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Trade, growth and intellectual property

Accompanying the document

**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"**

{COM(2014) 389 final}

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1. INTRODUCTION

This document accompanies the Commission Communication entitled '*Trade, growth and intellectual property — Strategy for the protection and enforcement of intellectual property rights in third countries*'. The new Communication follows on from the *Strategy for the enforcement of IPRs in third countries*¹ adopted by the Commission in 2004. The 2004 Strategy and a recent assessment of its impact are summarised in chapter 4 below.

The challenges to intellectual property (IP) have evolved considerably in the last 10 years, both in nature and scope. This paper will describe this evolution against the background of the continued relevance of IP and of the socio-economic impact of IP abuse, and focus on today's key challenges to the protection and enforcement of intellectual property rights (IPR). This analysis has led the Commission to review and update its current IPR strategy vis-à-vis third countries, which is spelt out in the Communication. Implementing a revised strategy will not only support continued technological innovation within the EU and thus drive long-term economic growth, but will also help to achieve wider societal objectives both in the EU and in the developing world.

Previous positions of the Commission

The new strategy is linked to several other Commission initiatives, such as the '*Europe 2020*' strategy², which cites intellectual property rights (IPR) as one of the means to '*improve framework conditions for business to innovate*', the '*Trade and Investment Barriers Report 2011*'³, the 2010 Communication on the future Trade policy⁴, and a series of Communications regarding trade ('*Global Europe: Competing in the World*'⁵) and IPR protection in the internal market (e.g. '*Enhancing the patent system in Europe*'⁶ in 2007, '*An Industrial Property Rights Strategy for Europe*'⁷ in 2008, '*A Single Market for Intellectual Property Rights*'⁸ in 2011).

Position of other EU institutions

Other EU institutions have also called for an effective IPR strategy vis-à-vis non-EU countries.

¹ Strategy for the enforcement of intellectual property rights in third countries, 2005/C129/03, OJ C129, 26.5.2005.

² Europe 2020 Strategy (COM(2010) 2020).

³ Trade and investment barriers report 2011 (COM(2011) 114).

⁴ Trade, growth and world affairs. Trade policy as a core component of the EU's 2020 Strategy (COM(2010) 612).

⁵ 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.

⁶ Communication enhancing the patent system in Europe, of 3 of April 2007, COM(2007) 165 final.

⁷ Communication on an Industrial Property Rights Strategy for Europe, of 16 July 2008, COM(2008) 465 final.

⁸ Communication on a single market for Intellectual Property Rights boosting creativity and innovation to provide economic growth, high quality jobs and first class products and services in Europe, of 24 May 2011, COM(2011) 287 final.

In 2008, the Council adopted a Resolution⁹ inviting the Commission and the Member States to ‘*step up the protection of intellectual property rights internationally*’, followed in 2009 by another Resolution defining a *EU Customs Action Plan to Combat IPR Infringements 2009-2012*¹⁰ (updated in 2012¹¹) which included a section on *International cooperation*. In this respect, the new Council Resolution on the EU Customs Action Plan to combat IPR infringements for the years 2013 to 2017 (OJ C80 - 19.3.2013) is also aiming to strengthen cooperation with key source, transit and destination countries and to build capacity in candidate and neighbouring countries on IPR enforcement actions.

The European Parliament has frequently called for better protection and enforcement of IPR. For instance, in its Resolution of 22 September 2010¹² the European Parliament:

- ‘*Calls on the Commission to step up its cooperation with priority third countries with regard to intellectual property and promote a balanced approach in the context of the negotiations on intellectual property*’;
- ‘*Supports the continuation and enhancement by the Commission of bilateral cooperation initiatives*’; and
- ‘*Notes that the biggest challenge for the internal market lies in combating infringements of intellectual property rights at the EU’s external borders and in third countries; in this respect, calls on the Commission to create more intellectual property helpdesks in third countries (notably in India and Russia)...*’.

2. THE RELEVANCE OF INTELLECTUAL PROPERTY RIGHTS

The protection of intellectual property is recognised as a right in the *Universal Declaration of Human Rights*¹³ and also in the *Charter of Fundamental Rights of the European Union*¹⁴.

The rationale behind intellectual property regimes is that, in the absence of rules safeguarding creators and other producers of intellectual goods and services by granting them certain time-limited rights to control the use made of those productions, the low(er) cost of copying such works will enable competitors to profit from someone else's efforts without expending any energy or costs other than the relatively minor costs required to duplicate the socially valuable creation. If the ‘original’ creators are not able to reap pecuniary rewards for their efforts or even recover their costs, because competitors are simply copying their works and undercutting

⁹ Council Resolution of 25 September 2008 on a comprehensive European anti-counterfeiting and anti-piracy plan, OJ C253, 4.10.2008.

¹⁰ Council Resolution of 16 March 2009 on the EU Customs Action Plan to combat Intellectual Property Rights infringements for the years 2009 to 2012, OJ C71, 25.3.2009.

¹¹ Resolution on the EU Customs Action Plan to combat Intellectual Property Rights infringements (2013 to 2017), of 10 December 2012, Council of the European Union.

¹² Enforcement of Intellectual Property Rights in the internal market. European Parliament Resolution of 22 September 2010, 2009/2178(INI).

¹³ Cf. Art. 27.2: ‘*Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author*’, <http://www.un.org/en/documents/udhr/index.shtml>

¹⁴ Cf. Art. 17.2: ‘*Intellectual property shall be protected*’, http://www.europarl.europa.eu/charter/pdf/text_en.pdf

their prices, this will in turn greatly reduce, or even eliminate, the incentives to develop new knowledge and create new forms of innovative expressions.

However, all intellectual property rights are an attempt to balance two public goods — the need for new innovative works on the one hand, and affordable access to them on the other. Striking the right balance between the interests of right-holders and those of society in general has always been delicate. It goes to the heart of how we stimulate innovation, not only to enable progress and enjoy culture, but also to help solve wider societal issues.

IPR legislation has always varied widely, across countries and over time. That is why new measures have been adopted periodically to address new situations, for instance, to facilitate access to medicines in developing countries, or to protect emerging technologies.

Moreover, IPR promotes the dissemination of knowledge and technology, as well as competition. As a *World Bank* study on IPR and Development put it¹⁵: *‘Seen properly, IPRs do not necessarily generate monopoly market positions that result in high prices, limited access, and exclusive use of technologies. They are more similar to standard property rights, in that they define the conditions within which a right owner competes with rivals (UNCTAD 1996). Except in particular sectors, cases are infrequent in which a patent holder or copyright owner becomes a strong monopolist. Rather, there are likely to be competing products and technologies, including new ones that do not infringe the property right.’*

Adequate IPR regimes are conducive to innovation, especially for technological companies. Moreover, the protection of IPR is a pre-requisite to its licensing, which may enable companies to generate additional revenue without any need to expand their production capacities. Similar reasoning applies to universities and other public research organisations, which have no industrial/commercial activities but can leverage their Research and Development (R&D) results by licensing them.

A climate favourable to innovation and creativity depends on a well-functioning IPR system that covers the entire spectrum of IPRs, including in particular patents, trademarks, copyrights, designs and geographical indications, as well as trade secrets. It also requires effective mechanisms to enforce these rights when they are abused by others, since protection without enforcement is of little use.

2.1. Economic relevance of IPR

IPRs have been described as the ‘currency of the knowledge economy’. The EU competitiveness (growth and jobs) relies heavily on inventions and other intellectual assets, rather than on tangible assets such as raw materials or basic manufactured goods.

The economic and trade relevance of intellectual property has led the EU and other countries to promote harmonising and strengthening of IPR protection and enforcement worldwide, either bilaterally or multilaterally. Creating a level playing field of regulatory frameworks facilitates trade for all countries concerned, whether developed or developing. It is also an important factor in attracting foreign investment, promoting transfer of technology, and

¹⁵ *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.

ensuring citizens' access to the most innovative and efficient technologies. Nevertheless, it is not a simple task to obtain precise figures about the overall value or impact of IPR in the economy. There are millions of right-holders for the different types of intellectual property (copyright, trademarks, patents, geographical indications, designs, plant varieties, etc.), covering the entire range of the economic activity (from culture to agriculture, from pharmacy to aircraft manufacturing, from software to textiles). Available data is often either limited to specific sectors, limited to specific countries or regions or relatively outdated, and the methodology used varies. Some data is provided by stakeholders and has therefore been subject to criticism about its objectivity. There is consequently a pressing need to work on a more precise quantification of the value of IPR.

Recently the European Observatory on Infringements of Intellectual Property Rights, together with the European Patent Office (EPO), produced a noteworthy study demonstrating the considerable impact that IPR has on the European economy. In the EU, around 39% of total economic activity (worth some EUR4.7 trillion annually) is generated by IPR-intensive industries, and approximately 26% of all employment (56 million jobs) is provided directly by these industries. Also, 90% of EU exports are accounted for by IPR-intensive industries¹⁶.

Other studies have shown that:

- Between 50 % and 80% of the market value of many large companies derives from their intellectual property¹⁷.
- In 2012, the EU exported over EUR 39 billion a year in licenses and royalties. This covers only the income for IPR related services, i.e. for the remuneration received for allowing third parties to use certain intellectual properties. It is therefore only a fraction of the much higher income resulting from the exports of physical goods incorporating IPR, such as cars, pharmaceuticals, chemicals, luxury goods, wines & spirits, etc.¹⁸
- The value of the top 10 brands in each EU country amounts to almost 10% of GDP per capita. In smaller countries, valuable brands can amount to over 30% of GDP per capita.¹⁹
- Trade mark intensive industries account for 21% of EU27 employment, i.e. they employ 45.6 million people.²⁰

¹⁶ *Intellectual property rights intensive industries: contribution to economic performance and employment in the European Union*, Industry-Level Analysis Report, Joint project between the EPO and OHIM, Munich and Alicante, 2013.

¹⁷ *Redefining Intellectual Property Value – The case of China*, Price Waterhouse & Coopers, 2005, http://www.pwc.com/en_us/us/technology-innovation-center/assets/ipr-web_x.pdf. Previously, in 2002, a survey of the Fortune 500 companies estimated that anywhere from 45% to 75% of the wealth of individual companies comes from their Intellectual Property Rights.

¹⁸ Eurostat International transactions in royalties and licence fees: exports, imports and balance (2012) http://epp.eurostat.ec.europa.eu/portal/page/portal/product_details/dataset?p_product_code=TEC00071

¹⁹ Commission Staff Working paper Impact Assessment: Accompanying document to the proposal for a Regulation of the European Parliament and of the Council amending Council Regulation (EC) No. 207/2009 of 26 February 2009 on the Community Trade Mark and the proposal for a Directive of the European Parliament and of the Council to approximate the laws of the Member States relating to trade marks. <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:52013SC0095>

- Employment in creative industries increased by an average of 3.5% a year in the period 2000-2007, against just 1.0% a year for the EU economy as a whole²¹.
- Book publishing employs 140 000 people full-time and contributes approximately EUR 23 billion to EU GDP²².
- The total value of the EU recorded music market is around EUR 6 billion. The recorded music market accounts for about a fifth of the music market, which as a whole is worth close to EUR 30 billion²³.
- Motion picture production, distribution and box office takings, as well as video rentals and sales account for 10% of copyright turnover. The audio-visual industry in Europe produces more than 1 100 films a year and employs over a million people²⁴.

2.2. Economic impact of IP abuse

IPR infringement and its economic impact are intrinsically difficult to quantify^{25,26}, particularly due to the illegal and underground nature of the phenomenon. Moreover, while infringements of patents and trade secrets may entail significant financial losses for individual companies (e.g. regarding technologies applied in costly goods such as railway equipment or power plants), they are often more difficult to assess than for consumer goods protected by trademarks or designs. Internet-based copyright infringements are also difficult to identify and measure, considering the intangible nature of digital goods as well as the ease of copying and disseminating these.

Due to inherent difficulties, the attempts that have been made to quantify the impacts of IPR infringement are often criticised^{27,28}, especially when provided by industry. However, even if some bias cannot be ruled out, industry is well placed to assess the extent to which it is itself affected by IPR infringement, and its data should not simply be disregarded. Furthermore, the lack of coherence of the available data sources is also a problem, as it is obviously not easy, and sometimes impossible, to compare or combine sets of figures concerning different geographical areas, different sectors, different IPRs and/or different periods.

All of these considerations point to the need for more reliable and coherent data on IPR infringement. At EU level, this reasoning led to the creation of a *European Observatory on Infringements of Intellectual Property Rights*²⁹ in 2011. One of its priorities is to assist the

²⁰ Supra note 16.

²¹ European Competitiveness Report 2010, Commission Staff Working Document, SEC(2010) 1276

²² Federation of European Publishers: <http://fep-fee.eu/The-profession,16>

²³ http://europa.eu/rapid/press-release_IP-13-931_en.htm?locale=FR

²⁴ *Multi-territory licensing of audiovisual works in the European Union*, KEA study, October 2010, p. 2, <http://www.keanet.eu/docs/mtl%20-%20full%20report%20en.pdf>

²⁵ As confirmed e.g. in a US governmental report in 2010: <http://www.gao.gov/new.items/d10423.pdf>

²⁶ *Measuring IPR infringements in the internal market. Development of a new approach to estimating the impact of infringements on sales*, S. Hoorens et al., Rand Europe (prepared for the European Commission), Cambridge, 2012.

