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CORRIGENDUM:

This document corrects document SWD(2019) 452 final of 20.12.2019

Deletion of Brazil on page 12 in second last paragraph last sentence.

The text shall read as follows:

COMMISSION STAFF WORKING DOCUMENT

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

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COMMISSION STAFF WORKING DOCUMENT

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

1. INTRODUCTION

1.1. Objective

Efficient, well-designed and balanced intellectual property (IP) systems are a key lever to promote investment in innovation and growth. Intellectual Property Rights (IPRs) are one of the principal means through which companies, creators and inventors generate returns on their investment in innovation and creativity¹.

This report is part of the efforts of the European Commission to strengthen the protection and enforcement of IPR in third countries². It has been published biennially since 2006, the last one dating from 21 February 2018.

The main objective of this report is to identify third countries in which the state of IPR protection and enforcement (both online and offline) gives rise to the greatest level of concern and thereby to establish an updated list of so called "priority countries". This is not an exhaustive analysis of IPR protection and enforcement around the world. "Priority countries" are not necessarily those where IPR protection and enforcement is the most problematic in absolute terms but rather those where such deficiencies are deemed to cause the greatest economic harm to EU interests.

This report will help focus efforts and resources of the European Commission on countries and on the specific areas of concern, with the aim of improving IPR protection and enforcement worldwide. It devotes special attention to new developments since the last report and until 31 August 2019.

This report also aims to inform right holders, in particular small and medium-sized enterprises, about potential risks to their IPR when engaging in business activities in certain third countries and thus to allow them to design business strategies and operations to protect the value of their intangibles. The report should also be useful for authorities in third countries as a source of information.

For the first time, a separate annex is dedicated to the protection and enforcement of plant variety rights. This is justified by the importance of the protection of plant varieties in the context of global environmental challenges, as well as by their high exposure to IPR infringements. Many EU plant varieties are reportedly suffering from weak protection and abuses in third countries with important economic losses for EU breeders and the consequent loss of incentives for further investment and research in this area.

¹ European Commission, Communication 'Trade, growth and intellectual property', COM(2014) 389 and European Commission, Communication 'A balanced IP enforcement system responding to today's societal challenges', COM(2017) 707, <https://ec.europa.eu/transparency/regdoc/rep/1/2017/EN/COM-2017-707-F1-EN-MAIN-PART-1.PDF>

² See footnote 1

Improved yield, more efficient use of nutrients, resistance to plant pests and diseases, salt and drought tolerance and better adaptation to climatic stress are some of the features that allow breeders of new plant varieties to increase productivity and quality in agriculture, horticulture and forestry, whilst minimizing the pressure on the environment. According to the recent report of the Intergovernmental Panel on Climate Change (IPCC) on *Climate Change and Land* (2019)³, advances in plant breeding are crucial for enhancing food security under changing climatic conditions for a wide variety of crops. Breeding new crops can reduce greenhouse gas emissions, increase drought and heat tolerance and enhance nutrition and food security.

1.2. Economic importance of IPR and negative effects of counterfeiting and piracy

Effective IPR protection and enforcement are crucial for economic growth and for the EU's ability to stimulate innovation and stay competitive globally. According to a joint study by the European Intellectual Property Office (EUIPO) and the European Patent Office (EPO) from September 2019,⁴ IPR-intensive industries⁵ generated around 84 million or 38.9% of all jobs in the EU during the period 2014-2016 (including indirect jobs⁶). Over the same period, IPR-intensive industries accounted for around 45% of the EU GDP, worth some € 6.6 trillion annually.

Table 1: Contribution of IPR-intensive industries to EU employment and GDP (2014-2016 average)

IP right	Direct employment	Share of total direct employment (%)	Direct & indirect employment	Share of total direct and indirect employment (%)	Value added / EU GDP (€ million)	Share of total EU GDP (%)
All-IPR industries	62,962,766	29.2%	83,807,505	38.9%	6,551,768	44.8%
Copyright-intensive industries	11,821,456	5.5%	15,358,044	7.1%	1,008,383	6.9%
Patent-intensive industries	23,571,234	10.9%	34,740,674	16.1%	2,353,560	16.1%
Plant variety-intensive industries	1,736,407	0.8%	2,618,502	1.2%	181,570	1.2%
Trade mark-intensive industries	46,700,950	21.7%	65,047,936	30.2%	5,447,857	37.3%
GI-intensive industries	n/a	n/a	399,324	0.2%	20,155	0.1%
Design-intensive industries	30,711,322	14.2%	45,073,288	20.9%	2,371,282	16.2%

³ Available at <https://www.ipcc.ch/srccl-report-download-page/>

⁴ Intellectual Property Rights Intensive Industries and Economic Performance in the European Union, Industry-Level Analysis Report, joint EPO/EUIPO study, 3rd edition, September 2019, https://euipo.europa.eu/tunnel-web/secure/webdav/guest/document_library/observatory/documents/IPContributionStudy/performance_in_the_European_Union/performance_in_the_European_Union_full.pdf

⁵ Defined as those having an above-average use of IPR per employee, as compared with other IPR-using industries. As shown in the EPO-EUIPO Study, these industries are concentrated in manufacturing, technology and business services sectors.

⁶ Jobs generated by IPR-intensives industries in sectors dependent on these industries.

Source: *IPR-intensive Industries and Economic Performance in the European Union, Industry-Level Analysis Report, joint EPO/EUIPO study, 3rd edition, September 2019.*

Note: due to overlapping use of IP rights, the sum of the figures for the individual IPR exceeds the total figure for IPR-intensive industries

The economic importance of IPR is also reflected in the contribution of IPR-intensive industries to the EU's external trade. In 2016, taking both goods and services into account, 80% of EU imports and 82% of EU exports were generated by the IPR-intensive industries, which translates into a trade surplus of around € 182 billion.

Table 2: Contribution of IPR-intensive industries to EU external trade (2016)

IP right	Exports (€ million)	Imports (€ million)	Net exports (€ million)
TOTAL EU TRADE	2,590,889	2,425,202	165,687
All-IPR industries	2,122,465	1,940,510	181,955
Copyright-intensive industries	294,856	202,738	92,119
Patent-intensive industries	1,438,117	1,307,850	130,267
Plant variety-intensive industries	7,552	3,885	3,667
Trade mark-intensive industries	1,613,366	1,600,703	12,663
GI-intensive industries	12,490	1,360	11,130
Design-intensive industries	1,261,774	1,194,885	66,889

Source: *IPR-intensive Industries and Economic Performance in the European Union, Industry-Level Analysis Report, joint EPO/EUIPO study, 3rd edition, September 2019*

Note: due to overlapping use of IP rights, the sum of the figures for the individual IPR exceeds the total figure for IPR-intensive industries

In practical terms, IPR is directly linked to the production and distribution of new and authentic goods and services from which all citizens benefit. This requires an optimal and economically efficient IP "infrastructure" which covers the legal recognition, registration, utilisation, and effective and adequate enforcement of all forms of IPR in both physical and online marketplaces.

There are various practical challenges and limitations which have a negative impact on IP protection for EU companies in third countries such as forced technology transfer, procedural deficiencies, backlogs in rights registrations, non-registration of certain rights, non-deterrent level of sanctions, lack of expertise, corruption, lack of awareness and lack of transparency.

Another practical challenge is the protection of IPR in the domain name system. IPR protection calls for effective access to domain name registration data through the WHOIS

protocol⁷ in line with EU data protection rules; therefore, the ongoing review of the WHOIS protocol in ICANN⁸ should be swiftly concluded and implemented.

According to a recent EUIPO-OECD study on *Trends in Trade in Counterfeit and Pirated Goods* (2019)⁹, in 2016, counterfeit and pirated goods accounted for up to 3.3% of world trade and up to € 121 billion or 6.8% of EU imports from third countries. These numbers are alarming, in particular when compared to the figures of 2013 under the previous EUIPO-OECD study on *Mapping the economic impact of trade in counterfeit and pirated goods* (2016)¹⁰: they indicate that the share of counterfeit and pirated goods in world trade increased by up to 10.4% and the share of fakes in EU imports by up to 42.3% between 2013 and 2016.

The EUIPO's *2019 Status Report on IPR infringement*¹¹ contains the latest quantification of IPR infringements by sector in the EU. As illustrated in Table 3 below, IPR infringements have serious negative consequences for a large variety of sectors, not only in terms of lost revenue but also in terms of job losses.

Table 3: Quantification of IPR infringement by sector in the EU (average annual figures, 2012-2016)

Sector	Sales Lost by the Sector	Revenues Lost by the Sector	Sales Lost in Related Sectors	Direct Jobs Lost	Direct & Indirect Jobs Lost	Government Revenue Lost
Cosmetics & Personal Care	10.5%	€ 7.1 bn	€ 4.1 bn	71.984	118.654	€ 2.6 bn
Clothing, Footwear & Accessories	9.7%	€ 28.4 bn	€ 17.5 bn	335.053	473.031	€ 8.6 bn
Sports Goods	4.1%	€ 300 mn	€ 300 mn	1.756	3.625	€ 100 mn
Toys & Games	7.4%	€ 1.0 bn	€ 600 mn	3.679	8.158	€ 300 mn
Jewellery & Watches	6.2%	€ 900 mn	€ 800 mn	5.683	11.882	€ 300 mn
Handbags & Luggage	7.4%	€ 1.0 bn	€ 1.1 bn	8.169	16.550	€ 400 mn
Recorded Music	3.6%	€ 100 mn	€ 100 mn	580	1.343	€ 100 mn
Spirits & Wine	5.9%	€ 2.4 bn	€ 3.7 bn	6.049	38.885	€ 2.1 bn
Pharmaceuticals	3.9%	€ 9.6 bn	€ 6.9 bn	33.133	80.459	€ 1.7 bn
Pesticides & Agrochemicals	9.8%	€ 1.0 bn	€ 1.1 bn	1.749	7.993	€ 300 mn
Smartphones*	8.3%	€ 4.2 bn	n.A	n.a	n/a	n.a

⁷ WHOIS is an online protocol that is widely used for querying databases that store registered data on the users of a domain name, the IP address, the name of the registrar, starting date and expiration date of the domain name, etc. The protocol stores and delivers database content to those using the protocol for searching.

⁸ The Internet Corporation for Assigned Names and Numbers is a nonprofit organization responsible for coordinating the maintenance and procedures of several databases related to the namespaces and numerical spaces of the Internet, ensuring the network's stable and secure operation.

⁹ https://euiipo.europa.eu/tunnel-web/secure/webdav/guest/document_library/observatory/documents/reports/trends_in_trade_in_counterfeit_and_pirated_goods/trends_in_trade_in_counterfeit_and_pirated_goods_en.pdf

¹⁰ https://euiipo.europa.eu/tunnel-web/secure/webdav/guest/document_library/observatory/documents/Mapping_the_Economic_Impact_study/Mapping_the_Economic_Impact_en.pdf

¹¹ Available at https://euiipo.europa.eu/ohimportal/en/web/observatory/status-reports-on-ip-infringement#Synthesis_Report_2019

Counterfeit and pirated products continue to follow complex trading routes, exploiting a set of intermediary transit points. Many of these transit economies host large free trade zones that are important hubs of international trade, including also illicit trade.¹² The use of small shipments for trade in fakes also keeps growing. Small shipments, sent by post or express services are a way for infringers to reduce the chance of detection and minimise the risk of sanctions. The proliferation of small shipments raises the cost of checks and detention for customs and introduces additional significant challenges for enforcement authorities.

According to the EUIPO-OECD study on *Why Do Countries Export Fakes?* (2018)¹³ there are five sets of indicators that shape economies' propensities to become important actors in trade in counterfeit and pirated goods. These are the "*production facilities, governance, free trade zones, trade facilitation policies and logistics capacities and facilities*". Furthermore, the study identifies "*poor governance (i.e. high levels of corruption and poor enforcement of intellectual property rights) [...] as a crucial element that amplifies the effects of other drivers*".

It is important to note that adequate IPR protection and enforcement are equally important for leveraging the trade potential of intellectual assets, safeguarding tax revenues and jobs, attracting inward investment and voluntary technology and knowledge transfer as well as for improving public health and consumer safety. Finally, IPR plays an important role in addressing global environmental challenges, not least because it incentivises investments in green and climate change mitigation technologies (CCMTs).¹⁴

2. METHODOLOGY

2.1. Sources

The Commission services conducted a public consultation between 18 March and 26 May 2019. The results of this consultation form the basis of the present report. In addition, a number of other sources have been taken into account in the selection of the priority countries and in the information provided on the state of IPR protection and enforcement in these countries.

In the public consultation, the Commission services sought specific information on the state of IPR protection and enforcement in countries outside the EU, including:

- (a) legal provisions which are not compatible with international norms and standards or which otherwise negatively affect the commercial exploitation of IPRs;
- (b) practical challenges and limitations (such as forced technology transfer, procedural deficiencies, backlogs in rights registration, non-deterrent level of sanctions, lack of expertise,

¹² For further information, see the OECD Study on *Trade in Counterfeit Goods in Free Trade Zones* (2018) <https://www.oecd.org/gov/trade-in-counterfeit-goods-and-free-trade-zones-9789264289550-en.htm>

¹³ Available at [https://euiipo.europa.eu/tunnel-web/secure/webdav/guest/document_library/observatory/documents/reports/Why do countries export fakes/2018 Why do countries export fakes OECD-EUIPO report_EN.pdf](https://euiipo.europa.eu/tunnel-web/secure/webdav/guest/document_library/observatory/documents/reports/Why%20do%20countries%20export%20fakes/2018%20Why%20do%20countries%20export%20fakes%20OECD-EUIPO%20report_EN.pdf)

¹⁴ As explained in the joint EPO-EUIPO study of September 2019 (See Footnote 4), CCMTs will play an important role in achieving the goals set out in the Paris Agreement on climate change.

corruption, lack of political will, lack of awareness and lack of transparency) which have a negative impact on IP protection and enforcement;

(c) concrete examples of deficiencies of administrative and judicial mechanisms in the area of IPR (e.g. IP offices, customs, police and courts);

(d) any other systemic problems in the country concerned, including information on the nature, scope and economic dimension of counterfeiting and piracy as well as on the level of cooperation between enforcement authorities and right holders; and

(e) any action or measure taken by the respondent to address the problems identified and the outcome of such efforts.

Invitations to take part in the public consultation were sent to right holders, consumer groups, industry associations, universities, EU Delegations and EU Member States. More than 70 responses were received, covering more than 40 countries. The majority of the respondents were undertakings, mainly but not exclusively from the creative and innovative industries, and associations representing right holders, e.g. industry federations or collective management organisations. Individuals, universities, law firms and chambers of commerce also participated in the public consultation.

As indicated in the public consultation, respondents are not identified and their contributions are not published.

Beyond the public consultation, the following additional sources have been taken into account in the preparation of the report:

- Information received from EU Delegations and commercial representations,
- Information received from the Commission's Directorate-General for Taxation and Customs Union 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,
- Findings in EU IPR SME Helpdesk reports,
- The 2018 Counterfeit and Piracy Watch List¹⁵,
- World Intellectual Property Organisation's (WIPO) committee reports.

2.2. Selection

The following indicators were used for the selection of the priority countries:

¹⁵ Available at http://trade.ec.europa.eu/doclib/docs/2018/december/tradoc_157564.pdf

- Level of importance for EU operators,
- Level of counterfeiting and piracy,
- Level/quality of IP legislation,
- Level of effectiveness of the implementation of legislation,
- Attitude in bilateral relations and level of respect for IPR in international fora,
- Level of respect for legal decisions in international fora (WTO Dispute Settlement),
- Level of economic development (e.g. Gross National Income per capita levels, World Bank index ranking).

3. UPDATED LIST OF PRIORITY COUNTRIES

As in previous Third Country Reports, the updated list of priority countries remains split into three categories:

Priority 1: China

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

Priority 3: Argentina, Brazil, Ecuador, Malaysia, Nigeria, Saudi Arabia and Thailand

China continues to be a **Priority 1** country for the EU because of the scale and persistence of problems in the area of IPR protection and enforcement. The Commission's *Report on EU Customs Enforcement of IPR (2018)*¹⁶ and the EUIPO-OECD study on *Trends in Trade in Counterfeit and Pirated Goods (2019)*¹⁷ show that China is at the origin of a dominant share of counterfeit and pirated goods arriving in the EU, in terms of both value and volume. More than 80% of the seizures of counterfeit and pirated goods by EU customs authorities originate from China and Hong Kong. Forced technology transfer is an increasingly important trade irritant.

