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Intellectual Property Rights as a Challenge to Providing Global Public Goods

The cases of public health, food security and climate stability

Clara Brandi
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Abbreviations

AIDS	Acquired Immune Deficiency Syndrome
AMC	Advance Market Commitment
ARIPO	African Regional Intellectual Property Organization
ARV	Antiretroviral
CAMR	Canada's Access to Medicines Regime
EU	European Union
FTA	Free Trade Agreement
FTAA	Free Trade Agreement of the Americas
GATS	General Agreement on Trade in Services
GATT	General Agreement on Tariffs and Trade
GMO	Genetically Modified Organism
GPG	Global Public Good
GSP	Generalised System of Preferences
HIV	Human Immunodeficiency Virus
IP	Intellectual Property
IPCC	Intergovernmental Panel on Climate Change
IPR	Intellectual Property Right
LDC	Least Developed Country
LIC	Low-Income Country
MNC	Multinational Company
OAPI	Organisation Africaine de la Propriété Intellectuelle
OECS	Organization of Eastern Caribbean States
PEPFAR	President's Emergency Plan for AIDS Relief
PGR	Plant Genetic Resources
PPP	Public Private Partnership
PPVFR	Protection of Plant Varieties and Farmers' Rights Act
PVP	Plant Variety Protection
R&D	Research and Development
TRIPS	Trade Related Aspects of Intellectual Property Rights
UN	United Nations
UNCTAD	United Nations Conference on Trade and Development
UNFCCC	United Nations Framework Convention on Climate Change
UPOV	L'Union internationale pour la protection des obtentions végétales
US	United States
WTO	World Trade Organization

Summary

Most of the development of new knowledge takes place in industrialised countries. Some of this knowledge contributes to providing global public goods: Development of new medicines helps combat the spread of diseases, modified seeds contribute to food security and clean technologies help mitigate climate change. This highlights the particular need for mechanisms that optimise the balance between the development of this kind of knowledge, and its utilisation and diffusion.

This paper aims at assessing the effect of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) as the central international agreement for the protection of intellectual property on providing three selected global public goods. TRIPS is an agreement that is legally binding to the member states of the World Trade Organization (WTO). Countries that are parties to the agreement are legally bound to it and must incorporate the treaty into their national legal systems in order to comply with its provisions.

In the context of public health, intellectual property rights (IPRs) can hinder access to affordable medicines for poor people. In the context of food security, they can raise the prices for improved seeds, block follow-up research and hinder seed-saving. In securing climate stability, they may raise the price of clean technologies such as renewable energies, thereby blocking their diffusion to developing countries and constraining their ability to reduce greenhouse gas emissions.

On the other hand, the protection of IPRs is meant to secure their role as a driver for innovation. Private companies will not engage in research and development, if they cannot secure their research investment costs once a product is on the market. It is therefore vital to find a balance between the need for the diffusion of knowledge and products at affordable prices, especially to developing countries, and effective incentives for innovation.

The role of TRIPS for providing public health, food security and climate stability differs widely. While acting as a very relevant barrier to access to affordable medicines, the role of IPRs in food security seems to be less pronounced. In the case of renewable energies, IPRs do not seem to constitute a major barrier. Instead, a lack of absorptive capacity for the host country and high ex-ante investment costs impede fast diffusion. Therefore, there is no blueprint solution to all of the global challenges analysed in this paper. However, some major similarities and differences will be identified. The following table aims at providing a systematic overview of these parallels and disparities, thereby allowing for comparability across the three policy fields.

IPR protection in the area of public health means that the production, import and commercialisation of pharmaceuticals are, for a certain period, subject to exclusive rights that allow the patent holders to charge high mark-up prices considerably above marginal costs. Competition is constrained by high market concentration and the possibility to block patents. Especially for poor people living in developing countries, higher prices for medicines may mean, that a large part of the population is restricted from access to drugs they need. Therefore, IPRs constitute a significant barrier to the dissemination of medicines to the poor. As for some diseases, where only a few drugs exist or new generations of medicines can substantially reduce undesired side-effects, the demand for access to cutting-edge technology is high.

Table 1: Classification of technologies for global public goods provision			
Technologies to be disseminated	**Medicines**	**Improved seeds**	**Renewable energies**
Demand for access to cutting-edge technology	high	disputed: traditional plant varieties are argued to be sufficient	high
Market concentration	high	high	depends
Mark-up pricing	very high	high	low
Potential for blocking patents	high	high	low
IPRs as a barrier to dissemination	strong	strong	weak
Relative relevance of other barriers	lower	high	very high
Source: Own illustration			

Yet, the TRIPS Agreement also contains provisions that allow for a degree of flexibility for countries to accommodate their own IP systems and public health needs. One example is compulsory licensing, which allows – under certain conditions – for the production of patented products or processes without the permission of the patent holder. The Doha Declaration on the TRIPS Agreement and Public Health (2001) and the so-called Paragraph 6 decision (2003) affirm important principles under the TRIPS agreement regarding the protection of public health. But two major challenges remain. First, in many countries there is a need for appropriate national legislation to enshrine the flexibilities provided for under the TRIPS agreement and the Paragraph 6 decision. However, progress in implementing these to improve access to medicines is hindered by inadequate capacity in low to middle income countries, as well as pressure from powerful trading partners to avoid such measures. Second, the flexibilities available under the TRIPS agreement to protect public health, face erosion by the recent wave of bilateral and regional free trade agreements negotiated outside of the WTO. Due to an inequality in bargaining power and a lack of negotiation capacities in a number developing countries, many agreements include so-called TRIPS-plus measures, which require higher levels of intellectual property protection for medicines than those mandated by the TRIPS Agreement. The core political issue is how public policy makers can move forward to both secure access to medicines and safeguard TRIPS flexibilities.

An additional major problem is that the current IPR system provides insufficient incentives for research and development in medicines for so-called neglected diseases that disproportionately affect the poor in developing countries. Potential solutions to this problem fall into two broad categories that can be characterised as push mechanisms and pull mechanisms: push programmes diminish the cost of carrying out research by making complete or partial R&D funding available up front, while pull programmes are intended to provide incentives for innovation by rewarding successful innovators based on profits or some other type of remuneration.

In the area of seeds, countries can use the flexibilities the TRIPS Agreement provides in Article 27.3(b) to exclude animals, plant varieties and essentially biological processes from patenting. However, "non-biological" and "microbiological" processes may not be excluded. In recent years, extensive – often strategic – patenting was common practice in the agribusiness and biotechnological industry. In many cases the only purpose of patenting was to block competitors. The strategic importance of IP portfolios is also one of the main reasons for the heavy market concentration in the biotechnology and agribusiness sector, because IP ownership motivates mergers and acquisitions. Apart from patents, firms also use other ways to protect their IP, mostly through means such as bio-safety data and biological processes such as hybridisation. As in the case of medicines, this shift risks a general neglect of the particular concerns of the global poor.

On the other hand, it is not certain whether farmers need access to improved seeds to safeguard food security. Patent rules do not prohibit farmers from using traditional varieties even if they contain protected characteristics. Problems occur, however, if these plants or their products are needed for further research. Moreover, IPRs push private research away from the needs of poor farmers, because other areas of research are more profitable. Patents on processes and microorganisms hinder public research on plant varieties and other important issues that are relevant to the poor. The case of India shows that WTO member states can implement laws that largely protect farmers and breeders from IPR issues. However, whether other countries may change their actual patent protection system to one with lower protection standards is not clear.

Improved varieties are only one piece of the puzzle to achieve food security. They can only be successfully adapted if the necessary infrastructure is available, such as adequate irrigation systems. The successful adaptation and cultivation of improved varieties is constrained by the lack of certain necessary preconditions, such as expertise in relevant farming methods or non-availability of other necessary inputs.

The relevance of IPRs and their protection by schemes such as TRIPS to the transfer of clean technologies has to be put into context. Mark-up pricing allowed for by IPRs might be a barrier to the dissemination of research intensive technologies with relatively low hardware costs, but this does not seem to apply to most of renewable energy technologies. These technologies, such as solar photovoltaic, concentrated solar power or wind energy, typically involve high investment costs. Competition within each sector (for example solar photovoltaic) and with conventional energy technologies, impedes monopoly pricing and drives prices lower. Many advanced developing countries have proven their ability not only to access renewable energy technologies, but even to become competitive global players and innovators in the particular markets. These countries could even benefit from the protection of intellectual property possessed by their citizens.

In contrast, least developed countries (LDCs) still have difficulties accessing renewable energy technologies. However, IPRs do not seem to be the major barrier. In many LDCs, the relevant technologies are not protected, i.e. there is no patent in force in the country seeking to acquire the technology. Instead, limited market size and an unfavourable investment climate discourage technology transfer from abroad. In addition, the limited technological capability of local firms prevents the absorption of the few technologies flowing into the country. Technological capacity building and the transfer of the tacit knowledge inherent in renewable energy technologies is therefore vital. Undoubtedly,

LDCs will require international assistance in this. A careful analysis of each country's technological needs should be conducted to identify the basis for international cooperation.

IPRs may, however, become a barrier to the development and dissemination of future renewable energy technologies, such as second and third generation biofuels. In this case, consensual solutions such as the publicly funded purchase of licenses for developing countries should be explored before applying unilateral measures such as compulsory licensing. Solutions from other areas such as public health or agriculture should not be seen as models, as these areas usually feature different conditions, and may thus not be appropriate for solving the challenges of the transfer of renewable energy technology.

This paper's findings allow for a number of policy recommendations. Some of them apply in general. However, as IPRs differ in relevance to the three areas analysed, most of the recommendations are case-specific.

Public Health

- Public-health safeguards should be recognised as the foundation of all multilateral trade agreements. The strong members of the WTO should exclude them from the high-level horse-trading that routinely takes place between negotiating parties.
- Developed countries, and other countries with manufacturing and export capacity, should take the necessary legislative steps to allow compulsory licensing for exports, in accordance with the TRIPS agreement.
- National legislation should be reviewed to ensure that the entire range of TRIPS flexibilities is incorporated, so that public-health needs and objectives can be adequately addressed.
- Pharmaceutical companies should adopt patent and enforcement policies that facilitate greater access to the drugs needed in developing countries.

Food Security

- Developing countries should make use of the *sui generis* option to facilitate research and breeding using modern breeding techniques.
- Public research institutions should focus on crops that are essential to the poor but have so far been neglected by the private sector, due to an expected lack of returns.
- Governments should make sure that the national IPR legislation does not undermine seed policies that ensure the basic human right for food.

Climate Stability / Renewable Energy

- More empirical in-depth studies are needed to understand the role of IPR protection for the transfer of renewable energy technology and for the transfer of other climate-related technologies. These studies must form the foundation of policy decisions.
- A lack of access to tacit knowledge and technological capacity often constitute more powerful barriers to the transfer of renewable energy technology than IPRs. Any technology transfer policy must ensure that not only hardware, but also the inherent know-how and capabilities are transferred.

General recommendations

- Less developed countries should have access to independent, technical assistance and counsel in trade negotiations.
- Pooled procurement among low and middle income countries enhances market power. This may help in negotiating lower prices and thereby mitigating the impact of monopoly positions caused by IPRs.
- "South-South" partnerships could be used to compensate for weaknesses in capacity. For example, developing countries with established pharmaceutical industries could lead efforts in innovation and technology transfer. Technologies invented in developing countries can be particularly suitable to meet the needs of other developing countries.
- As intellectual property rights are a market instrument, research is drawn towards purchasing power. The needs of the poor are mostly neglected. The international community should therefore finance public research focused on the needs of the poor.
- Emerging economies can benefit from joint research with developed countries. Publicly funded joint research may offer a solution to IPR issues, as the resulting products can be made publicly available.
- Ministries of health, agriculture, or energy and environment should be "involved" in discussions on trade that have an impact on their respective areas of responsibility. To that end, ministries will have to develop expertise outside their traditional spheres.
- Least developed countries need assistance to strengthen the technological capacity of their companies, research institutions and universities. Also, a lack of competence in their public sector needs to be addressed. Training and education should be conducted in cooperation with, and at least partly funded by, the developed countries.

Last but not least, the problem of developing countries' access to medicines, improved seeds and modern forms of energy is linked to wider development issues. Additional resources to improve services, delivery mechanisms and infrastructure are critical.

1 Introduction: Knowledge, intellectual property rights and public goods provision

In the course of the past century, the world has become increasingly interconnected. International trade, cooperation and investment opportunities, and growing mobility offer chances of growth and wellbeing. However, this interlinkage also increases the necessity of joint and cooperative solutions to today's challenges. While the crises of the past were mostly restricted to limited areas, the challenges humanity faces today take on an increasingly global dimension. Growing mobility causes diseases to spread rapidly over large distances, food crises arise from price surges on the global markets and greenhouse gases emitted locally affect the global climate system.

These global challenges cause great and sometimes irreversible damage, and drain resources that are required for development. Developing countries, on top of to their already precarious situation, have the least capacity to cope and adapt to changing conditions and so suffer the most. They often have to deal with challenges whose causes are to be found in the developed world. It is not only imperative to help these countries adapt and recover after a crisis has struck, but to work towards a stabilisation of global systems. This requires a careful analysis of the root causes of these global challenges.

