

Strasbourg, 1.7.2014 COM(2014) 389 final

# COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE

Trade, growth and intellectual property - Strategy for the protection and enforcement of intellectual property rights in third countries

{SWD(2014) 204 final}

EN EN

#### 1. Introduction

The March 2014 European Council reaffirmed the importance of intellectual property (IP) as a key driver for growth and innovation and highlighted the need to fight against counterfeiting to enhance the EU's industrial competitiveness globally. Intellectual Property Rights (IPR) are one of the principal means through which companies, creators and inventors generate returns on their investment in knowledge, innovation and creativity.

A recent study has estimated that IPR-intensive sectors account for around 39% of EU GDP (worth some EUR 4.7 trillion annually) and, taking indirect jobs into account, up to 35% of all jobs<sup>1</sup>. In practical terms, through the granting of temporary exclusive rights, IP is directly linked to the production and distribution of new and authentic goods and services, from which all citizens benefit. The key to achieving these goals is an optimal and economically efficient IP "infrastructure" which spans the legal recognition, registration, utilisation and balanced enforcement of all forms of IPRs.

The EU needs innovation to stay competitive relative to countries with lower labour, energy and raw materials costs, and must create the conditions that stimulate innovation so that European businesses can help us trade our way out of the crisis. This is why knowledge-based industries play a core role in the 'Global Europe' and 'Europe 2020' strategies.

Intellectual creations need protection if creativity and innovation are to flourish, and this is the role of IPRs, which also play an important function in promoting development<sup>4</sup> and in addressing some of today's global challenges. For developing countries, a pragmatic and flexible approach will help them maximise the potential of their own intellectual assets and further their integration into international trade, while achieving broader societal welfare.

Some estimate that the EU loses about EUR 8 billion of its GDP a year because of counterfeiting and piracy<sup>5</sup>, and that global costs could reach as high as USD 1.7 trillion by 2015. The EU has over many years developed a modern, integrated IPR regime that makes a major contribution to growth and job creation while at the same time ensuring that a proper balance is struck between the interests of right-holders and users.

Intellectual property rights intensive industries: contribution to economic performance and employment in the European Union, Industry-Level Analysis Report, Joint project between the European Patent Office and the Office for Harmonisation in the Internal Market, Munich and Alicante, 2013.

See Communication on global Europe: competing in the world. A contribution to the EU's growth and jobs strategy, of 4 October 2006, COM(2006) 567 final.

http://ec.europa.eu/europe2020/index en.htm

Intellectual property and development. Lessons from recent economic research, Eds. C. Fink, K.E. Maskus, copublication of the World Bank and Oxford University Press, Washington DC, 2005.

CEBR, *The impact of counterfeiting on four main sectors in the European Union*, Centre for Economic and Business Research, London, 2000.

Global impacts study. A new study, conducted by Frontier Economics examines the global economic and social impacts of counterfeiting and piracy, ICC, February 2011. available at <a href="http://www.iccwbo.org/Advocacy-Codes-and-Rules/BASCAP/BASCAP-Research/Economic-impact/Global-Impacts-Study/">http://www.iccwbo.org/Advocacy-Codes-and-Rules/BASCAP/BASCAP-Research/Economic-impact/Global-Impacts-Study/</a>

The EU, including the European Commission, and major international organisations (WIPO, WHO, WTO, WCO, OECD, G20<sup>7</sup>) have called for measures to combat IPR infringement<sup>8,9,10</sup>.

In 2004, the Commission Communication "Strategy for the enforcement of intellectual property rights in third countries" defined a broad framework for fighting IPR infringements in third countries, as well as specific action lines, which have since been implemented.

But, as noted in the accompanying *Commission Staff Working Document* (SEC(2013)30), not only has there been significant technological change but also the nature and scope of the challenges and risks to European companies' IP, and IPR-related societal evolutions, have evolved considerably in the last 10 years.

This Communication therefore reviews the approach adopted by the Commission in 2004 and sets a revised strategy to promote IPRs and combat IPR infringements abroad. It will highlight ways in which existing policy approaches can be improved in keeping with the times, and also proposes tools and ideas to deal with new realities. A blend of continuity and change will help to ensure we sustain and encourage innovation and creativity, while balancing the interests of all stakeholders.

The Communication is complemented by an EU Action Plan that focuses on the enforcement of IPRs on the Single Market and the development of deeper cooperation between customs authorities in the EU and in third countries with respect to trade of IP-infringing goods, as foreseen in the EU Customs Action Plan.

#### 2. CHANGES IN THE EXTERNAL CONTEXT SINCE 2004

# **2.1.** The 2004 Strategy

An evaluation<sup>12</sup> of the 2004 Strategy took place in 2010 and confirmed its relevance. Several recommendations were made intended to enhance and fine-tune it, e.g. strengthening consultation with all stakeholders, embracing the development agenda, and further developing technical cooperation programmes. The main conclusions of this assessment, as well as a large amount of additional information, can be found in the accompanying *Commission Staff Working Document* (SWD(2014)204).

\_

WIPO (World Intellectual Property Organisation), WHO (World Health Organisation), WTO (World Trade Organisation), WCO (World Customs Organisation), OECD (Organisation for Economic Cooperation and Development), G20 (Group of Twenty)

Council Resolution 2008/C253/01 of 25 September 2008, on a comprehensive European anti-counterfeiting and anti-piracy plan, OJ C253, 4.10.2008.

Council Resolution 2009/C71/01 of 16 March 2009, on the EU Customs Action Plan to combat IPR infringements for the years 2009 to 2012, OJ C71, 25.3.2009.

European Parliament Resolution of 22 September 2010, 2009/2178(INI).

Strategy for the enforcement of intellectual property rights in third countries, 2005/C29/03, OJ C129, 26.5.2005.

