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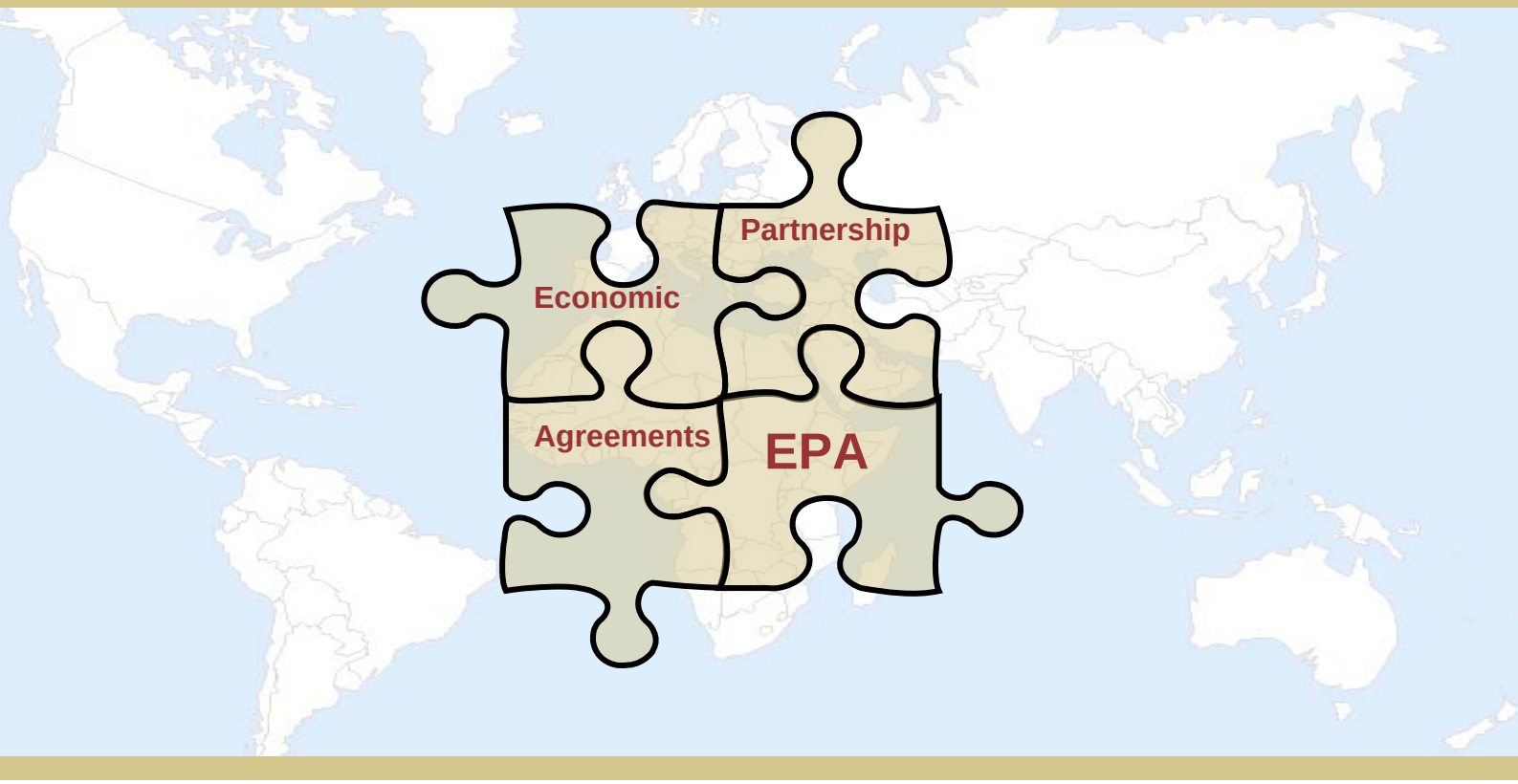

Ensuring Development Friendly Economic Partnership Agreements (EPAs)

The TRIPS agenda: Access to Knowledge and Technology

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Ensuring Development Friendly Economic Partnership Agreements –
The TRIPS Agenda: Access to Knowledge and Technology

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List of Abbreviations

ACP	Africa, Carribean, and Pacific States
AIDS	Acquired Immune Deficiency Syndrome
CARIFORUM	Carribean Forum of ACP
EC	European Commission
EU	European Union
EPA	Economic Partnership Agreement
FTA	Free Trade Agreement
G8	Group of Eight
GATT	General Agreement on Tariffs and Trade
GMP	Good Manufacturing Practices
HIV	Human Immunodeficiency Virus
IPR	Intellectual Property Rights
LDC	Least Developed Country
PC	Personal Computer
SACU	Southern African Customs Union
TRIPS	Trade-related Intellectual Property Rights
UPOV	Union for the Protection of New Varieties of Plants
USA	United States of America
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

1 Introduction

Economic Partnership Agreements (EPAs) are going to replace the preferential trade chapters under the Cotonou Agreement. They are intended to be “broad agreements, helping build regional markets and diversify economies in the ACP regions” (EC 2006).