They are frequently the result of an insufficient provision of public goods. Providing public goods poses challenges due to specific features of these goods (Samuelson 1954). First, 'pure' public goods are characterised by non-rivalry in consumption, i.e. they can be used by many persons without exhaustion. The second criterion is non-excludability, which implies that it is not possible to exclude anyone from using them, other than by artificial means. However, providing these goods creates costs. As no-one can be excluded from their use once public goods are provided, there is no incentive to pay for them. The first person to explicitly describe this so-called 'free-rider' problem was David Hume. He noted that working jointly for a common good would fail because the best and most rational strategy for individual actors is to let others provide the goods – and then enjoy them free of charge (Hume 1739). As individuals have a strong motivation not to cooperate, there is a need for institutional arrangements to make sure the costs of providing public goods are shared.

One example of a public good is knowledge (Stiglitz 1999). An additional "user" of existing knowledge does not diminish the amount of knowledge available (non-rivalry). Moreover, in many cases, others cannot be excluded from using existing knowledge. For example, the invention of rayon showed the feasibility of synthetic fibre production. Although the knowledge about rayon production was protected by a patent, the knowledge of the process was used by other inventors to find alternative synthetic fibres (Stiglitz 1999, 310). Ideas and knowledge play a significant role in today's economies and constitute an increasingly important part of trade. Most of the value of high technology products such as new medicines is generated in research, design and testing, not in the actual production process.

One possibility to safeguard the provision of knowledge as a public good is the legal arrangement of intellectual property rights (IPRs), e.g. in the form of patents. These are utilised to convert the public good aspects of knowledge into club good aspects. Club goods are non-rivalrous, but excludable, and thus belong to the class of 'impure' public goods.

IPRs enable the inventor to exclude others from using his knowledge. The inventor can enjoy the profits from his invention by setting a monopoly price and thereby recoup the costs of research. This monopoly price provides incentives for further research and spurs innovation. On the other hand, excludability hampers the diffusion of knowledge. This trade-off has to be balanced carefully. A second type of 'impure' public goods entails so-called commons. They are non-excludable but rivalrous and thus especially prone to over-exploitation. Classical examples are high-sea fish stocks and the Earth's atmosphere.

The discovery, transmission or utilisation of knowledge is not limited geographically. In addition to being a pure public good, knowledge therefore belongs to the class of so-called global public goods (Stiglitz 1999, 310). In the literature, the concept of 'global public goods' (GPGs) is, however, usually used in a broader sense. Kaul et al. define GPGs as goods whose benefits extend to all countries, people and generations. This concept includes natural and man-made commons as well as desired policy outcomes which can only be achieved by international coordination, such as global peace, financial stability, environmental sustainability and, last but not least, food security (Kaul et al. 2003).

Some types of knowledge contribute to providing other global public goods: Knowledge of new medicines helps combat the spread of diseases like malaria and HIV/AIDS, modified seeds contribute to food security and clean technologies help mitigate climate change. This highlights the particular need for mechanisms to optimise the balance between the production of this kind of knowledge and its use and diffusion.

Most of new knowledge is generated in developed countries (World Bank 2008a, 3). However, global public goods have to be provided to all parts of the world. The case of climate change clearly illustrates this: Regardless of whether a ton of carbon dioxide is emitted in Germany or in Ghana, the effect is global warming. Clean technologies therefore have to be available in all countries. Equally, especially from a human rights perspective, everybody should have access to the medicines and the seeds that are necessary to meet the right to health and the right to food. The system of patents as it currently exists may however generate an inequitable distribution of knowledge and related costs and benefits between countries.

The aim of this paper is to assess this issue by analysing the role of the WTO Agreement for Trade-related Aspects of Intellectual Property Rights (TRIPS) to providing three global public goods. In the context of public health, IPRs may hinder access to affordable medicines for poor people. In the context of food security, they may raise the prices of improved seeds, block follow-up research and hinder seed-saving. In securing climate stability, they may raise the prices of clean technologies such as renewable energies, thereby blocking their diffusion to developing countries and constraining their ability to reduce greenhouse gas emissions. The following analysis will not quantify these effects. However, the combined assessment of three global public goods in one paper allows for a comparison and systematisation of the role of the TRIPS agreement for each of these areas.

This paper is structured as follows. Section 2 introduces the TRIPS agreement as the central international agreement to govern intellectual property. Section 3 examines the role of TRIPS for the accessibility of existing medicines and for research and development of new medicines. Section 4 discusses the role of TRIPS for food security. Section 5 addresses climate stability and the role of TRIPS for the transfer of technologies to mitigate climate change. Section 6 compares the results and offers policy recommendations.

2 The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

The TRIPS Agreement, negotiated by the member countries of the World Trade Organization (WTO) in the Uruguay Round (1986-94), introduced intellectual property rules into the multilateral trading system for the first time.[1] The Agreement sets global minimum standards for protecting and enforcing nearly all forms of intellectual property rights, including instruments such as patents (WHO / WTO 2002, 2).[2] Patents grant patent holders a monopoly on an invention for a minimum of 20 years, by preventing others from using their invention. This monopoly allows patent holders to charge high prices that recoup research and development costs and generate profits that provide the incentive for further investments in research and development. TRIPS is an agreement that is legally binding for the member states of the WTO. Countries that are parties to the agreement must incorporate the treaty into their national legal systems in order to comply with its provisions.

The TRIPS Agreement states that IP protection should contribute to technical innovation and the transfer of technology. Both producers and users should benefit, and economic and social welfare should be enhanced (WTO 2010). To achieve this, the inventor must disclose the technical details of the invention in exchange for the patent rights (Foray 2007, 4). This information may be used by other innovators for additional improvement of the invention. After the patent expires it can be used freely. Generally, TRIPS requires countries to make patents available "for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application" (TRIPS, Art. 27.1). To further balance the long term social objective of incentives for research and the short term objective of the utilisation of existing inventions, the Agreement contains certain flexibilities such as compulsory licensing and parallel importing (see Box 1).

1 As in the General Agreement on Tariffs and Trade (GATT) and the General Agreement on Trade in Services (GATS), the basic principles of the TRIPS Agreement are national treatment and most-favoured-nation treatment. National treatment requires WTO members to treat foreigners equal to domestic residents, while most-favoured-nation treatment requires them to treat residents of all WTO trading partners as equal.

2 The TRIPS Agreement covers two types of intellectual property: Copyright and industrial property. The latter consists of two main areas. One is the protection of distinctive signs, in particular trademarks and geographical indications. The other serves to stimulate innovation, design and the creation of technology. Industrial designs, trade secrets and inventions form part of this category. Inventions are protected by patents.

Box 1: Flexibilities of the TRIPS Agreement

Exemptions from Patentability: TRIPS offers some flexibility for national legislations: "Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law" (TRIPS Art. 27.2). Since these patentability criteria are not defined further, they leave some national policy space for different scope of patentable inventions in each country.

Exceptions to Exclusive Patent Rights: Article 30 of the TRIPS Agreement states that WTO members "may provide limited exceptions to the exclusive rights conferred by a patent". Countries may thus automatically allow the use of a patented invention for certain purposes without the consent of the patent owner, "provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner". These prerequisites are not further defined, which opens up a certain national policy space.

Compulsory Licenses are granted by an administrative or judicial authority to a third party without consent of the patent owner. These licences can be issued on patented inventions subject to a number of conditions and procedural steps such as the payment of compensation to the patent owner. The legal foundation is in Article 31 of the TRIPS Agreement. There are several justifications for compulsory licensing, such as the prevention of anticompetitive behaviour or so-called "public interest" licences. The latter may be issued if public interest requires the patented goods to be made available in greater quantities or at lower prices than the patent owner is willing to accept. However, as the use of compulsory licensing risks triggering trade-related retaliation measures it is usually applied with caution.

Parallel Importing refers to the import of a patented product marketed in another country without consent of the patent-holder. Once patent holders have sold a patented product, they cannot prohibit the subsequent resale of that product, since their rights have been exhausted by selling the product. Parallel importing can be an important tool enabling access to affordable medicines because there are substantial price differences between the same pharmaceutical products sold in different markets.

Source: Dutfield / Muraguri / Leverve (2006); Smith / Correa / Oh (2009)

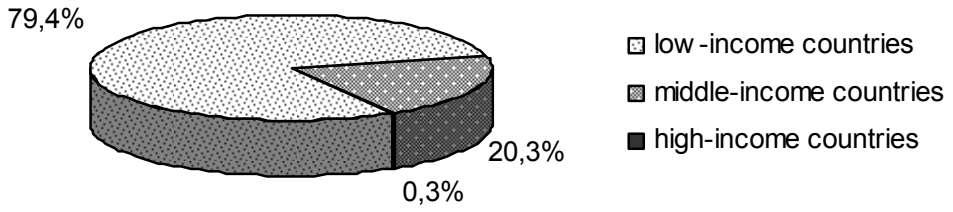
3 The TRIPS Agreement and public health

The fight against infectious diseases affecting poorer countries is both a global public good in itself, and it necessitates significant investments in global public goods that exceed the means or incentives of any single government (Labonte et al. 2004). Global public goods for public health minimally include disease eradication, disease research and control of epidemics and diseases (CMH 2001).[3]

Medicines, like any other products, can be protected by IPRs, such as patents. The impact of intellectual property protection in the pharmaceutical sector continues to be a central issue in this debate. While the scale of the problem is much more severe in the developing world, high costs of pharmaceutical products pose serious challenges for both developing and developed countries. The implications of trade agreements to public health, and in particular the impact of the TRIPS Agreement on access to affordable medicines, have been the subject of intense controversy.

3 The category of global public goods for health is sometimes broadened to include air and water pollution, emissions control and prevention of global warming, and can be further enlarged to include poverty reduction and disaster relief, technical assistance and training in health care to the degree that these are necessary to achieve the 'purer' global public goods of disease eradication and control of epidemics (Labonte et al. 2004).

Figure 1: People without access to essential medicines, as % of global total without access



Source: WHO (2004)

What are the main links between TRIPS and public health? Tackling global health problems poses the dual challenge of developing new products including vaccines, diagnostics and treatments, and improving access to existing medicines. First, developing countries are concerned that TRIPS will affect not only the choice but also the price of medicines available to them. Second, the protection of intellectual property rights in the TRIPS Agreement is a key element in promoting research and development (R&D) in pharmaceuticals. One major concern in this context is that TRIPS provides insufficient incentives for research and development into medicines for diseases that disproportionately affect developing countries.

Providing access to affordable medicines constitutes an extremely urgent challenge. Every year, six million people die worldwide from communicable diseases such as AIDS, tuberculosis, and malaria, for which medicines exist, but are inaccessible – over 16 000 preventable deaths every day (Walker 2005). The burden of these three diseases falls most heavily on the less developed countries of the world. Overall, two billion people in the developing world, more than one third of the world's population, lack regular access to essential medicines. In some countries in Africa, around 50% of the population have no regular access to medicines (WHO 2004).[4] For example, nearly 10 million children under 5 years of age die in developing countries each year. Almost all of these deaths could be prevented if those at risk had access to essential medicines (WHO 2007). In 2007, around 7.1 million people needed antiretroviral (ARV) treatment for HIV – but only around 2 million had access to ARVs in low- and middle-income countries (UNAIDS / WHO 2007).

4 The issue of access to affordable medicines also poses challenges to industrialised countries and the sustainability of their health systems. Industrialised economies are growing at less than 2% per year on average, while drug expenditure is increasing quickly. For example, in OECD countries, expenditure on medicines has increased at about 6.1% per year on average from 1998-2003 (OECD 2004). Yet, the challenge of providing access to medicines is evidently much more acute in the developing world, where people are dying for lack of access to essential drugs.

This section assesses the extent to which the TRIPS Agreement constitutes a barrier to access to medicines in developing countries. Patent protection in line with TRIPS means that the production, import and commercialisation of medicines are, for a given period, subject to exclusive rights that allow patent holders to charge prices above marginal costs. These higher prices may have the implication that a large portion of the world's population, chiefly in developing countries, does not have access to medicines (3.1). This section also examines whether and how this barrier is addressed in the TRIPS Agreements, or amendments to TRIPS, and provides a brief outline of the progress to date on the protections to public health available in the context of the TRIPS Agreement (3.2). Moreover, it explores the extent to which the available TRIPS flexibilities are being implemented by developing countries. This section shows that, despite important clarifications, there are still concerns about the capacity of developing countries to implement specific measures that allow them to accommodate their public health needs. In that context, the section considers both economic and ideational power asymmetries (3.3) and the threat posed by so-called TRIPS-plus measures negotiated in bilateral and regional trade agreements outside the WTO (3.4), and calls for their critical assessment. Last but not least, this section examines the role of the current patent system for innovation and research in public health (3.5).

3.1 Access to affordable medicines

Providing incentives for pharmaceutical research and development, for example by granting patents, is essential as developing any drug is an enormously expensive process due to high rate of loss of potential products as they go through laboratory, animal and various human trials, as well as the high costs for trials needed for regulatory approval. Only 21% of medicines that enter the human testing phase, are eventually approved. While contentious, the stated average cost of drug development is approximately $800 million, with half that being actual outlays, and the rest being cost of invested capital (Barton / Emanuel 2005). Use of a new drug by the first generation of patients covers the investments for research.[5] Without the prospect of higher monopoly prices, pharmaceutical companies would not have any incentives to develop innovative medicines that can subsequently become available as generic drugs in the future.

In contrast to the cost of innovation, imitation costs are very low in the case of pharmaceutical products. When the relevant patent expires, usually after 20 years, the price of a drug normally decreases because of competition with generic medicines, which are then available at up to 10% of the price of patented medicines. Thus, the main reason why newer medicines are expensive is that they are brand products under patent.

