

DRAFT PIECE FOR DISCUSSION

Recommendations for the ECOWAS in respect to access to medicine and genetic resources under the EPA Context

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I. Introduction

Following the ratification of the *Cotonou Agreement* in 2000, the EU started negotiations with six distinct groups of ACP countries aimed at the conclusion of new set of trade and development relations between the two groups of countries, and named Economic Partnership Agreements (EPAs). The *Cotonou Agreement* is modelled substantially on the 1999 South Africa-EU free trade agreement (TDCA)¹, contains a paramount feature of these new arrangements is that they are bound to be WTO-compliant with regards to GATT Article XXIV, in particular. These Agreements, whose negotiations are tentatively scheduled to be finalized in December 2007, cover a wide range of trade issues, mainly: market access, agriculture, trade in services, investments. The EPAs may also lead to significant changes in the area of intellectual property rights (IPR) as well.

I. Negotiations on the EPAs under the *Cotonou Agreement* and its implications on intellectual property

With the aim of finalizing its negotiations by December 2007, the EU is currently negotiating with six ACP country groups:

- CARIFORUM/CARICOM (Caribbean): the EPA negotiations with the EU commenced in April 2004; in this context, these countries have proposed some IPR provisions submitted to the EU, which issues a *Non-paper* in response. This joint negotiating text is under discussion;
- CEMAC (Central Africa): EPA negotiations with the EU commenced in October 2003; so far they have preliminary discussions on IPR, but no proposal tabled yet;
- ECOWAS (West Africa): EPA negotiations with the EU commenced in October 2003; joint IP reports drafted and a very recent proposal from the EU on April 2007;

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¹ Agreement on Trade, Development and Cooperation between the European Community and its Member States and the Republic of South Africa

- ESA (East Africa); the Pacific Forum: EPA negotiations with the EU commenced in February 2004; so far they have preliminary discussions on IPR, but no proposal tabled yet;
- SADC (Southern Africa): EPA negotiations with the EU commenced in July 2004; negotiations framework submitted, but no proposed IP provisions yet;
- Pacific Forum: EPA negotiations with the EU commenced in September 2004; draft EPA text submitted, but no proposed IP provisions in existence.

Apart from the Caribbean countries, ESA and recently the ECOWAS, no substantive talks in the area of IP is taking shape under the EPAs process, but the EU is strongly advocating the inclusion of substantive IP provisions in the negotiations framework. While the *Cotonou Agreement* (arts. 46.1, 46.2) did recognize the significance of appropriate protection of IPR for development, it made few demands on ACP countries and did not contain an obligation to accede to any international IPR agreements.

Together with granting freedom to ACP countries in this area, the *Cotonou Agreement* (art. 46.6) did establish an IPR cooperation framework between the Parties. Of the 79 ACP Members: (i) 55 are WTO Members and are under various stages of implementing the TRIPS Agreement; (ii) 47 are WIPO Patent Cooperation Treaty (PCT) Members; (iii) 16 are WIPO Copyright Treaty Members; (iv) 16 are WIPO Performances and Phonograms Treaty Members; (v) over 90% of ACP States have both a copyright office and an industrial property office that conducts patent examinations.

The cooperation framework laid down under the *Cotonou Agreement* extends to the following areas: (i) the preparation of laws and regulations for the protection and enforcement of intellectual property rights; (ii) the prevention of the abuse of such rights by rightholders and the infringement of such rights by competitors; and (iii) the establishment and reinforcement of domestic and regional offices and other agencies including support for regional intellectual property organisations involved in enforcement and protection of IP rights.

However, following new trend in the regional trade agreement "second generation", the EU has recently significantly strengthened its efforts in the international IP arena and the desire to put the protection of IPR at the core level in the ongoing EPA negotiations, sometimes even more stringent than those imposed by the TRIPS Agreement. The European Union has advanced three basic arguments to support its

calls for the inclusion of TRIPS-plus obligations in its EPAs with ACP States:

- The necessity to conform the currently non-reciprocal trade relationship between the Parties to WTO rules (GATT Art. XXIV, WTO Enabling Clause);
- The mandates included in Article 46 of the Cotonou Agreement; and
- The premise that strong IPR protection is conducive to the very promise of the *Cotonou Agreement*, i.e. the development *as an integral component of the new relationships among the two parties.*

But, it is interesting to note that the compatibility test set under the GATT Article XXIV, and which triggers the very EPAs process, does not include any IPR component. The parameters set for the conformity do only apply to trade in goods. Further, it should be noted that, even though there may be strong connections between the IPR and development, there are no empirical evidence that fully sustain such statement.