²⁷ *Revue internationale de droit économique* 2009/3, De Boeck Supérieur; see § 2.1.

²⁸ *Is the devil in the data? A literature review of piracy around the world*, N. K. Kariithi, *The Journal of World Intellectual Property*, 2011, <http://onlinelibrary.wiley.com/doi/10.1111/j.1747-1796.2010.00412.x/pdf>

²⁹ http://ec.europa.eu/internal_market/iprenforcement/observatory/index_en.htm

Commission in the development of a methodology that quantifies the scope, scale and impact of IPR infringements on the European economy. The Commission presented a first report on *Measuring IPR infringements in the internal market* in September 2012³⁰. In 2013 the Observatory and EPO published a study on the contribution of IP to economic performance and employment in Europe³¹, as well as a study on public perception of IPR³². The Observatory has also been working on a study on the impact of IPR infringements³³.

Nevertheless, the available data on IPR abuse strongly indicate that the scale of the problem is very serious, growing, and has a considerable negative impact on the European and global economy:

- The OECD estimated international trade in counterfeit and pirated products up to USD 250 billion in 2007 (excluding domestic market and internet sales) — exceeding the GDPs of 150 national economies and affecting nearly all product sectors³⁴. Other sources even put this figure around USD 650 billion a year, against global narcotics trade of an estimated USD 322 billion³⁵.
- An European Parliament *Report on the impact of counterfeiting on international trade* (2008/2133(INI)) states that ‘*The counterfeiting market is worth approximately EUR 500 billion, accounting for some 7-10% of world trade.*’³⁶.
- A report by *Frontier Economics* estimates the total value of counterfeit and pirated products at between USD 455 billion and USD 650 billion³⁷, and that 2.5 million jobs were lost due to counterfeiting and piracy in 2009 in G20 countries alone³⁸.
- The number of registered cases of IPR infringements by customs over the last 10 years has risen from 7553 in 2001 to 90473 in 2012, an increase of 1200 % over a decade, reflecting the growing practice of shipping such goods in small postal consignments.

³⁰ Supra note 23.

³¹ Supra note 16.

³² https://oami.europa.eu/ohimportal/en/web/observatory/ip_perception

³³ <https://oami.europa.eu/ohimportal/en/web/observatory/observatory-publications>

³⁴ OECD, *The economic impact of counterfeiting and piracy*, June 2008, http://www.oecd.org/document/4/0,3746,en_2649_34173_40876868_1_1_1_1,00.html

³⁵ *An assessment of the social and economic causes and impacts of counterfeiting and piracy in Ghana. An analysis of consumer and industry survey findings.* The National Crusade Against Counterfeiting Products Project Ghana, Project No. 2007/46046 – Lot 11 Country: Ghana, DFC, Spain, 2008.

³⁶ Report on the impact of counterfeiting on international trade of 9 November 2008, Committee on International Trade –European Parliament, 2008/2133(INI).

³⁷ *Estimating the global economic and social impacts of counterfeiting and piracy*, Frontier Economics - BASCAP, 2011, <http://www.iccwbo.org/uploadedFiles/BASCAP/Pages/Global%20Impacts%20-%20Final.pdf>

³⁸ *The impact of counterfeiting on governments and consumers*, Frontier Economics -BASCAP, 2009, <http://www.icc.se/policy/statements/2009/BASCAP.pdf>

3. THE INITIAL IPR STRATEGY FOR THIRD COUNTRIES

3.1. Objectives

The purposes of the 2004 Strategy were to (1) provide the first long-term plan of action for the Commission with the goal of achieving a significant reduction of the level of IPR violations in third countries; (2) describe, prioritise and coordinate the mechanisms available to the Commission services for achieving this goal; (3) inform right-holders and other entities concerned of the means and actions already available and to be implemented, and raise their awareness of the importance of their participation; and (4) enhance cooperation with right-holders and other private entities concerned, by seeking their input on the identification of priorities and establishing public-private partnerships regarding e.g. technical assistance, awareness-raising.

It did not intend to impose unilateral solutions to the problem, propose a one-size-fits-all approach to promoting IPR enforcement, copy other models of IPR enforcement, or create alliances against third countries.

3.2. Tools / Action lines

The 2004 Strategy on IP relied on eight action lines:

1. **Identifying priority countries** (cf. the list of ‘priority countries’³⁹ regularly updated on the basis of surveys and additional sources of input) on which to focus the EU's efforts
2. **Multilateral/Bilateral agreements** (work related to the implementation of the TRIPS agreement by third countries, negotiation of international treaties such as ACTA or those administered by WIPO, IPR chapter included in bilateral trade agreements of the EU with third countries, etc.)
3. **Political dialogue** (‘IP Dialogues’ or other kinds of periodic meetings between the EU and authorities of certain third countries, intended to address specific IPR issues)
4. **Incentives/Technical cooperation** (assistance regarding e.g. the drafting of domestic legislation, the training of judges or other officials, public awareness raising, etc.)
5. **Dispute Settlement/Sanctions** (based e.g. on the dispute settlement mechanisms provided for in multilateral and bilateral agreements (such as that of the WTO), or on the *Trade Barriers Regulation* mechanism)
6. **Creation of public-private partnerships** (relying on companies and associations which are active in the fight against piracy/counterfeiting, on the setting-up of helpdesks in certain third countries, etc.)
7. **Awareness raising** (e.g. of right holders, of users/consumers in third countries, etc.)

³⁹ <http://ec.europa.eu/trade/creating-opportunities/trade-topics/intellectual-property/enforcement/>

8. **Institutional cooperation** (between the Commission services responsible for the different aspects of IPR enforcement, including by ensuring coordination with other IPR-related Commission initiatives).

4. PREPARATION OF THE NEW IPR STRATEGY

4.1. Evaluation of the 2004 Strategy

It was decided in 2010 that it would be timely to submit this *IPR Enforcement Strategy* to an evaluation, given that it had been in force for 5 years.

The evaluation⁴⁰ which subsequently took place attempted to assess, to the extent possible, the effectiveness of the 2004 Strategy in relation to its ultimate goal which is a significant reduction of IPR infringement.

As noted above, it remains difficult to quantify the magnitude and impact of IPR infringement in third countries, and consequently to establish trends to assess progress. Indicators were designed at various levels, for example on actions undertaken in the context of the Enforcement Strategy, actions undertaken by governments to improve enforcement, and impact indicators in terms of overall IPR enforcement trends, to give a sense of whether progress was being made.

Accordingly, the 2010 study sought to examine these indicators and concrete results of the work accomplished so far on the basis of the 2004 Strategy. The evaluation of the actions in place helped further reflection on the existing Strategy and what changes could be pursued in order to further increase the effectiveness of the fight against IPR infringements on a global scale.

Conclusions of the evaluation: It was felt that the 2004 Strategy was targeting a real and relevant problem by aiming to address IPR enforcement issues in third countries. However, understanding the scale of this problem was difficult because of data gaps and this was seen as an important obstacle when developing policy. It was noted that the Strategy also needed to take more account of the development agenda. It pointed to the need for coherence within the EU institutions and Member States on IP promotion and IPR protection in order to convey consistent messages to third countries. It suggested that EU institutions needed to be more proactive in their outreach to a wider base of stakeholders and that communication and awareness-raising needed to be better targeted to have more impact. In terms of technical cooperation, the Commission was felt to be most successful when projects were carried out as part of bilateral arrangements involving third country input.

Recommendations of the evaluation: The evaluation proposed that the Commission approach be more consistent, comprehensive, more widely-known, and its objectives and priorities clearer. The evaluation also saw scope for improved consultation mechanisms vis-à-vis stakeholders. It also called for efforts to 'Build respect for IP' to be better incorporated in the development agenda. It recommended that resources be developed for ambitious technical

⁴⁰ *Evaluation of the Intellectual Property Rights enforcement strategy in third countries*. Final report, Vol. I- Main report, DG Trade - Contract N°SI2.545084, Analysis for Economic Decisions (ADE) and European Commission, Louvain-la-Neuve, 2010.

cooperation programmes that were well designed, targeted and customised to local needs, particularly bi-laterally with key countries. It suggested that legislative improvements should only be pursued in countries where adequate legislation did not exist. It recommended that a methodology be developed for improving statistics on counterfeiting and piracy. The EU Observatory should be the centralised point for creation and dissemination of best practice, and become the single reference point within the Commission for external parties. It noted that adequate resources were needed for EU harmonisation, which according to the evaluation should be increased.

These conclusions and recommendations are on the whole in line with the Commission's own assessment and they are therefore to a large extent reflected in the revised *IPR Strategy* set forth in the Communication to which this document is an annex. However, the Commission does not endorse all of the evaluation's recommendations. For instance, the EU already dedicates considerable resources to technical assistance programmes and these are fully designed in cooperation with the beneficiary countries. Also it is not the purpose of the EU Observatory to be the external reference point for IPR related matters for external parties (although the Observatory can nevertheless facilitate cooperation with third countries); its competences essentially relate to the collection and analysis of data regarding infringements of IPRs within the internal market, and to awareness raising.

Annex 1 below includes a table comparing the structure of the *IPR Strategy* with the study's recommendations.

4.2. Key IPR-related conclusions from the public consultation on the *Future EU Trade Policy* (2010)⁴¹

As part of the preparation for the review of the existing strategy the Commission sought input from the public through a public consultation held in 2010. Most respondents called for the need to strengthen IPR protection and enforcement, in order to more effectively fight IPR infringements and protect investments. It was also suggested that the EU must intensify its efforts to provide companies with better protection against counterfeiting, although it was recognised that in order to boost legal certainty in general, the affected trading partners would need to be convinced of the advantages that accrue from the effective protection of IPRs.

There was general agreement among respondents that these issues should be addressed through both bilateral and multilateral agreements. The WTO TRIPS agreement was seen as the key agreement at global level which establishes minimum IPR protection standards. Respondents therefore stated that effective TRIPS compliance should be considered as one of the top priorities in the EU's bilateral negotiations. Finally, one respondent in the private sector suggested integrating IPR legislation and practices that will apply to all EU Member States and set up a Special Commission to invite all other non-EU countries to participate as an International Working Group to establish a unified system of implementing, supervising and policing all aspects of the process from application to enforcement.

Respondents also called on the EU to address the surge in counterfeiting and piracy in its bilateral relations with key strategic partners such as for example China and India. At the multilateral level it was suggested that the EU should, through WTO and OECD, push for

⁴¹ The public consultation on the future EU trade policy – overview of contributions. Final report, see Question 18, http://trade.ec.europa.eu/doclib/docs/2010/september/tradoc_146556.pdf

promoting IPR enforcement efforts in third countries. Many respondents consider that the EU was already doing a lot to improve enforcement but that more could be done. Another suggestion was that a yearly report could list examples of positive developments in third countries. Finally, in order to provide companies, especially SMEs, with practical assistance, some called for the EU to establish additional IPR help-desks in countries such as India, South Korea and Turkey.

A limited number of replies, however, recommended avoiding excessively strict IPR enforcement provisions such as TRIPS+, which in their view could be detrimental to developing countries (in particular to access to medicines) and to citizens' rights to privacy (on the Internet). It was also suggested that the EU should be encouraging the development and transfer of technology to meet the needs of developing countries. One respondent found that agreements such as ACTA were negative and that excessive attention to demands of IPR lobbies had harmed the public image of WTO.

Some argued that IP protection on medicines had to be relaxed, rather than the EU pushing for a range of IPR measures that support the commercial interests of the pharmaceutical industry, while hampering the opportunities for innovation and access to medicines in developing countries. Others found that the existing legislative initiatives aimed at combating counterfeit medicines were needed due to the risk of counterfeits penetrating into the legal supply chain with the risk of deaths, injuries and untreated conditions due to bad medicines. There was also a call for the insertion of a clear and internationally agreed definition for 'counterfeit medicines' as the one developed by the WHO, which should replace the EU terminology of 'falsified medicinal products' as it would better encompass the criminal relevance of such activities and the term was understood globally. Some replies emphasised the relevance of geographical indications (GIs) (also for handicrafts) and suggested that improving the protection of European geographical indications outside of the EU should be a priority. At the same time it was seen as important to include GIs in bilateral and multilateral agreements in order to enhance local, regional and national economies through their traditional products. Others mentioned the need for better cooperation with the USA and Japan on IPR matters (harmonisation), the need for more technical assistance to developing countries (awareness and training). Specific problems, such as systematic (abusive) demands for technology transfer to local companies in order to access for example the Chinese market, were also mentioned.

Finally, some replies noted the need for internal market mechanisms such as an EU patent system with a corresponding litigation system. One government suggested promoting international patent law harmonisation instead, with the aim to provide for a more efficient global patent system.

4.3. 'Revised IPR Strategy' public hearing held on 10 May 2011

The Commission organised a public hearing on the Protection and Enforcement of IPR in Third Countries on 10 May 2011 in Brussels. All interested parties were invited. Participants were mostly right-holders, with some participants from civil society. The aim of the hearing was to obtain feedback on the previous strategy and ideas on what those attending expected to see in the new IPR strategy.