DG Trade - Contract N°SI2.545084. Evaluation of the Intellectual Property Rights enforcement strategy in third countries. Final report, volume I- main report, Analysis for Economic Decisions (ADE) and European Commission, Louvain-la-Neuve, 2010.

# 2.2. Changes and challenges

Growth and employment remain vital in today's challenging economic environment. Globalisation and developments in technology not only represent huge trade opportunities but also major challenges. The share of the BRIC<sup>13</sup> countries in world trade increased from 8% in 2000 to 18.2% in 2010<sup>14</sup> and it is estimated that developing countries will account for nearly 60% of global GDP by 2030<sup>15</sup>. While their relationship with IP is changing from imitation to creation, counterfeiting, piracy, IP theft and other forms of IP misappropriation are still widespread. There is a huge drive by developing countries to continue their impressive economic growth and move up the value chain by mastering or gaining access to foreign technology, through legitimate competition or, by some actors, illegitimate means. Therefore, it is not sufficient just for the EU to get its IPR policy right – we must also strive to enhance protection and enforcement of IP abroad, in particular among our key trading partners.

Indeed, despite increasing legislation worldwide, IPR infringement has reached unprecedented levels, facilitated in particular by digital technology that allows low-cost, high quality reproduction in bulk. International trade in counterfeit and pirated goods in 2008 was estimated to be worth approximately USD 250 bn (i.e. 2 % of world trade)<sup>16</sup>.

The success of the internet makes it easier not only for legitimate businesses, but also for those that engage in IP infringement, who are increasingly organised and quick to adapt their business models to exploit loopholes in IP protection, to market themselves locally, nationally and internationally at relatively low cost.

A policy response is needed, not just to ensure effective protection and enforcement of IPRs internationally, but also to raise public awareness of the economic and other impacts of IPR-infringing goods and their detriment to innovation and also on health and safety. In a globalised economy of international supply chains, lack of proper IP protection in some jurisdictions can dramatically affect business and therefore sustainable job creation as well as consumers practically anywhere in the world. IPR-infringing goods and services are produced with little regard for labour and environmental standards<sup>17</sup>. The growing involvement of organised crime is also a particularly serious concern for governments<sup>18</sup>.

Given the scope of change in the IP landscape, it is thus essential to ensure that the current Strategy responds to today's challenges. This Communication reviews and updates EU policy approaches, and introduces new tools and ideas. It aims to help the EU to achieve not only growth but also wider societal goals, including in relation to the developing world.

Brazil, Russia, India, China.

WTO, Eurostat, IMF.

OECD, Economy: Developing countries set to account for nearly 60% of world GDP by 2030, according to new estimates, June 2010.

OECD, Magnitude of counterfeiting and piracy of tangible products: an update, November 2009, <a href="http://www.oecd.org/dataoecd/57/27/44088872.pdf">http://www.oecd.org/dataoecd/57/27/44088872.pdf</a>

http://www.unep.org/roap/Portals/96/Trade% 20in% 20Intellectual% 20Property-21Nov2013.pdf

Cf. e.g. IP crime: the new face of organised crime – from IP theft to IP crime, B. Godart, Journal of Intellectual Property Law and Practice, 2010, Vol. 5, No. 5, <a href="http://jiplp.oxfordjournals.org/cgi/reprint/5/5/378?etoc">http://jiplp.oxfordjournals.org/cgi/reprint/5/5/378?etoc</a>

#### 2.2.1. Enforcement

Access to effective remedies internationally is important for right holders to protect their rights – incentives to invest are reduced in jurisdictions where these are uncertain – hence the need for solid and predictable IPR frameworks that create environments conducive to innovation and sustainable growth and offer effective enforcement. There have been significant IP regulatory reforms in many third countries as a result of the WTO's *Trade-Related Intellectual Property Rights* (TRIPS) agreement, but their enforcement efforts have not always matched these. Often the possibilities for effective enforcement of IPRs are limited due to serious deficiencies in the IPR framework, e.g. customs authorities lacking ex-officio powers, courts issuing insufficiently deterrent sanctions, officials lacking sufficient knowledge and training on IPR. Enforcement efforts may also be hindered by a lack of political will.

The EU experienced a tripling in the number of IPR infringing goods detained at EU borders between 2005 and 2012. E-commerce has led to increased trade in small consignments, which makes detection of IPR infringements harder. Due to this new pattern, customs cases involving IPR infringements in the EU more than doubled from 2009 to 2012. In 2012, almost 90,000 detention cases were registered by Customs, involving almost 40 million detained articles (the value of the equivalent genuine products is estimated to be worth nearly EUR 1 billion<sup>19</sup>).

Effective IPR enforcement is of limited use if clear and suitable rules and procedures regarding IPR protection are not in place. Substantive rules (e.g. patentability criteria), including properly crafted exceptions, and procedures to protect IP, should be clear and proportionate. At the same time, the rules need to be strict enough to avoid IPRs being abused and becoming an end in themselves, and to ensure that rights are of adequate 'quality' to prevent a proliferation of spurious rights (e.g. bad faith registrations). Examination backlogs and low-quality rights create legal uncertainty that is detrimental to applicants and third parties.

#### 2.2.2. Public debate

Support for IPR systems in some sectors of public opinion has waned over recent years. A growing disregard of IPRs could reduce their intended benefits. The increasing prevalence (and lower cost) of infringing goods may have impacted consumer sentiment to the extent that consumers are more willing to buy them. Some recent initiatives have been affected by concerns expressed by the public. These concerns appear to be driven by a combination of factors. First, a perception of overreach by right-holders, making certain goods or services unaffordable and/or difficult to access. Second, a perception that counterfeiting and piracy are victimless crimes. Third, in some areas, a lack of awareness of the rationale and effects of IPRs and the economic and wider implications of their infringement on the economy.

While policymakers must continuously review whether the existing rules are suitable for today's challenges, a reasonable balance must be maintained between (1) the need to improve access to goods and services protected by IPRs and (2) the need to incentivise right-holders to continue to invest in innovation, and (3) the need to balance different fundamental rights.