India, Indonesia, Russia, Turkey and Ukraine remain **Priority 2** countries. Serious systemic problems have been identified in the area of IP protection and enforcement in these countries, causing significant harm to EU businesses. Compared to the previous report, these countries have made no progress or only limited progress in addressing these concerns.

Argentina, Brazil, Ecuador, Malaysia and Thailand remain **Priority 3** countries and the Commission services have selected two new Priority 3 countries: Nigeria and Saudi Arabia. Priority 3 countries show some serious problems in the area of IP, causing considerable harm to EU businesses. The gravity and the number of problems identified in these countries are lower than in Priority 2 countries.

Nigeria was selected due to its growing importance as a transit country for counterfeits. In the EUIPO-OECD studies on *Why do countries export fakes? (2018)*¹⁸, on the *Misuse of Small Parcels for Trade in Counterfeit Goods (2018)*¹⁹ and on *Mapping the Real Routes of Trade in*

¹⁶ Available at <https://publications.europa.eu/en/publication-detail/-/publication/64dda5ad-c197-11e8-9893-01aa75ed71a1/language-en/format-PDF>

¹⁷ See footnote 9

¹⁸ See footnote 13

¹⁹ Available at https://euiipo.europa.eu/tunnel-web/secure/webdav/guest/document_library/observatory/documents/reports/Trade_in_fakes_in_small_parcel/Trade_in_Fakes_in_Small_Parcels_en.pdf

Fake Goods (2017)²⁰, Nigeria was listed among the main transit points in the global trade of counterfeit electronic and electrical equipment produced in China for re-export to other Western African economies and the EU.

Saudi Arabia was selected because of its global role as a regional transit country for counterfeit and pirated goods destined for the EU, and because stakeholders report high-scale satellite and online piracy and ineffective enforcement measures to tackle them.

In addition, this report dedicates again a section to some of the countries with which the EU has already concluded or is about to conclude free trade agreements and where there is a particular need to monitor the IP situation. This category of countries includes Canada, South Korea, Mexico and Vietnam. The Commission will also closely monitor the situation in other countries where IP enforcement gives rise to concerns such as Israel, Morocco, Paraguay, the Philippines, South Africa, Switzerland and the United Arab Emirates.

The Philippines was removed from the priority list and included in the group of countries, which need to be closely monitored (see below). This is due to the very few complaints received from stakeholders and the increase in the relative importance of other countries for EU right holders. However, the situation in the Philippines has not improved over the last years and according to the EUIPO-OECD studies on *Mapping the Real Routes of Trade in Fake Goods* (2017)²¹, on *Trends in Trade in Counterfeit and Pirated Goods* (2019)²² and on *Why do countries export fakes?* (2018)²³, the Philippines has remained an important country of origin of counterfeit goods destined for the EU in a number of product categories such as leather articles, handbags, pharmaceuticals, footwear, games, toys and sport equipment. The EUIPO-OECD Study on the *Misuse of Small Parcels for Trade in Counterfeit Goods* (2018)²⁴ also indicates that the Philippines is among the top provenance of small parcel trade in fake jewellery.

The United Arab Emirates appears in the group of countries that need to be closely monitored because of its global role in trade of counterfeit and pirated goods destined for the EU. According to the EUIPO-OECD studies on *Mapping the Real Routes of Trade in Fake Goods* (2017)²⁵ and on *Why do countries export fakes?* (2018)²⁶, the United Arab Emirates are one of the top transit countries of counterfeits in several products categories and a host of several high risk free trade zones in terms of illicit trade.

The US was removed from the priority list in light of the good cooperation in international fora such as the TRIPS Council and the OECD as well as its engagement in bilateral discussions in the context of the Trans-Atlantic Working Group on IPR. Nevertheless, the Commission services remain concerned about the lack of progress in implementing the WTO panel decision on Irish Music²⁷.

²⁰ Available at <https://euipo.europa.eu/ohimportal/fr/web/observatory/mapping-the-real-routes-of-trade-in-fake-goods>

²¹ See footnote 20

²² See footnote 9

²³ See footnote 13

²⁴ See footnote 19

²⁵ See footnote 20

²⁶ See footnote 13

²⁷ WTO DS 160 : United States – Section 110(5) of US Copyright Act, https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds160_e.htm

4. SUMMARY OF THE FINDINGS

Forced technology transfer practices continue to be a systemic problem in China. These practices discourage investment and put foreign operators – particularly in high-tech sectors – at risk of losing their competitive edge.

A **low level of protection for trade secrets** and **IP theft** in a number of countries, notably in China and India, also causes irreparable harm to European businesses.

Weak **IP enforcement** is an acute problem in all the countries listed in the report. The main problems with IP enforcement are linked to the lack of political will and resources. This materialises in deficiencies in adequate technical infrastructure, capacities and resources, expertise of the judicial and enforcement authorities as well as insufficient public awareness of the value of IPR.

The **level of counterfeiting remains high** in many of the EU's trading partners, causing serious revenue losses for both the EU and local industry. The problem is particularly serious in China, which is the main source country of counterfeit goods imported into the EU. India and Southeast Asian countries such as Indonesia, Malaysia, Thailand and Vietnam are also significant sources of counterfeits while transit hubs such as Hong Kong (China), Saudi Arabia, Singapore and the United Arab Emirates also play an important role in this context.

Copyright piracy, especially online and satellite piracy, remains a major issue for European creative sectors. The problem is widespread and rampant in countries such as Argentina, Brazil, China, Ecuador, India, Indonesia, Mexico, Russia, Saudi Arabia, Thailand, Ukraine and Vietnam.

A serious problem in the area of enforcement is the **lack of authority for customs authorities to take *ex officio* actions** to detain, seize or destroy counterfeit and pirated goods at the border or to take action with respect to goods in transit. Substantial improvements would in particular be needed in the border enforcement regimes of Canada, Ecuador, India, Indonesia, Mexico and Thailand.

Stakeholders also report that **counterfeit and pirated goods are often not destroyed** by the enforcement authorities and find their way back to the market. On other occasions, **destruction procedures take too long or may be dissuasively expensive** for right holders. Concerns related to the destruction of infringing or allegedly infringing goods were reported with respect to India, Indonesia, Mexico, Nigeria, Saudi Arabia and the United Arab Emirates.

As regards **sanctions and penalties imposed for IP infringements**, stakeholders report they **are too low to have a deterrent effect** in countries such as Argentina, Brazil, India, Nigeria, Russia, Saudi Arabia, South Korea, Thailand, Turkey, United Arab Emirates and Vietnam. As regards the **registration of patents, trademarks and related procedures** (e.g. renewal or opposition), the IP Offices in Argentina, Brazil, India, Thailand and the United Arab Emirates have a considerable backlog. The duration of patent examination in some countries, such as Brazil and Thailand, is overly long and covers most of the patent term.

Local working requirements for patents in Indonesia and Ecuador create legal uncertainty, which is not conducive for innovation in these countries. These requirements oblige patent

holders to manufacture the patented product or use the patented process in Indonesia or Ecuador. The non-compliance with the requirement triggers the risk of issuing a compulsory licence.

Restrictive patentability criteria applied in Argentina, India, Indonesia and Russia reduce or remove incentives to innovate, for instance in order to find more stable forms of compounds with longer shelf-lives, medicines which may be easier to store, dosages which are safer or reduce side-effects.

Failure to recognise **geographical indications as conferring rights in domain name disputes** on the internet (the UDRP – Uniform Domain-Name Dispute-Resolution Policy) facilitates channels for marketing counterfeits²⁸.

Moreover, stakeholders report that very **broad, vague and arbitrary criteria are applied for granting compulsory licences**, which undermine the effective patent protection in Ecuador, India, Indonesia and Turkey, notably for pharmaceuticals and chemicals but also for other sectors where local production is being promoted. Another serious concern for the industry is the **interference of the health authority** in Brazil and of the **competition authority** in Russia in pharmaceutical patent protection. 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 a marketing approval** for pharmaceuticals and plant protection products. This problem affects the European industry mainly in Argentina, Brazil, China, India, Indonesia, Malaysia, Russia, Saudi Arabia, Ukraine and the United Arab Emirates.

Problems with the functioning of the system of **collective management of rights** in Nigeria, Russia, Ukraine and Thailand cause losses for right holders and create mistrust amongst users, which ultimately has a negative effect on the creative industries in these countries.

Various trading partners of the EU have not yet acceded to important international conventions. India, Indonesia, Argentina, Brazil, Ecuador, Malaysia, Mexico, Nigeria, Saudi Arabia, Thailand, the United Arab Emirates and Vietnam have not yet acceded to the Geneva Act of the Hague Agreement Concerning the International Registration of Industrial Designs and, with the exception of Vietnam, to the 1991 Act of the International Convention for the Protection of New Varieties of Plants (UPOV 1991). Argentina, Ecuador, Malaysia, Nigeria, Saudi Arabia, the United Arab Emirates have not yet acceded to the Madrid Agreement Concerning the International Registration of Marks and the Madrid Protocol. Brazil, Saudi Arabia, Thailand and Vietnam have not yet acceded to the WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty. Argentina has not yet acceded to the Patent Cooperation Treaty.

As far as the **protection and enforcement of plant variety rights** are concerned, EU breeders face problems which can be grouped as follows: lack of effective plant variety rights legislation (in accordance with the 1991 Act of the UPOV Convention); absence of UPOV membership; difficulties in implementing effective administrative proceedings by designated national authorities; and lack of an effective system for the collection and enforcement of royalties at both judicial and administrative levels.

²⁸ The UDRP is the reference dispute resolution system applied in respect of the majority of top-level domain designations around the world.

5. EU ACTIVITIES IN THE CONTEXT OF IPR

5.1. Bilateral and Regional Level

5.1.1. Trade negotiations

The EU is negotiating a series of **bilateral and regional trade agreements** that include comprehensive IPR chapters. The IPR chapters aim at setting comparable levels of IPR protection to those existing in the EU, while taking into account the level of development of the trading partners. **In doing so, the EU seeks to go beyond the TRIPS Agreement** to address new challenges, most notably the need to protect IPR in the digital environment. The EU also promotes adequate enforcement rules in its trade negotiations.

Since the last Third Country Report, the EU has concluded or is about to conclude agreements (including IPR chapters) with Japan, Singapore and Vietnam; and finalised or is about to finalise the negotiations with Kyrgyzstan, Mercosur and Mexico. Negotiations are currently ongoing with Australia, Azerbaijan, Chile, Indonesia, New Zealand, Tunisia and Uzbekistan. The EU and China have recently concluded the negotiations on a bilateral agreement on Geographical Indications (GI).

5.1.2. IP Dialogues and IP Working Groups

The Commission services engage in IP Dialogues and IP Working Groups with partner countries around the world, including those with which an agreement is in place covering IP issues. In this context, since the last Third Country Report, the Commission has had such dialogues or working groups with countries of the Andean Community (Colombia, Peru and Ecuador), Central America, Canada, China, Hong Kong (China), South Korea, Taiwan, Thailand, Turkey, Ukraine and the US.

Concerning geographical indications, continuous dialogue and the organisation of technical cooperation aim at improving the understanding of the trading partners in view of better addressing cases of insufficient or poor protection.

5.1.3. Technical assistance programmes

The Commission finances and steers various technical cooperation programmes, which aim at strengthening IPR protection and enforcement in third countries and/or to assist our right holders seeking IP protection in these countries.

The Commission has signed an agreement with the EUIPO for the technical implementation of **three IP Key cooperation programmes**²⁹ for the period 2017-2020: China (€7 million), Southeast Asia (€7 million) and Latin America (€6 million). These multi-annual programmes are designed to enhance the EU's cooperation with the respective countries through concrete activities in the area of intellectual property rights protection and enforcement.

In the framework of the Union for Mediterranean³⁰, the European Commission implements the **Action Plan on Euro-Mediterranean Cooperation on the Fight against**

²⁹ <http://www.ipkey.org/en/>

³⁰ <http://trade.ec.europa.eu/doclib/press/index.cfm?id=1817>

Counterfeiting and Piracy³¹, which was endorsed at the 10th Union for the Mediterranean Trade Ministerial in March 2018. The Action Plan is designed to assist Euro-Mediterranean countries, including Turkey, in the fight against counterfeiting and piracy.

In May 2019, the EU adopted a **four-year cooperation programme for Africa** with the aim to improve the standards of protection and enforcement of intellectual property rights in the African continent and to support the Pan-African Free Trade negotiations. The programme intends a) to promote international agreements in the area of IPR and to reinforce cooperation between the EU and Africa, b) to strengthen national and regional IP institutions, networks and tools for more efficient and user-friendly IP protection and enforcement systems, c) to strengthen the capacities of MSMEs concerning the importance and value of IP in the African society and d) to implement priority actions identified by the work plan linked to the African Continental Strategy for Geographical Indications.

The Commission also contributes actively to the Africa GI Consultative Committee, established to ensure an effective implementation of the African Continental Strategy for GIs³².

5.2. Multilateral Level

5.2.1. WTO

The Commission is an active contributor to IP protection and enforcement at multilateral level, in particular in the WTO TRIPS Council. In 2018, the Commission co-sponsored discussions on “*The Societal Value of IP in the New Economy*” with the so-called “Friends of IP and Innovation” like-minded group, which includes countries such as Australia, Canada, Japan, New Zealand, Singapore and the US. These discussions provide an overview of WTO Members’ national and international IP policies, initiatives and case studies, which is a useful reference for legal, regulatory and policy developments.

The EU has submitted annual reports³³ on actions taken or planned in pursuance of its commitments under Article 66.2 of the TRIPS Agreement (incentives provided to their enterprises or institutions for the purpose of promoting and encouraging technology transfer to least developed country Members). In addition, the EU has submitted annual reports³⁴ in accordance with Article 67 of the TRIPS Agreement on technical cooperation programmes provided by the European Union and EU Member States in favour of developing and least developed country Members, with the objective to facilitate the implementation of the TRIPS Agreement.

³¹ See footnote 30

³² The Commission brings together continentally IP actors, including the African Union Commission, the two African IP regional offices (Organisation Africaine de la Propriété Intellectuelle and African Regional Intellectual Property Organization), Food and Agriculture Organization, WIPO and the Agence Française de Développement.

³³ https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=251124&CurrentCatalogueIdIndex=0&FullTextHash=371857150&HasEnglishRecord=True&HasFrenchRecord=True&HasSpanishRecord=True

³⁴ https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=94903&CurrentCatalogueIdIndex=0&FullTextHash=371857150&HasEnglishRecord=True&HasFrenchRecord=True&HasSpanishRecord=True

On 1 June 2018, the EU filed a case against China at the WTO on *Certain Measures on the Transfer of Technology* (DS549). The scope of the case was subsequently expanded by the EU filing a revised consultation request on 20 December 2018 that covered legislation in the sectors of new energy vehicles (NEVs) and crop seeds, in addition to legislation related to joint ventures (JV law and JV Regulation) and the licensing of imported technology (TIER). In this case, the EU challenges measures that require European companies to give up sensitive technology and know-how as a precondition for doing business in China.

5.2.2. WIPO

Concerning geographical indications, the European Commission adopted its instrument of accession to the *Geneva Act of the Lisbon Agreement on Appellations of Origin and Geographical Indications*, an international agreement administered by WIPO, on 26 November 2019. As the fifth eligible party, the EU's accession will allow the entry into force of the Agreement already in February 2020. The revised and modernised Agreement expands the scope beyond appellations of origin to all GIs and is fully compatible with the WTO Agreement on Trade-Related Intellectual Property Rights (TRIPS).

The European Commission is actively engaged also in WIPO's work on the enforcement of IP rights. This concerns in particular, but not exclusively, the Advisory Committee on Enforcement (ACE)³⁵. In the annual meetings of ACE in September 2018 and 2019, the European Commission contributed to the discussion on initiatives taken to address online IP infringements. The European Commission presented the state of play on two "Memoranda of Understanding" (MoU) launched within the EU³⁶. In December 2018 the European Commission also actively participated in a stakeholders' meeting on Building Respect for IP (BRIP) Database Project³⁷.

5.2.3. OECD

The European Commission has been actively involved in the development of the *OECD Recommendation on Countering Illicit Trade: Enhancing Transparency in Free Trade Zones*³⁸. This Recommendation, adopted on 21 October 2019³⁹, proposes measures to enhance

³⁵ The Advisory Committee on Enforcement (ACE) (hyperlink: <https://www.wipo.int/enforcement/en/ace/>) was established by the 2002 WIPO General Assemblies with a mandate to carry out technical assistance and coordination in the field of enforcement. The ACE focuses on coordinating with public and private organizations to combat counterfeiting and piracy, public education; assistance, coordination to undertake national and regional training programs for all relevant stakeholders, and exchange of information on enforcement issues.

