

At the NAT/AAE seminar and in submissions to the FRA repeated reference was made to the importance of educating people with HIV in their rights and of appropriate surveillance and monitoring of relevant laws and their application (where the work of the FRA and the stigma index were cited, as well as the criminalisation scan of GNP plus).

We hope central to the conclusions and recommendations of the Commission will be a vision for legal systems which protect and promote the rights of people with HIV and affected communities in practice and reality, with concrete proposals as to how to arrive there.

AIDS Action Europe
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South Centre

Dear Members of the Commission,

The South Centre is pleased to respond to the call for specialist submissions by the Commission on how can the law be used to scale up effective HIV responses and how can the law be a 'game-changer'.

In this submission we explain how intellectual property law and its implementation in national legislation may affect public health and access to medicines, including effective HIV responses. We forward some suggestions on how the flexibilities in the intellectual property system may be used by countries to promote public health objectives, particularly access to antiretrovirals (ARVs). This submission particularly focuses on the standards of patentability criteria and the use of compulsory licenses as key flexibilities necessary for developing countries' with respect to public health.¹

We note that the UNDP has been undertaking important work in this regard and we can only hope that this work continues.

I. The work of the South Centre on Public Health

The South Centre has a long experience in working with developing countries to facilitate informed approaches to address health implications of trade and globalization-related issues at the national, subregional and regional levels.

The South Centre strategy focuses on access to health care technologies relevant to all diseases, conditions or problems, as well as on research and development for areas diseases or conditions of significant public health importance in developing countries for which an adequate treatment for use in resource-poor settings is not available or affordable.

The South Centre's work plan for health and development, focuses on four key interventions: 1) policy and technical guidance on health and development 2) training and enhancing capacity; 3) direct country support; and 4) monitoring and analysis.

The South Centre is highly aware that the law may be a game changer, and in that respect, undertakes research

¹ While this submission focuses on the patentability requirement and compulsory licenses, various other flexibilities under the TRIPS Agreement are also crucial with regard to public health objectives. These are: transition periods, public, non-commercial use (government use), parallel imports, exceptions to patent rights, and limitations on data protection. For a detailed analysis of how the TRIPS flexibilities can promote access to medicines, see, Sisule F. Musungu and Cecilia Oh, *The Use of Flexibilities in TRIPS by Developing Countries: Can they Promote Access to Medicines?* (South Centre and World Health Organisation, April 2006), available at http://www.who.int/intellectualproperty/studies/TRIPS_flexibilities/en/index.html

and provides policy advice to developing countries on issues related to public health, intellectual property rights and innovation.

The South Centre develops technical and policy guidance in the form of technical publications, research papers and briefing documents. These are available on the South Centre website at www.southcentre.org.

The South Centre organizes and facilitates training workshops for developing country policy makers, with a focus on enhancing the capacity of trade negotiators, policy makers and institutions to understand and monitor the impact of trade agreements, and to build negotiating skills.

The South Centre provides briefings and information to Geneva diplomatic missions and direct country support in the review of national policy and legal frameworks. Such country support focuses on developing public health sensitive patent legislation and incorporating the flexibilities of the Agreement of Trade Related Aspects of Intellectual Property Rights (TRIPS) within the domestic legislation.

Furthermore, the South Centre monitors and analyses the impact of trade agreements on public health and access to essential medicines, including the impact of new trends and developments.

II. The need for access to medicines and sustainable long term R&D for medicines on a needs basis

Of the 20 million people which the WHO, UNICEF and UNAIDS in their 2010 report consider should have received a retroviral treatment, only 5.2 million had access to the therapy at the end of 2009. A third of the world's population does not have regular access to essential medicines, and this ratio even reaches levels of half the population in certain developing countries. Medicines are a key tool which society has in order to prevent, relieve or cure diseases, and having access to them is a fundamental right of the citizens, it is a part of the right to health as established by international treaties law, and even by the Constitution itself in many countries.

The financial burden of the expenditure in medicines in most of the developing countries falls on the individuals and not on the health insurances (private or public), as occurs in the developed countries. In countries where the per capita income (PCI) is less than 1,000 US dollars per year, individuals, as well as the State will not be able to bear the cost of a second-line anti-retroviral treatment at a cost of 1,200 to 4,000 US dollars per year. According to World Bank figures, one billion people currently live in extreme poverty (less than one dollar per day) and this is precisely the population which has the most serious health problems.