Report on EU customs enforcement of IPRs: results at the EU border 2012: European Commission (2013).

Stronger enforcement alone will not solve this problem, which must be addressed through debate and awareness-raising, targeting consumers and producers. Consumers should be made more aware of the wider consequences of IPR infringement. These relate to incentives to create, but also the impact on the kind and number of works available, on the loss of EU jobs, if rights are weakened or made more difficult to enforce. This also applies in certain developing countries, where the production of goods infringing IPRs is often facilitated by weak IPR frameworks.

#### 2.2.3. The internet and IPR

The internet has become vital for many sectors, especially the cultural and creative ones. It accounts for about 3.4% of GDP in the 13 countries surveyed in a recent study<sup>20</sup>, and even 6% in the UK and Sweden. In the G8 countries, South Korea and Sweden, the internet economy has generated 21% of the growth in GDP from 2006 to 2011. While this growth has brought about huge opportunities, IP infringements on the internet are growing at an even faster rate (reportedly, almost a quarter of global internet traffic infringes copyright<sup>21</sup>). This involves not only digital goods such as music, audio-visual content and software, but also physical goods that are increasingly traded on e-commerce platforms.

This rapidly-changing environment, as well as the fact that the internet has no frontiers, unlike IP laws, makes it difficult to develop timely, well-balanced policies. WIPO's 'Internet treaties' – the WIPO Copyright Treaty (WCT) and the WIPO Performances and Phonograms Treaty (WPPT), adopted in 1996 – were a welcome development to address these issues, but many challenges remain.

One such regulatory challenge relates to the responsibility of intermediaries such as *internet service providers*. Given their role in both legitimate and infringing activities, their obligations continue to be debated. Service providers hosting IPR-infringing sites are especially problematic to tackle when established in third countries lacking appropriate legislation and/or willingness to act.

The legal framework needs to be properly balanced between rights of individuals on the one hand – including fundamental rights such as freedom of expression, protection of personal data, procedural rights – and respect for IP – also a fundamental right - on the other<sup>22</sup>.

In addition to public policy, creators and intermediaries need to cooperate in taking operational initiatives within the law to combat IPR infringements. This can be done through soft law measures that complement legal frameworks, for example initiatives, on a voluntary basis establishing a code of practice in the fight against such sales, and enhancing collaboration.<sup>23</sup>

Internet matters: The Net's sweeping impact on growth, jobs, and prosperity, M. Pélissié du Rausas et al., Report from McKinsey Global Institute, May 2011.

Technical report: An estimate of infringing use of the internet-Summary, Envisional, January 2011, http://www.mpaa.org/Resources/8aaaecf5-961e-4eda-8c21-9f4f53e08f19.pdf

Report of the Special Rapporteur on the promotion and protection of the right to freedom of opinion and expression, Frank La Rue, United Nations General Assembly- Human Rights Council. 17<sup>th</sup> session, Agenda item 3, A/HRC/17/27, May 2011.

As is the case with the *Memorandum of Understanding on the Sale of Counterfeit Goods over the Internet*, http://ec.europa.eu/internal\_market/iprenforcement/docs/memorandum\_04052011\_en.pdf

# 2.2.4. The potential contribution of IPRs to development

For developed, as for emerging and middle-income developing countries, experience and evidence suggest that effective IPRs have several benefits, especially when complemented by improvements in other aspects of the investment and business climate<sup>24</sup>.

## These include:

- leveraging the trade potential<sup>25</sup> of intellectual assets, e.g. agricultural products (including geographical indications and plant varieties)
- safeguarding tax revenues and jobs by combating IPR infringement more effectively
- improving legal certainty and promoting innovation, making it more conducive to inward investment and technology transfer<sup>26</sup>.
- indirect benefits that can exist on health and safety from eliminating IPR infringing goods should also not be underestimated<sup>27</sup>.

As noted earlier, emerging economies are increasingly becoming exporters of IP-intensive goods, and thus benefitting from stronger IP regimes, although these haven't reached EU standards yet. This absence of a level playing field with emerging countries harms EU and third countries' growth and development, and IP infringers seek to exploit such differences.

Effective IPR regimes, complemented by an enabling environment and sufficient capacity to absorb technology, can help developing countries to put in place a sound, viable technological base locally. They can upgrade R&D capabilities, prompt top-performing domestic firms to intensify their R&D activities, and give incentives to multinational firms to introduce innovation in these markets. In particular, such regimes can play a positive role in stimulating technology transfer and foreign direct investment – which involves opportunities for rights holders as well as for recipients – including technologies that may help solve global challenges such as climate change.

There are several types of technologies as well as several channels of transmission and indeed technology transfer is often one component of a more complex project, rather than a standalone activity. The acquisition by LDCs of a sound and viable technological base does not depend solely on the provision of physical objects or equipment, but also on the acquisition of know-how, on management and production skills, on improved access to knowledge sources as well as on adaptation to local economic, social and cultural conditions.

Intellectual Property Rights: Economic principles and trade rules, C. Fink, May 2007- revised version. In: Handbook of Trade Policy for Development, A. Lukauskas et al., Oxford Scholarship Online, 2014.

Creative economy report 2010: A feasible development option, partnership between UNCTAD and the UNDP Special Unit for South-South Cooperation, 2010, <a href="http://unctad.org/en/Docs/ditctab20103\_en.pdf">http://unctad.org/en/Docs/ditctab20103\_en.pdf</a>

Intellectual Property Rights, imitation, and foreign direct investment: theory and evidence, L. Branstetter et al., Working Paper 13033, National Bureau of Economic Research, Cambridge, 2007.