Today, the multilateral trade agenda covers more than traditional trade liberalization that reduced barriers at the borders only. WTO-members have decided to develop the “shallow integration” of the former GATT into a form of “deep integration” by including regulatory policies traditionally falling under national states’ sole authority. Among other issues, the multilateral trade regime regulated trade-related intellectual property rights (TRIPS) from 1995 onwards.

The TRIPS agreement strengthens the rights of technology owners which predominantly come from industrialized countries. Developing countries – particularly LDCs – are basically users of knowledge and technology generated in industrialized countries. All other things equal, the TRIPS agreement leads to higher prices for technology and in this sense increases the barriers for LDCs to access new technology.

In order to effectively diversify the economies of ACP countries, these countries need lower access barriers to knowledge and technology. Hence, the bottom line for a development-friendly EPA should be that any protection of intellectual property shall not exceed the commitments of the TRIPS agreement. This holds particularly, but not exclusively, for the health sector (patents for medicines). At the same time, the EPAs provide the option to positively influence technology creation in EPA countries by parallel measures. In this respect, the EC should go further than the commitments under the WTO to foster technology transfer to LDCs (Art. 66 and 67 TRIPS) which suffer from not being operationalized in the multilateral framework.

2 Background: The economics of intellectual property protection

Intellectual property rights (IPRs) confer exclusive rights to innovators and creators. Owners of intellectual property are allowed to prevent others from using and selling the protected knowledge, art work, good or technology for a certain period of time.

One should regard IPRs as an instrument of public policy that regulates the conditions of competition among knowledge bearers. Economically speaking, knowledge has the characteristics of a public good: First, its use is non-rival, i.e. an additional user does not preclude others to use the same knowledge. Second, frequently it is not possible to exclude

additional users from using the knowledge. The first condition implies that as many people as possible should use the knowledge in order to maximize global welfare. However, the second condition leads to the problem that innovators cannot appropriate an innovation rent so that there is no incentive to invest in the creation of knowledge and technology. This could hamper technological progress and economic growth – important preconditions for development.

National states in industrialized countries employ IPRs as a second-best instrument to balance two public policy goals: In one regard, IPRs confer temporary monopoly rights to innovators which allow them to appropriate an innovation rent in order to spur technological progress. On the other hand, however, public policy wants to ensure the quick dissemination of knowledge. Therefore the rights are limited in duration and incentives are set to trade the knowledge as smooth as possible. For example, IPRs require that the inventor publishes the knowledge in exchange for the rights so that the knowledge remains in the public domain after the termination of the exclusive rights. Moreover, IPRs facilitate the creation of a market for knowledge since the inventor has an interest to sell his knowledge.

However, there are alternative ways to foster technological progress by public policy. Two of the most important ones are publicly financed research activities and prizes that are paid in case of successfully creating a desired technology or good. Compared to IPRs, public research prevents the static welfare costs while possibly suffering from X-inefficiency since there are no market mechanisms at work. It is widely used for basic research all over the world. Prizes, on the other hand, employ a patents-like market mechanism and are welfare-maximising in cases where the innovation causes external benefits and where the benefits can be calculated quite easily in advance (see the example of drugs for neglected diseases further below). IPRs, finally, have their strengths in areas where the benefits are not known and where a “market test” is socially well accepted. At least in Western societies, the notion is deeply grounded that users of – say – PC games should pay for the innovation costs themselves instead of requesting the state to subsidize the knowledge creation.

Traditionally, it has fallen under the competence of national states to confer IPRs according to their laws (and according to the internal political power constellations leading to those laws). While there have been important international conventions to coordinate national states’ efforts to protect intellectual property, national states reserved a large discretionary freedom to adapt IPR-laws to the conditions in the country.[1] Generally speaking, the protection of intellectual property has been stronger the richer the country has been and the further advanced its technological capacities have been. This reflects the welfare maximizing strategy of national states, which recommends stronger IPRs only if inhabitants of the own country can appropriate large innovation rents. If this is not the case (due to insufficient

[1] Many industrialized countries, even Germany and Switzerland, have for example excluded pharmaceutical patents from its patent laws until the 1960s and 1970s.

technological capacities), strengthening IPRs leads to a rent transfer into foreign countries and thus to a welfare reduction in the own country.