Stakeholders made presentations on the *International Fund for Innovation*, to be based on a tax on patent applications, from which revenues could be reallocated to manufacturing patented products under a licence.

One association stressed the need to put Protection of Plant Varieties on the IPR dialogues agenda.

A major IP Office said it was crucial to link technical assistance to the political negotiations/agenda and trade discussions. Awareness-raising too needed to be improved by showcasing best practices and success stories.

A manufacturer of industrial equipment made a presentation on a recent IPR infringement impacting the company. It involved the illicit transfer of a licence to a subsidiary company that profited from the transaction in various countries. The manufacturer concluded that it took too much time and money for EU companies to enforce their IPRs and that the EU needed a system of recognition of Singapore International Arbitration rulings, along with a EU blacklist of companies that infringe rights.

There was a call for more reliable data on IP infringements and their impact. This would ensure that EU legislation was balanced and appropriate. It also called for more impact studies on the cost of enforcing rights, not just direct costs, but also the costs of poor enforcement.

Discussion on the effects of the initial IPR strategy and on ways of improving the situation followed and the main conclusions were:

- The initial strategy included several action points that are still very relevant and should be addressed again in the new strategy. These included IPR dialogues, which are a good opportunity to promote tools and mechanisms for countries that want to pursue research. They also enable capacity-building, promoting partnerships with non-EU countries. Several participants welcomed the new-generation FTA and multilateral trade agreement negotiations, but said they should include commitments to accede to the major IPR International Agreements/Treaties.
- It is important to have adequate rules on IPR enforcement: the new strategy should continue to focus on bilateral and multilateral discussions to this end.
- Universal multilateral consensus should be sought, especially on enforcement.
- Technology cooperation is still a very important component of every IPR strategy.
- The new strategy should aim for better political dialogue, such as high level dialogues with China.
- The new strategy should continue to tailor actions to the needs of non-EU countries. The EU should assist other countries in developing their own enforcement strategies.
- The approach for the above should be tailored to the level of development of each country involved.
- Experts based in Delegations have had important impact in some countries, such as China. Having them on site is an example of best practice.

- The current list of priority countries covers those in which there are major problems, e.g. emerging markets in which there are no or weak rules for copyright infringements. Some participants argued that Russia needed closer monitoring, as despite joining the WTO, it has an IPR enforcement system that does not comply with WTO membership requirements.

4.4. Input from Member States

Informal input was also solicited from Member States' administrations. Below are the main points that emerged:

All Member States agreed that all elements of the initial strategy should be kept. However, one commented that it would prefer a strategy with a clear, comprehensive vision, accompanied by an action plan.

Regarding thematic focus, some Member States recommended paying more attention to counterfeit medicines, to IPR infringement on the internet, or to the protection of GIs. They noted that issues such as technology transfer and biodiversity-related IPRs are important concerns for many developing countries, but that FTAs were not considered to be the most appropriate or effective vehicle to address these.

Regarding geographical focus, some Member States said that *least developed countries should only be relevant to the strategy in terms of technical assistance, programmes incentivising technology transfer and the EU's multilateral work*. Others recommended relying either on the World Bank's income classification (low-income/middle-income/high-income), or concentrating on countries on the priority list, which are either industrialised, or advanced emerging economies.

Regarding sanctions, conflicting opinions were expressed, e.g.:

- *'Additional remedies should be introduced to ensure that third countries introduce and apply effective measures to deal with infringement of IPRs. Sanctions for not doing so should be expedient and effective, and should allow for countries to be restricted or removed from participation/funding in EU programmes, or for other meaningful penalties.*
- *Introducing additional remedies would contravene principles such as of non-conditionality in aid and GSP Regulation. It would also be a heavy-handed and counter-productive approach, likely to damage relations with third parties and undermine confidence in the EU's commitment to development; and could fall foul of WTO rules on non-discrimination.'*

There was also debate on the relative importance of bilateral and multilateral initiatives:

- *Some saw "improving the legislative framework for IP via bilateral agreements as the main avenue for enhancing IPR protection and enforcement. Multilateral negotiations and initiatives should be the priority if feasible."*

- Others felt that *"bilateral agreements are probably less effective than other measures and agreements. They should be given less priority because they can undermine the drive for multilateral agreements."*

Other highlights:

- An annual seminar could be organised to let stakeholders express their views on the implementation of the strategy.
- The collection of data focused on IPR issues relevant to trade with non-EU countries needs to be improved.
- As regards institutional cooperation, efforts should be made to improve the relationship with the European Parliament in the light of the Lisbon Treaty.

5. KEY CHALLENGES – THE NEED FOR A REVISED IPR STRATEGY

The impact of counterfeiting and piracy is not limited to companies whose rights are violated but are felt throughout society. The impact includes:

- **Economic and social:** IPR infringements deprive right-holders of revenue from their investment in R&D, marketing, creative effort or quality control. They negatively affect sales volume, reputation, jobs^{42,43,44} and ultimately the viability of certain IPR-based activities/companies which may be incentivised to relocate their business to countries that are perceived as having stronger IPR regimes. High levels of IPR violations also discourage foreign investment and the transfer of technology.
- **Health and consumer protection:** The producers of pirated and counterfeit goods most often disregard health, safety and quality requirements and provide no after-sales service, guarantees or operating instructions. Such products not only present dangers for the workers that produce them, since companies that are involved in such practices tend to have scant regard for the health and safety standards for their workers, but also represent a danger to consumers as evidenced by the increasingly frequent seizures of fake medicines^{45,46}, food products, car and plane parts⁴⁷, electrical appliances and toys.

⁴² Regarding the impact of piracy on EU jobs in the audio-visual and software sectors, for instance, see this recent BASCAP report: Report on the application of Directive 2004/48/EC of the European Parliament and the Council of 29 April 2004 on the enforcement of intellectual property rights, of 22 December 2010, COM(2010) 779 final.

⁴³ A study commissioned by BASCAP in 2009 estimated that due to counterfeiting *'approximately 2.5 million jobs are destroyed across the G20 countries and potentially as many as 160 000 individuals unable to find re-employment'* — Opinion on the Proposal for a Regulation of the European Parliament and of the Council on entrusting the Office for harmonisation in the Internal Market (Trade Marks and Designs) with certain tasks related to the protection of intellectual property rights, including the assembling of public and private sector representatives as a European Observatory on Counterfeiting and Piracy, of 7 and 15 June 2011, COM(2011) 288 final and 2011/0135 (COD).

⁴⁴ IFPI estimates at 1.2 million the number of jobs projected to be lost in the European creative industries due to piracy by 2015 — cf. IFPI digital music report 2011. Music at the touch of a button, IFPIA, 2011.

⁴⁵ <http://www.interpol.int/Crime-areas/Pharmaceutical-crime/The-dangers>

- **Public order and security:** Criminal organisations are becoming increasingly involved in large-scale international trafficking of counterfeit and pirated goods⁴⁶. The business is very lucrative, and the risk perceived as lower than for other criminal activities. The scale of the problem and the sums of money involved mean piracy is as complex to tackle as drug trafficking or money laundering. Europol, Interpol and other EU police forces have created special departments in this regard, and tackling organised crime involvement in counterfeit and substandard goods is one of the priorities under the EU policy cycle 2013-2017. Counterfeiting and piracy are often seen as victimless crimes, and the public is often unaware of the extent of organised crime involvement, as Europol has pointed out.
- **Fiscal:** IP crime is illegal and clandestine. This means that the states lose tax revenue (VAT, revenue taxes, customs duties), which is also the case when IPR-infringing goods are sold at a lower price through official retail channels. This issue is particularly sensitive in countries where there are economic sectors such as tobacco or alcohol are under strict state control.

More specific challenges are examined next.

Case study: Invisible hands

Pirated and counterfeit goods are usually produced 'underground' by makers that pay no heed to health, safety and quality requirements. In the European automobile market, about 10% of all spare parts are counterfeit, while in Asia, that figure could be as high as 30%. Inspections of goods seized have revealed sub-standard manufacturing, including fake brake pads made of compressed grass and wood chip (source: Walpole IP Working Group). More effective IPR protection and enforcement would reduce such risks.

5.1. External challenges to EU IP

With the increasing globalisation of trade in products and services, and as companies have sought value chain optimisation, such as through outsourcing, the way in which products are created has changed. At the same time, technological changes such as digitisation have made IP more volatile. This, combined with the rapidly growing capabilities of third country manufacturers in particular in emerging economies, and with the latter's appropriation of IP through legal and sometimes illegal means, is having an unprecedented impact on European industry.

The result is that third country attitudes to IP matter more than ever. With a greater proportion of corporate value now tied to intangibles, the risk that this value is exposed to when production or R&D is outsourced to emerging economies must be factored in any corporate IP value management strategy. Policy also has a role to play so as to help ensure that other

⁴⁶ In particular see Operation Biyela, where more than 1 billion illicit products were seized in 10 days, including 550 million medicines, <http://www.wcoomd.org/en/media/newsroom/2013/june/wco-and-iracm.aspx>

⁴⁷ Cf. e.g. The crash of the *Partnair Flight 394* in 1989, in which 55 people died, due to counterfeit bolts.

⁴⁸ 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, <http://jiplp.oxfordjournals.org/cgi/reprint/5/5/378?etoc>

countries enforce IPR and that they have legal frameworks in place that enable European companies to protect and enforce their IPR.

In particular there is a need to address the 'IPR erosion' increasingly noticed in a number of non-EU countries. This phenomenon entails a combination of practices (very restrictive patentability criteria; low threshold for compulsory licensing linked e.g. to a local manufacturing requirement; questionable revocations of granted patents; etc.) which, especially when combined, result in a substantial weakening of IPR protection and thus in a serious deterioration of the innovation climate in the countries concerned.

5.1.1. Protection and enforcement

Even for companies whose main market is the EU, fighting IPR infringements in non-EU countries is important so as to reduce the risk of counterfeits made abroad being sold in the EU. The 2005 *Communication on a customs response to latest trends in counterfeiting and piracy*⁴⁹ already highlighted the impact of IPR infringement from an external trade perspective.

Following the adoption of TRIPS, the regulatory framework for IP in third countries is – at least on the surface – generally reasonable, and most of the problems tend to relate to how laws are enforced. Several aspects of protection, however, such as validity criteria, duration of protection, timeliness of registration, quality of examinations, are just as important as enforcement, since right-holders can only enforce the rights they have been granted.

Many of these issues are, however, not covered in detail in the TRIPS agreement. For instance, its regulatory data protection provisions applicable to pharmaceuticals (Article 39.3) are drafted in such a broad way that significant discrepancies may appear between how these obligations are implemented in different countries. In addition, the TRIPS agreement does not include any definition of the notions of 'novelty' or 'inventive step' which are key criteria applicable to patents, nor of the novelty/originality criterion applicable to industrial designs.

Some right-holders have, for instance, expressed concerns as to the excessively restrictive manner in which some non-EU countries interpret the patentability criteria or even introduce additional ones, sometimes allegedly to prevent the phenomenon characterised as 'ever-greening' particularly in the area of pharmaceutical patents⁵⁰. The term 'ever-greening' is somewhat pejorative and wrongly suggests that the basic patentability criteria are not sufficient to prevent attempts to patent products that are not new or do not involve an inventive step. An overly restrictive definition of "inventive step" is often used in India to deny patent protection for innovative pharmaceuticals that build upon pre-existing products. Countries such as Israel have also designed *patent term restoration* rules applicable to pharmaceuticals in such a way as to work to the detriment of foreign companies.

⁴⁹ Communication on a customs response to latest trends in counterfeiting and piracy, of 11 October 2005, COM(2005) 479 final.

⁵⁰ "Patent evergreening" generally refers to the strategy of obtaining successive patents that cover different aspects of the same product, typically by obtaining patents on improved versions of existing products.

In many non-EU countries, the quality of the IPRs granted by the examining authorities is significantly lower than in the EU (particularly for patents^{51,52}), in particular due to difficulties or inadequate resources regarding the examination process. This may lead to a proliferation of IPRs of dubious legal value, hampering economic activity in certain (sub-) sectors, and encourage unnecessary or even bad-faith litigation. Such situations may be aggravated by lengthy, biased and costly invalidation procedures that may discourage third parties from attempting to invalidate dubious IPRs. Such issues need to be addressed, as a matter of priority.

Quality is also important for trademarks, as a weak assessment of the examination criteria by certain trade mark offices and Courts results in the registration of quasi-descriptive terms. This raises the risk of accidental infringement, a fact sometimes exploited by owners, leading to a proliferation of litigation.

The continuously growing demand for IPRs puts IP offices under strain and risks either affecting the quality of the rights granted or delaying the granting of rights. Backlogs have a negative impact on both applicants and third parties, particularly as regards legal certainty. A study by London Economics (2010) estimates that ‘*an additional year of pendency at the three Trilateral (US, Japan, EPO) offices is estimated to impose costs of £7.6 billion per annum on the global economy*’⁵³.

Certain cooperation mechanisms are already in place or being developed (based on the *Patent Cooperation Treaty* – PCT – and/or on initiatives such as *Patent Prosecution Highways*) to ensure that at least part of one patent office’s work (e.g. prior art search work) can be reused by other offices at which a patent application for the same invention has been filed. It remains to be seen if this will be enough to cope with the high volumes of filings in certain parts of the world, such as China or Brazil.

