Implementation of TRIPS public healthflexibilities to improve access to medicines in Belarus, Georgia, Moldova and Ukraine

This analytical report was produced by the ICO East Europe and Central Asia Union of PLWH within the project “Promoting universal access to treatment for people living with HIV, as an inalienable human right” funded by AIDSfonds

2013

Contents

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1 Summary

This analytical report analyses, focussing on access to medicines, the landscape and some major issues related to the implementation of the TRIPS Agreement in Belarus, Georgia, Moldova and Ukraine.

First, it provides an overview of the international obligations of states in relation to ensuring access to essential medicines. Next, it describes how the situation in the field of intellectual property for pharmaceutical products changed with the adoption of the TRIPS Agreement.

Furthermore, the authors describe flexibilities contained in the TRIPS Agreement that are important for ensuring balance between patent holders' rights protection and public health interests. Additionally, the authors identify frequently used TRIPS-plus provisions that are adopted by some states as a result of pressure during WTO accession negotiations or bilateral agreements with the US or EU. The provisions have negative effect on access to medicines.

Consequently, the authors analyse the legislation of Belarus, Georgia, Moldova and Ukraine to define what TRIPS flexibilities, TRIPS-plus provisions exist, the implementation in te respective national legislation.
Based on the results of the analysis recommendations are provided how to improve national patenting and medicine legislation with regard to access to medicines within the framework of the TRIPS Agreements.

2 Abbreviations

AIDS	acquired immunodeficiency syndrome
ARVs	antiretroviral medicines
DRA	Drug Regulatory Agency
FTA	free trade agreement
HIV	Human Immunodeficiency Virus
ICCPR	International Covenant on Civil and Political Rights
IGO	Intergovernmental organization
ICESCR	International Covenant on Economic, Social and Cultural Rights
IPR	intellectual property rights
LDC	Least developed country
NGO	Non-governmental organization
Sakpatenti	National Centre of Intellectual Property of Georgia
SSIP	State Service on Intellectual Service of Ukraine
TRIPS	Agreement on Trade-related Aspects of Intellectual Property Rights
Ukrpatent	Ukrainian Institute of Industrial Property
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNDP	United Nations Development Programme
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

3 Introduction

The right to the highest attainable standard of physical and mental health is protected by international human rights instruments and is included in most national constitutions.[1] Access to essential medicines[2] is widely recognised as an indispensable part of the right to health and is seen as a minimum core obligation, which is non-derogable and must not be violated based on lack of available resources. States have an obligation under the right to health to ensure that medicines are available, financially affordable, and physically accessible on a basis of non discrimination to everyone within their jurisdiction.[3]

At the same time, most of the people who live in developing countries and countries with economies in transition have far less probability to have access to medicines to treat wide range of life-threatening illnesses from HIV to heart disease, than people in developed countries.[4] Vast inequalities in access to medical care, including treatment, still exist around the world, largely as a result of HIV/AIDS but also because of resurgence of other infectious diseases and a growing burden of noncommunicable diseases[5]. Around 2 billion people lack access to essential medicines and around 50-90% of essential medicines costs in developing countries are paid by patients.[6] Inequalities in access to medical care are thus still plentiful,

[1] UNAIDS, WHO, UNDP, Policy Brief: Using TRIPS flexibilities to improve access to HIV treatment http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2049_PolicyBrief_TRIPS_en.pdf

[2] According to WHO definition: "Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford. The implementation of the concept of essential medicines is intended to be flexible and adaptable to many different situations; exactly which medicines are regarded as essential remains a national responsibility." http://apps.who.int/medicinedocs/en/d/Js4875e/5.2.html The WHO has published a model list of essential medicines. It has been updated every two years since 1977. Each country is encouraged to prepare their own lists taking into consideration local priorities. At present over 150 countries have published an official essential medicines list.

[3] Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover "Promotion and protection of all human rights, civil, political, economic, social and cultural rights, including the right to development", A/HRC/11/12, 31 March 2009, paragraph 11.

[4] OSI, Playing by the rules: Using Intellectual Property Law and Policy to Improve Access to Essential Medicines, July 2008, Access to Essential Medicines Initiative, p. 4

[5] WHO, Public Health Innovation and Intellectual Property Rights, A Report of the Commission on Intellectual Property Rights, Innovation and Public Health (Geneva, 2006) p. 1 http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf.

[6] Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover "Promotion and protection

despite great technological and economical progress in the past 30 years[7],Improving access to essential medicines will save lives and improve the quality of life of billions of people living in the global South.

As mentioned above, one of the dimensions of the right to health is the right to access of medicines. Medicines should be physically accessible and economically affordable. Economic affordability is seen as a part of access to medicines dimension and is influenced by the pricing of medicines which is quite often based on monopoly rights of pharmaceutical companies. Intellectual property rights (IPRs), as an example of private rights, can play a significant role on restricting access to essential medicines. IPRs give their owners the opportunity to gain exclusive protection over a certain period and potentially monopolize markets and set high prices not affordable for the majority of population in the developing world. In such situations, balancing of rights conferred by patents and the right to have access to essential medicines plays an important role in addressing needs of developing countries.

At the same time the World Trade Organization (WTO) Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS Agreement) that came into force on 1 January 1995, introduced a stronger international protection framework for intellectual property rights worldwide. The TRIPS Agreement obliged all WTO members to introduce intellectual property (IP) protection, including patent protection for medicinal products. The TRIPS Agreement obligations are legally enforceable through Dispute Settlement Body and backed by sanctions.[8] One of the main characteristics that distinguish the TRIPS Agreement from other international agreements regulating intellectual property were the enforcement provisions setting domestic procedures, remedies for the enforcement of intellectual property and framing intellectual property protection within the World Trade Organization. These regulations provide stronger encouragement for states to protect intellectual property.

Some of the TRIPS Agreement provisions rendered WTO member-states with discretion to incorporate public interest considerations into domestic legislations while implementing TRIPS Agreement, often reffered to as "TRIPS flexibilities". Some of the TRIPS-flexibilities provisions can be used for public health interests. These flexibilities are perceived as 'steps

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of all human rights, civil, political, economic, social and cultural rights, including the right to development", A/HRC/11/12, 31 March 2009, paragraphs 13-14.

[7] Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover "Promotion and protection of all human rights, civil, political, economic, social and cultural rights, including the right to development", A/HRC/11/12, 31 March 2009, paragraph 12.

[8] Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover "Promotion and protection of all human rights, civil, political, economic, social and cultural rights, including the right to development", A/HRC/11/12, 31 March 2009, paragraph 24.

and tactics'[9], that help countries balance public health interests and private interests.This paper endeavours to describe the TRIPS flexibilities provided in the TRIPS Agreement and to research ways in which TRIPS flexibilities are implemented in domestic legislations of Belarus, Georgia, Moldova and Ukraine. Further, the authors elaborate recommendations that could be used by non-governmental organizations (NGOs) activists in Belarus, Georgia, Moldova and Ukraine to advocate for better public health-related TRIPS flexibilities implementation.

[9] OSI, Playing by the rules: Using Intellectual Property Law and Policy to Improve Access to Essential Medicines, July 2008, Access to Essential Medicines Initiative, p. 7

4 Access to Medicines and the TRIPS Agreement

The right to the highest attainable standard of health is enshrined in the Univeral Declaration of Human Rights (UDHR), International Covenant on Economic, Social and Cultural Rights (ICESCR), several other human rights instruments and WHO Constitution.[10] In the Universal Declaration of Human Rights health and medical care are mentioned in the context of adequate standard of living. It declares that everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing, medical care, necessary social services; and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.[11] The Article 12 of the ICESCR, which is binding for 85% of the WTO Members,[12] clarifies the content of the right to the enjoyment of the highest attainable standard of physical and mental health by stating that:

> "1. The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.
>
> 2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:
>
> (a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;
>
> (b) The improvement of all aspects of environmental and industrial hygiene;
>
> (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;
>
> (d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness."

[10] In the International Convention on the elimination of all Forms of racial Discrimination (1965): article 5(e)iv; International Covenant on economic, social and Cultural rights (1966): article 12; Convention on the elimination of all Forms of Discrimination against Women (1979): articles 11(1)f, 12 and 14(2)b; International Convention on the rights of the Child (1989): article 24; International Convention on the Protection of the rights of all migrant Workers and members of their Families (1990): articles 28, 43(e) and 45; Convention on the rights of Persons with Disabilities (2006): article 25.

[11] Art. 25 of the Universal Declaration of Human Rights.

[12] H. Hestermeyer, Human Rights and the WTO: The Case of Patents and Access to Medicines, OUP 2008, p. 103

In the context of access to medicines subparagraphs 12(2)(c) and (d) are very important as they clarify that the content of the right to health includes the prevention, treatment of epidemic and other diseases; and the availability of medical service and medical attention in the event of sickness. Access to medicines is an integral part to most therapies and therefore is essential in prevention, treatment and control of diseases, as well as for medical service in the event of sickness.[13] Courts in several countries have also confirmed that access to medicines is a part of the right to health.[14]

There are four elements that are contained in all forms and levels of the right to health: (i) availability of medicines in sufficient quantity; (ii) accessibility of medicines to everyone; (iii) acceptability of treatment from cultural and ethical perceptions and; (iv) appropriate quality of medicine.[15] Accessibility means that health facilities, goods and services have to be accessible to everyone without discrimination. This means that essential medicines should also be accessible to anyone who needs them within the territory of the state. Accessibility has the following dimensions:

1. Non-discrimination in the context of access to medicines means that medicines must be accessible to all, without discrimination, especially to the most vulnerable or marginalized groups of the population;
2. Physical accessibility refers to medicines being within safe, physical reach for all groups of the population;
3. Economic accessibility means that medicines must be affordable for all. 'Payment for health-care services, as well as services related to the underlying determinants of health, has to be based on the principle of equity, ensuring that these services, whether privately or publicly provided, are affordable for all, including socially disadvantaged groups. Equity demands that poorer households should not be disproportionately burdened with health expenses as compared to richer households.'[16]
4. Information accessibility means the right to seek, receive and impart information about medicines.

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[13] H. Hestermeyer, Human Rights and the WTO: The Case of Patents and Access to Medicines, OUP 2008, p. 105

[14] See Minister of Health v Treatment Action Campaign *et al* 2002 (5) SA 721 (CC); 2002 (10) BCLR 1033 (CC) (5 July 2002) by Constitutional Court of South Africa; Cruz Bermúdez v Ministerio de Sanidad y Asistencia Social by Supreme Tribunal of Justice of Venezuela, Case No 15.789, Decision No 916 (1999).; Jorge Odir Miranda Cortez v El Salvador by the Inter-American Commission on Human Rights, Report No 29/01. Case 12.249, paras 35 ff, 49 (7 March 2001).

[15] H. Hestermeyer, Human Rights and the WTO: The Case of Patents and Access to Medicines, OUP 2008, p. 106 and CESCR General Comment No. 14, dated 11 August 2000 E/C.12/2000/4, paragraph 12 http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G00/439/34/PDF/G0043934.pdf?OpenElement.

[16] CESCR General Comment No. 14, dated 11 August 2000 E/C.12/2000/4, paragraph 12 http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G00/439/34/PDF/G0043934.pdf?OpenElement.

The right to health includes corresponding obligations for the states: to respect, to protect and to fulfill this right. As it was noted by the Committee on Economic, Social and Cultural Rights (CESCR) in relation to the right to health those obligation shall have the following meaning:

> "The obligation to respect requires States to refrain from interfering directly or indirectly with the enjoyment of the right to health. The obligation to protect requires States to take measures that prevent third parties from interfering with article 12 guarantees. Finally, the obligation to fulfil requires States to adopt appropriate legislative, administrative, budgetary, judicial, promotional and other measures towards the full realization of the right to health."[17]

In relation to access to medicines, the obligation to respect means that the state should refrain from denying or limiting equal access to essential medicines. Next, the obligation to protect means that states must ensure that pharmaceutical manufacturers do not limit the accessibility of essential medicines, especially by high pricing of medicines.Developed countries may ensure affordability by providing medicines free of charge; however, developing countries can adopt effective competition policy and adjust patent systems to avoid excessive pricing. Finally, the obligation to fulfill in the domain of medicines means that states shall provide information about available pharmaceutical treatment of diseases such as HIV, adopt pharmaceutical policy, including policy on generic medicines, take positive measures on providing medicines to indigents.[18]

The Committee on Economics, Social and Cultural Rights addresses the different aspects of implementing the legal provisions in General Comment No. 14. The Committee acknowledges that countries may experience difficulties in fulfilling economic, social and cultural rights due to limits in available resources. However, it also describes that the Covenant contains various obligations of immediate effect, most significantly the obligation to take steps to the maximum of a State Party's available resources and, in Article 2(2) of the ICESCR the principle of nondiscrimination.[19]

The CESCR in its General Comment No. 3, devoted to the nature of states parties' obligations under the ICESCR, based on its extensive practice on working with states reports, came to the conclusion that minimum core obligation to ensure the satisfaction of, at the very least, minimum essential levels of each of the rights is incumbent upon every State party.[20] Later, in General Comment No. 14, the CESCR defined that right to health includes

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[17] Ibid., paragraph 33.

[18] H. Hestermeyer, Human Rights and the WTO: The Case of Patents and Access to Medicines, OUP 2008, p. 111

[19] CESCR General Comment No. 14, dated 11 August 2000 E/C.12/2000/4, p. 30 http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G00/439/34/PDF/G0043934.pdf?OpenElement.

[20] General Comment No. 3 (1990), paragraph 10 http://www.unhchr.ch/tbs/doc.nsf/(Symbol)/94bdbaf59b43a424c12563ed0052b664?Opendocument.

the core obligation of states "to provide essential drugs, as from time to time defined under the WHO Action Programme on Essential Drugs".[21]

The CESCR chose a strict position on whether the core minimum obligations in the context of the right to health could be non-complied due to constraints of available resources. In General Comment No. 3 it generally accepts the possibility of non-compliance by stating that "in order for a State party to be able to attribute its failure to meet at least its minimum core obligations to a lack of available resources it must demonstrate that every effort has been made to use all resources that are at its disposition in an effort to satisfy, as a matter of priority, those minimum obligations"[22]. However, in General Comment 14 the CESCR took a strict stance that "**a State party cannot, under any circumstances whatsoever, justify its non-compliance with the core obligations… which are non-derogable**."[23] Thus under the ICESCR **access to *essential* medicines is recognized as a minimum core obligation that must not be violated and is non-derogable.** Additionally, some scholars believe that access to *life-saving* medicines is a part of the right to life. The right to life is also non-derogable, recognized as *jus cogens* and more justiciable than right to health as it is guaranteed by the International Covenant on Civil and Political Rights (ICCPR) and the European Convention of Human Rights (ECHR). Furthermore, access to life-saving medicines is guaranteed under general international law in situations of health emergencies, such asin pandemics.[24]

When states do not have enough budgetary resources to provide access to essential medicines for their population, they can use non-financial measures to ensure access. Such measures include for example **enforcing competition rules and changing patent laws, if latter are contributing to high prices of medicines.** This assertation could be used as additional argument as to why states cannot avoid responsibility for non-compliance with ensuring access to essential medicines obligation by pleading lack of financial resources.[25]

At the same time the protection by the state of monopoly patent rights of pharmaceutical companies is increasingly seen and proven to be an obstacle to the realization of the right to health in developing countries. Patents confer exclusive rights on patent holders that are mainly negative rights to prevent others from making, using, offering for sale, selling or importing the

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[21] CESCR General Comment No. 14, dated 11 August 2000 E/C.12/2000/4, paragraph 43 http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G00/439/34/PDF/G0043934.pdf?OpenElement.

[22] General Comment No. 3 (1990), paragraph 10 http://www.unhchr.ch/tbs/doc.nsf/(Symbol)/94bdbaf59b43a424c12563ed0052b664?Opendocument.

[23] CESCR General Comment No. 14, dated 11 August 2000 E/C.12/2000/4, paragraph 47 http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G00/439/34/PDF/G0043934.pdf?OpenElement.

[24] H. Hestermeyer, Human Rights and the WTO: The Case of Patents and Access to Medicines, OUP 2008, p. 117-118 and 137.

[25] Ibid., p. 113.

patented invention.[26] Product or process patents on medicines enable the patent holders to set high prices to return investments in development of the medicine.[27]

Upon adoption of the TRIPS Agreement that introduced minimum standards of IP protection for all WTO Members; many NGOs, scholars and UN bodies noted that the agreement could harm the accessibility of medicines. Several reasons were given: (i) the TRIPS Agreement creates obstacles to realization of the right of access to medicines; (ii) the adoption of patent legislation leads to charging of higher prices by corporations-patent owners that makes patented pharmaceuticals unaffordable to the general population; (iii) this price effect infringes the right to access to medicine and it is not justified by the need to incentivize innovation.[28]

Thus, according to the Article 27.1 of the TRIPS Agreement WTO Members are required to make patents "available for any inventions, whether products or processes, in all fields of technology" without discrimination, which includes patents for pharmaceutical products. The minimum term of patent protection that a country must make available under the TRIPS Agreement is 20 years from the filing date of a patent application.[29] In contrast, in 1986, at the start of the Uruguay Round of negotiations that led to the creation of the WTO, countries were free to determine the duration of patents; about 50 countries did not grant patent protection for pharmaceutical products at all, while some also excluded pharmaceutical processes.[30]

In 2012, the Medicines Patent Pool[31] published an analysis of data of its database of patents of antiretroviral medicines (ARVs) used for treatment of HIV. First, the conclusions describe that adoption of the TRIPS Agreement itself created a surge in patenting of ARVs in many of the countries whereas these medicines were not patented before. Second, in the post-TRIPS era, an increase in patents was found in both countries with significant manufacturing capacity of generic versions of ARVs as well as in other

[26] Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover "Promotion and protection of all human rights, civil, political, economic, social and cultural rights, including the right to development", A/HRC/11/12, 31 March 2009, paragraph 18.

[27] Although, in many cases new medicines are developed with the help of public funding.

[28] H. Hestermeyer, Human Rights and the WTO: The Case of Patents and Access to Medicines, OUP 2008, p. 79

[29] Article 33 of the TRIPS Agreement.

[30] UNAIDS, WHO, UNDP, Policy Brief: Using TRIPS flexibilities to improve access to HIV treatment, p. 2 http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2049_PolicyBrief_TRIPS_en.pdf

[31] A Swiss foundation created by UNITAID to improve the health of people living with HIV in low- and middle-income countries by increasing their access to life-saving medicines. Patent holders voluntarily share their patents with the Pool, where interested generic companies or product development partnerships can then access them http://www.medicinespatentpool.org/what-we-do/how-it-works/.

countries. Despite the decline in the discovery of new chemical entities for pharmaceutical use, secondary patents that cover minor, incremental innovations are widely sought and granted worldwide. This in turn creates in some cases artificial extentions of exclusivity beyond the basic patent term.[32] A study conducted in Argentina, Brazil, Colombia, India and South Africa has shown a significant proliferation of 'evergreening' pharmaceutical patents that can hamper generic competition and consequently limit access to medicines.[33]

These findings show that reinforcement by the TRIPS Agreement of legal framework on IPR protection throughout the world created an incentive to greater patenting. It also should be noted that implementation of TRIPS standards itself requires significant work of most developing countries, to revise domestic legislation and requires considerable financial and human resources needed to address IP issues.[34]

Notwithstanding strong IP policy contained in the TRIPS Agreement, the latter was a compromise for developed countries due to opposition of developing countries. Therefore, developed countries continue to spread standards of IP protection incorporated in their domestic laws that are stricter than established by the TRIPS Agreement, through conclusion of various bilateral and multilateral free trade agreements (FTAs) with developing countries.[35]

In conclusion, a conflict exists between policies promoted by developed countries (also through the WTO and the TRIPS Agreement) aimed at a strong and comprehensive system of IPRs protection and the aim to inensure minimum standards of health for the population in developing countries and LDCs. The following chapter discusses measures to reconcile this conflict that have been implemented by some developing countries. Furthermore, negative trends in implementation of IPR protection ,due to strong lobby of big pharmaceutical companies and developed countries' governments, are discussed.

[32] ARV patents on the rise? An analysis of ARV patent status in 75 low- and middle-income countries, presented by Esteban Burrone, Medicines Patent Pool, XIX AIDS Conference, Washington, 25 July 2012 http://www.medicinespatentpool.org/wp-content/uploads/ARV-Patenting-Trends-FINAL2.pdf

[33] Carlos M. Correa, Pharmaceutical innovation, incremental patenting and compulsory licensing, Research Papers 41, South Centre, 2011, p. 8

[34] C. Deere, The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries, OUP 2008, p. 12

[35] Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover "Promotion and protection of all human rights, civil, political, economic, social and cultural rights, including the right to development", A/HRC/11/12, 31 March 2009, paragraph 23.

5 Public Health-Related TRIPS Flexibilities and TRIPS plus Provisions

5.1 TRIPS flexibilities

The TRIPS Agreement does not have direct application and WTO member states must adopt national provisions that meet the TRIPS requirements. The TRIPS Agreement contains flexible provisions that could be used by WTO member states to transpose the Agreement's provisions into domestic law. According to Article 1 of TRIPS members are free to determine the appropriate method of implementing the provisions of the TRIPS Agreement within their own legal system and practice. Thus flexibility is given to WTO Members with regard to the manner in which obligations are implemented; this has been recognized by the WTO Appellate Body in the *India-Mailbox* decision.[36] Some of the TRIPS flexibilities could be used in the field of health care to improve access to medicines. Thus, Article 8 of TRIPS specifies that Members may adopt measures to protect public health when formulating or amending their laws and regulations. The Doha Declaration explicitly recognized that the TRIPS Agreement should be implemented in a manner supportive to promoting access to medicines for all and reaffirmed the right of WTO members to use to the full extent TRIPS flexibilities.[37]

As acknowledged by scholars, IGOs and NGOs, the use of TRIPS flexibilities can promote access to medicines in developing countries.[38] However, one of the arguments frequently raised against the wide use of the TRIPS flexibilities is that such policy can disincentivize pharmaceutical companies to invest in development of new medicines. However, this argument could be overruled by economic data on pharmaceutical companies' R&D investments and profits. Since 90% of the big pharmaceucal companies' sales produced in developed countries and only around 5-7% profits are generated in low- and middle-income countries[39].

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[36] Frederick M. Abbott and Carlos M. Correa, World Trade Organization Accession Agreements: Intellectual Property Issues, Quaker United Nations Office, 2007, p. 1 http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1915338 and WTO Appellate Body, India - Patent Protection for Pharmaceutical and Agricultural Chemical Products, AB-1997-5, WT/ DS50/AB/R, 19 Dec. 1997.

[37] Declaration on the TRIPS agreement and public health (Doha Declaration) adopted by the WTO Ministerial Conference in 2001, paragraph 4 http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

[38] Sisule F. Musunga, Cecilia Oh, The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?, CIPIH, August 2005, p. iii.

[39] Frederick M. Abbott and Carlos M. Correa, World Trade Organization Accession Agreements: Intellectual Property Issues, Quaker United Nations Office, 2007, p. 36 http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1915338

Consequently, adoption of TRIPS flexibilities by developing countries will not significantly influence profits of pharmaceutical companies. Further, R&D expenses represented only 16,7% of research based pharmaceutical companies' total sales in 2011[40] and around 10-20% of pharmaceutical companies general budgets, as they spend substantial sums on advertising, promotion and general administrative costs. In general, pharmaceutical companies earn high levels of profits.[41]

Countries vary significantly in the extent to which they implemented TRIPS flexibilities.[42] There are many examples of successful use of TRIPS flexibilities that led to price reductions on medicines.[43] Although it appears that TRIPS flexibilities are not as widely and successfully used by developing countries to date as it was expected. This could be explained by many reasons, such as pressure of developed states not to use these opportunities to balance IPRs with access to medicines, technical difficulties that TRIPS flexibilities implementation involves, lack of national experts and lack of relevant legal framework.

As was stated above, from the perspective of the right to health, developing countries should be allowed to use TRIPS flexibilities. The following flexibilities should be implemented into domestic legislations:

(a) Make full use of the transition periods;
(b) Define the criteria of patentability;
(c) Issue compulsory licences and provide for government use;
(d) Adopt the international exhaustion principle, to facilitate parallel importation;
(e) Create limited exceptions to patent rights, including Bolar exception;
(f) Allow for opposition and revocation procedures.

5.1.1 Transition periods

According to the Transitional Arrangements section of the TRIPS Agreement several types of transition periods exist:

[40] PhRMA, Pharmaceutical Industry Profile 2012, p. 51 http://www.phrma.org/sites/default/files/pdf/phrma_industry_profile.pdf

[41] Frederick M. Abbott and Carlos M. Correa, World Trade Organization Accession Agreements: Intellectual Property Issues, Quaker United Nations Office, 2007, p. 28 http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1915338

[42] Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover "Promotion and protection of all human rights, civil, political, economic, social and cultural rights, including the right to development", A/HRC/11/12, 31 March 2009, paragraph 26.

[43] UNAIDS, WHO, UNDP, Policy Brief: Using TRIPS flexibilities to improve access to HIV treatment, pp. 5-7 http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2049_PolicyBrief_TRIPS_en.pdf

1. The period in which developing countries could not apply the provisions of the TRIPS Agreement (except Articles 3, 4, 5) until January 2000;[44]

2. Member states who are in the process of transformation from a centrally-planned into a market, free-enterprise economy. Such states that undertake structural reform of its intellectual property system and face special problems in the preparation and implementation of intellectual property laws and regulations could also benefit from the same period of delay;[45]

3. To the extent that a developing country member state is obliged by the Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that member state (January 1st, 2000), it could delay the application of the provisions on product patents of Section 5 of Part II to such areas of technology for an additional period of five years, which is until January 1st, 2005;[46]

4. In view of the special needs and requirements of least-developed member states, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such member states shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65, that is until January 1st, 2006.[47] This period was extended by the Council for TRIPS decision until 1 July 2013, or until such a date on which they cease to be a least-developed member state, whichever date is earlier.[48] In case of pharmaceutical products, the transition period was extended for LDCs until 1 January 2016 by the decision of the Council for TRIPS.[49]

Without prejudice to mentioned transition periods in relation to LDCs, the Council for TRIPS, upon duly motivated request by a least-developed country Member, shall accord extensions of the period provided for in paragraph 1 of Article 66 of the TRIPS Agreement.[50] On 11th June 2013, the

[44] Article 65.2 of the TRIPS Agreement.
[45] Article 65.3 of the TRIPS Agreement.
[46] Article 65.4 of the TRIPS Agreement.
[47] Article 66.1 of the TRIPS Agreement and Frederick M. Abbott and Carlos M. Correa, World Trade Organization Accession Agreements: Intellectual Property Issues, Quaker United Nations Office, 2007, p. 10 http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1915338
[48] Decision of the Council for TRIPS of 29 November 2005, paragraph 1 http://www.wto.org/english/news_e/pres05_e/pr424_e.htm
[49] Decision of the Council for TRIPS of 27 June 2002, paragraph 1 http://www.wto.org/english/news_e/pres02_e/pr301_e.htm
[50] Decision of the Council for TRIPS of 27 June 2002, paragraph 2 http://www.wto.org/english/news_e/pres02_e/pr301_e.htm and Decision of the Council for

WTO TRIPS Council took the decision (IP/C/64) to extend for a further 8 years until 1 July 2021, the flexibility of least developed country (LDC) Members under Article 66.1, to not apply the provisions of the TRIPS Agreement except for Articles 3, 4 and 5 (which concern national treatment and most-favored nation treatment). This decision was taken in response to the "duly motivated request" submitted by Haiti on behalf of the LDC Group in November 2012, seeking an unconditional extension for as long as a WTO Member remains a LDC.