This is basically what happens by the TRIPS agreement from a developing country point of view. The agreement leads to a significant strengthening of IPRs in developing countries which in most cases do not have the technological capacities to benefit from higher innovation rents within their boundaries. TRIPS causes a large rent transfer from developing countries to industrialized countries by preventing free-rider behaviour of developing countries. In the short and medium term, most developing countries lose welfare compared to a situation without strong intellectual property protection since they now have to pay (more) for gaining access to existing knowledge and technology. Moreover, countries with no (sufficient) technological base will hardly benefit from technology transfer via foreign direct investment or licensing agreements. This is not to say that there are no sensible forms of intellectual property protection even in developing countries, for example copyright protection to foster local music industries. Other examples might be some form of plant variety protection, utility models (petty patents) as an incentive for incremental innovations or trademarks. However, the level of IPR protection should be adapted to the circumstances of the country and its technological capacities.

According to all available estimates, the TRIPS agreement is useless and harmful for Least Developed Countries.[2] These countries will hardly have any capacities to generate innovative knowledge and technology which is suitable for intellectual property protection. At the same time, their markets are not economically attractive for innovators from industrialized countries so that IPRs will not work as an incentive device for the creation of new knowledge (for example for drugs against neglected diseases). Put simply: IPRs will not help LDCs to create new knowledge while at the same time making it more difficult for them to access existing knowledge. Any further strengthening of IPRs is not in the current interest of LDCs and comparable countries.

Since the completion of the Uruguay-Round and the subsequent implementation of the TRIPS Agreement, industrialized countries have frequently tried to further tighten the rules for intellectual property protection in developing countries. It is important to note that – although the TRIPS agreement significantly strengthens IPRs in developing countries – TRIPS does not lead to a complete harmonization of IPR standards around the world. The agreement provides Members with (limited) flexibilities to adapt the standards and procedures to their respective needs. Thus, Members can be more or less creative when transforming TRIPS into national law. This policy space reflects the need for industrialized countries to make at least some concessions in multilateral negotiations. Industrialized countries should not force developing countries in bilateral or regional negotiations to go beyond TRIPS standards of IPR protection.

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2 See for example Liebig (2007) and Maskus (2000).

3 Regulation on intellectual property protection in free trade and economic integration agreements

3.1 WTO regulation: The TRIPS agreement

The TRIPS agreement constitutes the single most important international agreement strengthening the protection of intellectual property rights. It encompasses all relevant instruments of intellectual property protection and provides for high levels of protection across economic sectors. Moreover, the agreement extends the two important WTO principles of national treatment and most-favored nation to the protection of IPRs. Articles 7 and 8 constitute the base to interpret the TRIPS agreement and its successive provisions. The articles show that the TRIPS agreement is meant to strike a balance between differing objectives and interests.

> Article 7 (Objectives)
>
> *The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.*
>
> Article 8 (Principles)
>
> *1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.*
>
> *2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.*

The TRIPS agreement contains several flexibilities in order to allow Members a form of implementation suitable to their economic and social needs.[3] Apart from these specific flexibilities, for developing countries the transitional arrangements have been of great importance (Article 65). Developing countries were given additional time until 2000 or – in areas of technology where they did not previously grant IPR protection – until 2005. These transition periods mainly recognized that a certain amount of time was needed to implement

[3] Some of them are particularly important with regard to protect public health and will be discussed further below.

the provisions of the TRIPS agreement. LDCs have been singled out of the group of developing countries and conferred special and differential treatment (Article 66):

> Article 66 (Least-Developed Country Members)
>
> *1. In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members 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. The Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period.*
>
> *2. Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base.*

In October 2005, Zambia, on behalf of the LDCs, presented a request to the TRIPS Council for 15 additional years of the transition period. In November 2007, the Council for TRIPS finally extended the deadline to 1 July 2013, i.e. another seven and a half years.

It is important to note that the reasoning for the transition period is different for developing countries and LDCs. “Although financial and administrative constraints for the implementation of the TRIPS agreement are a component of the rationale for Article 66.1, the particular requirements of LDCs and their need for flexibility to create a viable technological base clearly constitute the central objective of the provision. Art. 66.1 aims to provide LDCs not merely with time to comply, but with time to develop their national policies and economies to ensure that the eventual application of the intellectual property protection provided for by the TRIPS agreement will promote rather than undermine their social, economic, and environmental well-being.” (South Centre / CIEL 2006:2).

In this context Article 66.2 has to be read as a strong, though not operationalized commitment by industrialized countries to support these policies by promoting technology transfer to LDCs. To date, industrialized countries have not yet fulfilled this commitment, leading to frequent complaints by LDCs.