II. Elements on intellectual property rights in a regional context

IPR have always been a matter of national sovereignty and, as such, have been addressed under the national purview, since the inception in the nineteen century. With the globalization and the booming piracy activities, new trends emerged to tackle these issues on a wider context. In this regard, following the creation of the WTO, the then WIPO administered IPR agreements felt under the TRIPS Agreement.

A regional dimension is set forth under the TRIPS Article 4, d. This provision is setting rules for regional integration, parallel with the GATT Article XXIV and the GATS Article V. Article 4, d states that:

With regard to the protection of intellectual property, any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members. Exempted from this obligation are any advantage, favour, privilege or immunity accorded by a Member:

(d) deriving from international agreements related to the protection of intellectual property which entered into force prior to the entry into force of the WTO Agreement, provided that such agreements are notified to the Council for TRIPS and do not constitute an arbitrary or unjustifiable discrimination against nationals of other Members.

We may assert that the *Organisation Africaine pour la Propriete Intellectuelle* (OAPI)² may be the only regional entity enjoying this requirement on the regional dimension for the protection of the IPR. But the understanding and implementation of these derogatory provisions are from performed within the Member countries of this African regional organisation.

Thus, the regional economic communities (REC) can play a major role in interpreting the flexibilities offered by the TRIPS agreement, allowing neighbouring countries to work together and pool resources, even though they do not have to be in the same continent. So we have inter-regional approaches as well as intra-regional approaches. These schemes can either have an effect on enhancing competition through the improved availability and supply of products, or to have an effect on enhancing local production. Regional approach also entails coordinated efforts on the IPR administration both at the regional and national levels.

The *OAPI* comprises 16 African francophone countries³ and is one of the most advanced regional integration in the area of the IPR. The Member countries enjoy the same law, patent office, judicial process and have made their countries operating under a single territory. The *ARIPO*⁴ is mainly directed to African Anglophone countries⁵ and is more a common secretariat than a real tentative to adopt substantive IPR schemes. With potential members up to 14 other African countries⁶, the ARIPO is a wide regional entity aimed at the promotion of the IPR in Africa. The total territorial coverage of the two RECs equals to 46 countries of the 53 African countries. This is a huge potential to develop.

Same attempts do exist among either other developing countries and/or with developed countries. In this respect, there are legal and economic considerations that would need to be taken into account in considering a regional approach. It is equally important to strike a delicate balance between a regional patent scheme and the powers granted to national authorities. IPR need to be understood by member

² <http://www.oapi.wipo.net/fr/index.html>

³ Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Congo (Republic of), Côte d'Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea-Bissau, Mali, Mauritania, Niger, Senegal, Togo.

⁴ www.aripo.org

⁵ Botswana, the Gambia, Ghana, Kenya, Lesotho, Malawi, Mozambique, Namibia, Sierra Leone, Somalia, Sudan, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe (Total: 16 Member States).

⁶ Angola, Algeria, Burundi, Egypt, Eritrea, Ethiopia, Liberia, Libya, Mauritius, Nigeria, Rwanda, Seychelles, South Africa and Tunisia.

states of RECs but more importantly there needs to be political will and political leadership to ensure that regional approaches can be pursued.