Despite the importance of transition periods for the adoption of relevant legislation and preparing for the introduction of TRIPS-compliant regime, most acceding countries were unable to secure this flexibility.[51]

As the scope of this work does not cover LDCs and transition periods for developing countries and economies in transition had expired to date, the transition periods will not be considered within each country's implementation analysis below.

5.1.2 Patentability criteria

Article 27(1) of the TRIPS Agreement sets out that patents "shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application".

Article 27(1) of the TRIPS Agreement was characterized by Professor Carlos Correa as "the most important flexibility under the TRIPS Agreement in the area of patent law: [which provides] the possibility of rigorously defining the criteria under which the standards of patentability are applied."[52] According to the joint paper of WHO and WTO "WTO Agreements and Public Health", article 27.1 of the TRIPS Agreement does not contain any specification about the concept of 'invention' nor about the precise way in which the patentability criteria are to be applied. Therefore, there is room for WTO Members to interpret in good faith the concept of 'invention' within their legal systems, and to adopt more or less strict criteria to apply the patentability standards.[53]

Patentability standards vary from country to country. Contries that set a loose of patentability standards allow patents to be granted without much

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TRIPS of 29 November 2005, paragraph 6 http://www.wto.org/english/news_e/pres05_e/pr424_e.htm

[51] Frederick M. Abbott and Carlos M. Correa, World Trade Organization Accession Agreements: Intellectual Property Issues, Quaker United Nations Office, 2007, p. 11 http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1915338

[52] Correa, Carlos M., Pharmaceutical innovation, incremental patenting and compulsory licensing. Research Papers 41, South Centre, 2011, pp. 20

[53] Ibid., pp. 20-21 and WTO Agreements and Public Health: A joint study by the WHO and the WTO Secretariat, 2002, p. 43

difficulty, while contries with high patentability standards allow for good quality patents,[54] creating obstacles to obtaining weak patents.

According to Article 27(2) Members may exclude, the prevention within their territory of the commercial exploitation if necessary to protect *public order* or morality, including protection of human life or health, from patentability inventions. WTO members may also exclude from patentability elements addressing diagnostic, therapeutic and surgical methods for the treatment of humans or animals.[55] The TRIPS Agreement does not provide for the exhaustive list of exclusions from patentability in Article 27, thus giving states opportunity to exclude certain categories of inventions in order to protect public health.[56]

Discretion to define patentability standards could be effectively used against evergreening practices. Evergreening is a practice of obtaining new patents on a patented medicine by making minor changes to it "in the absence of any apparent additional therapeutic benefits"[57], which extends patent monopoly for additional period. Furthermore, patents on minor developments are used, often aggressively, by some patent holders to delay or block generic competition.[58] Evergreening practice delays entry of cheap generic medicines on the market and prevents price reductions from happenning. To fight this practice countries may exclude from patentability of new forms, formulations or combinations of known substance that do not contain enhanced efficacy in comparison to known substance; and new (or second) uses and combinations of known substances. India and Philippines are examples of countries who introduced this practice.[59] Also, in Brazil a system prior to granting a patent coordination of patent application related to medicines with National Sanitary Supervision Agency (ANVISA) was introduced.[60]

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[54] Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover "Promotion and protection of all human rights, civil, political, economic, social and cultural rights, including the right to development", A/HRC/11/12, 31 March 2009, paragraph 32.

[55] Article 27(3)(a) of the TRIPS Agreement.

[56] Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover "Promotion and protection of all human rights, civil, political, economic, social and cultural rights, including the right to development", A/HRC/11/12, 31 March 2009, paragraph 33.

[57] "…There are studies which find that many new medicines offer little or no improvement over existing medicines. For instance, in a recent Canadian study, the conclusion was that in British Columbia, 80% of the increase in drug expenditure between 1996 and 2003 was explained by the use of new, patented drugs that did not offer substantial improvements over less expensive alternatives available before 1990" - WHO, Public Health, innovation and intellectual property rights, Report of the Commission on Intellectual Property Rights, Innovation and Public Health, 2006, p. 131

[58] WHO, Public Health, innovation and intellectual property rights, Report of the Commission on Intellectual Property Rights, Innovation and Public Health, 2006, p. 132

[59] Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover "Promotion and protection of all human rights, civil, political, economic, social and cultural rights, including the right to development", A/HRC/11/12, 31 March 2009, paragraph 34-35.

[60] Brazil, Law No. 10.196 of February 2001.

Additionally, governments may consider developing guidelines for patent examiners on how properly to implement patentability criteria and, if appropriate, consider changes to national patent legislation.[61]

"Preventative Measure—India's Section 3(d) and the Novartis Case

When conforming its patent law with the TRIPS Agreement requirements that pharmaceutical products should be patentable, India adopted patentability criteria by introducing Section 3d to its Patent Act. According to this criterium ,"the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant", is not considered an invention and is thus not patentable under the Indian Patent Act.

In 2007, the Indian Patent Office, following an opposition filed by a patient organization, relied on this section in its refusal to grant the pharmaceutical company Novartis a patent for the cancer drug imatinib mesylate. The patent office considered the beta-crystalline form of imatinib mesylate to be a new form of a known substance without the enhancement in efficacy required under Section 3d and thus rejected the patent application under India's revised Patent Act.

In response, Novartis filed two lawsuits. In the first lawsuit, the company challenged the decision of the Patent Office, claiming that imatinib mesylate fulfils the patentability requirements under the Indian Patent Act as it enhances the efficacy of a known substance. In the second lawsuit, Novartis claimed that Section 3d does not comply with the TRIPS Agreement and violated the Indian Constitution.

On August 6, 2007 the High Court in Madras rejected the constitutional challenge. The High Court decided that it was not the forum to address questions on compliance with the TRIPS Agreement and upheld the validity of India's 2005 Patents Amendment Act. On 6 June 2009 the Intellectual Property Appellate Board of Chennai rejected the lawsuit against the decision of the Patent Office. This judgement was appealed by the patent applicant and a decision is pending. The decision whether a new form of a known substance can be patented has major implications for many drugs used in HIV care, now and in the future."[62]

[61] WHO, Public Health, innovation and intellectual property rights, Report of the Commission on Intellectual Property Rights, Innovation and Public Health, 2006, p. 134

[62] Good Practice Guide: Improving Access to Treatment by Utilizing Public Health Flexibilities in the WTO TRIPS Agreement, UNDP 2010, p. 21

5.1.3 Exceptions

Article 30 of TRIPS provides the conditions that should be applied to the exceptions derived from the rights conferred by the patent. Those conditions are cumulative and independent requirements, which means that failure to comply with any of them makes an exception impossible under Article 30, and include the following ones[63]:

1. The exceptions should be 'limited';
2. Such exceptions should not 'unreasonably conflict with the normal exploitation of the patent';
3. The exceptions should not 'unreasonably prejudice the legitimate interests of the patent owner'.

Additionally, 'the legitimate interests of third parties' should be taken into account when applying these three conditions to the exception. This gives states flexibility to design exceptions from patent rights that will improve access to medicines.

Controversty exists around the precise meaning of these conditions. This causes uncertainty for the countries that would wish to apply this article in dealing with public health crisis. For example, in Carlos Correa's view the following exceptions could be regarded as valid under the Article 30 of the TRIPS Agreement:

- importation of a product that has been put in the market elsewhere by the patentee, with his consent or by an otherwise authorized person;
- acts done privately and on a non-commercial scale or for a non-commercial purpose;
- using the invention for research and experimentation and for teaching purposes;
- seeking regulatory approval for marketing of a product before expiry of the patent;[64]
- preparation of medicines for individual cases according to a prescription;
- use of the invention by a third party who started – or undertook bona fide preparatory acts – before the application for the patent (or of its publication).[65]

Most typical access-maximizing exceptions that are mentioned are experimental use and Bolar exception. The experimental use exception is permitting use of the invention without compensation to the owner for such

[63] Hiroko Yamane, Interpreting TRIPS: Globalisation of Intellectual Property Rights and Access to Medicines, Oxford and Portland, Oregon, 2011, p. 169
[64] Called Bolar exception.
[65] Carlos M. Correa, Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement, OUP 2007, p. 303

purposes[66] and can serve as encouragement for researchers and manufacturers for invention of new medicines.

During the process of obtaining marketing approval the applicant may need to manufacture samples of product which could be considered as a violation of patent. The regulatory review ('Bolar') exception allows for developing information needed for marketing approval, including production of a first batch of the product. This exception is a widely implemented TRIPS flexibility by about 48 countries[67], and was confirmed by the WTO panel in case of Canada – Pharmaceutical patents of 2000 and favours early entry of generics on the market just after patent expiration.

"South Africa Adopts a Bolar Provision in 2002

South Africa amended its Patent Act in 2002 in order to introduce a Bolar type provision, as well as other amendments. Under South African law it is now possible to make, use, exercise, dispose or import a patented product on a non-commercial scale, solely for the purposes reasonably related to the obtaining, development and submission of information required under any law of South Africa that regulates the manufacture, production, distribution, use or sale of a product."[68]

5.1.4 Compulsory Licensing and Government Use

The exceptions from rights conferred by the patent that fail to meet any of conditions set in Article 30 of the TRIPS Agreement may be further assessed under additional conditions and requirements set forth in Article 31. This article provides special exceptions (which include use by the government or third parties authorized by the government,) not covered by Article 30, setting the conditions that should be met for such special exceptions to be acceptable. In other words, it sets the reqiurements that should be observed by the governments when granting compulsory licenses ("**CL**"). The latter mean, governmentally mandated authorizations, allow third parties to use another's intellectual property upon payment of a specified fee without authorization of the patent owner.[69] This authorization may be given to a third party, or, in the case of government use, to a government agency or to a third party authorized to act on the government's behalf.[70]

[66] Correa C., Integrating Public Health Concerns into Patent Legislation in Developing Countries, South Centre 2000, p.66

[67] WHO, WIPO, WTO, Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and innovation, 2012, p. 14, 174

[68] Good Practice Guide: Improving Access to Treatment by Utilizing Public Health Flexibilities in the WTO TRIPS Agreement, UNDP 2010, p. 38.

[69] Nuno Pires de Carvalho, The TRIPS Regime of Patent Rights, Third Ed., 2010 Kluwer Law International BV., p. 427

[70] WHO, WIPO, WTO, Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and innovation, 2012, p. 174.

There are no restrictions in the TRIPS Agreement on grounds upon which the government may issue compulsory license. As an example of such grounds could be used (a) refusal to license; (b) public interest; (c) public health and nutrition; (d) national emergency or situation of extreme urgency; (e) anti-competitive practices; (f) dependent patents; and (g) failure to exploit or insufficiency of working.[71]

States are *free to establish new grounds* for the issuance of CLs.[72]

Article 31 of the TRIPS Agrement provides the following conditons for the issuance of compulsory license:

(a) authorization by the government of such use shall be considered on its individual merits, as such compulsory license may be issued only on a case-by-case basis;

(b) prior efforts to obtain authorization from the patent holder should have taken place and such efforts should not have been successful within a reasonable period of time. This requirement could be waived in cases of national emergency, or other circumstances of extreme urgency, or public non-commercial use (Article 31(b));

(c) the scope and duration of the compulsory license shall be limited to the purpose for which it was authorized;

(d) the compulsory license shall be non-exclusive, i.e. patent holder shall have an opportunity to voluntary license the invention to third parties;

(e) the compulsory license shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

(f) the compulsory license shall be used predominantly for the supply of the domestic market of the country issuing the license, which means no exports are permitted under CL;

(g) the compulsory license shall be terminated when the circumstances which led to its establishment cease to exist and are unlikely to recur;

(h) the patent holder shall be paid adequate remuneration (royalty) in the circumstances of each case, taking into account the economic value of the CL; In legislation of some countries the word "compensation" is used

[71] Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover "Promotion and protection of all human rights, civil, political, economic, social and cultural rights, including the right to development", A/HRC/11/12, 31 March 2009, paragraph 36.

[72] Doha WTO Ministerial Declaration on the TRIPS agreement and public health, adopted on 14 November 2001, p. 5(b)

instead of the word "remuneration" in reference to the need to pay royalties for the CL. The word "compensation" is undesirable because it involves compensatory understanding of payments for the CL, which may lead to legal action when the owner of the patent may consider that royalty (compensation) for the CL is too small. In international practice, the amount of remuneration under compulsory licenses in the field of HIV ranges from 0.5% (Thailand, Indonesia) to 4% (Malaysia) from the price of manufactured/supplied generic product under the CL.[73]

"Compulsory License for Lopinavir/Ritonavir in Ecuador

In October 2009, the President of Ecuador signed a decree allowing compulsory licenses in the country. The President justified his decision with provisions on the right to health in the Ecuadorean Constitution, as well as with Article 31 of the TRIPS Agreement and the Doha Declaration. On 14 April 2010, the Ecuadorean intellectual property office (IEPI) granted its first compulsory license for the ARV combination lopinavir/ritonavir, to Eskegroup, a local distributor for the Indian generic pharmaceutical Cipla. The compulsory license is valid until 30 November 2014. By the time the license ends, the patent would expire.

The owner of the patent for lopinavir/ritonavir, marketed as Kaletra®, is the US pharmaceutical company Abbott Laboratories. IEPI has instructed Eskegroup to pay remuneration to Abbott based on the tiered royalty method (TRM). This method is described in the "Remuneration Guidelines for Non-voluntary Use of a Patent on Medical Technologies", authored by Love and co-published by UNDP and WHO (www.who.int/hiv/amds/ WHOTCM2005.1_OMS.pdf)

After the compulsory license was issued the Ecuadorean Ministry of Health purchased lopinavir/ritonavir with a discount of USD 150,000 compared to the original offer."[74]

(i) a judicial review shall be available to contest the legal validity of state authorities decision related to issuance of compulsory license and setting remuneration to patent holder.

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(k) WTO Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive.

[73] Remuneration guidelines for non-voluntary use of a patent on medical technologies WHO/TCM/2005.1, WHO 2005, p. 41

[74] Third World Network Info services on Health Issues, 4 May, 2010; There have been developments since this information was published. Now Ecuador has achieved 70% savings and pays only 30% of the original price of orginator LPV/RTV.

The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

"Use of Competition Law in South Africa to Improve Access to Medicines

In 2002, a civil society coalition in South Africa filed a complaint against two multinational pharmaceutical companies (GlaxoSmithKline and Boehringer Ingelheim) with the South African Competition Commission. The coalition argued that these companies were engaging in anticompetitive practices through its excessive pricing of their patented ARVs (zidovudine, lamivudine, and nevirpaine). The complainants maintained that, while taking into account costs of research and development, costs of production, reasonable profit, and other costs; the prices charged by the companies were excessive and unjustifiable.

South Africa's Competition Commission agreed with the complainants, and concluded that the companies had engaged in excessive pricing, and in addition had denied generic competitors with an "essential facility" (in this case, licenses to manufacture these medicines), and recommended to South Africa's Competition Tribunal that a compulsory license be issued on the patents covering these ARVs, along with punitive measures.

Before the matter could be heard by the Competition Tribunal, considering the possible effect of the Competition Commission's findings, the companies agreed to grant voluntarily licenses for their patents to generic producers at a royalty not in excess of 5% of the sale price of the generic versions.

Again, in 2007, South Africa's Treatment Action Campaign (TAC) brought a complaint against the multinational Merck Sharp & Dohme (MSD) for refusing to license its patent on the ARV efavirenz on reasonable terms. Before the matter could be referred to the Competition Tribunal, MSD and TAC reached a settlement whereby MSD agreed to grant multiple licenses on its efavirenz patent to generic producers, for supply of both the public and private sectors. Further, MSD agreed to allow the generic producers to export their products to 10 other African countries, and waived any right to a royalty."[75]

The Doha Declaration on the TRIPS Agreement and public health in Paragraph 6, recognizes that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector shall face difficulties

[75] Good Practice Guide: Improving Access to Treatment by Utilizing Public Health Flexibilities in the WTO TRIPS Agreement, UNDP 2010, p. 44

with implementation of compulsory licensing provided in the TRIPS Agreement. Therefore, they instructed the Council for TRIPS to find an expeditious solution to this problem. As a result, the WTO General Council adopted a decision on 30 August 2003 (the "**Decision**") in which it prescribed a mechanism of issuance compulsory licenses for exporting purposes. The Decision waived the requirement for the exporting country that compulsory license may be issued predominantly for domestic purposes[76]. However, it has established a rather burdensome system of exporting-importing pharmaceuticals. Thus, according to the Decision, in order to participate within the system, the importing country has to issue a compulsory license for the import of relevant pharmaceuticals, as well as the exporting country must issue a compulsory license for the export of relevant pharmaceutical product. Further, the importing country has to make a notification to the Council for TRIPS, specifying the names and expected quantities of the product(s) needed, and confirming that the country has insufficient or no manufacturing capacity, etc.; and the exporting country must notify the Council for TRIPS of the grant of the exporting licence, including the conditions attached to it. Also, products produced under such compulsory licence shall be clearly identified as being produced under the system set out in the Decision through specific labelling or marking. Additionally, suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves.[77] Renumeration to the patent owner shall be payable only under the compulsory licence issued in exporting countries, while royalties under the importing country compulsory license are waived.[78]

While many countries have incorporated mechanisms of CL issuance or government use in their domestic legislations, the grounds for the CL issuance vary and procedures in many cases need to be simplified and streamlined.[79] The legislation of some countries (e.g. Belarus, Moldova) provide issuance of CL only by court order, which is undesirable from the point of view of the effectiveness and efficiency of the mechanism of CL for health care, for which the most desirable is a simple administrative procedure for issuing of CL by decision of the Ministry of Health.

Government Use Authorizations in Thailand and Brazil

Thailand and Brazil's public health services are commonly considered to be among the best in the developing world. Thailand introduced a universal health care scheme in 2002, making health care services available to its citizens for a small co-payment. In Brazil, the right to health is enshrined in the Constitution, and legislation has specifically incorporated universal access to medicines as part of that right. However, due to the success of these programmes, the costs to the

[76] Article 31(f) of the TRIPS Agreement.
[77] WTO General Council Decision of 30 August 2003, paragraph 2.
[78] Ibid., paragraph 3.
[79] Sisule F. Musungu, Cecilia Oh, The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?, CIPIH, August 2005, p. v.

government are considerable. 65% of Thailand's total expenditure on health comes from the government, while Brazilian government's burden is at 44%. Therefore, both governments have taken strong and effective actions to lower the costs of the medicines they procure through government use authorisations.

From 2006–2008, Thailand issued a series of government use authorisations on a number of patented medicines. Cost savings to the Thai government were significant, for instance, the generic version of the heart medication clopidogrel that was sourced from India was 98% cheaper than the patented version. Although the Thai government came under fierce (and largely groundless) criticism for its actions by developed countries and industry groups, the Thai government maintained that its actions were perfectly compatible with both domestic law and TRIPS requirements.

Similarly, Brazil has been successful in using the credible threat of issuing compulsory licenses as a negotiating tool to achieve significant price concessions on patented essential medicines. Finally, in 2007, after lengthy negotiations had failed, Brazil issued a government use order for the patent on efavirenz, allowing Brazil to manufacture generic equivalents. By doing so, Brazil was able to reduce the price of efavirenz from USD 1.56 to USD 0.45 per dose. According to estimates by the Brazilian government, cost savings are expected to reach approximately USD 237 million between 2007 and 2012 when the patent for efavirenz expires in Brazil. The examples of Thailand and Brazil demonstrate the effectiveness of issuing compulsory licenses/government use authorisations to significantly lower the costs of essential medicines.[80]

5.1.5 Parallel Import

Parallel import based on regional pricing policy of pharmaceutical companies enables purchase and importation of branded medicines from lawful sources from an exporting country, where those medicines may cost significantly less than in the importing country.

The parallel import mechanism is based on the concept of exclusive rights exhaustion. This means that 'while a patentee has the exclusive right to prevent others from manufacturing or marketing the patented product, the principle of exhaustion bars the patentee from further exercising exclusive rights once the product is sold on the market'.[81]

[80] Good Practice Guide: Improving Access to Treatment by Utilizing Public Health Flexibilities in the WTO TRIPS Agreement, UNDP 2010, pp. 33-34

[81] Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover "Promotion and protection of all human rights, civil, political, economic, social and cultural rights, including the right to development", A/HRC/11/12, 31 March 2009, paragraph 43.

There are three concepts of exhaustion: national, regional and international. Under the national concept the patent holder may prohibit importation of medicines marketed abroad at lower prices, while under international or region concept of exhaustion it is possible to import medicines from other countries as once the product is sold in any part of the world (region) the patent holder may not prevent it further use.[82] According to Article 6 of the TRIPS Agreement states have discretion to determine the type of exhaustion concept. Countries that have incorporated an international exhaustion regime have greater ability to facilitate access to medicines.[83]

"International Exhaustion Regimes in the Philippines and Kenya

Both Kenya and the Philippines have amended their patent law to allow parallel importation of medicines from anywhere in the world, referred to as an international exhaustion regime. Unlike other international exhaustion regimes, however, both countries have included wording in their legislation that does not limit the possible source of import from a third country to products put on the domestic market by the original patent holder, but opened it up to equivalent products placed on the market by anybody who was authorised to do so. Whereas in most international exhaustion regimes the patent act limits the import of medicines from third countries to products that have been put on the market by the patent holder, the Philippines' wording of the provision allows for the importation into the country if they have been placed on the market anywhere in the world by "the patent owner, or by any party authorized to use the invention." Similarly, in Clause 37 of Kenya's Intellectual Property Regulations (2002) the international exhaustion regime outlined in the country's IP Act specifically allows for the importation of "…articles that are imported from a country where the articles were legitimately put on the market". Thus, in addition to products placed on the market by the patent holder or any of his authorised licensees, these wordings permit to import a medicine placed on the market by a generic company if no domestic patent protection existed. The provision also applies to products that were produced, for example, under a compulsory license, as the recipient of the compulsory license would have been authorized to use the invention. Since Kenya's change of legislation the provision has been used to import a range of generics that were still under patent protection in the country. Until now Kenya has not been challenged for its interpretation of international exhaustion, nor its use, at WTO."[84]

[82] WIPO Committee on Development and Intellectual Property, Patent Related Flexibilities in the Multilateral Legal Framework and Their Legislative Implementation at the National and Regional Levels, Geneva, April 2010, p. 17.

[83] Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover "Promotion and protection of all human rights, civil, political, economic, social and cultural rights, including the right to development", A/HRC/11/12, 31 March 2009, paragraph 45.

[84] Good Practice Guide: Improving Access to Treatment by Utilizing Public Health Flexibilities in the WTO TRIPS Agreement, UNDP 2010, p. 39-40

5.1.6 Patent Oppositions

Patent offices are often understaffed and overloaded with patent applications. Many of these in the field of pharmaceuticals claim protection of second uses of known substances or new forms of the products already in the market and frequently do not satisfy patentability criteria. In order to curb granting of improper patents many countries adopt opposition or observation system[85]. Such a system may also serve as one of the mechanisms to facilitate access to medicines at pre-grant of patent stage. These systems may provide for the right of third parties (including patient organisations) to file patent opposition after publication of the application but before the grant of the patent

Pre-grant oppositions examples

The Indian patent opposition proceedings allow for a pre-grant opposition to be filed at any time after the patent application is published and before the patent is granted. An alternative pre-grant opposition mechanism has been established in Brazil, where the requirement was introduced into the national Industrial Property Code to get 'prior consent' by the National Sanitary Supervision Agency (ANVISA) before a pharmaceutical patent can be granted. Paraguay has also adopted a similar requirement.[86]

and/or the right to challenge the patent before the patent office at any time or within a certain period after the grant of the patent.[87]

Patent opposition help to submit patents to greater scrutiny, which can be a great tool to limiting impact of patents on medicines.[88]

5.2 TRIPS-plus provisions

While member states of WTO adapt their legislation to new intellectual property requirements of the TRIPS Agreement, the US, EU and EFTA and other developed countries and organizations representing them started further negotiations. The lobby within bilateral and regional free trade

[85] Correa C., Integrating Public Health Concerns into Patent Legislation in Developing Countries, South Centre 2000, p.83

[86] Good Practice Guide: Improving Access to Treatment by Utilizing Public Health Flexibilities in the WTO TRIPS Agreement, UNDP 2010, pp. 23-24

[87] Correa C., Integrating Public Health Concerns into Patent Legislation in Developing Countries, South Centre 2000., p.84

[88] Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover "Promotion and protection of all human rights, civil, political, economic, social and cultural rights, including the right to development", A/HRC/11/12, 31 March 2009, paragraph 52.

agreements for **provisions that go further raising the standards of IPR protection in developing countries, beyond TRIPS Agreement requirements, so called TRIPS-plus provisions**.[89] The latter may have significant implicaitions for the pharmaceutical patents protection and restrict access to medicines, as these standards delay or restrict introduction of generic competition.[90]

In relation to the countries in scope, the FTAs with EU are the main sources of the TRIPS-plus provisions. It could be argued that policy of EU to impose TRIPS plus obligations on developing countries, like Georgia, Moldova and Ukraine, contradicts with EU Members international (extra-territorial) obligations under the ICESCR.[91] As was noted by the CESCR when interpreting the right to health in Article 12 of ICESCR: 'States parties should ensure that the right to health is given due attention in international agreements and, to that end, should consider the development of further legal instruments. In relation to the conclusion of other international agreements, States parties should take steps to ensure that these instruments do not adversely impact upon the right to health.'[92]

In this regard it should be noted that in European Parliament Resolution of 12 July 2007 on the TRIPS Agreement and access to medicines, addressed to the Council of the European Union, the European Parliament:

> "8. Asks the Council to support the developing countries which use the so-called flexibilities built into the TRIPS Agreement and recognized by the Doha Declaration in order to be able to provide essential medicines at affordable prices under their domestic public health programmes;
>
> 9. Encourages the developing countries to use all means available to them under the TRIPS Agreement, such as compulsory licences and the mechanism provided by Article 30 thereof;
>
> …11. Calls on the Council to meet its commitments to the Doha Declaration and to restrict the Commission's mandate so as to prevent it from negotiating pharmaceutical-related TRIPS-plus provisions affecting public health and access to medicines, such as data exclusivity, patent extensions and limitation of grounds of compulsory licences, within the

[89] Correa C., Implications of bilateral free trade agreements on access to medicines, Bulleting of WHO, May 2006, 84(5), p. 399

[90] Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover "Promotion and protection of all human rights, civil, political, economic, social and cultural rights, including the right to development", A/HRC/11/12, 31 March 2009, paragraph 69.

[91] Most of EU-Members are parties to ICESCR. http://treaties.un.org/Pages/ParticipationStatus.aspx

[92] Paragraph 39 of General Comment No. 14 (2000) E/C.12/2000/4 The right to the highest attainable standard of health (article 12 of the International Covenant on Economic, Social and Cultural Rights) http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G00/439/34/PDF/G0043934.pdf?OpenElement.

framework of the EPA negotiations with the ACP countries and other future bilateral and regional agreements with developing countries;"[93]

This progressive, from access to medicines standpoint, policy remarks, endorsed by the European Parliament, could be used as an additional argument by the Georgian, Moldovian and Ukrainian governments when defending public health interests during negotiations with EU representatives.[94]

Although TRIPS-plus provisions in FTAs or accession protocols to WTO (Working Party reports) vary, their main purposes are as follows:

1. to extend the patent term;
2. to introduce data exclusivity;
3. to introduce patent linkage with marketing authorisation;
4. to create new enforcement mechanisms for IPRs.