Better alignment of substantive legislation between one country and another would certainly help, as this would make work-sharing and mutual recognition⁵⁴ a possible option, but discrepancies in rules and in quality mean that much remains to be done. Nevertheless, promoting the accession of the EU’s commercial partners to international Treaties such as the PCT, the *Madrid Protocol* on trademark registration and the Hague Agreement on design registration, is a way of reducing costs and complexity for EU right-holders seeking protection in these countries.

Another sensitive issue linked to protection is that of exceptions and limitations. IP laws allow certain limitations on exclusive rights, that is to say, cases in which IPRs may be used without the authorisation of the right-holders (with or without compensation) but there is an on-going debate at international level⁵⁵, and a balanced approach taking all stakeholders’ situations into

⁵¹ *Study on the quality of the patent system in Europe*, G. Scellato et al., Patqual, 2011, http://ec.europa.eu/internal_market/indprop/docs/patent/patqual02032011_en.pdf

Patent quality from a European Patent Office perspective: what is it? How do we recognize it? How do we control it?, Y. Skulikaris, <http://www.epip.eu/conferences/epip06/papers/Parallel%20Session%20Papers/SKULIKARIS%20Yannis.pdf>

⁵³ *Economic study on patent backlogs and a system of mutual recognition*, to the Intellectual Property Office prepared by London Economics, Newport, 2010.

⁵⁴ Supra note 49.

⁵⁵ <http://www.wipo.int/copyright/en/limitations>

account must be adopted. In particular, to maintain the right balance between the interests of right-holders and the need to incentivise innovation on the one hand and the interests of users of protected works and goods on the other.

Improving IPR enforcement internationally is the logic which underlies our initial IPR enforcement Strategy, which is based on the acknowledgement that the standards set in the TRIPS agreement for enforcement can no longer deal adequately with all of today's challenges.

At a bilateral level, the EU will continue to encourage its partners to ensure that IPRs are effectively enforced in their territory. This will include implementing action plans on IPR enforcement or promoting cooperation on customs matters. Bilateral cooperation has led to several successes. For instance, the EU and China have established effective, lasting co-operation on IPR issues since 2004 through, in particular, an IP Dialogue and an IP Working Group; in that context we have been able to provide input regarding the revision of various Chinese IP laws and helped ensure that the coordinating structure for the 2009-2010 *Special Campaign* against counterfeiting and piracy was made permanent. In the area of IPR border protection EU and China Customs authorities have been implementing since 2009 an Action Plan concerning EU-China Customs Cooperation on IPR. The Action Plan provides for *inter alia* enhanced targeting of high risk consignments by information exchange on relevant cases between key seaports and airports from both sides. It also caters for effective cooperation with right holders in deterring cross-border IPR infringement.

5.1.2. *Biodiversity and traditional knowledge*

Biodiversity and traditional knowledge are particularly sensitive topics for developing countries. There are a number of operational initiatives underway that may be beneficial both for the EU and for developing countries. For instance, India's *Traditional Knowledge Digital Library* (TKDL)⁵⁶, an extensive compilation of India's ancient medical knowledge, is now available to European Patent Office (EPO) examiners. This helps to improve the quality of European patents and to prevent ancient Indian remedies from being patented by e.g. Western applicants (although this database is not publicly available).

IP on traditional knowledge is indeed an important issue. Ensuring the right protection of third countries traditional knowledge can help creating confidence when developing cooperation (in R&D, industrial projects etc.). This goes beyond biodiversity issues and the use of genetic resources and should be open to include also other areas and technologies such as house building. In case further research is done based on traditional techniques, or based on properties of traditional materials, this may have consequences for the definition of shared intellectual property and its protection. For example traditional earthquake resistant assembly techniques can be improved by modelling.

⁵⁶

<http://www.tkdil.res.in/tkdil/langdefault/common/Home.asp?GL=Eng>

The EU has also been active in the international debate on biodiversity-related IPR issues and the protection of traditional knowledge, crucial for many developing countries. The EU helped bring about a successful conclusion to negotiations on a Protocol to the *Convention on Biological Diversity* (CBD) on access to genetic resources and the sharing of benefits arising from their use (Nagoya 2010⁵⁷). By 2005, the EU had submitted a proposal to WIPO and WTO setting out a balanced and effective way of including a requirement to disclose the origin or source of genetic resources and associated traditional knowledge in patent applications in international patent law. In the context of the WTO Doha Development Agenda (DDA) negotiations, the EU has expressed readiness to amend the TRIPS agreement to make it compulsory to disclose the country providing material, or the source of genetic resources and/or associated traditional knowledge (for which a definition would be agreed) in patent applications. That would be part of a package of IP-related amendments (cf. ‘W/52’ proposal).

5.1.3. Technology transfer

Developing countries, especially LDCs, see technology transfer as the corollary of protecting IPRs. The TRIPS agreement includes a number of provisions on this point. For example, it requires developed countries’ governments to provide incentives for their companies to transfer technology to LDCs, so that the latter can create a sound, viable technological base (Article 66.2⁵⁸).

The EU and its Member States strongly support the facilitation of voluntary transfers of technology between its right-holders and partners in developing countries and launched a number of initiatives towards this end, for example the EU’s *Intra-ACP Support to the Centre for Development of Enterprise* programme⁵⁹, and UK DFID’s *Technology Programme for Branchless Banking*⁶⁰. Submissions from the EU⁶¹ and other developed countries are reviewed by the TRIPS Council on an annual basis. Members may ask questions, request additional information, discuss the effectiveness of the incentives provided, and review the reporting procedure. The EU is fully committed to this process and submits an annual report on EU/MS technology transfer activities. The issue of technology transfer from developed countries to LDCs has been discussed in the TRIPS Council and in dedicated WTO workshops.

In most cases, technology (and the related IPRs) belong to private owners, and cannot be ‘expropriated’ for the sake of technology transfer. This is why the above-mentioned initiatives need to concentrate on *incentives* to encourage voluntary transfers.

⁵⁷ The Nagoya Protocol on access and benefit-sharing: <http://www.cbd.int/abs/>

⁵⁸ Article 66.2 TRIPs requires that ‘*Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base*’.

⁵⁹ Commission Decision on the Support to the Centre for Development of Enterprise (CDE) to be financed from the 10th European Development Fund, of 12 December 2011, C (2011)9425.

⁶⁰ Speech by Hilary Benn, Secretary of State for International Development, at Holyrood, Edinburgh: <http://webarchive.nationalarchives.gov.uk/+http://www.dfid.gov.uk/Media-Room/Speeches-and-articles/2006-to-do/Governance-and-Development/>

⁶¹ *Climate change and technology transfer. Can Intellectual Property Rights work for the poor?*, K. Kretzschmar, Prague Global Policy Institute Glopolis, Prague, 2012.

In 2007, ICTSD published a report⁶² identifying changes over recent decades:

- a number of developing nations have become much more technologically sophisticated, with an enormous change in the skills available to a large portion of the developing world;
- the world is now globalised in the sense that free trade has spread, with many production facilities serving more than one nation, and increasing specialisation and trade;
- because of free trade rules, an indigenous firm in the developing world may be less able to start operations in a protected market.

Some countries have introduced measures that are potentially detrimental to foreign right-holders. For example, the Chinese ‘indigenous innovation’ rules (concerning the accreditation procedure imposed to be eligible to public tendering), according to which, in key areas such as high technology or new-energy vehicles, there are requirements for a high percentage of domestic IP and/or technology content. While the initial rules have been heavily debated and then substantially amended, continued monitoring of implementation is needed.

Some countries have also developed legislation requiring non-consensual technology transfer of foreign companies to local partners (for instance in China⁶³), which may have a potentially detrimental impact on EU companies.

India's demand for “local working requirement” can also be seen in this light, since it creates an obligation for a right-holder to produce the IPR-bearing good domestically if it is to benefit from IPR protection. This runs counter to the concept of free international trade: if all WTO Members imposed a local working requirement there would be no international trade of IPR-protected goods. Requiring companies to produce locally in every country where they have obtained a patent, a trademark or a design also goes against business rationale and discourages the entry of foreign operators into such markets.

It may be tempting to consider that such measures provide short-term gains for domestic users, but overall they are not conducive to long-term innovation and growth. This actually harms the countries concerned, since it results in a regulatory environment which deters innovation and foreign investment in innovative sectors. Innovators realise this, and logically take local IPR factors into account when making investment decisions.

Also, taxation and legal requirements hampering joint ventures or private sector cooperation between domestic and foreign companies should be revised to facilitate technology transfer or, at least, not impede it. It is clear that in some emerging economies the situation needs to be improved on these points⁶⁴, there so as to create an environment conducive to technology transfer.

⁶² *New Trends in Technology Transfer. Implications for National and International Policy*, J.H. Barton, ICTSD Programme on IPRs and Sustainable Development, Issue Paper No. 18, Geneva, 2007.

⁶³ *Technology transfer to China: Guidance for businesses*, China IPR SME Helpdesk, European Communities, 2008.

⁶⁴ In Brazil, for example, some examination processes of technology transfer contracts, conducted by the patent office, are reported to have lasted over a year and have lacked transparency over their purpose.

5.1.4. Climate change

Climate change is clearly one of the key global challenges of the century. Developing countries in tropical and sub-tropical regions are expected to experience the most severe effects of global warming. In the context of on-going international negotiations (UNFCCC), there is controversy over the role of IPR vis-à-vis climate change. A number of developing countries argue that IPRs are barriers to the deployment of ‘green’ technologies. They have proposed weakening IPR rules (e.g. through compulsory licensing or patentability exclusions), making a parallel with ‘access to medicines’. This ignores fundamental differences between the two issues and several studies⁶⁵ demonstrate the flaws in this argument, and conclude that – contrary to the above positions – by providing a legal mechanism to promote the dissemination of information and the reward for much needed further R&D and investment in ‘green’ technologies, IPRs acts as a catalyst and not as a barrier.

A recent study⁶⁶ conducted by the European Patent Office regarding the licensing of green technologies states that ‘70 per cent of respondents said they were prepared to offer more flexible terms when licensing to developing countries with limited financial capacity’. This is positive, and further supports the view that IPR issues are not the main factor affecting the transfer of such technologies to developing countries.

There have been a number of other interesting initiatives recently, including *WIPO Green*⁶⁷, fast-tracking mechanisms at certain patent offices⁶⁸, classification initiatives⁶⁹ facilitating access to ‘green patents’, or the *Green Intellectual Property (GIP) project*⁷⁰, which all seek to maximise the benefits of a balanced and effective IPR system towards progress in environmental technologies.

The EU's position in climate negotiations is to be at the forefront of promoting and providing financing for access to technology by developing countries while maintaining that IPR is an essential pillar, not a barrier, to the dissemination of innovative green technologies.

5.1.5. Geographical indications

Geographical Indications (GIs) identify the name of a product whose quality, reputation or characteristics are essentially attributable to its geographic origin. They protect legitimate producers against misuse and imitation, and encourage them to diversify production and develop related tourism.

The legal protection of GIs is increasingly important for their producers, and often represents a key element of their business development strategy. GIs are an effective marketing tool

Additional taxation and legal constraints also exist: repatriation of royalty fees from subsidiary to parent company are limited to 5%.

⁶⁵ E.g. http://trade.ec.europa.eu/doclib/docs/2009/february/tradoc_142371.pdf

⁶⁶ http://documents.epo.org/projects/babylon/eponet.nsf/0/cc5da4b168363477c12577ad00547289/USDFILE/patents_clean_energy_study_en.pdf

⁶⁷ *WIPO Green: The sustainable technology marketplace*, WIPO, 2011, <https://webaccess.wipo.int/green/>

⁶⁸ <http://www.ipo.gov.uk/types/patent/p-applying/p-after/p-green.htm>

⁶⁹ Sustainable technologies. Access to patents for climate change mitigation technologies, <http://www.epo.org/news-issues/issues/classification/classification.html>

⁷⁰ Green Intellectual Property Project. A tool for greening our society, <http://www.greenip.org/policy.html>

capable of adding value to a product, and those with significant commercial value are indeed exposed to misappropriation, misuse and counterfeiting.

Ensuring that EU GIs can fulfil their potential properly requires an adequate level of protection not only in the EU territory but also internationally. Existing international rules on GIs present some weaknesses that reduce their effectiveness. The ongoing revision process of the Lisbon Agreement is aimed at making it more appealing while keeping a high level of protection of appellations of origins and geographical indications. While TRIPS remains the only truly multilateral agreement to include protection for GIs it remains an incomplete agreement as far as this category of intellectual property is concerned. TRIPS, for example, offers considerable flexibility in terms of the legal means Members may choose to protect geographical names at the national level. The EU has been pushing for better protection of GIs at the international level due to increasingly frequent misappropriation that European GIs with high economic value (e.g. Champagne) face in many third countries. The abuse of GIs limits access to certain markets for the original producers and undermines consumer loyalty; such situations are detrimental not only to producers, but also to consumers, which are misled about true origin and qualities of the products found in the market.