In short, patents provide an incentive for invention or creation that may benefit both society, and the rights holder, but they also impose costs on the users of the patented product. A recent survey which examined the availability and price of 32 medicines found that innovator products were priced at 34% higher than the lowest price generics in Bangladesh, 40% higher in Nepal, 90% higher in Pakistan, 135% higher in Brazil, 175% higher in Sri

5 For a "blockbuster" drug, each month of exclusivity could be worth $100 million or more (see Barton / Emanuel 2005).

Lanka and 257% higher in Malawi. In some cases the cost of innovator brands was 10 times higher than their generic counterparts (Mendis et al. 2007).

That high prices are a key barrier to access to medicines becomes apparent if one takes a look at the cost of originator/brand name antiretroviral therapy to treat HIV/AIDS (see also Table 2). When patent-protected antiretroviral treatments were first introduced, the cost of such a therapy was more than US$10,000 per patient per year, or approx US$30 a day (WHO 2005).

Prices of older antiretrovirals have decreased substantially due to competition among multiple manufacturers. The cost of treatment with a triple antiretroviral first-line regimen may now be as low as US$99 per year. The new treatment guidelines (2006) recommended by the WHO, however, include improved first-line and second-line regimens and newer medicines that are more expensive because of the lack of generic competition (Médecins Sans Frontières 2006). Moreover, more than 2 billion people live on less than US$2 a day (Wise 2006), who also have the highest average rates of HIV infection.

Many new antiretrovirals were developed after countries like Thailand, India and Brazil – major producers of generic medicines – had to start granting pharmaceutical patents to comply with TRIPS rules.[6] That means that by and large generic manufacturers in those countries cannot now produce affordable generic versions of the newer medicines without infringing on the patents held by the originator companies in those countries. Therefore, competition among multiple manufacturers that led to the dramatic drop in prices for the first generation of antiretrovirals cannot take place.[7]

Table 2: Brand versus generic prices of medicines (2007)

	Therapeutic Class	**Lowest Originator Price**	**Generic Price**
DIDANOSINE	HIV-1 and HIV-2 nucleoside reverse transcriptase inhibitor (NRTI)	$288	$132
NEVIRAPINE	HIV-1 non-nucleoside reverse transcriptase inhibitor (NNRTI)	$219	$48
RITONAVIR	HIV-1 and HIV-2 protease inhibitor (PI)	$190	$83

Source: Médecins Sans Frontières (2006)

6 Dictionaries tend to define a "generic" as a product – particularly a drug – that does not have a trademark. Sometimes "generic" is also used to mean copies of patented medicines, or medicines whose patents have expired. Generic copies are legal from the patent perspective when they are made after the patent has expired, or under voluntary or compulsory licence – but pirated and counterfeit products are illegal by definition.

7 For an assessment of the impact of IP initiatives in the context of TRIPS on access to vaccines (see Milstien / Kaddar 2006).

In developed countries, strict standards of patent protection and high drug prices may not produce an immediate health crisis, as the majority of the population can pay such prices, either privately or through insurance schemes or other public health services. However, in many developing countries, where pharmaceuticals are paid for out-of-pocket and health insurance is rare, high prices can deny patients access to medicines.

Essential medicines that are vital to human health and survival are not simply another commodity. Providing access to essential medicines is part of fulfilling the right to health. Health as a fundamental human right is reiterated in numerous UN legal instruments, beginning with the Declaration of Human Rights.[8] There are of course many factors that influence the accessibility of medicines, but price is of crucial importance, particularly to the poor. Because of low and restricted expenditures for public health in developing countries, health care spending comes more directly from limited household budgets. In poor countries, drugs are the largest household expenditure and second largest public expenditure of the total expenditure for health care (WHO 2008). It is widely documented that the high cost for treatments relative to household income means that the poor often delay or do not seek treatment when they are sick. It can also force diversion of household funds from other essential areas such as education or food.

3.2 The Doha Declaration

Prior to TRIPS, over 40 countries in the world did not grant patent protection for pharmaceutical products. Before 1995, developing countries engaged in robust trade in generic and recently marketed medicines produced in countries where patent rights were ignored. For the importing country, this trade was a source of less expensive medicines, especially critical to countries with severe resource constraints facing major public health problems such as HIV/AIDS. Since 1995, compliance with TRIPS has required WTO member states to restrict such trade, and to grant exclusive rights to produce and sell protected drugs to the patent holders alone. However, least-developed countries (LDCs) were allowed to postpone the implementation of their obligations under the TRIPS Agreement until 2006.

Moreover, as indicated in section 2, TRIPS also allows for a degree of flexibility for countries to accommodate their own IPR systems and public health needs, for example on the basis of compulsory licensing and parallel importing. From its inception, however, the TRIPS Agreement has been the subject of intense controversy, focused on how its provisions affect the access of the world's poor to affordable medicines.

Some governments were unsure of how the TRIPS flexibilities would be interpreted and how far their right to make use of them would be respected. In 2001, the Declaration of the TRIPS Agreement on Public Health (known as the Doha Declaration) aimed at clarifying the ambiguity between the demand for governments to apply the principles of public

8 Moreover, in 2002, the UN Commission on Human Rights appointed a Special Rapporteur with a mandate to focus on the right of everyone to enjoy of the highest attainable standard of physical and mental health. In 2009, the Human Rights Council of the UN adopted a resolution, which stresses "that the application of international agreements is supportive of public health policies that promote broad access to safe, effective and affordable medicines" and "recognises that intellectual property protection is important for the development of new medicines, as well as the concerns about its effects on prices." See also (United Nations General Assembly 2009)

health and the terms of the TRIPS Agreement (Barton 2004). The Declaration underscored member states' right to interpret and implement TRIPS in a manner supporting the protection of public health and, in particular, access to medicines, and to make use of the flexibilities built into the TRIPS Agreement, including compulsory licensing and parallel importing (Labonte / Sanger 2006). The Declaration also extended the transition period on pharmaceutical patent protection for least-developed countries to implement the TRIPS obligations from 2006 to 2016.[9]

While initially well-received, concern soon arose over the interpretation of a specific paragraph of the Doha Declaration on compulsory licensing (Doha Declaration, Paragraph 6): although existing provisions of the TRIPS Agreement permit granting compulsory licences to enable generic production of medicines, countries without domestic manufacturing capacities cannot benefit from this flexibility. The option of importing generic medicines is hampered by Article 31(f) of the TRIPS Agreement, which says that products made under compulsory licensing must be "predominantly for the supply of the domestic market." This paragraph precluded generic drug production for export to countries without their own manufacturing capacity, leaving the poorest countries that have insufficient or no manufacturing facilities without access to generic medicines (WHO 2005).

In 2003, the WTO Decision on the Interpretation of Paragraph 6 was announced, specifying under which circumstances countries can import generics made under compulsory licensing if they are unable to manufacture the drugs themselves (Abbott 2005). The WTO solution is essentially a waiver of the export restriction under Article 31(f), thereby allowing the production under a compulsory licence to be exported to meet the needs of importing countries. The 2003 waiver is provisional; the ultimate goal is to amend the TRIPS Agreement itself. The amendment – a direct translation of the waiver – will come into force when two thirds of members accept it.[10] The full impact of the Paragraph 6 Decision will depend on the extent to which national laws allow for its provisions.

So far, the Paragraph 6 Decision has only been applied once, to exports from Canada to Rwanda (see Box 2), and this has led to questions whether the system is working effectively. In March 2010, WTO members came together to debate whether the Paragraph 6 decision, designed to improve access to medicines, is working. Although opinions expressed in the TRIPS Council varied, members agreed that they should look at real-life experience in order to assess the system.

9 So long as a medicine is not patented in a least-developed country, the government does not need to issue a compulsory licence to import. But the supplying country would have to issue a compulsory licence to export a generic copy of a medicine that is patented in that country.

10 WTO-members originally gave themselves until 1st December 2007 to do this. The deadline was extended to 31st December 2011 under a decision by the WTO General Council on 17th December 2009.

Box 2: Canada's implementation of the paragraph 6 decision
Following the implementation of the Paragraph 6 Decision, Canada was among the first countries to amend its patent law. As a result, Canada's Access to Medicines Regime (CAMR) allows for the production and export of generic medicines to developing countries without manufacturing capacity. Yet, CAMR has been the subject of much criticism due to its limited ability to ensure fast access to urgently needed medicines for least developed and developing countries (Cohen-Kohler / Esmail / Cosio 2007). In July 2007, Rwanda became the first country to attempt to use the scheme by notifying the WTO of its intention to import a shipment of a triple fixed-dose of antiretroviral therapy from Apotex, a Canadian generic drug manufacturer. In September, the Canadian patent commissioner granted Apotex a compulsory license to produce and export this drug, which is held under patents by three different companies. Apotex had asked these companies for voluntary licences. Apotex was willing to sell the products at cost. While all three companies issued statements that they agreed to allow Apotex to proceed, none issued a licence. Instead, they made Apotex go through the steps of obtaining a compulsory licence under CAMR. In October 2007, the WTO received the first notification by any government from Canada that it had authorised a company to make a generic version of a patented drug for export under special WTO Paragraph 6 provisions agreed on in 2003. In 2008, Apotex announced that it has won Rwanda's public tender and started its production. In the fall of 2008, Apotex finally announced that its first shipment of its drug was shipped to Rwanda. Since its conception, CAMR has been subject to criticism for being too bureaucratic and convoluted (Kohler / Cosio / Yeh 2010). The difficulties involved in applying it can be seen from the fact that CAMR has been in place since 2004, and in force since 2005, yet Rwanda has been the only country to take advantage of it.
Source: Cohen-Kohler et al. (2007); Tsai (2009)

3.3 Rules versus reality: The implementation of TRIPS flexibilities

The Doha Declaration and the Paragraph 6 Decision were initially regarded as a victory by advocates of public health. However, with one-third of the world's population still lacking access to essential medicines, the challenges to the public health community are two-fold. One problem is that progress in implementing the TRIPS flexibilities to improve access to medicines is slow. The Doha Declaration and the Paragraph 6 Decision do not obviate the need for each country to take the necessary steps at the national level to avail itself of TRIPS flexibilities to secure the availability of medicines at affordable prices (Oliviera et al. 2004). However, as will be explained below, experience to date suggests that there still is slow progress in implementing TRIPS flexibilities.

While there are remarkable exceptions, for example in Thailand (see Box 3), there is a general reluctance among developing countries to fully test the flexibilities for compulsory licensing available under TRIPS. Countries relying on trade with powerful trading partners have remained hesitant to exercise the available flexibilities, for fear of incurring retaliation in other trade areas, legal threats, political lobbying and diplomatic pressure (Lee / Bradford 2007).

There are two main ways in which power is exerted in the context of the implementation of the provisions of TRIPS: economic and ideational power (Deere 2008). Economic pressures frequently referred to include trade threats and corporate lobbying to secure stringent IP reforms and stronger international IP rules (Deere 2008). For example, prominent measures of economic pressure included bilateral trade, IP and investment deals, WTO accession agreements, trade sanctions, the threat of sanctions and withdrawal of aid, WTO

dispute settlement procedures as well as diplomatic intimidation. To prevent precedents for weaker IP standards in poorer countries, threats were issued regarding market access in terms of political alliances. Further, developed countries used new trade deals and, more subtly, capacity building, assisted by the World Intellectual Property Organisation (WIPO) and others to leverage faster compliance and higher standards than required in TRIPS.

Box 3: Implementing compulsory licenses in Thailand

So far, the most noteworthy example for implementing compulsory licensing and asserting waiver of Article 31(f) is the case of Thailand (Ford et al. 2007). In 2003, the Thai government introduced the policy of "Universal Access to antiretroviral medicines or ARVs." However, high prices of many patented essential medicines had hampered the full implementation of this policy. To address this problem, in 2006, the Thai government authorised the Government Pharmaceutical Organisation to manufacture generic versions of the antiretroviral drug efavirenz (Stocrin®) and to import generic versions from India until domestic production came on line.

While the Stocrin® manufacturer Merck conceded that the action was in compliance with TRIPS, Merck claimed the Thai government had not engaged in sufficient consultation to allow negotiation on a possible reduced price for the drug (Lee / Bradford 2007). The US government also questioned the validity of the license and pressed Thailand to rescind the decision and renegotiate with Merck.

Unwavering, Thailand took yet another step in January 2007, issuing two further compulsory licenses, one of them for Kaletra®, patented by Abbott. Abbott responded by announcing that it would withhold new medicines from the Thai market, including a new version of Kaletra® that does not need refrigeration, which is especially important in tropical climates.

In April 2007, the Office of the US Trade Representative placed Thailand on its 301 Priority Watch List, citing "further indications of a weakening of respect for patents, as the Thai Government announced decisions to issue compulsory licenses for several patented pharmaceutical products." There was also growing pressure against Thailand from the US pharmaceutical industry, which was lobbying the US government to effectively raise tariffs on Thailand's exports by removing the nation's benefits under the Generalised System of Preferences (GSP). But in 2008, the new Thai Minister of Public Health announced that he was reviewing the compulsory licenses that had been issued, as well as four more proposed compulsory licenses for cancer medications.

The lesson to be learned from the case of Thailand is that implementing compulsory licences requires great determination and substantial efforts from all stakeholders, both at the domestic and the international level.