5.2.1 Patent term extension

In the pre-TRIPS era, the average term of patent protection in developing countries was 5-10 years, and 15-17 years in developed countries.[95] According to the TRIPS Agreement, the term of patent protection shall be no less than 20 years.[96] Provisions of some FTAs provide for extension of

[93] Paragraphs 8, 9, 11 of the European Parliament resolution of 12 July 2007 on the TRIPS Agreement and access to medicines http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P6-TA-2007-0353+0+DOC+XML+V0//EN

[94] According to the EU Competition Inquiry into Pharmaceutical Sector, launched in 2008 by the EU Commission to investigate possible anti-competitive conditions in the pharmaceutical sector, "it takes too long for generic medicines to reach the market. On average, consumers wait 7 months for cheaper generic medicines to become available once patents for brand-name medicines expire. One reason is that drug companies use a variety of techniques to extend the commercial life of their medicines. When brand-names are forced to compete with generics, prices go down and more patients can be treated. The decreases can be quite substantial. For a sample of medicines we calculated that additional savings of 20% would have been possible if the generic version had become available immediately after the original patent expired."

As a result of the inquiry "the Commission will scrutinise the sector more closely and where appropriate prosecute specific companies for alleged violation of competition law; and EU countries will be urged to:
• take action against misleading campaigns questioning the quality of generic medicines
• introduce mechanisms to significantly accelerate approval procedures for generic medicines – such as immediate/automatic pricing;
• introduce measures supporting speedy uptake of generic medicines and improved price competition." (Citizens' summary EU competition inquiry into pharmaceutical sector http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/citizens_summary.pdf)

[95] Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover "Promotion and protection of all human rights, civil, political, economic, social and cultural rights, including the right to development", A/HRC/11/12, 31 March 2009, paragraph 76.

[96] Article 33 of the TRIPS Agreement.

patent term for pharmaceutical products to compensate for delays in examination of the patent application and for the regulatory approval delay.[97] The extension of patent life in developing countries may cause additional expenses for national health budgets and impact access to medicines[98] (e.g. it is estimated that 4-year patent term extension under US-South Korea FTA would cost US$ 722.5 billion for the national health insurance system in South Korea).[99]

5.2.2 Test data exclusivity

To introduce a new medicine to the market the pharmaceutical company has to provide clinical trials[100] data (test data) to the national drug regulatory authorities (DRA) to prove the medicine's safety and efficacy. When a generic company applies for the subsequent marketing authorisation for the equivalent product it may refer to test data of the original product for registration purposes, and is thus not obliged to produce its own clinical trials data. This speeds up the entry of generics to the market. Based on reference to the clinical data of the original product the DRA may grant a marketing authorisation to an equivalent generic. Data exclusivity prohibits such reliance on the original clinical data by the DRA[101] for a number of years.[102] Data exclusivity periods are not affected by patent expiration and delay generic medicines entry separately from barrier that patents create.

Although the TRIPS Agreement does not require countries to provide data exclusivity,[103] a data exclusivity requirement is contained in several bilateral FTAs pushed by the US and EU.

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[97] Correa C., Implications of bilateral free trade agreements on access to medicines, Bulleting of WHO, May 2006, 84(5), p. 400

[98] Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover "Promotion and protection of all human rights, civil, political, economic, social and cultural rights, including the right to development", A/HRC/11/12, 31 March 2009, paragraph 77.

[99] The Hankyoreh, "U.S. FTA may cost drug industry $1.2 billion" (18 Oct 06) http://www.hani.co.kr/arti/english_edition/e_business/165065.html

[100] It should be emphasized that clinical trials are a significant investment, according to brand pharmaceutical companies (this statement is contested by some NGO activists), and generic companies can not afford to hold them. At the very concept of a generic drug incorporated the concept of "copy" - that is, the confirmation of bioequivalence to reference medicine, without the need for repeated clinical trials.

[101] Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover "Promotion and protection of all human rights, civil, political, economic, social and cultural rights, including the right to development", A/HRC/11/12, 31 March 2009, paragraph 78.

[102] For example, data exclusivity periods in US is 5 years, and in EU it could be up to 11 years. - WHO, Public Health Innovation and Intellectual Property Rights, A Report of the Commission on Intellectual Property Rights, Innovation and Public Health (Geneva, 2006) p. 125 http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf.

[103] Correa C., Implications of bilateral free trade agreements on access to medicines, Bulleting of WHO, May 2006, 84(5), p. 401

It is argued that data exclusivity in developing countries only delays the onset of generic competition and thus prevents possible reductions in the cost of medicines causing added health-care costs[104] (e.g., it is estimated that if data exclusivity is introduced in Peru an average price of generic products would have been 94.3-114,4% higher than in the absence of DE provisions).[105]

The WHO Commission on Intellectual Property Rights, Innovation and Public Health therefore recommended to developing countries not to introduce restrictions for the use of test data that will exclude fair competition.[106]

5.2.3 Patent-Registration Linkage

The US FTAs require that medicine marketing authorisation must be linked to patent protection. The national DRA must refuse to register a generic medicine, which is infringing patent in force, unless it is registered by consent of patent owner.[107] EU does not have a system of patent linkage[108]. The US FDA only informs a patent owner about the generic product application that relates to patent (i.e. a simplest form of patent linkage[109]).[110]

Patent linkage systems contribute to the delay of generic medicines entering the market, and are frequently abused as was demostrated by studies in Canada and US[111] and 'unjustifiably extend exclusivity if the regulatory agency is unable to begin a review of the generic drug application during the patent period'.[112]

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[104] WHO, Public Health Innovation and Intellectual Property Rights, A Report of the Commission on Intellectual Property Rights, Innovation and Public Health (Geneva, 2006) p. 125 http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf.

[105] Correa C., Implications of bilateral free trade agreements on access to medicines, Bulleting of WHO, May 2006, 84(5), p. 401

[106] WHO, Public Health Innovation and Intellectual Property Rights, A Report of the Commission on Intellectual Property Rights, Innovation and Public Health (Geneva, 2006) p. 126 http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf.

[107] Correa C., Implications of bilateral free trade agreements on access to medicines, Bulleting of WHO, May 2006, 84(5), p. 401

[108] Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover "Promotion and protection of all human rights, civil, political, economic, social and cultural rights, including the right to development", A/HRC/11/12, 31 March 2009, paragraph 87.

[109] WHO, WIPO, WTO, Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and innovation, 2012, p. 187.

[110] Correa C., Implications of bilateral free trade agreements on access to medicines, Bulleting of WHO, May 2006, 84(5), p. 402

[111] Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover "Promotion and protection of all human rights, civil, political, economic, social and cultural rights, including the right to development", A/HRC/11/12, 31 March 2009, paragraph 88.

[112] WHO, WIPO, WTO, Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and innovation, 2012, p. 187.

5.2.4 IP Enforcement measures

IP enforcement mechanisms can create obstacles and have a chilling impact to the generic competitors and by this serve as a barier to access to medicines.

For example, some countries' border regulations are applicable to patents. This is a TRIPS-plus provision, as article 51 of the TRIPS Agreement requires border measures only for trademark counterfeit and copyright piracy; or permit suspension of goods in transit that may violate patent in the transit country, while article 51 of the TRIPS Agreement is only applicable to importation. Border regulations, applied to medicines in transit, appear to contradict international obligations of states under ICESCR. As was clarified by CESCR in General Comment 14: 'state parties should refrain at all times from imposing embargoes or similar measures restricting the supply of another State with adequate medicines and medical equipment. Restrictions on such goods should never be used as an instrument of political and economic pressure.'[113]

Although criminal prosection and procedures are not required under the TRIPS Agreement, except 'in cases of wilful trademark counterfeiting or copyright piracy on a commercial scale',[114] many countries have adopted a TRIPS-plus provision extending criminal liability on patent infringement.[115] Criminalization of patent infringement is particularly worrisome as patents that are challenged in the court by the infringer are often found invalid.[116] Such provisions may have a chilling impact on generic manufacturers and are not recommendable from access to medicines view.[117]

[113] See paragraph 42 of General Comment No. 14 (2000) E/C.12/2000/4 The right to the highest attainable standard of health (article 12 of the International Covenant on Economic, Social and Cultural Rights) http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G00/439/34/PDF/G0043934.pdf?OpenElement

[114] Article 61 of the TRIPS Agreement.

[115] Frederick M. Abbott and Carlos M. Correa, World Trade Organization Accession Agreements: Intellectual Property Issues, Quaker United Nations Office, 2007, p. 25 http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1915338

[116] Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover "Promotion and protection of all human rights, civil, political, economic, social and cultural rights, including the right to development", A/HRC/11/12, 31 March 2009, paragraph 91.

[117] Ibid., paragraph 91.

6 Implementation of the Public Health-Related TRIPS Flexibilities in Belarus

6.1 General Considerations: Belarus

Unlike Georgia, Moldova and Ukraine, the Republic of Belarus is not a member of the WTO, but since 1993 Belarus has been in negotiations about accession to the WTO. Now Belarus is in the process of harmonizing its legislation with WTO standards, including the TRIPS Agreement.[118] In addition, the Agreement on Common Regulatory Principles for the Protection and Enforcement of Intellectual Property Rights, aiming at the development of the Single Economic Space came into force on the January 1, 2012 and Belarus is the party to this treaty. The agreement provides that the parties share the principles, established by the TRIPS Agreement.[119] All this suggests that the Republic of Belarus, while not being a member of the WTO, has shown intention to comply with the principles of the TRIPS Agreement.

Also, the Treaty on the Functioning of the Customs Union in the Framework of the Multilateral Trading System was signed on 19th May 2011. The treaty was ratified by the Member States of the Customs Union including Belarus (The Law of the Republic of Belarus, 11th November 2011 № 310-W). According to the provisions of the Treaty the WTO obligations of the Russian Federation will be obligatory for Belarus in the course of further negotiations on the accession of the Republic of Belarus to the WTO, which means that the WTO obligation of Russian Federation to provide data exclusivity period for at least 6 years[120] shall be mandatory for Belarus during negotiations within WTO.

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[118] *See* "Negotiations on the accession of Belarus to the WTO", the Ministry of Foreign Affairs of the Republic of Belarus http://www.mfa.gov.by/export/wto/accession/; also, *see* Resolution of the Council of Ministers of the Republic of Belarus of 26 May 2011 № 669 "On the State Program of innovative development of Republic of Belarus for 2011-2015", which defines one of innovative policy priorities as "the development of legislation in the field of intellectual property in accordance with international standards in this field, in particular the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), and its harmonization with the laws of the basic geopolitical and economic partners of the Republic of Belarus, including through appropriate regional associations (unions) of states;".

[119] *See* Article 2 of the Agreement on Common Regulatory Principles for the Protection and Enforcement of Intellectual Property Rights, signed on December 9, 2010.

[120] Pp. 1450 and 1295 of the Report of the Working Party on the Accession of the Russian Federation to the WTO, WT/ACC/RUS/70, WT/MIN(11)/2, 17 November 2011.

As of 1 June 2013, the Republic of Belarus had not entered into any free trade agreements with the European Union, the United States and the European Free Trade Association. Also, the Republic of Belarus has not yet signed or ratified the Council of Europe Convention on the counterfeiting of medical products and similar crimes that threaten public health. All this suggests that Belarus does not have any international TRIPS-plus obligations, and it could be assumed that the change of the national legislation in order to use public health-related flexibilities or to delete national patent law provisions that are identical to TRIPS-plus provisions would not violate international treaties, which Belarus is a party to.

At the same time the Republic of Belarus participates in the conclusion of a free trade agreement between the European Free Trade Association and the countries of the Customs Union (Belarus, Kazakhstan, Russia). On 1-4 July 2013 Geneva hosted the ninth round of consultations of United negotiating delegation of the Republic of Belarus, Republic of Kazakhstan and the Russian Federation, representatives of the Eurasian Economic Commission with delegation of the European Free Trade Association (EFTA) about draft Free Trade Agreement between the Republic of Belarus, the Republic of Kazakhstan, the Russian Federation and the EFTA countries.[121] It is important to attract attention of Belarussian government and to advocate for the need to consider the interests of public health during negotiations of this agreement, and to refuse taking any TRIPS-plus commitments in the framework of the FTA with EFTA.

It should also be noted that, in addition to the possibility of obtaining a national patent in the Republic of Belarus in accordance with the Law of the Republic of Belarus "On Patents for inventions, utility models, industrial designs" (hereinafter - the "**Law**")[122], Belarus is a member of the Eurasian Patent Convention, which greatly expands the possibilities for pharmaceutical companies to obtain patents valid in Belarus. Eurasian patents are more attractive to pharmaceutical companies compared to some national patents as the Eurasian patent system allows patent protection on the territories of the eight states of the Eurasian Patent Convention (EAPC) - Turkmenistan, the Republic of Belarus, the Republic of Tajikistan, the Russian Federation, the Republic of Kazakhstan, the Republic of Azerbaijan, the Kyrgyz Republic and the Republic of Armenia.[123] Thus, ARV medicines in the Republic of Belarus are protected (can be protected) by national and Eurasian patents, which could potentially create a greater number of patent barriers and, therefore, adversely affect the availability of

[121] *See* http://www.mfa.gov.by/press/news_mfa/e04f8466ccb10e34.html «The Belarusian delegation was headed by Deputy Director of the Foreign Economic Relations Department of the Ministry of Foreign Affairs Igor Nazaruk. The delegation included representatives of the Ministry of Foreign Affairs, the State Customs Committee, the National Intellectual Property Center, the State Committee for Standardization, Institute of System Studies in the agricultural sector of the National Academy of Sciences, the National Scientific and Practical Center of Hygiene.»

[122] Law of the Republic of Belarus "On patents on inventions, utility models and industrial designs" (http://www.pravo.by/main.aspx?guid=3871&p0=H10200160&p2={NRPA})

[123] See. http://www.eapo.org/ru/feature.html

ARVs in Belurus. To date there has not been any cancellations/invalidations of Eurasian patents on ARVs in Belarus.

6.2 Implementation of the TRIPS Flexibilities in Belarus

6.2.1 Patentability Criteria

In accordance with the Law patent protection could be conferred in respect of medicinal products and their manufacturing processes.

Diagnostic, therapeutic and surgical methods of treatment are not excluded from patent protection. The possibility of patent protection of such objects is the TRIPS-plus provision and can be used for arbitrary monopolization of the market by pharmaceutical companies, therefore it is advisable to exclude such possibility by expressly stating in the Law that diagnostic, therapeutic and surgical methods of treatment are not patentable subject matter. It should be noted that even in the developed countries (e.g., Germany) and provisions of the European Patent Convention exclude these methods from patentability considering patenting of methods of treatment as "monopolization of medical practice".

In accordance with paragraph 3 of Article 2 of the Law inventions contrary to public interests, principles of humanity and morality shall not be recognized as patentable (these provisions may also apply to diagnostic, therapeutic and surgical methods for the treatment and inventions the commercial exploitation of which may be detrimental to the protection of life or health). This provision is consistent with Article 27 (2) of the TRIPS Agreement and is positive from access to medicines standpoint.

The legislation of Belarus contains the basic requirements of the TRIPS Agreement to the patentability of inventions. Thus, paragraph 1 of Article 2 of the Law provides that the invention in any field of technology is granted legal protection if it relates to a product or process that is new, involves an inventive step and is industrially applicable. For the purposes of the Law "product" means an item as a result of human labor, "process" - a process, method or technique of conducting interrelated activities to the object(s), or application of process, method, technique or product for a particular purpose. An invention is new if it is not part of the prior art. The invention has the inventive level if to a person skilled in art it does not obviously follow from the prior art. Art includes any information made available in the world before the priority date of the invention. The invention is industrially applicable if it can be used in industry, agriculture, health care and other fields. Thus, Belarus established the principle of international novelty, which is better than local novelty rule, as the patent office is required to assess the novelty of a substance from the point of view of world achievements in the pharmaceutical industry, not the national level of knowledge in this area.

Paragraph 1 of Article 3 of the Law provides utility model legal protection to technical solutions related to devices that are new and industrially applicable. In this regard, the utility model patent for a medicine in Belarus can not be obtained, which is a desired situation in terms of access to ARVs.

New uses/indications of known substances, new forms, formulas, or combinations of known medicines are not excluded from patent protection in Belarus, while TRIPS does not oblige Member States to provide protection for new uses. Additional criteria for patentability (except for novelty, inventive step and industrial applicability) for new uses, new forms, formulas, or combinations of known medicines is not provided by the legislation of the Republic of Belarus. With the exception of the following, a composition consisting of at least two well-known ingredients is patentable if it provides a synergetic effect, the ability to achieve which is not obvious from the prior art (i.e., quantitative measures of at least one of these properties are higher than properties of the individual ingredient).[124] Also, a new use of the medicine can not be protected by a patent, when a new indication is conditioned by the known properties, structure of this substance and it is known that these are the properties, structure required for the implementation of this new indication.[125]

Patenting of new uses of medicines is closely related to abusive patenting, so-called "evergreening" practice[126] and requires stricter criteria of patentability for new uses/indications of the known medicines, new forms, formulas, or combinations of known compounds.

6.2.2 Patent oppositions

Before examining the provisions of the legislation of Belarus on patent oppositions, and taking into account that Belarus is a member state of the Eurasian Patent Convention, the following should be noted. In case of disagreement with the decision of the Eurasian Office to refuse the grant of a Eurasian patent only applicant may file an objection with the Eurasian Office within three months from the date of receipt of notification of this refusal, which shall be considered by a panel of the Eurasian Office. The collegium should include at least two examiners who did not take a decision on the merits of the objection.[127] Thus, the circle of persons who may file a patent opposition in relation to the Eurasian patent is limited only to the applicant and makes it impossible to file patent oppositions by patient

[124] *See* § 473.3 Regulation on the procedure of application for a patent for an invention, conducting examination and taking decision based on results of examination approved by the Council of Ministers of the Republic of Belarus of 02.02.2011 № 119 (http://www.pravo.by/main.aspx?guid=3871&p0=C21100119&p2={NRPA})

[125] *See* § 472.7 Regulation on the procedure of application for a patent for an invention, conducting examination and taking decision based on results of examination approved by the Council of Ministers of the Republic of Belarus of 02.02.2011 № 119 (http://www.pravo.by/main.aspx?guid=3871&p0=C21100119&p2={NRPA})

[126] See above subchapter on Patentability Criteria of chapter on TRIPS-flexibilities.

[127] Article 15(8) of the Eurasian Patent Convention.

organizations or generic companies.

Belarusian legislation does not provide for filing patent oppositions to the patent office (National Intellectual Property Center) during the examination of a patent application. At the stage of patent application review only the applicant may appeal against the decision, which was adopted based on the results of the preliminary examination.[128]

Furthermore, according to paragraph 10 of Article 21 of the Law, if an applicant disagrees with the decision of the patent authority's refusal to grant a patent, the applicant has the right, within three months from the date of receiving the decision or copies of materials opposed to the patent application, to apply to Patent Authority (National Center of Intellectual Property) with a request for patent re-examination. Thus, the Belarusian legislation does not allow third parties, including patient organizations, to file patent oppositions at the pre-grant stage.

With respect to the pre-grant patent oppositions, Article 33 of the Law provides that a patent for an invention during its period of validity may be declared invalid in whole or in part in the following cases:

1) when patented invention does not correspond to the patentability criteria, established by the Law;
2) the presence of claims in formula of invention, which were absent in the original description (formula);
3) unlawful indication in the patent of author (co-authors) or patent holder (holders).

Any natural or legal person may file a patent opposition to the Appellate Board of the Patent Office (patent body functions are currently performed by the National Intellectual Property Center) on the grounds 1) and 2) stated above.[129]

Opposition against the grant a patent must be considered by the Appellate Board of the Patent Office within six months from the date of its receipt. The person who filed an opposition and the patent holder has the right to participate in the hearing.

The decision of the Appeals Board on the opposition to the grant of the patent can be challenged by the person who filed an opposition or patent

[128] Paragraphs 2, 3, 4 of the Regulation on procedure of filing and processing of complaints, oppositions and applications by the Appellate Board of patent authority, approved by the decision of the Council of Ministers of the Republic of Belarus on 22 December 2009 № 1679 http://www.pravo.by/main.aspx?guid=3871&p0=C20901679&p2={NRPA}

[129] According to article 33 of the Law these are the following grounds: 1) when patented invention does not correspond to the patentability criteria, established by the Law; 2) the presence of claims in formula of invention, which were absent in the original description (formula);

holder in court within six months from the date of receipt of the decision.[130]

Oppositions against granting of a patent on the ground 3)[131] are considered by the court.

A patent for an invention, utility model, industrial design, declared invalid in whole or in part, is deemed as such from the date of filing the patent authority.

Procedure for consideration of oppositions by the Appellate Board of the Patent Office is provided in the Regulation on filing complaints, oppositions, applications and their review by the Appellate Board of the Patent Office (the "Regulation").
Accordind to the Regulation, the patent opposition could be filed by any person, or his representative.[132] Such opposition may be filed within the term of the patent.[133] The opposition againts the grant of a patent for an invention shall be considered at the board meeting of the Appellate Board of the Patent Office within six months from the date of its receipt by the Appellate Board. [134]
When considering the oppositions the Appellate Board is guided by the legislation and international treaties of the Republic of Belarus in the field of intellectual property. When considering the oppositions againts the grant of patents for inventions investigation carried out by Appellate Board is limited to the materials of information search conducted by the Patent Authority, and it does not perform additional search. [135]

According to the Article 39 of the Regulation when considering patent oppositions the Board may invite the patentee to amend the patent claims only in cases when without such changes the contested patent should be invalidated completely and upon such an amendment may be declared invalid in part.
These changes may include:

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[130] Paragraph 3 of Article 33 of the Law.

[131] In case of unlawful indication in the patent of author (co-authors) or patent holder (holders).

[132] Paragraph 4 of the Regulation on procedure of filing and processing of complaints, oppositions and applications by the Appellate Board of patent authority, approved by the decision of the Council of Ministers of the Republic of Belarus on 22 December 2009 № 1679 http://www.pravo.by/main.aspx?guid=3871&p0=C20901679&p2={NRPA}

[133] P. 10 of the Regulation on procedure of filing and processing of complaints, oppositions and applications by the Appellate Board of patent authority, approved by the decision of the Council of Ministers of the Republic of Belarus on 22 December 2009 № 1679 http://www.pravo.by/main.aspx?guid=3871&p0=C20901679&p2={NRPA}

[134] P. 22 of the Regulation on procedure of filing and processing of complaints, oppositions and applications by the Appellate Board of patent authority, approved by the decision of the Council of Ministers of the Republic of Belarus on 22 December 2009 № 1679 http://www.pravo.by/main.aspx?guid=3871&p0=C20901679&p2={NRPA}

[135] Pp. 35-36 of the Regulation on procedure of filing and processing of complaints, oppositions and applications by the Appellate Board of patent authority, approved by the decision of the Council of Ministers of the Republic of Belarus on 22 December 2009 № 1679 http://www.pravo.by/main.aspx?guid=3871&p0=C20901679&p2={NRPA}

- removing from the claims characteristics that were not in the original application materials;
- removing the independent claim, which is not patentable, from the claims of invention;
- removing from the formula of invention dependent claim, provided that with this claim the protected invention does not meet the patentability of "industrial applicability" or contrary to the public interest and the principles of humanity and morality;
- inclusion in the independent claim part or the totality of the dependent claim;
- inclusion of characteristics into independent claim of the formula of invention, which were disclosed in invention description and that exclude grounds for considering invention non-patentable.

Based on the results of the opposition hearing the Appellate Board adopts one of the following decisions:

1) to leave the opposition without consideration;
2) to safisfy opposition;
3) to partially satisfy the opposition;
4) to dismiss the opposition.

The decision of the Appellate Board in relation to the patent opposition shall take effect upon expiry of the time limit for its appeal, established by law.[136]

The decision of the Appellate Board in relation to the patent opposition can be challenged by the person who filed an opposition or patent holder in court within six months from the date of receipt of the decision.[137]

In accordance with Article 359 of the Civil Procedure Code of the Republic of Belarus[138] ("CPC"), a person who does not agree with the decision of the Appellate Board of the Patent Office may file a appeal to the Supreme Court of the Republic of Belarus. The appeal is considered by the judicial board for Intellectual Property of the Supreme Court consisting of three judges. Based on the hearing of the appeal on decision of the Appellate Board of the Patent Office the court may take one of the following decisions:

on dismissal of the appeal against a decision of the Appellate Board of the Patent Office;

on recognition of appeal as justified and on revocation of the decision of the Appeals Board of the Patent Office.

The court's decision (Judicial Board for Intellectual Property of the Supreme

[136] P. 43 of the Regulation on procedure of filing and processing of complaints, oppositions and applications by the Appellate Board of patent authority, approved by the decision of the Council of Ministers of the Republic of Belarus on 22 December 2009 № 1679 http://www.pravo.by/main.aspx?guid=3871&p0=C20901679&p2={NRPA}

[137] P. 3 of Article 33 of the Law.

[138] CPC see here http://etalonline.by/?type=text&regnum=HK9900238#load_text_none_1_

Court) is not subject to appeal or to appeal in cassation.[139]

However, the decision of the Board on intellectual property-related cases of the Supreme Court may be reviewed within the procedure of judicial supervision. Thus, judgments which had entered into force, except decisions of the Plenum of the Supreme Court of the Republic of Belarus, may be reviewed within judicial supervision procedure based on the protests of officials listed in Article 439 of CPC. [140] According to article 439 CPC supervisory protests against judicial decisions (decisions, rulings) of the Board on cases of intellectual property of the Supreme Court of the Republic of Belarus may brought by the Chairman of the Supreme Court, the Attorney General of the Republic of Belarus and their deputies.

The following grounds exist for Causes for the beginning of protest within judicial supervision procedure (supervisory appeal):

complaints (judicial review complaints) by the persons legally interested in the outcome of the case, as well as those whose rights or legitimate interests in proceedings violated by the court decision;

submission of judge who participated in the examination of the case, or considering another case, for which the judgment that came into force has legal significance;

submissions of president of court;

initiative of officials who have the right to bring protest within judicial supervision procedure on court decions that entered into force.

Significant violations of substantive and procedural law are the grounds for bringing supervisory protest against judicial decisions.

Supervisory appeal may be filed within three years from the date of entry into force of the court decision. Supervisory appeals submitted after the deadline will not be considered, except for the complaints of the defendants in the judicial decisions given in their absence without proper notice of the time and place of the hearing, provided that the case file is not destroyed due to the expiration of the data retention period established by law.[141]

Cases of protests on final judgments and rulings of the Board on cases of intellectual property of the Supreme Court are considered by the Presidium of the Supreme Court of the Republic of Belarus. [142]

In accordance with Article 33 of Law patent oppositions may be filed directly with the court (judicial board for the intellectual property of the Supreme Court) in the cases of unlawful indication in the patent of author (co-authors) or patent holder (holders).

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[139] Article 360 of the Civil Procedure Code of Republic of Belarus (http://etalonline.by/?type=text&regnum=HK9900238#load_text_none_1_)

[140] Art. 436 CPC.

[141] Art. 437 CPC.

[142] Art. 440 CPC.