Record seizure of illicit medicines in Africa. The World Customs Organization (WCO) and the Institute of Research Against Counterfeit Medicines (IRACM) issue a new warning on the health and safety of African populations, Paris, 2013, http://www.wcoomd.org/en/media/newsroom/2013/june/wco-andiracm.aspx

The EU ensures a differentiation in its policy (as confirmed in a recent Commission Communication on "Trade, growth and development" by taking into account the level of development<sup>29</sup> and institutional capacity in developing countries. Depending on the country concerned, our Strategy may thus rely more on technical assistance in capacity building than on negotiations aiming to improve IPR regimes. In particular, the EU will fully honour the TRIPS requirement that developed countries should offer their companies incentives to transfer technology to least-developed countries (LDCs)<sup>30</sup>, in line with the approach presented in 2003<sup>31</sup>, and work to encourage LDCs to building enabling environments for technology transfer.

#### 2.2.5. Emerging economies

The growth rate of middle-income countries – and the increasing role they play in the world economy – represents enormous opportunities for EU and international business, but has also raised the stakes for IPR-owning companies, which are more exposed than before to IPRrelated risks abroad.

Some emerging economies have engaged in aggressive policies that seek to appropriate foreign technology and to boost national champions, in particular in sectors considered strategic, e.g. through 'forced technology transfer', local content requirements, and domestic innovation policies aimed at 'leapfrogging'<sup>32</sup>. Such policies, combined with rapidly growing capabilities of their companies and the lack of an effective IPR framework, mean that some companies resort to appropriating foreign IP through any means, in some cases through illegal means, and this is having an unprecedented effect on industrialised countries' industry. There are increasing reports that some of these activities may be State-sponsored<sup>33</sup>.

On the other hand, changes are occurring as many are increasingly recognising the benefits of IPRs to enhance their competitiveness as they seek to move up the value chain. Companies in these countries are therefore increasingly generating and protecting their own IP. For example in China, patent applications grew on average by 34% per year from 2003 to 2007, and European patent applications filed by Chinese entities increased about tenfold between 2001 and 2010.

Nevertheless, the risks of abusive practices to access EU technology must be effectively addressed. These may occur in areas such as:

Public procurement. Many EU companies suffer IPR-related problems such as breaches of confidentiality, protectionist measures entailing forced technology

<sup>28</sup> COM(2012)22 - Trade, growth and development. Tailoring trade and investment policy for those countries most inneed, European Commission, Belgium, 2012, http://trade.ec.europa.eu/doclib/docs/2012/january/tradoc 148992.EN.pdf

<sup>29</sup> http://content.undp.org/go/cms-service/stream/asset/?asset\_id=1948200 — see Chapter 11.

<sup>30</sup> Climate change and technology transfer. Can Intellectual Property Rights work for the poor?, K. Kretzschmar, Prague Global Policy Institute Glopolis, Prague, 2012.

<sup>31</sup> Communication from the European Communities and their Member States to the TRIPs Council of 13 February 2003, Ref. 032/03 – final.

I.e. accelerated economic development.

<sup>33</sup> Policy recommendations to combat state sponsored IP theft (SSIPT), Trans Atlantic Business Dialogue, http://transatlanticbusiness.org/s/TABD-Trade-Secrets-Policy-Recommendations-December-2012.pdf

transfer<sup>34</sup>, if not the mere offering (by third-country bidders) of technologies they have not acquired legitimately;

- Investment and conformity assessment procedures, where similar problems arise (e.g. making access to non-EU markets conditional on technology transfer, or conformity assessments requiring the disclosure of sensitive information without proper IP guarantees), along with other trade-restrictive measures<sup>35</sup>;

Situations in which third countries have implemented or are proposing measures imposing technology transfer on EU companies established locally must be closely monitored, and lead to action where appropriate.

#### 2.2.6. Research, innovation and ICT

The global landscape of research and innovation has changed drastically over the past decade. Emerging economies have invested considerably in the strengthening of their research and innovation systems and, as a result, a multipolar system is developing in which countries such as the BRICs exert increasing influence.

Research and innovation is increasingly an international endeavour. Internationally coauthored publications are on the rise, research organisations are establishing offices abroad and research and innovation investment of multinational companies is often targeted towards the emerging economies.

Societal challenges such as climate change and sustainable development are global. They require the EU to step up its cooperation on research and innovation with its international partners, while at the same time becoming more strategic in setting adequate framework conditions for cooperation. To this extent the Commission adopted in 2012 a new strategy for international cooperation in research and innovation<sup>36</sup>. While the strategy aims for an increase in cooperation activity, it also acknowledges the fact that this at the same time brings with it new risks and that the Union's economic interests must be safeguarded. In this context, increased efforts must also be made to ensure fair and equitable treatment of IPR in partner countries to avoid uncontrolled loss of the Union's know-how.

In the context of the ICT industry, which has to seek globally interoperable networks and devices, the global protection of IPR embedded in standards is also important. It is essential that the international standardisation system acknowledges not only the need to ensure access to the technologies included in international standards but also safeguards an efficient way to reward fairly and timely the investment in the development of these technologies.

# 2.2.7. The challenges of access to medicines

36

Access to affordable, safe and effective medicines is crucial to all countries, and the challenge is particularly large when it comes to LDCs and developing countries. Recognising this, the

Technology transfer to China: Guidance for businesses, China IPR SME Helpdesk, 2008, <a href="http://www.china-iprhelpdesk.eu/docs/publications/Tech transfer English.pdf">http://www.china-iprhelpdesk.eu/docs/publications/Tech transfer English.pdf</a>

DG TRADE, Ninth Report on Potentially Trade Restrictive Measures, September 2011-May 2012, Report on G-20 Trade Measures, WTO,

http://trade.ec.europa.eu/doclib/docs/2012/june/tradoc 149526.pdf COM(2012) 497.

EU is a major contributor to health-related aid - e.g. the *Global Fund to Fight AIDS*, *Tuberculosis and Malaria* and other key organisations<sup>37</sup>. It also initiated the European and Developing Countries Clinical Trials Partnership (EDCTP) to accelerate the clinical research development process for medicines against neglected diseases related to poverty.