Source: Ford et al. (2007)

In addition, several scholars observe that monitoring by developed countries, the WTO TRIPS Council, and industry, created a "web of surveillance" that put additional pressure on developing countries (Sell 2003).[11] For instance, the annual US Special 301 Report (Office of the United States Trade Representative 2009) unilaterally evaluates US trading partners in terms of the effectiveness and adequacy of their intellectual property right protections and IPR enforcement. Countries may be put on the Priority Watch List, or given Section 306 Monitoring status, which can ultimately result in trade sanctions against offenders.

11 For a discussion of the role and activities of the TRIPS Council, see Matthews (2005).

3.4 TRIPS-Plus: Safeguarding public health protection in bilateral and regional trade agreements

An additional challenge in applying existing TRIPS flexibilities is the recent wave of bilateral and regional free trade agreements (FTAs). As efforts to progress trade liberalisation through multilateral channels have stalled since 2003, major industrialised countries have attempted to induce forum shifting by pursuing negotiations to establish new bilateral and regional trade agreements outside the WTO (Abbott 2004). A common feature of these agreements is that they include so-called "TRIPS-plus" provisions. These more restrictive standards of IPRs risk undermining public health protections: They require even higher levels of intellectual property protection for drugs than those mandated by the TRIPS Agreement, and in some cases go beyond what is required in the developed countries that are promoting them. Seeking to fuel economic growth through trade, governments of developing countries have agreed to such measures, for instance, in exchange for access to potentially lucrative export markets for key sectors such as agriculture and textiles. TRIPS flexibilities and provisions to protect access to medicines have been bargained away in a number of ways, including the following three.

- **Patent term extension:** TRIPS-plus measures may extend the period of patent protection. A related form of patent extension is "evergreening", a method by which producers keep updating their products, with the intent of maintaining patent protection for longer periods of time than would normally be permissible. "New use" for existing compounds, or a change in the dose or form, can be the basis for applying for an extension of the period of patent protection, thus preventing less expensive generic versions of the drug from being produced. While not permitted under TRIPS, many FTAs include "new use" clauses.[12]
- **Data exclusivity:** Other TRIPS-plus measures increase provisions concerning data exclusivity, enabling large pharmaceutical companies to prevent or delay competition by generics. *Data exclusivity* guarantees additional market protection of originator pharmaceuticals by preventing health authorities from accepting applications for generic medicines during the period of exclusivity. While TRIPS already provides for the protection of such data, many bilateral and regional agreements extend both the scope and duration of such protections. Such stronger protections raise concerns because they reduce the capacity of a country to issue or use compulsory licensing. If required to wait for the data exclusivity to end, a country is basically unable to make effective use of a license.

  A related issue is that many bilateral and regional trade agreements do not allow the so-called Bolar Provision. This provision, also known as "early working" exeption, permits the utilisation of a patent protected invention without authorisation, in order to facilitate regulatory approval of a generic product before its patent expires. This makes it possible for a generic product to enter the market more quickly, speeding up access to less expensive medicines. Under TRIPS-plus measures, a patent owner has to consent to marketing approval for a generic version during the patent's term.
- **Scope for compulsory licensing and parallel importing:** The scope for compulsory licensing and parallel importing has been a particular focus of TRIPS-plus restrictions,

12 Even if an application for "new use" does not succeed, the process of application can create considerable delays, especially when applications become embroiled in disputes over a potential patent violation.

narrowing down the instances when parties are permitted to use such measures. For example, in negotiations for a Free Trade Agreement of the Americas (FTAA) it is proposed that compulsory licensing would only be permitted under specific conditions, for example in situations of "national emergency," with a body to be set up over and above the WTO to rule in disputes.

In short, these higher standards of protection will, among other things, by their very nature delay or restrict generic competition and thereby reduce access to medicines (see the case of Jordan outlined in Box 4).[13] There is therefore a great need to understand the impact of the new intellectual property provisions in bilateral and regional free trade agreements, and to consider how the public health community must act to prevent the goal of providing better access to medicines from being undermined further.

Box 4: TRIPS plus – The US-Jordan Free Trade Agreement (2001)

Under the terms of its accession to the WTO in 2000, Jordan was required to introduce TRIPS-plus provisions into its national patent laws. Shortly thereafter, the US and Jordan negotiated a free trade agreement (FTA). It was the first FTA to introduce a new framework of TRIPS-plus rules. Since 2001, the US has initiated 11 bilateral and regional free trade agreements with 22 other countries, which further expanded TRIPS-plus measures.

In terms of FTAs negotiated by the US, the following aspects are noteworthy (Correa 2006): First, the patent term may be extended to compensate for delays in the process of examination of patent applications. Second, data exclusivity, apart from patents, blocks the registration and marketing approval of generic medicines for five or more years. Third, US FTAs call for linking drug registration and patent protection, the likes of which are not present in the TRIPS Agreement. Consequently, the national health authority is obliged to decline marketing approval to a generic version of a product if there exists a patent on it, except if there is consent or acquiescence by the patent holder. Fourth, in addition to the above-mentioned TRIPS-plus standards, some US FTAs limit WTO Members' freedom to establish the grounds for compulsory licenses, as approved by the Doha Declaration. For example, in the case of the FTAs agreed upon between the US and Australia, Jordan and Singapore, such grounds are restricted to cases of anticompetitive practices, public non-commercial use, national emergency, or other circumstances of extreme urgency (Correa 2006).

Drug prices in Jordan have increased by 20 per cent since 2001 (Oxfam 2007). This increase can partially be attributed to TRIPS-plus rules, which will also postpone or obstruct the use of public health safeguards to decrease the price of new medications in the future. In particular, data exclusivity has delayed generic competition for 79 per cent of medicines newly introduced by 21 multinational pharmaceutical companies between 2002 and mid-2006. These drugs would otherwise have been available in an affordable, generic form (Oxfam 2007). Moreover, in Jordan, more stringent intellectual property protection seems to have produced hardly any benefits with respect to foreign direct investment or domestic research and development.

Against this background, other countries negotiating FTAs that include TRIPS-plus measures should assess and take into account the relevant effects on public health.

Source: Correa (2006)

13 For a discussion of the FTA between Thailand and United States, see Akaleephan et al. (2009).

3.5 Public health research and innovation

So far, this section has addressed TRIPS as a challenge to access to affordable medicines. A second major problem with the current set up of the existing IP system is that recovery of research costs through patent monopoly causes the demand of the market, rather than public health needs, to determine research priorities. The patent system provides incentives that encourage the pharmaceutical industry to focus on developing products for rich countries and chronic diseases, but it fails to ensure that investments in research and development reflect public health needs of developing countries. The pharmaceutical companies invest very little in research on diseases endemic to developing nations, because there is no commercial market from which they can recover R&D costs.[14]

Malaria, pneumonia, diarrhoea and tuberculosis, which together account for 21 percent of the global burden of disease, receive 0.31 percent of all public and private funds devoted to public health research (GFHR 2004). Purely tropical diseases tend to be the most neglected: Of the 1,393 new drugs approved between 1975 and 1999, only 13 were specifically indicated for tropical diseases and, of these 13, five were by-products of veterinary research and two had been commissioned by the military; an additional three drugs were indicated for tuberculosis (Trouiller et al. 2002). The next five years brought 163 new medicines, of which five were for tropical diseases and none for tuberculosis. Tropical diseases and tuberculosis together account for 12 percent of the total burden of disease (Chirac / Toreelle 2006).

Proposed solutions to tackle this problem can be grouped into two broad categories. They allude to various financing mechanisms: *push programmes*, in which innovators are provided with funding to undertake particular research, and *pull programmes*, in which a reward of some kind is offered to the first to achieve some valued innovation.[15]

Developing drugs for developing countries: Push programmes

The most widespread type of push mechanism is research grants, either provided by governments or other sources of funding. A second frequent kind of push funding is public-private partnerships (PPPs), in which public or non-profit institutions subsidise research carried out by private firms, granted they agree that the ensuing innovative products will be offered at prices that are not exorbitant to the poor. In the public health arena, there are currently 60-80 PPPs, including the *Global Fund* to Fight AIDS, Tuberculosis and Malaria, the Drugs for Neglected Diseases Initiative, the International AIDS Vaccine Initiative, the Medicines for Malaria Venture and the Global Alliance for Tuberculosis Drug Development (Johnston / Wasunna 2007).[16]

14 Similarly, they have few incentives to invest in paediatric diseases, preventive treatments, vaccines and relatively rare diseases that only occur in developed countries.

15 For a detailed discussion of push and pull mechanisms, and additional, alternative and complementary solutions, including direct purchases such as the US PEPFAR (President's Emergency Plan for AIDS Relief) programme, drug price reduction efforts and patent pools, see (Hollis / Pogge 2008, chapter 9)

16 For a discussion of the inefficiency of push mechanisms compared to pull mechanisms, see (Hsu / Schwartz 2008)

Developing drugs for developing countries: Pull programmes

Pull programmes are intended to provide incentives for innovation by rewarding successful innovators with some form of remuneration. The current patent system is itself a case of a pull mechanism, which rewards innovators with a temporary market monopoly. Whereas the existing patent system is effective in terms of promoting innovation for markets that can afford monopoly pricing, the challenge is to devise a system that replicates this reward structure, but is able to facilitate innovation of medicines for neglected diseases. Pull mechanisms that are intended to do this, seek to increase the returns that a successful innovator can expect to generate from a socially desirable drug that would not otherwise be a lucrative target of R&D.

Pull mechanisms have several advantages (Hollis / Pogge 2008, 103). They are more effective than push mechanisms because they do not reward unsuccessful research and provide incentives to innovators to work quickly and efficiently toward early achievements. Because pull mechanisms provide rewards only for successful innovations and can set a low market price for newly developed medicines as a prerequisite for receiving rewards, the cost of the treatments can be considerably lower than they would be through push mechanisms. Thus, pull programmes can not only be expected to generate more successful innovations, the innovations they encourage are also likely to be more affordable and therefore more easily accessible (Hsu / Schwartz 2008).

There are a number of existing proposals for pull mechanisms, among them Advance Market Commitments and the Health Impact Fund proposal:

— *Advance Market Commitments* (AMCs) are to provide incentives for the commercial development of vaccines based on a commitment by sponsors to purchase new vaccines that meet certain conditions clearly defined in advance (Berndt et al. 2007; Hollis / Pogge 2008). The AMC assures a specific price per treatment by augmenting the market price as long as the treatments are sold at a predetermined, low price. In this manner, the AMC compensates innovators for the revenues lost by selling a patented drug at competitive market prices rather than at monopoly prices. One AMC – funded by Italy, the UK, Canada, Russia, Norway, and the Gates Foundation – already exists as a pilot scheme for pneumococcal disease, a major cause of pneumonia and meningitis among the poor in developing countries.

— The *Health Impact Fund* envisages a new mechanism that challenges the existing IP system as the exclusive instrument to incentivise and reward research and innovation. The main idea of the Fund is not to reward innovators of pharmaceuticals via monopoly prices, but based on the health impact of their products, if they consent to sell them at affordable prices (Hollis / Pogge 2008). Innovators would give up the freedom to price at monopoly prices, in exchange for payments from the Fund, based on health impact. Patents would continue to exist but firms would make use of the Fund system if they expected higher profits from these rewards than from monopoly prices. The Fund, financed primarily by governments, would have a fixed annual pay-out, which it distributes to the firms which decide to be rewarded in this way. Products would be rewarded strictly in proportion to their health impact. The Health Impact Fund would be most appealing when applied to medicines, which are expected to have a large global health effect, but relatively low profitability through monopoly pricing. Consumers would benefit from the availability of new drugs at low prices. Low prices would be further encouraged, because rewards will hinge on the actual health effect of the medicines, and so innovators will have incentives to ensure their medicines are extensively accessible to those who need them.

Because of the risk of global repercussions, including the increasing spread of diseases and political and social instability, promoting public health research that addresses the needs of developing countries can not only be regarded as a moral imperative, but is in the interest of all nations. While publicly funded pull mechanisms are a comparatively recent suggestion, they could potentially gain broad political backing, both from pharmaceutical companies and taxpayers (Hollis / Pogge 2008). Pull mechanisms imply relying mostly on private risk and entrepreneurial innovation, thereby imitating the merits of the market system (Hollis / Pogge 2008). Pharmaceutical companies would be competing on terms similar to those of the existing patent system familiar to them, while private citizens are more likely to support programmes that do not subsidise failed research.

4 The TRIPS Agreement and food security

The world's population is increasing rapidly, making food security one of the most important challenges of the coming decades (Herrera-Estrella 2000). The right to food is clearly stated in Article 25 of the Universal Declaration of Human Rights, but is still far from assured for a large part of the global population. Since land and water are the most limiting factors in food production, the only option for working towards attaining food security – in combination with a more equal distribution of existing food stocks and changing food consumption patterns, especially in rich countries – is to increase yields on available land (Chrispeels 2000).

The contribution of modern breeding techniques and biotechnologies to achieve this objective is subject to intense debate. Some authors vehemently argue that traditional plant varieties as they are found in nature or varieties modified with traditional breeding techniques suffice to achieve food security, so long as the necessary infrastructure is provided (Shiva 2002).[17]

Other authors trust in the achievements and progresses of modern breeding and biotechnological technologies to improve a variety's potential and support the distribution of such varieties to achieve food security. Improved varieties generate high yields and reduce the need for insecticides and pesticides, and so promise to pay off despite higher seed prices (Qaim / De Janvry 2003; Toenniessen / O'Toole / DeVries 2003; Subramanian / Qaim 2009). Proponents therefore consider it necessary to use "modern" varieties in times of a growing global population and changing environmental conditions (von Braun 2010; Longping 2004). While this debate is beyond the scope of this paper, this section will show that patents are more relevant to the latter group than to the advocates of traditional varieties.