³⁶ The MoU on the sale of counterfeit goods via the Internet (hyperlink: https://ec.europa.eu/growth/industry/intellectual-property/enforcement/memorandum-understanding-sale-counterfeit-goods-internet_en) brings together major Internet platforms and right holders who suffer from frequent online sales of counterfeit or pirated versions of their products. The MoU on online advertising and IPR (hyperlink: https://ec.europa.eu/growth/industry/intellectual-property/enforcement/memorandum-of-understanding-online-advertising-ipr_en) helps limit advertising on websites and mobile applications that infringe copyright or disseminate counterfeit goods.

³⁷ The BRIP Database (hyperlink: https://www.wipo.int/edocs/mdocs/enforcement/en/wipo_ace_14/wipo_ace_14_9.pdf) is a secure online platform designed to aggregate lists of websites suspected of infringing copyright ('sites of concern') that are being managed by several national administrations around the world. By checking with the BRIP Database, advertisers and advertising intermediaries can ensure that advertising does not accidentally appear on copyright-infringing websites.

³⁸ <http://www.oecd.org/gov/risk/recommendation-enhancing-transparency-free-trade-zones.htm>

³⁹ See footnote 38

transparency in free trade zones in order to prevent criminal organisations from taking advantage of them. To that end, the Recommendation calls on OECD Members and non-Members to ensure adequate levels of oversight and control of free trade zones and to encourage their operators to comply with a Code of Conduct which forms part of the Recommendation.

The European Commission has also been involved in the development of the *OECD Report on International Technology Transfer Policies*.⁴⁰ This Report presents a discussion of the range of measures related to international technology transfer and aims to identify those measures that pose the greatest concerns over their potential to compel disclosure of commercially valuable and sensitive technology.

5.3. Other Activities

On 7 December 2018, DG Trade published for the first time the Counterfeit and Piracy Watch List, which presents examples of reported marketplaces and service providers whose operators or owners are allegedly resident outside the EU and which reportedly engage in, facilitate or benefit from counterfeiting and piracy. The aim of the Watch List is to urge the operators and owners as well as the responsible local enforcement authorities to take the necessary actions and measures to reduce the availability of IPR infringing goods or services on these markets and to raise consumer awareness.

6. COUNTRY-SPECIFIC ANALYSIS

6.1. Priority 1

China

Progress

China has recently put in place a substantive reform of its administration responsible for IPR. The former State Intellectual Property Office of China (SIPO) has been transformed into the Chinese National Intellectual Property Administration (CNIPA) with extended responsibilities for all IPR, except copyright and agricultural GIs, now covering patents, designs, trademarks and geographical indications for non-agricultural products. CNIPA reports to the new State Administration for Market Regulation (SAMR), also overseeing enforcement matters, which in turn reports directly to the State Council. The National Copyright Administration of China (NCAC) remains responsible for copyright issues, the Ministry of Agriculture and Rural Affairs handles matter related to agriculture GIs. It is too early to assess the effect of this administrative reform.

The establishment of three specialised IP Courts in Beijing, Shanghai and Guangzhou is a clear progress. It has been followed by the creation of specific Internet Courts in Hangzhou, Beijing and Shanghai also dealing with IPR infringements. In early 2019, China created a specialised IP court as part of the Supreme People's Court (SPC) to focus mainly on patent cases. The creation of such a specialised IP court within the SPC is promising as it could increase coherence of court decisions at all levels.

⁴⁰ Available at [http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=TAD/TC/WP\(2018\)8/FINAL&docLanguage=En](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=TAD/TC/WP(2018)8/FINAL&docLanguage=En)

Over the last years, China has made efforts to review and update its IP legislation. Work on the revision of the patent law and the copyright law as well as a comprehensive revision of the trademark law⁴¹ continues. The draft patent law published for comments included a number of positive elements, such as the potential inclusion of patent right extensions and an increase in the level of damages. The revision of the law on plant varieties is also ongoing. Adoption of the law would bring China closer to joining UPOV 1991, which would be welcome.

On 20 April 2019, the National People's Congress amended several IP laws: it strengthened the trademark law regarding bad faith registrations, and modified the anti-unfair competition law to reinforce the protection of trade secrets. In January 2019, China launched a public consultation on draft guidelines related to bad faith trademark applications. These draft guidelines should now be adapted to reflect the new provisions in the law.

Although not going as far as the EU had hoped for, the new e-commerce law that entered into force in January 2019 recognises the necessity to protect IPR and addresses the matter of online infringements by platforms.

Concerns and areas for improvement and action

While the Chinese legal system for the protection of IPR has substantially developed during recent years, concerns remain about the lack of clarity of legal provisions, which often seem to provide the authorities with an unusually broad margin of discretion for the practical implementation of laws and regulations.

The number of Chinese **patent applications** is growing exponentially. Quantity-based top-down incentives set by the Chinese government centrally and locally seem to play a significant role; a good example is China's patent commercialization strategy set out in the 2014-2020 IP Strategy⁴². Serious concerns remain about the quality of granted invention 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. Another problem highlighted by stakeholders is the frequent use of invalidation proceedings against patents of foreign companies that sought legal protection against Chinese infringers.

EU companies hold a number of important **standard essential patents** (SEPs) for technologies that are essential for the functioning of certain standards, such as the telecommunication standard '4G'. EU stakeholders report that Chinese companies widely use these technologies without paying adequate royalties. Chinese competition authorities are reported to often impose heavy fines on foreign holders of SEPs, setting unreasonably low royalty rates, or using "informal" investigations to influence business to business negotiations. The applicable rules and guidelines do not ensure sufficient legal certainty.

With respect to **trademarks**, the main concern in China continues to be the registration of bad faith applications. China's trademark law has recently been strengthened. However, important loopholes remain in the protection of trademark owners against the use of their signs as

⁴¹ http://english.gov.cn/premier/news/2019/07/17/content_281476769686890.htm

⁴² <https://chinaipr.com/2014/12/30/action-plan-for-further-implementation-of-the-national-ip-strategy-2014-2020-approved/>

company names. It remains to be seen if the April 2019 amendment of the trademark law in relation to bad faith registrations will lead to tangible progress.

EU stakeholders continue to raise concerns regarding the short duration of the protection of **designs** in China. The pending revision of the design law is expected to extend the term of protection of design patents to fifteen years to bring the Chinese system in line with the Hague system in preparation of a possible membership, which would be welcomed by the EU.

As regards **copyright**, the long-awaited amendment of China's law is still pending. Open issues include the introduction of a right of remuneration for performers and producers for public performances and broadcasting of phonograms published for commercial purposes as well as the extension of the copyright term of protection.

EU stakeholders raise concerns regarding **regulatory data protection** for chemical entities. China provides for different registration categories, which define chemical entities as "new" only when they have never been marketed in any country. This practice de facto discriminates against foreign products.

As regards **trade secrets**, EU stakeholders are concerned about the non-effective protection in administrative and regulatory proceedings in which they are required to disclose confidential business information. European companies continue to complain about the extraction of trade secrets and/or other concessions including the transfer of technology from foreign companies for access to the Chinese market⁴³. This is possible in the Chinese regulatory and administrative environment, since China confronts foreign companies with often opaque and cumbersome licensing and authorisation systems, as well as a lack of proper administrative review possibilities, leaving ample room for the authorities, sometimes in coordination with Chinese joint-venture partners, to extract foreign technology. EU companies also face difficulties in obtaining effective and efficient protection before courts against unfair commercial use and unauthorised disclosure of business information. It remains to be seen whether the recent modifications of the anti-unfair competition law will have an effect in practice.

Another increasingly important trade irritant is China's objective to absorb foreign technology and make it Chinese ('re-innovate'), particularly in key technological areas defined by the state, such as through the China 2025 strategy. The policy tools employed to reach this objective are manifold. In parallel, the law on scientific and technological progress⁴⁴ provides that IPR and technology obtained in projects funded by the Chinese government should be preferably used within China. This is reinforced by the 18 March 2018 (number 19) State Council Measures on the Transfer of Intellectual Property Rights to Foreign Parties, which make the transfer of IPR to foreign entities subject to approval by Chinese authorities⁴⁵. Similar requirements are also embedded in the Chinese rules related to the human genetic resource review. Stakeholders also report that many Chinese public procurement procedures are used to require foreign companies to disclose their technology or know-how.

⁴³ European Chamber, Business Confidence Survey 2019

⁴⁴ 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 (available at http://english.www.gov.cn/archive/laws_regulations/2014/08/23/content_281474983042277.htm)

⁴⁵ http://www.gov.cn/zhengce/content/2018-03/29/content_5278276.htm

Indeed, induced or **forced technology transfer** (FTT) continues to be a systemic problem in China⁴⁶. It is a complex phenomenon which includes a variety of practices carried out by the government or government-influenced private actors that require, pressure or induce foreign firms to transfer their technology to China in exchange for market access, investment access or other administrative approvals. For example, China forces foreign companies to license technology, often at below market rates, as a pre-condition to access and operate on certain markets. Such technology transfers are induced or forced through policy guidance, legal instruments and practices, including through joint venture requirements/equity caps, authorisation or licencing procedures, or insufficient protection of intellectual property rights and trade secrets⁴⁷.

The Commission services take note of the prohibition of forced technology transfer introduced by the new Foreign Investment Law⁴⁸ as well as of the removal of restrictions on the use of certain licence conditions from the Technology Import and Export Regulations (TIER)⁴⁹ and will monitor the implementation of those new provisions.

While acknowledging the efforts of the Chinese government to fight **counterfeiting**, the measures in place do not seem to keep pace with new technologies and the sheer amount of infringements. According to the OECD-EUIPO study *Mapping the economic impact of trade in counterfeit and pirated goods* (2016)⁵⁰, China is the world's main producer of counterfeit goods. The Commission's *Report on EU customs enforcement of intellectual property rights* (2018)⁵¹ shows that, including Hong Kong (China), around 80% of seized counterfeit goods by article came from China. This includes the production of all types of fakes such as technologically advanced items, expensive fashion items as well as fake medicines and toys, which are potentially dangerous for consumers. While stakeholders acknowledged the efforts made by the Chinese authorities to improve the situation, they also underlined that the situation remains very problematic. The digital environment has clearly 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.

Stakeholders also raise concerns in relation to the new **e-commerce** law that was adopted in 2018 and entered into force in January 2019. They report that the liability and take down provisions in the legislation could render enforcement more difficult due to unclear notice-and-take down procedures. It would therefore be important for China to follow up on its new e-commerce legislation by issuing guidelines for its application.

Stakeholders also express major concerns about the expected consequences of the Chinese Belt & Road Initiative (BRI). They highlight that strict measures will be necessary, in particular in the area of **customs** controls, to avoid the increase in the flow of counterfeit goods from China into the EU.

⁴⁶ The transfer of technology is a normal development in the economic process of a catch-up economy and unproblematic as long as it is voluntary and based on market terms and conditions.

⁴⁷ For an overview of technology transfer practices see: https://www.oecd-ilibrary.org/trade/international-technology-transfer-policies_7103eabf-en

⁴⁸ See http://www.fdi.gov.cn/1800000121_39_4872_0_7.html

⁴⁹ State Council Decision no. 709, paragraph 38 of March 2019

⁵⁰ See footnote 9

⁵¹ See footnote 16

Stakeholders also raise concerns about **discrimination** of foreign right holders in comparison with local right holders, both in court procedures and by law enforcement bodies. This appears to be particularly problematic regarding trade secrets in administrative and court proceedings, but also in relation to the handling of foreign right holders' concerns more generally in dealing with Chinese authorities.

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

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 often the amount of **damages** actually awarded for IPR infringements neither compensates for losses nor deters future infringements.

The important shortcomings of **IPR enforcement** in China are also due to significant differences between its various provinces and cities. In cities like Beijing or Shanghai, the standards of administrations and courts are reported as being, in general, more satisfactory and expected to improve further, whereas lack of expertise continues to be serious problems in the less developed parts of China.

Stakeholders also point to deficient cooperation between different administrative and law enforcement agencies competent to address IPR infringements, and to the difficulties for foreign right holders to obtain coordinated enforcement action from those authorities.

China has not yet ratified the Geneva Act of the Hague Agreement concerning the International Registration of Industrial Designs and has not acceded to the International Convention for the Protection of New Varieties of Plants in its latest version, 'UPOV 1991'.

EU action

Different tools and mechanisms have been deployed to support China's efforts to improve IPR protection and enforcement.

The **EU-China Dialogue** has been in place for fourteen years. This mechanism allows both sides to exchange views 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, organised usually twice a year.

The technical cooperation programme **IP Key China**⁵², implemented by the EUIPO, provides for concrete opportunities to strengthen cooperation and exchange best practices in priority areas, with a view to improving IPR protection and enforcement in China. The latest IP Key China programme started in September 2017 and will be running for four years.

The EU-China **Joint Customs Cooperation Committee** also represents an important avenue of cooperation on IPR enforcement. It was established in 2009 and is in charge of the strategic

⁵² <https://ipkey.eu/en/china>

framework for customs cooperation and for the EU-China Customs IPR action plan.⁵³ Since many goods suspected of infringing IPR come from Hong Kong (China), the Commission has also established an action plan on cooperation in customs enforcement of IPR directly with authorities in Hong Kong⁵⁴ (China).

The Commission has also established an **IPR SME Helpdesk** in China⁵⁵, in support of the EU's small and medium sized enterprises which seek to protect and enforce their IPR in China. The services and information provided by the IPR helpdesk, such as the helpline, trainings and web-based materials are free of charge. The term of the China IPR SME Helpdesk was extended for another three years at the beginning of 2018.

The EU and China concluded the negotiations on a **bilateral agreement** to protect 100 European Geographical Indications (GI) in China and 100 Chinese GI in the EU against imitations and usurpation.⁵⁶ 175 additional names on each side will benefit from the same level of protection within four years of entry into force of the agreement. The Agreement will follow the internal EU legislative procedure before it can enter into force.

6.2. Priority 2

India

Progress

Some improvements can be noted in India's IPR protection. In December 2018, India acceded to the WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty. Furthermore, in June 2019, India also acceded to the Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks.⁵⁷

In February 2019, the Department of Industrial Policy and Promotion (now Department for Promotion of Industry and Internal Trade (DPIIT)) published a draft National e-Commerce Policy for public consultation.⁵⁸ The anti-counterfeiting and anti-piracy measures described in this policy document have the potential to improve the situation in the online environment and to reduce the availability of counterfeit or pirate offers, content and services on e-commerce platforms.

EU stakeholders report some positive developments regarding patent protection, notably the hiring of additional examiners and improvements of the Indian Patent Office's online filing system which help to address the existing patent application backlog. Other positive developments include ongoing actions undertaken by the recently formed Maharashtra Cyber Digital Crime Unit (MCDCU), the Telangana Intellectual Property Crime Unit (TIPCU) and the Indian domain registry NIXI to suspend domains engaged in infringing activities.

⁵³ https://ec.europa.eu/taxation_customs/sites/taxation/files/docs/body/action_plan_eu_china_ipr_2014_2017.pdf

⁵⁴ Action Plan on Cooperation in Customs Enforcement of Intellectual Property Rights in the European Union and Hong Kong (China)

⁵⁵ <http://www.china-iprhelpdesk.eu/frontpage>

⁵⁶ https://ec.europa.eu/commission/presscorner/detail/en/IP_19_6200

⁵⁷ https://dipp.gov.in/sites/default/files/DraftNational_e-commerce_Policy_23February2019.pdf

⁵⁸ See footnote 58

India seems to continue its focus on administrative improvements, awareness raising and capacity building with a view to improving the efficiency of its IPR system. The website of the Cell for IPR Promotion and Management (CIPAM),⁵⁹ established by the Ministry of Commerce and Industry, provides the most recent statistics on patent, design, trademark and copyright applications as well as free of charge educational resources available for download.

Concerns and areas for improvement and action

Several constraints on **patent protection** continue to be 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 licences or for revoking patents, make effective patent protection in India very difficult, notably for pharmaceuticals and chemicals but also for other sectors where local production 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.

As far as **trademarks** are concerned, EU stakeholders report a continued large backlog of older trademark applications and renewals while new applications appear to be prioritised and processed more quickly. They are also concerned about premature refusals of trademark applications without due consideration of all relevant factors such as trans-border reputation, international use and acquired distinctiveness.

As regards **copyright** and related rights, the DIPP's Office Memorandum of September 2016⁶⁰ still gives rise to serious concerns as it seems to suggest that all online transmissions, including on-demand online services such as music streaming, should be considered as "broadcasting" (not as an act of making available to the public under Article 8 of the WIPO Copyright Treaty) and fall under India's statutory licensing system for broadcasting organisations pursuant to Section 31D of the Indian Copyright Act⁶¹.