The role of IP in access to medicines has been highly debated. As a recent WHO-WTO-WIPO study notes, the "lack of access to medical technologies is rarely due to a single isolated factor" There are many factors affecting access (explained in more detail in the accompanying *Commission Staff Working Document* (SEC(2013)30)), but mostly unrelated to IPRs, such as lack of access to quality health care, poor infrastructure, lack of distribution and supply systems, and lack of quality control. Still, IPRs may affect the price of medicines. The challenge is to come up with a broad response to this complex and multifaceted problem and to ensure affordable access to medicines without undermining the incentives needed for continued pharmaceutical research. It should be noted that generic medicines play an important role and should not be equated with counterfeit medicines.

The EU addresses these IPR challenges, in line with a European Parliament resolution<sup>40</sup>, through policies intended to reduce obstacles to trade in both innovative and generic medicines, while also promoting innovation and curbing trade in counterfeit and falsified medicines that can be dangerous for patients<sup>41</sup>.

# In particular, the EU:

- ensures that any multilateral and bilateral agreements reflect these objectives;
- supports the *Doha Declaration on TRIPS and Public Health* (implemented through Regulation 816/2006);
- has adopted rules on 'tiered pricing' 42,43,44 and harmonised clinical trial exceptions 45.

The Commission is also looking into ways of improving its support for developing countries implementing the TRIPS Agreement — including its flexibilities in appropriate cases, such as health emergencies.

# 2.2.8. Environmental challenges

IP can bring an important contribution to solving global environmental challenges. Despite

2'

Including GAVI, WHO, UNICEF.

Promoting Access to Medical Technologies and Innovation. Intersections between public health, intellectual property and trade, Trilateral study by WHO, WIPO and WTO, Geneva, 2012.

It is worth noting that certain concepts such as substandard, spurious or falsified medicines do not entail any IPR aspects – see related WHO discussion at <a href="http://apps.who.int/gb/ssffc/pdf\_files/A64\_16-en.pdf">http://apps.who.int/gb/ssffc/pdf\_files/A64\_16-en.pdf</a>

European Parliament Resolution of 12 July 2007, B6-0288/2007.

Counterfeit drugs kill!, final brochure WHO and IMPACT, Updated May 2008, http://www.who.int/impact/FinalBrochureWHA2008a.pdf

Council Regulation (EC) No 953/2003 of 26 May 2003 to avoid trade diversion into the European Union of certain key medicines, OJ L135/5, 3.6.2003.

I.e. prices enabling exporters to deliver essential medicines to poor countries at prices only slightly above their own production costs.

The EU will initiate an evaluation of Regulation 953/2003 in 2014.

The EU introduced a 'Bolar-type exemption' in Directive 2004/27/EC.

attempts to weaken IPR protection (e.g. through systematic compulsory licensing or patentability exclusions), IPR incentives are crucial to promote investment<sup>46</sup> in green technologies. With regard to climate change, appropriate IPR regimes can play a positive role in stimulating the transfer and dissemination of innovative green technologies, which involves opportunities for right holders as well as for recipients.

The EU has been at the forefront in climate change discussions to promote and provide climate finance, which includes support for green technology. The EU also actively contributed to the successful conclusion of negotiations on the Nagoya Protocol to the Convention on Biological Diversity (CBD) on access to genetic resources and the sharing of benefits arising from their use. The EU implemented and ratified the Nagoya Protocol in April 2014 and will continue to play an active role in the global debate on IPR-related environmental issues.

#### 3. A REVISED IPR STRATEGY VIS A VIS THIRD COUNTRIES

It is appropriate to update the 2004 strategy to take account of the insights from the 2010 evaluation, and generally pursue the challenges reviewed above.

While right-holders are responsible for taking adequate steps to protect and enforce their IPRs both in the EU and in third countries, and for adopting operational measures (e.g. technological protection measures for digital copyrighted works), public authorities also have their role to play, namely by providing a framework that supports innovation and creativity and protects IPRs. The EU has a range of 'tools' available, such as working through international organisations or bilateral agreements, monitoring and reporting on the adequacy of IP protection and enforcement in third countries, and cooperating with third countries to address specific IPR problems.

The effectiveness of these tools varies greatly. In some cases the EU has legal rights that can ultimately be enforced e.g. through dispute settlement procedures. In other cases the EU's ability to achieve results depends on the willingness of third countries to address its concerns.

In the EU focus is placed on the economic potential of IP and its role as a key driver for innovation, growth and employment. IPRs are indeed paramount for the inventor's/creator's trail as they provide a safe environment in which ideas can be first invented and then brought to market, rewarding investment. IPRs are also assets for innovative companies as they help them attract funding and therefore allow them to thrive, create jobs, propose new products and services to consumers and finally export these products and services to third countries. This virtuous circle induced by the inventor's/creator's trail can have a similar positive impact on growth and employment in third countries.

Are IPR a barrier to the transfer of climate change technology?, Report commissioned by the European Commission (DG Trade), Copenhagen Economics A/S and The IPR Company ApS, 2009, http://trade.ec.europa.eu/doclib/docs/2009/february/tradoc\_142371.pdf

#### Improving stakeholder engagement 3.1.

#### *3.1.1.* Present situation

The increasingly tangible influence of IPR policy on our daily lives means that it is more than ever in the public eye and, naturally, increasingly discussed in a wider spectrum of debate. Certain IP policy initiatives have suffered from negative reactions which have resulted in their rejection, whether at European level (cf. the proposed Anti-Counterfeiting Trade Agreement) or elsewhere (cf. the SOPA and PIPA legislative proposals in the USA). There are different reasons for the failure of these initiatives, but a common thread was a view that public concerns had not been sufficiently taken into account, e.g. whether these rules were fit for a digital economy or the impact these measures might have on fundamental rights as well as what is referred to as 'internet freedoms'.