In the field of agriculture, IPRs affect two types of agricultural input factors: plant genetic resources (PGRs) in the form of seeds and chemical inputs, such as fertilisers, pesticides and herbicides. For the latter, the usual IPR measures apply. For plant genetic resources, as will be discussed in this section, the situation is more complex. The debate about IPRs

17 Furthermore, there are concerns about ecological and health problems related with the use of genetically modified organisms (GMOs), which are one form of modern breeds. However, the general debate about genetically engineered organisms is beyond the focus of this section.

in this sector is very intense and emotional and ideologically charged. For example, there are ethical concerns about whether patents on life forms are acceptable in the first place. There are also ecological concerns that biodiversity could be reduced considerably if seeds are mainly supplied by a few patent-owning multinational seed companies providing only a handful of varieties, in contrast to the millions of different local varieties and landraces bred and cultivated by farmers. Biodiversity in turn is essential in order to safeguard food security: For example, biological diversity contains countless plants that provide food for people, many crop varieties and aquatic species with specific nutritional characteristics, livestock species adapted to harsh environments, insects that pollinate fields and micro-organisms that regenerate agricultural soils. Moreover, agriculture is a highly important and sensitive sector of the economies of most developing countries: The agricultural sector involves cultural values and is the foundation of the livelihoods of 900 million rural poor (World Bank 2008b) – making imposing any barriers on the use of seeds etc. an ethically questionable and therefore sensitive political issue.

Furthermore, and more to the point for food security, the introduction of IPR protection for plant varieties and biotechnology products has caused two important trends in agricultural innovation: A growing level of involvement of the private sector in industrialised nations in agricultural R&D and an increasingly proprietary and competitive research environment. In the face of decreasing public-sector research expenditure in both developed and developing countries, these changes may increase corporate control over seed production and distribution, and potentially create even more monopolistic market structures (von Braun / Díaz-Bonilla 2008, 18).

There are several ways in which TRIPS may affect food security. These will be discussed in this section with a special focus on the access of poor farmers to traditional as well as improved seeds and on the provision, dissemination and application of modern biotechnologies. As will be shown, different forms of protection apply to different kinds of seeds, with varying consequences for farmers and breeders (4.1). This section also addresses the concern that relevant research is impeded by (strategic) patenting of essential research tools (4.2). Moreover, this section explores the role of ownership structures in the agribusiness market (4.3). Last but not least, it examines the use of the relevant flexibilities the TRIPS Agreements provides in the case of plant varieties (4.4) and discusses additional factors that are essential in order to achieve food security.

4.1 Seeds and different forms of intellectual property protection

Plant genetic resources are crucial for food security as they are the basic element of most of our food. As indicated above, TRIPS requires all WTO Members to make patents available "for any inventions, whether products or processes, in all fields of technology" (TRIPS, Art. 27.1). However, Members may exclude plants and animals from patentability (TRIPS, Art. 27.3). But if plant varieties are not protected by patents, for example like in the United States, they have to be protected by an effective *sui generis* system[18] or a

18 Laws extending IP-type protection to subject matter not meeting traditional definitions of protected intellectual property are referred to as *sui generis* protection laws. *Sui generis* is a Latin expression, literally meaning *of its own kind* or unique in its characteristics.

combination of patents and other forms of IPRs (TRIPS, Art. 27.3). Such *sui generis* systems, for example plant variety protection (PVPs) mechanisms, are less restrictive than patents. Yet, TRIPS requires microorganisms and certain "non-biological" and microbiological processes for the production of plants or animals to be protected by patents (TRIPS, Art 27.3(b)).[19]

Whether these TRIPS provisions constitute a barrier to access to seeds for farmers, most of all for poor ones, and other input factors depends on the kind of seed and on the form of IP protection that applies (see Table 3). From the farmers' perspective, a critical question in this context is whether IPRs prevent them from saving, re-using and exchanging seeds. Current possibility for patenting plants and special characteristics of plants etc. cause severe concerns that the key to food security will be in the hands of just a few private owners, who may prevent farmers without purchasing power from accessing improved varieties. An even more troubling concern, which is often mentioned in the literature, is that farmers might not be permitted to use their traditional varieties insofar as they contain protected material or characteristics. The rest of this sub-section will examine the extent, to which these concerns are justified.

Table 3: Seeds and their respective forms of IP protection

Seeds		
Traditional varieties / landraces	Improved varieties	GMOs
	conventional breeding techniques or biotechnological methods	biotechnological methods
No protection	• Plant variety protection (PVP) or Patent on the variety • Patents on processes in the case of biotechnological methods	• Patents on processes • Patents on microorganisms introduced into the variety • Patent on the variety or PVP

Source: Own compilation

Plants as they are found in nature cannot be patented. In the case of traditional varieties or varieties that have been modified with traditional breeding techniques, the TRIPS provisions do not constitute a problem. However, there has been some uncertainty in the litera-

19 What exactly counts as such a process is contested. TRIPS Art 27.2 and Art 27.3 merely specify that "members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law. Members may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (b) plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis*-system or by any combination thereof."

ture as to whether the use of traditional varieties containing protected genes or plant cells infringe patents. If a gene or cell is patented in the particular country in which it is to be used, the patent-holder is protected against the use of the gene by another biotechnologist. But the patent leaves anyone free to use and breed organisms naturally containing this gene. Thus, in such a case biotechnological research is restricted, but there are no limits for a farmer to use an organism naturally containing a protected gene (Correa 2000). Therefore, this aspect of TRIPS does not pose a threat to developing countries' farmers' use of traditional varieties.

In the case of improved varieties and genetically modified organisms (GMOs) that have been produced with modern breeding techniques and/or biotechnological methods, the IP situation is different from the case of traditional varieties. TRIPS requires that they are either protected by patents or by plant variety protection. Plant variety protection systems are less stringent than patents and usually contain exemptions for farmers and breeders, which allow them to save seeds and to use protected varieties for further research (see Box 5). Granting such exemptions is up to national law, but they are in effect in most countries.

Box 5: Plant variety protection and UPOV

Plant variety protection is an alternative type of IP that differs from patent protection in some important aspects. It is a special form of protection to cover the sexually reproduced varieties of seed bearing plants, often excluding fungi, bacteria and first generation hybrid varieties. The internationally relevant treaty defining PVP standards is UPOV (Union internationale pour la protection des obtentions végétales), which is also accepted as a *sui generis* system by the TRIPS Agreement.

Generally, a plant variety protection certificate prohibits others from breeding and marketing the protected variety, and also using it to produce another variety. The decisive difference to patents is that plant variety protection does not prohibit other breeders from using the protected variety for developing a new variety that is distinctly different from the protected variety. The protected variety can be used as a parent for hybridisation or mutation or any other basic and applied research. But granting this so-called 'breeder's exemption' and the 'farmer's exemption', i.e. the permission for farmers to save seeds, is not compulsory any more for member countries of the UPOV (in its latest version), but up to national law (Tripathi 2008, 7).

In the case of patented seeds, seed-saving is not permitted. As a result, farmers are forced to re-purchase new seeds every year. Because it is difficult to control farmers, companies also use biological methods like hybridisation (see also 4.3) to induce annual or seasonal buying. Furthermore, companies use biotechnological methods to modify their varieties such that company-specific pesticides or herbicides and other inputs become indispensable for the plant to bear fruit.

For farmers in developing countries, the key question is whether using these more costly, patented varieties pays off in terms of higher yield or better quality. Whether more costly varieties are worth their higher price to farmers depends on a variety of factors, including the presence of the necessary infrastructure, such as irrigation systems (see also 4.7). In many cases, the higher price for patented varieties does pay off. However, there have been some cases where agribusiness companies were very active in promoting their new varieties in developing countries and where farmers were attracted by promises about high yields and low susceptibility to pests and diseases, but where these promises did not hold, resulting in disastrous crop losses, which threatened food security and the livelihoods of the rural poor (Steinberger 2006).

To sum up, TRIPS poses different constraints for farmers and researchers and for different kinds of seeds. Since traditional varieties are not patentable, there is no restriction for farmers to use these varieties, even if they contain certain protected characteristics. However, different forms of protection may apply in the context of improved varieties, which in turn impede access to seeds for poor farmers due to higher prices, and prevent farmers from saving seeds. For researchers, research with such protected material is not possible with

4.2 Research and innovation in the field of plant genetic resources

As set out above, plant varieties have to be modified to be patentable. In the case of an improved but not genetically modified variety, seeds, as well as possibly some of the relevant processes in their production, may be subject to patents.[20] Genetically engineered seeds or plant cultivars offer the most possibilities for patenting. They contain three components that may be protected as IP: gene sequences that code for specific traits of the plant, research tools needed to transfer the new genetic trait into plant cells and to regenerate from these engineered cells modified plants, and the genetically transformed seed or plant cultivar itself (Charles 2001; ETC Group 2008).

The existence of a patent prevents the production or commercialisation of any product containing the invention. If, for instance, a plant variety is protected, it may not be possible to use the reproductive material of that variety for commercial purposes, including the breeding of new varieties. Similarly, if modified plant cells are patented, any plant composed of those cells infringes that patent (Correa 2000, 177). This means that patents can decelerate or even inhibit follow-up research for a number of reasons.

First, the fact that any product containing the invention at issue is subject to a patent can lead to complex situations where a number of owners have valid patent entitlements on the technologies and genetic contents included in one cultivar, or on particular aspects of each technology. This in turn results in high transaction costs for research on plant varieties. For example, in the development of β-carotene-enriched rice, researchers used at least 40 patented or proprietary methods and materials belonging to about a dozen different IP owners in the gene transfer process (UNCTAD 2006, 22).

Patenting poses challenges for research on plant varieties, because access to existing genetic material is essential for the continuous adaptation and improvement of plants for food production and agriculture. A new plant variety cannot be created from scratch. The improvement of crops can only take place based on the utilisation and modification of what already exists. Innovation in breeding activities works gradually in that it progresses on the principle of successive changes to available varieties (Correa 2000, 176).

20 The reason is that isolated sequences of DNA count as patentable inventions; accordingly, genes do not necessarily have to be genetically modified in order to be patentable.

Box 6: Seeds as a challenge for an IPR system

Plant genetic resources in the form of seeds present several important challenges for an IPR system.

1. Seeds are biological products that are easily reproduced and whose very use entails multiplication.
2. The users of seeds (and potential 'copiers' of the technology that is incorporated in these seeds) are millions of individual farmers whose compliance with any protection regime is difficult and expensive to monitor.

It is not undisputed if something already existing in nature can be an invention, or whether it is merely a discovery and therefore not patentable.

Furthermore, as mentioned above, processes may not be excluded from patenting. In the case of process patents, the patentee has the exclusive right not only over the process itself but also over the commercialisation of all products obtained directly by that process. Accordingly, if a process to produce a plant (e.g. a transgenic plant) is patented, exclusive rights also apply with respect to the plant obtained with that process (Correa 2000, 176).

Last but not least, competitive research is hindered if central techniques and tools are patented. Therefore, perhaps more important than the sheer number of patents in the respective IP portfolio is the 'centrality' of the respective patent: 'Blocking patents' are an essential part of the biotechnological research business and the majority of these patents, which are crucial for the agricultural, but also the public health sector, is owned by private companies. For example, the agribusiness company Monsanto holds patent rights to many such 'central' tools (UNCTAD 2006). The ownership of these techniques and materials constitutes essential barriers for competitors of Monsanto.

In sum, even if a country makes use of the flexibilities provided in the TRIPS Agreement and excludes plants from patenting, firms may use rights on processes and microorganisms, which cannot be excluded from patent protection, to block competitors by strategically hindering research through extensive patenting. From a development perspective, this is of special importance because these patents do not only hinder private research (and make it much more expensive) but also decelerate research conducted by public institutions, which better caters to groups with less purchasing power, or with specific needs.

The problem is that, like in the case of medicines (see section 3.5), IP pushes research to fields where high (monetary) returns on investment are expected. Current application of modern biotechnology, which is still in an early phase, is focused on industrial country agriculture (Pinstrup-Andersen / Cohen 2000). Most of the transgenic crops that have been produced to date, especially by the private sector, are aimed either at reducing production costs in agricultural areas that already have high productivity levels or at increasing the value of the final product (Herrera-Estrella 2000). Problems of tropical countries have largely been ignored by private sector research until now, because firms cannot expect sufficient returns to cover costs (Pinstrup-Andersen / Cohen 2000). But process patents and patents on research tools as well as on certain gene sequences etc. hinder research by other institutions in these areas.

For example, metal toxicity and nutrient deficiency problems that affect acidic soils, which constitute a good proportion of the soils in the tropics, are investigated by only a handful of scientists in developed countries, and this issue has been largely neglected by large agribusiness companies (Herrera-Estrella 2000). Furthermore, big corporations do

not do research on the crops of the poor, such as cassava, millets, sorghum, sweet potatoes, yams, and legumes (other than soybeans). Rice, an important crop of the poor, is an exception, with some research in the corporate sector and considerable research in the public sector taking place, primarily on the initiative of the Rockefeller Foundation (Chrispeels 2000).