A dedicated GI policy helps to promote traditional cultures, geographical diversity and production methods. It can help promote rural development by capitalising on natural competitive advantages for agricultural and cultural products and it can contribute to quality policy. It supports small-scale production and small communities by helping to boost income and developing tourism. GIs can also contribute to preserving natural resources, rare plants or breeds, and traditional know-how. GI labelling helps consumers looking for products with qualities that have a strong link with a specific region.

At EU level, specific rules have been developed to protect GIs for wines⁷¹ and spirits⁷², as well as agricultural products and foodstuffs⁷³. In 2007, Protected Designations of Origin (PDOs) and Protected Geographical Indications (PGIs) of European agricultural products (excluding wines and spirits) had an estimated wholesale value (in the EU) of EUR 14.2 billion. The total sales value of GI products (including wines and spirits) was estimated at EUR 54.3 billion in 2010⁷⁴, with exports on extra-EU markets estimated at EUR 11.5 billion⁷⁵. There was a rise in value (+ 12 % between 2005 and 2010)⁷⁶. The sales value of the European food and drink sector was estimated at EUR 956 billion in 2010 by FoodDrinkEurope.⁷⁷ The share of GIs was 5.7% in 2010.

⁷¹ http://ec.europa.eu/agriculture/markets/wine/leg/index_en.htm

⁷² Regulation No. 110/2008 of the European Parliament and of the Council of 15 January 2008 on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks and repealing Council Regulation No. 1576/89, OJ L39, 13.2.2008.

⁷³ Council Regulation No. 510/2006 of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs, OJ L93, 31.3.2006.

⁷⁴ External study: *Value of production of agricultural products and foodstuffs, wines, aromatised wines and spirits protected by a geographical indication*. Final report, October 2012, http://ec.europa.eu/agriculture/external-studies/2012/value-gi/final-report_en.pdf

⁷⁵ Takes into account also re-exports. Some GI products marketed on the intra-EU market are exported to the extra-EU market by stakeholders which are not located in the Member State of production of the GI. This phenomenon was particularly important for GI wines.

⁷⁶ External study: *Value of production of agricultural products and foodstuffs, wines, aromatised wines and spirits protected by a geographical indication*. Final report, October 2012, http://ec.europa.eu/agriculture/external-studies/2012/value-gi/final-report_en.pdf

⁷⁷ *Data and trends of the European food and drink industry 2011*, Food Drink Europe, Brussels, 2011.

Protection of GIs is therefore an important part of the EU's agricultural quality policy⁷⁸ and trade policy. The EU is actively participating in international negotiations via the World Trade Organisation⁷⁹. It is seeking to improve and facilitate GI protection through extending the type of protection that applies to wines and spirits GIs to other products. This would involve setting up a multilateral GI register with meaningful legal effects. The EU is also engaged in the review of the Lisbon System of Appellations of Origin at the World Intellectual Property Organisation⁸⁰.

The EU has negotiated bilateral agreements on GIs for wines (e.g. with the USA, Australia, Canada)⁸¹, and bilateral agreements covering GIs for agricultural products and foodstuffs (e.g. with Switzerland, South Korea, Central America, Columbia, Peru)⁸². It is currently negotiating with several other trading partners.

5.2. Public debate

The increasingly tangible influence of IPR policy on our daily lives (for example, on the way we can 'consume' music and movies via the Internet), means that it is more than ever in the public eye and IP is no longer the reserve of 'experts'. There is often controversy, and even opposition, when it comes to proposals to strengthen, let alone reform, IP regimes. Some stakeholders argue that IPRs may hinder innovation, as well as access to essential goods (such as medicines or 'green' technologies) or digital goods (e.g. multi-media content), and that the law is sometimes unclear or detrimental regarding consumers rights.

There has been, especially since the 1990's, a continuing debate on how to design IPR rules, and in particular on how to strike the right balance between the rights of right-holders and public interests in access (concerning mainly copyright and patents). This debate has also been prompted by the negotiations of and later the entry into force of TRIPS, and has focused on whether developing countries should adopt more stringent IP standards, with a particular focus on how to maximise the so-called TRIPS flexibilities and in particular on issues such as access to medicines. The emergence of new technologies has raised questions about how IP should apply to areas such as biotechnology (cf. biotech directive), software (debate on software patenting) and not least to the internet (see below).

Existing research reveals common patterns in consumer decisions to buy counterfeits and pirated goods and shows that such practices are a widely-tolerated and unspoken social problem⁸³. There is no doubt that some consumers see benefits in IPR-infringing goods

⁷⁸ http://ec.europa.eu/agriculture/quality/index_en.htm

⁷⁹ *Intellectual Property: Geographical indications and biodiversity*, December 2008 package: briefing notes, http://www.wto.org/english/tratop_e/dda_e/status_e/gi_e.htm

⁸⁰ Review of the Lisbon System: <http://www.wipo.int/lisbon/en/review.html>

⁸¹ http://ec.europa.eu/agriculture/markets/wine/third/index_en.htm

⁸² Agreement between the European Union and the Swiss Confederation on the protection of designations of origin and geographical indications for agricultural products and foodstuffs, amending the Agreement between the European Community and the Swiss Confederation on trade in agricultural products, OJ L297, 16.11.2011.

Council Decision No. 2011/265/EU of 16 September 2010 on the signing, on behalf of the European Union, and provisional application of the Free Trade Agreement between the European Union and its Member States, of the one part, and the Republic of Korea, of the other part, OJ L127, 14.5.2011.

⁸³ See for example BASCAP's *Research Report on Consumer Perceptions and Attitudes on Counterfeiting and Piracy*, 2009, <http://www.iccwbo.org/Data/Documents/Bascap/Consumer-Perceptions/Consumer-Research-Report/>

because they tend to be cheaper or perceived as free. However, this is a narrow and short term perception, which ignores the wider economic and social impact of counterfeiting and piracy, such as the potential risks to consumer health and safety, as well as the wider long term negative impact on society in terms of, for example, lost jobs in legitimate businesses, and innovation in general.

It is clear that any strategy to combat counterfeiting and piracy will also have to address the demand side of the problem. This will in the first place require further work to better understand consumers' attitudes toward such products and second to devise awareness raising initiatives aimed at changing these attitudes.

5.2.1. *Development*

There has equally been a long running debate about the role of IP in the development policies and strategies of developing countries, where some question whether IP policies can play a positive role in efforts to foster development. Because most right-holders are based in developed countries it is sometimes suggested that IPR protection and enforcement are therefore less relevant or even counter-productive for developing countries⁸⁴.

Developing countries obviously vary greatly in terms of their innovative potential, the education of their work force, and the structure and funding of research and development (R&D). However, emerging markets are catching up fast as regards the balance of ownership. For instance, in 2010 Chinese applicants filed 293 066 Chinese patent applications (which was more than the total number of European patent applications, irrespective of their applicants' origin), and their share of all European patent applications increased from 0.7 % in 2002 to 6.9 % in 2011.

The benefits of IPR for developing countries include protection of their intellectual assets which will allow them to compete in higher added value sectors of the economy, combating health⁸⁵ and safety risks, safeguarding jobs and tax revenues⁸⁶, and promoting foreign direct investment (FDI) and transfer of technology. For example, an IPR holder can serve a foreign market through exports, FDI, or licensing. The OLI (ownership-location-internalization⁸⁷) framework suggests that firms that possess ownership advantages — for example in the form of IPRs — tend to choose foreign production over export, if the attributes of a particular location (for example, lower wages or proximity to international markets) favour production abroad. The choice between FDI and licensing would depend on internalization advantages and IPR policies can have an effect on both location advantages and internalization advantages, such that strengthened protection can lead a firm to invest in different places and switch from wholly owned production to licensing. In other words, a good IP regime can help attract either FDI or technology transfer although in itself would not necessarily be sufficient. As a working paper of the *National Bureau of Economic Research* put it: *'IPR reform in the South leads to increased FDI ... as Northern firms shift production to Southern affiliates.*

⁸⁴ As analysed for instance in the report *Making Global Trade Work for People* resulting from a project sponsored by the United Nations Development Programme, 2003, see Chapter 11, http://content.undp.org/go/cms-service/stream/asset/?asset_id=1948200

⁸⁵ <http://www.interpol.int/Crime-areas/Pharmaceutical-crime/The-dangers>

⁸⁶ For example, in Ghana a survey revealed that 96% of companies feel that the harm caused by counterfeiting and piracy threatens enterprise existence, http://www.acpbusinessclimate.org/PSEEF/Documents/Final/ghana_impact_en.pdf

⁸⁷ http://en.wikipedia.org/wiki/Eclectic_paradigm

*This FDI accelerates Southern industrial development. The South's share of global manufacturing and the pace at which production of recently invented goods shifts to the South both increase.*⁸⁸ Evidently, IP reforms are only one of the many factors able to attract investment; other factors to create an attractive investment and business climate need to be in place, in particular for countries that are trying to move up the value chain.

Trade policy has an important role to play in development, as the *Doha Development Agenda* shows, and as highlighted in the Commission Communication on '*Trade, growth and development*'⁸⁹.

The World Bank notes that the effects of IPR reforms depend on circumstances, and that a 'one-size-fits-all' approach is unlikely to work⁹⁰: '*Although the current international framework for the protection of intellectual property provides for some degree of harmonisation of global IPR standards, TRIPS, in particular, still leaves important room to adjust IPR norms to domestic needs.*'

Similarly, a UK report⁹¹ on '*Intellectual property and development*' (2001-02) observed that:

- '*The question is how they [developing countries] can mould their IP systems to suit their own economic, social, and technological conditions, as developed countries did in the past.*'
- '*We need to ensure that the global IP system evolves so that the needs of developing countries are incorporated and, most importantly, so that it contributes to the reduction of poverty in developing countries by stimulating innovation and technology transfer relevant to them, while also making available the products of technology at the most competitive prices possible.*'

The Commission's *Policy Coherence for Development Work Programme 2010-2013*⁹² includes a section on IPR, mentioning three targets:

- '*To make better use of IPRs for development, for example, to promote investment and innovation and to facilitate IPR protection in the EU of export products from developing countries.*
- '*Ensure that balanced IPR provisions (e.g. in bilateral agreements) help developing countries to leverage the value of their intellectual creations and to promote technological progress, innovation and support domestic and foreign investment.*
- '*Preserve access to affordable medicines in line with the principles of the Doha Declaration and subsequent WTO agreements and EU legislation.*'

⁸⁸ *Intellectual Property Rights, imitation, and foreign direct investment: theory and evidence*, L. Branstetter et al., Working paper 13033, NBER, Cambridge, 2007.

⁸⁹ Communication on trade, growth and development. Tailoring trade and investment policy for those countries most in need, of 27 January 2012, COM(2012)22 final.

⁹⁰ Supra note 15.

⁹¹ *Integrating Intellectual Property Rights and Development Policy*, Commission on Intellectual Property Rights, London, 2002.

⁹² Commission Staff Working Document Policy Coherence for Development Work Programme 2010-2013, of 21 April 2010, SEC(2010) 421 final.

The Commission recognises that there needs to be a differentiated approach regarding protection and enforcement vis-à-vis low-income developing countries. To assist *least developed countries* (LDCs), the WTO decided in 2005 that they would have until 2013 to comply with the TRIPS agreement⁹³, and even up to 2016⁹⁴ regarding pharmaceuticals. In November 2012, there had been a proposal by LDCs to extend this deadline beyond that date. The Commission supported an extension and as such the deadline has now been extended for a further eight years until 2021.

5.2.2. IPR in Free Trade Agreements

There is a wider, trade-related aspect of the above-mentioned controversy which affects the inclusion of IP provisions in bilateral trade agreements or other international agreements. Some stakeholders both in Europe and abroad oppose any further strengthening of IPR legislation through FTAs including what they characterise as ‘TRIPS+’ provisions. However, focusing on whether a particular provision constitutes a TRIPS+ element or not misses several important points.

First, the TRIPS agreement was concluded more than 18 years ago and the changes in technology (e.g. the internet) and society that have occurred since then have transformed the nature of the IPR landscape. This is already reflected in many countries’ national legislations that strictly speaking go beyond TRIPS because they seek to address emerging challenges. Second, negotiations of free trade agreements also provide an opportunity for countries to stimulate bilateral trade by providing legal certainty for economic operators by reducing some of the constructive ambiguities contained in TRIPS. Third, many so-called ‘TRIPS+’ provisions actually have an objective other than strengthening IPR legislation: e.g. they relate to the ratification of purely procedural treaties (destined to harmonise or facilitate the registration of rights), or they are of primary interest to developing countries (e.g. provisions on bio-diversity).

That is why it is essential for the EU to continue to negotiate with its trade partners a number of provisions, not just to address technical⁹⁵ or commercial⁹⁶ developments, but also to clarify uncertainties around IPR⁹⁷ or to improve the functioning of the system. It is also crucial that public authorities, including the EU, are more open to dialogue with all stakeholders, including business as well as civil society, to clearly discuss the importance and benefits of IPR but also its limitations and abuses.

5.2.3. Digital technology and the internet

Digital technology and the internet have emerged as major opportunities and channels for information, culture, leisure and business. They undoubtedly contribute to economic growth

⁹³ *Poorest countries given more time to apply Intellectual Property rules*, WTO : 2005 press releases, Press/424, of 29 November 2005.