#### *3.1.2.* Way forward

Recent debate has revealed a need for broader dialogue with stakeholders about the role and importance of IP and the impact of IPR infringements. It is also important to ensure that the IP framework remains flexible enough to facilitate, rather than obstruct, the capacity for digital technology to deliver growth while at the same time stimulating innovation.

There is thus a need to improve interaction not just with right-holders, but also with public authorities, civil society (possibly using existing mechanisms such as the Commission's Civil Society Dialogue and Market Access Strategy tools)<sup>47</sup> and the European Parliament so as to discuss the EU's goals and the impact of IPR infringements in third countries, and explain the EU's efforts to enhance IPR enforcement in those countries and the environment to promote the inventor trail.

#### 3.2. Providing better data

#### 3.2.1. Present situation

In the last 15 years research into the economics of IP has expanded considerably (of which the recent study on the contribution of IP to economic performance and employment in Europe is particularly valuable)<sup>48</sup>. Certain data such as the scale and impact of IPR infringements is inherently difficult to obtain given that it deals with an underground phenomenon and because right-holders are often reluctant to disclose details<sup>49</sup>. There are still areas where further studies are needed to support evidence-based policy-making and to more precisely quantify the role of IP and the impact of IPR infringements.

<sup>47</sup> 

http://ec.europa.eu/trade/creating-opportunities/trade-topics/market-access/

http://ec.europa.eu/internal\_market/intellectual-property/docs/joint-report-epo-ohim-finalversion en.pdf

Thus, although the 2010 evaluation study rightfully states that "While there are numerous indications that the volumes of IPR infringements are increasing, the overall degree to which products are being counterfeited and pirated is unknown, and there are, as yet, no methodologies that could be employed to develop an accurate overall estimate", there are limits to what can be done in the circumstances.

Various industry associations (e.g. BSA, IIPA) and law firms<sup>50</sup> publish reports on specific sectors, and key international organisations such as the OECD and WIPO are also performing similar work.

# 3.2.2. Way forward

Improved data will be important to policymakers for informed policy debate and any awareness raising efforts; there are already several on-going initiatives. The Commission annually compiles data regarding goods detained at EU borders<sup>51</sup>, suspected of infringing IP rights, and has set up a *European Observatory on Infringements of Intellectual Property Rights*<sup>52</sup>. Among other tasks, the *Observatory* should ensure that comprehensive and reliable data is available regarding IPR infringements in the EU. In 2013 it produced the aforementioned study on the value of IP in the EU, and has also published a study on the public perception of IPR. It will also produce 'country guides' on several key countries. The Commission regularly conducts surveys about the IPR situation in non-EU countries<sup>53</sup> (the technical background of which is now provided by the Observatory), which help to establish priorities and to inform stakeholders.

## 3.3. Building on EU legislation

#### 3.3.1. Present situation

Harmonisation has intrinsic benefits in creating a simpler and more predictable framework for consumers and industry, which contributes to growth and jobs. Moreover, harmonised EU IPR legislation (e.g. the *Customs Regulation*<sup>54</sup> or the *Enforcement Directive*<sup>55</sup>) facilitates negotiations with third countries because it provides a clear basis for establishing the EU's negotiating position.

In recent Free Trade Agreement negotiations requests have often been made, for example, to include the protection of trade secrets, and certain non-food products as geographical indications, of which there is currently no EU acquis. The lack of EU harmonisation in some IPR areas, therefore, can complicate or at least limit the EU's scope for addressing some IP issues through negotiations with non-EU countries.

# 3.3.2. Way forward

The Commission is launching a new Communication on an Action Plan addressing Intellectual Property infringements in the EU. Non-legislative actions are envisaged in promoting proportionate and equitable IP enforcement measures, and prioritising policy actions to bring more focus, better coordination and streamlining to current policies in protecting IPR.

http://www.taylorwessing.com/ipindex

http://ec.europa.eu/taxation\_customs/customs controls/counterfeit\_piracy/statistics

http://ec.europa.eu/internal\_market/iprenforcement/observatory/index\_en.htm

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

Regulation (EU) No 608/2013 of the European Parliament and of the Council of 12 June 2013 concerning customs enforcement of intellectual property rights and repealing Council Regulation (EC) No 1383/2003, OJ L181/15, 29.6.2013.

Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights, OJ L157/45, 30.4.2004.

The Commission has also recently adopted a legislative proposal (directive) on trade secrets (as part of the 2013 Commission Work Programme) in order to improve conditions in the EU for innovative business activity. Given the importance of trade secrets, this may inspire others to follow suit in providing such protection.

As harmonisation may be promoted not only at EU level but also by international treaties, it would increase the EU's leverage if all Member States ratified the relevant international treaties. For example, some treaties such as the *Trademark Law Treaty* and the *Geneva Act of the Hague Agreement* (concerning industrial designs), for instance, have been signed by the EU but not by all of its Member States.

# 3.4. Enhancing cooperation within the EU

#### 3.4.1. Present situation

Cooperation between the Commission and Member States on the ground in non-EU countries is often good. It is important that Member States' diplomatic representations and EU Delegations are better aware of each other's activities in third countries. This ensures a strategic, coherent approach, and enhances the EU's ability to effectively address IP issues in the countries concerned.

# 3.4.2. Way forward

The scope for further improving the cooperation between the Commission and Member States (of information sharing, for example) should be explored building on the partnership that has, for example, been established between the Commission, Member States and business to implement the *market access strategy* and thus to be more resource-efficient.

# 3.5. Improving protection and enforcement of IPRs in third countries

#### 3.5.1. Multilateral and plurilateral level

#### 3.5.1.1. Present situation

International harmonisation enables broad alignment of rules and thereby a more predictable IP environment. It entails the negotiation of new multilateral treaties, their ratification and implementation, as well as the extension of their membership to more non-EU countries (e.g. UPOV for plant variety protection). In the post-TRIPS era, however, only a few significant multilateral IPR agreements have been concluded (e.g. WIPO's *internet treaties*<sup>56</sup>, and the Marrakesh<sup>57</sup> and Beijing<sup>58</sup> treaties).