3.2 US free trade agreements

The USA have been particularly active in using bilateral and regional free trade agreements to negotiate higher standards of intellectual property protection in developing countries. These so-called “TRIPS-plus” rules partly differ in the respective trade agreements but do all increase the level of protection over and above the TRIPS provisions. There are two ways to achieve this objective: either by imposing higher or new substantive protection standards (e.g. longer protection periods) or by further restricting the flexibilities that the TRIPS

agreement leaves Member countries to implement the agreement. The second point is of prime importance to the health sector, where TRIPS-plus rules have been widely criticized as being against the spirit of the Doha Declaration. Oxfam (2006) gathered the following list of TRIPS-plus rules in US free trade agreements which relate to public health:

- "Expanding the scope of pharmaceutical patents, including to new indications (new therapeutic uses of existing medicines) and formulations,
- Enhancing protections for clinical trial data by providing at least five years of marketing exclusivity for the data (known as data exclusivity)
- Limiting the grounds for issuing compulsory licenses to emergencies, government non-commercial use, and competition cases,
- Barring parallel trade of patented medicines sold more cheaply elsewhere,
- Extending patent monopolies for administrative delays by patent offices and drug regulatory authorities,
- Linking drug registration to patent status, thereby preventing registration and sale of generics during the patent term,
- Enforcing patent violations and granting pharmaceutical companies investor-based rights to sue, including for improvidently granted compulsory licenses,
- Prohibiting pre-grant patent oppositions, and making it more difficult to revoke invalid patents."

Free trade agreements of the USA include TRIPS-plus rules in other economic sectors as well: Copyright protection is further strengthened by prolonging the term of copyright protection or by giving copyright holders the right to block parallel imports. Frequently the USA has pressed to limit the exceptions for the patentability of genetic resources. More generally, provisions to enforce IPRs that go beyond TRIPS commitments have been included in the agreements (Fink / Reichenmiller 2005; Vivas-Eugui 2003).

The example of the only US-FTA involving Sub-Saharan Africa is a case in point: starting in 2003, the USA and the South Africa Customs Union (SACU) – composed of South Africa, Botswana, Namibia, Lesotho and Swaziland – attempted to conclude a comprehensive free trade agreement. After difficult negotiations with a lot of interruptions, talks were finally suspended in 2006. At the end of 2006, both partners agreed to take a rather slim approach and to concentrate on a so-called trade and investment cooperation agreement. Although there is little reliable information on the substance of the negotiations, civil society groups cite the US-stance on intellectual property rights as one central stumbling block for the conclusion of the FTA. The USA apparently aimed at using a "template-like"-framework, i.e. they wanted to use older FTAs with Morocco, Mexico and Bahrain as a template for the US-SACU-FTA. Among other issues, this would have implied more restrictive conditions for

introducing generic medicines and for allowing domestic production of generics than required by the TRIPS agreement.[4]

3.3 EU free trade agreements including first drafts of EPAs

Until recently, the EU has been criticized less for trying to introduce TRIPS-plus standards. The main reasons are twofold: On the one hand, the EU has put less emphasis than the US on further increasing protection standards beyond TRIPS rules. On the other hand, the EU has simply been more hesitant to include stringent IPRs in its bilateral trade agreements as it has long preferred the multilateral path. Nevertheless, there is anecdotic evidence that the EU has successfully included TRIPS-plus rules in some recent free trade agreements with developing countries. The bilateral agreement with Chile, for example, mentions about 25 intellectual property related treaties or amendments thereof. It is not easy to estimate in how far these provisions go beyond TRIPS since one would have to go into the substantive details of all these treaties. But it is of course easy to guess why the EU would want to include all these references if one single reference to the TRIPS agreement had fulfilled the same objective.

EPAs will bring a new quality to the bilateral free trade agreements concluded by the EU because most of the potential signatories to these agreements are LDCs, and each EPA grouping includes a mix of LDCs and non-LDCs. Therefore, it is important to carefully monitor IPR-related provisions in EPAs and to ensure that they will not contradict the spirit of the compormises and waivers granted at the multilateral level, in order to safeguard the interests of the LDCs in particular.

Since the draft versions of the EPAs are confidential, it is difficult to get reliable information about the state of the negotiations and about the stance the EU is taking in the negotiations. Recently, a “non-paper” of the European Commission which presents elements for a section on IPRs for the EPA with the 15 Caribbean countries (CARIFORUM) became public (New 2006). The non-paper includes several provisions that exceed the commitments of the TRIPS agreement. Among other issues, the non-paper suggests the adoption of provisions based on the European Union enforcement directive, which some have criticized as overly restrictive. Moreover, the text refers to a range of treaties negotiated at the World Intellectual Property Organization (WIPO) that TRIPS does not require, including the so-called 1996 WIPO “Internet treaties” on performers and producers, as well as copyrights on the Internet. It seems that the current draft version of the CARIFORUM-EPA includes the non-paper to a large extent.

