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**Patent Protection, Biotechnology and
Globalisation**

**The TRIPs Agreement and its Implications
for the Developing Countries**

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1 Introduction

Globalisation is often seen as one of the dominant trends of our times. Besides technological innovations, one of its driving forces is the liberalisation of the world economy. The founding of the GATT's successor "World Trade Organisation" (WTO) in 1995 can be viewed as an important step towards worldwide economic integration. The "Agreement on Trade-Related Aspects of Intellectual Property Rights" (TRIPs) is one of the WTO's components. The TRIPs Agreement aims at harmonising the level of intellectual property protection in all WTO member states at a fairly high level.

The TRIPs Agreement indicates rather clearly that the WTO's scope goes far beyond that of previous multilateral treaties on external trade. WTO does not merely define and monitor standards for trade liberalisation, but its mandate now encompasses the setting of new global standards of external and internal regulation. In so far, the WTO serves, on one hand, as an engine of liberalisation, deregulation and globalisation, but, on the other hand, it is on its way to become a regulating body in the globalisation process itself. Therefore some authors suggest, that WTO is a central building block of global governance (Messner/Nuscheler 1996). Global Governance is here defined as a new form of political regulation, incorporating different actors (from nation states and international organisations as well as non-governmental and business actors) who operate at different political levels (from local to global). In this context the analysis of the TRIPs agreement can contribute to the understanding and the developing of the concept of global governance. For purposes of sim-

plification our analysis focuses on the patent system; except for the protection of plant varieties, all other kinds of intellectual property rights (copyrights, trade marks etc.) will not be discussed in this study.

The key questions are: first, why was the TRIPs Agreement established and which are its main elements, and second, which are the implications this system will probably have, especially on developing countries. To answer these questions, an overview on the development and the structural causes of international patent protection is given in the next two chapters. It will turn out, that the TRIPs provisions on patents are primarily based on "western" concepts of intellectual property and industrialised countries' standards (chapter 4). This will be underlined by the presentation of some theoretical considerations upon patent standards and the effects on developing countries (chapter 5). A case study on patent protection in the biotechnological sector will intensify these reflections (chapter 6).

2 The Growing Importance of the Protection of Intellectual Property in the Process of Globalisation

The Protection of Intellectual Property, with its juridical roots reaching back to 15th century Europe, has since been a cause of repeated quarrels not only within but also between states. These conflicts over the rights to commercially exploitable knowledge reached their peak in the second half of the 19th century, when the concept of patent protection was harshly criticised by the proponents of free enterprise and free trade (many of them economists) and abolished in several countries. As the patent controversy of the nineteenth cen-

tury ended with a political victory of the patent advocates (mostly lawyers, engineers and industrialists), statutory patent systems were (re-) established almost all over Europe (Machlup/Penrose 1950). Holland and Switzerland which at first did not follow this line, experienced international pressure which, among other things, led to the implementation of patent systems in these countries as well. From this period came the first international treaties on the Protection of Industrial Property (Paris Convention of 1883) and the Protection of Copyrights (Berne Convention of 1886).

Several additional conventions followed during the 20th century which, along with the Paris and Berne conventions, were transferred into the newly founded "World Intellectual Property Organisation" (WIPO) in 1967 (WIPO 1996). Although the number of WIPO agreements meanwhile rose to 19 they could not prevent a perceivable increase in the amount of inter-state conflicts about patent laws and copyrights. In contrast to the previous century these quarrels do not so much take place between contemporary industrialised countries, since almost all of them nowadays feature institutions of industrial legal and copyright protections that are comparable to a large degree. Rather, the current conflicts about these rights do increasingly take place between western industrialised countries on the one hand and Asian and Latin American developing countries as well as some transition countries on the other. The 1996 quarrel between the US and China about Chinese companies' "piracy" of American software, film and music productions, where the US is known to have threatened trade sanctions, is only one of more than fifty examples of these tendencies. Reasons for this development can be found in the fact, that numerous "third

world" countries possess a much weaker legal protection system, following the WIPO regulations reluctantly or not effectively translating them into action.