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 unauthorised disclosure. To date, there seems to be no statute that specifically addresses regulatory data protection for pharmaceuticals and for the protection of trade secrets, which creates legal uncertainty.

IPR enforcement remains a source of serious concern. While EU stakeholders report that cooperation with customs authorities has improved, IPR infringements are still widespread due to the lack of enforcement capacities, appropriate training and dissuasive sanctions. EU stakeholders report that civil enforcement remains a costly and lengthy matter, particularly outside of Delhi. Commercial divisions have been set up in a number of high courts following the adoption of the High Courts Act⁶², but stakeholders are concerned that judges often lack relevant IP expertise.

As regards **customs enforcement**, India made a step backwards in June 2018 by removing patents from the scope of its Intellectual Property Rights (Imported Goods) Enforcement

⁵⁹ <http://cipam.gov.in/>

⁶⁰ https://dipp.gov.in/sites/default/files/OM_CopyrightAct_05September2016.pdf

⁶¹ <https://www.wipo.int/edocs/lexdocs/laws/en/in/in107en.pdf>

⁶² No. 4 of 2016 Act on the Commercial Courts, Commercial Division and Commercial Appellate Division of High Courts

Rules.⁶³ Following this amendment, customs authorities have no power to detain goods suspected of infringing patents anymore.

EU stakeholders report that the lack of prescribed timelines for adjudicating **customs seizures** has led to long delays in the destruction of counterfeit goods. Stakeholders also report that right holders find it difficult and cumbersome to obtain reimbursement for storage and destruction costs and that customs authorities have no mechanism to identify recidivist importers.

According to the OECD-EUIPO study *Illicit Trade - Trends in Trade in Counterfeit and Pirated Goods* (2019)⁶⁴, India is the third largest source of counterfeit and pirated goods in the world (both in terms of its share in the world export of fakes and the value of fake exports) and has become the fifth most important source of counterfeit imports into the EU. According to the EUIPO's *2019 Status Report on IPR infringement*⁶⁵, India is the main producer of counterfeit goods after China.

The situation is particularly worrying as regards medical products. The latest *Report on the EU customs enforcement of intellectual property rights* (2018)⁶⁶ showed that 71% of all medical products detained in 2017 came from India, which shows an increase of more than 9 percentage points compared to the figures in 2016. In terms of the number of articles detained in postal traffic into the EU, almost 17% were medicines in 2017. The fact that IPR-infringing medicines are often sent in small consignments continues to be challenging for customs to take action. Overall, according to that report, India remains among the top 7 source-countries of goods suspected of infringing IPR.

India 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

At the last EU-India Sub-Commission on Trade in July 2019, both sides agreed to launch a regular and dedicated **IPR dialogue**.

The **EU-India IP cooperation project**, financed under the EU Programme Capacity Building Initiative for Trade Development (CITD)⁶⁷ and managed by the EUIPO, has made a positive contribution from February 2015 to March 2018. In this context, the EUIPO cooperated 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. In January 2018, a user-friendly practical guide on “The Madrid Protocol: A route to Global Branding” was published to increase awareness of the Madrid Protocol, notably among Indian MSMEs, and to promote the effective use of the

⁶³ <http://www.egazette.nic.in/WriteReadData/2018/186661.pdf>

⁶⁴ See footnote 9

⁶⁵ See footnote 11

⁶⁶ https://ec.europa.eu/taxation_customs/sites/taxation/files/report_on_eu_customs_enforcement_of_ipr_2017_en.pdf

⁶⁷ <http://citd-standards.com/>

Madrid Route to enforce brand owners' rights.⁶⁸

The Commission is planning to launch an **IPR SME Helpdesk** in India in 2020, with the aim to support the EU's small and medium sized enterprises in protecting and enforcing their IPR in India through the provision of free information and services. The rendered services include a free-of-charge helpline, trainings and web-based materials.

Indonesia

Progress

Some improvements can be noted in Indonesia over the last two years. Indonesia has developed an Infringing Website List⁶⁹, which identifies websites engaged in substantive online piracy. The list helps online advertising agencies to minimise the placement of advertising on websites that infringe copyright on a commercial scale. Furthermore, Indonesia has issued administrative orders to block over 480 copyright-infringing websites.

As far as trademarks are concerned, Indonesia adopted the necessary implementing regulations⁷⁰ for the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks and thus brought its trademark law closer to international standards.

The Ministry of Law and Human Rights adopted Regulation 15/2018⁷¹, which allows patent holders to request the postponement of the local working requirement that is set out in the Indonesian Patent Law⁷². Notwithstanding the aforementioned Regulation, EU stakeholders reported that the legal uncertainty has remained high and underlined the need for the amendment of the Patent Law to fully eliminate the local working requirement⁷³.

Concerns and areas for improvement and action

Restrictive **patentability** criteria make effective patent protection in Indonesia very difficult, notably for pharmaceuticals and plant protection products. Despite complaints from stakeholders, the Indonesian Patent Law⁷⁴ continues to provide for a local working requirement. Stakeholders also complain about *Ministerial Regulation No. 39 of 2018 on Procedures of Imposition of Patent Compulsory Licence (Regulation 39/2018 on Patent Compulsory Licences)*⁷⁵ as it seems to confirm the possibility that compulsory licences can be granted on the basis of mere non-compliance with the local working requirement but also

⁶⁸ <https://www.ipc-eui.org/sites/default/files/news/files/2018%20Madrid%20Protocol%20Booklet%20IPC-EU%20India.pdf>

⁶⁹ Not available online

⁷⁰ <https://peraturan.bpk.go.id/Home/Search?tema=13> and <http://www.dgip.go.id/peraturan-perundang-undangan-terkait-merek>

⁷¹ Minister of Law and Human Rights Regulation No. 15/2018 on patent implementation by patent holders - <http://www.dgip.go.id/images/ki-images/pdf-files/uu-pp/permenkumham-paten-15-2018.pdf>

⁷² Law N° 3 of 2016 on Patents - <http://risbang.ristekdikti.go.id/wp-content/uploads/2017/11/UU-nomor-13-tahun-2016-tentang-paten.pdf>

⁷³ The local working requirement means that patent holders are 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 licence.

⁷⁴ Law N° 3 of 2016 on Patents

⁷⁵ Minister of Law and Human Rights Regulation No. 39/2018 on procedure of compulsory licensing of patent - <http://ditjenpp.kemenkumham.go.id/arsip/bn/2018/bn1787-2018.pdf>

because it appears to establish vague and potentially arbitrary criteria to issue compulsory licences (e.g. if a patent is “detrimental to the public interest”).

As regards **trademarks**, EU stakeholders report that bad faith registrations of foreign trademarks by local companies continue to be a problem with the consequence that right holders have to undertake expensive legal proceedings in courts to cancel them.

Another area of continued concern is the absence of an effective system for protecting **undisclosed test and other data** generated to obtain marketing approval for pharmaceutical products and plant protection products. To date, there seems to be no law that would provide for data protection for innovative medicines, which makes the market entry of generics possible right after the marketing approval of the originator medicine, even if they rely on the same clinical data.

IPR enforcement remains a source of serious concern. Improvements of the law on civil proceedings are needed in order to ensure that 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 IPR as well as the materials predominantly used for the manufacture of those goods. EU stakeholders reported that Indonesia does not have a dedicated IP crime unit, trained and equipped to deal with online copyright infringements, in particular illegal camcording and live streaming piracy.

As far as **customs enforcement** is concerned, EU stakeholders report problems with the customs recordation system. Trademark right holders without a local office in Indonesia are not able to record their trademarks in the customs register. Stakeholders also report that the customs recordation system is not available for copyright holders. The police requires copyright recordation with the IP Office as a precondition to conduct raids, which makes enforcement more complicated and less efficient.

According to the OECD-EUIPO joint study *Why do countries export fakes?* (2018)⁷⁶, Indonesia was among the main producers of fake leather and footwear, foodstuff, watches and jewellery, toys and games. The updated OECD-EUIPO joint study *Mapping the real routes of trade in fake goods* (2017)⁷⁷ also highlights that Indonesia is among the main producers of fake foodstuff, handbags and leather articles, jewellery, optical, photographic and medical equipment exported directly to the EU.

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

EU action

Negotiations on an **EU-Indonesia free trade agreement** were launched in July 2016. Nine rounds have been held so far. The objective is to conclude a comprehensive economic and partnership agreement with a robust IPR Chapter. Beyond that, the EU cooperates with like-minded countries (through joint demarches with the US, Japan and Switzerland) to raise

⁷⁶ See footnote 13

⁷⁷ See footnote 20

concerns about Regulation 39/2018 on Patent Compulsory Licences⁷⁸ and the local working requirement.

Under the **IP Key Southeast Asia** Programme,⁷⁹ which started in September 2017, a series of activities have been organised in Indonesia, to improve and modernise the technical capacity of IP Offices, and to exchange best practices.

The **ASEAN Regional Integration Support** from the EU (ARISE Plus) programme⁸⁰ has continued with the aim of supporting greater economic integration in ASEAN countries inter alia by improving IPR protection and enforcement. Under the IPR component of ARISE Plus, the EU supports ASEAN countries, such as Indonesia, to participate in global protection systems, to develop regional platforms and to strengthen the network of ASEAN IP Offices. Activities include enhancing IP awareness in society and the IP capacity of the productive sector.

Finally, the **ASEAN IPR SME Helpdesk**⁸¹ has continued to support the EU's small and medium sized enterprises in protecting and enforcing their IPR in the region, including Indonesia, through the provision of free information and other services. The rendered services include a free-of-charge helpline, trainings, and web-based materials.

Russia

Progress

Only few positive developments have been noted in Russia since the last report. As regards patent and regulatory data protection infringements, thanks to a legislative change⁸² in 2018, the judicial authorities have now the authority – at the request of the applicant – to issue a preliminary injunction against an alleged infringer. This should allow patent holders in the pharmaceutical sector to prevent the market entry of generic medicines during the term of regulatory data protection. It remains to be seen how this new provision will be applied by judicial authorities in Russia.

Russia adopted Federal Law No. 156⁸³, which came into force on 1 October 2017. This law allows for pre-existing website-blocking orders to be extended to include also clone and mirror websites containing infringing content. Such websites can be blocked in an extra-judicial procedure, on the basis of existing court rulings related to the original infringing website, without the need for a new application to the court. In 2018 another Federal Law⁸⁴ was adopted, which introduced financial penalties for attempts to bypass website blocking orders. This law has also introduced penalties for search engine operators, if blocked websites remain accessible in their search results.

⁷⁸ <http://www.dgip.go.id/peraturan-perundang-undangan-terkait-paten>

⁷⁹ <https://ipkey.eu/en/south-east-asia>

⁸⁰ https://eeas.europa.eu/delegations/indonesia/49555/arise-plus-indonesia-eu-commits-%E2%82%AC10-million-help-indonesia-grow-trade_en

⁸¹ <http://www.southeastasia-iprhelpdesk.eu/en/frontpage>

⁸² https://eeas.europa.eu/delegations/indonesia/49555/arise-plus-indonesia-eu-commits-%E2%82%AC10-million-help-indonesia-grow-trade_en

⁸³ <https://rulaws.ru/laws/Federalnyy-zakon-ot-01.07.2017-N-156-FZ/>

⁸⁴ Federal Law of June 27, 2018 No. 155-FZ. <http://publication.pravo.gov.ru/Document/View/0001201806270048?index=0&rangeSize=1>

Concerns and areas for improvement and action

Several constraints on **patent protection** remain problematic for EU companies. Restrictive patentability criteria, inefficient regulatory data protection and patent enforcement as well as vague grounds for the issuance of compulsory licences make effective patent protection in Russia very difficult, notably for pharmaceuticals.

In January 2018, Russia adopted a Roadmap for the Development of Competition in the Healthcare Sector⁸⁵ and, in October 2018, the Ministry of Economic Development issued Order No 527⁸⁶ on the patenting of pharmaceutical compositions and their uses. Both the Roadmap and the Order, if implemented, would exclude follow-on inventions (patent applications on new indications, new methods of treatment, new combinations, new pharmaceutical forms and new manufacturing methods of a known active ingredient) from patent protection. It would negatively affect the pharmaceutical sector by applying more restrictive patentability criteria than those applied in other sectors, which raises concerns in terms of compliance with the TRIPS Agreement.

As regards the prevention of **parallel imports**, stakeholders report negative developments. In February 2018, the Russian Constitutional Court ruled that judicial authorities are not allowed to apply the same sanctions against parallel imports as against counterfeit goods unless the parallel import causes harm similar to counterfeit goods. This interpretation causes serious legal uncertainty for right holders concerning the extent of their entitlement to prevent parallel imports.

Another negative development reported by stakeholders is the possible amendment of the Russian Civil Code to authorise parallel imports for certain goods, which could facilitate the imports of counterfeit and low quality consumer products in Russia.

As regards **copyright** and related rights, stakeholders report that state-owned collective management organisations are unaccountable to right holders concerning the amount of royalties collected and distributed. Collective management organisations need to improve their transparency rules and allow right holders – both natural and legal persons – to be represented in their governing bodies.

As far as **undisclosed know-how** and business information are concerned, stakeholders report a high volume of IP theft and misappropriation of trade secrets in Russia, notably in innovative sectors such as pharmaceuticals, engineering and telecommunication. The absence of effective measures, procedures and remedies for the protection of undisclosed information against their unlawful acquisition, use and disclosure remains detrimental for EU companies.

Another area of continued concern reported by stakeholders is the absence of an effective system for protecting **undisclosed test and other data** generated to obtain marketing approvals for pharmaceutical and agrochemical products. In June 2016, the Russian Supreme Court ruled⁸⁷ that the regulatory data protection regime was not applicable to clinical and other data available in the public domain including to data made available by the European Medicines Agency (EMA). This interpretation of the Russian Supreme Court is followed by

⁸⁵ <http://static.government.ru/media/files/vyoWQD6EZYQkBaQKfKFKAPZqqgtmcHDH.pdf>

⁸⁶ <https://www1.fips.ru/documents/npa-rf/prikazy-minekonomrazvitiya-rf/prikaz-minekonomrazvitiya-rossii-01102018-527.php>

⁸⁷ http://www.vsrp.ru/stor_pdf_ec.php?id=1442412

the marketing authorities and creates an opportunity for generic medicines to obtain a marketing authorisation during the regulatory data protection period of an originator medicine.

The Europol-EUIPO Study on *Intellectual Property Crime – Threat Assessment 2019*⁸⁸ singles out Russia for its organised crime groups targeting primarily western European countries with a range of different counterfeit medicines, primarily via the Internet. The OECD-EUIPO study *Mapping the real routes of trade in fake goods* (2016)⁸⁹ refers to Russia as one of the top sources of counterfeit foodstuff imported into the EU.

Despite recent reforms in the area of **civil enforcement**, EU stakeholders report that copyright infringements continue to be a serious problem, including, but not limited to, online piracy. A number of online pirate sites are still hosted in Russia and the enforcement measures are neither efficient nor deterrent enough to tackle the problem.

As far as **patent infringements** are concerned, stakeholders report that preliminary injunctions remain difficult to obtain. Moreover, delays in judicial proceedings often lead to the marketing of generic medicines without the authorisation of the right holder of a valid patent. Furthermore, even if the patent holder is eventually successful, it is usually not possible to obtain sufficient damages to compensate for the harm caused to the patent holder by the unauthorised market entry of the generic medicine. These provisions raise doubts in terms of compliance with Articles 41 and 50 of the TRIPS Agreement.

EU action

The European Commission organised two workshops and a conference in April and May 2018. The *2018 FIFA World Cup in Russia – Fight against counterfeiting and piracy* workshops and conference were dedicated to discuss the piracy of sport content and counterfeiting of sporting goods in the EU and Russia, with special focus on online infringements and IPR border measures. During the workshops and the conference, the participants discussed anti-piracy and anti-counterfeiting trends, specific legislative and non-legislative initiatives as well as initiatives taken by the private sector to reduce the volume of counterfeiting and piracy.

Turkey

Progress

Only few positive developments have been noted recently in Turkey. The Industrial Property Code⁹⁰, which was adopted in January 2017, brought about positive developments with respect to the protection of well-known trademarks and the invalidation of bad faith registrations. The Code has increased the level of alignment of certain provisions on geographical indications with the relevant EU legislation and has introduced important changes to the former implementation process. Stakeholders report that the enforcement of well-known trademarks has become faster and more effective in recent years. The Turkish

⁸⁸ https://euiipo.europa.eu/tunnel-web/secure/webdav/guest/document_library/observatory/documents/reports/2019_IP_Crime_Threat_Assessment_Report/2019_IP_Crime_Threat_Assessment_Report.pdf

⁸⁹ See footnote 20

⁹⁰ Act N° 6769 on Industrial Property

Patent and Trademark Institute continued to expand the use of online applications and developed its call centre services, especially with regard to trademarks.