⁹⁴ *Declaration on the TRIPS Agreement and public health*, WTO Ministerial Conference, fourth session, of 20 November 2001, Doha, WT/MIN(01)/DEC/2.

⁹⁵ E.g. The considerable development of Internet.

⁹⁶ E.g. The increasing importance of GIs and designs in certain sectors.

⁹⁷ For instance regarding the data protection provisions, as analysed in a WHO Briefing Note: http://www.searo.who.int/entity/intellectual_property/data-exclusively-and-others-measures-briefing-note-on-access-to-medicines-who-2006.pdf

and social progress. The *European Competitiveness Report 2010*⁹⁸ says: ‘The creative industries account for 3.0 per cent of total employment (2008) and 3.3 per cent of GDP (2006). [...] In terms of exports, creative goods account for 4.3 per cent of the EU-27’s external exports.’ Although there is no direct correlation between digital goods and the ‘creative industries’, these figures confirm the significance of the latter, which increasingly rely on the digital marketplace. However, the success of the internet has not only made it easier for legitimate businesses but also for those that engage in counterfeiting and piracy to market themselves locally, nationally and internationally at relatively low cost and on a massive scale.

The huge impact of the internet on the production, distribution and consumption of cultural and other goods has made IPR a part of daily life, and has prompted calls for a profound review of relevant business models and IPR rules.

In this debate it is critical to have a better understanding of the potential consequences of the various options on the different actors in the IP value chain and to maintain a balance between the need to improve access to content and the need to incentivise content providers.

The relevance of IPR in the context of the digital world is not restricted to the aspects presented above. The development of new computing concepts such as "big data" and "cloud computing" has also significant cross-border implications in terms of IP. Huge amount of data generated by users requires clarification the best IPR regime applying to contextualised data, and under which IP regime these data may be reused in cross border application scenarios. Contracts for cloud computing services have to specify: (i) the ownership of the hosted data; and (ii) whether the data hosted in the cloud are possessed by the cloud company or just guarded, as each of them implies different rights/obligations for the cloud company (the possessor has certain legal rights, while the guardian mainly obligations) and possible liabilities for copyright-infringing content uploaded onto the cloud.

5.2.4. *Research and innovation*

The global landscape of research and innovation has changed drastically over the past decade. While until recently, the European Union, the USA and Japan dominated the scene, a number of emerging economies have invested considerably in the strengthening of their research and innovation systems. As a result, a multipolar system is developing in which countries such as Brazil, China, India, Russia or South Korea exert increasing influence.

At the same time, research and innovation itself is increasingly an international endeavour. Internationally co-authored 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, food security or infectious diseases, are important drivers for research and innovation. They are often global in nature and do not stop at borders and therefore require critical mass to be built at global level in order for them to be tackled in an efficient manner.

⁹⁸ *European Competitiveness Report 2010*, Commission staff working document, SEC(2010)1276.

All of the above require the Union to step up its cooperation on research and innovation with its international partners, while at the same time becoming more strategic in the choices it makes and in setting adequate framework conditions governing the cooperation. To this extent the Commission adopted in 2012 a new strategy for international cooperation in research and innovation.⁹⁹ While the strategy aims for an increase in cooperation activity, it also acknowledges the fact that this at the same time also 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.

Should it wish to do so, the Commission may restrict the participation in Horizon 2020 of legal entities established in third countries where conditions for the participation of legal entities from Member States in the third country's research and innovation programmes are considered to be prejudicial to the Union's interests¹⁰⁰.

5.2.5. Medicines

Ensuring access to medicines in less developed countries is a matter of major importance for the European Union. The EU has consistently sought to address the complex challenges involved. It has supported countries in reforming and in strengthening their health care systems, and is a major donor to organisations and funds dedicated to achieving improvements (e.g. WHO, UNICEF, Global Fund, GAVI,).

For some years a debate has been raging about the role that IPR plays in the accessibility to medicines, and this debate has also influenced public attitudes towards IPR. In particular, the increased level of patent protection provided for by TRIPS has been criticised because of concerns about the effects this could have on drug prices. Some, for example, argue that IPRs are a major factor in restricting access to medicines in developing countries and should be relaxed. While TRIPS does offer safeguards to remedy possible negative effects of patent protection or abuse, some call for these flexibilities to be used systematically.

In fact, patents are only one of many factors influencing access. Indeed it is worth noting that many off-patent medicines (which account for 95% of the list of essential medicines, as defined by the *World Health Organisation*) still remain unavailable in some countries. High taxes on imports imposed by certain developing countries on pharmaceutical products, mark-ups on the price of medicines imposed by intermediaries, weak pharmaceutical regulation, inadequate health infrastructure that, for example, prevent people from accessing a particular medicine, inefficient distribution and supply systems, irrational use of medicines, and lack of access to information play a far more significant role. This was explicitly recognised in a

⁹⁹ COM(2012) 497

¹⁰⁰ See Article 7.2 of the Rules of Participation: "The relevant work programme may restrict the participation in Horizon 2020 or parts thereof of legal entities established in third countries where conditions for the participation of legal entities from Member States, or of their affiliated entities established in a third country, in the third country's research and innovation programmes are considered to be prejudicial to the Union's interests." http://ec.europa.eu/research/participants/data/ref/h2020/legal_basis/rules_participation/h2020-rules-participation_en.pdf

European Parliament Resolution in 2007¹⁰¹, and also by the *World Health Organisation*¹⁰².

Another issue relates to the need for a system that provides sufficient incentives for undertaking the investments required in R&D. IPRs are fundamental to ensure that new medicines are developed because they allow innovative pharmaceutical companies the possibility to recover their investments.

But there needs to be a careful balance between longer term goal of stimulating pharmaceutical research into new treatments and the short term goal of ensuring that medicines are available and accessible for those who need them. Given the importance of ensuring that IPRs do not hinder access to medicines, a number of exceptions have been introduced to IPR legislation, particularly through some of the so-called ‘TRIPS flexibilities’. Some countries (such as India¹⁰³ or Israel) have used TRIPS flexibilities widely to develop a strong domestic industry in generic medicines. There is, however, concern that some countries may be starting to use these flexibilities less due to public health concerns and more to pursue industrial policy goals for the benefit of their domestic industry and to the detriment of foreign competitors.

It should also be noted that LDCs are not obliged to implement their TRIPS obligations in the areas of pharmaceutical patents and data protection until 1 January 2016.

Case study: Fake medicines are a hazard to health

Fake medicines are a real threat to public health. Patients taking them risk treatment failure, and even death. Many countries in Africa and parts of Asia and Latin America have areas where over a third of the medicines on sale may be fakes. (Source: WHO). Africa's efforts to combat malaria are being compromised by widespread use of fake medicines that could undermine the effectiveness of even the most powerful treatments currently available. (Source: Malaria Journal, January 2012)

The EU strongly supports the *Doha Declaration on TRIPS and Public Health* and reaffirms that the TRIPS agreement does not and should not prevent countries from taking measures to protect public health. It rapidly implemented the WTO mechanism allowing compulsory licences for the manufacture and export of generic medicines to developing countries with public health problems and lack of sufficient production capacities (Regulation 816/2006).

In addition, the EU adopted rules (Regulation 953/2003)¹⁰⁴ on strongly reduced — so-called ‘tiered’ — prices enabling exporters to deliver essential medicines for the treatment of some major communicable diseases to developing countries¹⁰⁵ at prices only slightly above their own production costs, by preventing their re-export to the EU. So far, only one pharmaceutical company has made use of this mechanism. The Commission will explore how

¹⁰¹ *TRIPS Agreement and access to medicines*. European Parliament Resolution of 12 July 2007, P6_TA(2007)0353.

¹⁰² Intervention of Margaret Chan, Director-General of the WHO, 5th High-Level Symposium on Global Health Diplomacy, Geneva, 2011.

¹⁰³ *Five years into the product patent regime: India's response*, S. Chaudhuri et al., UNDP, New York, 2010.

¹⁰⁴ Council Regulation No. 953/2003 of 26 May 2003 to avoid trade diversion into the European Union of certain key medicines, OJ L135, 3.6.2003.

¹⁰⁵ Identified in Annex II of the Regulation.

to make the tiered pricing mechanism more effective. To assess the continued usefulness and current functioning of this EU legislative instrument, as well as to answer the question of whether the current instrument remains fit for purpose, and to make proposals/recommendations on possible courses of action, a formal evaluation of the instrument is necessary and will take place in 2014.

Effective enforcement of competition rules also helps to ensure optimal regulation. In 2008, the Commission conducted a detailed inquiry regarding competition in the pharmaceutical sector in the EU¹⁰⁶. This concluded that certain ‘innovative’ pharmaceutical companies had adopted debatable strategies so as to delay the marketing of generic drugs after a period of exclusivity had expired. The resulting Communication¹⁰⁷ warns against patent linkage mechanisms¹⁰⁸: ‘*The Commission will continue to strictly enforce the applicable Community law and, for instance, act against patent linkage as, according to Community legislation, marketing authorisation bodies cannot take the patent status of the originator medicine into account when deciding on marketing authorisations of generic medicines*’. Subsequently, the 2010 and 2011 reports on the monitoring of patent settlements in the pharmaceutical sector¹⁰⁹ showed that there were fewer likely problems, demonstrating the effectiveness of the Commission's efforts to seek a balance between the interests of IPRs-holders and those of society as a whole.

On the political front, the EU has actively participated in the work of the WHO — the *Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG)*¹¹⁰ — to address urgent health needs in developing countries, and played a key role as facilitator to reach consensus on issues such as access to compound libraries, patent pools, misappropriation of traditional knowledge, assistance on TRIPS flexibilities and technology transfer.

Public-sector projects are sometimes complemented by private-sector initiatives, such as the *Medicines Patent Pool*¹¹¹, the *Global Responsibility Licensing (GRL) Platform*¹¹² or the Defend proposal (*‘Developing Economies’ Fund for Essential New Drugs*)¹¹³.

It is also well established that fake medicines can severely damage patients’ health. That being said, ‘falsified or substandard medicines’ are not to be confused with IPR-infringing medicines or even with the sub-category of IPR infringements constituted by counterfeit medicines (in common language this expression generally refers to a certain type of trademark infringement). ‘Falsified or substandard’ medicines may or may not infringe an IP right, and IPR-infringing medicines may or may not be ‘falsified or substandard’, depending on whether or not they contain ingredients which are of low quality or in wrong dosage.

¹⁰⁶ <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html>

¹⁰⁷ Communication from the Commission, Executive Summary of the pharmaceutical sector inquiry report, http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf

¹⁰⁸ Patent linkage mechanisms typically lead to marketing authorisation being refused as long as a relevant patent is in force.

¹⁰⁹ First Report on the monitoring of patent settlements (period: mid 2008 - end 2009), of 5 July 2010, http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report1.pdf

¹¹⁰ Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG), <http://www.who.int/phi/igwg/en/index.html>

¹¹¹ <http://www.medicinespatentpool.org>

¹¹² <http://globalaccessinaction.org/gaa-grl-platform>

¹¹³ *A point of view on parallel imports*, D. Joshi and I. Limited, Global Policy Essay, 2012.

IPR legislation is by no means the main answer to the health hazard aspects of the problem. However, IPR-infringing medicines, in particular when they infringe a trademark (counterfeit medicines), are often found to include products with wrong ingredients. Both branded and generic products may be subject to counterfeiting.

Clearly the problem is wider than an IPR issue, but the question is whether IPR can make a positive contribution or not. The answer is yes. For example, trademarks have a role to play in guaranteeing the authenticity, and hence the quality of the medicine supply (which companies themselves strive to maintain, thereby guarding their reputation for producing quality goods). Not only does a solid regulatory framework, including IPR systems, help ensure quality, but also, in developed markets such as the US and the EU, the existence of well-functioning and competent regulators such as the FDA or EMA.

Directive 2011/62 addresses the prevention of the entry into the legal supply chain of falsified medicinal products¹¹⁴. Equally relevant is the *Council of Europe's* recent draft convention¹¹⁵ which would, for the first time, offer a binding international instrument in the field of criminal law regarding counterfeiting of medical products and similar crimes involving threats to public health.

Drugs in transit

In 2008, there were several detentions by Dutch customs authorities of medicines in transit from India to Brazil, through the Netherlands, that led India and Brazil to initiate a WTO dispute settlement case in 2010. Following discussions, the EU and India reached an understanding so as to suspend the case.

The Commission acknowledged that implementing Regulation 1383/2003 dealing with IPR enforcement by customs authorities should not hamper legitimate trade in generic medicines. Accordingly, the Commission took initiatives to draw the attention of EU customs authorities and the pharmaceutical industry¹¹⁶ to this issue, insisting on the need for correct implementation of the Regulation and emphasising the EU's commitment on access to medicines.

Given the need to clarify the relevant EU legislation for customs enforcement of IPRs, a Commission proposal¹¹⁷ was adopted in 2011 to amend Regulation 1383/2003. This was adopted on 12 June 2013 as Regulation (EU) No 608/2013. The revised Regulation is intended to clarify that customs authorities should determine if there is a substantial risk of

¹¹⁴ Directive No. 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive No. 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products, OJ L174, 1.7.2011.