The text explicitly recognizes that LDCs shall not be required to apply the provisions of the TRIPS agreement. Consequently, LDCs will as well be exempted from the IPR regulations of

[4] For more information, see http://www.bilaterals.org/rubrique.php3?id_rubrique=15

the EPA. However, it is questionable why non-LDC developing countries should be forced to sign on TRIPS-plus rules. It would be even more problematic if the CARIFORUM-EPA serves as template for the other EPAs still under discussion since the other regions comprise a lot more LDCs and developing countries with limited technological capacities.

On the other hand, the draft CARIFORUM-EPA includes extensive references to support measures for innovation and technology transfer. This is laudable from a development point of view. However, it is too early to assess if the provisions only embody “best-endeavour” clauses or real commitments.

4 Special areas of conflict: Learning from the TRIPS experience

During the negotiations of the TRIPS agreement, special areas of conflict arose. Since they are still relevant today, they will probably appear in future agreements. Most prominently, patents for medicines, protection of plant varieties and genetic resources and the protection of software have been contested. In what follows, we will shortly comment on the last three points before covering the pharmaceutical sector in more detail.

4.1 Plant varieties, genetic resources and software

The strong protection of plant varieties and genetic resources has been a major interest of the biotechnology industry of the USA and the EU. The industry wanted patent protection for both since this is the strongest form of protection. Developing countries, on the other hand, strongly opposed this wish since their rural areas have been characterized to a large extent by small-scale agriculture where it is common to withhold seeds after the harvest and to reuse them during the years to come. Patent-protected seeds would have prohibited this old practice. As a compromise, the TRIPS agreement provides for plant variety protection or any other similar form of protection. Plant variety protection gives breeders protection of their intellectual property but at the same time leaves farmers the right to withhold seeds and to improve the seeds on their own. In industrialized countries, plant variety protection has been codified and administered by the International Union for the Protection of New Varieties of Plants (UPOV), which only in recent years has included more and more developing country-members. The TRIPS agreement does not require developing countries to become members of UPOV but industrialized countries pressure them to accede to UPOV. This is not necessarily a problem but should be avoided anyway since developing countries should decide on their own (and with competent and neutral advice) if they want to accede UPOV or rather prefer to provide a similar form of protection outside UPOV. Thus, EPAs should not require that ACP countries join UPOV.

Regarding patent protection for genetic resources, TRIPS leaves it to Member States if they wish to provide patents or not. Only in specific cases, WTO-Members have to provide

patents while in general a lot of policy space to regulate this area is left to national states. EPAs should not force ACP countries to increase protection for genetic resources.

The same holds for the protection of software. While copyright protection is mandatory (like it has been the case in most industrialized countries before), patent protection is not necessary. Developing countries will have to watch carefully trends in industrialized countries to increase the use of patents as the preferred protection instrument by the big software companies. However, up to now, the EU does not seem to push developing countries into this direction.

4.2 TRIPS and health

The most far-reaching consequences for developing countries arising from TRIPS are happening in the health sector. A lot of developing countries have out-ruled product patents for medicines in the past in order to spur generic competition and to keep drug prices low. Moreover, some countries – particularly India – have used a low level of patent protection for medicines strategically as an industrial policy instrument. India today has one of the most efficient generic industries in the world and produces more than a quarter of worldwide generic medicines. This helped to bring down medicine prices not only in India but also in most LDCs that import a large share of their generics from India. Generics from India particularly helped to significantly lower the prices of drugs for the treatment of HIV/AIDS (the Anti-Retrovirals – ARVs) which are urgently needed in most ACP-countries.

In 2005, the transition period for developing countries to implement the TRIPS agreement in the pharmaceutical sector ended, expecting all WTO Members to have implemented full patent protection for medicines. However, in 2002, the Council for TRIPS, on the basis of Article 66.1, decided to grant LDCs a longer transition period in the pharmaceutical sector which now allows LDCs to postpone patent protection for medicines until 1 January 2016. This has been one important element included in the 'Doha Declaration on the TRIPS Agreement and Public Health' which all WTO members unanimously approved at the Doha Ministerial Meeting in 2001.