In 2018, Turkey increased its criminal penalties against counterfeiting and seizures by the police and customs authorities. The establishment of specialised IP courts has strengthened the quality of IPR enforcement in Turkey by creating a framework in which consistent jurisprudence can be developed.

Concerns and areas for improvement and action

As far as **patents** are concerned, stakeholders report that the Industrial Property Code establishes vague and potentially arbitrary criteria to issue compulsory licences as it allows the Turkish government to issue such licences in situations when the level of availability on the Turkish market is claimed to not satisfy the domestic demand.

In the Industrial Property Code of 2017⁹¹, Turkey replaced the national exhaustion principle with the international exhaustion principle, which liberalised **parallel imports**, depriving EU right holders of the ability to control the exploitation of the goods put on the market by the right holder or with their consent. Since Turkey is in a customs union with the EU, the application of a different exhaustion regime than the EU creates serious problems in relation to the free circulation of goods.

As far as **trademarks** are concerned, stakeholders report that revocation, opposition and invalidation procedures for trademarks are disproportionately expensive and overly long.

As regards **copyright** and related rights, EU stakeholders complain about certain provisions of the draft law amending the Copyright Law, which has been under discussion for many years. In the last available version of the draft, some provisions would seem to undermine the exercise of the exclusive right of distribution and to introduce an international exhaustion regime.

Another area of continued concern reported by stakeholders is the absence of an effective system for protecting **undisclosed test and other data** generated to obtain marketing approval for pharmaceutical and agrochemical products. Despite the fact that Turkey has in place a regulatory data protection regime since 2005, stakeholders are concerned that its scope does not cover biologics and that the term of protection is only six years. Stakeholders also raised other shortcomings such as ineffective implementation, unreasonably slow procedures to process applications for a marketing authorisation and a term of protection that runs from the first marketing authorisation inside the customs union with the EU.

According to the EUIPO-OECD study *Why Countries Export Fakes?* (2018)⁹², Turkey remains among the top three sources of counterfeit and pirated goods traded worldwide (both in terms of value and diversity of counterfeit goods). According to this study and the EUIPO-OECD study on *Mapping the Real Routes of Trade in Fake Goods* (2016)⁹³, Turkey exports mainly counterfeits in the following product categories: articles of leather and footwear, clothing, electronic and electrical equipment, foodstuff, optical, photographic and medical

⁹¹ <https://wipo.lex.wipo.int/en/legislation/details/16609>

⁹² See footnote 12

⁹³ See footnote 20

equipment, perfumery and cosmetics, watches and jewellery, toys and games. These are transported mainly by road to the EU. The latest *Report on the EU customs enforcement of intellectual property rights (2018)*⁹⁴ confirms the above findings. In terms of economy-specific patterns, the EUIPO-OECD study on the *Misuse of Small Parcels for Trade in Counterfeit Goods (2018)*⁹⁵ indicated that Turkey is among the top sources of small parcel trade. Turkey is one of the main sources in particular of fake articles of leather, handbags, clothing and textile fabrics. Moreover, Turkey is a key transit point for counterfeit electronic and electrical products into the EU.

Stakeholders are concerned about the widespread availability of counterfeit goods and pirated books in domestic marketplaces. They report that Turkey is a key transit point for labels, tags and packaging materials. They are reportedly exported to the EU, separately from the goods, and used for completing the infringement within the EU (e.g. by affixing the counterfeit labels and tags to the goods or by packaging them with the counterfeit packaging materials). The Industrial Property Code seems to cause legal uncertainty for right holders also because the empowerment of customs authorities to detain and seize goods in transit is not laid down explicitly.

As regards **criminal enforcement** procedures, the Turkish legislation still does not appear to provide a legal base to empower the police to take action *ex officio*, without a complaint lodged by right holders. EU stakeholders report that Turkish criminal judicial authorities of first instance rarely order the search and seizure of counterfeit goods and reject these requests without any justification. Obtaining preliminary injunctions also remains difficult and the level of deterrence of the penalties ordered by judicial authorities is reportedly low.

Stakeholders report that Turkish **customs** authorities grant only three days for trademark proprietors to verify the counterfeit nature of detained goods, which is an unreasonably short deadline compared to the 10-days-deadline under EU law.

EU stakeholders also report that **enforcement authorities**, in particular the police and judges, lack sufficient resources and training to take efficient action against IP infringements. Widespread piracy, especially for physical goods and illegal translations of books in English cause serious harm for the European creative industries.

EU action

The EU and Turkey continue to hold annual **IP working group** meetings. In this framework, the EU and Turkey exchange information on IP legislation and practices and identify shortcomings and proposals for improvement. Moreover, the EU assists Turkey in the fight against IPR infringements in the context of the **Action Plan on Euro-Mediterranean Cooperation on the Fight against Counterfeiting and Piracy**. The Action Plan was endorsed at the 10th Union for the Mediterranean Trade Ministerial in March 2018 and it envisages a multi-annual cooperation framework, with the objective to assist Euro-Mediterranean countries, including Turkey, in the fight against counterfeiting and piracy.

Ukraine

Progress

⁹⁴ See footnote 23

⁹⁵ See footnote 19

Despite the major regulatory approximation that Ukraine committed to in the EU-Ukraine Association Agreement, which entered into force in 2016, only limited progress can be noted in the last two years. A positive development has been the adoption of Law No 2415 “*On Collective Management Organizations*”⁹⁶ in May 2018. For many years, lack of transparency and legal uncertainty undermined the collective rights management in Ukraine. Despite the fact that the law needs to be further amended in order to ensure compliance with international standards, its adoption shows a genuine effort to reform this area.

Concerns and areas for improvement and action

In the area of **patents**, three draft laws have been submitted to the Verkhovna Rada (the Parliament) in the last two years. These laws would introduce restrictive patentability criteria and deny protection for certain substances (salts, ethers, combinations, polymorphs, metabolites, etc.) and new uses of medicines of known medicinal product. Such exclusions would limit incentives to innovate in order to find more stable forms of compounds with longer shelf lives and dosages, which are safer or reduce side-effects. These draft laws are not in line with international standards and the European Patent Convention.

In the area of **trademarks**, Ukraine does not provide protection against bad faith registrations. The current trademark act⁹⁷ still does not provide for the legal possibility to invalidate a trademark registered in bad faith. Stakeholders also report that under the current trademark law, it is not possible to rely on the opposition procedure. This is because the proprietors of registered trademarks are not informed about applications that conflict with their trademarks and are not given a clear deadline after the examination by the Trademark Office to file an opposition against the conflicting applications.

As regards **copyright** and related rights, the recent law on collective management organisations raises serious problems in terms of the definition of cable retransmission and tariff setting.

EU stakeholders report that public broadcasting organisations continue not to pay royalties to performers and phonogram producers for the use of their performances and phonograms despite their legal obligation under the Ukrainian copyright law⁹⁸.

EU stakeholders report that **regulatory data protection** remains ineffective in Ukraine for a number of reasons. Firstly, Ukraine makes the eligibility for regulatory data protection dependant on the filing of the first marketing authorisation in Ukraine within two years after a marketing authorisation has been granted anywhere in the world, which forces early market entry on pharmaceutical companies, often against their business interests. Secondly, the status of the reference medicine is not checked during the registration of a generic medicine, since the State Expert Committee is not responsible for reviewing the regulatory data protection status. This leads to market entry of generic medicines during the regulatory data protection period. Thirdly, information on medicines subject to an ongoing marketing authorisation procedure is not publicly available, which undermines the adequate enforcement of regulatory data protection.

⁹⁶ <https://zakon.rada.gov.ua/laws/show/2415-19>

⁹⁷ <https://zakon.rada.gov.ua/laws/show/3689-12>

⁹⁸ <https://zakon.rada.gov.ua/laws/show/3792-12>

Further progress remains necessary as regards **IPR enforcement**. According to the EUIPO-OECD Study on *Trends in Trade in Counterfeit and Pirated Goods* (2019)⁹⁹, Ukraine continues to be one of the four main transit points for fake goods to the EU market. According to the EUIPO-OECD Study on *Why do countries export fakes?* (2018)¹⁰⁰, Ukraine is a transit point for shipments of counterfeits into the EU especially in the following sectors: foodstuff; watches and jewellery; toys and games; clothing; optical, photographic and medical equipment.

EU stakeholders report that **online piracy** remains a significant problem and the weaknesses of the current law have resulted in an increase in the number of pirate sites being hosted in Ukraine.

EU stakeholders also report that there are still major problems with the efficiency of **customs** authorities because there are no adequate facilities to destroy certain types of counterfeit products (e.g. pesticides). Stakeholders point out that even the simplified customs procedure is time-consuming and expensive. In general, there seems to be a lack of effective procedures for the destruction of seized counterfeit products and equipment used for their manufacture. The new draft customs code, submitted to the Verkhovna Rada, contains provisions, which, if adopted, would bring closer the Ukrainian IPR border measures to the EU standards.

EU action

The **EU-Ukraine Association Agreement** requires Ukraine to reinforce its level of IP protection and enforcement. The Association Agreement represents a regulatory approximation of the Ukrainian IP law with the EU *acquis* in the area of copyright and related rights, trademarks, designs, topographies of semiconductors, patents, plant varieties and civil and border enforcement.

The **IPR Dialogue**, which has been set up by the aforementioned Association Agreement, forms part of the broader cooperation between the EU and Ukraine in the context of the European Neighbourhood Policy¹⁰¹ and enables 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. Since the publication of the last report, two IPR Dialogues have taken place.

The EU funded a Twinning Project to assist Ukraine in the implementation of the DCFTA and assists Ukraine in the elaboration of new draft laws on IPR.

The EU has also financed a **technical assistance programme** to support the development of a geographical indications system in Ukraine. A draft law has already been prepared in the framework of this programme, which will run until 31 August 2020.

6.3. Priority 3

Argentina

Progress

⁹⁹ See footnote 9

¹⁰⁰ See footnote 13

¹⁰¹ https://ec.europa.eu/neighbourhood-enlargement/neighbourhood/overview_en

Some progress can be noted in Argentina over the last two years in the area of IP. Stakeholders report that cooperation between right holders and enforcement authorities has improved. Law enforcement agencies (City Police, Federal Police) carried out operations that led to seizures of a higher volume of counterfeit goods in 2018 compared to previous years. A draft Criminal Code¹⁰² has been prepared and submitted to the Parliament, which, if adopted, would facilitate landlord prosecution when tenants are involved in counterfeiting. The IP Office (INPI) started using electronic filing for patent, trademark and industrial design applications in October 2018, which simplifies and speeds up these processes. Argentina is reportedly considering the accession to the Patent Cooperation Treaty.

Concerns and areas for improvement and action

The level of IP protection and enforcement continues to be weak, which discourages investment in innovation and creativity.

Several constraints on **patent** protection remain detrimental to EU companies, and research and innovation more broadly. Restrictive patentability criteria¹⁰³ combined with difficulties to enforce patents granted, as well as the patent examination backlog make effective patent protection in Argentina very difficult, notably for pharmaceuticals, agro-chemicals and biotechnological innovations. As a result, Argentina is the only G20 member where the number of patent applications has decreased over the last two years. Measures to address the patent examination backlog have not borne fruit and it still takes up to 10 years to examine a patent in the pharmaceutical, agro-chemical and biotechnology fields. This backlog is reportedly due in part to the fact that INPI does not have enough specialised staff in these areas and limited financial autonomy.

As regards **copyright** and related rights, Argentina does not provide adequate legal protection against the circumvention of technological protection measures for performers and phonogram producers as required in Article 18 of the WIPO Performances and Phonograms Treaty (WPPT).

Another area of continued concern reported by stakeholders is the absence of an effective system for protecting **undisclosed test and other data** generated to obtain marketing approvals for pharmaceutical and agrochemical products. The uncertain protection of regulatory test data deters innovators from bringing modern medicines to the Argentinian market.

IPR enforcement remains a source of serious concern. While EU stakeholders report that cooperation with the police has improved, IPR infringements are still widespread in Argentina due to the lack of enforcement capacities, appropriate training, dissuasive sanctions and the low number of seizures by customs authorities. Stakeholders report that addressing IP infringements is not a priority for the government. The improved cooperation with the police is not replicated in customs where seizures have actually decreased over the last two years.

¹⁰² See <https://www.batimes.com.ar/news/argentina/government-sends-bill-to-senate-to-overhaul-criminal-code.phtml>

¹⁰³ Joint Regulation 118/2012, 546/2012 and 107/2012 issued on May 8, 2012 and the Biotech Regulation 283/2015

As regards **copyright piracy**, stakeholders report that many universities still copy complete works of varying genres, around 70% of software used is pirated and enforcement of copyright infringements (audio-visual, e-books and music) is almost non-existent – unlicensed music and audio-visual services are widely available. There is no notice and take down procedure, and hence, all notifications need to go via the judicial system. This is ineffective, especially regarding urgent or provisional measures. There is a lack of specialised judges in general and there are no specialised IP courts at the regional level. Without the necessary expertise, court decisions lack consistency and preliminary injunctions are almost impossible to obtain, in particular with regard to patents. Sanctions and sentences actually imposed appear not to be deterrent enough to prevent further infringements.

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 Patent Cooperation Treaty.

EU action

The negotiations of the trade part of the Association Agreement between the EU and MERCOSUR reached political conclusion on 28 June 2019. The IP Chapter of the Association Agreement contains detailed rules on copyright, trademarks, designs, trade secrets, enforcement and border measures. Argentina will make best efforts to adhere to the Patent Cooperation Treaty and is encouraged to protect plant varieties in line with the UPOV 1991 standards. The IP Sub-Committee set up in the framework of the Association Agreement will provide a regular forum for discussion on implementation and any issue related to IPR the Parties wish to raise.

The Association Agreement also contains a comprehensive article on cooperation in the field of IPR. The EU technical cooperation programme, **IP Key Latin America**¹⁰⁴, which started in September 2017, will continue to be a useful instrument in general to enhance the protection and enforcement of IPR in Latin America, including Argentina, and to assist with the implementation of the Association Agreement in particular. IP Key has provided a series of activities throughout the continent, including Argentina, to improve and modernise the technical capacity of IP Offices, to exchange best practices, contribute to achieving a high standard of protection and enforcement of IP and provide a more level playing field for IP stakeholders.

In addition, the **IPR SME Helpdesk** in Latin America continued over the last two years with the aim to support the EU's small and medium sized enterprises in protecting and enforcing their IPR in the region, including Argentina, through the provision of free information and services. The rendered services include a free-of-charge helpline, trainings, and web-based materials.

Brazil

Progress

¹⁰⁴ <https://ipkey.eu/en/latin-america>

Positive developments have been noted over the last two years. The Brazilian IP Office (INPI) has made efforts to address the patent and trademark backlogs via accelerated and simpler procedures¹⁰⁵. In order to reduce the backlog of patent applications, INPI has agreed to Patent Prosecution Highways with several IP Offices (US, Japan, European Patent Office, China, UK, Denmark and some PROSUR¹⁰⁶ members) and issued Resolution No 208 introducing Guidelines for the examination of Patent Applications¹⁰⁷.

The Brazilian Film Agency set up a Technical Working Group to Combat Piracy and the National Council to Combat Piracy (CNCPI) approved a three-year National Plan to Combat Piracy, which includes coordinated activities among various public authorities and private sector organisations.

Concerns and areas for improvement and action

As regards **patents**, despite the increased number of patent registrations in 2018 and the efforts made by INPI to reduce the patent backlog, it still takes about 10 years for a patent application to be examined (13 years for information technologies and pharmaceutical patents)¹⁰⁸. Another area of continued concern reported by stakeholders is the interference of the Brazilian health authorities (ANVISA) in pharmaceutical patent applications before they have been examined by the INPI.

As far as **copyright** and related rights are concerned, no significant progress has been made over the last two years. The provision on the resale right in the current copyright law¹⁰⁹ (Article 38, 9.610/1998) lacks procedural mechanisms, making the management of this right and its enforcement very difficult for right holders who thus do not receive any royalties.

Another area of continued concern reported by right holders is the absence of a system for protecting **undisclosed test and other data** generated to obtain marketing approvals for pharmaceutical products for human use against unfair commercial use, as well as their unauthorised disclosure. To date, there seems to be no law that specifically addresses regulatory data protection for pharmaceuticals for human use, which creates legal uncertainty.