In conclusion, in Belarus and within the Eurasian Patent Organization there is no procedure of pre-grant patent oppositions by third parties, including patients and their organizations, which must be corrected by the introduction of such a procedure into the Law. However, there is a procedure of post-grant patent oppositions that could be used by patient organizations in Belarus in case of grant of a patent on the ARV-medicine that does not meet the criteria for patentability.

6.2.3 Compulsory licensing

In Belarus there is no special legal act regulating the procedure for issuing a compulsory license. The possibility of compulsory licensing (including in respect of patents for pharmaceuticals) provided for in Article 38 of the Law.

In accordance with Article 38 of the Law for non-use or lack of use of the invention, the patent holder for five years from the date of publication of a patent, any person willing and ready to use the patented invention, in case of refusal of the patent holder to enter into a license agreement may apply to the court (judicial Board on Intellectual Property Cases of the Supreme Court of the Republic of Belarus) with an application for a compulsory license. If the patent holder cannot prove that non-use or lack of use of the invention occurred due to legitimate reasons, the court shall grant the license and shall define the limits of use, volumes, time limits and procedure of payments under the license.

The decision of the Board on Intellectual Property Cases of the Supreme Court to grant a compulsory license may be reviewed only in the judicial supervisory review (see paragraph on patent oppositions above). Amount of the remuneration for the compulsory use of the patent holder invention is defined by the court based on the facts of the case.

In 2008, the judicial board in cases of intellectual property of the Supreme Court considered the case about compulsory license to use the patent on medicine. Claim to issue compulsory license was dismissed by the court.

The judicial procedure for issuing a compulsory license is a less effective option [143] in terms of protecting the interests of public health, than an administrative order that is allowed by Article 31 of the TRIPS Agreement. Moreover, the condition of non-use or lack of use of the patent for the first 5 years significantly reduces the instances for the issuance of a compulsory license, contrary to the TRIPS Agreement, which does not limit the grounds for issuing compulsory licenses.
Additionally, that the procedure for calculating the "reasonable period of

[143] It should be noted that, unlike the Ministry of Health, the courts may underestimate considerations for health budget savings to expand treatment coverage. In addition, pharmaceutical companies often have much more possibilities to provide adequate legal support for such litigations than patient organizations and government agencies.

time" during which efforts should be made to obtain authorization the patent holder before issuing a compulsory license, as well as the procedure for calculating compensation for the compulsory use of the patent, is not defined in the legislation of the Republic of Belarus.

Taking the above into account, it is necessary to review the provisions of the Law concerning the regulation of compulsory licensing by the introduction of administrative procedures for the issuance of a compulsory license in the health sector by the Ministry of Health. This will require changes in the Law and development of the regulation for compulsory licensing of patents on medicines.

6.2.4 Government Use

There is no special legal act regulating the procedure for government use of patents in Belarus.

Article 10 of the Law provides that the use of products containing the patented inventions, utility models, industrial designs, in cases of extreme and unavoidable circumstances under the given conditions (force majeure), followed by the payment of reasonable compensation to patentee, is not recognized as an infringement of the exclusive right of the patent holder.

This provision may be used by the government of Belarus for government use of patents on antiretroviral medicines to combat HIV, provided that the epidemic will be recognized as extraordinary and unavoidable under the given conditions. In mentioned above regulation on compulsory licensing of patents on medicines may also be provided a detailed procedure for the adoption of decisions by government on use of patents on medicines.

6.2.5 Parallel Import

A regime of national exhaustion of rights to inventions is foreseen in Belarus[144], as well as in relation to industrial designs.

Thus, parallel imports of goods, which use patented inventions in Belarus, is not allowed. Violators of patent rights may face civil, administrative and criminal liability under the laws of the Republic of Belarus. This situation can be remedied by making changes in particular of Article 10 of the Law, by providing for a rule of international exhaustion of rights.

In accordance with Article 13 of the Agreement on common regulatory principles for the protection and enforcement of intellectual property rights (signed on 9 December 2010 as one of the basic international treaties that form the Common Economic Space of Belarus, Kazakhstan and the Russian Federation) and paragraph 5 of Article 20 of the Law "On Trademarks and

[144] Article 10 of the Law
http://www.pravo.by/main.aspx?guid=3871&p0=H10200160&p2={NRPA}

service Marks" since 2012 a regime of regional exhaustion of trademark rights is introduced in Belarus. However, taking into account the national regime of exhaustion of rights to inventions, parallel imports from Kazakhstan and Russia to Belarus is not possible. And not viable taking into account that branded ARVs are sold in Russia and Kazakhstan at a higher price than for Belarus.

It should also be noted that labeling language on the packaging of medicines may be an obstacle to implementation of schemes of parallel imports. Therefore, the provisions of Article 8 of the Law of the Republic of Belarus "On medicines" that require labeling on the package to be done in Belarusian or Russian language should also be take into account.

6.2.6 Exceptions to Patent Rights

In accordance with Article 10 of the Law the following cases does not constitute an infringement of the exclusive rights of the patent holder:

1. scientific research and experiment on object that involves the invention protected by the patent;
2. use of objects, in which the patented invention is used, for personal purposes without a profit;
3. occasional preparation of medicines in pharmacies by prescription with the use of the invention protected by the patent;
4. use, offer for sale, sale, importation or possession of the product containing the invention protected by the patent and introduced into civil circulation in the Republic of Belarus without violating the rights of the patent holder.

The legislation of the Republic of Belarus on protection of of intellectual property rights does not permit import, manufacture and use a patented product by third parties before the expiration of the patent. Thus, Belarusian legislation does not provide Bolar exception that will not allow generic companies to carry out preparatory acts for registration of generics in Belarus immediately after the expiry of the patent, despite the fact that the law does not prohibit the experimental use of patented medicine.

6.3 TRIPS-plus provisions in Belarus

6.3.1 Patent Term Extension

In accordance with paragraph 3 of Article 1 of the Law patent is valid for 20 years from the filing date of a patent application for the invention to the state agency "National Center of Intellectual Property" (Patent Office).

If from the date of filing of the application for a patent for an invention relating to a medicine, pesticide or agrochemical, the use of which in accordance with the legislation requires approval of the authorised state body, to the date of the first such approval lapsed more than five years, the term of a patent on that invention may be extended by the patent authority at

the request of the patent holder. The patent term shall be extended by the time that elapsed from the date of filing of the application for the invention to the date of the first authorization for use of the medicine, pesticide or agrochemical in which the invention is used, minus five years. In addition, the validity of a patent may not be extended for more than five years. An application for patent term extension is applied during the term of a patent before the expiration of six months from the date of the first authorization for use of the medicine, pesticide or agrochemical, in which the invention is used, or the date of publication of the patent in the official bulletin of the patent authority (the official newsletter) depending on which of these expire later.[145]
The procedure of extension of patent terms is defined by the Regulations on the procedure for extension of the patent for invention, utility model, industrial design, approved by the Council of Ministers of the Republic of Belarus of December 15, 2010 № 1824.

As TRIPS Agreement does not contain requirements for the expansion of the term of the patent, mentioned provisions are TRIPS-plus provisions creating obstacles to competition from manufacturers of generic versions of antiretroviral drugs, and should be removed from Article 1 of the Law.

6.3.2 Data Exclusivity

Belarusian legislation does not provide the prohibition to refer to the clinical trial data submitted during the registration of the original drug for the purpose of registering the generic drug.

According to the Subparagraph 4.1 of paragraph 4 of the regulation on state registration (re-registration) of medicinal products and pharmaceutical substances, approved by the Council of Ministers on September 2, 2008 № 1269 it is foreseen that the state registration (re-registration) of medicinal products, active pharmaceutical ingredients includes receiving the registration dossier by Republican Unitary Enterprise "Centre for Expertise and Testing in Health Care", including the documents required for state registration of medicinal products and pharmaceutical substances.
In accordance with paragraph 10.14 of the Unified list of administrative procedures for state registration (re-registration) and the issuance of the registration certificate for foreign medicines the following documents shall be filed:
- certified by the applicant (manufacturer) copy of the *report on bioavailability (bioequivalence) for generic medicines* (if any) during registration of the drug;
- certified by the applicant (manufacturer) copy of the report of the pre-clinical trials of the drug (*with the exception of generic medicines*, including pharmacotoxicological tests in accordance with Good Laboratory Practice) during registration of the drug;

[145] Article 1 of the Law
http://www.pravo.by/main.aspx?guid=3871&p0=H10200160&p2={NRPA}

- certified by the applicant (manufacturer) copy of the report of clinical trials of the drug conducted in accordance with Good Clinical Practice during registration of the drug (*with the exception of generic medicines*, if a report of bioequivalence trials).

Despite this positive situation on data exclusivity in Belarus the following possible threat should be noted. As mentioned above, on May 19, 2011 the Republic of Belarus signed an Agreement on the Functioning of the Customs Union within the Framework of the Multilateral Trading Systems. Taking into account the provisions of the Treaty in the course of further negotiations on the accession of the Republic of Belarus to the WTO the obligations of the Russian Federation to the WTO will be taken into account, which in addition to the TRIPS Agreement include the requirement to provide data exclusivity for a period of 6 years.[146] As it was noted in the general part of this report, data exclusivity helps to maintain high prices for medicines, therefore it is necessary to notify the negotiating representatives of Belarus about the dangers that poses the data exclusivity to access to medicines.

6.3.3 Patent Linkage to Marketing Authorization

Law "On medicines" of Belarus does not require from DRA to check at the time of registration whether applicant has a patent license agreement or consent of the patent holder.

At the same time, according to the Annex 1 to the Decree of the Ministry of Health of the Republic of Belarus on May 8, 2009 № 52 "On the requirements to the documents for medicines, pharmaceutical substances applied for state registration (re-registration), and the documents submitted for amendments to the registration dossier for the medicine (pharmaceutical substance), previously registered in the Republic of Belarus, and the annulment of the decision of the Ministry of health of the Republic of Belarus of November 21, 2008 № 199" an indication by the applicant in the application for state registration (re-registration) of medicinal product information about patent protection in the Republic of Belarus (the owner of the patent, number, issue date, expiration date), and the guarantee of the applicant that the rights of third parties protected by a patent are not infringed in connection with the registration of the medicinal product is required.

In accordance with Chapter 4 of the Regulation on state registration (re-registration) of medicinal products and pharmaceutical substances, approved by the Council of Ministers on September 2, 2008 № 1269, the Ministry of Health may decide to suspend the registration certificate issued for the medicinal product, pharmaceutical substance in cases when registration (re-registration) dossier contained false information. The period of suspension

[146] Pp. 1450 and 1295 of the Report of the Working Party on the Accession of the Russian Federation to the WTO, WT/ACC/RUS/70, WT/MIN(11)/2, 17 November 2011.

of the registration certificate may not be more than six months. Import, manufacture, sale and use of medicinal products, pharmaceutical substances in the Republic of Belarus, is prohibited during suspension of the registration certificates. The applicant within the period of the suspension of the registration certificate shall remedy the circumstances that caused the suspension of the registration certificate, and send written notice to the Ministry of Health about this with attachment of documentary evidence.

In case of failure to eliminate the circumstances, which caused the suspension of the registration certificate, the Ministry of Health shall take decision to cancel the registration certificate indicating the reasons for cancellation.

Thus, Belarusian legislation provides patent linkage with state registration, which is typical TRIPS-plus position.[147] This provision should be removed from the legislation of Belarus by amending mentioned above Annex 1 to the Decree of the Ministry of Health, adopted on May 8, 2009 № 52.

6.3.4 Enforcement: Border Measures

Rules of the customs law that provide for detention of goods suspected of infringing patent are contained in Chapter 12 "Features of the customs clearance of goods containing objects of intellectual property" of the Customs Code of the Republic of Belarus.

In accordance with Article 91 of the Customs Code, the right holder or any other person representing his interests (the applicant), who have reasons to believe that the movement of goods across the customs border violated or may violate holder's rights to intellectual property, has the right to submit to the State customs Committee of the Republic of Belarus declaration on the implementation by the customs authorities of measures to protect its IPRs.

Article 92 of the Customs Code provides that the application on the implementation of customs measures for the protection of intellectual property, that the applicant may file to the State Customs Committee of the Republic of Belarus shall contain the following data:

- information about the manufacturer, indicating the intellectual property rights which may be violated, and the time period during which the customs authorities will take measures to protect the IPRs;
- a detailed description of goods containing objects of intellectual property, as well as information about the place of manufacture of such products, their manufacturers, and persons who have a permit or license for use of intellectual property;

[147] Pp. 84-89 of the Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover "Promotion and protection of all human rights, civil, political, economic, social and cultural rights, including the right to development", A/HRC/11/12, 31 March 2009.

- a description of the goods in respect of which it is assumed that the goods are counterfeit;
- other information to identify counterfeit goods.

Article 95 of the Customs Code of the Republic of Belarus provides that if during customs clearance of goods containing objects of intellectual property included in the customs register of intellectual property rights, customs authorities found signs pointing to the fact that the goods may be counterfeit, *customs clearance of such goods shall be suspended for ten working days*. At the request of the applicant the time limit may be extended, but not for more than another ten working days if the right holder filed claim with authorized for the protection of the IPRs state authorities (courts).

If, before the expiration of the suspension period there will be no decision of authorized body on withdrawal, arrest or confiscation of products, the day following the date of expiry of the suspension period, customs clearance of such goods shall be resumed.

Right holder is liable for property damage caused to the declarant, owner, and recipient of the goods as a result of the suspension of customs clearance of goods in accordance with this chapter, unless as prescribed by law it is determined that the goods (including packaging and label) are counterfeit.

While in practice the measures for the protection intellectual property used by the customs authorities in respect of trademarks, copyrights, applying customs measures for patent protection is TRIPS-plus provision. Such provisions of the Customs Code of Belarus may have a negative impact on competition, as it can create psychological pressure for potential importers of generic drugs.

In conclusion, it should be noted that within the Customs Union of Belarus, Kazakhstan and the Russian Federation, customs measures in respect of goods containing objects of intellectual property are regulated by Chapter 46 of the Customs Code of the Customs Union and the Agreement on Unified Customs Register of Intellectual Property Objects of the Member States of the Customs Union. The Agreement applies only to copyright and related rights, trademarks, service marks, thus depriving patent holders the ability to apply such a mechanism, which is completely in accordance with the requirements of the TRIPS Agreement.

6.3.5 Enforcement: Criminal Liability

Despite the provisions of Article 61 of the TRIPS Agreement, which do not require Belarus to introduce criminal liability for patent infringement, in accordance with Article 201 of the Criminal Code of the Republic of Belarus:

"... 2) unlawful distribution, or otherwise unlawful use of copyright, related rights or of objects of industrial property rights (including the invention) committed within a year after the imposition of an administrative penalty for the same offense or associated with obtaining income on a large scale - shall be punished by community service or a fine, or restraint of liberty for up to three years, or imprisonment for a term not exceeding two years;

3) the actions specified in 1) and 2) committed repeatedly or by a group of persons by prior conspiracy, or by an official using his official powers or that caused damage on a large scale - shall be punished by a fine or imprisonment for up to six months, or restraint of liberty for a term up to five years, or imprisonment for the same term."

Large amount of income (loss) in Article 201 of the Criminal Code of the Republic of Belarus equals to the sum that five hundred (appr. 4000 EUR) or more times exceeds the size of the base unit, mounted on the day of the crime commitment.

The current size of the base unit in the Republic of Belarus is 100,000 Belarusian rubles (approx. 8 euros).

It should also be noted that Article 9.21 of the Code of Administrative Offences foresees that the illegal distribution or other illegal use of objects of copyright, related rights or industrial property rights (including inventions) as well as varieties of plants or integrated circuit is punished by a fine in the amount from twenty to fifty base units (160-400 EUR) with confiscation of the subject of an administrative offense or without confiscation, for the individual entrepreneur - up to one hundred base units (800 EUR) with confiscation of the subject of an administrative offense or without confiscation, for the legal entity - up to three hundred base units (2400 EUR) with confiscation of the subject of administrative offense or without confiscation.

Such provisions of the Criminal Code and the Code of Administrative Offences of Republic of Belarus may have a negative impact on manufacturers of generic products and are not recommended in terms of access to medicines.

6.4 Conclusions and Recommendations for Belarus

Thus, Belarusian legislation contains the following TRIPS-flexibilities and TRIPS-plus provisions:

Public health-related TRIPS-Flexibilities	Presence or absence of provision
Diagnostics and therapeutic methods are not patentable	No (-)[148]
Second use, new forms are not patentable	No (-)
Compulsory licensing is provided	Yes (+)
Government use is provided	Yes (+)
Parallel import is permitted	No (-)
Bolar exception	No (-)
Experimental use exception	Yes (+)
Pre-grant patent oppositions	No (-)
Post-grant patent oppositions	Yes (+)
TRIPS-plus provisions, which restrict access to medicines	**Presence or absence of provision**
Utility models for pharmaceuticals	No (-)
Patent term extension	Yes (-)
Data exclusivity	No (-)

[148] „(-)" or „(+)" characterizes the negative or positive potential impact of presence or absence of TRIPS-flexibility or TRIPS-plus provision in the legislation of the country.

Patent linkage with market authorisation	Yes (-)
Customs measures	Yes (-)
Criminal liability for patent infringement	Yes (-)

In light of the above analysis the following changes of the legal framework could be recommended by the NGO activists to the Belarusian government:

1. to exclude diagnostic, therapeutic and surgical methods from patentable subjects;
2. to exclude from patentability new uses of known substances or introduce an exception for pharmaceutical products in the Law;
3. develop and introduce into the Belorusian Patent Law stricter rules on patentability of pharmaceutical products to prevent granting "evergreening" secondary patents or patent applications that are against public health interests (as a model could be used provisions of the Indian Patent Act, in particular, Article 3(d) [149]);
4. to delete possibility of patent term extension for medicinal products;
5. stipulate in the Law right of third parties, including patient organisations, to file pre-grant patent oppositions with the patent office;
6. to consider introducing rules on compulsory licensing to the Belarusian Patent Law with further development of detailed Procedure on the issuance of compulsory licenses and government use in the field of public health;
7. when Belarus shall become a member of WHO, it appears commendable to accede to the 30 August 2003 Decision mechanism of exporting-importing under compulsory licenses[150] as a potentially importing country;
8. to introduce Bolar exception into the Law. Wording of Article 55.2 (1 and 6) of the Canadian Patent Act could be used as a model for Bolar exception;[151]

[149] Please see in more detail chapter 5.1.2 Patentability criteria above, and brief analysis of article 3(d) of the Indian Patent Law http://www.ipfrontline.com/depts/article.aspx?id=26756&deptid=4

[150] See Decision of the General Council of 30 August 2003 on Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm

[151] Article 55.2 (1 and 6) of the Canadian Patent Act stipulates that "(1) It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product. (6) For greater certainty, subsection (1) does not affect any exception to the exclusive property or privilege granted by a patent that exists at law in respect of acts done privately and on a non-commercial scale or for a non-commercial purpose or in respect of any use, manufacture,

9. to introduce international regime of patent right exhaustion for pharmaceutical products;
10. to notify the negotiating representatives of Belarus with WTO about the dangers that poses the data exclusivity to access to medicines and on the need to avoid taking obligations on implementation of data exclusivity in Belarus;
11. to exclude from the Annex 1 to the Decree of the Ministry of Health of the Republic of Belarus on May 8, 2009 № 52 "On the requirements to the documents for medicines, pharmaceutical substances applied for state registration (re-registration), and the documents submitted for amendments to the registration dossier for the medicine (pharmaceutical substance), previously registered in the Republic of Belarus, and the annulment of the decision of the Ministry of health of the Republic of Belarus of November 21, 2008 № 199" provisions on patent linkage;
12. to exclude applicability of customs measures provided in Chapter 12 "Features of the customs clearance of goods containing objects of intellectual property" of the Customs Code of the Republic of Belarus to patented inventions;
13. to decriminalize liability for patent infringement or at least criminal sanctions should be significantly relaxed;

construction or sale of the patented invention solely for the purpose of experiments that relate to the subject-matter of the patent." http://laws-lois.justice.gc.ca/eng/acts/p-4/page-28.html#docCont

7 Implementation of Public Health-Related TRIPS Flexibilities in Georgia

7.1 General Considerations: Georgia

According to the Constitution of Georgia domestic legislation shall correspond to universally recognised principles and rules of international law. International treaties, to which Georgia is a party, shall prevail upon domestic law unless they contradict to the Constitution of Georgia or the Constitutional Agreement.[152] Therefore Georgia is bound by the international treaties and agreements it acceded to without the need of additional incorporation into its domestic law.

Georgia acceded to the ICESCR and ICCPR on 3 May 1994[153], thus it has an obligation to ensure right to health to its citizens, including ensuring access to essential or life-saving medicines. Among other, Georgia is obliged under human rights treaties to find a balance in regulating intellectual property protection issues in order to ensure that such regulations do not create obstacle to the access to essential medicines.

At the same time, Georgia has been a member of WTO and is a party to the TRIPS Agreement since 14 June 2000, therefore it is bound to maintain minimum standards of intellectual property protection established by the TRIPS Agreement. According to the Working Party Report Georgia committed to apply the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights no later than the date of its accession to the WTO, without recourse to any transitional periods,[154] thus leaving itself out of scope of one of the basic TRIPS flexibility.

Intellectual property rights are inviolable according to Article 23 of the Constitution of Georgia. The system of intellectual property protection in Georgia was designed before accession to WTO to comply with the requirements of multilateral treaties in this field, including the the TRIPS Agreement, the Paris Convention for the Protection of Industrial Property and the Berne Convention for the Protection of Literary and Artistic

[152] Article 6 of the Constitution of Georgia, as amended on 27 December 2006 http://www.parliament.ge/files/68_1944_951190_CONSTIT_27_12.06.pdf
[153] See status of human rights treaties on http://treaties.un.org/Home.aspx?lang=en
[154] Report of the Working Party on the Accession of Georgia to the World Trade Organization, WT/ACC/GEO/31, 31 August 1999, paragraph 161.

Works.[155] Main intellectual property laws (6 laws) were adopted in 1999 in the course of prepartion of accession to WTO.[156]

Georgia concluded a Partnership and Cooperation Agreement with EU that provides that: "…Georgia shall continue to improve the protection of intellectual, industrial and commercial property rights in order to provide, by the end of the fifth year [1 July 2004] after the entry into force of this Agreement, for a level of protection similar to that existing in the Community, including effective means of enforcing such rights."[157] Taking into account that EU's regime of intellectual property protection is a TRIPS-plus regime, such obligation means that Georgia has to raise its standards of intellectual property protection to the TRIPS-plus level. Furthermore, on 29 November 2013 Georgia initialled an Association Agreement with EU which foresees several TRIPS-plus provisions.[158]

It should be mentioned that the Georgian Patent Law contains a definition of medical product harmonized with EU law. Thus, paragraph 2(1)(r) of the Georgian Patent Law provides that medical product is an active substance or combination of active substances intended for human or animal treatment or prevention of disease, as well as substance or combination of substances that could be prescribed to human or animal for medical diagnosis and recovery, correction or modification of physiological function.

7.2 TRIPS flexibilities: Georgia

7.2.1 Patentability criteria

Patents are granted in Georgia for inventions which were considered new, involve an inventive step, and are industrially applicable,[159] which is a general patentability criteria established by the Article 27 of the TRIPS Agreement. The invention is new if it does not relate to the existing state of the art.[160] An invention involves the inventive step where, for the date of establishing priority, it is not known at current state of the art.[161] An invention is industrially applicable where it implies the capability of its production or use in industry or agriculture.[162] State of the art under Patent Law of Georgia, 2010 (Georgian Patent Act) means all data that, before the date of establishing priority, has become publicly accessible in writing, by

[155] Report of the Working Party on the Accession of Georgia to the World Trade Organization, WT/ACC/GEO/31, 31 August 1999, paragraph 128.
[156] Comments on the Legislation of Georgia in the Field of Intellectual Property Protection, WIPOlex, p. 1 http://www.wipo.int/wipolex/en/text.jsp?file_id=208971
[157] Article 42(1) of the EU-Georgia Partnership and Cooperation Agreement http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1999:205:0003:0038:EN:PDF .
[158] Text of the Association Agreement between Georgia and EU http://www.eeas.europa.eu/georgia/assoagreement/assoagreement-2013_en.htm
[159] Article 12(1) of the Georgian Patent Law.
[160] Article 12(2) of the Georgian Patent Law.
[161] Article 12(3) of the Georgian Patent Law.
[162] Article 12(4) of the Georgian Patent Law.

verbal description, public use or from other source. In addition to this criterion state of the art also includes all applications for invention and utility model filed with Sakpatenti (Georgian Patent Office), provided that such applications have an earlier priority compared to an application whose novelty is being determined and such applications were published after establishing priority date of the application.[163] From all of this it appears that Georgia has established an international novelty criterion, which is good practice from access to medicines standpoint.

Further, according to the Article 17 of the Georgian Patent Law a patent is not granted for inventions against public order; inventions related to surgical, therapeutic and diagnostic methods of treatment of humans and animals; inventions related to plant varieties and breeds of animals, as well as primarily biological methods for plant and animal breed selection. These provisions completely correspond to the flexibility provided in Article 27(2-3) of the TRIPS Agreement.

Pharmaceutical products can be also protected in Georgia as a utility model, which is not required under the TRIPS Agreement and is a TRIPS-plus provision.[164] A utility model is patentable where it satisfies the same criteria of patentability, as for the invention, namely, novelty, inventive step and industrial applicability, but in contrast to an invention it is characterized by lesser inventive step compared to invention[165] and is simpler to obtain.[166] The patent validity term for utility model is 10 years from the day of application.[167] The applicant may apply simultaneously for the patent and the utility model for the same invention. Additionally, during the course of examination of the patent application, it could be transformed into the utility model application. The utility model patent protection is easier to obtain, while giving the same protection as patent only for the the shorter period of time. It could create serious obstacles for the generic competitors, and medicines should be excluded from the scope of the utility model protection.

According to the Instruction on Procedures Related with Drafting and Filing Applications for Inventions and Utility Models and Granting a Patent, approved by Order No. 4 of the Chairman of Legal Entity of Public Law, National Intellectual Property Center of Georgia Sakpatenti, on December 12, 2011, in the case when the object of protection is a medicinal product and/or a method of its obtaining, the patent application shall contain:

a) data on medical indications of the product;
b) data confirming that use of the product for medical purposes is possible, data on pharmaceutical forms of the product, their dosage and ways of introducing into the organism;

[163] Article 12(5-6) of the Georgian Patent Law.
[164] Article 1100 of the Civil Code of Georgia, 1997 http://www.wipo.int/wipolex/en/text.jsp?file_id=209011;
[165] Article 71-1(1) of the Georgian Patent Law.
[166] Article 71-1(7) of the Georgian Patent Law.
[167] Article 71-1(5) of the Georgian Patent Law.

c) data confirming the possibility of the realization of the product ability with a relevant purpose, including data on the effect of this product on definite links of physiological or pathological processes or on connection with them.

As patent search is a rather complicated and costly endevour, above requirment simplifies the task of patent search of medicinal product, including ARVs.

Although the Georgian Patent Law does not explicity provide for the patentability of second uses of known medicines as Article 12(8) that permitted patenting of second use was repealed in 2010, the Instruction on Procedures Related with Drafting and Filing Applications for Inventions and Utility Models and Granting a Patent still provides that "if a medical product and/or the active ingredient contained in it is known from the state of the art, the detailed description shall contain the data which will confirm clearly the possibility of solving the technical task set in the invention."[168] This provision creates an opportunity for patenting of second indications of existing medicines, which is a TRIPS-plus provision and therefore it should be deleted from the Instruction.