In addition to the problem of access to medicines, there is a problem of insufficient innovation in medicines, particularly to tackle diseases that mainly affect developing countries. While some governments are providing incentives, and there a number of foundations' and private firm initiatives, the fact remains that there is insufficient funding for biomedical innovation to address the global burden of disease that disproportionately affects developing countries.

A major challenge for sustainable financing of global health research and development, particularly for neglected diseases, is that existing investments are primarily sourced from voluntary contributions from business and private foundations, whose funding priorities are susceptible to change. Hence, there is no assurance of sustainable financing of global health research.

Biomedical innovation for diseases that mainly affect developing countries is not taking place largely because there is low purchasing power, by either the government or the patient, to create sufficient market-based profit incentives for private pharmaceutical firms to invest in new products to treat such diseases. Developing countries only account for 10% of global sales of pharmaceuticals (CIPIH 2007). Biomedical innovation also involves substantial public sector support for upstream research, which developing countries have limited ability to fund.

One of the limitations of current initiatives to purchase and fund R&D in new medicines for diseases that mainly affect developing countries is the question of their long-term sustainability, as most depend from voluntary financial contributions from donors. With the current economic crisis, it is reported that donors have reduced funding for public development partnerships (PDPs) and other related initiatives for health research. Moreover, to date there is no global initiative that effectively works to improve biomedical innovation in parallel to improving access to existing medicines. It is thus necessary to examine alternative mechanisms that would ensure sustainability of R&D.

A priority in increasing biomedical R&D to address the global burden of disease is to increase the involvement in R&D by developing countries. Given the advantage of lower labor and other fixed costs and increased R&D capabilities in some countries, there is significant potential to do so.

In 2008, countries agreed at the World Health Assembly of the WHO to a Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA). The Global Strategy recognizes the urgent need to explore and promote new thinking on innovation and access to medicines, including the possibility of an international agreement or convention, as an alternative or complementary form of funding R&D for pharmaceutical products. A Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG) was set to “examine current financing and coordination of research and development, as well as proposals for new and innovative sources of funding to stimulate research and development related to Type II and Type III diseases and the specific research and development needs of developing countries in relation to Type I diseases..” (WHA Resolution 63.28). At its second meeting that took place on 7-8 July 2011, the CEWG made two important preliminary recommendations: to strengthen global financing and coordination mechanisms for R&D for health needs of developing countries under the auspices of WHO, and that formal intergovernmental negotiations should begin for a binding global instrument for R&D and innovation for health.

III. The Impact of Intellectual Property Law on Public Health and Access to Medicines

Today, it is recognized that intellectual property law has a significant impact on the entire pharmaceutical sector, and more specifically on medicine prices, to the extent where it may even hamper access to medicines by the poor populations of the Southern countries. It is also alarming that rules which are included in the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) are not necessarily appropriate for those who are making an effort to meet health and development needs.

In its 2002 report, the United Kingdom Commission on Intellectual Property Rights (CIPR) recommended countries to “ensure that their IP protection regimes do not run counter to their public health policies and that they are consistent with and supportive of such policies.” Patents are a key factor in the determination of the prices of medicines, and the TRIPS agreement imposes that all WTO member countries grant exclusive patent protection for a period of 20 years from the filing date of patent application. Even though the TRIPS agreement obliges WTO members to provide patent protection for medicines, it also allows them to take certain social interest measures, such as compulsory licenses, parallel imports, exceptions to patent rights, and the rigorous definition of patentability criteria. These flexibilities can be implemented as a means to balance patent rights with public interest, stimulate competition, protect consumers, and in the case of pharmaceuticals, allow the substitution of branded by generic medicines so as to encourage access there at prices affordable to governments and consumers.

In 2006, the WHO report on “Public Health, Innovation and Intellectual Property Rights” stated that “the TRIPS Agreement allows countries a considerable degree of freedom in how they implement their patent laws, subject to meeting its minimum standards including the criteria for patentability laid down in TRIPS. Since the benefits and costs of patents are unevenly distributed across countries, according to their level of development and scientific and technological capacity, countries may devise their patent systems to seek the best balance, in their own circumstances, between benefits and costs. Thus, developing countries may determine in their own ways the definition of an invention, the criteria for judging patentability, the rights conferred on patent owners and what exceptions to patentability are permitted (...).”