However, some agribusiness companies have agreed to transfer proprietary technologies to developing countries without charging royalties, as there is little potential for commercial prospects (Pinstrup-Andersen / Cohen 2000).[21] Using high-performing germplasm open to the public would imply that farmers will neither be prevented from saving seeds, nor will they be under monopoly pricing for seeds (Cohen 2005). But as of now, access to proprietary genetic resources is still extremely limited in developing countries (Cohen 2005), and the possibilities for protection are still extensively used for strategic patenting (ETC Group 2008).

Therefore, a big risk of modern biotechnology for developing countries is that technological development will bypass poor farmers and poor consumers (Pinstrup-Andersen / Cohen 2000). This results in a dilemma posed by the conflict between intellectual property protection and private sector participation in research on the one hand, which are key to continued technological innovations, and the moral obligation to ensure that scientific research helps to address the needs of poor people and safeguards the environment for future generations on the other (Serageldin 1999).

In sum, as in the case of medicines, private research in the context of plant varieties is driven to the most profitable areas – which do not sufficiently reflect the needs of the poor. On the other hand, public research, which attends more adequately to the needs of poor farmers, may be hindered by the extensive patent practices of the private sector.

4.3 Ownership structures within the agribusiness market

Although patents are the most important form of IPRs in the biotechnology sector, the plant breeding industry does not rely solely on formal IPR systems to protect its varieties and to limit their use. Alternative possibilities include conventional seed law, contract law, and biosafety regulations, apart from TRIPS-regulated measures such as patents, trademarks and trade secrets. Furthermore, in the case of seeds, companies can use additional alternative measures, such as keeping biosafety data secret and using hybridisation to protect their IP.

– Biosafety regulations determine what type of transgenic varieties may be sold on the market (Traynor / Komen 2002). Biosafety data can be a very valuable property because it requires data from extensive testing to demonstrate environmental and food safety. Such testing is very expensive, especially when field and food trials are necessary (Louwaars et al. 2005). Since smaller firms may not have the facilities or the

21 There are a few examples of such changes of policy: Monsanto decided to make the rice genome "public". This cooperation is likely to help breeders; whether it will help genetic engineers, depends on the conditions that Monsanto will attach to the use of the information. Another example is the recent decision by Astra Zeneca to help develop "golden rice". Similarly, the Novartis Foundation for Sustainable Development conducts a number of projects in developing countries.

budget to conduct these tests themselves, they may be reliant on buying this data from other companies to market their varieties.

— Hybridisation is a very old but still highly important way to protect IP incorporated in a plant variety. Hybrids are the products of cross-breeding two (or more) inbred lines. The seed of hybrid origin will lose some yield potential and other valuable characteristics in subsequent generations, which drastically reduces farmers' incentives for seed saving. In addition, competing seed companies need access to the hybrids if they want to duplicate the hybrid variety (Louwaars et al. 2005, 41).

Box 7: The agricultural market

From the point of view of multinational companies (MNCs), who are very important stakeholders in this field, agriculture is a big market and still has promising prospects: While proprietary seeds account for over 80 per cent of the commercial seed supply, approximately three-quarters of the world's farmers routinely save seeds from their harvest and grow locally-bred varieties. Globally, at least 1.4 billion people still depend on farmer-saved seeds (ETC Group 2008, 8). But despite this considerable market share of the informal sector, in 2007 the global proprietary seed market was valued at 22,000 million US-Dollars and the total commercial seed market at 26,700 million US-Dollars in 2007 (ETC Group 2008, 11). The end-user market value for agrochemicals (herbicides, insecticides, fungicides, and other agrochemicals) was estimated at 32,665 million US-Dollars in 2004 (UNCTAD 2006).

The numerous ways to control research tools and the use of protected products has resulted in a process of consolidation within the global agribusiness in recent years, the outcome of which is the domination by a few major integrated companies, each controlling proprietary lines of agricultural chemicals, seeds and biotech traits (Yoon 2006). The degree of substitutability between varieties from different firms may vary, but the level of competition between firms is much lower than in other sectors. Market power is heavily determined by the patent-portfolios of the respective stakeholders, which have been the reason for numerous mergers and acquisitions in the last years, resulting in the actual situation where the top 10 corporations have a global market share of 89 per cent in agrochemicals and 67 per cent share of the proprietary market in seeds (ETC Group 2008, 4).

A recent study has analysed changes in patent ownership of more than 3,000 agriculture-related biotech patents issued between 1976 and 2000 to US and European companies. The study reveals that by 2002, 95 per cent of patents originally held by seed companies or small firms had been acquired by large chemical or multinational corporations. The top five corporations hold 41 per cent of agricultural biotechnology patents issued between 1982 and 2001 in the United States (UNCTAD 2006, 26). Additionally, vertical integration was taken as a chance to improve market power: The world's six largest agrochemical manufacturers also are seed industry giants (ETC Group 2008).

The various possibilities for protection raise concerns about the resulting market power of large seed companies. As indicated above, the concern is that these companies use their ownership of major food crops to modify their varieties such that the firms own pesticides or herbicides and other inputs become indispensable, or charge high monopoly prices – thereby undermining food security.

4.4 Rules versus reality: The *sui generis* option and its implementation

A crucial question is whether the *sui generis*-option is a meaningful flexibility for developing countries leaving enough scope for national legislation to protect small marginal farmers and safeguard adequate public research possibilities.

In principle, the *sui generis* option of Article 27.3(b) of the TRIPS Agreement offers the possibility for countries to exclude some sectors from patenting. As a result, countries can exclude genes and entire plants from patenting, either by not defining them as inventions, by defining them as non-patentable inventions, or by excluding all living material from patentability. For example, Mexico has excluded genetic material from patentability while Argentina, Brazil and the Andean Group excluded all materials existing in nature (Blakeney 2002, 9).

But despite these possibilities, many developing countries did not make use of the flexibilities granted in the TRIPS Agreement. It is very curious that many of the poorest countries have made least use of the room to manoeuvre, while still securing some extra concessions. As in the case of public health, the reason is that at the urging of industry lobbyists, powerful countries backtracked on the flexibilities in TRIPS and pursued even stronger global IP rules. In the case of agriculture, developed countries pushed for the extension of patents to new sectors, such as plant varieties and genes, and the adoption of UPOV-1991 as the PVP system (Deere 2008, 178). For example, in 1996, the EU and the US filed law suits against India because of the alleged absence of patent protection for pharmaceuticals and agricultural chemical products, and the absence of formal systems that permit the filing of patent applications and provide exclusive marketing rights for such products (Deere 2008, 157). But despite various sources of political and economic pressure, India, for example, made a very farmer- and breeder-friendly law, which is now often taken as a best practice example where securing farmers' rights is concerned (see Box 8).

Several advantages helped India in withstanding external pressures regarding IP-protection. First, India has already had a patent system for a relatively long time, with both the expertise and experience to counterbalance its deficiencies. Second, in the case of agriculture particularly, India can rely to a well-established national seed industry, which implies that breeding and research tools are available. In contrast to other developing countries, India is therefore not solely dependent on MNCs for access to new technologies. Last but not least, India has a democratic government, implying the exigency to pay at least some attention to the huge constituency farmers represent. Moreover, India has a very strong and well-organised farmers' lobby. Farmers associations like the KRRS (Karnataka State Farmers Association) and several NGOs played a very important role in preventing patent protection for plants and parts of living organisms and in securing farmers' rights. Smaller developing countries are unlikely to be able to withstand external pressures in the context of intellectual property protection as well as India was (Raju 2002; Chaudhuri 2003).

Box 8: IPR protection in the agricultural Sector: The case of India

India is among the first countries in the world to have passed its own *sui generis*-system for PVP in the form of the 'Protection of Plant Varieties and Farmers' Rights Act, 2001' (PPVFR) (Government of India 2009). India's law is unique in that it simultaneously aims to protect both breeders' and farmers' rights. The Indian case is of immense importance, due to the country's leadership in establishing a legal framework on farmers' rights and its international contribution to negotiations on farmers' rights. India's case is also significant as the Indian sub-continent is recognised for its wealth of native plant genetic resources (Ramanna 2003).

Indian law explicitly recognises the role of farmers as cultivators and conservers and the contributions of traditional, rural and tribal communities to the country's agro-biodiversity by rewarding them for their contributions through benefit sharing and protecting the traditional rights of these farmers (PPVFR, Statement of Objectives and Reasons of the PPVFR, Art. 5 (i) - (iii)). The PPVFR Act grants farmers' rights in their broadest definition: "The farmers' rights include the traditional rights to save, use, share or sell his farm produce of a variety protected under the Act, provided the sale is not for the purpose of reproduction under a commercial marketing arrangement" (PPVFR, Art. 6). Moreover, genes, plants and methods of agriculture or horticulture are excluded from patentability.

A further fortification of farmers against big seed corporations is the provison that farmers shall be protected from exaggerated performance claims by seed companies with respect to their registered varieties. The breeder is obliged to disclose to farmers the expected performance of the variety under given conditions. If the material fails to perform as specified, farmers may claim compensation from the breeding company through the authority set up to administer the Act (PPVFR, Art. 39.2). However, there remain serious concerns about the enforceability of this provision.

In addition, safeguards against innocent infringement by farmers are included. Farmers who unknowingly violate the rights of a breeder are not to be punished if they can prove that they were not aware of the existence of such a right (PPVFR, Art. 42).

The Act also provides for researchers' rights in that it states that the use of a registered variety for conducting research or as initial resource for creating another variety may not be prevented (PPVFR, Art. 30). The authorisation by a breeder of a registered variety is only required, where the repeated use of such a variety as a parental line is necessary for commercial production of another newly developed variety (PPVFR, Art. 30).

Overall, India has a quite far-reaching legal system for the protection of farmers' and researchers' rights. It is questionable if all these provisions are enforceable. But at least the PPVFR offers 'passive' protection of farmers against multinational companies since farmers are allowed to save their seeds, and exchange and sell them in small amounts. The PPVFR thereby restrains the impact of TRIPS on agriculture.

This example is not intended to gloss over the fact that every country has different prerequisites and needs concerning seed policies. But the Indian case may serve as an example for the use of flexibilities on the one hand and the various difficulties on the other concerning the implementation of TRIPS Article 27.3(b).

In this context, a crucial question is whether countries may change their patent protection system to one with lower protection standards, once they have already established a patent system. Some authors argue that established standards are not to be lowered (Seiler 2000, 10) so that the implementation of a *sui generis* law comparable to the Indian PPVFR would not be possible for those countries already having signed UPOV. Whether such a change is impossible for legal reasons or merely for reasons of political pressure, is not yet clearly identified, and points to further avenues for future research.

4.5 Other relevant policy measures

While safeguarding farmers' possibilities to save, re-use and exchange seeds and to improve public research to develop improved varieties for poor farmers, is crucial in order to successfully work towards food security, additional factors are also of great importance, above all providing infrastructure in every respect. From a development policy perspective, one major objective is to increase the productivity and profitability of smallholder farms (Serageldin 1999). As the Green Revolution showed, the successful adoption of new technologies depends on access to water, fertilisers and pesticides, credits, market access etc. If this infrastructure is not available, technological improvements will under-perform and inequality between well-endowed and resource-poor areas will increase because of the lack of prerequisites to take advantage of new technologies (Pinstrup-Andersen / Cohen 2000). Moreover, additional factors such as access to (reasonable) credits, irrigation facilities and marketing opportunities urgently need to be improved in most regions of developing countries.

5 The TRIPS Agreement and renewable energies

If current greenhouse gas emission patterns prevail, they may lead to a rise in temperature of up to 6°C relative to pre-industrial levels. Climate change of this magnitude would be catastrophic. Hundreds of millions of people, mainly in the developing world, might be exposed to water stress, hunger and extreme weather events of unprecedented magnitude and frequency. The situation urgently calls for a change in production and consumption patterns to protect the global climate system as a public good.

In contrast to the fields of public health and food security, access to climate change mitigation technologies is not declared a human right. Here, the line of argument rather goes *vice versa*: Developed countries need the developing countries to join the effort of reducing greenhouse gas emissions. As the climate crisis affects every country, it is in the developed countries' own interest to support developing countries' access to mitigation technologies. In 2005, carbon dioxide accounted for more than three quarters of global greenhouse gas emissions (World Resources Institute 2010). About 80 per cent of CO_2 emissions were caused by the energy sector, 37 per cent of that in the production of electricity and heat (World Resources Institute 2010). While already high, the emissions are projected to rise further. In a business-as-usual scenario the International Energy Agency (IEA) estimates a rise of global energy-related emissions by 45 per cent between 2006 and 2030. Almost all of this increase is expected to occur in non-OECD countries, mostly as a result of a greater use of coal. Thus, business-as-usual is not an option.

A technological change towards clean energy sources is imperative. However, as these technologies are regarded as important future markets, there are heated debates about appropriate measures to support deployment. Many of the technologies have only recently been developed, and the intellectual property they entail is often protected by patents.
In the international climate change negotiations, developed countries argue that intellectual property rights are key to fostering innovation. As many clean technologies still are in

an early stage of their development, further research and innovation is necessary. Developing countries, on the other hand, argue that the protection of intellectual property rights and the ensuing additional costs, such as licence fees, impede the widespread deployment of these technologies. They draw analogies especially to the impact of patents on public health. The debate is thus characterised by a north/south divide. India in particular sees the regulation of intellectual property on clean technologies by international rules such as TRIPS as a barrier to their access. This is not surprising, considered that India has very little domestic ownership of climate change technologies and therefore a low interest in strong IPR protection (Dechezleprêtre et al. 2008, 20; Copenhagen Economics 2009, 23). Developed countries such as Japan and the United States argue in favour of strong patenting rules. With 40.8 per cent, the largest proportion of patents on climate-related inventions is situated in Japan. The United States rank second with 12.8 per cent (Dechezleprêtre et al. 2008, 17).