IPR enforcement remains a source of serious concern. According to the EUIPO-OECD Study on *Mapping the Real Routes of Trade in Fake Goods* (2016)¹¹⁰, Brazil was among the top seven provenance economies for counterfeit foodstuff in 2011-13, on the basis of its share in the global seized value. EU stakeholders confirm that the overall situation has not improved over the last two years and IPR infringements are still rampant in Brazil due to the lack of enforcement capacities, appropriate training and dissuasive sanctions. Stakeholders

¹⁰⁵ Use of prior art searches from other jurisdictions; normative instruction 70/2017 to expedite analysis of technology transfer and franchise agreements; normative instruction 232/2019 on industrial design guidelines.

¹⁰⁶ In 2010, the PTOs of Argentina, Brazil, Chile, Colombia, Ecuador, Paraguay, Peru, Surinam and Uruguay started to work on the collaborative project funded by the Inter-American Development Bank. The aim of the project, which keeps each country's sovereignty to regulate IP matters according to its own local law, is to consolidate the process of technical and institutional cooperation between the PTOs of the South American region. The first specific step of the project focused on the non-binding exchange of patent examination results.

¹⁰⁷ http://www.inpi.gov.br/menu-servicos/arquivos-dirpa/DIRETRIZESQUIMICAresolucao208_dez17.pdf

¹⁰⁸ A CNI (National Confederation of Industry in Brazil) study from July 2018 estimates that the patent backlog will stand at 350,000 in 2029.

¹⁰⁹ <http://www.wipo.int/wipolex/en/details.jsp?id=514>

¹¹⁰ See footnote 20

also report that the availability of counterfeit and pirated offers on e-commerce platforms and pirate websites (audiovisual and music downloading, streaming and peer-to-peer file sharing websites) has increased. IP enforcement procedures, including both of the customs and the judiciary, are overly complex, not fully transparent and unreasonably long.

Brazil has not yet ratified the WIPO Copyright Treaty, the WIPO Performances and Phonograms Treaty, as 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 negotiations of the trade part of the Association Agreement between the EU and MERCOSUR reached political conclusion on 28 June 2019. The IP Chapter of the Association Agreement contains detailed rules on copyright, trademarks, designs, trade secrets, enforcement and border measures. Brazil will make best efforts to adhere to the Patent Cooperation Treaty and is encouraged to protect plant varieties in line with the UPOV 1991 standards. The IP Sub-Committee that will be set up in the framework of the modernised Association Agreement will provide a regular forum for discussion on implementation and any issue related to IPR the Parties wish to raise.

The Association Agreement also contains a comprehensive article on cooperation in the field of IPR. The EU technical cooperation programme, **IP Key Latin America**¹¹¹, which started in September 2017, will continue to be a useful instrument in general to enhance the protection and enforcement of IPR in Latin America, including Brazil, and to assist with implementation of FTAs in particular. IP Key has provided a series of activities throughout the continent, including Brazil, to improve and modernise the technical capacity of IP Offices, to exchange best practices, contribute to achieving a high standard of protection and enforcement of IP and provide a more level playing field for IP stakeholders.

In addition, the **IPR SME Helpdesk** in Latin America continued over the last two years with the aim to support the EU's small and medium sized enterprises in protecting and enforcing their IPR in the region, including Brazil, through the provision of free information and services. The rendered services include a free-of-charge helpline, trainings, and web-based materials.

Ecuador

Progress

There has been only limited progress in Ecuador over the last two years. Positive developments have been noted regarding trademarks. A solution was found by means of implementing guidelines to measures introduced by Decree 522¹¹² on pharmaceuticals, as regards labelling requirements that were unjustifiably encumbering the use of the trademark once the patent had expired and raised concerns on compliance with TRIPS Article 20.

¹¹¹ See footnote 105

¹¹² 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

In July 2018, Ecuador launched a public consultation on the draft regulations implementing the Organic Code on Social Economy of Knowledge, Creativity, and Innovation (IP Code)¹¹³, with a view to align Ecuador's legislation with international norms.

The Ecuadorian IP Office, also in charge of IP enforcement, stepped up its efforts to reduce the availability of counterfeit and pirated goods and organised raids that allowed for coordinated seizures of IPR-infringing goods in a number of different commercial establishments in Guayaquil, Manta and Portoviejo.

Concerns and areas for improvement and action

Several constraints on **patent** protection remain. The IP Code appears to include a local working requirement that raises concerns in view of Ecuador's compliance with Article 27 of the TRIPS Agreement. The contested provisions may oblige the patent holder to manufacture the patented product or use the patented process in the territory of Ecuador and non-compliance with the requirement may trigger the possibility of issuing a compulsory licence. These provisions appear to discriminate against imported patented products, in favour of locally produced ones.

As regards **copyright** and related rights, the IP Code contains broad exceptions and limitations. This is notably the case for the limitations and exceptions to the public performance and broadcasting rights, which seem to be contrary to Ecuador's international obligations and to its commitments under the EU-Columbia, Peru and Ecuador Trade Agreement.

As far as music broadcasting is concerned, EU stakeholders report that CNT, the public broadcasting organisation, continues using music without authorisation and without paying royalties to authors, performers and phonogram producers, despite Ecuador's international obligations. There are indications that the competent authorities in Ecuador may be willing to address this issue. The EU will continue to monitor further developments.

IPR enforcement remains a source of serious concern. EU stakeholders report widespread availability of counterfeit and pirated goods across the country, including both online and in physical marketplaces. Despite the IP Office's broader responsibility and increased efforts against IP infringements, the enforcement regime remains weak.

Another area of continued concern reported by right holders is the absence of effective **customs** procedures for the detention and seizure of goods suspected of infringing an IP right at the border. EU stakeholders report that the main problem is that the IP Code provides only a limited scope of action for the customs authorities, which are no longer empowered to act *ex officio*.

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).

¹¹³ Organic Code of Social Economy of Knowledge, Creativity and Innovation, Official Journal Supplement No. 899 of 9 December 2016

EU action

Ecuador's accession to the EU-Colombia and Peru **Trade Agreement** (Trade Agreement) took effect on 1 January 2017.

In the context of the implementation of IPR commitments under the Trade Agreement, the EU has been urging Ecuador to address problematic issues in its IP Code, including via implementing regulations that Ecuador has not yet adopted. The Trade Agreement requires Ecuador to raise the level of IP protection and enforcement. The EU will continue to monitor developments as to the effective implementation of Ecuador's obligations under the EU-Colombia, Peru and Ecuador Trade Agreement.

The EU technical cooperation programme, **IP Key Latin America**¹¹⁴, which started in September 2017, will continue to be a useful instrument in general to enhance the protection and enforcement of IPR in Latin America, including Ecuador, and to assist with implementation of FTAs in particular. IP Key has provided a series of activities throughout the continent, including Ecuador, to improve and modernise the technical capacity of IP Offices, to exchange best practices, contribute to achieving a high standard of protection and enforcement of IP and provide a more level playing field for IP stakeholders.

In addition, the **IPR SME Helpdesk** in Latin America continued over the last two years with the aim to support the EU's small and medium sized enterprises in protecting and enforcing their IPR in the region, including Ecuador, through the provision of free information and services. The rendered services include a free-of-charge helpline, trainings, and web-based materials.

Malaysia

Progress

Positive developments have been noted recently in the area of IPR. Malaysia appears to be in the process of acceding to the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks (Madrid Protocol). At the same time, the Parliament is discussing the Trademark Bill 2019, which seeks to amend the Trademark Act from 1976 not only with respect to Malaysia's obligations under the Madrid Protocol, but also to modernise its legal framework, for instance, by providing for the protection of non-traditional trademarks and collective marks.

EU stakeholders report a continued engagement by the Malaysian authorities' in raising IPR awareness and in taking enforcement action.

Concerns and areas for improvement and action

With respect to 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.

¹¹⁴ See footnote 105

IPR enforcement remains a source of serious concern despite the efforts of the Malaysian government.

According to the OECD-EUIPO report *Illicit Trade - Trends in Trade in Counterfeit and Pirated Goods* (2019)¹¹⁵, Malaysia remains among the top provenance economies for counterfeit and pirated goods traded worldwide and has moved up in the top 10 provenance economies of counterfeit imports into the EU.

IPR-infringing goods continue to be widely accessible both on physical and online markets. EU stakeholders report that the Batu Ferringhi Night Market in Penang as well as the Petaling Street in Kuala Lumpur continue to be among the high number of problematic physical markets with a high presence of fake products.

As regards **copyright piracy**, EU stakeholders report that few copyright infringing websites have been subject to site blocking orders, despite over 100 applications since site blocking has been introduced in 2015. They note that the referral process is complicated and lengthy, inter alia because two government ministries are involved. They also note, however, that, in February 2019, the Minister of Communications and Multimedia of Malaysia recognised the need to streamline the process and speed up action.

EU stakeholders report that enforcement authorities lack sufficient resources to take efficient action against IP infringements, including in major cities like Kuala Lumpur where counterfeiting activities are high. Moreover, EU stakeholders note that burdensome requirements have to be fulfilled by right holders in order for customs authorities to take action. There also seems to be a lack of information concerning the destruction of IP infringing goods.

Malaysia has not yet ratified 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

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 of the negotiations is being considered. Any future agreement would include an extensive chapter dedicated to IPR protection and enforcement, including enhanced civil and border enforcement.

Under the **IP Key Southeast Asia Programme**¹¹⁶, which started in September 2017, a series of activities were organised throughout the region, including Malaysia, to improve and modernise the technical capacity of IP Offices, to exchange best practices, contribute to achieving a high standard of protection and enforcement of IP and provide a more level playing field for IP stakeholders.

Further technical assistance is granted to Malaysia under the **ASEAN Regional Integration Support from the EU** (ARISE Plus) programme¹¹⁷ which aims to support greater economic

¹¹⁵ See footnote 9

¹¹⁶ <https://ipkey.eu/en/south-east-asia>

¹¹⁷ <http://ariseplus.asean.org/>

integration in ASEAN countries inter alia by improving IPR protection and enforcement. Under the IPR component of ARISE Plus,¹¹⁸ the EU continues to support 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 aimed at private stakeholders 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, utilisation, administration and enforcement in the ASEAN region.

In addition, the **IPR SME Helpdesk** in Southeast Asia continued over the last two years with the aim to support the EU's small and medium sized enterprises in protecting and enforcing their IPR in the region, including Malaysia, through the provision of free information and services. The rendered services include a free-of-charge helpline, trainings, and web-based materials.

Nigeria

Progress

In October 2017, Nigeria acceded to the WIPO Copyright Treaty, the WIPO Performances and Phonograms Treaty, the Marrakesh Treaty to Facilitate Access to Published Works by Visually Impaired Persons and Persons with Print Disabilities and the Beijing Treaty on Audiovisual Performances. While the accession to these treaties is welcome, Nigeria still needs to complete the implementation process and amend its Copyright Act accordingly.

Nigeria and in particular its National Agency for Food and Drug Administration and Control (NAFDAC) is a pioneer in the fight against counterfeit medicines in West Africa. By 2006, the share of counterfeit drugs had dropped from 41% (2001) to 16% (2006) due to smartly calibrated measures taken by the agency. The efforts to combat the counterfeiting of pharmaceuticals in Nigeria began with the restriction of pharmaceutical imports to only two airports and two seaports, each staffed by NAFDAC officials. To prevent consumers to buy counterfeit medicines, Nigeria has developed an application to check medicines via mobile phone.

The UPOV Council took a positive decision on the conformity of the “Plant Variety Protection Bill of Nigeria” (“Draft Law”) with the 1991 Act of UPOV Convention, which allows Nigeria, once the Draft Law is adopted without changes and enters into force, to deposit its instrument of accession to the 1991 Act.

Concerns and areas for improvement and action

As regards **copyright** and related rights, Nigeria has not introduced a protection against the circumvention of technical protection measures and protection for rights management information as required by the WIPO Performances and Phonograms Treaty and the WIPO Copyright Treaty. As far as collective rights management is concerned, the Nigerian system has serious shortcomings. Stakeholders report that in 2018, the Nigerian Copyright Commission (NCC) suspended the operating licence of COSON limited liability company, which is the collective management organisation managing the broadcasting and public

¹¹⁸ <https://euiipoef.eu/en/ariseplusipr>

performance rights of many international music right holders in Nigeria. The NCC has not provided reasons for its suspension and the situation makes the collection and distribution of royalties to right holders practically impossible.

IPR enforcement remains a source of serious concern. IPR infringements are widespread in Nigeria due to gaps in the legal framework on enforcement, the lack of enforcement capacities, appropriate training and dissuasive sanctions.

According to the EUIPO-OECD studies on *Why do countries export fakes?* (2018)¹¹⁹, on the *Misuse of Small Parcels for Trade in Counterfeit Goods* (2018)¹²⁰ and on *Mapping the Real Routes of Trade in Fake Goods* (2017)¹²¹, Nigeria was listed among the main transit points in the global trade of counterfeit electronic and electrical equipment produced in China for re-export to other Western African economies. Widespread counterfeiting of alcohol and medicines also constitute a serious health risk in the country.

EU stakeholders report that **online piracy** remains a significant problem and the weaknesses of the current law have resulted in an increase in the number of pirate sites. Some online pirates have intentionally moved their servers and operations to Nigeria in the past few years to take advantage of these weaknesses. Nigeria has become a host to a number of unlicensed online music services and there has been no enforcement action against them over the last two years. Nigerian-based infringing services, especially cyberlockers, are reportedly highly active internationally.

Weaknesses in enforcement mechanisms including the lack of adequate authority for **customs** authorities to seize and destroy counterfeit and pirated goods at the border continue to be a concern for right holders. The enforcement measures are not efficient and deterrent enough to tackle the high level of counterfeiting. Despite the right holders' efforts, customs authorities do not order the destruction of counterfeit goods and it is reported that these goods often re-enter the market.

Nigeria 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

The Commission has provided incentives for the purpose of promoting and encouraging voluntary technology transfer to Nigeria. Nigeria was one of the beneficiaries of the **Second European and Developing Countries Clinical Trials Partnership Programme**, which contributes to the reduction of the social and economic burden of poverty-related diseases among others in Nigeria, by accelerating the clinical development of effective, safe, accessible, suitable and affordable medical interventions for these diseases.

Saudi Arabia

Progress

¹¹⁹ See footnote 13

¹²⁰ See footnote 19

¹²¹ See footnote 20

Some improvements can be noted in Saudi Arabia's IPR legislation despite longstanding challenges. The Ministry of Commerce and Investment recently established the Saudi Authority for Intellectual Property Rights (SAIPR) as an initiative within the government's National Transformation Program 2020, which aims to harmonise the jurisdiction of IPRs under a single entity. Stakeholders report that the number of seizures has increased over the last two years and customs authorities are more cooperative with right holders than previously.

Concerns and areas for improvement and action

As far as **patents** are concerned, stakeholders report that, in the last two years, the Saudi Arabia Food and Drug Authority (SFDA) has granted marketing approvals to Saudi companies for the production of generic versions of medicinal products which are still under patent protection in Saudi Arabia or in the Gulf Cooperation Council (GCC) member countries.

Another area of continued concern reported by stakeholders is related to the inefficiency of the system for protecting **undisclosed test and other data** generated to obtain marketing approvals for medicines for human use against unfair commercial use, as well as their unauthorised disclosure. Stakeholders report that in 2018, the SFDA granted marketing approvals for generic medicines that relied on the clinical data of reference medicines before the expiry of their regulatory data protection period.

IPR enforcement in Saudi Arabia features serious shortcomings. Stakeholders report widespread satellite and online piracy. An allegedly Saudi operator called BeoutQ currently makes available – without authorisation – content belonging to EU sport event organisers and EU right holders (authors and related rights holders) in the territory of Saudi Arabia, in the Middle East and North Africa (MENA) as well as in the EU. Saudi Arabia has reportedly not taken sufficient steps to stop the infringement despite the fact that the satellite services of BeoutQ are being transmitted by the satellite (Badr-4/Arabsat- 4b) of the partly state-owned Arab Satellite Communications Organisation.

As regards **criminal enforcement**, stakeholders report that the Ministry of Culture and Information has a discretionary right to authorise or deny access to the Copyright Committee, which is the sole entity responsible for copyright infringements in Saudi Arabia, and also to approve or disapprove the decisions of the Copyright Committee, which does not seem to be compatible with the TRIPS Agreement. These rules make the availability of criminal judicial procedures and sanctions conditional on political or subjective considerations.