III. Implications of the EPAs on intellectual property rights

Article 46 of the *Cotonou Agreement* states that:

- 1. Without prejudice to the positions of the Parties in multilateral negotiations, the Parties recognise the need to ensure an adequate and effective level of protection of intellectual, industrial and commercial property rights, and other rights covered by TRIPS including protection of geographical indications, in line with the international standards with a view to reducing distortions and impediments to bilateral trade.*
- 2. They underline the importance, in this context, of adherence to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to the WTO Agreement and the Convention on Biological Diversity (CBD).*
- 3. They also agree on the need to accede to all relevant international conventions on intellectual, industrial and commercial property as referred to in Part I of the TRIPS Agreement, in line with their level of development.*
- 4. The Community, its Member States and the ACP States may consider the conclusion of agreements aimed at protecting trademarks and geographical indications for products of particular interest of either Party.*
- 5. For the purpose of this Agreement, intellectual property includes in particular copyright, including the copyright on computer programmes, and neighbouring rights, including artistic designs, and industrial property which includes utility models, patents including patents for bio-technological inventions and plant varieties or other effective sui generis systems, industrial designs, geographical indications including appellations of origin, trademarks for goods or services, topographies of integrated circuits as well as the legal protection of data bases and the protection against unfair competition as referred to in Article 10a of the Paris Convention for the Protection of Industrial Property and protection of undisclosed confidential information on know how.*
- 6. The Parties further agree to strengthen their cooperation in this field. Upon request and on mutually agreed terms and conditions cooperation shall inter alia extend to the following areas: the preparation of laws and regulations for the protection and enforcement of intellectual property rights, the prevention of the abuse of such rights by right holders and the infringement of such rights by competitors, the establishment and reinforcement of domestic and regional offices and other agencies including support for regional intellectual property organisations involved in enforcement and protection, including the training of personnel.*

1) Implications of the EPAs on intellectual property rights in the context of the access to medicines

Once the TRIPS Agreement started being implemented in national legislations, its effect on access to medicines (ATM) became an issue that has generated increasing concern around the world. Even in the United States of America, probably the country that had to introduce fewest changes in its laws, the implementation of the agreement had a high social cost for extending the patent term from 17 years from the granting of a patent to 20 years from its filing. According to a study, this extension would "result in a cost of more than \$6 billion to American consumers⁷." If this was the cost paid in the US, one can only imagine what it was and will be in other nations where the adjustment to the TRIPS Agreement had entailed the introduction of more comprehensive changes, particularly in those where pharmaceuticals have been previously excluded from patent protection. In this regard, the Brazilian experience illustrates the scope and nature of the implications⁸.

Another implication is the pooled procurement initiatives, maimed at decreasing the prices of medicines and at improving the quality and availability resulting from improved access to information. There are four pooled procurement/regional cooperation models: (i) informed buying, where member countries share information about prices and suppliers but procure individually; (ii) coordinated informed buying, where member countries undertake joint market research, share supplier performance information and monitor prices but they continue to procure individually; (iii) group contracting, where, member countries jointly negotiate prices and select suppliers and agree to buy from the selected suppliers although each country eventually purchases individually; (iv) central contracting, where member countries jointly conduct tendering through an organization acting on their behalf and a central purchasing agency manages the purchases on behalf of all the member countries. National initiatives such as in Thailand and regional schemes such as in the Caribbean (*Eastern Caribbean Drug Service*) are yielding satisfactory results, up to a 44% price reduction in the cost of their pharmaceutical products.

The most prominent implication of the IPR on the ATM relates to the adoption, in 2001, at the fourth WTO Ministerial Conference, of *the*

⁷ S. Schondelmeyer, "Economic Impact of GATT Patent Extension on Currently Marketed Drugs", PRIME Institute, University of Minnesota, March 1995.

⁸ The Pharmaceutical Industry-Brazil – Author: Tereza Mendonca and Approving Officer: Americo Tadeu – US Foreign Commercial Service and US Department of State - 1999

Doha Declaration on TRIPS Agreement and the Public Health. The main features of the text and its subsequent decisions, in 2002 and 2003⁹, extend to the following: an extension of the transition period granted to the LDCs to waive the implementation of the patents on pharmaceutical products; the setting of the regional approach to improve the ATM; a commitment to fostering the transfer of technology to the developing countries, in particular to the LDCs.

In this context, the OAPI country members have drafted a capacity-building project aimed at utilising the flexibilities recognised to developing countries and LDCs to improve the ATM, through increasing imports and production of pharmaceutical products on a regional basis in the OAPI Zone.