Countries may, hence, use certain flexibilities contained in the TRIPS Agreement, which were approved and confirmed in different international fora. However, developing countries that applied them have been subjected to bilateral pressures. These flexibilities have also been eroded by TRIPS-plus obligations in free trade agreements (see below). The Global Strategy on public health, innovation and Intellectual property, approved by the World Health Assembly in May 2008, recognizes this problem and proposes technical assistance as one of the elements to overcome this obstacle: “International intellectual property agreements contain flexibilities that could facilitate

increased access to pharmaceutical products by developing countries. However, developing countries may face obstacles in the use of these flexibilities. These countries may benefit, inter alia, from technical assistance."²

III.1. Patentability requirements

Although the ordinary meaning of 'invention' evokes an intellectual activity leading to unexpected or surprising outcomes, the large majority of patents granted in the world protect mere incremental changes to existing products and processes. Protected inventions are often the result of routine production or development activities that do not require significant investment. The pharmaceutical sector is a paradigmatic example of the proliferation of patents of low or inexistent inventive step.

While the number of new chemical entities of therapeutic use developed and tested per year has drastically declined in the last decade, the number of patents relating to pharmaceuticals has grown significantly. They cover formulations, combinations, doses, salts, ethers, polymorphs, isomers, etc. of existing drugs, the development of which in most instances does not require any inventive activity.

Why are patents on these minor developments -sometimes called 'secondary' patents- applied for? Acquiring them allow pharmaceutical companies to delay the entry of generic products and thereby artificially extend exclusive rights on a particular drug. There is increasing evidence on the use of patents as a strategic tool to exclude competition rather than as a means of obtaining a reward for genuine innovation. An investigation carried out by the European Commission, for instance, identified a number of strategies with that purpose, such as filing for up to 1,300 patents EU-wide in relation to a single medicine (so-called "patent clusters"), engaging in disputes with generic companies leading to nearly 700 cases of reported patent litigation, and concluding settlement agreements with generic companies to stop generic entry. The additional costs caused by these practices was estimated for a sample of drugs at 3 billion Euros for 2000-2007. The report also found that 'originator companies develop and practice defensive patenting strategies primarily in order to block the development of new competing products. This can lead to obstacles to innovation, in form of higher costs for competing pharmaceutical companies (e.g. for royalties) or in delays'³. A previous study by the Federal Trade Commission in the USA had also found evidence on the misuse of patents to block or delay generic competition⁴.

Most patent laws in the world do not define what an invention is. The concept of 'invention' as applied in various countries significantly differs. The TRIPS Agreement does not interfere with such diversity. The wording of Article 27.1 indicates that WTO Members have been left room to interpret in good faith the concept of 'invention' within their legal systems, subject only to the application of the rules for interpretation set out by the Vienna Convention on the Law of the Treaties⁵. Similarly, the TRIPS Agreement allows WTO Member countries to adopt their own definitions of the patentability standards (novelty, inventive step/non-obviousness, industrial applicability /utility). Article 27.1 prescribes, in effect, that patents "shall be available for any inventions ... provided that they are new, involve an inventive step and are capable of industrial application", but does not contain any specification about the precise way in which these criteria are to be applied.

The definition of the patentability criteria constitutes a key aspect of patent policy, with implications in other areas, such as industrial and public health policies. If patents are granted on the basis of lax standards of patentability, undue limitations on competition may arise out without any significant trade-off in terms of more innovation to address society's needs. Limitations resulting from patents granted without a rigorous application of the patentability criteria are noticeable in the case of several ARVs. For instance, a number of patents following the base compound patent for ritonavir relate to incremental developments, including polymorphs and new

² WHO, *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property*, Resolution of the 61st World Health Assembly, WHA 61.21, 24 May 2008, paragraph 12, p.6, available at http://www.wipo.int/edocs/mdocs/govbody/en/wo_pbc_18/wo_pbc_18_14.pdf.

³ See European Commission (2009), *Pharmaceutical Sector Inquiry Report*, available at <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html><http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html>.

⁴ See Federal Trade Commission (2002), *Generic Drug Entry Prior to Patent Expiration*. FTC Study, available at <http://www.ftc.gov>.