¹¹⁵ http://www.coe.int/t/dghl/standardsetting/medicrime/CDPC%20_2009_15Fin%20E%20Draft%20Convention%2009%2011%2009CM.pdf

¹¹⁶ http://www.bio.org/sites/default/files/Access_to_Medicines_Policy_Statement_Final.pdf

¹¹⁷ As stated in COM(2011) 285, http://ec.europa.eu/taxation_customs/resources/documents/customs/customs_controls/counterfeit_piracy/legislation/com285_en.pdf

diversion of the goods onto the EU market when assessing whether IPRs are infringed. Customs authorities can identify any such risk through their inspections¹¹⁸. In 2012 the Commission also published guidelines¹¹⁹ for EU customs officials.

5.3. Building on EU legislation and coordination at EU level

5.3.1. EU legislation

The scope of harmonised EU legislation often determines the level of ambition of bilateral trade agreements, i.e. what the EU can negotiate (since bilateral trade agreements are typically not used as a way to introduce changes in EU legislation).

Lack of harmonisation can complicate the EU's ability to negotiate with third countries, in so far as issues not falling within the scope of the Common Commercial Policy are concerned. For those issues, absent any decision to exercise competence at EU level, consensus must be achieved amongst Member States in order to arrive at a common negotiating position. For example, the EU's ability to negotiate criminal IPR enforcement provisions¹²⁰ – which are useful as a deterrent, at least in the case of wilful and commercial-scale infringements and in countries where civil litigation is often ineffective – has been complicated by the absence of an EU *acquis*. Other examples have been the previous absence of a EU patent and the lack of a EU-wide regime to regulate trade secrets or geographical indications for non-agricultural products.

The 2010 Commission Communication on trade policy states: '*further harmonising IP rules within the EU would enhance the Commission's capacity to negotiate on behalf of the EU stronger IP commitments with our key trading partners*'¹²¹. Many areas of IP law have been harmonised by EU legislation with an impact on external trade, such as the *Customs Regulation*¹²² or the *Enforcement Directive*¹²³, but also substantive rules creating unified EU-wide IPRs for trademarks, designs, geographical indications for agricultural products, rights related to copyright and, more recently, the EU patent.

¹¹⁸ Inspections are also necessary because: '*Transshipment is of growing concern because fraudsters break routes to disguise the origin of the goods. Countries generally regarded as low risk by Customs, such as Japan and USA, are becoming higher risk due to transit and transshipment traffic in fakes. A seizure in 2004 showed that fake car mechanisms entered the Community from the US although the goods were in reality of Chinese origin. Cases have also occurred where the Community itself is used to disguise the origin of goods (e.g. fake medicines from Asia transhipped through the EU on route to Africa).*' COM(2005) 479,

http://ec.europa.eu/taxation_customs/resources/documents/comm_native_com_2005_0479_3_en_acte.pdf

¹¹⁹ http://ec.europa.eu/taxation_customs/resources/documents/customs/customs_controls/counterfeit_piracy/legislation/guidelines_on_transit_en.pdf

¹²⁰ The International Trademark Association (INTA) highlighted inconsistencies in criminal enforcement of trademark counterfeiting and copyright piracy laws within Member States, <http://www.inta.org/Advocacy/Documents/INTAEUCriminalSanctions20082009.pdf>

¹²¹ Trade, Growth and World Affairs: Trade Policy as a Core Component of the EU's 2020 Strategy. COM(2010)612

¹²² 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.

¹²³ 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, 30.4.2004.

5.3.2. Cooperation within the EU for promoting IPR in third countries

Commission services, particularly those with external responsibilities have an important and well-defined role in terms of promoting IPR in third countries. However, the most ‘operational’ enforcement responsibilities lie with Member States. The most visible and/or immediate results in this fight are undertaken by the national customs authorities, the police and national courts. There have already been steps to improve coordination with national authorities in Member States with responsibility for IPR issues, but there is a need for further improving information exchange and coordination regarding IPR protection in third countries.

In the US, for instance, internal coordination was recently improved by the appointment of a central *Intellectual Property Enforcement Coordinator*¹²⁴ chairing an interagency ‘*Senior Intellectual Property Enforcement Advisory Committee*’, and by the creation of a ‘*National IPR Coordination Center*’¹²⁵. Similarly, Japan’s ‘*National IP strategy*’¹²⁶ is coordinated by an ‘*IP Strategy Headquarters*’ involving all ministers.

Europe benefits from highly competent IP Offices. While the *Office for Harmonisation in the Internal Market (Trade Marks and Designs)* (OHIM) and the *Community Plant Variety Office* (CPVO) are EU bodies, the *European Patent Office* is not, though all EU Member States are involved in its decision-making process (and represent the majority of its contracting states). The two EU agencies are in charge of the implementation of Union harmonised legislation for plant variety protection (CPVO) and trademark and design (OHIM); within their mandate, they are active at international level and support a harmonised approach in terms of intellectual protection.

Attention should be drawn to the fact that, in order to combat the problem more efficiently and to dismantle international fraud networks involved in the traffic of counterfeit and pirated goods at the external borders of the EU, the *European Anti-Fraud Office* (OLAF), which has long been investigating the illegal trade in counterfeit cigarettes and tobacco products, coordinates also investigations related to other counterfeit goods that enter the EU through its external borders. However, due to its internal procedures and the limited resources available, OLAF's investigative capacities are only allocated to significant cases with specific emphasis on counterfeit goods posing a risk for the environment or public health and safety.

In accordance with the customs mutual administrative assistance provisions concluded with third countries, OLAF may also participate upon request in investigations carried out in third countries in order to obtain all the necessary evidence.

OLAF's investigations into fraud related to counterfeit goods, which are carried out in close cooperation with the EU Member States, significantly and constructively contribute to the activities currently undertaken by other Commission services.

¹²⁴ 2010 U.S. *Intellectual Property enforcement coordinator annual report on Intellectual Property enforcement*, Executive Office of the President of the United States, 2011, <http://www.whitehouse.gov/omb/intellectualproperty>

¹²⁵ <http://www.ice.gov/ipcenter/>

¹²⁶ *Intellectual Property policy outline*, Strategic Council on Intellectual Property, 2002, http://www.kantei.go.jp/foreign/policy/titeki/kettei/020703taikou_e.html

6. CONCLUSION

This *Staff Working Document* helps clarify the background to the Communication which it accompanies, and which provides a coherent and consistent policy message on IP vis-à-vis third countries. The Commission has taken on board the responses and evaluation of its initial Strategy from 2004. What is clear is that IP has become increasingly more relevant, valuable and personal. This necessitates a well thought-out and balanced policy approach. Given the increasing impact of IP on growth and society, the Commission must continue work to support effective IP regimes in third countries, in order to promote innovation and protect social welfare, so that the related benefits can be shared by all.

**Annex 1 – Structure of the 2014 IPR Strategy in relation to the
2010 Evaluation of the 2004 Strategy**

Objectives of the 2014 IPR Strategy		Actions envisaged by the 2014 IPR Strategy	Recommendations of the 2010 Evaluation
Promote EU competitiveness, growth and jobs			Recommendation 1: More comprehensive approach
	Enhance IPR protection and enforcement in selected third countries	Continue multilateral efforts to improve the international IPR framework, including by encouraging further ratification of existing treaties	Recommendation 5: Pursue legislative improvement where needed
		Ensure a strong and coherent role for the EU in international IPR fora in line with the Lisbon Treaty	
		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	Recommendation 2: Embrace the development agenda
		Continue and where possible enhance 'IP Dialogues' with key third countries	Recommendation 6: Pursue bilateral agreements
		Leverage high-level trade and political dialogues to ensure progress on identified IPR issues	
		Provide, and promote awareness of, appropriate technical assistance programmes to third countries, including the possible use of IP flexibilities	Recommendation 7: Develop technical cooperation programmes
Leverage the expertise of relevant international organisations in implementing technical assistance programmes	Recommendation 8: More focussed training and awareness-raising		
	Ensure the Commission can make judicious recourse to dispute settlement mechanisms or other remedies where the EU's rights under international agreements are infringed		

		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	
	Provide assistance to EU right-holders in key third countries	Continue assistance to right-holders (through projects such as <i>IPR Helpdesks</i>) and consider their possible expansion Enhance networking and coordination between EU and MS representations in third countries Consider further posting of IPR experts to key EU delegations Establish a stronger relationship between the Commission, Member States and EU business, to directly support economic operators in overcoming concrete difficulties on IP issues	Recommendation 4: Strengthen consultation with all stakeholders
	Improve outreach and awareness-raising vis-à-vis all stakeholders	Ensure regular interaction with all stakeholders to raise awareness and guide policy Enhance data collection and reporting, so as to improve our understanding of the role of IPR and the impact of infringement	
	Enhance harmonisation and coordination at EU level	Promote ratification of relevant IPR treaties by all EU Member States	
		Enhance intra-EU cooperation regarding third countries, e.g. using existing fora for IPR discussions between the Commission and Member States	Recommendation 3: Ensure adequate organisational set-up
	<i>(Global)</i>	Conduct regular surveys in order to maintain a list of 'priority countries' for focused EU efforts	

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Annex 3 – Glossary

Disclaimer: The definitions offered below are not necessarily shared throughout the world, and do certainly not override any definitions included in relevant legislation. Moreover, some of these concepts may be subject to debate, in the absence of any legal definition, e.g. as regards fake medicines. The definitions offered below therefore simply constitute a *bona fide* informal attempt to help non-specialised readers understand this *Staff Working Document* and the Communication it accompanies.

Further glossaries and general information on IPR can be found on relevant websites such as WIPO's¹²⁷. Specific glossaries are also available, for instance a WIPO glossary relating to IPR, genetic resources and traditional knowledge¹²⁸.

Intellectual property	<p>Intellectual property ('IP') refers to intellectual creations such as inventions, literary and artistic works, brands and logos – which may be protected by IPRs (see below).</p> <p>Intellectual property is usually divided into two branches: 'literary and artistic property' on the one hand (including e.g. books, movies, songs, photographs, software and artistic performances), and 'industrial property' on the other hand (including e.g. inventions, brands, logos, designs, plant varieties, geographical indications and trade secrets).</p>
Intellectual property rights	<p>Intellectual property rights ('IPRs') are titles of property on specific inventions, brands or other pieces of IP. With the exception of copyright and related rights, they are granted by public authorities under well-defined rules and procedures. An IP right allows for a monopoly by a creator, usually for a limited duration, in the sense that it makes it possible for its owner to prevent third parties from using the invention, brand, etc. concerned without his authorisation (cf. 'Enforcement' below).</p> <p>There are many types of IPRs, such as copyright and related rights, patents, industrial designs, trademarks and geographical indications.</p> <p>IPRs are 'territorial' in the sense that a French patent protects an invention only in France, a German patent only in Germany, etc. This means that it is often necessary to file applications in several countries to adequately protect an invention, or trade mark, etc.</p> <p>However, certain regional IP systems exist, such as the Community trade mark and the Community design, which make it possible to ensure protection in a number of countries bound by a specific treaty or other arrangement. For instance, a 'Community trade mark' covers by</p>

¹²⁷ <http://www.wipo.int/tools/en/faqs.html>, <http://www.wipo.int/sme/en/>, <http://www.wipo.int/ipstats/en/statistics/glossary.html>

¹²⁸ *Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore*, WIPO Second Intersessional Working Group, Geneva, 2011.

	<p>definition all EU member states.</p> <p>Most of these rights have a limited duration (only trademarks can be renewed indefinitely), which depends from the right and country concerned (e.g. patents have a typical maximum duration of 20 years).</p>
Copyright and related rights	<p>Copyright protection is enjoyed by creators (authors of original creations) for their literary and artistic works, such as books, poems, plays, newspapers, computer programmes, databases, films, musical compositions, choreography, paintings, drawings, photographs, sculpture, architecture, engravings, maps, etc.</p> <p>Authors can authorise or prohibit the reproduction, the recording, the broadcasting, the public performance, the rental and lending, the translation and adaptation of their works as well as the 'making available' of their works online. In the EU, copyright (the time during which authors can receive money in exchange for their permission for someone to use their work as listed in the rights above) last for 70 years after the author's death. Authors also enjoy moral rights, which have no time limit. Moral rights allow the author or his heirs to oppose changes to the work that could harm the author's reputation.</p> <p>'Related rights' developed around copyrighted works and are held by performing artists (such as actors and musicians) in their performances, producers of sound recordings in their recordings (such as CDs), and broadcasting organisations in their radio and television programs. The length of protection in the EU for live performances and broadcasting organisations is 50 years, and for recorded performances it is 70 years (for both the producer and the performer).</p> <p>Unlike most other IPRs¹²⁹, copyright and related rights do not have to be registered (no formalities) and automatically appear at the moment of creation, performance, broadcast or recording.</p>
Patents	<p>Patents are IPRs specifically intended to protect inventions, in particular products (mechanical or electrical devices, chemical products and pharmaceuticals, etc.) and processes (e.g. manufacturing processes for chemicals). Their maximum duration is 20 years, with up to 5 more years for pharmaceuticals in well-defined circumstances (in the EU). The three patentability criteria are novelty, inventive step (non-obviousness) and capacity for industrial application (or usefulness).</p> <p>Three ways can be used to obtain patent protection in the EU:</p> <ol style="list-style-type: none"> (1) filing a national patent application in each of the countries of interest, (2) filing a <i>European patent application</i>, which will undergo a single examination procedure (conducted by the European Patent Office) and give rise to national patents in the designated countries once (if) the

¹²⁹ This is also the case for unregistered designs and trademarks (where they exist), as well as trade secrets.