The Decision of the TRIPS Council of 30 August 2003 aims to help countries with insufficient or no manufacturing capacities in the pharmaceutical sector to import needed products and, if possible, to enhance the production of generic versions of patented products for the treatment of diseases mentioned in the Decision. The flexibility offered by this Decision is only extended to countries belonging to regional economic groups with the majority of members being least-developed countries (LDCs).

The capacity-building project aims to assessing the necessary legal and institutional framework for countries with insufficient manufacturing capacities. Furthermore, it will examine appropriate ways for the implementation of a capacity-building programme for pharmaceutical products manufacturing on a regional basis, so as to duly respond to the drugs needs in the fight against diseases in the OAPI region.

OAPI has a double advantage: it meets the relevant WTO criteria and so far constitutes a good and unique example of complete regional integration in the field of intellectual property. The following lines show the membership of OAPI states in some RTAs:

- eight OAPI member states are also members of the West African Economic and Monetary Union (WAEMU), which has been duly notified as a RTA to the WTO (February 2000): Benin, Burkina Faso, Côte d'Ivoire, Guinea-Bissau, Mali, Niger, Senegal and Togo;
- six OAPI member states are also members of the Central African Economic and Monetary Community (CAEMC), which is also a RTA, duly notified to the WTO (September 2000): Cameroon, Central

⁹ WTO document entitled "Implementation of Paragraph 6 of Doha Declaration on TRIPS and Public Health", WT/L/540, dated 2 September, 2003

African Republic, Chad, Democratic Republic of Congo, Equatorial Guinea, and Gabon;

- Guinea is member of the Economic Community of West African States (ECOWAS);
- Mauritania is member of the Arab Maghreb Union.

The ECOWAS and the Arab Maghreb Union do not appear in the list of RTAs notified to the WTO¹⁰, but the ECOWAS meets the conditions defined by the WTO on the eligibility of RTAs to use the mechanism of paragraph 6, i.e. to comply with the definition of GATT Article XXIV and the provisions of the Enabling Clause¹¹, and to have LDCs constitute more than half of the RTA's membership.

Regardless of the approach pursued, the initiative will have to be taken under the aegis of the OAPI, which offers the double advantage of ensuring and enhancing the international visibility of the organization as well as the effectiveness and the maximization of the advantages expected from the implementation of the WTO Decision.

2) Implications of the EPAs on intellectual property rights in the context of the genetic resources

For the ACP countries, the objectives are to protect the local productions, in particular the food products and their exports as well. In this regard, the issue of protecting the geographical indications (GIs) through an extended system of notification and registry is also important.

As well, the traditional knowledge (TK) and the biodiversity are integral part of the resources to protect and to develop in a sustainable manner. Traditional knowledge is a knowledge that is not 'modern', held either individually or collectively, that cannot easily be protected under existing IPR laws and treaties. TK is to be protected in order to ensure acknowledgment of its use (prior consent) thus triggering benefit sharing. In this regard, the CBD (Article 8,j) allows for ensuring protection of TK on its commercial and non-commercial uses.

TK and inventions of local communities should be protected under appropriate regimes, on the understanding that the TRIPS Agreement provides only minimum standards and does not prevent Members from adopting additional areas of protection. In this regard, it is important to develop mechanisms for ensuring equity in relation to the

¹⁰ http://www.wto.org/english/tratop_e/region_e/

¹¹ See Decision dated 1979, on Decision on Differential and More Favourable Treatment, Reciprocity and Fuller Participation of Developing Countries, L/4903

use of traditional knowledge through appropriate international arrangements and mechanisms to supplement domestic laws and measures in this regard.

An important issue in the genetic resource relates to the plant varieties protection, i.e. the protection of knowledge related to plant varieties by breeders and farmers. In the IPR context, it refers to the rights granted to commercial plant breeders as framed under the *International Convention for the Protection of New Varieties of Plants* (UPOV), 1978/1991. What are farmers' rights? Under a narrow conception, it refers to the recognition of farmers' contribution to the conservation and development of plant genetic resources through rights to save, use, exchange and sell farm-saved seeds and plants. Under a broader conception, it deals with the protection of traditional knowledge relevant to plant genetic resources through benefit sharing and participatory rights.