The Doha Declaration is an important move to reconcile conflicting interests of industrialized and developing countries in the health sector. Specifically, it states (Art. 4, Doha Declaration):

> *"We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health, and, in particular, to promote access to medicines for all. In this connection, we affirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose."*

Although the Doha Declaration does not amend the TRIPS Agreement, it carries an important political message which shapes the future interpretation of the TRIPS Agreement, for example in dispute settlement cases. The Declaration confirms the rights of Member States to implement all necessary measures to protect public health. These measures, known as public health safeguards, enable countries to obtain cheaper patented medicines or generic equivalents. In addition, Members are empowered with flexibilities to determine the circumstances under which they apply the safeguards (Oxfam 2006). The most important public health safeguards are:

- Parallel Importation (Art 6 TRIPS): Allows countries to import a patented product marketed in another country at a lower price. This provision spurs price competition particularly in small markets.
- Compulsory licensing and government use (Art 31 TRIPS): Allows governments to temporarily override a patent and authorize production of generic equivalents of patented medicines in the public interest without consent of the patent owner. TRIPS defines some conditions on the issuance of compulsory licenses but leaves a lot of discretion to the country. Compulsory licenses are an important instrument to lower medicine prices since they limit the monopolistic pricing power of the patent owner. However, compulsory licenses only achieve this end if there are pharmaceutical producers in the country capable of producing the medicine in question without the support of the patent owner.
- 'Bolar provision': Allows testing and regulatory approval of generic medicines before the patent expires to ensure that generic copies can be introduced immediately upon patent expiry.

Important flexibilities how to implement the TRIPS Agreement in the context of public health related policies are the following:

- Definition of novelty: A patent may only be granted for inventions that are new, contain an inventive step and have a commercial use. Governments and patent offices have some leeway to define novelty and the inventive step. For pharmaceuticals, governments should exclude new uses of already known medicines from patentability since pharmaceutical companies frequently use this practice to prolong the life of a patent without really giving back to society an innovative medicine.
- Simple and wide public interest provisions: In various laws and regulations governments can introduce public interest provisions that help to limit patent rights. For example, compulsory licenses may be issued easier and faster if the respective regulation is designed to foster the public interest of cheap medicines.
- Quick regulatory approval of generic versions of medicines: The faster and the more efficient regulatory agencies are working the more probable will be the desired price effect. If, for example, one allows the use of test data of the patented medicine for the generic version of the medicine (which has been common in the past but is under fire

from pharmaceutical companies), then one can introduce the generic medicine immediately upon patent expiry. Moreover, one can avoid costly doubling of tests.

The Doha Declaration contains one key issue that the Doha Ministerial could not solve: How to assist countries, which desire to exercise their right to protect public health through the use of compulsory licenses, if they do not have sufficient manufacturing capacity in the pharmaceutical sector? The problem arose because Article 31 of the TRIPS agreement mandates Members which issue a compulsory license to limit production "predominantly for the supply of the domestic market". This would prevent countries without sufficient manufacturing capacity from importing medicines on the basis of a compulsory license. Consequently, under Paragraph 6 of the Doha Declaration WTO Members recognized the problem and instructed the Council for TRIPS to find an expeditious solution to the problem. On 30 August 2003, the General Council adopted a decision to implement Paragraph 6 of the Doha Declaration as a temporary mechanism. Finally, on 6 December 2005, the General Council adopted an amendment of the TRIPS agreement as the permanent solution to the paragraph 6 problem.

The decision (and the amendment) contains three waivers to solve the legal problem (WTO 2006):

- "Exporting countries' obligations under Article 31(f) are waived — any member country can export generic pharmaceutical products made under compulsory licences to meet the needs of importing countries.
- Importing countries' obligations on remuneration to the patent holder under compulsory licensing are waived to avoid double payment. Remuneration is only required on the export side.
- Exporting constraints are waived for developing and least-developed countries so that they can export within a regional trade agreement, when at least half of the members were categorized as least-developed countries at the time of the decision. That way, developing countries can make use of economies of scale."

Sophisticated conditions apply to pharmaceutical products imported under the new system. These conditions aim to ensure that beneficiary countries can import the generics without undermining patent systems, particularly in rich countries. They include measures to prevent the medicines from being diverted to the wrong markets. And they require governments using the system to keep all other members informed, although WTO approval is not required. Nevertheless, it is heavily contested if the amendment creates a workable system to protect public health or if it makes the working so burdensome and economically unattractive that it can hardly work in practice. Until today, no developing country has made use of the system.

The third waiver mentioned above deserves special attention with regard to the EPAs: There are some EPAs which involve LDCs and non-LDC countries. It is important that EPAs do not preclude the option for non-LDC countries to export patented medicines within the regional

trade agreement if at least half of the members are categorized as least-developed countries. The paragraph 6 solution is imperfect but, at least, it offers the possibility of realizing economies of scale which should not be undermined by an EPA.

5 Intellectual property protection in the Economic Partnership Agreements: The negotiation agenda

5.1 Framework set by the TRIPS agreement

The TRIPS agreement has to be read in the light of Articles 7 and 8 cited above. Any amendments have to respect the critical balance between interests of producers and users of knowledge and technology.