	<p>European patent is granted, or (3) filing an international application under the PCT system (<i>Patent Cooperation Treaty</i> – which involves an international phase to be followed by national/regional phases where desired).</p> <p>In all cases, however, enforcement takes place at a national level. This shortcoming will be addressed from 2014 onwards by the future <i>unitary EU patent</i> and <i>Unified European Patent Court</i>.</p> <p>In addition to patents as such, some countries make it possible to register ‘utility models’, which may be considered as a simpler (and shorter-duration) variety of patents, available only for certain categories of inventions (e.g. not for processes).</p>
Trademarks	<p>Trademarks are IPRs specifically intended to protect distinctive signs such as names, numbers, logos, shapes and even sounds. Such signs are always protected in connection with specific goods and/or services.</p> <p>In the EU, trademarks are initially registered for 10 years, but can be renewed indefinitely for additional periods of 10 years.</p> <p>Three ways can be used to register a trademark in the EU: (1) filing a national trademark application in each of the countries of interest¹³⁰, (2) filing an application for a Community trademark at the <i>Office for Harmonisation in the Internal Market</i> (OHIM) – a Community trademark has unitary character; it has uniform effect throughout the EU –, or (3) filing an international trademark application at the <i>World Intellectual Property Organisation</i> (WIPO) (or via a national office) under the ‘<i>Madrid system for the International Registration of Marks</i>’ so as to protect the trademark in up to about 100 countries by filing a single application.</p> <p>National or international trademarks are enforced at a national level while Community trademarks having a unitary nature and are enforced at EU level by specialised <i>trademarks courts</i>. Therefore a decision by a German <i>trademark court</i> on a Community trademark is enforceable in any other EU Member State.</p>
Designs	<p>Industrial designs (or, in short, ‘designs’) are IPRs specifically intended to protect the appearance of the whole or a part of a product resulting from features such as lines, contours, colours, shape and/or texture of the product itself and/or its ornamentation. Designs may be 3-D (e.g. furniture and car body parts) or 2-D (e.g. patterned cloth and wallpaper).</p> <p>Like for trademarks, there are also three ways to register a design in the</p>

¹³⁰ Some countries also recognise unregistered trademarks, whose protection is based on their use, which do not require any formalities.

	<p>EU:</p> <p>(1) filing a national design application in each of the countries of interest,</p> <p>(2) filing an application for a Community design before the <i>Office for Harmonisation in the Internal Market (OHIM)</i> – a Community design has unitary character; it has equal effect throughout the EU, or</p> <p>(3) filing an international design application at WIPO (or via a national office) under the <i>Geneva Act of the Hague Agreement</i> system, so as to protect the design in up to about 60 countries by filing a single application.</p> <p>In the EU, in addition to registered Community designs, it is also possible to claim protection for an <i>unregistered Community design</i>. An unregistered design is protected only by the simple act of making it available to the public, without any formalities.</p> <p>In the EU, registered industrial designs are in force for 5 years renewable (by periods of 5 years) up to a maximum of 25 years, and unregistered Community designs are protected for a maximum of 3 years (not renewable).</p> <p>National and international designs are enforced at a national level while Community designs having a unitary nature are enforced at EU level by specialised <i>designs courts</i>. Therefore a decision by a Spanish <i>design court</i> on a Community design is enforceable in any other EU Member State.</p>
Geographical indications	<p>Geographical indications (GIs) are names that identify products as originating in a territory where a given quality, reputation or other characteristic of the product is essentially attributable to its geographical origin (e.g. ‘Champagne’, ‘Tequila’ or ‘Roquefort’).</p> <p>While GIs may apply to all kinds of goods (including handicraft), they are essentially used for wines, spirits and agricultural products.</p> <p>A registered GI entitles its producers and those trading or selling the original product – but no other parties – to use the registered name. Unlike other IPRs which usually have a single and well-defined owner, there only exists a collective interest in the protection of a GI: no single producer from the related geographical area can claim exclusive rights to a certain GI. All operators fulfilling the conditions laid down in the product's ‘specification’ can use the protected name. At the same time, third parties from outside the region (or not complying with the specification) are not allowed to use the protected name.</p> <p>The list of GIs for agricultural products and foodstuffs recognised in the EU can be found in the DOOR database (http://ec.europa.eu/agriculture/quality/door/list.html).</p>

	<p>Wine GIs can be found in the E-BACCHUS database (http://ec.europa.eu/agriculture/markets/wine/e-bacchus) and 'E-SPIRIT-DRINKS' (http://ec.europa.eu/agriculture/spirits) is the database on GI protected in the EU for spirits.</p>
Protection of IPRs	<p>Inventions, trademarks, etc. may be protected by different kinds of IPRs, subject to well-defined procedures in certain cases (e.g. filing a patent application) but not in others (e.g. for copyright). Actually one should not refer to the 'protection of IPRs', which is an improper shortcut (an IP right protects an invention, trademark, movie, etc.).</p> <p>In this context, 'protection' – as opposed to 'enforcement' – relates to the substantive rules defining the conditions under which an invention, trademark, etc. may be protected by an IP right (e.g. patentability criteria, procedural rules for the registration of trademarks, etc.).</p>
Enforcement of IPRs	<p>'Enforcing' an IP right means to ensure that it is respected, namely by initiating legal proceedings (civil, criminal or administrative), or possibly at other levels (e.g. by customs authorities), on the basis of the principle that an IP right enables its owner to prevent third parties from e.g. manufacturing, using, advertising or importing the underlying invention, trade mark, copyrighted work, etc.</p> <p>The exact definition of the prohibited acts, as well as the applicable rules, procedures and sanctions, may vary considerably according to the type of IP right and to the country concerned.</p> <p>However, in 2006 the remedies available to IPR owners were harmonised across the EU by the 'Enforcement Directive' (<i>Directive 2004/48/EC on the enforcement of intellectual property rights</i>), which aimed to ensure compliance with TRIPS, and to strengthen and harmonise the enforcement of IPRs.</p>
Piracy	<p>'Piracy' is often interpreted as designating copyright infringement involving (quasi-)identical copying, on the basis of a footnote of the TRIPS agreement which defines 'pirated copyright goods' as <i>'any goods which are copies made without the consent of the right holder or person duly authorized by the right holder in the country of production and which are made directly or indirectly from an article where the making of that copy would have constituted an infringement of a copyright or a related right under the law of the country of importation'</i>. This means that piracy does not cover all cases of copyright infringement (e.g., the unauthorised translation of a book would not be considered as piracy).</p> <p>It is worth noting that the situation may be different in languages other than English. In Germany, for instance, an informal distinction is made between 'trademark piracy' (Markenpiraterie) and 'product piracy' (Produktpiraterie), depending on whether it is just the trademark which is counterfeited or the product itself (regarding e.g. patent or design</p>

	<p>rights).</p> <p>One may also note that the EU ‘Customs Regulation’ (Council Regulation 1383/2003) defines ‘pirated goods’ as <i>‘goods which are or contain copies made without the consent of the holder of a copyright or related right or design right’</i>, which goes beyond the TRIPs definition as it also covers designs.</p>
Counterfeiting	<p>Similarly, ‘counterfeiting’ is often interpreted as designating trademark infringement involving (quasi-)identical reproduction of a trademark, on the basis of the same footnote of TRIPS which defines ‘counterfeit trademark goods’ as <i>‘any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation’</i>. This means that counterfeiting does not cover all cases of trademark infringement.</p> <p>It is worth noting that the situation may be different in languages other than English. In French, for instance, ‘contrefaçon’ designates all kinds of IPR infringements.</p>
Generic medicines	<p>From a pharmaceutical perspective, a generic medicine is the same as a medicine that has already been authorised, and contains in particular the same active substance(s).</p> <p>From an IPR perspective, the patent protection of a ‘generic’ medicine, as well as its data protection, have expired (or never existed) in the country at stake (indeed, IPR matters are always to be discussed on a territorial basis, i.e. country-by-country). This approach is taken in the Commission's <i>Pharmaceutical Sector Inquiry</i> (2009), according to which generics are <i>‘products that can enter the market upon loss of exclusivity of the original product’</i> – whether this is about a loss of patent, data or market exclusivity.</p> <p>This implies that a certain medicine may be generic in one country and still patent-protected in another one. Moreover, a generic medicine (even if it has lost patent, data and market exclusivity in the whole world) may still be protected by other IPRs, in particular trademarks, in certain countries.</p>
Counterfeit medicines	<p>Various definitions exist for ‘counterfeit’ medicines, including WHO's: <i>‘A counterfeit medicine is one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.’</i></p>

	<p>This definition clarifies that generic medicines may happen to be counterfeits (infringing trade marks), as already mentioned above.</p>
<p>Fake (falsified) medicines</p>	<p>Fake / falsified medicines are distinct from counterfeit medicines. While the former concepts do not specifically involve IPR aspects, the latter refers more directly to trademark infringements (and is applicable to both branded and generic medicines), as explained above.</p> <p>Falsified medicines usually contain sub-standard or falsified ingredients, or no ingredients or ingredients, including active substances, in the wrong dosage thus posing an important threat to public health¹³¹.</p> <p>No official definition could be identified for ‘fake’ medicines. It is often informally stated that fake medicines ‘<i>make false claims about what they contain or where they are from</i>’, which does not particularly focus on IPR aspects.</p> <p>The definition of ‘falsified medicinal product’ included in EU Directive 2011/62 is not IPR-related either.</p>
<p>Data protection</p>	<p>Data protection is made mandatory by TRIPs Art. 39.3, which obliges WTO members' public authorities, where they require the submission of data as a condition of approving the marketing of pharmaceutical or of agricultural chemical products (e.g. clinical trials data), (1) to ensure the confidentiality of such data, and (2) to protect them against unfair commercial use. This definition has been interpreted in various ways by different countries. It should be stressed that this protection only applies to regulatory data, not to any product as such.</p>
<p>Data exclusivity</p>	<p>Once a new pharmaceutical or agro-chemical product (developed by an ‘originator’) has been authorised for marketing, the EU (as most other developed countries) prevents other companies from merely relying on the originator's test data – i.e. claiming that products are similar, therefore asking for an authorisation based on the data provided by the originator – during a certain period which is considered adequate in respect of the time and resources that invested in the generation of the originator's test data. Data exclusivity is a particular way of enforcing the ‘protection against unfair commercial use’ obligation (TRIPs Art. 39.3), namely by interpreting it as a ‘non-reliance’ obligation. This protection also only applies to regulatory data, not to any product as such.</p>
<p>Compulsory licensing</p>	<p>Compulsory licensing (CL) is a mechanism allowed by the TRIPs agreement (Art. 31) – one of the ‘TRIPs flexibilities’ –, making it possible for a country's authorities to force the owner of a certain patent</p>

¹³¹ Directive No. 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive No. 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products, OJ L174, 1.7.2011.

	<p>to license it to third parties, for instance in order to address the insufficient domestic availability of patented goods (e.g. medicines). This mechanism is normally used in exceptional circumstances only, such as health emergencies, as it represents a serious curtailment of the patentee's rights. A number of conditions and procedural steps need to be fulfilled for a CL to be granted, e.g. prior unsuccessful negotiation with the patentee.</p>
TRIPS agreement	<p>This is the WTO's agreement on <i>Trade-related Aspects of Intellectual Property Rights</i>, which all WTO members need to comply with. Its text can be found at http://www.wto.org/english/docs_e/legal_e/27-trips.pdf. This agreement defines basic common principles relating to the protection and enforcement of IPRs, while leaving some freedom to WTO members to define more specific rules, and to implement certain 'flexibilities' (exceptions – e.g. regarding compulsory licensing).</p> <p>It should be noted that TRIPs does not cover all categories of IPRs; for instance it does not cover utility models nor unregistered industrial designs.</p>
Bilateral trade agreements (BTAs)	<p>BTAs, which include for instance <i>Free Trade Agreements</i> (FTAs), are comprehensive agreements, between two countries, or between the EU and a third country, addressing a broad range of trade-related issues, including for instance market access rules, investment, services, public procurement, intellectual property, etc. BTAs usually include an 'IP chapter' defining a number of rules regarding intellectual property matters, with the objective of creating a level playing field between the countries concerned.</p> <p>More information on IPR aspects of BTAs can be found at http://trade.ec.europa.eu/doclib/docs/2012/november/tradoc_150081.pdf.</p>
WIPO	<p>The <i>World Intellectual Property Organisation</i> is a UN agency responsible for the negotiation and administration of most of the international IPR treaties, as well as for the operation of certain international registration systems (such as the <i>Patent Cooperation Treaty</i>, the <i>Madrid Agreement concerning the International Registration of Marks</i> and the <i>Hague Agreement concerning the International Registration of Industrial Designs</i>).</p>