Finally, it should be noted that neither the Georgian Patent Law, nor the the Instruction on Procedures Related with Drafting and Filing Applications for Inventions and Utility Models and Granting a Patent contain any rules aimed at prevention of 'evergreening' practice.

7.2.2 Patent Oppositions

Georgian law provides for the pre-grant and post-grant patent oppositions procedures within the patent authority, as well as possibility to declare patent invalid by court, which shows a significant scrutiny that patents could be subjected to by interested party in Georgia. Additionally, a broad definition of parties that can submit patent oppositions creates opportunity for the patient organizations to subject patents on life-saving medicines to public scrutiny.

Thus, within the pre-grant opposition procedure an interested party has the right to file an appeal to the Chamber of Appeals of the Georgian Patent Office against decision of the patent examination, claiming non-compliance with the requirements to patentable subject matter or with the criteria of novelty and inventive step. The appeal should be filed to the Chamber of Appeals within three months from the date of publication/receipt of the decision in question. The Chamber of Appeals hears the appeal and renders decision within three months from the filing date. Decision by the Chamber of Appeals may be appealed in court within the term provided by law for appealing administrative-legal acts.[169]

[168] Article 14(2) of the Instruction on Procedures Related with Drafting and Filing Applications for Inventions and Utility Models and Granting a Patent, approved by Order No. 4 of the Chairman of Legal Entity of Public Law, National Intellectual Property Center of Georgia Sakpatenti, on December 12, 2011.
[169] Article 40-3 of the Georgian Patent Law.

In relation to granted patents an interested party has the right to request re-examination of an invention within the term of patent validity, on the grounds that an invention does not meet the patentability criteria. An application for re-examination should be supported by the following documents:

a) written argument pertaining to non-compliance of an invention with the patentability criteria;
b) copies of all issued and published patents that form the basis for party's argument. [170]

Within 3 working days from the receipt of a request for conducting re-examination of an invention, Sakpatenti shall send this request to the patent holder and give him/her a 2-week term for submission of a response shall, as determined by Law. Within 2 months from the expiration of the 2-weeks period the Board of Experts shall be set up and conduct re-examination. On the basis of the results of re-examination, the Georgian Patent Office shall take a decision on refusal of invalidation of the patent or on full or partial invalidation of the patent.[171]

Finally, a court shall declare a patent invalid where it has established that:

a) an object of patent is not patentable;
b) a patent does not describe an invention to the degree that makes its realization possible;
c) object of patent falls in the category of objects that cannot be patented (e.g. discovery, presentation of information, etc.);
d) object of patent falls in the category of objects that cannot be considered an invention (e.g., surgical, therapeutic and diagnostic methods);
e) object of patent falls beyond the scope of application in respect of which the priority was established, or the patent is granted on the basis of a divisional application and its object is beyond the scope of the first application;
f) if the patent owner had no right to hold patent.[172]

7.2.3 Compulsory licensing and Government Use

It appears that the Georgian law does not provide for one of the most important TRIPS flexibilities that is widely used worldwide to improve access to life-saving medicines. Before the accession to the WTO the law of Georgia provided that non-exclusive compulsory licences could be granted after 4 years of patent issuance upon the request of any interested persons,

[170] Article 42-1 of the Georgian Patent Law.
[171] Article 41 of the Instruction on Procedures Related with Drafting and Filing Applications for Inventions and Utility Models and Granting a Patent, approved by Order No. 4 of the Chairman of Legal Entity of Public Law, National Intellectual Property Center of Georgia Sakpatenti, on December 12, 2011.
[172] Article 57 of the Georgian Patent Law.

provided that the proposed user had made efforts to obtain a license from the right holder on reasonable terms.[173] Since accession to the WTO Georgia had introduced detailed provisions on compulsory licensing, to the Georgian Patent Law,[174] which among other foreseen that the Ministry of Economy could issue a compulsory license for public health needs.[175] Although, unfortunately, these provisions were excluded from article 61 of the Georgian Patent Law in 2010.

Additionally, according to the Article 52 of the Georgian Patent Law the use of invention in cases of natural disaster, catastrophe, epidemic or other emergency situations is not considered a violation of patent rights.[176] Thus, the law leaves an opportunity for compulsory licensing and government use, although in a very limited set of grounds, which is a TRIPS-plus provision.

7.2.4 Parallel Import

It is not clear from the provisions of Georgian law whether it permits the parallel import, as the law does not explicitly define which concept of exhaustion (national or international/regional) Georgia has adopted.

Thus, Article 52(a) of the Georgian patent law provides that "the following shall not be considered a violation of exclusive rights: a) further dissemination or other use of the product produced by the patent owner or under his/her permission and put on the market". As it is not defined whether the "market" is national or international/foreign it is not possible to come to definite conclusion whether legislator meant international concept of exhaustion or not.

7.2.5 Exceptions

Under the Georgian Patent Law the following shall not be considered a violation of exclusive rights:

a) further dissemination or other use of the product produced by the patent owner or under his/her permission and put on the market;
b) private use of invention for personal ends, unless such action is not intended for commercial purposes;
c) use of invention abroad the foreign vessel, aircraft or land transport present on the territory of Georgia. In such cases, invention should be used exclusively aboard such transportation means and not for entrepreneurial purposes;

[173] Report of the Working Party on the Accession of Georgia to the World Trade Organization, WT/ACC/GEO/31, 31 August 1999, paragraph 150
[174] WTO, Council for TRIPS, Review of Legislation, Georgia, 10 December 2001, pp. 32-33.
[175] Comments on the Legislation of Georgia in the Field of Intellectual Property Protection, WIPOlex, p. 1 http://www.wipo.int/wipolex/en/text.jsp?file_id=208971
[176] Article 52 of the Georgian Patent Law.

d) use of invention in cases of natural disaster, catastrophe, epidemic or other emergency situations.[177]

Additionally, prior use of invention by a person that has been using invention in good faith or conducted preparatory works for its use prior to the date of filing patent application, is not considered a violation.[178]

It appears that the Georgian law does not contain such an improtant from access to medicines view exceptions as experimental use and Bolar exception. Georgian government should consider using these flexibilities.

7.3 TRIPS-plus provisions: Georgia

7.3.1 Patent Term Extension

The term of patent protection in Georgia is 20 years.[179] According to the Article 5 of the Georgian Patent Law patent validity of an invention related to medical product, which requires consent of competent authority for entry into the Georgian market, can be extended by request of the patent owner for additional term which corresponds to the period from the date of application to the Georgian Patent Office until receiving consent from the competent authority, but no longer than 5 years. Application requesting additional term for patent validity shall be submitted by patent owner within a year from the date of obtaining consent of the competent authority.[180]

Such extension is a classical TRIPS-plus provision which should be deleted or revised in the course of harmonization with the EU law, where the period, which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorization to place the product on the market in the EC shall be reduced by a period of five years (a period which is protected by supplementary protection certificates in EU)[181]. Such harmonization shall occur in the nearest future as draft Association Agreement between Georgia and EU foresees described regime of supplementary protection certificates.[182]

7.3.2 Data exclusivity

The law of Georgia provides for the protection of data submitted for the registration of medicinal product from disclosure and for the indefinite data exclusivity period reqirement. Thus, Georgian law protects trade secrets by vesting exclusive rights to the technological, organizational or commercial

[177] Article 52 of the Georgian Patent Law.
[178] Article 53 of the Georgian Patent Law.
[179] Article 5(1) of the Georgian Patent Law.
[180] Article 5(5) of the Georgian Patent Law.
[181] Article 13 of the Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products.
[182] See Article 186 of the draft Association Agreement between Georgia and EU http://www.eeas.europa.eu/georgia/assoagreement/assoagreement-2013_en.htm

information of extraordinary importance that justifies the taking of necessary and adequate measures for keeping it in secrecy.[183] According to the Law "On Medicines and Pharmaceutical Activity" the test data filed with the Ministry of Labour, Health and Social Protection for the pharmaceutical product registration shall be confidential and should not be publicly disclosed.[184]

Further, Article 4(2)(b) of the Law of Georgia "On Medicines and Pharmaceutical Activity" establishes that the use of scientific and technical information about already registered pharmaceutical product for the purposes of taking decision on registration of generic product is prohibited. In other words, this provision sets out an indefinite term of data exclusivity in Georgia and obliges generic manufacturers to rely on their own data when registering pharmaceutical products in Georgia.[185] This provision is a TRIPS-plus provision and poses a very significant barier for access of generic products to the pharmaceutical market in Georgia. Thus, according to WHO data base on the registration status of ARVs[186] in the state of Georgia on July 1, 2013 were recorded by the national registration procedure (as opposed to recognizing the registration regime described below) only original ARVs and no generic products.

Along with the national regime of state registration of a pharmaceutical product described above, since 2009 there has been introduced a regime of recognition of a pharmaceutical products already registered in other countries. This regime allows to import pharmaceutical products on the Georgian market in a simplified manner without a re-examination of the same or similar safety requirements, quality and therapeutic efficacy of pharmaceutical products.

Thus, medicines and medical tests may be registered in Georgia on the basis of their recognition by inter-state body that regulates pharmaceutical activity, of approval by the foreign regulatory authority (European Medicines Agency (EMA), the regulatory authorities of various European countries, the USA, Japan, Australia and New Zealand). The law does not restrict who can import and for what purpose. The procedure of simplified registration can initiate any natural or legal person who wishes to register / import products, regardless of the purpose of that person. Also, much less technical information is required than in general national registration mode.

[183] Article 1105 of the Civil Code of Georgia.
[184] Article 5 of the Law of Georgia "On medicines and pharmaceutical activity", dated 17 April 1997, N 659 – II.
[185] According to the WTO, Council for TRIPS, Review of Legislation of Georgia, on 10 December 2001, pp. 63: "All other applications for marketing approval shall rely on their own test data."
[186] The Drug Regulatory Status Database
http://apps.who.int/hiv/amds/patents_registration/drs/

In special cases, such as natural disasters, epidemics, for humanitarian purposes with the permission of the Minister of Health medicines could be used on the territory of Georgia without registration. [187]

All of this can compensate for the prohibition to refer to original product test data to register generic medicines in the Georgian legislation. [188]

Finally, it should be noted that in Article 187 of the draft Association Agreement between EU and Georgia, initialled on 29 November 2013, a data exclusivity period of 6 year is foreseen (with possibility to prolongate for one additional year for new therapeutic indications).[189]

7.3.3 Patent Linkage

It appears that the Georgian Law does not contain such TRIPS-plus provision, which is positive from standpoint of access to medicines.

7.3.4 Enforcement: Border Measures

Under the Law of Georgia on Border Measures Relating to Intellectual Property a special register shall be created by the Revenue Service of Georgia, where the interested right holder may register his object of intellectual property and declare the information necessary for identification of goods.[190] At finding of the suspicious goods the customs authorities shall be authorized to suspend these goods[191], which further could be destructed if there are sufficient grounds.[192]

Fortunately, this law does not apply to the inventions and therefore is not applicable to the situations of infringement of patent on medicine, which is in compliance with the TRIPS Agreement and is one of the TRIPS flexibilities, provided in Article 51 of the TRIPS Agreement that Georgia used.

7.3.5 Enforcement: Criminal Procedures

Contrary to the flexibility contained in Article 61 of the TRIPS Agreement the Criminal Code of Georgia provides in Article 189 a criminal liability for patent infringement.

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[187] Article 11-13 of the Law of Georgia "On medicines and pharmaceutical activity".
[188] Presentation "Prices for HCV diagnostics in Georgia: ideas for prices decrease", Partnership for Research and Action for Health, Tamar Chitashvili, MHP&M, George Kamkamidze, MD, PhD, MS, Mamuka Djibuti, MD, PhD.
[189] Please Article 187 of the draft Association Agreement between Georgia and EU http://www.eeas.europa.eu/georgia/assoagreement/assoagreement-2013_en.htm
[190] Articles 3 and 4 of the Law of Georgia on Border Measures Relating to Intellectual Property, June 23, 1999, N 2159 – II.
[191] Article 5 of the Law of Georgia on Border Measures Relating to Intellectual Property, June 23, 1999, N 2159 – II.
[192] Article 8 of the Law of Georgia on Border Measures Relating to Intellectual Property, June 23, 1999, N 2159 – II.

Misappropriation of right on other person's invention or utility model, as well as illegal multiplication for distribution purposes, distribution, disposal, import, export or otherwise use of such piece without a prior consent of the author, other person possessing patent rights shall be punishable by fine or by corrective labour for up to two years in length.

Disclosure of information on invention or utility model without a prior consent of the author or other person possessing right shall be punishable by fine or by restriction of freedom for up to two years in length.

These crimes perpetrated repeatedly or that has substantially prejudiced the interest of the author, other person possessing exclusive rights or the right allied thereof, as well as coercion into co-authorship, shall be punishable by restriction of freedom for up to three years in length or by imprisonment similar in length.[193]

7.4 Conclusions and Recommendations for Georgia

Thus, Georgian legislation contains the following TRIPS-flexibilities and TRIPS-plus provisions:

Public health-related TRIPS-Flexibilities	Presence or absence of provision
Diagnostics and therapeutic methods are not patentable	Yes (+)[194]
Second use, new forms are not patentable	No (-)
Compulsory licensing is provided	No (-)

[193] Article 189 of the Criminal Code of Georgia, adopted on July 22, 1999, No. 2287-rs, as amended in 2012 http://www.carim-east.eu/media/legal%20module/natfr/GE_3.2%20CriminalCode_En.pdf

[194] „(-)" or „(+)" characterizes the negative or positive potential impact of presence or absence of TRIPS-flexibility or TRIPS-plus provision in the legislation of the country.

Government use is provided	No (-)
Parallel import is permitted	No (-)
Bolar exception	No (-)
Experimental use exception	No (-)
Pre-grant patent oppositions	Yes (+)
Post-grant patent oppositions	Yes (+)
TRIPS-plus provisions, which restrict access to medicines	**Presence or absence of provision**
Utility models for pharmaceuticals	Yes (-)
Patent term extension	Yes (-)
Data exclusivity	Yes (-)
Patent linkage with market authorisation	No (+)
Customs measures	No (+)
Criminal liability for patent infringement	Yes (-)

In light of the above analysis the following changes of the legal framework could be recommended by the NGO activists to the Georgian government:

1. to exclude from utility model protection technical solutions related to chemical and pharmaceutical substances and/or processes, technical solutions related to biological material;
2. to exclude from patentability new uses of known substances or introduce an exception for pharmaceutical products (Article 14(2) of the Instruction on Procedures Related with Drafting and Filing Applications for Inventions and Utility Models and Granting a Patent, approved by Order No. 4 of the Chairman of Legal Entity of

Public Law, National Intellectual Property Center of Georgia Sakpatenti, on December 12, 2011);

3. develop and introduce into the Georgian Patent Law stricter rules on patentability of pharmaceutical products to prevent granting "evergreening" secondary patents or patent applications that are against public health interests (as a model could be used provisions of the Indian Patent Act, in particular, Article 3(d) [195]);
4. to delete possibility of patent term extension for medical products or revise provisions of Article 5(5) of the Georgian Patent Law on patent term extension to harmonize with the EU law, where the period, which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorization to place the product on the market in the EC shall be reduced by a period of five years;
5. to consider introducing rules on compulsory licensing to the Georgian Patent Law with further development of detailed Procedure on the issuance of compulsory licenses and government use in the field of public health;
6. it appears commendable for Georgia to accede to the 30 August 2003 Decision mechanism of exporting-importing under compulsory licenses[196] as a potentially importing country;
7. to introduce into Article 52 of the Georgian Patent Law experimental use and Bolar exceptions. Wording of Article 55.2 (1 and 6) of the Canadian Patent Act could be used as a model for Bolar exception;[197]
8. to clarify in the Article 52(1)(a) of the Georgian Patent Law that the regime of exclusive rights exhaustion includes importing to the customs territory of Georgia or introduce international regime of patent right exhaustion only for pharmaceutical products;
9. to amend Georgian law, including Article 4(2)(b) of the Law of Georgia "On Medicines and Pharmaceutical Activity", in order to entitle generic manufacturers to rely on test data of originator's pharmaceutical product for the purposes of state registration;

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[195] Please see in more detail chapter 5.1.2 Patentability criteria above, and brief analysis of article 3(d) of the Indian Patent Law http://www.ipfrontline.com/depts/article.aspx?id=26756&deptid=4

[196] See Decision of the General Council of 30 August 2003 on Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm

[197] Article 55.2 (1 and 6) of the Canadian Patent Act stipulates that "(1) It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product. (6) For greater certainty, subsection (1) does not affect any exception to the exclusive property or privilege granted by a patent that exists at law in respect of acts done privately and on a non-commercial scale or for a non-commercial purpose or in respect of any use, manufacture, construction or sale of the patented invention solely for the purpose of experiments that relate to the subject-matter of the patent." http://laws-lois.justice.gc.ca/eng/acts/p-4/page-28.html#docCont

10. not to undertake additional international obligations or introduce amendments to the Georgian law that will introduce patent linkage of medicines state registration and or data exclusivity provisions;
11. to decriminalize liability for patent infringement or at least criminal sanctions should be significantly relaxed;
12. not to introduce customs measures in relation to patents for pharmaceutical products.

8 Implementation of the Public Health-Related TRIPS-Flexibilities in Moldova

8.1 General Considerations: Moldova

The Republic of Moldova has been a member of the WTO since July 26, 2001, therefore, Moldova is bound by the TRIPS Agreement, which is part of a package of agreements adopted by countries acceding to the WTO. In addition, the Republic of Moldova had been a part of the Eurasian Patent Convention since 16 February 1996 until 26 April 2012. In accordance with Article 2 of the Republic of Moldova "On the Protection of Inventions" (the "Law of Moldova on inventions"), the rights arising out of a Eurasian patent shall be recognized and protected in the Republic of Moldova. However, this provision does not affect all of Eurasian patents, as since April 27, 2012 Agreement between the Government of the Republic of Moldova and the Eurasian Patent Organization on the legal protection of inventions in the territory of the Republic of Moldova has been in force after the denunciation by Moldova of the Eurasian Patent Convention. Eurasian patents issued prior to April 26, 2012, and the patents, patent applications for which were filed prior to that date, are binding for Moldova. This should be considered when implementing a patent search in respect of ARVs registered in Moldova. Also, orientation of the Law of Moldova on inventions for compliance with the European Patent Convention and the EU Directives should be noted.[198] This means that some of the TRIPS-plus provisions will be included in the Law of Moldova on inventions, and it will be difficult to eliminate those provisions because they are backed by considerations of European integration.

8.2 Implementation of the Public Health-Related TRIPS-flexibilities in Moldova

8.2.1 Patentability criteria

In accordance with the Law of Moldova on inventions, the patent is available for the invention in any field of technology, the subject of which is a product or a process, provided that it is (i) new, (ii) involves an inventive step, and (iii) industrially applicable.[199] The invention is considered new if it is not part of the prior art. Art includes all the knowledge that became available to the public by written or oral description, by use or in any other

[198]See preamble to the Law of Republic of Moldova "On Protection of Inventions", dated 7 March 2008 № 50-XVI.

[199]Article 1 of the Law of Republic of Moldova "On Protection of Inventions", dated 7 March 2008 № 50-XVI.

way before the filing date of the patent application or before the priority date.[200] Consequently, the principle of international novelty is applied in Moldova, which is positive in comparison to the local novelty, in terms of access to medicines, as the Patent Office is required to assess the novelty of matter from the point of view of world achievements in the pharmaceutical industry, and not the national level of knowledge in this area.

In full compliance with Article 27(2) of the TRIPS Agreement in Moldova patents for inventions the publication or exploitation of which is contrary to public order or morality, including harmful to the health and lives of people are not issued.[201]

Although the TRIPS Agreement allowed to exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals,[202] Moldova did not take advantage of this flexibility, and at the moment there is no provision of Moldovan legislation, which would exclude diagnostic, therapeutic and surgical methods of treatment from patent protection. Moreover, in paragraph 92 of the Regulation on the Procedure for Submission and Consideration of a Patent Application for the Invention and Issuance of a Patent, approved by Government Decision № 528 of September 1, 2009, it is stated that an invention relating to a method of treatment, diagnosis or prevention of disease in humans or animals, the following information should be described: information about the applied therapeutic agent (medicinal products, physical factors, devices, and equipment), and their quantitative characteristics (dose, wavelength, frequency, etc.), a method of assigning and applying a sequence of operations, and the effect of these factors on the etiopathogenesis of the disease, and in the absence of such information, - significant evidence for the suitability of the method for the treatment, diagnosis or prevention of the disease.

Legislation in developed countries (e.g., Germany), and the provisions of the European Patent Convention excludes these methods from patentability, considering such patenting practices as "the monopolization of medical practice". This TRIPS-plus situation should be resolved by the Government of Moldova.

The legal protection of industrial designs and models in Moldova is governed by the Law of the Republic of Moldova № 161/2007 "On the protection of industrial designs." The appearance of a product or part that is created, in particular, by the lines, contours, colors, shape, texture and / or materials of the product itself and / or its ornamentation can be protected as an industrial design or model. The object of protection may be two-dimensional (industrial design) or three-dimensional (industrial model), or

[200]Article 8 of the Law of Republic of Moldova "On Protection of Inventions", dated 7 March 2008 № 50-XVI.
[201] Article 7 of the Law of Republic of Moldova "On Protection of Inventions", dated 7 March 2008 № 50-XVI.
[202] Article 27(3) of the TRIPS Agreement.

their combination.[203] Thus, the regime of industrial designs and models is not applicable to medicines.

The Law of Moldova on inventions foresees a separate regime of short-term patents with duration of 6 years.[204] However, the short-term patents are not issued for the biological material and the chemical or pharmaceutical substances and / or methods, i.e. there is no possibility to obtain a short-term patent for medicine.[205]

Further, the Law of Moldova on inventions does not prohibit the patenting of a second or subsequent use of a known substance, while TRIPS does not oblige Member States to provide protection for new indications. Thus, the Regulation on the Procedure for Submission and Consideration of Patent Application and Issuance of a Patent, approved by Government Decision № 528 of September 1, 2009, defines the use of the product, process or method as - use them for a specific purpose, provided that it does not follow clearly from the known properties of the product used, the manner or method. Use of the substance for pharmaceutical purposes is considered medical use of the substance. In this case, the first use of a known substance (natural or synthesized) is the first medical use of the substance. A second or subsequent use of a known substance as a medicine (natural or synthesized) in other therapeutic purposes and with other result is regarded as a *second medical use* of that substance.[206] Patenting of new uses of medicines is closely related to the abuse of patenting, the so-called practice of "evergreening" (see section 5.1.1 above). Countries such as India and the Philippines excluded from patentability of new forms of known substances, new (or second) uses, and the use of combinations of known substances, unless they are therapeutically much more effective.[207] Such provisions help to fight harmful to competition patenting practices and improve access to medicines.

8.2.2 Patent Oppositions

Patent oppositions subject patent to greater scrutiny, which can be an effective tool to limit the impact of patents on access to medicines.[208]

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[203] Article 6 of the Law of the Republic of Moldova "On Protection of Industrial Designs and Models", dated 12 July 2007 №161-XVI.

[204] Article 18 of the Law of Republic of Moldova "On Protection of Inventions", dated 7 March 2008 № 50-XVI.

[205] Article 12(3 of the Law of Republic of Moldova "On Protection of Inventions", dated 7 March 2008 № 50-XVI.

[206] Pp. 3-5 Regulation on the Procedure for Submission and Consideration of Patent Application and Issuance of a Patent, approved by Government Decision № 528 of September 1, 2009.

[207] Indian Patents Act, 1970, article 3 (d); Intellectual Property Code, Philippines (as amended by article 5 of the Universally Accessible Cheaper and Quality Medicines Act of 2008), article 22.1.

[208] Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover "Promotion and

In the TRIPS Agreement there are no direct provisions prescribing the procedure of patent oppositions, at the same time the possibility of patent revocation is referred to in Article 32 of the Agreement. Therefore, Member States at their sole discretion have an option to establish procedures for patent oppositions in domestic law, thereby subjecting patents to greater scrutiny.

Moldovan legislation provides for the possibility for any person, including the organization of the patients or by the manufacturer of generics to file post-grant patent oppositions. Thus, within six months from the date of publication of the decision to grant a patent, any person may file an opposition by filing with the State Agency on Intellectual Property (AGEPI) ("Agency") an application. The opposition shall be examined within three months by a division of the Agency that made the decision to grant a patent.

The opposition is made in writing and shall be based on the following motives:

a) the subject of the patent is not patentable;
b) patent does not disclose the invention sufficiently clear and completely, so that an expert in the art can implement it;
c) the subject of the patent exceeds the content of the application in the form in which it was filed, or, if the patent was granted on the basis of the divisional application or a new application filed in accordance with Article 16, the subject of the patent exceeds the content of the original application in the form in which it was filed.[209]

If the division of the Agency, which took the decision to grant the patent, shall find that at least one of the above reasons for opposition is an obstacle to the grant of the patent, the decision on patent issuance shall be cancelled. Otherwise, the opposition shall be rejected. [210]

This decision of the Agency may be appealed to the Board of Appeals of the Agency by any person affected by the decision. Protest shall be filed in writing within two months from the date of decision and must be substantiated.[211]

After consideration of the protest the Board of Appeals takes a final decision or refers the case to the division of the Agency which had taken the appealled decision to conduct re-examination. The procedure of consideration of protests is foreseen in the Regulations of the Board of Appeals of the State Agency for Intellectual Property, approved by the Government Decision № 257 of April 2, 2009.

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protection of all human rights, civil, political, economic, social and cultural rights, including the right to development", A/HRC/11/12, 31 March 2009, paragraph 52.

[209] Article 57 of the Law of Republic of Moldova "On Protection of Inventions", dated 7 March 2008 № 50-XVI.

[210] Article 57(4) of the Law of Republic of Moldova "On Protection of Inventions", dated 7 March 2008 № 50-XVI.

[211] Article 58 of the Law of Republic of Moldova "On Protection of Inventions", dated 7 March 2008 № 50-XVI.

Any decision of the Board of Appeals may be appealed within two months from its publication to the court in accordance with the provisions of the Civil Procedure Code.

In addition to the administrative appeals procedures of the patent, in accordance with the Law of Moldova on inventions patent may be challenged in the courts at any time during the term of a patent by any person[212], including patient organizations, for the following reasons:
a) the subject of the patent is not patentable;
b) patent does not disclose the invention sufficiently clear and completely, so that an expert in the art can implement it;
c) the subject of the patent exceeds the content of the application in the form in which it was filed, or, if the patent was granted on the basis of the divisional application or a new application, the subject of the patent exceeds the content of the original application in the form in which it was filed;
d) the scope of protection conferred by a patent has been expanded;
e) the patent holder was not entitled to a patent under Article 14 (as he/she was not an inventor or his assignee), or in case of inventions created by an employee.[213]

An action for annulment of a Eurasian patent in the territory of the Republic of Moldova shall be made in accordance with the provisions of the Eurasian Convention, the Regulations on the Application of the Eurasian Convention and national legislation.[214]

Thus, the legislation of Moldova provides for the possibility of post-grant oppositions in administrative or judicial procedures, allowing patients and their organizations, as well as generic companies-competitors to challenge weak patents. The procedure of pre-grant patent oppositions, at the stage of examination of the application, is an effective measure to ensure issuance of patents on medicines that are inventive enough. It is not foreseen in the legislation of Moldova.