The increasing interest of many industrialised countries in an effective international patent law and copyright protection is directly connected to the process of globalisation. It can generally be put down to three interdependent elements:

- structural changes in the international division of labour and in demand
- technical progress and its economic consequences
- global liberalisation of the flow of commodities, services and investments

2.1 International Division of Labour

In the wake of changing economic and technical structures the usability of human creative potential for export has become increasingly important for the industrialised countries. Parallel to growing interconnectedness of trade relations, the competition between companies from developing and developed countries increased. This is the case especially for the labour intensive and so called "low tech" branches of industry. Many traditional western producers of technical goods are particularly hard pressed by the success of South East Asian companies, which to no small amount stems from their strategy of imitating western products or production methods. Furthermore, several of the developing economies have begun a course of continuous expansion of their world market shares in the middle technology sectors. Consequently the industrial countries increasingly locate their competitive advantages in human capital intensive sectors. Export activities have significantly shifted towards the expanding markets for relatively know-how intensive goods and

services (e.g. high-tech, highly qualified services and entertainment in sound, film and print) (Gadbaw/Richards 1988: 4f.). With the international Patent Laws and Copyright Protection the western industrialised countries now see a possibility to further their "immaterial" comparative advantage and most of all, to better guard it from imitation by foreign competitors (Fisch/Speyer 1995:66).

2.2 New Technologies and Products

Technological progress - or more specific: the transformation of knowledge and ideas into new products and processes as a source of economic growth - is not only an aim, but also the reason behind the demands of industrialised countries for a tightening of international intellectual property protection. The rising technological level has contributed to a steady increase in average R&D-expenditure necessary to develop new products, while at the same time technical progress has simplified and reduced the cost of technological reproduction of know-how intensively produced goods. Additionally, technical progress has expanded and globalised markets (e.g. transportation and communication technologies), spawned new markets and, as a consequence, has created a demand for patent political clarity (e.g. how to protect "intellectual property" in the fields of genetic engineering and how to handle software-algorithms) (Gadbaw/Richards 1988: 3ff).

2.3 Liberalisation of markets

Imitations and copies as well as original products have more and more easily been able to penetrate regional markets because of world-wide liberalisation of trade. In

relation to this, many innovative companies increasingly suffer sales and revenue losses which they would have made if they effectively were granted the sole international utilisation rights for their invention (USITC 1988:103; Preusse 1996:32). Western foreign investors additionally press for a tightening of international protection measures for intellectual properties, since, by a better protection of their accumulated know-how, they would be able to profit more from the general liberalisation of international capital flows, esp. foreign direct investment.

3 From WIPO to WTO

Triggered by current international conflicts the "Agreement on Trade-Related Aspects of Intellectual Property Rights" (TRIPs Agreement) came into effect on January 1st 1995 as a part of the likewise newly founded "World Trade Organisation" (WTO).¹ TRIPs were put on the agenda of multilateral trade policy by the US with support from the EC and other industrialised countries and resulted, against strong initial resistance from the developing countries, in the aforementioned TRIPs Agreement.

By this, international trade policy as well as international patent and copyright law have made a qualitatively remarkable step. Multilateral trade policy has reached a new stage of intensity by which it does not only influence domestic economic politics indirectly, but - similar to EU or NAFTA - intrudes directly into domestic economic policy making. The approximately 130 WTO-countries for example have committed themselves to converting some of the central agreements of the WIPO treaty

¹ For an overview of the components of the TRIPs-Agreement see Reichman 1995.

and additional regulations legally and materially.² The set period of time for this lies between one and ten years, depending on the type of technology, legal area and group the country is belonging to, with the least developed countries (LDCs) de facto being able to prolong this transitional period indefinitely.

In turn, a novum for international politics for the protection of intellectual property is the fact that failure to comply with established standards can be punished: If one WTO-member is able to substantiate damage to its economy because of insufficient patent law protection or similar lack of regulations in another member state, the former is entitled to limit the import of goods from the latter country. Furthermore, the TRIPs Agreement supplements the principle of national treatment (WIPO) with the most-favoured-nation principle (TRIPs art 4). As a result, it is not allowed to discriminate between patent holders of different nationalities, regardless of the concrete patent protection the respective foreign state offers. Furthermore, all member states commit themselves for the first time on an international level to protect undisclosed information and trade secrets from being disclosed to third parties by legal measures (art 39). Additionally the TRIPs-Agreement introduces diverse reforms in the international mark laws, copyright and related areas.

The following text will focus on the area of international patent protection, because it is most heavily influenced by the TRIPs Agreement: In fact this is the first time that unified obligatory patent standards are established globally.