Another area of continued concern reported by stakeholders is **customs enforcement** due to the lack of sufficient resources and capacity to handle the ever-growing number of counterfeit goods transiting or destined for the country, inconsistent and non-deterrent sanctions and lack of *ex officio* actions by the customs. The destruction of counterfeit and pirated goods is reportedly very rare in Saudi Arabia.

According to the EUIPO-OECD studies on *Mapping the Real Routes of Trade in Fake Goods* (2017)¹²², on *Trends in Trade in Counterfeit and Pirated Goods* (2019)¹²³ and on *Why do*

¹²² See footnote 20

¹²³ See footnote 9

countries export fakes? (2018)¹²⁴, Saudi Arabia is a regional transit country for counterfeit goods destined to Africa and to the EU, especially in product categories such as foodstuff, perfumery and cosmetics, pharmaceuticals, watches, jewellery, toys, games and sport equipment. According to the *World Customs Organisation's Illicit Trade Report* (2017)¹²⁵, IPR products were smuggled through 2,413 unique trafficking routes, touching 1,102 cities across 22,930 trafficking instances with known transit information. Two of the top six cities counting enough instances to be considered as high-risk hub were Dammam with 1,163 instances and Riyadh with 3,022 instances in Saudi Arabia.

Saudi Arabia has not yet ratified the WIPO Copyright Treaty, the WIPO Performances and Phonograms Treaty, 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

In August 2018, the EU made an **official demarche** to request Saudi Arabia to take appropriate actions against satellite and online piracy of TV programmes belonging also to EU right holders. In the absence of any reaction or action, the EU made a third party written submission in WTO DS/567– *Measures concerning the protection of intellectual property rights* due to its systemic interest in the correct and consistent interpretation and application of the TRIPS Agreement and the Berne Convention as well as its concerns about the impact on EU stakeholders.

An **IPR cooperation programme** was launched in 2019 focusing on IP enforcement in the framework of the EU-Gulf Cooperation Council (GCC)¹²⁶.

Thailand

Progress

Despite the political commitment of the current Thai government and clear efforts of the Department of Intellectual Property, there has been limited progress in Thailand over the last two years. The coordination between the different authorities and agencies dealing with IPR enforcement has improved through the establishment of the National Committee on Intellectual Property and the Subcommittee on Enforcement against IP infringements. In January 2019, Thailand acceded to the Marrakesh Treaty to Facilitate Access to Published Works by Visually Impaired Persons and Persons with Print Disabilities. Following Thailand's accession to the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks in November 2017, the system of international applications for trademarks is running well. Relevant recent legislative changes include the amendments to the Computer Crime Act¹²⁷. The Thai authorities showed genuine willingness to steer discussions between Thai e-commerce, social media platforms and brand owners, and

¹²⁴ See footnote 13

¹²⁵ Available at <http://www.wcoomd.org/en/media/newsroom/2018/november/the-wco-releases-the-2017-illicit-trade-report.aspx>

¹²⁶ <https://ec.europa.eu/trade/policy/countries-and-regions/regions/gulf-region/>

¹²⁷ Computer Crime Act (No 2) B.E. 2560 (2017)

facilitated the conclusion of a Memorandum of Understanding between these interested circles with the aim to reduce the availability of counterfeit offers on e-commerce platforms.

Considerable efforts have been made to improve the administration of patent applications and to reduce the huge backlog in this area.

Concerns and areas for improvement and action

EU stakeholders report that there are still significant challenges with the IPR protection and enforcement in Thailand.

As far as **patents** are concerned, EU stakeholders report that – despite the increased number of examiners – the Thai IP office lacks resources to keep up with the volume of applications, resulting in a considerable patent backlog. The duration of the patent examination covers most of the patent term provided in Thailand. It remains to be seen whether the steps taken recently to reduce the backlog will be effective to address the concerns.

As regards **copyright** and related rights, EU stakeholders report that the collective rights management system does not apply minimum transparency, accountability and good governance standards. 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. Users are reluctant to pay royalties because there is a general mistrust vis-à-vis collective management organisations in Thailand.

EU stakeholders also report that the lack of adequate legal protection against the circumvention of technological protection measures and against the unauthorised alteration or removal of rights management information causes them considerable harm. The Copyright Act¹²⁸ provides legal protection against the circumvention of technological protection measures, but includes a list of overly broad exceptions which pre-empt the protection.

EU stakeholders report that **IPR enforcement** remains a serious concern due to the widespread availability of counterfeit and pirated goods. According to the EUIPO-OECD Study on *Trends in Trade in Counterfeit and Pirated Goods (2019)*¹²⁹, Thailand is consistently among the top six provenance countries based on the total number of customs seizures of counterfeit and pirated goods worldwide. The EUIPO-OECD study on *Mapping the Real Routes of Trade in Fake Goods (2017)*¹³⁰ has also shown that Thailand is among the top ten source countries of counterfeits in all sectors, including food, pharmaceuticals, cosmetics, leather goods and footwear.

EU stakeholders report that the volume of online sales of counterfeit goods has increased over the last two years. The Thai language e-commerce and social media platforms allegedly offer a wide variety of counterfeit goods and the cooperation between the platforms and the right holders is not efficient.

As regards **online piracy**, despite the adoption of the amendments to the Computer Crime Act which provides for a procedure for disabling access to pirate content online, EU stakeholders report that there have only been few cases. The procedure established under the Act appears

¹²⁸ Copyright Act (No 2) B.E. 2558 (2015)

¹²⁹ See footnote 9

¹³⁰ See footnote 20

to be overly lengthy, complicated and costly. In a number of cases, compliance with the orders under this procedure has not been ensured.

As far as **border enforcement** is concerned, EU stakeholders report a lack of adequate and effective IPR border measures as a result of limited manpower and resources. Stakeholders also report a significant decrease in the number of seizures of counterfeit goods at the border over the last two years, and that Thailand has become a major transit hub for counterfeit goods originating mainly in China and destined for the EU and other parts of the world. A steep decline was noted for *ex officio* actions taken by customs authorities.

As regards **civil and administrative enforcement**, EU stakeholders reportedly face difficulties in enforcing their rights because judicial and administrative proceedings are slow and inefficient. While the law enforcement agencies are engaged and take action against counterfeit and piracy networks, the judicial proceedings are particularly complex. Penalties, including fines, in particular for repeat infringers, are low and do not have any deterrent effect.

Although in preparation for several years now, 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 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. However, due to the political situation, the negotiations have remained suspended over the last two years.

On an annual basis, the EU and Thailand hold **IP Dialogues** which allow both sides to exchange information on the state of IPR protection and enforcement. Ongoing legislative procedures as well as the preparation of accessions to multilateral treaties and specific data on IPR enforcement activities are addressed in each IP Dialogue.

Under the **IP Key Southeast Asia** Programme, which started in September 2017, a series of activities were organised throughout the region, including Thailand, to improve and modernise the technical capacity of IP Offices, to exchange best practices, to contribute to achieving a high standard of protection and enforcement of IP and to provide a more level playing field for IP stakeholders.

The **ASEAN Regional Integration Support** from the EU (ARISE Plus) programme has also continued with the aim 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 continued supporting the legal and regulatory IP frameworks to enable ASEAN countries like Thailand 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, utilisation, administration and enforcement in the region.

Finally, the **ASEAN IPR SME Helpdesk**¹³¹ continued to support the EU's small and medium sized enterprises in protecting and enforcing their IPR in the region, including Thailand, through the provision of free information and other services. The rendered services include a free-of-charge helpline, trainings, and web-based materials.

¹³¹ <http://www.southeastasia-iprhelpdesk.eu/en/frontpage>

7. MONITORING THE IMPLEMENTATION OF FREE TRADE AGREEMENTS

Canada

Progress

Positive developments have been noted over the last two years. In July 2018, Canada acceded to the Geneva Act of the Hague Agreement Concerning the International Registration of Industrial Designs. In March 2019, Canada also acceded to the Madrid Protocol, the Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks and the Singapore Treaty on the Law of Trademarks. Canada is currently in the process of modernising its patent regime to implement the Patent Law Treaty.¹³² Relevant amendments to the Patent Act and the new Patent Rules came into force on 30 October 2019.

In April 2018, Canada's Minister of Innovation, Science and Economic Development announced a new IP strategy. Among other things, this strategy aims to address different forms of IP misuse (such as trademark squatting) and seeks to increase IP awareness. In line with this IP strategy, the Budget Implementation Act 2018¹³³ led to respective amendments of Canada's Copyright Act, Patent Act and Trade-marks Act.

Concerns and areas for improvement and action

The Canadian IPR system still features certain shortcomings. Despite recent positive developments, a number of issues remain to be addressed, in particular in copyright and related rights as well as in enforcement.

Broad exceptions in **copyright** law are applied in a way that appears to be detrimental to right holders. EU stakeholders are particularly concerned about the fair dealing exception for educational purposes and the exception for non-commercial user-generated content. Moreover, EU stakeholders are also concerned that Canada does not grant a remuneration right to phonogram producers and performers for a number of uses of their music in broadcasting and public performance.

Stakeholders indicate that the "notice and notice" regime for online **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 infringements 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.

EU stakeholders also report that Canada remains a host to websites providing access to pirated content. In cases where the identity of the operator is unknown, due to the use of services enabling anonymous registration of website domains, 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).

¹³² <http://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr04653.html>

¹³³ Budget Implementation Act, 2018, No. 2.

Weaknesses in **enforcement** mechanisms including adequate authority for **customs** authorities to seize and destroy counterfeit and pirated goods at the border continue to be of concern for right holders. While EU stakeholders' experience with Canadian civil courts has been more positive, they report that customs authorities often lack resources to effectively tackle IPR infringements at the border. Police forces are reportedly rather passive in taking on criminal cases.

EU action

The **EU-Canada Comprehensive Economic and Partnership Agreement (CETA)**, 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 the time that elapses 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.

Canada grants protection to 143 EU geographical indications (GI) under CETA, and has expanded its pre-existing system for the protection of wine and spirits GIs to accept requests for GI protection for food products. In June 2019, the EU published a practical business guide on geographical indications in Canada.¹³⁴ In May 2018, the CETA Committee on Geographical Indications discussed the implementation of CETA provisions related to the protection of GIs. The EU intends to continue improving the practical implementation of the grandfathering clause¹³⁵.

In June 2018, the EU and Canada held an informal meeting on intellectual property rights in Ottawa. The discussions included **exchanges of information** on a variety of subjects pertaining to both the implementation of commitments in the CETA IP chapter as well as other issues of bilateral interest such as updates on various IP legislative and policy initiatives. Cooperation in this area continues.

Mexico

Progress

Positive developments have been noted over the last two years. Mexico adopted legislative changes, which introduced the invalidation and opposition proceeding against trademark applications and registrations in bad faith¹³⁶, extended the term of protection for registered industrial designs up to 25 years¹³⁷, opened the trademark registry to non-traditional trademarks, and introduced the protection of geographical indications, including the recognition of foreign GIs¹³⁸. In the area of copyright enforcement, Mexico introduced more stringent measures against copyright piracy, which can now qualify as a criminal offense.

¹³⁴ <https://trade.ec.europa.eu/doclib/html/157873.htm>

¹³⁵ Feta, Asiago, Fontina, Gorgonzola, Munster, Nürnberger Bratwürste, Jambon de Bayonne and Beaufort.

¹³⁶ Amended industrial property law published in the Official Journal of the Mexican Federation on 13 March, 2018. Statute came into effect on April 27, 2018.

¹³⁷ <https://wipolex.wipo.int/en/legislation/details/18059>; http://www.dof.gob.mx/nota_detalle.php?codigo=5515853&fecha=13/03/2018

¹³⁸ <https://wipolex.wipo.int/en/legislation/details/18059>; http://www.dof.gob.mx/nota_detalle.php?codigo=5515853&fecha=13/03/2018

Mexico has negotiated comprehensive IP chapters in trade negotiations with the US and Canada as well as with the EU over the last two years. There are thus high expectations for the future when these commitments will be implemented.

Concerns and areas for improvement and action

As regards **copyright** and related rights, the list of rates established by the Federal Copyright Law has not yet been published and, hence, it is difficult to collect remuneration for reprography. Stakeholders report that the scope of application of the exception for visually impaired persons is overly broad. Despite the fact that Mexico ratified the WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty in 2002, it does not provide for the protection against the circumvention of technological protection measures and the unauthorised alteration or removal of rights management information.

IPR enforcement remains a source of serious concern. Stakeholders report widespread counterfeiting and piracy across the country and a low efficiency level of customs authorities. According to stakeholders, Mexico is the second largest foreign source of illegally recorded films. The many markets where counterfeit products can be bought openly seem to be areas where the police almost never conducts raids and seizes counterfeits.

Stakeholders report that **judicial and administrative proceedings** are overly complex and lengthy despite the existence of a specialised IP court. In administrative procedures, preliminary measures are ineffective because they can be lifted without any burden of proof on the alleged infringer in cases where the latter files a counter-bond, which makes it difficult to stop the continuation of infringements.

As regards **customs enforcement**, stakeholders report that Mexico took steps backwards. Customs procedures have become more burdensome and unclear. EU stakeholders report that the lack of prescribed timelines for adjudicating customs seizures has led to long delays in the destruction of counterfeit goods. The destruction procedure can reportedly last up to ten years. Stakeholders also note that right holders find it difficult and cumbersome to obtain reimbursement for storage and destruction costs.

Customs authorities still do not have ex officio powers to seize goods and hence require an official document from the Attorney General's Office (AGO) which slows down the process considerably. Customs regulations allow the release of a shipment after 5 days if no irregularities are found, but the seizure order from AGO takes up to a month to obtain and, hence, it arrives at the customs authorities long after the complaint was filed. In addition, customs authorities do not have sufficient resources and the capacity to handle the ever-growing number of counterfeit products entering the country.

As regards **criminal enforcement**, stakeholders report problems related to the so-called "chain of custody". Upon a complaint by a right holder, the prosecutor orders the police to obtain documentary evidence. The police, however, usually finds the shipment opened (since customs opened it to check for infringement) and prosecutors often refuse the evidence as unreliable because the shipment may have been altered. Right holders then have to submit an appeal that lengthens the process.

Mexico 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 Mexico completed negotiations for the modernisation of the EU-Mexico **Association Agreement** in 2018 and bilateral discussions on IP issues will be held annually via the IP Sub-Committee and discussions on geographical indications via the GI Sub-Committee.

The EU technical cooperation programme, **IP Key Latin America**¹³⁹, which started in September 2017, will continue to be a useful instrument in general to enhance the protection and enforcement of IPR in Latin America, including Mexico, and to assist with implementation of FTAs in particular. IP Key has provided a series of activities throughout the continent to improve and modernise the technical capacity of IP Offices, to exchange best practices, to contribute to achieving a high standard of protection and enforcement of IP and to provide a more level playing field for IP stakeholders.

In addition, the **IPR SME Helpdesk**¹⁴⁰ in Latin America continued over the last two years with the aim to support the EU's small and medium sized enterprises in protecting and enforcing their IPR in the region, including Mexico, through the provision of free information and services. The rendered services include a free-of-charge helpline, trainings, and web-based materials.

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 South Korea has continued to improve. There have been successful efforts to combat counterfeit goods on street markets, notably in the Seoul area, and to curb online infringements.

As regards the online sale of counterfeits, under the active guidance of the Korean Intellectual Property Office (KIPO), large online platforms, seem to have stepped up their efforts and their cooperation with South Korean authorities and EU stakeholders to clean up the online market place. KIPO has shown genuine willingness to steer discussions between South Korean e-commerce and social media platforms as well as brand owners, and to facilitate the conclusion of a Memorandum of Understanding between these interested circles with the aim to reduce the availability of counterfeit offers on relevant platforms. While at this stage an MoU between right holders and platforms has not been concluded yet, in September 2019 KIPO and several South Korean online platform companies including Naver and Kakao, signed an MoU for the prevention of the distribution of counterfeit goods on-line. In practical terms, it seems KIPO can now request more easily and speedily on-line platform companies to provide data and information necessary for KIPO's investigations.

¹³⁹ See footnote 105

¹⁴⁰ <https://www.latinamerica-ipr-helpdesk.eu/>

The Ministry of Culture, Sport and Tourism (MCST) has amended a presidential decree¹⁴¹ with the aim of increasing the range of venues that will pay royalties for the communication to the public of copyright protected music. The decree¹⁴² has entered into force on 23 August 2018. However, this is only a partial and very limited solution for the problem of the lack of remuneration for public performance.