Article 71 of TRIPS provides for a review of the agreement after the expiration of the transitional period. Member states have initiated the review in 1999 just before the Seattle Ministerial. However, the first years have been characterized by formal discussions about the substance of the review: Should the review be limited to the implementation of the agreement (industrialized countries' position) or should it include a critical review of the substance of the agreement (developing countries' position)? After a while, Members agreed on the terms of the review which comprises both implementation-related and substantive issues. Since then, discussions are ongoing in the Council for TRIPS without reaching an agreement on any of the critical points, apart from the above mentioned amendment of Article 31 concerning TRIPS and public health.

The TRIPS agreement sets minimum standards of IPR protection. It does not preclude Members to enforce higher standards of protection. Therefore, regional free trade agreements can include TRIPS-plus rules without running into conflict with the provisions of TRIPS. However, Members of a free trade agreement have to be aware of the fact that it is difficult to conceive an IPR protection system which differentiates between foreign creators of knowledge. Moreover, all WTO Members have to respect the principles of national treatment and most-favored nation, even if they are LDCs. Higher standards of protection will therefore apply for all WTO Members and will not be limited to the Members of the free trade area.

5.2 Framework set by the Cotonou Agreement

The Parties have undertaken commitments with regard to IPRs in Article 46 of the Cotonou agreement. Among other points, Article 46 states:

> *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.

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 rightholders 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.

5.3 Agenda set by the negotiating mandate of the EU Council

The negotiating mandate of the EU Council is virtually silent on questions of intellectual property. They are simply mentioned in form of a listing under the general heading of "trade-related areas" without going into any detail. This weak mandate could be interpreted as a commitment to not negotiate higher standards of intellectual property. This interpretation holds especially if read in context with the statement about "nature and scope of the agreements" in general:

> *"EPAs shall aim at fostering the smooth and gradual integration of the ACP States into the world economy, with due regard for their political choices and development priorities, thereby promoting their sustainable development and contributing to poverty eradication in the ACP countries."*

Having in mind the importance of preserving policy space for developing countries in IPR-related policies, the mandate should exclude the possibility of introducing TRIPS-plus rules in EPAs.

6 Possible development-friendly aspects of an EPA involving intellectual property and innovation provisions

The main message of this checklist is straightforward: It is not conducive to the development in ACP countries if EPAs include intellectual property provisions that exceed the rules of the TRIPS agreement. It is consequently questionable why IPR-provisions should be mentioned in an EPA at all. There are multilateral fora to competently discuss IPR-issues and to find mutually agreeable solutions. It is therefore recommended that the EU concentrates on these multilateral fora to discuss IPR-issues and that it excludes IPRs from the negotiation of

EPAs. It should be sufficient to introduce a reference to Article 46 of the Cotonou Agreement into the EPAs.

This recommendation holds especially, though not exclusively, with respect to IPRs and public health. After long and controversial discussions, WTO Members agreed on a compromise that conveys additional flexibilities to developing countries that try to improve public health via access to cheaper generic medicines. It is indispensable that EPAs do not reduce this policy space through the backdoor. On the positive side, it would be an important signal from the EU to non-LDC partner countries to offer them the same flexibilities as LDCs.

Given this baseline recommendation, EPAs could indeed be constructed more development-friendly by making clear references to the support of technology transfer to ACP partner countries. Development requires access to knowledge and technology – and the EU could improve access through a variety of measures (Maskus 2004). This would be a welcome move from the point of view of developing countries who have for long criticized that industrialized countries do not live up to the promises made in the past, which have been codified for example in Article 66.2 of the TRIPS agreement.

- Host-country policies could be supported by investing in the absorptive capacity of developing countries for technology imports and learning processes. This might be promoted through different instruments of development cooperation geared at capacity building in technology-related sectors. Equally important, the EU should, in its trade-related capacity building efforts, emphasize less the issue of implementation of IPR-laws and concentrate instead on technical, judicial and legal expertise underlying effective technology transfer.
- Source-countries could provide stronger incentives for technology transfer. It is difficult to conceive fiscal incentives for research undertaken in developing countries since this would obviously conflict with national economic objectives. But there is much room for improvement in the design of international research cooperation that work in the mutual interest.
- Finally, the EU should encourage multilateral initiatives which foster research and development through incentive mechanisms beyond the IPR-system. The WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property, for example, has the mandate to find solutions for the development of neglected medicines. However, industrialized countries seem to put less negotiating effort in such fora compared to bilateral free trade negotiations.

Apart from these general measures to promote technology transfer, EPAs should include references to support regional integration of regulatory policies related to intellectual property and innovation policies. Access to knowledge frequently depends on the quality of regulatory institutions. This is particularly important in the health and agricultural sectors – both critical for the development in ACP countries. Regulatory institutions responsible for quality assurance have to test, register and approve for example new medicines. Similar institutions are active when marketing new seeds, fertilizer or insecticides.