Apart from the UPOV Treaty, these issues are in the TRIPS Agreement Article 27(3)b. Are also relevant the Convention on Biological Diversity (CBD) and the International Treaty on Plant Genetic Resources for Food and Agriculture, adopted by the FAO members in 2001. Both the TRIPS Agreement and the CBD should be implemented in a mutually supportive and consistent manner. In this regard, Members retain the right to require, within their domestic laws, the disclosure of sources of any biological material that constitutes some input in the inventions claimed. On 8 March 2005, in a landmark decision, the European Patent Office upheld a decision to revoke in its entirety a patent on a fungicidal product derived from seeds of the *Neem*, a tree indigenous to the Indian subcontinent. This case exemplified how international law was being misused to transfer biological wealth from the South into the hands of a few corporations, scientists, and countries of the North. The proponents were able to establish that TK systems can be a means of establishing "prior art" and thus used to destroy the claims of "novelty" and "inventiveness" in these bio piracy patents. It must be further developed and transposed into overall international legal frameworks so that this type of theft is no longer possible.

Within the African context, two instruments are attempting to set forth regional dimension on the genetic resources: the Model Law, adopted by the African Heads of States and Governments in Lusaka (Zambia), in 2001. It aims at providing a common framework for the drafting of legislations on biodiversity, genetic resources and on the ways and means to reap the full benefits from these resources. The Model Law is in stark contrast to the TRIPS Agreement Article 27,3,b and to the UPOV provisions. But, this draft does not enjoy wide support from

African countries. Some did join the UPOV Treaty; others did not ratify the text and its legal status is still on hold.

The second legal instrument in Africa is the Revised Bangui Agreement from the OAPI member countries, through the Draft Annex X. This document deals with the genetic resources and is strongly duplicating the UPOV provisions, contrary to the majority of the developing and the African countries. These systemic and institutional shortcomings strongly impede the adoption of a unified position in Africa on the contours of legislation on the genetic resources.

IV. Recommendations

1) From a general perspective: to foster the development of the ACP countries

Given the level of economic development in ACP countries, it is an open question whether the EU-ACP economic partnership negotiations should include a chapter on substantive IP obligations at all. If the answer is in the affirmative, the next issue is the scope and depth of such negotiations. To facilitate a development-supportive outcome of the EPA negotiations for ACP countries, it is thus crucial for civil society to step up its advocacy and raise awareness in the countries presently negotiating the EPAs.

Another element in having an IPR component in the EPAs should relate to the research and development (R&D), especially to deal with the neglected diseases and to foster the transfer of technology to the ACP countries. Pursuant to this, the issue of subsidies should be carefully examined and some GATT provisions may be of use to provide a legal basis for such funding programs.

2) Recommendations from a negotiating perspective

The recommendations that follow represent the best case scenario for making full use of TRIPS flexibilities by ACP countries. The recommendations should inform both independent revisions of national legislation, as well as the EU-ACP EPA negotiations. Many of these recommendations reflect an emerging consensus by scholars and some policymakers regarding strategies for balancing the international IP system in a manner that is more conducive to stimulating innovation, promoting competition and making technology and information more readily accessible by developing countries. Before proceeding, it should be noted that the 24 ACP countries that are not WTO Member States are not subject to the same TRIPS

restrictions as WTO Member ACP States and therefore should have, as of present, greater leeway to adapt their IP policies to address their own needs.

Four categories of proposals may be put on the negotiating table.

i. The "Green Box": provisions that may be included in the EPAs without further negative impact