8.2.3 Compulsory Licensing

Use of an invention without the permission of a patent holder, under Article 31 of the TRIPS Agreement, is considered one of the main flexibilities of the TRIPS Agreement.

The legislation of Moldova contains provisions for the issuing of a compulsory license by the court. Thus, in accordance with Article 28 of the Law of Moldova on inventions, the court may grant to any person concerned a compulsory license on the grounds of non-use or lack of use of a patent on a lawsuit filed within four years from the filing date of the patent application or three years from the date of grant of the patent whichever expires later

[212]Article 65 of the Law of Moldova on Inventions.
[213]Article 64 of the Law of Moldova on Inventions.
[214]Article 65(4) of the Law of Moldova on Inventions.

the patent holder does not use a patent in the territory of the Republic of Moldova or failed to take real and substantial preparation for this purpose. In determining whether the non-use or insufficient use of a patent it does not matter whether patented products are domestic or imported.

It should be noted that such ground as insufficient use of a patent during 3-4 years significantly limits the possibilities for the use of compulsory licensing mechanism to reduce the prices of ARVs, as it is unlikely that the situation of "non-use of a patent" will develop in relation ARVs. In addition, the judicial procedure for issuing a compulsory license is less effective option[215] in terms of protecting the interests of public health, than an administrative procedure that is allowed by Article 31 of the TRIPS Agreement.

A compulsory license may also be provided in the event of a national emergency, or other emergencies, or in the case of public non-commercial use. The license in this case, most likely, will be produced for the purposes of the so-called government use, which is described below.

Further, the Law of Moldova on the inventions sets out the following compliant with the TRIPS agreement conditions for the grant of a compulsory license, which must be met simultaneously with the above ground of non-use or insufficient use of a patent.

Thus, the Law of Moldova on the inventions provides that a compulsory license is granted only if the person concerned has attempted to obtain permission of the patent holder on reasonable commercial terms and in reasonable ways, and if, for all his efforts, failed to obtain a permit within a reasonable time.[216] This requirement may be omitted in the event of national emergency or other emergency, or in the case of public non-commercial use.

In case of a compulsory license issuance the patent owner shall be immediately notified. [217]

Further, the court shall determine the type of use under the compulsory license, and the following conditions that must be met:

a) limits and duration of use shall be restricted by the purpose for which it was authorized;
b) such use shall be non-exclusive;

[215]Unlike the Ministry of Health, the courts may be reluctant to take into account considerations of health budget savings. In addition, pharmaceutical companies often have much more possibilities to provide adequate legal support for such litigations than that of patient organizations and government agencies.
[216]The procedure for calculating the "reasonable time" within which efforts should be made to obtain authorization from the right holder before issuing a compulsory license is not defined by the legislation of the Republic of Moldova.
[217]Article 28(2-3) of the Law of Moldova on Inventions.

c) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;
d) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use, except for where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive;
e) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated by the court upon motivate request if and when the circumstances which led to it cease to exist and are unlikely to recur. The court shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;
f) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization and the need to correct anti-competitive practices;[218]

The validity of any decision to grant a compulsory license and any decision on the remuneration provided in respect of the use of the patent under compulsory license may be subject to judicial review or other independent review by a higher authority.

If the holder of a compulsory license during one year since the date of the issuance has not taken any real and substantial measures to prepare for the exploitation of the invention, a compulsory license may be cancelled by the decision of the court. A compulsory license shall be terminated in any case, if the license holder fails to exploit the invention within two years from the date of its issuance. [219]

It is necessary to review the provisions of the Law of Moldova on inventions concerning compulsory licensing by introducing of administrative procedures for the issuance of compulsory license for public health needs by the Ministry of Health of Moldova. This will require changes in the Law of Moldova on the inventions and the adoption of the by-law regulation on the procedure for compulsory licensing of patents on medicines.

8.2.4 Government Use

The Article 28 of the Law of Moldova on inventions provides for the possibility of government use of patents. Thus, paragraph 3 of this article states that a compulsory license may be granted in the event of an emergency on a national scale, or other emergency, or in the case of public non-commercial use.

Based on the systematic interpretation of Articles 28-29 of the Law, it can be concluded that a compulsory license for government use is granted by the court, similarly to the compulsory license in case of non-use of a patent.

[218] Article 29 of the Law of Moldova on Inventions.
[219] Article 29(2, 4) of the Law of Moldova on Inventions.

In the case of public use, a departure from the necessity of preliminary negotiations with the patent holder is possible. [220]

As well as in situation with the compulsory licensing it is necessary to review the provisions of the Law of Moldova on inventions concerning the regulation of compulsory licensing for government use through the introduction of administrative procedures for the issuance of a compulsory license for public use in the health sector by the Ministry of Health of the Moldova Republic. This will require changes in the Law of Moldova on the inventions and the adoption of the aforementioned by-law procedure for compulsory licensing of patents on medicines.

It should be noted that Article 11 (7) of the Law of Moldova "On pharmaceutical activity" provides that, in special circumstances (natural disasters, catastrophes, epidemics, epizootics, mass poisoning, other cases of threat to human health, or in absence of equivalents or substitutes of certain medicine on the pharmaceutical market) the Ministry of Health has the right to authorize the importation, distribution and use in medical practice of pharmaceuticals and parapharmaceutical products that are not approved (registered) in the Republic of Moldova, but approved in country of their origin. Thus, ARV medicines may be imported with the permission of the Ministry of Health without prior registration in Moldova.

8.2.5 Parallel Import

Parallel imports depends on the regime of exhaustion of the exclusive rights under domestic law. Parallel importation is allowed when the law provides international or regional exhaustion of rights; and parallel importation is prohibited under national regime of exhaustion of patent rights. As Article 23 (1) of the Law of Moldova on Inventions provides that the rights conferred by a patent shall not extend to acts committed on the territory of the Republic of Moldova in relation to the product protected by the patent, after the product was put on the market of the Republic of Moldova by the patent owner or with his explicit consent, respectively, national exhaustion of rights regime is established in the Republic of Moldova and parallel import is not permitted.

Despite this, it should be noted that the Law of Moldova "On Medicines" provides for the possibility of indicating information in the official language or in one of languages of international communication on the packaging of imported drugs, thus facilitating the hypothetical possibility of parallel imports from other countries, if international or regional exhaustion regime is introduced in Moldova.

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[220] Article 28 (2) of the Law of Moldova on Inventions provides that "a compulsory license may be granted only if the person concerned has attempted to obtain a license of the patent holder on reasonable commercial terms and in reasonable ways, and if all these efforts failed within a reasonable time. It is not required to comply with this requirement in situation envisaged in paragraph (3) [*author – in case of government use*] . If a compulsory license granted the patent owner shall be immediately notified about it.

8.2.6 Exceptions to Patent Rights

Article 30 of the TRIPS Agreement provides that WTO Members may foresee limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties.

Law of Moldova on Inventions provided the following exceptions, which may be useful in terms of access to medicines:
a) acts carried out in the private sector and for non-commercial purposes;
b) acts carried out in respect of the patented subject matter for experimental purposes;
c) a single preparation of prescribed medicine in pharmacy as well as the acts in relation to medicines prepared in that way;

Article 22 (2) further establishes the conditions that should be complied with during the application of these exceptions: "the use of the subject of invention pursuant to paragraph (1) shall be allowed, provided that it does not unreasonably prejudice the normal exploitation of the invention protected by the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties. Otherwise, the patent holder has the financial compensation right for the recovery of material damages incurred as a result of unauthorized use of the invention."

The Moldovan legislation does not provide Bolar exception, which is highly desirable to include in the Law of Moldova on Inventions.

8.3 TRIPS-plus provisions: Moldova

8.3.1 Patent Term Extension

Extending of patent term protection in developing countries may lead to additional costs of national health budgets and shall negatively impact access to medicines.[221]

Part 2 of Chapter 5 of the Law of Moldova on inventions regulates the provision of supplementary protection certificate, which is harmonized with the provisions of European Council Regulation (EC) N 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for

[221] Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover "Promotion and protection of all human rights, civil, political, economic, social and cultural rights, including the right to development", A/HRC/11/12, 31 March 2009, p. 77.

medicinal products (published in the Official Journal of the European Union NL 182 of July 2, 1992).

Patent holder, which acts on the territory of the Republic of Moldova, with the medical or herbal medicine product as the subject of a patent (basic patent), for which a marketing authorisation is issued can obtain a supplementary protection certificate. The certificate shall take effect from the date of expiration of the lawful term of the basic patent for a period equal to the period between the filing date of the patent application and the date of issue of the first marketing authorization of the drug, reduced by five years. The period of the certificate may not exceed five years from the date of the expiration of the term of the basic patent.[222]

As the TRIPS Agreement does not contain requirements for the patent term extension the above provision is a TRIPS-plus provision and shall create barriers to competition from generics manufacturers.

It should be noted that the supplementary protection certificate may be issued only if the following conditions are met:
a) the product is protected by the basic patent in force in the Republic of Moldova;
b) the product is the subject of a valid permit to market it as a medical or phytopharmaceutical product;
c) the product has not previously been a subject of a certificate in the Republic of Moldova;
d) the marketing authorization is the first authorization to sell the product on the market of the Republic of Moldova as a medical or phytopharmaceutical product.

8.3.2 Data Exclusivity

The legislation of Moldova provides a simplified procedure for registration of generic medicines, without the necessity for manufacturers of generics to provide the data from clinical trials because of the possibility of referring to the data on referent/original product.

Thus, Article 3 of the Law of Moldova "On Medicines" [223] defines generic medicine as a medicinal product, which has the same qualitative and quantitative composition in active substances and the same dosage form as the original medicine,[224], and which bioequivalence of the referent/original medicine proved by appropriate bioavailability studies. Paragraph 12 of the Regulation on Authorization of Medicinal Products, approved by the Ministry of Health Order № 739 on July 23, 2012, provides the following

[222] Article 69 Law of Moldova on Inventions.
[223] Law of Moldova «On Medicines» http://base.spinform.ru/show_doc.fwx?rgn=3470#B3ML0LH7JU
[224] «Original/referent medicinal product (innovative or new chemical substance) – a medicine that was first approved based on pre-clinical and clinical trials;» (Article 3 of the Law of Moldova «On Medicines»).

types of applications depending on the content of the documentation submitted for authorization:
1) an application for marketing authorization based on its own complete documentation, with the presence of administrative data and information concerning the quality, safety and efficacy of the medicinal product submitted for the authorization (*"independent" application = "self-sufficient" application*).
2) the application for authorization, without data on toxicological, pharmacological and clinical trials. The applicant is not required to provide data on results of toxicological, pharmacological or clinical trials if he can prove that:
a) the medicinal product is a generic analog of the reference medicinal product (*application for generic medicinal products*);
b) the medicinal product comprises one or more active substance with a well studied medical application ("*bibliographic*" application for medicines with well known use);
c) the holder of the registration certificate of the reference medicinal product allows to the manufacturer use the pharmaceutical, pre-clinical and clinical documentation from the files of its medicinal product for the consideration of subsequent applications ("*application based on informed consent*").

Furthermore, legislation of Moldova does not have a requirement on data exclusivity. It is a TRIPS-plus provision which prohibits refer to clinical data submitted during the registration of the original/reference medicinal product for the purposes of the registration of generic medicines. This is a very positive situation in terms of access to medicines, which allows generic manufacturers to introduce their products to Moldovan market without additional delays. However, this situation shall be changed in the nearest future as on 29 November 2013 Moldova initialled an Association Agreement with EU which foresees 5+2+1 years data exclusivity formula[225], which is longer than DE periods foreseen in Association Agreements with Ukraine (5 years)[226] and Georgia (6+1 years)[227].

8.3.3 Patent Linkage with Marketing Authorisation

Legislation of the Republic of Moldova does not contain a requirement for DRA of Moldova (Medicines Agency Moldova) to check during the registration of the medicinal products existence of a patent, license agreement or consent of the patent holder, which is positive in terms of access to medicines.

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[225] See Article 315 of the Association Agreement between Moldova and EU http://eeas.europa.eu/moldova/assoagreement/pdf/md-aa-title-v-trade-related-matters_en.pdf

[226] See Article 222 of the Association Agreement between Ukraine and EU http://www.eeas.europa.eu/ukraine/pdf/5_ua_title_iv_trade_and_trade-related_matters_en.pdf

[227] See Article 187 of the Association Agreement between Georgia and EU http://www.eeas.europa.eu/georgia/assoagreement/pdf/ge-aa-title-iv-trade-related-matters_en.pdf

8.3.4 Enforcement: Border Measures

In Moldova, the border measures apply to the protection of patents for inventions in accordance with the Customs Code of the Republic of Moldova.[228]. Thus, Title XII of the Customs Code provides that the customs authority may put on hold customs clearance and / or suspend for three working days goods that infringe intellectual property rights, which are:
a) imported into the customs territory of the Republic of Moldova or exported from this territory;
b) declared with the customs authorities for the purpose of placing them under the final or preferential treatment regime;
c) under the customs survision in any other situation;
d) have not been declared upon entry into the country or leaving the country and detected by the customs authorities during customs control;
e) became the property of the state as a result of forfeiture or abandonment to the state.

If, within ten working days of receiving notification of the detention of the goods and / or suspension of customs clearance a patent holder does not file a lawsuit in court against declarant / consignee of the goods, the customs authority shall release of the goods.

When filing a claim to a court against declarant / consignee holder of intellectual property rights shall immediately inform the customs authorities about measures taken and the customs authority shall detain the goods until the court decision shall take force.[229]

These TRIPS-plus provisions of the customs legislation of Moldova may have an adverse effect on competition in the market of ARVs, as it can create psychological pressure, chilling effect (and material losses) for potential importers of generic ARVs.

8.3.5 Enforcement: Criminal Liability

Despite the provisions of Article 61 of the TRIPS Agreement, which do not require to criminalize patent infringement, Article 185-2 of the Criminal Code of the Republic of Moldova[230] foresees that manufacture, import, export, transport, offer for sale, sale and any other way of introduction to the economic circulation or storage of a product or use of a method that is invention or incorporates object of the invention, for which permission of rightsholder is necessary, committed without his permission, as well as the motivation of third parties to perform these actions, which caused damage on a large scale shall be punished by a fine of 800 to 1000 conventional units or by unpaid community service for 180 to 240 hours, and in the case of legal entity - by a fine of 3500 to 5000 conventional units with the

[228]Customs Code of Moldova, dated 20 July 2000, №1149-XIV http://base.spinform.ru/show_doc.fwx?rgn=3435
[229] Article 304 of the Customs Code of Moldova.
[230]Criminal Code of Moldova, dated 18 April 2002 №985-XV (http://base.spinform.ru/show_doc.fwx?rgn=3835)

deprivation of the right to engage in certain activities for a term from 1 to 5 years.

In addition, such actions committed by :
1. two or more persons;
2. organized criminal group or a criminal organization;
3. with physical or mental coercion;
4. in a large scale,
shall be punished by a fine from 3000 to 5000 of conventional units or by imprisonment from 3 to 5 years, and in case of legal entity - by a fine of 7000 and 10000 conventional units with the deprivation of right to engage in certain activities from 1 year to 5 years or liquidation.

One standard unit of penalty equal to 20 lei [231]

Such provisions may have a negative impact on manufacturers of generics and are not recommended in terms of access to medicines. [232]

8.4 Conclusions and Recommendations for Moldova

Thus, Moldovan legislation contains the following TRIPS-flexibilities and TRIPS-plus provisions:

Public health-related TRIPS-Flexibilities	Presence or absence of provision
Diagnostics and therapeutic methods are not patentable	No (-)[233]
Second use, new forms are not patentable	No (-)
Compulsory licensing is provided	Yes (+)

[231] Article 64 of the Criminal Code of Moldova.
[232]Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover "Promotion and protection of all human rights, civil, political, economic, social and cultural rights, including the right to development", A/HRC/11/12, 31 March 2009, p. 91.
[233]„(-)" or „(+)" characterizes the negative or positive potential impact of presence or absence of TRIPS-flexibility or TRIPS-plus provision in the legislation of the country.

Government use is provided	Yes (+)
Parallel import is permitted	No (-)
Bolar exception	No (-)
Experimental use exception	Yes (+)
Pre-grant patent oppositions	No (-)
Post-grant patent oppositions	Yes (+)
TRIPS-plus provisions, which restrict access to medicines	**Presence or absence of provision**
Utility models for pharmaceuticals	No (+)
Patent term extension	Yes (-)
Data exclusivity	No (+)
Patent linkage with market authorisation	No (+)
Customs measures	Yes (-)
Criminal liability for patent infringement	Yes (-)

In light of the above analysis the following changes of the legal framework could be recommended by the NGO activists to the Moldovan government:

1. to exclude diagnostic, therapeutic and surgical methods from patentable subjects;
2. to exclude from patentability new uses of known substances or introduce an exception for pharmaceutical products in the Law of Moldova on Inventions;
3. develop and introduce into the Moldovan Patent Law stricter rules on patentability of pharmaceutical products to prevent granting "evergreening" secondary patents or patent applications that are against public health interests (as a model

could be used provisions of the Indian Patent Act, in particular, Article 3(d) [234]);

4. stipulate in the Law of Moldova on Inventions right of third parties, including patient organisations, to file pre-grant patent oppositions with the patent office;
5. to consider introducing rules on compulsory licensing to the Moldovan Patent Law with further development of detailed Procedure on the issuance of compulsory licenses and government use in the field of public health;
6. it appears commendable for Moldova to accede to the 30 August 2003 Decision mechanism of exporting-importing under compulsory licenses[235] as a potentially importing country;
7. to introduce Bolar exception into article 22 of the Law of Moldova on Inventions. Wording of Article 55.2 (1 and 6) of the Canadian Patent Act could be used as a model for Bolar exception;[236]
8. to introduce by amending Article 22 of the Law of Moldova on Inventions international regime of patent right exhaustion for pharmaceutical products;
9. to notify the negotiating representatives of Moldova with EU on Asssociation Agreement about the dangers that poses the data exclusivity to access to medicines and on the need to avoid taking obligations on implementation of data exclusivity in Moldova;
10. to exclude applicability of customs measures provided in Chapter 12 of the Customs Code of the Republic of Moldova to patented inventions;
11. to decriminalize liability for patent infringement or at least criminal sanctions should be significantly relaxed.

[234] Please see in more detail chapter 5.1.2 Patentability criteria above, and brief analysis of article 3(d) of the Indian Patent Law http://www.ipfrontline.com/depts/article.aspx?id=26756&deptid=4

[235] See Decision of the General Council of 30 August 2003 on Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm

[236] Article 55.2 (1 and 6) of the Canadian Patent Act stipulates that "(1) It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product. (6) For greater certainty, subsection (1) does not affect any exception to the exclusive property or privilege granted by a patent that exists at law in respect of acts done privately and on a non-commercial scale or for a non-commercial purpose or in respect of any use, manufacture, construction or sale of the patented invention solely for the purpose of experiments that relate to the subject-matter of the patent." http://laws-lois.justice.gc.ca/eng/acts/p-4/page-28.html#docCont

9 Implementation of the Public Health-Related TRIPS Flexibilities in Ukraine

Before analyzing the landscape of the Ukrainian law provisions related to the TRIPS flexibilities and TRIPS plus provisions implementation there should be noted the following.

Ukraine has a serious problem with access to medicines for general population. For example, it is estimated that around 3,5 mln Ukrainians live with hepatitis, while no state funded treatment program exists and the cheapest treatment is available at approximately 5 000 USD per patient per year.[237]

The HIV epidemic in Ukraine is one of the worst in Eastern Europe and the Commonwealth of Independent States and together with the one in Russia is the fastest growing HIV epdiemic in the world. At the beginning of 2012 the number of people living with HIV in Ukraine was 230,000, while the coverage of antiretroviral treatment in 2012 was 22.0% of the estimated number of patients who needed it. [238]

9.1 Legal Framework

Ukraine is a party to almost all UN international human rights treaties.[239] Not ratified only the following human rights instruments:

1. Optional Protocol to International Covenant on Economic, Social and Cultural Rights of (signed, not ratified);
2. Optional Protocol to the Convention on the Rights of the Child on a communications procedure of 19 December 2011;
3. Convention for the Protection of All Persons from Enforced Disappearance of 20 December 2006;
4. Rome Statute of the International Criminal Court;

[237] According to the first MoH Ukraine tender for procurement of pegylated interferons under the state funded program in 2013.

[238] National HIV/AIDS Estimates in Ukraine as of beginning of 2012, Date of report: April 2012, Kyiv, Ukraine, p. 1-2

[239] United Nations, Treaty Collection web-site http://treaties.un.org/Pages/ParticipationStatus.aspx

5. Convention on the Protection of the Rights of All Migrant Workers and Members of their Families, 18 December 1990.

Article 9 of the Constitution of Ukraine states that "international treaties ratified by the Verkhovna Rada of Ukraine is part of the national legislation of Ukraine", which means that international human right treaties are binding for Ukraine without the need of adopting additional domestic laws and could be applied by the courts when interpreting certaing provisions of Ukrainian legislation or dealing with gaps in the law.

Thus, Ukraine is bound with international obligations to respect, protect and fullfil the right to health, including the right to access to medicines. Additionally, Constitution of Ukraine guarantees to everyone access to free medical care.[240]

At the same time, Ukrainian law established comparatively high standards of patent protection for medicines. Although Ukraine became a member of WTO since 16 May 2008[241], it has implemented many of TRIPS minimum and TRIPS plus standards before the WTO accession. The laws of Ukraine "On the Protection of Rights to Inventions and Utility Models" (hereinafter – "**Ukrainian Patent Law**"), "On medicines", the Criminal Code and the Customs Code were prescribing TRIPS and TRIPS plus standards even before Ukraine's obligations under the TRIPS Agreement entered into force.

Furthermore, Ukraine had accepted some of the TRIPS plus commitments during the process of accession to the WTO. According to the WTO General Council Decision on Accession of Ukraine the latter may accede to the WTO Agreement on the terms and conditions set out in the Protocol of the Accession.[242] In the Protocol of the Accession it is indicated that the Protocol of the Accession together with the commitments referred to in paragraph 512 of the Working Party Report, shall be an integral part of the WTO Agreement that Ukraine accedes to.[243] Therefore all the commitments indicated in paragraph 512 of the Working Party Report are binding on Ukraine as a part of WTO Agreement.

Thus, according to the Working Party Report Ukraine committed to apply the provisions of the Agreement on Trade-Related Aspects of Intellectual

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[240] Article 49 of the Constitution of Ukraine stipulates that "everyone shall have the right to health protection, medical care and medical insurance. Health protection shall be ensured through state funding of the relevant socio-economic, medical and sanitary, health improvement and prevention programmes. The State shall create conditions for effective medical service accessible to all citizens. State and communal health protection institutions shall render medical care free of charge; the existing network of such institutions shall not be reduced. The State shall promote the development of medical institutions under all forms of ownership."

[241] Ukraine and the WTO, Member information http://www.wto.org/english/thewto_e/countries_e/ukraine_e.htm

[242] Decision of WTO General Council of 5 February 2008 on Accession of Ukraine, WT/L/718 of 13 February 2008 http://www.wto.org/english/thewto_e/acc_e/completeacc_e.htm

[243] *See* paragraph 2 of the Protocol of the Accession of Ukraine, WT/L/718 of 13 February 2008 http://www.wto.org/english/thewto_e/acc_e/completeacc_e.htm

Property Rights no later than the date of its accession to the WTO, without recourse to any transitional periods,[244] thus leaving itself out of scope of one of the basic TRIPS flexibilities and took an obligation to provide for 5 year data exclusivity period in its legislation (data exclusivity shall be discussed in more detail below).

Additionally, due to the closeness and historical links between EU Member States and Ukraine[245] and aspirations of Ukraine of acceding to the union the Ukrainian government has seen cooperation with the EU as one of its priorities.[246] In 1998 Partnership and Cooperation Agreement between Ukraine and the European Communities have entered into force. It foresaw that Ukraine shall continue to improve the protection of intellectual property rights in order to provide, by the end of 2003 for a level of protection similar to that existing in the Community, including effective means of enforcing such rights.[247] In March 2012 Ukraine and EU had initialed the Association Agreement which provides more detailed provisions on protection of intellectual property rights related to medicinal products, in particular imposing on Ukraine some TRIPS plus requirements, including provisions on data exclusivity protection, supplementary protection certificates, border measures, etc. Although provisions of the unofficial draft of the Association Agreement shall be analyzed in the relevant parts of this document below, it should be noted that the sub-section devoted to patents in the Association Agreement starts with Article 219 named "Patents and public health" which stipulates that:

> "1. The Parties recognise the importance of the Declaration on the TRIPS Agreementand Public Health, adopted on 14 November 2001 (hereinafter referred to as the "Doha Declaration") by the Ministerial Conference of the WTO. In interpreting and implementing the rights and obligations under this Chapter, the Parties shall ensure consistency with the Doha Declaration.
> 2. The Parties shall contribute to the implementation of and shall respect the Decision of the WTO General Council of 30 August 2003 on paragraph 6 of the Doha Declaration."

Such a progressive from access to medicines view provision contained in EU-Ukraine Association Agreement could be seen as an allignment of EU external policy with the European Parliament resolution of 12 July 2007 on the TRIPS Agreement and access to medicines (see discussion above).

Also, on December 7, 2011, Ukraine has ratified a free trade agreement with the European Free Trade Association, which also contains a number of TRIPS-plus provisions.

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[244] Report of the Working Party on the Accession of Ukraine to the World Trade Organization, WT/ACC/UKR/152, 25 January 2008, paragraph 470.
[245] See Preamble of the Partnership and Cooperation Agreement between the European Communities and their Member States, and Ukraine, signed on 14 June 1994. http://ec.europa.eu/world/agreements/downloadFile.do?fullText=yes&treatyTransId=659
[246] *See* Mission of Ukraine to the EU web-page on EU-Ukraine relations http://ukraine-eu.mfa.gov.ua/en/ukraine-eu/relations.
[247] See Article 50 of the Partnership and Cooperation Agreement between the European Communities and their Member States, and Ukraine, signed on 14 June 1994 http://ec.europa.eu/world/agreements/downloadFile.do?fullText=yes&treatyTransId=659

The level of implementation of major TRIPS flexibilities and TRIPS-plus provisions that are important from access to medicines view shall be analysed in detail below.