⁵ See Articles 31 and 32 of the Convention. The method of interpretation codified by this Convention has been extensively used in GATT/WTO jurisprudence, including with regard to the TRIPS Agreement.

formulations, such as a soft-gel capsule and solid dispersion form (also known as the heat-stable form), the patentability of which would be questionable in the light of well-defined patentability criteria. Similarly, lopinavir polymorphic forms and formulations do not seem to present an inventive step sufficient for the grant of a patent. The combination of lopinavir with ritonavir, for which patents have been applied for in many jurisdictions, does not present either a synergistic effect of an inventive nature so as to justify the grant of protection. This means that appropriate patent policies to assess whether a claimed invention makes a genuine technical contribution to the state of the art may be crucial to ensure generic competition and thereby significantly increase the number of patients under treatment. Although compulsory licenses may be used to mitigate the impact of a granted patent (see next section), the application of rigorous standards of patentability at the time of the examination of the patent application, would avoid the need to resort to such licenses and, hence, the political strains sometimes associated to their grant. In addition, no royalties would be charged on products that should be in the public domain.

III.2. Use of Compulsory Licensing and Pricing of Medicines

Patents grant exclusive rights that allow its owner to exclude potential competitors during the whole patent term. Hence, he may charge the prices that the market bears, as monopolists do. This situation has been tangible in the case of many ARVs, particularly in respect of second line treatment. In order to improve access to patented medicines through a reduction of prices, governments may resort to compulsory licenses or government use (for non-commercial purposes) which authorize a private party or a government entity to use a patented invention against payment of a remuneration to the patent owner. The grant of compulsory licenses or government use is explicitly permitted by article 31 of the TRIPS Agreement, which determines the conditions but not the grounds that may be invoked therefor. In some cases, before a compulsory license is granted, it is necessary to enter into negotiations with the patent owner to obtain a voluntary license. Failure to reach an agreement opens the way for government action.

While until recently compulsory licenses/government use had been mainly utilized in developed countries (notably in the USA), in the past decade several developing countries have issued compulsory licences/government use in order to increase access to medicines (see Table I).

<i>Date</i>	<i>Country</i>	<i>Product</i>	<i>Duration</i>	<i>Royalties</i>	<i>Cost reduction</i>
April 2003	Zimbabwe	all HIV/AIDS-related medicines	not indicated	not indicated	Prices determined by the government
Oct. 2003	Malaysia	- didanosine, - zidovudine - FDC didanosine+zidovudine	2 years	not indicated	Ceiling prices determined by the government
Sept. 2004	Zambia	FDC lamivudine+stavudine+nevirapine	until notification of expiry of the compulsory licence	2.5%	
Oct. 2004	Indonesia	- lamivudine - nevirapine	7-8 years (end patent term)	0.5%	
Oct.	Ghana	- CL to			Price

2005		import ARVs from India			reduction almost 50%
Nov. 2006	Thailand	efavirenz	until 31 December 2011	0.5%	Price of the generic version around 50% of the original
Jan. 2007	Thailand	lopinavir/ritonavir	until 31 January 2012	0.5%	Generic version expected to cost 20% less than original
Jan. 2007	Thailand	clopidogrel	patent expiry or no longer needed	0.5%	Cost expected to drop from 120 baht per pill to 6-2 baht
March 2007	Indonesia	efavirenz	until 07 August 2013	0.5%	
May 2007	Brazil	efavirenz	5 years	1.5%	Generic version priced at 28% of the original
Jan. 2008	Thailand	Several cancer drugs	Patent expiry or no longer needed	3-5%	
April 2010	Ecuador	- ritonavir	until 30 November 2014	Tiered Royalty Method (WHO/UNDP) – 4 per cent of high income country price as base royalty, adjusted to relative per capita income or relative income per person with the disease	Initial price reduction between 20% and 27%

Source: own data and Sampath, P. (2011, unpublished) 'Promoting Local Pharmaceutical Capacity in Developing Countries: A Discussion on Inventive Step and Compulsory Licensing'.