As the 2010 evaluation study noted, "The Commission was an active contributor to IP enforcement at multilateral level, in particular at the WTO TRIPS Council, but it reaped only limited rewards owing mainly to third country opposition." Regarding geographical

-

WIPO Copyright Treaty, WIPO Performances and Phonograms Treaty

Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired or Otherwise Print Disabled

Beijing Treaty on Audio-visual Performances

indications<sup>59</sup>, longstanding negotiations have been taking place in the WTO and will continue to be pursued by the EU.

A plurilateral approach can be effective for smaller groups of countries sharing similar policy objectives.

# 3.5.1.2. Way forward

While these options should be used wherever they are available, opportunities are infrequent, and therefore other approaches merit attention. This does not mean that our efforts regarding multilateral work should be halted – for instance we will continue to promote better protection of geographical indications in the WTO and will also promote sound protection of GI's on the internet. At the same time it may be appropriate to reflect on a new strategy for WIPO to make the organisation better deliver on its mandate.

#### 3.5.2. Bilateral level

There is a need to focus efforts and resources on the most relevant countries. Bilateral interactions – of which several categories exist, as set out below – offer a useful opportunity to address in a tailored way specific issues and needs of individual partners (particularly with our 'priority countries'). Bilateral work can also be continued with relevant regional intellectual property organisations (e.g. OAPI, ARIPO<sup>60</sup>).

#### 3.5.2.1. Present situation

# - Bilateral trade agreements

Such agreements can address country-specific IPR challenges, and have "facilitated more progress on IPR enforcement in third countries", as the 2010 evaluation study noted. We take as a reference the existing EU legislation, and calibrate our level of ambition to the partner country's level of development. For least-developed countries and poorer developing countries, a more limited set of IPR provisions may be considered.

Recently concluded negotiations on trade agreements by the European Union have successfully integrated chapters on IP protection and enforcement. The most recent, those with countries in the Eastern Partnership (e.g. Georgia, Moldova, Ukraine) achieved significant regulatory standards as per the EU acquis. Others contain substantial improvements on TRIPS (e.g. Canada, Republic of Korea, Singapore) while others are also notable for improving beyond minimum international standards (e.g. Central America, Colombia, Peru).

Current negotiations on trade agreements include those with Mercosur, Morocco, Japan, Thailand, the US and Vietnam. A bilateral agreement specifically addressing the protection of geographical indications is under negotiation with China.

I.e. the negotiation of the establishment of a multilateral system of notification and registration of geographical indications for wines and spirits, and issues related to the extension of the protection of geographical indications provided for in Article 23 TRIPS to products other than wines and spirits.

Organisation Africaine de la Propriété Intellectuelle (OAPI), African Regional Industrial Property Organisation (ARIPO)

# IP Dialogues

For countries with which the EU is not engaged in negotiations, a practical way to address IPR challenges is to set up 'IP dialogues' or 'IP Working Groups' involving regular interactions between the EU and the relevant authorities in non-EU countries. The 2010 evaluation study highlighted the positive contribution of IP Dialogues to "raising the awareness levels of national authorities on these matters and to clarifying mutual interpretations and positions."

Several IP Dialogues are now underway. These enable the Commission to raise systemic IP issues, to share best practices and, where appropriate, to offer developing countries assistance, e.g. in developing domestic legislation and enforcement practices. The IP Dialogue and IP Working Group with China, for instance, enabled the EU to obtain commitments for strengthened enforcement activities, such as the so-called 'special campaign', and to provide input to domestic reviews of Chinese IP law. There are also Dialogues with partners that have similar IPR regimes, e.g. the US and Japan, to exchange information and views on problems and best practices.

IPR enforcement is also a priority identified in the EU's bilateral customs cooperation agreements. In this context, a new EU-China Customs Action plan on IPR enforcement was recently signed for the years 2014-2017.

#### Technical assistance

Developing countries wishing to improve their IPR system often lack the skills and/or resources to do so. IPR-related technical assistance aims to address this 61, through activities such as training of officials, awareness-raising and legislative assistance (e.g. to comply with international commitments, and to utilise available flexibilities).

While the impact of technical assistance actions is rarely felt in the short-term, the 2010 evaluation study noted that "EU funded projects and technical assistance have enhanced the technical capacity of national institutions and law enforcement agencies (LEAs) to handle IPR cases."

For example, the successful 'EU-China Project on the Protection of Intellectual Property Rights' (IPR2, 2007-11), with EUR 16 million in joint funding, reflects a mutual commitment to effective IPR enforcement in China. Involving organisations such as the European Patent Office, the Office of Harmonisation for the Internal Market (including through possible secondments to EU Delegations) and the Community Plant Variety Office will enhance our capacity to design and implement effective assistance.

# Dispute settlement and other remedies

The EU continues to monitor the IPR situation in third countries, and to push for compliance with international agreements, in particular through dialogue and negotiation. WTO dispute settlement procedures can also be resorted to for breaches of the TRIPS Agreement. Indeed, the mere existence of these procedures can act as a deterring mechanism to potential infringements. Similar procedures are also built into most of our bilateral trade agreements.

<sup>61</sup> 

The *Trade Barriers Regulation*<sup>62</sup> — which enables EU companies to lodge complaints regarding possible violations of international trade rules — has already been used to address breaches of IP rules, and remains available for use in appropriate cases.

# 3.5.2.2. Way forward

Although they are more resource-intensive than multilateral or plurilateral avenues, such bilateral ways of action have been intensively resorted to in the past, with positive results, and should still be pursued under the revised Strategy. It is important to aim at better coherence between IPR and other policies.