- Incorporation in the EPAs of all the flexibilities from the TRIPS Agreement under the Doha Declaration and its subsequent decisions, in particular: the transitional period until 2013 to implement the TRIPS obligations; the transitional period till 1 January 2016 to implement TRIPS provisions for patents & trade secrets protection of pharmaceutical products; the capacity-building for the production or importation;
- Incorporation of the relevant flexibilities in the domestic legislations: in order to be in a legal position to use these provisions, the developing countries and the LDCs are required to draft changes to their respective legislations (document IP / C / W / 363 / Add.1 23 July 2002);
- Adopt and Expand Compulsory Licensing Terms: countries should make full use of TRIPS terms by specifying broad grounds for compulsory licenses, in both the copyright and patent arenas. For patents, for example, the grounds for the granting of a compulsory license should include: failure to exploit, anti-competitive practices, dependent patents, and public interest. It is important that countries specify that compulsory licensing "in the public interest" is not just for national emergencies (and cases of "extreme urgency") but may also apply to situations where it is necessary to protect health, nutrition, or the environment.;
- Adopt International Exhaustion: the TRIPS Agreement Article 6 gives to Member countries of the WTO the liberty to set forth their own regime of IPR exhaustion system. In an international exhaustion regime, drugs legally sold in one country can be resold and exported into others. This promotes price competition, and enables access to medicine at lower cost. ACP States should provide for international exhaustion in order to facilitate parallel imports and take full advantage of this Doha flexibility;
- Limit Test Data Protection to the TRIPS Minimum: Adopt legislative language that would authorize later applicants to rely on previously submitted regulatory data.

Legislation should refer to information to be protected only as “undisclosed information;” the language used by TRIPS, so as not to require protection of information that has become public. Reject negotiation terms that would require data exclusivity beyond patent expiry. Adopt a strict definition of novelty for “new chemical entities.” This will prohibit patenting of inventions that have been made available to the public abroad;

- Adopt a Narrow Definition of Industrial Applicability: This suggestion should not pose a challenge for EU negotiations, since the EU also employs a narrow definition of industrial applicability. However it is important to amend legislation in anticipation of later negotiations with the US, which will likely push to define industrial applicability according to its own standard of utility, thereby opening up business methods and certain types of research tools to patentability;
- Implement the provisions of the TRIPS Agreement Article 70,8, (mailbox) and of the TRIPS Agreement Article 70,9 on the exclusive marketing rights (EMR);
- Implement the provisions of TRIPS Agreement Article 66,2 on the transfer of technology to the LDCs and, on a wider context, to foster productive capacities in the pharmaceutical sector;
- Restrict Patentability of Biological Organisms: the legislation should prohibit patents on plant and animal varieties, and on essentially biological processes;
- Require Disclosure of Origin of Biological Resources and Traditional Knowledge: Many, if not most, ACP States are nations with a high level of marine and terrestrial biodiversity. Therefore it is in their interest to require the disclosure of the source and the country of origin of biological resources (and/or traditional knowledge) used in an invention. As South Centre has noted, such a provision would “enable tracking of biological resources, improve the quality of patents, prevent misappropriation and ensure benefit sharing with local and traditional communities”¹²
- Adopt Broad Use Exceptions: the legislation should incorporate an experimental use exception, as well as an early working (Bolar) exception to allow the “use without the authorization of the patent owner shall also be

¹² South Centre, Development and Intellectual Property Under the EPA Negotiations, Policy Brief 6, 3 (March 2007), *available at* http://www.southcentre.org/info/policybrief/06Dev_IP_EPA_Negotiations.pdf

permitted . . . when the use of the invention is solely for purposes reasonably related to the development and submission of information required under any country that regulates the manufacture, construction, use or sale of any product;"¹³

- Prohibit New Use/Second Use Patents: applying for a "new use" (or "second use") of an already patented compound is one way that pharmaceutical companies extend their monopoly rights for a product beyond the natural patent term (a strategy known as "evergreening"). Prohibiting this category of patents will facilitate faster production of essential medicines and other generics;
- Adopt a *Sui Generis* plant protection regime: since TRIPS Agreement Article 27.3(b) requires only that Members adopt a *sui generis* system for the protection of plant varieties, all ACP States should resist EU pressures to join UPOV. ACP countries can look to India or Thailand for examples of workable *sui generis* alternatives to UPOV. In this regard, ACP States should reserve the right, not allowed under later UPOV Conventions, to determine which plants qualify for protection. This will best enable each country to adapt its policies to its own development needs. Legislation should allow for seed saving and seed exchange, prohibit double protection (by PVP and patent), allow for a breeder's exemption and provide different duration of protection for different categories of innovation (i.e., longer terms for long-generation plants such as trees, and shorter terms for shorter generation plants such as perennials);
- Technical assistance and capacity-building, training and human resource development.

ii. The "Blue Box": provisions that need further clarifications and assessment before inclusion in the EPAs

- Data Protection: there is an extremely dangerous trend with regards to this issue. Contrary to TRIPS Agreement Article 39.3, many countries are being pressured to establish a specific period of data protection of at least five years.
- Adopt a narrow definition for industrial application: EU countries have already adopted such definition, so this will likely not create any difficulties during EPA negotiations.