Compulsory licenses/government use have been grounded in many cases on a declaration of 'emergency' situations. It is up to each government to decide when such situations exist. The high cost of the patented products and the ensuing limitation in their supply to patients in need may be sufficient to consider that an emergency exists. In these cases, there is no need to negotiate with the patent owner a voluntary license as a pre-

condition to proceed. Compulsory licenses/government use have also been decided on other grounds, including general considerations of public interest. In most cases, the authorized use has been for the importation of the required medicines. The royalty rates applied on the price of the licensed product varied from 0,5% to 4%. Significantly, the grant of compulsory licenses/government use permitted the respective governments to obtain substantial savings in the purchase of the covered medicines.

The experience with the grant of compulsory licenses/government use shows that these are mechanisms that may be effective in increasing access to ARVs and other drugs. Some governments that used them (notably Thailand) were subject to pressures from the US government and the European Commission, as well as to retaliation by some pharmaceutical companies. However, this has not always been the case and it should not discourage governments from using these legitimate tools when needed. National laws should provide for simple and expeditious procedures for the grant of compulsory licenses and decisions of government use. If appealed by the patent owner, the execution of a compulsory licenses/government use should not be suspended. As indicated in the previous table, the rate of royalties should not exceed those generally applicable to commercial transactions; they can also be adjusted having the *per capita* GDP of a particular country into account.

III.3. Limitations of Paragraph 6 System

While, as mentioned the TRIPS Agreement allows countries some flexibilities in relation to patents that can be useful for ensuring access to medicines necessary for the treatment of diseases, including HIV/AIDS, the essential requirement for utilizing these flexibilities is the availability of a domestic industry capable of producing the required drugs. However, a critical impediment for many developing countries and LDCs is the lack of domestic pharmaceutical manufacturing capacity. The TRIPS Agreement allows compulsory licensing to supply predominantly the domestic market, which disentitles countries without a sufficient domestic manufacturing capacity to make use of a compulsory license.

In this context, paragraph 6 of the 2001 WTO Doha Declaration on TRIPS and Public Health recognized that countries with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement and instructed the TRIPS Council to find an expeditious solution to this problem and report to the General Council by the end of 2002.

Accordingly, the WTO General Council adopted a Decision on 30 August 2003 which established a system⁶ under which a country can issue a compulsory license for the purpose of exporting generic medicines to countries with insufficient or no manufacturing capacity, if such a country issues a notification specifying the name and quantity of the medicines needed, confirms its lack of manufacturing capacity, and the grant or intention to grant a compulsory license where the medicine is patented in its territory.

While the paragraph 6 system sought to facilitate the use of compulsory licenses for the purpose of exporting medicines to countries with insufficient pharmaceutical manufacturing capacity, the terms under which the system can be used has actually put in place obligations on importing countries that are more onerous than they are for countries that can use a compulsory license for the domestic market.

Therefore, while the paragraph 6 system has been celebrated as an important flexibility for developing countries and LDCs, in actual practice there has been a lack of willingness to use the system. This is largely due to the fact that the system is unnecessarily burdensome and complicated. Even in the Canada-Rwanda case, it took a long time to complete the requirements under the paragraph 6 system. Thus, the system has been less effective than it should have been. Therefore, it is important to examine the reasons behind the limited use of the system and also address systemic deficiencies.

Current Experience of Implementation of the Para 6 System

The experience suggests that there are hurdles within the Decision which make it difficult for countries with little or no manufacturing capacity to import a generic drug under a compulsory licence, and unattractive or well as difficult for generic manufacturers to export a drug under compulsory licence.

Limited number of countries adopted implementing legislation: To date, only a limited number of countries (Canada, Norway, China, India, Switzerland, Philippine, Singapore and the European Union, have adopted

⁶ The text of this Decision has been incorporated as article 31 *bis* of the TRIPS Agreement, subject however to its approval in accordance with WTO rules. So far (August 2011) only 34 members (including the European Union) have notified their approval of the amendment.

legislation to implement the August 30th Decision as an exporting country.

Limited use: Only one importing country (Rwanda) used the mechanism to import cheaper life-saving medicines (it means that 21 000 HIV/AIDS patients received the 3-FDC (AZT, 3TC, NVP) from the Canadian generic company Apotex.⁷

Notification: Under the terms of the Decision, a potential importing country must send a notification in writing to the WTO TRIPS Council, declaring its intention to import pharmaceutical products according to the provisions set out in the Decision. The notification must include the specific names and expected quantities of the product needed. Unless the importing country is classified as a least-developed country (LDC), it must also specify whether the product is under patent, and provide information that establishes that it lacks sufficient manufacturing capacity in the pharmaceutical sector to develop the drug being ordered.