One example is in relation to the Union's strategy for engaging in international cooperation on research and innovation, where ensuring fair and equitable treatment of IPR by the Union's partner countries is of the utmost importance. The Union's funding programmes for research and innovation, currently Horizon 2020, are fully open to participation from international partner countries, offering access to a European internal market with predictable and fair rules as regards IP protection. A long term goal should be to strive for this openness to be reciprocated by all of the Union's partner countries, including by ensuring equivalent protection of IPR.

In the context of trade defence instruments, granting market economy status depends, amongst other criteria, on IP protection in the country concerned.

For countries that persistently break international commitments on IP rules in ways that have a major impact on the EU, and where the authorities are unwilling to cooperate or where cooperation shows limited results, the Commission may consider restricting their participation or funding in specific EU-funded programmes in sufficiently serious and clearly targeted cases. This would not affect programmes financed by the European Development Fund or Development Cooperation Instrument. Commission policy dialogues with partner countries might also be utilised to engage on serious IPR infringement issues. To ensure coherence, efforts should be made to encourage Member States to apply such or other approaches in tandem.

As regards *Free Trade Agreements* it must however be recognised that the negotiation of IPR chapters will remain challenging. Many of the countries that the EU is in negotiations with (or about to start negotiations) have the perception that they stand little to gain from a strong IPR regime. To achieve meaningful outcome for the EU will therefore require continuous awareness-raising and outreach for all stakeholders at both technical and at times at political level.

# 3.6. Providing assistance to EU right holders in third countries

# 3.6.1. Present situation

Having expertise available on the ground is of great benefit both to assist EU right-holders<sup>63</sup> and to facilitate EU interactions with local authorities. This is why several Member States have 'IP attachés' within their delegations in key countries. For this reason as well, the

E.g. the *China IPR SME Helpdesk* — http://www.china-iprhelpdesk.eu

http://ec.europa.eu/trade/tackling-unfair-trade/trade-barriers

Commission has established three IPR Helpdesks to provide assistance for EU firms, especially SMEs. These helpdesks cover Greater China, South-East Asia, and South America. They aim to enable European SMEs to make the best IPR decisions for their business and to ensure they know how to effectively protect their intangible assets<sup>64</sup>.

# *3.6.2. Way forward*

The EU will explore the possibility for increasing the availability of IP expertise in EU Delegations in key regions, either through additional staff or through *IPR Helpdesks*. In the context of the 2014-2020 multiannual financial framework<sup>65</sup>, the Commission is considering extending the Helpdesk services for SMEs adapting them to new needs. The increase of IP expertise in EU delegations would build upon and integrate better existing resources (IP knowledge of attaches in EU delegations and Member States embassies, and IPR Helpdesks). The Commission and Member States would also ensure that the IP expertise is widely shared through EU initiatives that support the international expansion of SMEs<sup>66</sup>. This would allow the benefits of on-going networking to be extended, ensure better information to be gathered about the IP situation in key regions and allow businesses to better know the IP practices they would need to take into account when going international.

# 3.7. Geographical focus

#### 3.7.1. Present situation

Every two years, on the basis of a wide survey amongst European and international stakeholders, the EU updates its list of priority countries where EU right-holders suffer inadequate IPR protection and/or enforcement<sup>67</sup>.

### 3.7.2. Way forward

Such prioritisation has worked well and will continue since it enables a focused and resource-efficient approach.

#### 3.8. Action points

The present Strategy is intended to ensure continuity to the policy pursued by the European Union since 2004, by building on what worked well and enhancing it in view of the significant technological changes and IPR-related new challenges and societal evolutions arisen in the last 10 years. In order to tackle the above-mentioned issues, the following action points will be taken up by the Commission:

-

The helpdesks cooperate with local organisations and provide the following services: first-line personalised expert advice, general and customised training materials, specialised training workshops, liaison with outside experts and with target regions government administrations, business networking and awareness events.

See COSME (EU programme for the Competitiveness of Enterprises and Small and Medium-sized Enterprises), http://ec.europa.eu/enterprise/initiatives/cosme/index\_en.htm

http://ec.europa.eu/enterprise/policies/sme/documents/internationalisation/

See Commission Staff Working Document SWD(2013)30, http://trade.ec.europa.eu/doclib/docs/2013/march/tradoc\_150789.pdf

- Ensure regular interaction with all stakeholders to raise awareness and guide policy;
- Enhance data collection and reporting, so as to improve the understanding of the role of IPR and the impact of infringement; conduct regular surveys in order to maintain a list of 'priority countries' for focused EU efforts;
- Ensure a strong and coherent role for the EU in international IPR for a in line with the Lisbon Treaty;
- Continue multilateral efforts to improve the international IPR framework, including by encouraging further ratification of existing treaties; promote ratification of relevant IPR treaties by all EU Member States;
- Ensure that IPR chapters in bilateral trade agreements offer adequate and efficient protection for right-holders and address key weaknesses in partner countries' IPR systems while calibrating commitments to third countries' level of development;
- Ensure the Commission can make recourse to dispute settlement mechanisms or other remedies where the EU's rights under international agreements are infringed;
- Continue and where possible enhance 'IP Dialogues' with key third countries; leverage high-level trade and political dialogues to ensure progress on identified IPR issues;
- Provide and promote awareness of appropriate IP-related technical assistance programmes to third countries, including on the possible use of IP flexibilities; leverage the expertise of relevant international organisations in implementing technical assistance programmes;
- Establish a stronger relationship between the Commission, Member States and EU business to directly support economic operators in overcoming concrete difficulties on IP issues; enhance networking and coordination of actions between EU and Member States representations in third countries;
- Aim at better coherence between IPR and other policies, e.g. consider restricting participation or funding in specific EU-funded programmes in sufficiently serious and clearly targeted cases, and to improve coherence between the Commission and Member States in third countries in this goal;
- Continue assistance to right-holders (through projects such as *IPR Helpdesks*) and consider their possible expansion; consider further posting of *IPR* experts to key EU delegations.