Other than in the fields of public health or agriculture, the TRIPS Agreement's flexibilities have not been applied to support access to and the dissemination of clean technologies. The possible use of existing flexibilities is subject to heated discussions. The debate is further complicated by the fact that the definition of clean technologies is still fuzzy. There is no agreement what technologies exactly count as "clean". This applies to the discussion under the United Nations' Convention on Climate Change as well as the WTO, where clearly defining "environmental goods and services" poses difficulties (Chatham House 2007, 6). In addition, most products in question consist of a multitude of components which in turn may be protected by a multitude of patents. Many of these components can be used in other products which would not be classified as clean. It is thus difficult to draw a line and develop a clear-cut definition of patents protecting "clean" technologies.

As the boundaries of the definition remain unclear, most empirical studies resort to analysing technologies such as renewable energies that undisputedly count as clean. Solar photovoltaic is explicitly cited as an example for an environmental good in the OECD classification of environmental goods and services (OECD 2005, 2), see Box 9. This paper follows this line by focusing on renewable energies as both clean and highly relevant to solving the global climate challenge.

Box 9: OECD definition of environmental goods and services

"The environmental goods and services industry consists of activities which produce goods and services to measure, prevent, limit, minimise or correct environmental damage to water, air and soil, as well as problems related to waste, noise and eco systems. This includes cleaner technologies, products and services that reduce environmental risk and minimise pollution and resource use. (...) Cleaner technologies and products are goods that are intrinsically cleaner or more resource-efficient than available alternatives. For example, a solar photovoltaic power plant is fundamentally cleaner than a coal-fired one." (OECD 2005, 2)

The following section assesses whether TRIPS are a barrier to renewable energy access in developing countries (5.1), examines relevant TRIPS flexibilities in that context (5.2) and explores other obstacles to clean energy transfer and the use of renewable energy in the developing world (5.3).

5.1 TRIPS as a barrier to renewable energy access in developing countries?

Empirical evidence on the net impact of intellectual property rights on the transfer of clean technologies is still rare. However, the studies that are available indicate that the protection of intellectual property plays a less significant role in the renewable energy sectors analysed, than it does, for instance, in the public health sector (Barton 2007; Reichman et al. 2008; Abbott 2009). One factor to explain this is the difference in competitive situations. Drug patent holders may not face many substitute products, and thus hold a very strong market position, allowing them to charge a high mark-up on production costs. Research and development costs for a new drug are usually high, while production or re-engineering costs are low. Inventors of renewable energy technologies, in contrast, not only face competition within their own sector, but also from other energy technologies. This reduces the possibility of monopoly pricing to a minimum. Invention and production costs are in a different relation to each other than in the public health sector, as production costs of a wind farm or a solar thermal power plant are considerable. In addition, the studies suggest that patents in the renewable energy sector usually apply to specific, incremental improvements or features rather than basic technologies. Blocking patents for preventing competitors from follow-on research by patenting central features of a technology are therefore rare.

One of the more detailed studies is the work of (Barton 2007). The author analyses intellectual property rights as a barrier to access to solar photovoltaic (PV), wind and biofuel technologies. His findings indicate that for solar PV patents do not seem to be a major barrier to dissemination of the technology. These findings are supported by (Reichman et al. 2008). Even though the global PV market features an oligopoly market structure, the high number of entrants indicates accessibility. Among these entrants were also firms from developing countries. Suntech, a Chinese global player in the solar PV market, was able to become competitive through a combination of own technologies and purchases of firms from developed countries. Joint ventures also provide entry opportunities for developing countries, as demonstrated by the British-Indian joint venture Tata-BP Solar.

The market for wind technology seems to be more concentrated, implying higher market power of individual companies. However, early wind technologies have been available for decades. The challenge therefore lies in accessing cutting-edge technologies, rather than in accessing the technology as such. The Indian wind power company Suzlon indicates the ability of developing countries to enter the global market.

For first generation biofuels, intellectual property does not seem to be a barrier to market entry by developing countries either, as demonstrated by Brazil. However, in the production of second and third generation biofuels, patents on enzymes or microbial material may become a barrier. Here the challenges are similar to the agricultural sector (see Section 3). Research heavily depends on access to necessary data or resource inputs. In addition to agreements such as TRIPS, copyright provisions or *sui generis* laws may act as barriers. (Reichman et al. 2008) therefore propose the establishment of a worldwide microbial commons to increase the pace of technological progress.

It is certainly noteworthy that the developing countries analysed in the empirical studies mentioned above are relatively advanced in their technological capacity. They may even profit from strong protection of intellectual property, as foreign firms may be more willing to transfer cutting-edge technologies as a result (Maskus / Reichman 2004, 288). Also, inventors being residents of emerging economies profit from stronger protection. Residents of China, South Korea and Russia are respectively the fourth, fifth and sixth largest holders of patents on clean technologies worldwide, with a total global share of about 15 per cent (Dechezleprêtre et al. 2008, 17). About one third of the patents registered in emerging market economies are owned by residents of these countries, in particular Chinese residents (Copenhagen Economics 2009, 20 f.).

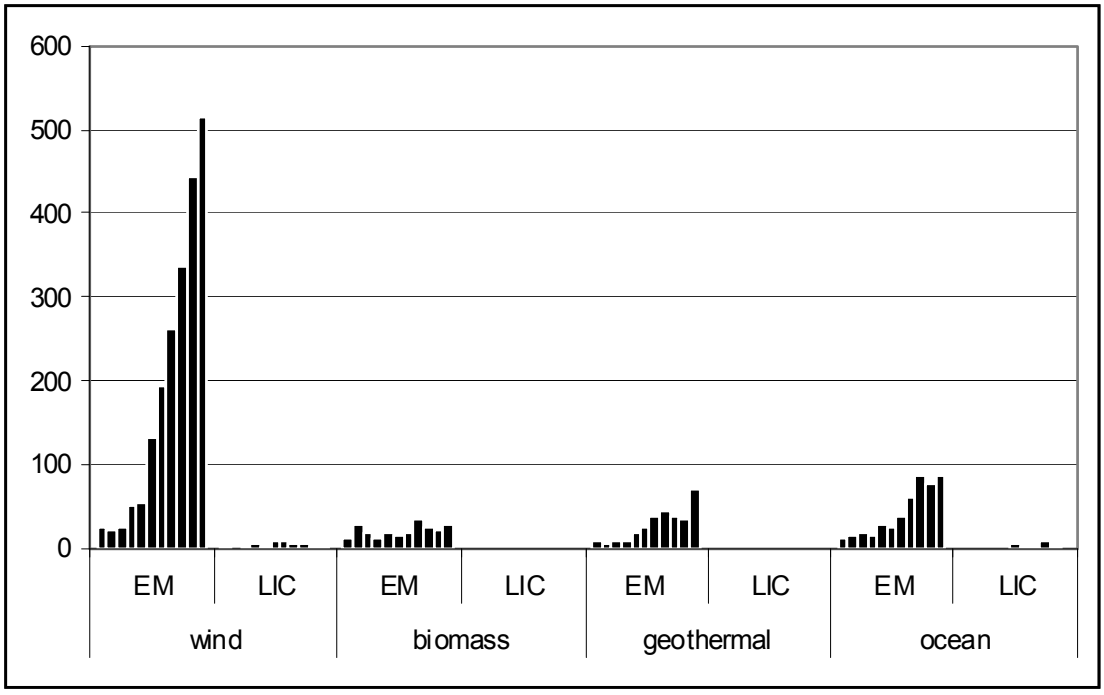
However, the question remains whether poorer developing countries are also able to access renewable energy technologies, and if not, whether the obstacles arise from the mark-up pricing facilitated by patenting, or from other factors. These countries hardly have any own innovation activities; they therefore depend on technology transfer. Any positive effects of intellectual property protection on innovation that may arise in emerging markets are unlikely to happen in countries at the initial stages of technological development. A report of the United Nations Conference on Trade and Development (UNCTAD) states that intellectual property rights can even act as a barrier to technological progress in the least developed countries (UNCTAD 2007, 118).

This being said, empirical studies show that developers of wind, biomass and other renewable energy technologies have not generally protected their inventions in least developed countries, see Figure 2 (Cannady 2009, 2; Copenhagen Economics 2009, 18).

The decision not to patent in least developed countries may have several reasons. One may be the inventors' lack of experience with the process of registering through regional systems such as the African Regional Intellectual Property Organization (ARIPO) or the Organisation Africaine de la Propriété Intellectuelle (OAPI). Another is the low risk of imitation in countries with low technological capacity which does not justify the cost of registering a patent. In addition to a lack of capacity, the small size of the market in most least developed countries does not allow for profitable imitation activities in the field of renewable energy technologies.

There thus is strong evidence that patents do not constitute the prominent barrier to the transfer of most renewable energy technologies. For the few exceptions, such as second and third generation biofuels, there may be viable solutions within the existing IP systems. These shall be discussed briefly below, focusing on the flexibilities of the World Trade Organization's TRIPS Agreement as the most comprehensive international agreement on the issue.

Figure 2: Registered patents for renewable energy technologies in emerging markets and low-income developing countries (LIC), 1998–2008



Source: Own illustration based on data from (Copenhagen Economics 2009, 19 f.)

5.2 Relevant TRIPS flexibilities

Already discussed or applied in the fields of public health and agriculture, the flexibilities within the TRIPS regime are now under consideration in the context of clean technology transfer. The option most discussed is compulsory licensing.

Expanding the use of compulsory licenses to clean technologies might involve a declaration on climate change similar to the Doha Declaration on Public Health. This declaration facilitated compulsory licensing of vital medicines in 2001 (see Section 2.2). However, such negotiations would most likely be time-consuming and tedious. In addition, other than in the fields of public health and agriculture, the United Nations Framework Convention on Climate Change (UNFCCC) already legally commits developed countries to support developing countries in accessing clean technologies (see Box 10). This includes financial support, which may also serve to buy licences developing countries cannot afford.

Box 10: Technology transfer commitment in the UNFCCC

UNFCCC, Article 4.5:

"The developed country Parties (...) shall take all practicable steps to promote, facilitate and finance, as appropriate, the transfer of, or access to, environmentally sound technologies and know-how to other Parties, particularly developing country Parties, to enable them to implement the provisions of the Convention. In this process, the developed country Parties shall support the development and enhancement of endogenous capacities and technologies of developing country Parties. (...)" UNFCCC (1994)

In addition to TRIPS flexibilities, other solutions may exist to accelerate innovation and diffusion of clean technologies. These may include market-pull mechanisms such as advance purchase commitments, where demand for products is guaranteed if they meet certain pre-defined criteria (also see Section I.3.5). Research may furthermore be conducted in international cooperation and supported by public funding. Resulting inventions can be made available to the public domain.

Unilateral trade measures should only be implemented if the ongoing UNFCCC negotiations fail to establish an effective mechanism for technology transfer. In the meantime, measures such as compulsory licensing serve as bargaining chips to exert pressure on developed country negotiators. However, technology transfer is far from being complete simply with obtaining the right to use a certain technology (Maskus 2010, 8). Compulsory licensing, for example, cannot mandate the transfer of tacit knowledge, which may be critical in learning how to use the technology. Therefore, developed and developing countries should not lose sight of other, often more powerful drivers and barriers to effective technology transfer.

5.3 Other barriers to clean technology transfer

Even though it is called for in many international forums and the term is widely used, there is no generally accepted definition of "technology transfer". As a result, it has to be interpreted contextually. While Article 66.2 of the TRIPS Agreement can be understood as alluding to technologies protected by intellectual property rights, the UNFCCC refers to all kinds of technologies in its Article 4.5, broadening the term by its emphasis on know-how transfer and capacity building, see Box 11. This broader understanding is further defined by the Intergovernmental Panel on Climate Change (IPCC), see Box 11.

Box 11: Technology transfer as defined by the IPCC

IPCC, Methodological and Technological issues in Technology Transfer:

"The term 'technology transfer' is defined as the broad set of processes covering the flows of knowledge, experience and equipment amongst different stakeholders such as governments, private sector entities, financial institutions, NGOs and research/educational institutions. The broad and inclusive term 'transfer' encompasses diffusion of technologies and technology cooperation across and within countries. It comprises the process of learning to understand, utilise and replicate the technology, including the capacity to choose it and adapt it to local conditions." (IPCC 2000)

These definitions used in the climate change context underline the fact that technology transfer is not limited to the transmission of hardware. It rather involves a much more complex process, where both the channels for technology transfer must be open and the host country has to feature a certain degree of absorptive capacity (Pegels 2007). The absorption of technologies may indeed critically depend on factors within the developing countries themselves.

Appropriate measures to support technology transfer have to be adapted to the developmental state of the targeted country. Emerging economies such as China, India or Brazil

typically have a sound basis of technological capacity. They are thus able to absorb technologies that are transferred and can focus on technology transfer channels, such as trade and foreign direct investment. These private sector activities can be supported by developing countries through a stable investment climate and an appropriate infrastructure. China in particular has been successful in attracting foreign direct investment and thus spurring technology transfer. In this context, stronger IP rights can be a means to support investors' trust in the protection of their intellectual property, removing investment uncertainty and raising the willingness to transfer technology (Maskus 2010, 17). However, openness in trade seems to be even more relevant for technology transfer than the protection of intellectual property (Dechezleprêtre / Glachant / Ménière 2010, 20).