No country has so far notified its intention to use the mechanism provided by the Decision.

Anti-diversion measures: The Decision imposes conditions for commercialization of the products made under the compulsory license. They must be clearly identified as being produced under the Decision through specific labelling; they should be specially packaged to be distinguishable from the branded product and its shape or colour, and the generic manufacturer must post specific information about the quantity of the product, its destination and distinguishing features. These measures are to ensure that the product will only be exported to the destination stated in the compulsory license.

Some key problems/hurdles of the mechanism

(1) Prior negotiation needed before a compulsory licence is granted

Before a generic company can apply to a government to issue a compulsory licence allowing the firm to begin exporting a drug under the August 30th Decision, the generic company has to engage in negotiations with the patent holder for a voluntary licence.⁸ Negotiations for a voluntary licence may be protracted and complex, and a source of considerable delays⁹. Prior negotiations act as a disincentive to generic manufacturers to participate in the process.

(2) The Decision comprises a succession of complex procedural steps

Let us assume a potential purchaser, under the terms of the Decision, has forecasted needs and identified a generic producer willing to participate in the process and fill the drug order, and the manufacturer has completed negotiations with the patent holder, and the terms for a voluntary licence have been rejected.

A first problem to overcome is that an offer for sale a patented product may be deemed an infringement of the patentee's exclusive rights (article 28 of the TRIPS Agreement). This may limit the participation in bidding procedures.

The generic firm must apply for a compulsory licence in its home country, from which the drugs will be exported and, unless the importing country has decided to make government use for non commercial purposes, the firm would also need to seek and obtain a compulsory license in the country where the pharmaceutical products are destined if they are under patent there. This requires considerable human and financial resources on the part of the generic firm, particularly when seeking to file a compulsory licence in the country of destination, where the generic may have no prior contacts or experience.

Each of these steps is time-consuming and holds no guarantee of success. The authorisation to export life-saving drugs can be delayed (if negotiations for a voluntary licence are prolonged), or even denied.

A compulsory licence for export can only be granted once the heavy procedural steps described have been completed successfully. It did not have to be this way; in fact the WTO chose to stay away from designing an

⁷ This product was already available from Indian generic companies.

⁸ For example, article 6.3 (b) and article 9 of the EC Regulation No. 816/2006 implementing the decision states that an applicant for a compulsory license has to produce evidence of efforts to have prior negotiations with the right-holder. See *Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems*, available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:157:0001:0007:EN:PDF>.

⁹ In order to avoid delays, the Canadian law provides, for instance, for a thirty days period of negotiations for a voluntary license with the patent holder, before filing an application for compulsory license. See Section 21.04 (3) (c) (i) of the Patent Act of Canada, available at <http://laws-lois.justice.gc.ca/eng/acts/P-4/page-10.html>.

automatic procedure which would have been possible under WTO law (based on article 30 of the TRIPS Agreement).

(3) Limited authorization

The August 30th mechanism is based on a drug-by-drug, country-by-country and case-by-case decision-making process. Indeed, the compulsory licence application must stipulate the destination and the quantity of drugs that are to be purchased and exported under the licence.

Drug needs must therefore be determined with precision beforehand. If medical needs increase, and more patients are included into a programme than forecasted in the compulsory licence application, the only way to purchase more drugs is to begin the process again, starting with the voluntary licence negotiations between brand and generic manufacturers detailed above. A stock-out due to the procedural hurdles may lead to the treatment being interrupted and as a consequence patients may develop increased drug resistance (as in case of HIV/AIDS), creating the need for more expensive treatment.

If, on the contrary, needs have been overestimated, and a quantity of drugs is unused, but are desperately needed in a third country, the entire process must also start again from scratch and the unused drugs may just remain stockpiled until they expire. Re-exportation of medicines imported under the system to another developing or least developed country in a similar situation is not permitted, unless there is a regional trade agreement between the two.

From a manufacturer's perspective, this means that the whole process must be undertaken each time it fills an order for a pharmaceutical product destined for export. This does not allow generic manufacturers to exploit economies of scale and creates a disincentive to produce and export medicines to meet the public health needs of third countries.

