. The agreement should be concluded in 2018. After the conclusion, in collaboration with the EU Delegation and IP Key programme¹²⁹, from 2018 onwards more emphasis is planned to support enforcement on the ground.

China provides for protection of GIs under three different systems, namely:

- State Administration for Industry and Commerce (SAIC), protection of collective and certification marks under the Trademark Law;
- General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) system, protection of GI products, a sui generis protection under the Provisions on the Protection of Geographical Indication Products, and

¹²⁸ <http://laws-lois.justice.gc.ca/eng/acts/T-13/20170921/P1TT3xt3.html>

¹²⁹ See footnote 7

- Ministry of Agriculture (MoA), protection of GIs of agricultural products, a sui generis protection under the Measures for the Administration of Geographical Indications of Agricultural Products.

One of the problems EU GIs face today is that it may be necessary to apply for GI protection under different systems at the same time when the GI meets the requirements for registration under different legislations, otherwise the GI cannot get effective protection as a GI and the GI holder cannot prevent a third party from dishonestly registering the GIs under the other systems.

Mercosur

Although Mercosur countries have national IPR legislations allowing registration of foreign GIs, only a very limited number of EU right holders were able to effectively register and secure protection for their GIs in these countries. This is mainly due to lengthy and burdensome registration procedures and a Mercosur food labelling regulation permitting the use of the expression "type" for food products (other than wine and spirits) made with specific technologies of geographical areas, thus increasing the risk that these names become "generic". As a result, there is a widespread misappropriation of European GIs.

Although foreign GIs can theoretically be registered in Argentina, not a single EU GI has so far succeeded. Protection of EU GIs is further complicated by the widespread use of familiar EU names for domestic food and wine products. Brazil stepped up efforts to protect GIs but favours local products; the registration of EU GIs is slow, sometimes pending for many years. The draft law to bring the definition of GIs in line with the TRIPS Agreement did not progress.

Within the on-going FTA negotiations with Mercosur, the EU shall seek to grant protection to a list of EU GIs with an effective enforcement.

Mexico

EU spirits GIs are currently protected in Mexico through the 1997 bilateral Agreement on mutual recognition and protection of designation for spirit drinks. Mexico, being a member of WIPO, offers also protection to some EU geographical indications (food and wines) of those EU Member States who are part of the Lisbon Agreement. Today, protection for EU food and wine GIs in Mexico is therefore insufficient, paving the way for a number of imitations and usurpations. Within the on-going negotiations for the modernisation of the 1997 Global Agreement between the EU and Mexico, the EU seeks both to grant a high level of protection, including effective enforcement, to a list of relevant food and wine EU GIs, and to enhance the level of protection of spirits GIs.

Within the on-going negotiations for the modernisation of the 1997 Global Agreement between the EU and Mexico, the EU shall seek to grant protection also to a list of EU GIs with an effective enforcement.

Peru, Colombia and Ecuador

The registration of EU GIs listed in Annex XIII of the 2012 Trade Agreement between the EU and Colombia and Peru has been a source of concern, in particular in Peru due to the complex registration process. All EU names have been protected in Colombia (116 names) while the process is still on-going in Peru, with a limited number of names still pending registration (out of 115 names on the EU list to be protected under the Agreement). Also, a number of corrections to already registered GIs have to be implemented in Peru. The Agreement with Ecuador, who joined the Multiparty Trade Agreement as of the 1 January 2017, protects the full list of 116 names.

In Peru, there are further serious concerns with regard to the enforcement of specific protected wine GIs as well as usurpation cases of EU foodstuff GI names. Also investigation is ongoing in Colombia as regards some Italian and Greek cheese GIs that may face enforcement action due to usurpation.

The need for proper enforcement of the GI protection is a message constantly conveyed by the EU in all possible fora, primarily in the IPR sub-committee of the FTA. The EU has in both cases urged competent authorities in the framework of the FTA to take effective action against the unlawful use of the protected EU GI names concerned.

South Korea

The EU-South Korea FTA entered into force in 2011. The Agreement currently protects 160 EU GIs. Enforcement is one of the topics discussed in the GI working group established under the FTA.

There are important pending cases where the EU is seeking effective enforcement of GI protection, relating to GI cheeses protected under the FTA. In 2015 South Korean Authorities undertook successful action against a product infringing an EU GI cheese.

Ukraine

Under the EU-Ukraine Deep and Comprehensive Free Trade Agreement (DCFTA) in force since 1 January 2016, there are transition periods for the phasing out of names such as Champagne, Cognac, Porto, Feta, Roquefort and Parmigiano Reggiano.

Technical assistance of around EUR 3 million is being made available to help Ukraine develop a GI system and to implement and enforce the agreement.

The first GI sub-committee took place on the 19 May 2017, where implementation of the agreement, including the protection and effective enforcement were discussed.

United States

EU GI wines have been protected in the US via a bilateral agreement (US-European Community Agreement on trade in wine). As regard spirits, an agreement with the US of

1994 protects five EU GI spirit names. With regard to other foodstuffs the United States does not have a specific ad hoc legislation for the registration of GIs and the only possibility is to register under the trademark law. Only a very limited number of EU GI names were able to effectively register, due to burdensome registration procedures, a limited level of protection and the lack of administrative enforcement, as well as the high costs of private enforcement. As a result, there are cases of misappropriation of EU GIs.

The EU is closely monitoring the situation in the United States with a view to finding ways to improve the protection of EU GIs.

1.3. EU action

The EU will continue to push for effective recognition and protection of GIs at the international level with a view to enhancing the overall framework for protection of GIs as well as contributing to the solution of outstanding problems regarding specific EU GIs in particular third countries.

The EU will closely follow up on "unresolved" infringement cases in third countries and will use all relevant mechanisms provided for under FTAs as well as other channels (such as IP Dialogues and IP cooperation programmes) to reach out to competent authorities in this regard.

Involvement of producers is crucial for the effective protection of GIs as producers often have information about the particular situation in countries where their products are exported and sold and therefore are aware of possible misuses of their respective GI. They also have an important role to respond to requests from enforcement authorities seeking to identify counterfeit products.