9.2 TRIPS Flexibilities: Ukraine

9.2.1 Patentability criteria

Ukrainian law contains basic TRIPS Agreement requirements to the patentability of inventions. Article 459 of the Civil Code of Ukraine and Article 7 of the Law of Ukraine "On the Protection of Rights to Inventions and Utility Models" (the Ukrainian Patent Law) set out that an invention meets the patentability requirements provided that it is new, involves an inventive step and is industrially applicable. A utility model meets the patentability requirements provided that it is new and industrially applicable.[248]

Article 7 of the Ukrainian Patent Law further clarifies the meaning of novelty by requiring that an invention (utility model) shall be considered to be new provided that it does not form part of the state of the art. The latter comprises everything made available to the pubic throughout the world before the date of filing of the application with the patent office or, if the priority has been claimed, before the date of its priority. Further, an inventive step patentability criterion shall be met if an invention is not obvious to a person skilled in the art, i.e. an invention does not proceed obviously from the state of the art. Finally, an invention (utility model) shall be considered to be industrially applicable provided that it may be used in industry or other field of activity.[249]

In compliance with Article 27(2) of the TRIPS Agreement Ukraine had excluded from patentability inventions that contradict the public order, humanity and morality.[250] While permitted by the TRIPS Agreement exclusion from patentability of diagnostic, therapeutic and surgical methods for the treatment of humans or animals was not used by Ukraine and there is no provision in Ukrainian legislation that excludes diagnostic, therapeutic and surgical methods for the treatment from patent protection. It should be noted that even developed countries (e.g. Germany) and provisions of the European Patent Convention exclude from patentability these methods considering patenting of methods as "monopolization of medical practice", while Ukraine being the developing country does not.[251] This is clearly a

[248] The Law of Ukraine "On the Protection of Rights to Inventions and Utility Models", Article 7, paragraph 2.
[249] The Law of Ukraine "On the Protection of Rights to Inventions and Utility Models", Article 7, paragraphs 3, 4, 7, 8.
[250] The Law of Ukraine "On the Protection of Rights to Inventions and Utility Models", Article 6, paragraph 1.
[251] Anastasiya Mindrul, Influence of Intellectual Property Protection on Access to Medicines after accession of Ukraine to WTO, Analytical Report, Kyiv 2010, p. 20-21.

TRIPS plus situation which should be addressed by the Ukrainian government.

Further, according to the WIPO currently 57 countries provide utility model protection; these include: Armenia, Azerbaijan, Belarus, Estonia, Georgia, Kazakhstan, Kyrgyzstan, Republic of Moldova, Russian Federation, Tajikistan, Ukraine, Uzbekistan.[252] The TRIPS Agreement does not require member states to provide the utility model protection to inventions, inspite of this the Ukrainian legislation provides for the possibility to obtain a 10-year utility model protection for pharmaceutical products, which is a TRIPS plus provision.[253] The 10-year term of utility models protection in Ukraine is one of the longest among the countries that protect utility models.[254] Patentability criteria are weaker for the utility model than for patent and do not include inventive step criterion, but only the novelty and industrial applicability criteria, which means that a patent for utility model is easier to obtain than a patent for invention. Also, the utility models do not undergo such scrutiny by the Ukrainian patent office as patents for inventions; and utility model protection is granted without in-depth examination of applications.[255]

It is permitted to file applications for patent and utility model for the same product/process. During the process of examination patent application could be converted into the utility model application. All this means that if the patent application is rejected the utility model protection could be obtained.[256]

Additionally, the Ukrainian patent law permits patenting of "the novel use of a known product or process" [257], while the TRIPS Agreement does not oblige member states to provide protection of new uses making this provision of Ukrainian Patent Law a TRIPS plus rule. Patenting of novel uses of medicines is closely related to the abusive patenting practice called 'evergreening'. As it was noted by the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover:

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[252] See, WIPO, Where can Utility Models be acquired? http://www.wipo.int/sme/en/ip_business/utility_models/where.htm

[253] Article 460 of the Civil Code of Ukraine, article 6 of the Ukrainian Patent Law.

[254] *The State of Ukrainian National Legislation: Opportunities to use TRIPS Flexibilities*. Unpublished background document prepared by Boyan Konstantinov for the seminar "Intellectual Property Rights and Access to Essential Medicines in Ukraine: Challenges and Opportunities in Free Trade Agreement Negotiations, Multilateral Instruments and National Laws", 21-22 June 2010, Kiev, Ukraine, p. 7.

[255] Anastasiya Mindrul, Influence of Intellectual Property Protection on Access to Medicines after accession of Ukraine to WTO, Analytical Report, Kyiv 2010, p. 21.

[256] *The State of Ukrainian National Legislation: Opportunities to use TRIPS Flexibilities*. Unpublished background document prepared by Boyan Konstantinov for the seminar "Intellectual Property Rights and Access to Essential Medicines in Ukraine: Challenges and Opportunities in Free Trade Agreement Negotiations, Multilateral Instruments and National Laws", 21-22 June 2010, Kiev, Ukraine, p. 7.

[257] Article 6(2) of the Ukrainian Patent Law.

> "From a right to health perspective, the "evergreening" of patents by pharmaceutical companies is of particular concern. Evergreening refers to the practice of obtaining new patents on a patented medicine by making minor changes to it. For example, patents are obtained on new uses, forms, combinations and formulations of known medicines in a bid to extend the period of the patentee's monopoly. Such evergreening delays the entry of competitive generic medicines into the market."[258]

Countries like India and Philipines exclude from patentability new forms of known substances unless they are significantly more efficacious and new (or second) uses and combinations of known substances.[259] Such provisions help to fight abusive patenting practices and improve access to medicines.

9.2.2 Patent Oppositions

There are no provisions in the TRIPS Agreement establishing patent oppositions procedure; while the chance of revocation or forfeiture of a patent is mentioned in Article 32. Therefore member states have discretion to set patent oppositions procedure in their domestic laws to subject patents to intense scrutiny.[260]

Under the Ukrainian Patent Law examination of the patent application for a utility model consists of the preliminary examination, formal examination and, for the patent application for an invention (secret invention), - the preliminary examination, formal examination and qualifying examination.[261] After the expiry of 18 months from the date of filing of the patent application and before the qualifying expertise the Ukrpatent shall publish in its official bulletin the defined data on the application. After publication of the information on the application, any person shall have the right to access to this data under the established procedure. Data on the application for granting a patent for a utility model shall not be published.[262]

In spite of statutory opportunity to access information contained in the filed patent application for the invention it is not possible to file a patent opposition at the stage of patent application examination.[263] Also, within

[258] Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover "Promotion and protection of all human rights, civil, political, economic, social and cultural rights, including the right to development", A/HRC/11/12, 31 March 2009, paragraph 34

[259] Indian Patents Act, 1970, section 3 (d), Intellectual Property Code, Philippines (amended by
section 5 of the Universally Accessible Cheaper and Quality Medicines Act of 2008), section 22.1.

[260] Anastasiya Mindrul, Influence of Intellectual Property Protection on Access to Medicines after accession of Ukraine to WTO, Analytical Report, Kyiv 2010, p. 28

[261] Article 16(1) of the Ukrainin Patent Law;

[262] Article 16(16) of the Ukrainin Patent Law;

[263] Anastasiya Mindrul, Influence of Intellectual Property Protection on Access to Medicines after accession of Ukraine to WTO, Analytical Report, Kyiv 2010, p. 28

two months upon decision on granting patent only an applicant may file a post-grant patent opposition with the Ukrpatent.[264]

It appears that when assessing patent applications for inventions in pharmaceutical field the Ukrainian Institute of Industrial Property ("**Ukrpatent**") does not subject these applications to intense scrutiny. As it was noted by lawyer and IP scholar Pascale Boulet in her report 'Reducing the costs and expanding access to antiretroviral medicines in Ukraine':

"Patents [on medicines] seem to be relatively easy to obtain in Ukraine based on low standards of patentability. E.g. several patents for antiretrovirals, drugs used for the treatment of HIV, which have been granted in Ukraine, were rejected in other developing countries for lack of novelty or inventive step."[265]

In light of the above the absence of opportunity for third parties to file patent oppositions to the Ukrpatent even more contributes to the low standards of patents scrutiny in Ukraine.

However, a patent may be opposed and recognized as null and void only within the court proceedings, which is a TRIPS plus provision, as TRIPS Agreement is not requiring nullification of patents only by courts.[266]

Under the Ukrainian Patent Law a patent may be fully or partially invalidated by the court in the following cases:

1. the patented invention (utility model) described in invention (utility model) claims does not meet the patentability requirements;
2. invention (utility model) claims contain indications that were not presented in the filed application.
3. the requirements of Paragraph 2 of Article 37 of this [Ukrainian Patent] Law are not fulfilled (Paragraph 2 of Article 37 sets out that if patenting of an invention (utility model) is accomplished according to the procedure established by the Patent Cooperation Treaty, and international application shall be filed with the Ukrpatent);
4. a patent has been granted in the result of filing of the application with the violation of rights of other persons.

A patent or a part of a patent shall be considered to be invalid from the date of publishing the data on granting a patent.[267]

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[264] Article 24(1) of the Ukrainian Patent Law;

[265] Reducing the costs and expanding access to antiretroviral medicines in Ukraine – some recommendations on compulsory licensing prepared by Pascale Boulet in October 2012, based on meetings in Kiev on 24-27 September 2012 and on documents made available by OSI/AEMI, IRF, UNDP and UCAB, p. 2

[266] *The State of Ukrainian National Legislation: Opportunities to use TRIPS Flexibilities*. Unpublished background document prepared by Boyan Konstantinov for the seminar "Intellectual Property Rights and Access to Essential Medicines in Ukraine: Challenges and Opportunities in Free Trade Agreement Negotiations, Multilateral Instruments and National Laws", 21-22 June 2010, Kiev, Ukraine, p. 9.

[267] Article 33(1,4) of the Ukrainian Patent Law;

A patent opposition to the court may be submitted by legal entities or physical persons for the protection of their violated or disputed rights and interests protected by law.[268] However, as it was noted by Mindrul patient organizations or patients may face some difficulties to substantiate before the court their right to submit claim opposing a patent as it would be hard to prove to Ukrainian courts existence of violation of its rights or interests by existence of low-quality patent. In this situation, established in the Constitutional Court of Ukraine decision dated December 1, 2004, No. 18-рп/2004 (case on protected by law interest) a doctrine of protected by law interest may be helpful for the patient organisation or a patient to substantiate their claims.[269]

9.2.3 Compulsory licensing

The use without authorisation of the right holder is regulated by Article 31 of the TRIPS Agreement as is regarded as one of the major TRIPS flexibilities.

Respective provisions that correspond to the Article 31 of the TRIPS Agreement are contained in the Article 30(3) of the Ukrainian Patent Law:

> "3. With the purpose to protect the health of population, ecological safety and other public interests, the
> Cabinet of Ministers of Ukraine may permit the use of the patented invention (utility model) by a defined person without the consent of the patent (declarative patent) owner provided that this owner has groundlessly rejected granting a license for the use of an invention (utility model).
>
> In this case:
> 1. the permission for such a use shall be granted with consideration of specific circumstances;
> 2. the volume and the duration of such a use shall be determined by purpose of the granted permission
> and, in the case of semiconductor technology this shall be purely noncommercial use by bodies of the
> state power or implementing an anticompetition practice by the decision of a relevant body of the
> state power;
> 3. the permission for such a use shall not deprive the patent owner of the right to grant permissions for
> the use of an invention (utility model);
> 4. the right to such a use shall not be transferred excluding the case when it is transferred together
> with the part of the enterprise or business practice in which this use is carried out;
> 5. the use shall be permitted mainly for providing the internal market needs;
> 6. the notification concerning the grant of the permission for the use of an invention (utility model)
> shall be sent to the patent owner at the first opportune moment;
> 7. the permission for the use shall be revoked in case of discontinuance of circumstances under which
> this permission has been granted;
> 8. an adequate compensation in accordance with an economic value of an invention (utility model)

[268] Article 1 of Commercial Procedure Code and Article 3 of the Civil Code of Ukraine.

[269] Anastasiya Mindrul, Influence of Intellectual Property Protection on Access to Medicines after accession of Ukraine to WTO, Analytical Report, Kyiv 2010, p. 32

shall be paid to the patent owner.

The resolution of the Cabinet of Ministers of Ukraine concerning the grant of the permission for the
use of an invention (utility model), the validity period and conditions of the grant, revocation of the
permission for the use, amount and procedure of paying a remuneration to the patent owner may be
appealed in court procedure."

The above provisions of the Ukrainian Patent Law almost fully reflect provisions of Article 31(a-j) of the TRIPS Agreement, except for a few differences.

Thus, the TRIPS Agreement sets out no restrictions on grounds for the issuance of a compulsory license, while the Ukrainian Patent Law provides that the use without the consent of the patent owner could be permitted "with the purpose to protect the health of population, ecological safety and other public interests". This non-exhaustive list of interests gives opportunity to the Ukrainian government to issue a compulsory license on a variety of grounds. Further, the TRIPS Agreement does not require a groundless rejection from patent owner to grant a license for the use of an invention, as it is provided by the Ukrainian Patent Law. Most important difference is that Article 30(3)(8) of the Ukrainian Patent Law requires to pay to the patent owner "an adequate *compensation* in accordance with an economic value of *an invention* (utility model)", while the TRIPS Agreement is requiring only an "adequate *remuneration* …taking into account the economic value of *the authorization*". Remuneration means a payment for economic value of the authorized use, while the compensation means broader compensational element that may include compensation of patent owner's lost profits or damages due to the compulsory license use. Interestingly enough that in Article 30(3)(paragraph 10) of the Ukrainian Patent Law when establishing the right of patent owner for appeal of the Cabinet of Ministers resolution on compulsory license conditions legislator uses the word "remuneration".[270]

It should be noted that the use under the compulsory license includes not only manufacturing, but also import, as the Ukrainian Patent Law defines "use" as "manufacturing a product with the use of a patented invention (utility model), the use of this product, an offer of a product for the market, including an offer via the Internet, selling, *import* (coming-in) and other its introduction into the commercial circuit as well as storing a product for defined purposes; the use of a process protected by a patent or an offer of a process for the use in Ukraine, provided that the person offering a process

[270] *The State of Ukrainian National Legislation: Opportunities to use TRIPS Flexibilities*. Unpublished background document prepared by Boyan Konstantinov for the seminar "Intellectual Property Rights and Access to Essential Medicines in Ukraine: Challenges and Opportunities in Free Trade Agreement Negotiations, Multilateral Instruments and National Laws", 21-22 June 2010, Kiev, Ukraine, p. 11.

shall know that the use of a process without the permission of the patent owner is prohibited or, considering the circumstances, it is obvious".[271]

The recent amendment introduced on 3 November 2011 to the Law of Ukraine "On Medicines" in relation to compulsory licensing provided that to ensure health of the population during the registration of medicinal product the Cabinet of Ministers of Ukraine may allow the use of a patented invention (utility model) that covers the medicinal product to the defined person without the consent of the patent owner. This provision could be interpreted in a restrictive way that narrows issuance of compulsory licenses for medicines only to the situations when the generic manufacturer is applying for the registration of the generic product. That is why it appears practical to amend this provision in order to accommodate use of registration data for the purposes of compulsory licensing.

The Procedure on the Issuance by the Cabinet of Ministers of Ukraine of Permits for the Use of Patented Invention (Utility Model) or Registered Topography of Integrated Circuits, as approved by the Resolution of the Cabinet of Ministers No. 8, dated 14.01.2004 (hereinafter – "**General Procedure**"), provides a detailed procedure for the issuance of the compulsory license. The General Procedure contains a rather complicated and time-consuming mechanism of issuance of compulsory license that involves decisions of three authorities to issue a license. It sets out that the permit may be granted to any person who intends to use the patented invention (utility model) on the grounds and in compliance with article 30 of the Ukrainian Patent Law.

The interested person may file to one of the central executive authorities, which is competent to address issues of the use of the invention (hereinafter - the competent authority), with an application for the issuance of compulsory license (CL) by the Cabinet of Ministers of Ukraine, in which the following should be indicated the name of the object for use, the corresponding patent number, information about the patent owner's address (or location) and information about the unreasonable refusal of the patent owner to grant a voluntary license to use the object. A justification of the need for the use in the public interest and a technical-economic justification of viability, conditions of the use and the amount of the compensation to the patent owner should be added to the application. The competent authority shall consider the application within a month and if it approves the application the latter shall be sent to the State Service of Intellectual Property. The latter shall consider the application within two weeks from the date of receipt, checks the validity of the relevant patent (certificate) whether the information about patent owner and its registration data match and prepares its proposal to grant or refuse to grant compulsory use of the object specified in the request and submits it to the Cabinet of Ministers of Ukraine. The Cabinet of Ministers of Ukraine shall consider proposal of the State Service of Intellectual Property and decides on the granting or refusal

[271] Article 28(2) of the Ukrainian Patent Law.

to grant the permit for compulsory use. The Cabinet of Ministers decision shall include a person who is permitted to use the object, time and conditions of the permit, the amount of compensation to be paid to the owner of the relevant patent, the procedure of compensation payment, and name of the state body exercising control over the use of the object.

While the General procedure is applicable to all fields of technology, the Ministry of Health of Ukraine has recently prepared a more specific procedure on compulsory licensing and governmental use of medicines, which was approved by the Cabinet of Ministers of Ukraine on 4 December 2013. The Procedure for the Ukrainian Cabinet of Ministers' Issuance of the Permit to Use the Patented Invention Related to a Medicinal Product ("**Medicines CL Procedure**") is less burdensome than the General Procedure as the role of the intellectual property authority is diminished to merely technical verification of patent information during 10 days; also it provides for the right to refer to information about original/referent medicines needed for the registration.[272] Among drawdacks of the draft are the use of word "compensation" which is rather problematic (see discussion above) and defining this compensation based on modified Tiered Royalty Method formula which could be complicated to apply in practice; need to indicate precise information about patent that shall be used under the CL; no government use procedure; a documented inability of patent owner "to satisfy the need" as a pre-condition for the issuance of any CL; the amount of "compensation" to a patent holder defined by the TRM formula should be additionally approved by the "authorized authority", which is not defined in the text of the Medicines CL Procedure and should be defined by additional decision of the Cabinet of Ministers of Ukraine, etc.

9.2.4 Government Use

Governmental use is essentially the same mechanism as the compulsory licensing with the only differences that this procedure is initiated by the governmental authority and there is no need to make efforts to obtain authorization from the patent owner prior to governmental use.

Ukrainian Law provides for the opportunity of governmental use in Article 31(2) of the Ukrainian Patent Law, which states that:

> "The use of the patented invention (utility model) shall not be considered to be the infringement of
> rights deriving from a patent provided that it is used:
> …
> without any commercial purpose;
> …

[272] Paragraphs 2.7 and 2.13 of the Draft Procedure for the Ukrainian Cabinet of Ministers' Issuance of the Permit to Use the Patented Invention Related to a Medicinal Product, as published on the MoH Ukraine web-site for public discussion http://www.moz.gov.ua/ua/portal/Pro_20130226_1.html [accessed on April 27, 2013]

in emergency conditions (natural disaster, accident, epidemic etc.) with the notification of the patent
owner as soon as possible and with the paying a relevant compensation to him."

Legislator again in the text of the Ukrainian Patent Law uses the word "compensation", instead of the word "renumeration" (*see* above discussion on difference of the meaning of these words). Although, it appears that it is possible to issue a governmental use authorisation under the Article 30(3) of the Ukrainian Patent Law as well.[273] Finally, it should be noted that the Article 17(5) of the Law of Ukraine "On Medicinal Products" sets out that in cases of natural disasters, catastrophes, epidemic diseases, etc. import of unregistered in Ukraine medicines could be permitted by a separate decision of the Ministry of Health if the documents confirming registration and use of these medicines are available in the countries of export.

9.2.5 Parallel Import

The parallel import flexibility is dependent on the exhaustion of exclusive rights regime defined by the domestic legislation. The exhaustion of patent rights regime in Ukraine is established in the Article 31(3) of the Ukrainian Patent Law, which states that

> "the introduction of a product that has been manufactured with the use of the patented invention into the stream of commerce by any person, which has obtained a product without violation of the patent owner rights, shall not be considered to be the infringement of rights deriving from a patent.
>
> The product manufactured with the use of the patented invention (utility model) shall be considered to be obtained without the violation of the patent owner rights provided that this product has been manufactured by the patent owner and (or) after manufacturing has been introduced into the commercial circuit by the patent owner or other person according to the special permission (license) of the patent owner."

From these provisions, it is not clear which kind of exhaustion of rights regime is established: national or international. Such an ambiguity poses an obstacle to the implementation of parallel importation schemes in Ukraine. The same issue is with the provisions of the Law of Ukraine "On protection of rights on trademarks for goods and services" and the Law of Ukraine "On protection of rights on industrial designs" which also contain no indication on the type of exhaustion regime. These laws are also important for the parallel import of medicines, as trademarks used on the packaging and the industrial design of the packaging could be used as a ground for the relevant IP rights infringement claims.[274] Further, the Law of Ukraine "On

[273] *The State of Ukrainian National Legislation: Opportunities to use TRIPS Flexibilities*. Unpublished background document prepared by Boyan Konstantinov for the seminar "Intellectual Property Rights and Access to Essential Medicines in Ukraine: Challenges and Opportunities in Free Trade Agreement Negotiations, Multilateral Instruments and National Laws", 21-22 June 2010, Kiev, Ukraine, p. 11.

[274] Anastasiya Mindrul, Influence of Intellectual Property Protection on Access to Medicines after accession of Ukraine to WTO, Analytical Report, Kyiv 2010, p. 53

medicines" requires that marking on packaging and instructions on medical use were in the Ukrainian language, which is a serious technical obstacle for the realization of parallel import scheme for the needs of Ukrainian market and one of the main factors contributing to the high costs of medicines produced for Ukraine.

9.2.6 Exceptions from Patent Rights

The Article 30 of the TRIPS Agreement provides that Members may provide limited *exceptions* to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

The Ukrainian Patent Law sets out the following exceptions from the rights of the patent owners that could be applicable to medicines:

1. prior use;
2. scientific and experimental use;
3. non-commercial use;
4. governmental use in case of emergency (*see* detailed description above).[275]

The prior use exception is stipulated in Article 31(1) of the Ukrainian Patent Law: "any person, which has honestly used a technology (technical) solution identical to the claimed invention (utility model) or has made considerable and serious preparations for such a use in the interests of its activity with the commercial purpose before the date of filing the application for granting a patent… shall have the right to extend this use free of charge or to use an inventions (utility model) as it was foreseen by the mentioned preparation (the right of previous use)." The right of previous use may be transferred to another person only together with the enterprise or business practice.[276]

The provisions of the Ukrainian law on experimental use exception not detailed enough, which makes it difficult to define whether this exception is applicable only for purely academic purposes, or for the commercial purposes as well. According to the Article 31 (2) the use of the patented invention (utility model) shall not be considered to be the infringement of rights deriving from a patent provided that it is used for scientific or experimental purposes. There is no further judicial clarification or authoritative interpretation giving guidance on how to apply this exception.[277]

[275] Article 31 of the Ukrainian Patent Law.
[276] Article 31(1) of the Ukrainian Patent Law.
[277] Anastasiya Mindrul, Influence of Intellectual Property Protection on Access to Medicines after accession of Ukraine to WTO, Analytical Report, Kyiv 2010, p. 43.

Also, the Ukrainian Patent Law permits non-commercial use of the invention, however for the individual purposes.[278]

In relation to the Bolar exception[279] it appears that the Ukrainian law does not have such provision and it would be good to incorporate this provision into the Ukrainian Patent Law.

9.3 TRIPS-plus provisions: Ukraine

9.3.1 Patent Term Extension

According to Article 465(3) of the Civil Code of Ukraine and Article 6(4) of the Ukrainian Patent Law the term of patent protection for an invention shall be 20 years as from the date of filing of the application with the patent office. The term of the patent protection for the pharmaceutical product may be extended at the request of the owner of this patent for a period that is equal to the period between the date of filing of the patent application and the date of the receipt of marketing authorisation (drug registration), but for no more than 5 years.[280] As the TRIPS Agreement does not contain a requirement of patent extension, the latter provision, enabling patent owners to obtain patent protection for pharmaceutical products up to 25 years is a TRIPS plus, creating obstacle for the generic medicines competition.

It should be noted that according to the draft Association Agreement between EU and Ukraine that was initialed in March 2012 there must be a supplementary protection certificate procedure giving additional protection for the period that elapses between the filing of the application for a patent and the first authorisation to place the product on the market (i.e. state registration of medicinal product) reduced for five years.[281] Actually, if signed and implemented, the latter provision could be more favourable for Ukraine than the existing Ukrainian Patent Law provision from access to

[278] *The State of Ukrainian National Legislation: Opportunities to use TRIPS Flexibilities*. Unpublished background document prepared by Boyan Konstantinov for the seminar "Intellectual Property Rights and Access to Essential Medicines in Ukraine: Challenges and Opportunities in Free Trade Agreement Negotiations, Multilateral Instruments and National Laws", 21-22 June 2010, Kiev, Ukraine, p. 11

[279] "The "early working" or Bolar exception, allows competitors to import, manufacture and use a patented product for the purpose of seeking regulatory approval. Allowing for the completion of registration requirements before patent expiry, facilitates the prompt entry of generic medicines on the market once a patent expires." (paragraph 48 of the Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover "Promotion and protection of all human rights, civil, political, economic, social and cultural rights, including the right to development", A/HRC/11/12, 31 March 2009).

[280] Article 6(4) of the Ukrainian Patent Law.

[281] See Article 220 of the draft EU-Ukraine Association Agreement http://www.modernukraine.eu/eu-ukraine-association-agreement-eng-version-full-text/

medicines perspective, as this rule as already used at the EU market led to just over 3 years on average of the supplementary term of protection.[282]

Further, it appears recommendable to harmonize the Ukrainian Patent Law with EU supplementary Protection Certificates regulations. In EU patent term extension for medicinal products through issuance of Supplementary Protection Certificates (SPC) is subject to a range of conditions, such as:

(a) the product is protected by a basic patent in force;

(b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate;

(c) the product has not already been the subject of a certificate;

(d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product.[283]

First condition means that the SPC may be issued only for the basic patents protecting active ingredient of the medicinal product[284] and may not be issued for the secondary patents protecting minor changes to a medicinal product such as a new dose, the use of a different salt or ester or a different pharmaceutical form[285].

Furthermore, the application for a certificate shall be lodged within six months of the date on which the market authorisation for the medicinal product was granted. Where the authorisation to place the product on the market is granted before the basic patent is granted, the application for a certificate shall be lodged within six months of the date on which the patent is granted.[286] According to the EC Pharmaceutical Sector Inquiry: Final Report

> "this creates legal certainty for potential generic competitors, since they will know at an early stage when the period of protection of the medicinal product is due to expire and when they can start preparations for market entry. Also, the Regulation [(EC) No 469/2009] provides that any person may submit an application or bring an action for a declaration of invalidity of the certificate. An appeal is also possible."[287]

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[282] Bengt Domeij, Pharmaceutical Patents in Europe, Stockholm: Kluwer Law International/Norstedts Juridik, 2000 p. 197.

[283] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:152:0001:0010:en:PDF

[284] According to the Article 1(c) of the Regulation (EC) No 469/2009 'basic patent' means a patent which protects a product as such, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a certificate.

[285] See Point 11 of the Explanatory Memorandum to the proposal for the Council Regulation (COM(90) 0101 final), as cited in Case C-431/04 Massachusetts Institute of Technology, judgment of 4 May 2006, [2006] ECR I-4089, paragraph 19.

[286] Article 7(1,2) of the Regulation (EC) No 469/2009.