The situation is different for less developed countries. Circumstances such as limited market size and weak overall investment climate impede the inflow of technology through private market activities. In addition, even if technology transfer channels such as trade and foreign direct investments are open, absorption of technology is not guaranteed. In fact, absorption is the crucial point where many technology transfer projects fail. The ability to absorb depends on the level of education in the recipient country, and especially on the technology-specific know-how. (Dechezleprêtre / Glachant / Ménière 2010) show that patent transfers used as a proxy for technology flows increase if the recipient country is conducting its own research in the technology field in question.

Foreign direct investments in the absence of absorptive capacity may even result in technological "silos", where affiliates of multilateral corporations do not integrate with the domestic market, but rather crowd-out domestic firms. This leads to a negative net effect on the host country's productivity.

Absorption can be supported if the transfer of equipment is accompanied by targeted training and measures of knowledge-transfer. In the past, many technical aid projects funded through development cooperation were bound to fail because they did not include capacity building and training. Local project partners must be enabled to operate, maintain, repair and adapt the technology to local conditions.

Eventually, capacity building and knowledge transfer should enable developing countries to build a domestic technological base and expertise as a foundation for their own innovation. Some former developing countries such as the "Asian Tigers"[22] have succeeded in building such a foundation and have become competitive in many sectors. Analysing the factors of their success shows a strong emphasis on policies strengthening education and research.

22 South Korea, Hongkong, Singapore and Taiwan experienced phases of rapid growth and are often referred to as the „Asian Tigers".

6 Conclusion and policy recommendations

The analyses of the previous sections have demonstrated the very heterogeneous relevance of intellectual property rights to providing global public goods. While acting as a very relevant barrier to access to affordable medicines, the role of IPRs in food security seems to be less pronounced. In the case of renewable energies, IPRs do not seem to constitute a major barrier. Instead, a lack of absorptive capacity of the host country and high ex-ante investment costs impede fast diffusion. Therefore, there is no blueprint solution that will fit all global challenges analysed in this paper. However, some major similarities and differences may be identified. Table 4 aims at providing a systematic overview of these parallels and disparities, thereby allowing a comparison across the three policy fields analysed in this paper.

Table 4: Classification of technologies for global public goods provision

Technologies to be disseminated	**Medicines**	**Improved seeds**	**Renewable energies**
Need for access to cutting-edge technology	high	disputed: traditional plant varieties are argued to be sufficient	high
Market concentration	high	high	depends
Mark-up pricing	very high	high	low
Potential for blocking patents	high	high	low
IPRs as a barrier to dissemination	strong	strong	weak
Relative relevance of other barriers	lower	high	very high

Source: Own illustration

Patent protection in the area of public health means that the production, importation and commercialisation of pharmaceuticals are subject, for a given period, to exclusive rights that allow patent-holders to charge prices considerably above marginal costs. Competition is constrained by high market concentration and the possibility of blocking patents. Higher prices for medicines may mean, especially for poor people living in developing countries, that a large part of the population is deprived access to the drugs they need. As only few drugs exist for some diseases, or new generations of medicines can substantially reduce unwanted side-effects, the need for access to cutting-edge technology is strong.

However, the TRIPS Agreement also contains provisions that allow a degree of flexibility for countries to accommodate their own patent and intellectual property systems and public health needs. The Doha Declaration (2001) and the Paragraph 6 decision (2003) affirm important principles under the TRIPS agreement, regarding the protection of public health. But two major challenges remain. First, in many countries there is need for appropriate national laws to enshrine the flexibilities provided for under the TRIPS Agreement and the

Paragraph 6 decision. However, progress in implementing these to improve access to medicines is hindered by an inadequate capacity of low to middle income countries and pressure from powerful trading partners to avoid using such measures. Second, the available flexibilities under the TRIPS agreement to protect public health, face erosion by the recent wave of bilateral and regional free trade agreements negotiated outside the WTO. Many of these agreements include so-called TRIPS-plus measures, which require levels of intellectual property protection for drugs higher than those mandated by the TRIPS Agreement. The core policy issue is how public policy makers can move forward to secure access to medicines and to safeguard TRIPS flexibilities.

A second major problem is that the current patent system provides insufficient incentives for research and development for medicines for so-called neglected diseases, which disproportionately affect the poor in developing countries. Potential solutions for this problem fall into two broad categories that can be characterised as push and pull mechanisms: Push programmes diminish the cost of carrying out research activities by making complete or partial R&D funding available up front, while pull programmes are intended to provide incentives for innovation by rewarding successful innovators on the basis of profits or some other type of remuneration.

In the area of seeds, countries can use the flexibilities the TRIPS Agreement provides in Article 27.3(b) to exclude animals, plant varieties and essentially biological processes from patenting. However, "non-biological" and "microbiological" processes may not be excluded. In recent years, extensive patenting – in many cases for strategic purposes – was usual business in the agribusiness and biotechnological industry. Apart from patents, firms also use other means to protect their IP, in many cases through means such as biosafety data and biological processes like hybridisation. As in the case of medicines, this shift risks a general neglect of the specific concerns of the world's poor.

On the other hand, it is not certain whether farmers need access to improved seeds to safeguard food security. Patent rules do not prohibit farmers from using their traditional varieties even if they contain protected characteristics. Problems occur, however, if these plants or their products are needed for further research. IPRs push private research away from the needs of poor farmers, because other areas of research are more profitable. Moreover, patents on processes and microorganisms hinder public research on plant varieties and other relevant matters. The case of India shows that WTO Members can implement laws that protect farmers and breeders from IPR issues to a large extend. However, whether other countries may change their current patent protection system to one with lower protection standards, is not clear.

Improved varieties are only one piece in the puzzle to achieve food security. They can only be successfully adapted if the necessary infrastructure such as adequate irrigation systems is available. The successful adaptation and cultivation of improved varieties is constrained by the lack of certain necessary preconditions such as knowledge of relevant farming methods or a lack of other necessary inputs.

The relevance of IPRs and their protection by regimes such as TRIPS for the transfer of clean technologies has to be put in context. Mark-up pricing facilitated by IPRs may be a barrier to the dissemination of research intensive technologies with relatively low hardware costs, but this does not seem to apply to most of renewable energy technologies.

These technologies, such as solar PV, concentrated solar power or wind energy typically feature high investment costs. Competition within the sectors and with conventional energy technologies impedes monopoly pricing and drives prices down. Many advanced developing countries have proven their ability not only to access renewable energy technologies but even to become competitive global players and innovators in the markets in question. These countries could even benefit from the protection of intellectual property possessed by their citizens.

In contrast, least developed countries (LDCs) still have difficulties in accessing renewable energy technologies. However, IPRs do not seem to be the major barrier. In many LDCs the technologies are not protected, i.e. there is no patent in force in the country seeking to acquire the technology. Instead, limited market size and an unfavourable investment climate discourage technology transfer from abroad. In addition, the limited technological capability of local firms prevents the absorption of the few technologies flowing into the country. Technological capacity building and the transfer of the tacit knowledge inherent in renewable energy technologies is therefore vital. Undoubtedly the LDCs will require international assistance in this task. A careful analysis of the countries' respective technological needs should be carried out to identify foundations for international cooperation.

IPRs may, however, become a barrier to the development and dissemination of future renewable energy technologies such as second and third generation biofuels. In this case, consensual solutions such as publicly funded purchases of licenses for developing countries should be explored before applying unilateral measures such as compulsory licensing. Solutions from other sectors such as public health or agriculture should not be used as blueprints, as these sectors usually feature different conditions, and they may therefore not be appropriate in solving the challenges of the transfer of renewable energy technology.

The negotiations on the current system of intellectual property rights protection were a lengthy and cumbersome process. At least in the short term, major changes are unlikely. However, access to relevant technologies and goods by the poor must be improved and safeguarded within all trade agreements.

The implementation of TRIPS flexibilities still poses challenges for developing countries. While the possibility to restrict the influences of IPRs exists, countries may face political pressure from trading partners preventing them from using such flexibilities. Furthermore, many developing countries lack the capacity to translate them into national law.

Legal capacity building is therefore vital to support developing countries in using the flexibilities at hand. However, the right to using knowledge alone is in many cases not sufficient to be able to meaningfully use a technology. This especially applies to renewable energies, where operation, maintenance and repair of utilities require a high amount of technological capacity. Most developing countries lack this capacity and require education, training and joint research.

The conclusions mentioned above allow for certain policy recommendations concerning IPRs and the provision of each of the three types of global public goods that have been assessed in this paper. Some of the recommendations apply in general. However, as IPRs differ in relevance to the three areas analysed, most of the recommendations are case-specific.

Public health

- Pharmaceutical companies should adopt patent and enforcement policies that facilitate greater access to the medicines needed in developing countries. For example, in low-income developing countries, companies should avoid filing patents or enforcing them in ways that might inhibit access. Companies are also encouraged to grant voluntary licences in developing countries, where this will facilitate greater access to medicines, and to accompany this with technology transfer activities.
- There should be better monitoring of the impact of trade agreements on public health. Key questions include: Are essential medicines and vaccines more expensive than they would have been if not patented? Is the expenditure for importation of medicines by a country which has no local production capacity increasing or decreasing? Is there any transfer of technology or direct foreign investment in developing countries to strengthen national capacity for production of drugs at affordable prices?
- Public-health safeguards should be recognised as a starting point within all trade agreements, and should be excluded by powerful WTO members from the high-level horse-trading that routinely takes place between negotiating parties.
- National legislation should be reviewed to ensure that the entire range of TRIPS flexibilities is incorporated, so that public-health needs and objectives can be adequately addressed. The key priorities for strengthening national legislation, particularly in developing countries, should include provisions for compulsory licensing for both import and export and parallel importing, and, for least developed countries, on how best to use the available transitional period for compliance.
- Developed countries, and other countries with manufacturing and export capacity, should take the necessary legislative steps to allow compulsory licensing for export consistent with the TRIPS Agreement.

Food security

- Developing countries should implement farmer- and research-friendly laws to secure locally adapted small-scale research and breeding that is best adapted to local conditions.
- Developing countries should make use of the *sui generis* option to design an IPR legislation that is adequate to their stage of development and meets the specific needs of their population.
- Public research institutions should provide improved varieties for stress-prone areas to face challenges caused by climate change or other factors, and that are relevant to poor farmers.
- Governments should provide the infrastructure that is necessary to obtain the highest possible yields, regardless of the type of varieties used. Furthermore, they should make sure that all information and prerequisites are available that are necessary for the adaptation of improved varieties.

Climate stability / renewable energy

- More empirical in-depth studies are needed to understand the impact of IPR protection on the transfer of renewable energy technology and on the transfer of other climate-related technologies. These studies must form the foundation of policy decisions.
- Lack of access to tacit knowledge often forms a more powerful barrier to the transfer of renewable energy technology than IPRs. Any technology transfer policy must en-

sure that not only hardware, but also the inherent know-how and capabilities are transferred.

— Least developed countries need assistance in strengthening the technological capacity of their companies, research institutions and universities. Also, a lack of capacity in their public sector needs to be addressed. Professional training and education should be undertaken in cooperation with and at least partly funded by developed countries.

— Favourable investment conditions are vital for private sector technology transfer. These conditions must be ameliorated especially in least developed countries. Policies should focus on macroeconomic stabilisation, infrastructure building and market creation. Again, international assistance is needed to achieve these goals.

— As the ex-ante investment costs of renewable energy facilities are usually high, international financial assistance is needed in most developing countries.

General recommendations

— IPRs are required to ensure private sector engagement and investment in research and development. However, these rights have to be weighed against the needs of developing countries. Moreover, the balance between innovation and diffusion should be in compliance with human rights.

— Less developed countries should have fair access to independent and technical assistance and counsel in the negotiation of free trade agreements.

— Pooled procurement among low and middle income countries as advocated by the World Health Organization enhances market power. Combining markets and improving economies of scale may help to negotiate lower prices. For instance, the Organization of Eastern Caribbean States (OECS), representing nine Caribbean countries, has reduced drug prices by about 44 per cent in the 1980s, compared to the original prices in the individual countries.

— "South-South" partnerships could be used to mitigate weaknesses in capacity. For example, developing countries with established pharmaceutical industries could lead efforts in innovation and technology transfer. Technologies invented in developing countries may be particularly suitable to meet the needs of other developing countries.

— As intellectual property rights are a market instrument, research is directed towards purchasing power. The needs of the poor, who often form the majority, are mostly neglected. The international community should therefore finance public research focused on the needs of the poor.

— Emerging economies can benefit from joint research with developed countries. Publicly funded joint research may offer a solution to IPR questions as the resulting can be made publicly available.

— Policies should be shaped according to national needs and capabilities. Therefore, technology needs assessments are a precondition to policy planning. As technologies and national conditions vary, there will not be a single policy that fits all.

— Ministries of health, agriculture, or energy and environment should be "involved" in discussions on trade that have an impact on their respective fields of responsibility. For this, ministries will have to develop capabilities outside their traditional spheres.

— Last but not least, the problem of developing countries' access to medicines, improved seeds and modern forms of energy is linked to wider development issues. Additional resources to improve services, delivery mechanisms and infrastructure are critical.

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