¹³ James Love, Draft Model Law for Use of Patent without Authorization of the Patent Owner, available at <http://www.cptech.org/ip/health/cl/model-cl-leg.html>.

Also, it is important for ACP countries to establish a position on this issue before negotiating free trade agreements with other countries.

- Adopt *Sui generis* terms that will enable farmers to save and exchange seed: If EU negotiators push for UPOV terms, aim for terms of the 1978 Act rather than the more restrictive 1991 Act. These terms are important to protect food security and the livelihood of subsistence farmers.
- Non-violation complaints: to refuse the use of such provisions and to wait until the WTO further clarifies the debate.

iii. The "Yellow Box": the "Neglected Provisions"

The provisions that some countries would like to see included in new trade agreements are as important as those that are simply missing. Many governments from developing countries do not have the necessary resources to engage in trade negotiations with a pro-active IPR agenda, with specific provisions that they would like to include in the final text. More often than not, the negotiations are based on the texts submitted by developed countries.

In addition, trade negotiations generally include other chapters besides intellectual property and, unaware of the risks posed by the "TRIPS Plus" provisions and anxious to obtain greater access to other markets for agricultural or other products, countries are often willing to grant concessions on intellectual property that over time may prove to be very costly both for its population and for the future development of the country.

Some of the neglected provisions that governments should want to include are:

- Establishment of provisions to prevent and sanction possible misuse of patent rights by patent holders;
- Establishment of strong sanctions to those companies that attempt to delay generic competition beyond the twenty-year patent term;
- Incorporation of mechanisms to prevent "evergreen patents", small additions or new uses being attached to the drug to extend its patent life;
- Imposition of sanctions for those companies that initiate frivolous litigations with the only purpose of extending their monopolies;
- Establishment of specific mechanisms to ensure the transfer of technology;

- In the case of an unjustifiable delay in the approval of a medicine under patent, the government should compensate the patent owner for the damages that such delay may have caused. There is no need to extend the patent, as this will just hurt consumers and generic companies that were not responsible for the delay. It is quite possible that if the government is the one that has to make the compensations, it will incur in less delays.

iv. The "Red Box": provisions that may not be included in the EPAs

Recommendations: Countries should not negotiate further IP agreements related to pharmaceuticals, until there is real data to assess the consequences of these agreements with respect to access to affordable medicines, transfer of technology and the alleged benefits that such protection would provide.

Conclusion

The protection of IP in regional economic agreements has become a key feature of strategies by developed country firms to protect their intangible assets as markets become more open and liberalized. Although IP protection is an important incentive for private investments in innovation and new technological products, the unbalanced protection of IP can lead to anti-competitive behavior and produce adverse effects on efforts of developing and least-developed countries to promote economic growth and establish sound development policies. ACP countries have an opportunity during these negotiations to carefully examine and determine how IP protection can best be adapted to advance important development goals such as public health and education, while also promoting an environment in which local firms can benefit from and effectively participate in the global market along side foreign counterparts.

The IP chapter of the EPAs must acknowledge the overriding development concerns of ACP countries and be negotiated in manner that allows these countries and regions to advance their domestic industries, enhance the competitive environment and facilitate effective access and dissemination of technology and other knowledge products without which development efforts will surely be hindered in the long term.

Clearly Africa is not deriving maximum benefits from the TRIPS agreement. Figures available indicate that payment of royalties, licenses, and fees for the use of Africa's intangible assets has been on

the decline. Africa's share of total world payments for royalties slumped from 2.9 percent in 1980 to 0.22 percent in 1995¹⁴.

Finally, it is essential to recognize that the protection of intellectual property goes far beyond the interests of the pharmaceutical industry. All economic sectors are affected by intellectual property protections – from high-tech and communications, to manufacturing and engineering to agriculture and media and entertainment.

¹⁴ Trade Related Intellectual Property Rights (TRIPS) a Sell Out, By Amos Safo, 2002