[287] EC Pharmaceutical Sector Inquiry: Final Report, 8 July 2009, p. 113 http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf

It appears that these conditions to the patent term extension provided in the EC Regulation (EC) No 469/2009 could be used by Ukraine as an example for amending relevant provisions of the Ukrainian Patent Law and the Instruction on procedure of patent term extension for inventions that require authorisations of competent state authorities, approved by the order of the MoH Ukraine No. 298, dated 13.05.2002.[288]

9.3.2 Data exclusivity

Among TRIPS plus commitments that Ukraine undertook during the accession to WTO process is the following commitment contained in paragraph 433 of the Working Party Report:

> "The representative of Ukraine confirmed that prior to accession his government would, in compliance with Article 39.3 of the TRIPS Agreement, enact amendments to the Law on Medicines and the Law on Agricultural Chemicals providing that undisclosed information submitted to obtain marketing approval, i.e., registration, of pharmaceutical and agricultural chemical products respectively would provide for a *period of at least five years of protection against unfair commercial use starting from the date of grant of marketing approval, in Ukraine for pharmaceutical products* and ten years for agricultural chemical products. During these periods, *no person or entity* (public or private), other than the person or entity who submitted such data, *could without the explicit consent of the person or entity who submitted the data, rely on such data in support of an application for product approval/registration*. During this period any subsequent application for marketing approval or registration would not be granted, unless the subsequent applicant submitted his own data meeting the same requirements as the first applicant. Furthermore, Ukraine would guarantee, during this period, the protection of such data against disclosure, except where necessary to protect the public or unless steps were taken to ensure that the data are protected against unfair commercial use. The representative of Ukraine confirmed that in its implementing regulations related to the Law "On Medicines, it would further clarify that the term "to use the registration information" included "relying upon, referring to, or otherwise using information". The representative of Ukraine confirmed that in implementing regulations they would clarify that a subsequent applicant who submitted his own data must meet the same requirements as a first applicant. The Working Party took note of these commitments."[289]

Thus a TRIPS plus requirement on 5 years data exclusivity period that is not provided in the TRIPS Agreement became an international commitment for Ukraine during the negotiations on accession to the WTO. This period was further prolonged up to 6 years under the FTA between Ukraine and EFTA[290] and implemented in the Law of Ukraine "On Medicines" in the following way. If a medicinal product is registered based on the given in full

[288] Anastasiya Mindrul, Influence of Intellectual Property Protection on Access to Medicines after accession of Ukraine to WTO, Analytical Report, Kyiv 2010, p. 27.
[289] Report of the Working Party on the Accession of Ukraine to the World Trade Organization, WT/ACC/UKR/152, 25 January 2008, p. 433
[290] See Article 5 of Annex 13 to the Free Trade Agreement between Ukraine and EFTA Member States, ratified by Ukraine on 7 December 2011.

registration information (hereinafter - reference / original medicinal product) for the first time in Ukraine, state registration of another medicinal product which contains the same active pharmaceutical ingredient as the reference / original medicinal product may not be earlier than five years from the date of first registration of the reference / original medicinal product in Ukraine. This requirement does not apply to cases where the applicant in accordance with law acquired the right to refer to and / or use the registration information about the reference / original medicinal product or filed its own complete registration information.[291] Notably, in the above provisions legislator clearly defined the local "novelty" of the medicinal product for the data exclusivity purposes, instead of choosing worldwide novelty that would narrow application of data exclusivity requirement.

Further the Law on Medicines states that the 5-years data exclusivity period could be prolonged for one year if during first three years of registration MoH Ukraine shall allow additional use for one or more indications that have significant advantage on existing indications.

One of the recently introduced progressive provisions related to data exclusivity in Ukraine that limits application of this TRIPS plus requirement stipulates that the data exclusivity period is applicable only to state registrations of those medicines that are filed within first two years starting from this medicinal product's registration anywhere in the world.[292] This provision shall play a role of counterbalance to the local novelty of medicinal product rule mentioned above.

According to the information that leaked from negotiations with EU on the Agreement of Association with Ukraine the EU was pushing for 8+2+1 year's formula of data exclusivity that works in EU itself.[293] Such reguirement would further complicate regulatory regime for medicines that will restrict competition from generics manufacturers. Fortunately enough, in the latest versions of the draft EU-Ukraine Association Agreement the 5 years data exclusivity period is saved, although Ukraine shall undertake to align its legislation concerning data protection for medicinal products with that of the EU at a date to be decided by the EU-Ukraine Association Committee meeting in Trade configuration (i.e. one of Association Agreement implementation bodies that shall moderate dialogue at the ministerial level).[294]

[291] Article 9(9) of the Law of Ukraine "On Medicines".
[292] Article 9(10) of the Law of Ukraine "On Medicines".
[293] *The State of Ukrainian National Legislation: Opportunities to use TRIPS Flexibilities*. Unpublished background document prepared by Boyan Konstantinov for the seminar "Intellectual Property Rights and Access to Essential Medicines in Ukraine: Challenges and Opportunities in Free Trade Agreement Negotiations, Multilateral Instruments and National Laws", 21-22 June 2010, Kiev, Ukraine, p. 12
[294] See Articles 222(2 and 3) and 460-465 of the unofficial draft EU-Ukraine Association Agreement http://www.modernukraine.eu/eu-ukraine-association-agreement-eng-version-full-text/;

Under the Ukrainian law for the registration of generic medicine in Ukraine it is not required to submit materials of pre-clinical (toxicologic and pharmacologic) and clinical trials if applicant can prove that the medicinal product is a generic product and owner of original / reference medicinal product permits reference to the registration data (pharmacologic, toxicologic and/or clinical trials materials) of reference product; or if bioequivalence of generic with reference product is proved by the relevant research.[295]

According to the Regulation on Conducting Expert Evaluation of Materials Pertinent to Medicinal Products Submitted for the State Registration (Re-Registration) and Expert Evaluation of Materials on Amending Registration Documents During Validity Period of Registration Certificate, approved by the Order of the MoH Ukraine No. 426, dated 26 August 2005, generic medicinal product (generic, interchangeable) (hereinafter - generic) is a medicinal product which has the same qualitative and quantitative composition of active pharmaceutical ingredients and the same pharmaceutical form as the reference product, and interchangeability of which with the reference product has been proven by relevant research. Various salts and simple esters, isomers, mixtures of isomers, complexes or derivatives of the active pharmaceutical ingredient are deemed as one and the same active pharmaceutical ingredient, provided that they do not differ significantly in terms of safety and efficacy. Various oral pharmaceutical forms with immediate release of the active pharmaceutical ingredient are deemed as one and the same pharmaceutical form.[296] It appears that such a broad definition of the generic medicine makes data exclusivity requirement widely applicable even to generic medicine that is different in some way from the original medicine, which is not commendable from access-maximizing point of view.

Even though under the Regulation it is explicitly permitted during data exclusivity period to conduct development of a generic medicine, including conducting research on equivalence between the generic and the reference medicinal product, to obtain registration certificate after expiration of data exclusivity period, this exception would be unfunctional if there is a patent protection for the referent medicine taking into account absence of Bolar exception in the Ukrainian Patent Law.

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[295] *See* Paragraph 3 of Procedure of State Registration of Medicinal Products, approved by Resolution of Cabinet of Ministers No 376, dated 26 May 2005 http://zakon4.rada.gov.ua/laws/show/376-2005-%D0%BF/paran2#n2 and Paragraph 6.4 of the Regulation on Conducting Expert Evaluation of Materials Pertinent to Medicinal Products Submitted for the State Registration (Re-Registration) and Expert Evaluation of Materials on Amending Registration Documents During Validity Period of Registration Certificate, approved by the Order of the MoH Ukraine No. 426, dated 26 August 2005 http://zakon4.rada.gov.ua/laws/show/z1069-05/print1360499355299861;

[296] Part 2 paragraph 15 of the Regulation on Conducting Expert Evaluation of Materials Pertinent to Medicinal Products Submitted for the State Registration (Re-Registration) and Expert Evaluation of Materials on Amending Registration Documents During Validity Period of Registration Certificate, approved by the Order of the MoH Ukraine No. 426, dated 26 August 2005 http://zakon4.rada.gov.ua/laws/show/z1069-05/print1360499355299861.

In light of the above it appears important for the Ukraine at least not to undertake additional international obligations to extend (up to 11 years) the duration of data exclusivity period as, for example, lobbied by the EU.

9.3.3 Patent Linkage with Registration

A linkage of patent protection and marketing approval is a typical TRIPS plus provision which is frequently included in Free Trade Agreements.[297]

The Law of Ukraine "On Medicines" in paragraph 14 Article 9 provides that for the issuance of the marketing approval the applicant should submit to the MoH Ukraine a copy of patent or license agreement together with guarantee letter indicating that the rights of patent owner or licensee shall not be infringed by the medicine registration. The MoH Ukraine may refuse in medicines registration if as a result of such registration there will be violated third party intellectual property right associated with manufacturing, use and sale of medicine.[298]

These provisions have been widely used by the patent owners in Ukraine to contest state registrations of generic version of antiretroviral medicines in the Ukrainian courts.[299]

9.3.4 Enforcement: Border Measures

The draft EU-Ukraine Association Agreement stipulates that border measures shall cover goods infringing patents, creating a TRIPS plus obligation for Ukraine to have border measures protecting rights of patent owners.

The Civil Code of Ukraine provides that courts in the cases and in the manner prescribed by law, may decide to desist crossing the customs border of Ukraine by the goods, import or export of which is violating IPR.[300] Additionally, the new Customs Code of Ukraine, adopted on 13 March 2013, contains a chapter devoted to protection of IPRs when crossing borders of Ukraine that establishes a customs register of IPR objects (the

[297] See paragraphs 84-89 of the Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover "Promotion and protection of all human rights, civil, political, economic, social and cultural rights, including the right to development", A/HRC/11/12, 31 March 2009.

[298] Law of Ukraine "On Medicines", Article 9(20) and paragraph 9 of the Procedure of medicinal products state registration (re-registration), approved by the Resolution of the Cabinet of Ministers of Ukraine No. 376, dated 26 May 2005; paragraph 3.8 of the Regulation on Conducting Expert Evaluation of Materials Pertinent to Medicinal Products Submitted for the State Registration (Re-Registration) and Expert Evaluation of Materials on Amending Registration Documents During Validity Period of Registration Certificate, approved by the Order of the MoH Ukraine No. 426, dated 26 August 2005 http://zakon4.rada.gov.ua/laws/show/z1069-05/print1360499355299861.

[299] Reducing the costs and expanding access to antiretroviral medicines in Ukraine – some recommendations on compulsory licensing prepared by Pascale Boulet in October 2012, based on meetings in Kiev on 24-27 September 2012 and on documents made available by OSI/AEMI, IRF, UNDP and UCAB, p. 3, 6, 9

[300] Article 432(2)(2) of the Civil Code of Ukraine.

"**Customs Register**"). Based on the information contained in the register customs office prevents crossing the Ukrainian border by counterfeit goods, including medicinal products infringing patent rights. Upon request of patent owner information about relevant medicinal product can be introduced to this register. [301] This is clearly TRIPS plus provisions as according to the Article 51 of the TRIPS Agreement only counterfeit trademark or pirated copyright goods shall be subject to border measures, and covering by border measures goods that involve infringement of other IPRs is at discreation of the Member states.

Contrary to the TRIPS Agreement safeguard contained in Article 52 there is no requirement in the Ukrainian law for the IPR holders to provide adequate evidence to show presence of *prima facie* infringement of IPRs as a condition for the initiation of border measures.[302] Also, provisions on security and equivalent assurance to prevent abuse of border measures that were introduced for a short period had been abolished by the new Customs Code.

Also, Ukrainian law provides for the right of customs office to act *ex officio* when there is sufficient evidence to believe that IPR shall be violated.[303] The *ex officio* suspension of goods by customs office on its own initiative could be initiated on the following grounds:

1. Upon the request of IPR holder for the objects of IPR that are not included in the Customs Register;

2. If customs office is officially notified about violations of IPRs by law enforcement and regulatory authorities, customs authorities of Ukraine and of other countries; or by international organizations, whose competence includes the protection of intellectual property rights.

3. If goods declared for customs clearance contain trademark that differs from the trademark, available in custom registry, by some elements and that is confusingly similar to the original trademark.[304]

If goods are suspended by customs office on its own initiative, it shall promptly notify the IPR holder about it. If IPR holder shall fail to submit an

[301] Article 398(2) and (5) of the Customs Code of Ukraine.
[302] See the form of application and the list of additional documents needed for the inclusion to the Customs Register in paragraph 2.3 of the Procedure on Registration in Customs Register of IPR Objects Protected by the Law, approved by the Order of Ministry of Finance of Ukraine No. 648, dated 30 May 2012 http://zakon4.rada.gov.ua/laws/show/z1034-12/paran20#n20
[303] Article 400 of the Customs Code of Ukraine.
[304] *See* List of Grounds for Ceasure of Customs Clearance of Goods, Not Included by the Right Holder in the Application on Protection of IPRs, Upon Initiative of Customs Office, approved by the Resolution of the Cabinet of Ministers of Ukraine on 21 May 2012, No. 432.

application for protection of its IPR the customs office shall release the goods. If IPR holder shall submit the application than 10 working days plus 10 working days periods formula contained in Article 55 of the TRIPS Agreement shall be applicable to such suspension.[305] It appears that ex officio suspension procedure provided in the Customs Code of Ukraine complies with Article 58 of the TRIPS Agreement, except for the 3 working days period given to the right holder for the filing application on suspension, which is a TRIPS plus provision.

In general, above provisions of the Ukrainian law have a negative effect on generic competition, as they create a chilling effect for the potential importers of generic medicinal product who have limited safeguards against border measures.

Additionally, it should be noted that according to the EU-Ukraine's Association Agenda to prepare and facilitate the implementation of the Association Agreement Ukraine shall

> "strengthen cooperation on the protection of the IPR by exchange of experience and organisation of joint actions on the IPR issues as well as continue a dialogue on IPR issues in order to:
>
> > proper implement standards embedded in the Enforcement Directive 2004/48/EC and the EC Council Regulation 1383/2003 concerning customs actions;
> >
> > take effective measures against counterfeiting and piracy and ensure effective implementation of the enforcement legislation and of sanctions for infringements of intellectual property rights;
> >
> > strengthen coherent and comprehensive enforcement capacity at public authorities level (administrative, judicial and operational authorities), in particular strengthen the number of State Inspectors at SDIP [State Service of Intellectual Property of Ukraine] and increase the enforcement resources regarding internet piracy within the Ministry of Interior."[306]

EC Council Regulation 1383/2003 is the one authorizing customs authorities to suspend goods in transit if there is a suspicion of patent infringement. It was used several times in the Netherlands to stop supplies of generic medicines, including life-saving like abacavir, in transit from India to Brazil, Peru, Columbia, Nigeria. Additionally the draft EU-Ukraine Association Agreement contains the same provision in article 250(2)[307] as

[305] See Article 400 of the Customs Code of Ukraine.

[306] EU-Ukraine Association Agenda to prepare and facilitate the implementation of the Association Agreement, adopted by the Cooperation Council in November 2009 http://eeas.europa.eu/ukraine/docs/2010_eu_ukraine_association_agenda_en.pdf p. 19.

[307] *Compare* Article 250(2) of draft EU-Ukraine Association Agreement "The Parties shall, unless otherwise provided for in this Section, adopt procedures to enable a right holder, who has valid grounds for suspecting that the importation, exportation, re-exportation, *entry or exit of the customs territory, placement under a suspensive procedure* or placement under a free zone or a free warehouse of goods infringing an intellectual property right may

the Article 1(1) EC Council Regulation 1383/2003 thus obliging Ukraine to introduce border measures for goods in transit on its territory. It is a clearly TRIPS plus Regulation contradicting to the Footnote 13 to the Article 51 of the TRIPS Agreement and that was criticized by scholars[308] and should not be implemented by the Ukrainian government.

9.3.5 Enforcement: Criminal Procedures

Contrary to the provisions of the Article 61 of the TRIPS Agreement and draft EU-Ukraine Association Agreement that do not oblige Ukraine to introduce criminal liability for patent infringement, the Criminal Code of Ukraine established criminal prosecution for illegal use of an invention or utility model where such actions caused a significant pecuniary loss of not less than 1147 EUR, thus introducing a TRIPS plus provision. Sanctions prescribed for this crime which may be aggrevated with several circumstances (i.e. if this crime is repeated, or committed by a group of persons upon their prior conspiracy or where they caused a gross (11470 EUR) or especially gross (57350 EUR) pecuniary loss) include fine in the amount of 340-5100 EUR or imprisonment up to 6 years with or without deprivation of the right to occupy certain positions or engage in certain activities for a term up to three years, and with the forfeiture and destruction of illegally made products and the equipment and material designated for their production.[309] Above sanctions appear to be very serious in comparison to other crimes, for example, violation of the right to free medical assistance by unlawful request to pay for medical assistance in public or community health care institutions is punishable by a fine up to 170 EUR or arrest for a term up to six months.[310]

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take place, to lodge an application in writing with competent authorities, administrative or judicial, for the suspension by the customs authorities of the release into free circulation or the detention of such goods." and Article 1(1)(b) of the EC Council Regulation 1383/2003: "1. This Regulation sets out the conditions for action by the customs authorities when goods are suspected of infringing an intellectual property right in the following situations: (b) when they are found during checks on goods *entering or leaving the Community customs territory* in accordance with Articles 37 and 183 of Regulation (EEC) No 2913/92, *placed under a suspensive procedure* within the meaning of
Article 84(1)(a) of that Regulation, in the process of being re-exported subject to notification under Article 182(2) of that Regulation or placed in a free zone or free warehouse within the meaning of Article 166 of that Regulation.

[308] Frederick M. Abbott, Seizure of Generic Pharmaceuticals in Transit Based on Allegations of Patent Infringement: A Threat to International Trade, Development and Public Welfare, W.I.P.O.J. 2009, pp. 43, 47, 49.

[309] See Article 177 of the Criminal Code of Ukraine http://www.legislationline.org/documents/action/popup/id/16257/preview.

[310] See Article 184 of the Criminal Code of Ukraine http://www.legislationline.org/documents/action/popup/id/16257/preview and *The State of Ukrainian National Legislation: Opportunities to use TRIPS Flexibilities*. Unpublished background document prepared by Boyan Konstantinov for the seminar "Intellectual Property Rights and Access to Essential Medicines in Ukraine: Challenges and Opportunities in Free Trade Agreement Negotiations, Multilateral Instruments and National Laws", 21-22 June 2010, Kiev, Ukraine, p. 14

9.3.6 Conclusions on Enforcement in Ukraine

It appears that Ukraine should consider carefully public health concerns during negotiations with EU and implementation of the EU-Ukraine Association Agreement provisions on enforcement measures. In particular, the chilling effect that strong enforcement creates for generic medicines suppliers should be kept in mind when harmonizing Ukrainian legislation with EU regulations.

Further, as Ukraine has committed to the TRIPS plus border measures covering patent rights, including exportation of patented goods, as it appears from draft EU-Ukraine Association Agreement, it is recommendable to introduce provided by the TRIPS Agreement safeguards in relation to border measures, e.g. obligation of IPR holder to provide adequate evidence showing presence of *prima facie* infringement of IPRs as a condition for the initiation of border measures and provisions on security and equivalent assurance. Ukrainian government should refuse to harmonize Ukrianian legislation with the application of border measures to goods in transit as prescribed in EC Council Regulation 1383/2003 or at least apply a high threshold for evidence that patent owners shall submit to prove that there is a substantial likelihood of diversion of medicines in transit onto the Ukrainian market.[311]

Finally, liability for patent infringement should be decriminalized or at least criminal sanctions should be significantly relaxed. Additionally, raising the threshold of pecuniary loss could be considered by legislators.

9.4 Conclusions and Recommendations for Ukraine

Thus, Ukrainian legislation contains the following TRIPS-flexibilities and TRIPS-plus provisions:

Public health-related TRIPS-Flexibilities	Presence or absence of provision

[311] Guidelines of the European Commission concerning the enforcement by EU customs authorities of intellectual property rights with regard to goods, in particular medicines, in transit through the EU. dated 1 February 2012, p. 5 http://ec.europa.eu/taxation_customs/resources/documents/customs/customs_controls/counterfeit_piracy/legislation/guidelines_on_transit_en.pdf

Diagnostics and therapeutic methods are not patentable	No (-)[312]
Second use, new forms are not patentable	No (-)
Compulsory licensing is provided	Yes (+)
Government use is provided	Yes (+)
Parallel import is permitted	No (-)
Bolar exception	No (-)
Experimental use exception	Yes (+)
Pre-grant patent oppositions	No (-)
Post-grant patent oppositions	No (-)
TRIPS-plus provisions, which restrict access to medicines	**Presence or absence of provision**
Utility models for pharmaceuticals	Yes (-)
Patent term extension	Yes (-)
Data exclusivity	Yes (-)
Patent linkage with market authorisation	Yes (-)

[312] „(-)" or „(+)" characterizes the negative or positive potential impact of presence or absence of TRIPS-flexibility or TRIPS-plus provision in the legislation of the country.

Customs measures	Yes (-)
Criminal liability for patent infringement	Yes (-)

Ukrainian IP legislation was harmonised with most of the TRIPS requirements, including TRIPS plus provisions, early before Ukriane's accession with WTO. This created a particularly strong legal framework for the protection of IPRs on medicines in Ukraine which was used by some of the big pharmaceutical companies to establish monopoly on the Ukrianian market for the particular medicinal products, for example, for such life-saving antiretroviral medicines like Aluvia by Abbott, Ziagen by GlaxoSmithCline.[313] This induced high pricing of medicines, including ARVs, for Ukraine, while state funded programs to fight HIV/AIDS or TB continue to be underfinanced. In such situation, changing Ukrainian legislation regulating monopoly rights on medicines should be one of the priorities in all range efforts that Ukrainian government takes to improve access to medicines in Ukraine. In light of the above the following changes of the legal framework could be recommended:

1. to exclude diagnostic, therapeutic and surgical methods for the treatment from patentability as invention or a utility model;
2. to exclude from utility model protection technical solutions related to chemical and pharmaceutical substances and/or processes, technical solutions related to biological material, diagnostic, therapeutic and surgical methods for the treatment;[314]
3. to exclude from patentability new uses of known substances or introduce an exception for pharmaceutical products (Article 6(2) of the Ukrainian Patent Law)[315];
4. develop and introduce into the Ukrainian Patent Law stricter criteria of patentability of pharmaceutical products to prevent granting "evergreening" secondary patents or patent applications that are against public health interests[316] (as a model could be used provisions of the Indian Patent Act, in particular, Article 3(d));

[313] Reducing the costs and expanding access to antiretroviral medicines in Ukraine – some recommendations on compulsory licensing prepared by Pascale Boulet in October 2012, based on meetings in Kiev on 24-27 September 2012 and on documents made available by OSI/AEMI, IRF, UNDP and UCAB, p. 3, 6, 9

[314] Anastasiya Mindrul, Influence of Intellectual Property Protection on Access to Medicines after accession of Ukraine to WTO, Analytical Report, Kyiv 2010, p. 96.

[315] *The State of Ukrainian National Legislation: Opportunities to use TRIPS Flexibilities*. Unpublished background document prepared by Boyan Konstantinov for the seminar "Intellectual Property Rights and Access to Essential Medicines in Ukraine: Challenges and Opportunities in Free Trade Agreement Negotiations, Multilateral Instruments and National Laws", 21-22 June 2010, Kiev, Ukraine, p. 15.

[316] Ibid, p. 15.

5. harmonize provisions of Article 6(4) of the Ukrainian Patent Law on patent term extension with Article 220 of EU-Ukraine Association Agreement and EC Regulation (EC) No 469/2009;[317]
6. stipulate in Articles 16 and 24 of the Ukrainian Patent Law right of third parties, including patient organisations, to file pre-grant and post-grant patent oppositions to the Ukrpatent as well as file claims with courts on invalidation of granted patents; authorize Ukrpatent to invalidate patents on its own initiative without court's decision by amending Article 33(1) of the Ukrainian Patent Act;[318]
7. to amend Article 30 and 31 of the Ukrainian Patent Law by replacing word 'compensation' with 'remuneration', clarifying methods of defining amount of adequate remuneration under compulsory license using UNDP/WHO "Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies"[319] and clarifying the meaning of 'unreasonable refusal [by patent owner] to grant a license';
8. it appears commendable for Ukraine to accede to the 30 August 2003 Decision mechanism of exporting-importing under compulsory licenses[320] as a potentially importing country;
9. to extend the provisions of Article 31(2)(4) of the Ukrainian Patent Act to introduce Bolar exception. Wording of Article 55.2 (1 and 6) of the Canadian Patent Act could be used as a model;[321]
10. to clarify in the Article 31(3) of the Ukrainian Patent Act that the regime of exclusive rights exhaustion includes importing to the customs territory of Ukraine. Wording of Article 17(2) of the Law of Ukraine "On protection of rights on topographies of integral circuts" could be used as a model;[322]

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[317] Anastasiya Mindrul, Influence of Intellectual Property Protection on Access to Medicines after accession of Ukraine to WTO, Analytical Report, Kyiv 2010, p. 27.

[318] Anastasiya Mindrul, Influence of Intellectual Property Protection on Access to Medicines after accession of Ukraine to WTO, Analytical Report, Kyiv 2010, p. 97.

[319] *The State of Ukrainian National Legislation: Opportunities to use TRIPS Flexibilities*. Unpublished background document prepared by Boyan Konstantinov for the seminar "Intellectual Property Rights and Access to Essential Medicines in Ukraine: Challenges and Opportunities in Free Trade Agreement Negotiations, Multilateral Instruments and National Laws", 21-22 June 2010, Kiev, Ukraine, p. 15

[320] See Decision of the General Council of 30 August 2003 on Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm

[321] Article 55.2 (1 and 6) of the Canadian Patent Act stipulates that "(1) It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product. (6) For greater certainty, subsection (1) does not affect any exception to the exclusive property or privilege granted by a patent that exists at law in respect of acts done privately and on a non-commercial scale or for a non-commercial purpose or in respect of any use, manufacture, construction or sale of the patented invention solely for the purpose of experiments that relate to the subject-matter of the patent."

[322] Anastasiya Mindrul, Influence of Intellectual Property Protection on Access to Medicines after accession of Ukraine to WTO, Analytical Report, Kyiv 2010, p. 54

11. not to undertake additional international obligations or introduce amendments to the Ukrainian law that will extend the duration of data exclusivity period as, for example, lobbied by the EU;
12. to exclude from Article 9 of the Law of Ukraine provisions on patent-registration linkage with medicines state registration;
13. to exclude from application to medicinal products provisions of part XIV of the Customs Code of Ukraine or at least introduce into part XIV of the Customs Code of Ukraine provided by the TRIPS Agreement safeguards in relation to border measures, e.g. obligation of IPR holder to provide adequate evidence showing presence of *prima facie* infringement of IPRs as a condition for the initiation of border measures and provisions on security and equivalent assurance.
14. to refuse to harmonize Ukrianian legislation with the application of border measures to goods in transit as prescribed in EC Council Regulation 1383/2003 or at least apply a high threshold for evidence that patent owners shall submit to prove that there is a substantial likelihood of diversion of medicines in transit onto the Ukrainian market.[323]
15. to decriminalize liability for patent infringement or at least criminal sanctions should be significantly relaxed. Additionally, raising the threshold of pecuniary loss could be considered.
16. to introduce provisions into article 9 of the Law of Ukraine "On Medicines" that stipulate that in case of compulsory licensing and government use orders data excusivity does not apply.
17. to rescind the Medicrime Convention and focus on control of quality safety and efficacy, which is very well-developed in Ukraine through its Pharmacopeia and through the work of its DRA.

[323] Guidelines of the European Commission concerning the enforcement by EU customs authorities of intellectual property rights with regard to goods, in particular medicines, in transit through the EU. dated 1 February 2012, p. 5 http://ec.europa.eu/taxation_customs/resources/documents/customs/customs_controls/counterfeit_piracy/legislation/guidelines_on_transit_en.pdf