4) The patent holder can control the process

Even after the process for production and subsequent export of the medicines under the system has initiated, and the respective notifications are made, the patent holder can intervene to detain or stall the use of the system. For example, the patent holder may decide to offer the medicines at lower cost or for free, thus making it unnecessary to use the system in that particular case. This also creates a huge uncertainty and creates additional risk and disincentives for the manufacturer in the country of export.

Impact of Free Trade Agreements

Access to medicines, particularly HIV treatment programmes, are likely to be severely affected due to the onerous obligations imposed on developing countries under bilateral and regional trade agreements, including free trade agreements (FTA), economic partnership agreements (EPA) and bilateral investment treaties (BITs). The report of the UN Special Rapporteur on the Right to Health finds that TRIPS and FTAs have a negative impact on access to affordable medicines and recommends that developing countries do not adopt TRIPS-plus standards of IP protection¹⁰.

The EPAs and FTAs tend to include provisions on IP protection and enforcement that expand the standards under the TRIPS Agreement or introduce additional obligations that go beyond the TRIPS Agreement. Hence, the standards in the EPAs and FTAs can reduce significantly the ability of developing countries to make full use of the flexibilities contained in the TRIPS Agreement, which is a necessary safeguard for most developing countries to address public health challenges of ensuring availability of affordable medicines and medical devices.

The TRIPS-plus requirements under such agreements include the following:

¹⁰ "Developing countries and LDCs should not introduce TRIPS-plus standards in their national laws. Developed countries should not encourage developing countries and LDCs to enter into TRIPS-plus FTAs and should be mindful of actions which may infringe upon the right to health." See *Promotion and Protection of all Human Rights, Civil, Political, Economic, Social and Cultural Rights including the Right to Development: 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*, 11th sesión of the Human Rights Council of the United Nations General Assembly, A/HRC/11/12, 31 March 2009, paragraph 108, p.29, available at http://www2.ohchr.org/english/bodies/hrcouncil/docs/11session/A.HRC.11.12_en.pdf .

- 1) *Increasing the scope of patent protection* to new uses or to new forms of old medicines, which can vest an additional 20 year monopoly on existing medicines based on new therapeutic indications for known drugs or minor changes in drug formulation or process.
- 2) *Extending the term of the patent beyond 20 years* to compensate for delays in the examination of the patent application or in securing necessary marketing regulatory approval.
- 3) *Patent linkage* requirements that will prevent marketing approval of generic versions of a patented medicine¹¹.
- 4) *Data exclusivity* requirements that will prevent governments from relying on clinical trial data to register generic medicines even where there is no patent infringement.
- 5) *Enhanced scope of IP enforcement through, for instance, border measures* which will enable customs to seize generic medicines in situations of import, export or transit on suspicion of infringement of a patent.
- 6) *Requiring IP enforcement action* to be directed against manufacturers, suppliers, distributors of generic medicines as well as treatment providers.

In addition, investment chapters in such agreements or bilateral investment protection treaties (BITs) can define IPRs as a form of investment, and regulatory action on right holders may thus be challenged, under certain circumstances, as an act of expropriation of investment.

The potential negative impact of FTAs on developing countries was also recognized by some members of the US Congress. A 2007 report of the Government Accountability Office (GAO) states that FTAs with developing countries threaten their ability to take necessary public health measures and could significantly delay the availability of lower cost generic medicines.¹²

III.4. Making Full Use of the TRIPS Flexibilities to Foster a Domestic Pharmaceutical Industry

An important challenge for developing countries and LDCs in order to realize the objective of ensuring access to affordable medicines and treatment for diseases like HIV/AIDS is to develop a strong domestic pharmaceutical industry that can produce generic versions of medicines to meet the public health requirements of the country. Some of those countries have adopted policies to that end. For example, the East African Community (EAC) adopted a Regional Pharmaceutical Manufacturing Plan of Action (RPMPOA) 2011-16, which serves as a roadmap to guide the EAC towards evolving an efficient and effective pharmaceutical manufacturing industry to supply essential medicines to national, regional and international markets¹³.