The Korean Institute of Intellectual Property (KIIP) has released a study on the positive impact of intellectual property rights (IPRs) on the South Korean economy, titled *Analysis on Economic Contribution of IP-Intensive Industries*¹⁴³ following broadly the methodology used by the EUIPO for similar studies.¹⁴⁴ Findings in this study show that IP-intensive industries added a total value of EUR 436 billion to South Korea's GDP, accounting for 43.1% of South Korea's total GDP in 2015. Moreover, 6.07 million jobs in South Korea were generated by IPR-intensive industries, accounting for 29.1% of the entire South Korean employment. Furthermore, it was shown that IPR-intensive industries pay higher wages, with a wage premium of 51.1% compared to non-IPR intensive industries. Overall, the findings provide valid quantitative confirmation of the importance of IPRs in South Korea and will help increasing the profile of IPR protection in South Korea.

Concerns and areas for improvement and action

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

As far as **copyright** and related rights are concerned, there has been no progress on the problems related to the remuneration of performers and phonogram producers for the public performance of music over the last two years. Overly broad exceptions and very low royalty rates continue to limit the applicability of these rights. South Korea has not brought its law into compliance with international commitments.

As regards **IP enforcement**, one of the remaining systemic deficiencies reported by stakeholders concerns the low level of sanctions which is considered insufficient to ensure adequate deterrence against IP infringements with regard to counterfeit and pirated goods.

According to the OECD-EUIPO study on *Mapping the Real Routes of Trade in Fake Goods* (2017)¹⁴⁵, South Korea is a source, albeit limited, of counterfeit electronics and electrical equipment.

¹⁴¹ <http://www.law.go.kr/lsInfoP.do?lsiSeq=209755&efYd=20190702#0000>;

<http://law.go.kr/LSW/eng/engLsSc.do?menuId=2§ion=lawNm&query=copyright&x=0&y=0#liBgcolor 12>

¹⁴² 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 South Korea approved the revision of the Presidential Decree of Copyright Act on 16th August 2017, to slightly widen the positive list of venues where right holders 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.

¹⁴³ https://www.kiip.re.kr/research_report/view.do?bd_gb=report&bd_cd=1&bd_item=0&po_item_gb=rgb 10&po_no=R0583

¹⁴⁴ https://euiipo.europa.eu/tunnel-web/secure/webdav/guest/document_library/observatory/documents/IPContributionStudy/performance_in_the_European_Union/performance_in_the_European_Union_full.pdf

¹⁴⁵ See footnote 20

EU action

The EU-Korea **Free Trade Agreement** entered into force in 2011. The annual **IPR Dialogue** and **Working Group on Geographical Indications** established by the FTA allow both sides to discuss ongoing legislative developments and to exchange experience on enforcement by customs and enforcement authorities as well as by administrative and judicial bodies.

Vietnam

Progress

Vietnam has made some progress on its IPR legal framework. In April 2018, new *Guidelines for Certain Number of Articles of the Intellectual Property Law and Law on Amendments to the Intellectual Property Law 2009 in Terms of Copyright and Related Rights*¹⁴⁶ entered into force. Among other things, these guidelines provide more legal clarity by specifying certain terms used in Vietnam's Intellectual Property Law.

In October 2018, Vietnam's Market Surveillance Agency was upgraded to the General Department of Market Surveillance under the Ministry of Industry and Trade, inter alia, to improve the fight against IPR infringements.¹⁴⁷ According to information available, 63 provincial-level market surveillance departments shall be established under this department.

Concerns and areas for improvement and action

As far as **IPR protection** is concerned, EU stakeholders report an increase in **bad faith trademark applications**. They also note that, while improvements of Vietnam's IPR legal framework are necessary to bring it in line with international standards, their main concern remains the lack of IPR enforcement.

According to the OECD-EUIPO report *Illicit Trade - Trends in Trade in Counterfeit and Pirated Goods* of 2019¹⁴⁸, Vietnam remains an important producer of counterfeit goods in many sectors. The latest report on *EU customs enforcement of intellectual property rights*¹⁴⁹ showed that Vietnam is among the top 4 provenance countries for goods suspected of infringing IPR detained by EU customs authorities without release for free circulation. The report showed that Vietnam represented almost 25% of all jewellery and other accessories and more than 31% of all cigarettes detained in 2017. As regards cigarettes, this shows an increase of more than 22 percentage points compared to the figures in 2016.

EU stakeholders are also concerned about **widespread piracy**, in particular in the online environment. They note that there is no effective system for site blocking and that right holders face unreasonable evidentiary requirements to enforce their rights without being permitted to conduct investigations, notably in situations where enforcement authorities take insufficient action against illegal websites, camcording and live streaming piracy as well as

¹⁴⁶ Decree No. 22/2018/ND-CP Decree No. 22/2018/ND-CP of February 23, 2013, on Guidelines for Certain Number of Articles of the Intellectual Property Law and Law on Amendments to the Intellectual Property Law 2009 in Terms of Copyright and Related Rights, available at <https://wipolex.wipo.int/en/text/472667>

¹⁴⁷ Decision No. 34/2018/QĐ-TTg dated 10 August 2018 of the Prime Minister, providing for the functions, tasks, powers and organizational structure of the General Department of Market Management directly under the Ministry of Industry and Trade

¹⁴⁸ See footnote 9

¹⁴⁹ See footnote 16

against piracy devices and apps that facilitate access to infringing content. Concerns have, moreover, 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. More generally, Vietnam's enforcement system has remained highly complex which makes it challenging for right holders to take effective and efficient action against IPR infringements.

Vietnam has not yet ratified 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

The EU-Vietnam **Free Trade Agreement** was signed on 30 June 2019 and it is now in the process of ratification. 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 authorisation process.

Vietnam continued to receive significant technical assistance in the field of IP from the EU. The **European Trade Policy and Investment Support Project (MUTRAP)**¹⁵⁰, which came to an end in December 2017, has successfully accomplished its objectives with the implementation of almost 130 technical assistance activities, the publication of 74 reports and research documents as well as the organisation of around 300 workshops and training courses in 31 cities and provinces.

Under the **IP Key Southeast Asia Programme**¹⁵¹, which started in September 2017, a series of activities were organised throughout the region, including Vietnam, to improve and modernise the technical capacity of IP Offices, to exchange best practices, to contribute to achieving a high standard of protection and enforcement of IP and to provide a more level playing field for IP stakeholders.

Further technical assistance is granted to Vietnam under the **ASEAN Regional Integration Support from the EU (ARISE Plus)** programme¹⁵² 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,¹⁵³ the EU continues to support 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 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, utilisation, administration and enforcement in the ASEAN region.

¹⁵⁰ <http://mutrap.org.vn/index.php/en/about-eu-mutrap-2>

¹⁵¹ <https://ipkey.eu/en/south-east-asia>

¹⁵² <http://ariseplus.asean.org/>

¹⁵³ <https://euiipoef.eu/en/ariseplusipr>

Finally, the ASEAN IPR SME Helpdesk¹⁵⁴ continued to support the EU's small and medium sized enterprises in protecting and enforcing their IPR in the region, including Vietnam, through the provision of free information and other services. The rendered services include a free-of-charge helpline, trainings, and web-based materials.

¹⁵⁴ <http://www.southeastasia-iprhelpdesk.eu/en/frontpage>

ANNEX: PROTECTION AND ENFORCEMENT OF PLANT VARIETY RIGHTS

1. INTRODUCTION

Pursuant to Article 27(3)(b) of the TRIPS Agreement, “Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof”.

The EU provides a *sui generis* protection¹⁵⁵ for plant variety rights fully in line with the International Convention for the Protection of New Varieties of Plants (the UPOV Convention; the latest revision is commonly referred to as the “UPOV 1991 Act”¹⁵⁶).

The UPOV 1991 Act establishes an effective, internationally recognised system for the protection of plant varieties. It defines the rights of the breeder of a protected variety as regards production or reproduction, conditioning for the purpose of propagation, offering for sale, selling or other marketing, exporting, importing and stocking. UPOV has a broad membership including countries from all continents and with different levels of development.

The potential benefits of UPOV membership are: (a) increased breeding activities, (b) greater availability of improved varieties, (c) more new varieties, (d) diversification of the types of breeders (e.g. private breeders, researchers), (e) supporting the development of a new industry sectors, and (f) improved access to foreign plant varieties and enhanced domestic breeding programmes.¹⁵⁷ Moreover, according to a recent report of the Intergovernmental Panel on Climate Change, “*advances in plant breeding are crucial for enhancing food security under changing climate for a wide variety of crops including fruits and vegetables as well as staples. Genetics improvement is needed in order to breed crops and livestock that can both reduce greenhouse gas emissions, increase drought and heat tolerance (e.g. rice), and enhance nutrition and food security*”¹⁵⁸. Plant breeding can serve to respond to climate change by developing varieties with larger root systems and with higher sugar content or by developing pest and disease resistant varieties and varieties with decreased sensitivity to atmospheric CO₂ concentration. The development of varieties resistant to drought, flood, heat and salinity helps also respond to the negative consequences of climate change.

In recent years, UPOV has published information assessing the impact of UPOV membership. For example, a study¹⁵⁹ on Vietnam estimated the impact on the country’s Gross Domestic Product (GDP) at around USD 5 billion per year, which is more than 2.5% of its national GDP. The Kenya Plant Health Inspectorate Service (KEPHIS)¹⁶⁰ explained how the UPOV system enabled Kenya to develop a USD 500 million cut-flower industry that employs 500,000 Kenyans. In Australia¹⁶¹, 95 % of wheat breeding programmes were funded by the

¹⁵⁵ <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31994R2100>

¹⁵⁶ <https://www.upov.int/export/sites/upov/upovlex/en/conventions/1991/pdf/act1991.pdf>

¹⁵⁷ Overview of UPOV, Publication No 437 of April 13, 2018 <https://www.upov.int/export/sites/upov/about/en/pdf/pub437.pdf>

¹⁵⁸ <https://www.ipcc.ch/site/assets/uploads/2019/08/Fullreport-1.pdf>

¹⁵⁹ Socio-economic benefits of UPOV membership in Viet Nam; An ex-post assessment on plant breeding and agricultural productivity after 10 years (Corresponding author: Steffen Noleppa) by HFFA Research GmbH

¹⁶⁰ <https://youtu.be/lwuXwN96O-Y>

¹⁶¹ <http://sciencemeetsbusiness.com.au/ip-wheat-industry/>

public sector before accession to the UPOV 1991 Act; following UPOV membership, wheat breeding is completely funded by the private sector due to the income generated by End Point Royalties. In Canada, the ratification of the UPOV 1991 Act has resulted in new investments from the private sector in wheat breeding, foreign-domestic partnership in cereal breeding, development of a public-private-producer breeding consortium to fund Canadian Prairie Spring Red Wheat (CPSR) and an increased number of new plant variety rights applications.

EU stakeholders, in particular SMEs, face different problems to protect and enforce their plant variety rights worldwide, in particular in those countries that have not yet acceded to the UPOV 1991 Act. The absence of an effective plant variety legislation, non-functioning administrative procedures, the lack of an effective system of royalties' collection and enforcement, high enforcement costs, weak or non-existing border enforcement and hardly accessible dispute resolution mechanisms are among the main concerns.

A number of third countries have introduced broad restrictions to breeders' rights, notably to allow farmers to sell or exchange seeds with each other for commercial purposes. Such an exception undermines the plant variety protection and hinders the propagation and marketing of new species in the countries concerned.

Plant variety rights are frequently infringed. Prevalent examples include unauthorised exports/imports, packaging of harvested crops (e.g. grain, ware potatoes) for sale as propagating material, non-authorised use of farm-saved seeds and the sale of a protected variety under another name.

Plant variety rights infringements endanger agricultural productivity, delay the introduction of improved varieties, reduce investments in plant breeding, compromises the quality of seeds, plants and fresh produce, provoke phytosanitary risks derived from clandestine activities and may be connected with criminal activities such as tax evasion, fraud, corruption and even labor exploitation.

2. COUNTRY-SPECIFIC ANALYSIS

EU stakeholders reported problems to protect their new plant varieties in a number of third countries. They reported particular concerns and high economic losses in Argentina, China, Ecuador and India. None of the four countries have acceded to the UPOV 1991 Act. Argentina, China and Ecuador are parties to the UPOV 1978 Act.

Argentina

The Argentinean Seed law No 22247 and its Implementing Decree No 2183/91 have several shortcomings. Stakeholders report that the Seed Law does not cover the protection of harvested material and the products directly obtained from that harvested material. It also includes a broad exception to breeders' rights allowing farmers to sell plant varieties obtained from protected products, for commercial purposes.

Argentina does not provide for provisional protection. The introduction of provisional protection from the filing date of the application until the grant of the right (as required by the 1991 UPOV Act) is important for breeders to launch their innovation at an early stage. In order to make provisional protection effective, the applicant should be entitled to enforce provisional rights during the application process.

Stakeholders also raised concerns about Article 28 of the Seed Law, which allows “restricted public use” in order to ensure an adequate supply of a protected plant variety in the country. Compulsory licences may be issued if the breeder does not satisfy the public need in terms of quantity and if prices are unaffordable. According to stakeholders, there is no public need in the commercialisation of fruit and ornamental varieties created by vegetative reproduction¹⁶² and therefore those should not be covered under this provision.

Stakeholders are also concerned about the absence of rules on essentially derived varieties¹⁶³. Regulating such varieties could prevent the exploitation of mutations of protected varieties and varieties that had undergone a minor change in relation to the initial variety, for example by using biotechnology, without the consent of the holder of the initial variety right.

China

Several challenges persist for breeders in China who want to rely on plant variety protection.

Only a limited number of species appear to be protectable in China. Article 27(3)(b) of the TRIPS Agreement obliges WTO Members to provide for the protection of plant varieties without differentiating between different types or species of plants.

The farmers' exception is overly broad as it allows growers in the area of vegetatively propagated ornamentals and fruits to produce their own cuttings and other propagating material and use them for further propagation.

According to the Chinese plant variety law, promotion (without commercial release of the product on the market) is a novelty-breaking act (novelty being a condition for protection). Furthermore, even if the propagating material of a breeder's variety is imported and propagated in China without the breeder's knowledge, it may lose its novelty status. These provisions do not seem to be in line with China's international commitment as a party to the UPOV 1978 Act, which clearly refers to *offering for sale or marketing, with the agreement of the breeder* as novelty-breaking acts. In addition, relevant authorities have an overly broad margin of discretion to determine if a variety is new.

The Chinese legislation does not regulate essentially derived varieties. Stakeholders consider it important to address such varieties in the legislation in order to prevent the exploitation of mutations of protected varieties and varieties that had undergone a minor change in relation to the initial variety, for example by using biotechnology, without the holder of the initial variety right being able to receive a share in the revenues. The holders of essentially derived varieties should be required to obtain the approval of the breeder of the initial variety and receive a share in the revenues.

¹⁶² Vegetative reproduction is a form of asexual reproduction of a plant. Only one plant is involved and the offspring is the result of one parent.

¹⁶³ Defined in Article 14(5) of the UPOV 1991 Act. It is predominantly derived from the initial variety, retains and conforms the essential characteristics of the initial variety, and clearly distinguishable from the initial variety.

Ecuador

The plant variety law of Ecuador provides for a period of protection of 18 years for vines and trees and 15 years for the rest of the crops, which is not in line with Ecuador's commitment in the Andean-EU FTA to ensure protection in line with the UPOV 1991Act.

Article 487 of the Ecuadorian Ingenuity Code (Código Ingenios), which determines the scope of the breeder's right, does not seem to be in line with the UPOV 1991 Act as it provides protection only for ornamentals, but not for crops.

Article 491 of the Ecuadorian Ingenuity Code allows farmers to propagate a protected variety without the authorisation of the breeder and to exchange propagating material with other farmers without authorisation. This provision appears to be inconsistent with Article 27 (3) (b) of the TRIPS Agreement which requires an "effective system" for the protection of plant varieties. In addition, the Ecuadorian provision seems incompatible with Article 5 of UPOV 1978 as the breeder's exclusive right includes the right to produce the propagating material for commercial marketing, selling and offering for sale.

Contrary to the UPOV 1991Act, the Ingenuity Code does not provide for a provisional protection from the filing date of the application until the grant of the right.

India

Only a very limited number of plant species is protectable in India. It does not seem to be in line with Article 27(3)(b) of the TRIPS Agreement, which obliges WTO Members to provide for the protection of plant varieties without differentiating between different types or species of plants.

The farmers' exception in the Indian law is broader than the farmers' exemption under the UPOV 1991 Act because it is not limited to agricultural crops and includes ornamentals and fruits. In addition, it allows growers in the area of vegetatively propagated ornamentals and fruits to produce their own cuttings and to use them for further propagation without authorisation and without paying royalties.