4 Multilateralisation of Western Patent Protection Standards

Technical know-how is first of all a public good, the benefit of which - once it has been disclosed - everybody is entitled to. With patent laws, however, technical knowledge is practically privatised, since the exclusive right of exploitation is temporarily assigned to one (natural or legal) person.

Patent protection has basically been justified on four different lines of arguments ("theses"), all of which however have been heavily disputed in scientific discourses (Machlup/Penrose 1950 and Machlup 1958):

- the "natural law" thesis (a moral right of the citizen to his intellectual property)
- the "profit-incentive" thesis (a direct incentive for R&D activities and to stimulate innovation by means of promising temporary monopolistic profits)
- the "reward" thesis (a just reward for the inventor for the increase in welfare brought about by his activities)
- the "exchange-for-secrets" thesis (the Patent functions as a means of the diffusion of knowledge: through the duty to comprehensibly reveal the invention, transparency in regard to the development of current scientific research and indirect incentives for innovation are created).

According to the understanding influenced by Europe and America, patentability covers technical inventions, which are new, based on inventive activity and are commercially exploitable. This definition is taken over by the TRIPs Agreement (art 27), which by its aims alone (art 7) can generally be classified as mainly orientated on the profit-incentive and natural law the-

² This also applies to WTO-members, that did not join the WIPO treaty.

ses. This becomes clearly visible in the patent-standards, with regard to which the TRIPs agreement noticeably differs from the until now authoritative WIPO-agreements:

- The minimum duration of patent protection is internationally standardised and, as is common in Western European countries, laid down to 20 years (art 33).
- The rights of the patent holder include the right to supply local markets by import (art 27 I and 28 Ia), meaning that a national patent cannot be revoked, regardless of whether it is used domestically or not.
- Basically no traditional area of technology may be excluded from patent protection (art. 27 I). This also applies to micro-organisms, as well as non-biological and microbiological processes (art 27 III). Countries are allowed to exclude plants and animals as well as the biological processes for the production of these, but they must at least protect plant varieties by an effective *sui generis* system (art. 27 IIIb). Exceptions are also possible for therapeutic methods of treating humans or animals (art 27 IIIa). Finally, inventions can be excluded from patentability, if this is necessary for the protection of security interests (art 73), *ordre public*, morality or health or for the avoidance of serious prejudice to the environment (art 27 II).

These standards have created a demand for legal action not only in most of the developing countries, but also in some developed countries. But the amount of alterations necessary in the Western World is in no way comparable with the far reaching changes in the Southern countries that the implementation of the TRIPs-standards

would cause. Critics fear, that with the application of western patent protection the developing countries would suffer economic loss and their developmental potential would be curtailed in the long run (Correa 1993). These fears are mirrored in the let-out clauses, which were put into the TRIPs Agreement mainly because of pressure from developing countries: Article 8 allows to adopt measures, which are suitable or "necessary to protect public health and nutrition and to promote the public interest in sectors of vital importance to their socio-economic and technological development" and to "prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology". At the moment, however, there is no concrete interpretation of these protective clauses by the panel-experts of the WTO. So far twelve WTO disputes over intellectual property protection occurred, but up to now (March 1998) only two dispute panels have been established. The only dispute so far that was settled by a panel's decision (U.S. versus India - patent protection for pharmaceutical and agricultural chemical products) did not touch the exception clauses mentioned above.³ As developing and transition economies have been allowed a transitional period of five years (art 65), it will take some years before any dispute panel will have to examine to which extent developing countries can recourse to the let-

³ The still active panel handles a EU-complaint versus India also concerning the alleged absence of patent protection for pharmaceutical and agricultural chemical products as well as the alleged absence of a proper filing system for patent applications. In all the remaining disputes - of which four were settled by mutual agreement - only one involves a developing country (Pakistan).

out clauses of the TRIPs-Agreement.⁴ Even if the panel-experts' future decisions, in principle, would favour developing countries' concerns, the developing countries could at best delay the transfer of western standards a little further. As soon as a broad interpretation of the let-out clauses threatens to undermine the patent protection, the US and the EC can be expected to negotiate a tightening of the protection clauses during one of the scheduled revisions of the TRIPs-Agreement.

The following chapter will try to sketch the effects of the patent protection for the southern countries obtained by the North.