The EAC also adopted a Regional Intellectual Property Policy and a Protocol on the Utilisation of Public Health Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation¹⁴. The Protocol seeks to provide guidance to the EAC Partner States on how their IP legislation should be adjusted to enable them to fully use the public health related TRIPS flexibilities, to restrict patentability of pharmaceutical products and medical devices in order to keep them in the public domain in order to promote a local pharmaceutical industry and ensure access to affordable medicines.

IV. Ensuring Sustainability of Pharmaceutical Industry in Developing Countries

In addition to promoting the growth a strong and effective domestic pharmaceutical industry, there is a critical need to ensure that the existing pharmaceutical capacity in the developing countries is sustained and

¹¹ The 'patent linkage' is typically imposed in FTAs with the USA.

¹² See United States Government Accountability Office (GAO), "United States Trade Policy Guidance on WTO Declaration on Access to Medicines May Need Clarification", Report to Congressional Requesters, Washington, D.C., 2007.

¹³ Press release of the East African Community on the meeting of the EAC Sectoral Council on Health where the EAC Regional Pharmaceutical Manufacturing Plan of Action (RPMPOA) was adopted, 1 April 2011, available at http://www.eac.int/health/index.php?option=com_content&view=article&id=136%3Aministers-of-health-meet-in-bujumbura&catid=33%3Apress-release&Itemid=42 .

¹⁴ See the EAC Regional Intellectual Property Policy, the Protocol on the Public Health Related WTO-TRIPS Flexibilities and the EAC Regional Pharmaceutical Manufacturing Plan of Action, available at http://www.eacgermany.org/index.php/documents-and-studies/cat_view/41-wto-trips .

strengthened. A crucial challenge in this context is the trend of takeover of generic pharmaceutical companies in developing countries, noticeably India, by multinational pharmaceutical companies. This is of particular concern in the context of HIV/AIDS, because the existence of a strong and sustainable generic industry in developing countries will be necessary to ensure availability of affordable generic forms of second-line HIV/AIDS treatment as increasing resistance grows to existing first-line treatment. It should be noted that the generic industry played a major role in supplying generic medicines for first line treatment which significantly brought down the prices for such medicines in developing countries . As domestic companies get taken over by MNCs, an important public health concern will be how to ensure similar availability of affordable second-line treatment. Governments in developing countries are concerned about this and there is a need to explore the role that governments can play to address such public policy concerns.

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15 United States

Individual(s)

TO: Global Commission on HIV and the Law

I thank the Global Commission on HIV and the Law for this opportunity to share my perspective on one of the Commission’s focus issues: HIV criminalization. As a practicing attorney involved in representing individuals with HIV and as an independent scholar of HIV law and policy issues for more than 25 years, I hope that my perspective on these issues will benefit the Commission’s important and timely mission.

My purpose in writing is not to provide an overview of HIV criminalization legal issues, which has been presented in many other publications, including my own. Instead, I want to point to several issues that I believe have been under-appreciated or overlooked by many advocates and organizations addressing this issue, but that are nevertheless important for effective advocacy.

My comments are intentionally brief and succinct, but if any point is unclear or if the Commission believes that a lengthier or more detailed discussion is appropriate, I would be pleased to respond as needed. Similarly, in the belief that Commission members are already very familiar with this subject and the literature addressing it, I have omitted extensive use of citations. But if the Commission deems it appropriate, I’d be happy to provide specific references to the statutes, cases, and secondary sources that are relevant to my discussion.

HIV criminalization efforts have been widely condemned by the HIV and human rights advocacy communities, and thus I take it as a given that the application of criminal laws to people with HIV does little if anything to deter knowing transmission of HIV via sexual contact, while at the same time enhancing the stigma of HIV and potentially frustrating prevention efforts that are based on confidentiality of health care information and confidence in health care and public health organizations. Moreover, specific prosecutions of individuals with HIV have resulted in unfair convictions - based on “expert” witness testimony that does not accurately reflect the state of our knowledge about HIV and how it is transmitted – or in disproportionately severe sentences compared with offenses involving similar risks of harm.

My focus here is on HIV criminalization in the United States, although many of the points will apply as well for laws and policies in other high income countries. Developments within the United States are also potentially influential on legal and policy trends and reforms where needed in other areas of the world.

The Nature and Extent of the HIV Criminalization Problem

Although many individuals with HIV have been prosecuted, convicted, and sentenced in the United States for crimes involving transmission or risk of transmission of HIV, we actually know very little about the nature and