Today, most ACP countries employ their own national regulatory institutions with these complex tasks. The registration of new medicines within a regional bloc becomes unnecessarily burdensome and takes a lot of time and money. Market size is extremely limited so that economies of scale can hardly be realized. For ACP countries, it is extremely important to reduce those transaction costs in order to facilitate the employment of new technologies and knowledge. Regional cooperation of regulatory institutions, of standard setting bodies, and harmonisation of cross-border measures are useful means to improve access to technology and to foster domestic research and development. The EU should support ACP countries in their efforts in these areas.

7 Recommendations for the German EU and G8-Presidency

Access to technology is the other side of the coin of intellectual property protection. In recent years, industrialized countries emphasized strengthening and enforcing intellectual property protection in developing countries. It is important now to give equal weight to the parallel important aspect of the subject, i.e. to improve access to technology and knowledge which is indispensable for development.

Germany has announced to place Africa prominently on the G8-Agenda. The G8-Presidency plans to discuss issues related to Africa under the heading: “Growth and responsibility in Africa – Good governance, sustainable investment, peace and security and the fight against HIV/AIDS”. At the same time, the stronger protection of intellectual property is one of the main issues for the general program of the German presidency.

It is easy to see tensions within the Agenda: A further strengthening of IPRs could well conflict with stepping up the fight against HIV/AIDS. It would be good if industrialized countries were willing to discuss these tensions in an open and transparent manner.

Yet, the emphasis on governance issues points to possible win-win constellations that should be exploited. As has been mentioned in the last chapter, regional regulatory institutions can and should foster regional economic integration. These comprise regulatory bodies to ensure the quality of goods that inhibit knowledge (like medicines and seeds). It is in the mutual interest of ACP and EU member countries to support these regional institutions since they improve the dissemination of knowledge, regardless if produced locally or abroad.

Finally, one can regard the local production of essential drugs in developing countries as an innovative path to improve access to medicines. Under certain conditions this could help to achieve public health goals (Liebig 2006). Industrialized countries should commit themselves to support developing countries in improving the economic, political and regulatory environment where local production of medicines takes place.

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Annex: Monitoring criteria for a development friendly EPA with references to TRIPS: overview

Suggested content	Neces-sary	Impor-tant	Recom-mended
Direct regulations within the Agreements (general)			
Protection of intellectual property shall not exceed the regulations of TRIPS (no TRIPS plus)	x		
ACP countries should be supported in adapting their national legislation so that they can use as much TRIPS flexibilities as possible.			x
Governments and enterprises from ACP Countries should be supported by: • Technology transfer • Value chain improvements • Building up absorptive capacity for technology adaptation		x	
Direct regulations within the Agreements (related to Public Health)			
Nothing in the agreements shall prevent ACP countries from using all flexibilities with relation to the production, import, export and marketing of essential drugs offered by TRIPS, especially: • patent protection only for processes • exclusion of pharmaceutical products from patentability • shorter patent terms • exclusion of new uses of known products from patentability (lack of novelty) • restrictions of exclusive rights to make and use protected products or processes • « Bolar » exception: patented substance may be used without patentee's authorization for purpose of obtaining quick marketing approval for generic drugs • a wide public interest exception • simplified formal requirements for compulsory licenses	x		

Suggested content	Neces-sary	Impor-tant	Recom-mended
• allowance for parallel imports of patented substances from abroad • express provision on protection of pharmaceutical test data: no exclusive rights, but possibility of regulatory authority to rely on already submitted data			
Nothing in the Agreements shall prevent ACP countries from taking any measure in relation to investment			x
Policy space for the regulation on the import, production, export and marketing of essential drugs and any raw or intermediate products or services needed to produce or market essential drugs should be perpetuated explicitly.	x		
Every flexibility offered by TRIPS to LDCs shall also been offered to all ACP countries within every EPA as soon as at least one member is an LDC		x	
Support of the ACP countries by the EC in WTO negotiations to make the flexibilities of TRIPS and other relevant rules within TRIPS work for health (including a longer timeframe beyond 2016 to implement TRIPS with relation to essential drugs) shall be explicitly mentioned			x
Special provisions on regional level (related to Public Health)			
ACP countries should be supported to build up a pharmaceutical quality infrastructure on national as well as on regional level: • authorisation of production • approval of drugs • inspection of enterprises • Market surveillance • certification of GMP according to international standards • training of quality personnel			x
ACP countries should be supported in adapting their national legislation so that they			x

Suggested content	Neces-sary	Impor-tant	Recom-mended
can use as much TRIPS flexibilities as possible.			
Governments and pharmaceutical enterprises from ACP Countries should be supported in: • Technology transfer (production methods, reverse engineering) • Value chain improvements • Testing of drugs for approval • GMP-related issues • Tendering procedures of national and international health programmes and private and intergovernmental organisations		x	

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