5 Winners and Losers

After last century's patent controversy the scientific discourse over questions of international patent laws has long been dominated almost exclusively by legal experts and engineers. Economic as well as other social sciences however, have addressed this field briefly in the 50s and then again only in the 1970s, concretely in the course of the discussion about a new economic world order and fair transfer of technology (Primo Barga 1990: 69). During the TRIPs negotiations the academic discussion over a world wide patent protection was taken up again and intensified since then. In this discussion economists have concentrated

on patents' functions to foster innovation (profit-incentive thesis).

5.1 Incentive-to-Invent or Rent-Shifting?

From an incentive-theoretical point of view the tightening of international patent protection increases world wide innovative activity, since the diminishing of "head start profits" ("pioneer profits") for innovators by imitating competitors (of the South) will be delayed. This innovation-supportive effect can generally occur in all countries (Primo Braga 1990:80). At present, however, this effect will be exclusive to the North, since almost all patentable products and processes have been invented by Western companies (Faust 1996:9), which, different from countries in the South, can rely on an ample supply of capital as well as a large pool of technically and scientifically highly qualified personnel. Regardless of this the South could profit from the increase in innovative activities indirectly (Fisch/Speyer 1995): Innovations (by the North) are the basis for the repetition of imitating and catching up strategies by the developing countries. Furthermore, the innovative activity increases income in the North, which in turn will be partially spend on products from the South. Against this incentive-theoretical view it is argued that there is no positive empirical proof for a general connection between R&D activities and patent protection. This can at best be stated for a few research intensive sectors like pharmaceutical and traditional chemistry, where R&D expenditures are high but the costs of copying are low (Primo Braga 1996:360). In most fields, however, the "head-start profits" are in any case high enough even without patent protection, so that R&D investments would pay for themselves. If

⁴ Different agreements were reached in respect to certain chemical products: From the start developing countries are obliged to implement a proper filing system of patent applications and to temporarily grant exclusive marketing rights, if the patentee (e.g. the product) meets certain requirements (art. 70). This is why the US as well as the EU could request a panel concerning their disputes with India despite her status as a developing country which qualifies her to delay the implementation of most TRIPs-requirements until the year 2000.

this is the case, the international unification of patent protection would have little innovation-increasing effects, but rather mainly result in a redistribution of wealth from the South to the North: The South as a net-importer of technology would have to pay a larger amount of royalties to western innovators, its dependency on imports would grow and consumer prices increase.

This very negative assessment of a western style universal patent system and its implications for the South certainly bears some truth in it, but it has several weaknesses. First, it is the result of a largely static analysis. Second, it does not differentiate between developing countries of different economical and technological levels.

5.2 Engine of Growth or Obstacle to Development?

An increase in patent protection can well result in impulses for growth in the developing countries in the medium or long run, since it forces local companies to innovate rather than to imitate. By consequence, Southern pioneers will realise and be able to temporarily guard "head-start profits" (Primo Braga 1990:80). The requirements for this (human and real capital), though, can mostly be met in the wealthier developing countries and the emerging economies.⁵

⁵ A number of those countries has tightened regulations concerning the protection of intellectual property by themselves anyway, at least in those sectors of technology, where they are innovative. India, which is marked by a growing software industry, for example, was one of the first countries to protect software under copyright law. As one of the largest movie factories it was again India that demanded along with the US a WIPO agreement for the protection of audiovisual products (Zeeb 1996:24).

For the technological policy of the remaining developing countries the import of know-how and technological products will still remain determinant. It is again disputed, whether global unification of patent protection will further or hinder the transfer of technology into the South. On the one hand negative effects are to be expected since the use of new foreign technologies might become more expensive or the patent holder may not allow their utilisation. On the other hand an improvement of patent protection in the South might lead to an increase of technology inflows, for which the Japanese post war experiences are often cited as an example. Since foreign holders of intellectual property rights will not any longer fear that their knowledge is commercially exploited by local producers without their consent (e.g. through compulsory licensing), foreign direct investments into the developing countries as well as the licensing to companies in the South might increase (Zeeb 1996: 25).

Several empirical studies have been attempting to measure the degree of influence patent protection has on direct investment and transfer of technology. The majority of these - in several ways insufficient - studies come to the result that there is a positive, if very small correlation (Primo Braga 1996:362). At the same time experiences in several African developing countries show, that the implementation of an effective patent protection is by no means sufficient to increase the flow of investment and technology. Rather, patent protection only seems to advance the transfer of technology and capital if other major and more important factors - such as qualified labour, adequate infrastructure, macro-economic and political stability - are already in place.

All in all it may be safe to assume that for some of the economically and technologically more advanced developing countries overall benefits from international patent protection could possibly exceed the short term costs. But, for the remaining developing countries, the immediate social costs are first of all harder to take and it is furthermore quite uncertain at what time will possibly occur and whether these future profits would in any way be sufficient to compensate for the short-term costs.

At first this question appears irrelevant to the LDCs, since the TRIPs Agreement has provided them a very generous transitional period (art 66) as well as promised them technical and financial support to a certain extent (art 67). On closer inspection though, LDCs might suffer welfare losses due to the effects that the TRIPs Agreement has on international competition and the functioning of the world markets, irrespective of the poorest countries' own patent laws and patent law enforcement.

5.3 Patents and International Competition

Stronger international patent protection may be expected to cause a rise of the world-market prices for innovative consumers and investment goods at least in the short and mid run, since the intensity of competition on the world market will be decreased at first. The increase in prices will be the higher, the less competition of substitute goods there is and the lower price-elasticity of demand is. Generally, consumers in every country will be affected by the price increase (Maskus 1990:403). The loss in consumers' surplus in the (potentially) technology exporting industrialised and emerging economies will be accompanied by a growth of producers' surplus and/or the reduction of research

subsidies, so that on balance overall gains in welfare are possible. Whereas the net result is almost definitely negative in the case of the poorer developing countries which lack the national economic potential for the invention and commercialisation of patentable products and hence will hardly experience a significant increase of producers' surplus.

Besides these distributional effects the resulting price increases might point to some undesirable allocative effects if they exceed the margin considered as a necessary incentive to invent or the margin that seems adequate to compensate for otherwise not performed R&D expenditure. In other words, worldwide patent protection becomes quite problematic, if it leads to an abuse of market dominance by the right holder which reveals itself among others in overpriced products. To prevent this abuse of an dominant market position and other unfair business practices of patent holders, an effective antitrust policy appears necessary. The TRIPs Agreement in these cases allows for the limitation of exclusive rights of the patent holder by the respective states (art 8 and 31c). For example, if a right holder can be proven to supply a local market at excessive prices or not at all, or if he links supplying to trade restraints, the respective state is entitled to compulsory licensing in order to enable third parties to utilise the patented invention and/or to supply the domestic markets with the patented products in question.

This measure may allow, if used consequently by all countries, to noticeably reduce the unfair abuse of intellectual property rights world-wide. Firstly this presupposes that all governments are interested in doing so. Secondly the countries must have at their disposal the means to control transnational companies as well as the requisite

institutional and economic infrastructure. In fact these prerequisites are often not given. This shortcoming could be countered by obligatory and efficient international regulations against private restraints of competition. At a domestic level, most industrialised already have linked their patent and antitrust law, but in fact only the US laws provide for punishment of abuse of patents in foreign countries. If a corresponding international policy regarding unfair trade practices would be made compulsory, the international abuse of patents would be counteracted not only by the importing countries, but also by the exporting (developed) countries.

5.4 Patents and Free-Trade

Many developing countries fear that imports from the South will be prohibited from the markets of the North on the grounds of a supposed failure to comply with international patent regulations in the exporting country (Correa 1993). This claim may be justified on one side, but on the other it is especially the integration of patent protection into the regulations of the free-trade oriented WTO and its settlement mechanisms that afford the respective countries some protection from arbitrary trade restrictions by other states. Whether this evaluation comes true will best be seen in the case of the future US policy on intellectual property rights. Since the establishment of the TRIPs Agreement the US government has more or less restrained from unilateral trade sanctions against countries that do not comply with intellectual property rights standards (except the threat against China which is not a member of the WTO). Instead they brought conflicts to the WTO's dispute settlement mechanism and it is to be seen whether they will continue to use and accept the

WTO as the forum to solve all trade-related intellectual property rights conflicts.

5.5. Weaknesses of the "Economistic" View

The "economistic" approach to the TRIPs agreement primarily focuses on the "incentive-to-invent argument" for the patent system and its transferability to a global scale. This approach shows several flaws. One of these flaws is the missing empirical evidence, that patents are first best to promote innovation on a national level, let alone on the international level. Unsurprisingly neither empirical studies nor purely theoretical analyses led to definite results regarding the implications of the TRIPs standards on the South. Furthermore, technological progress is defined as a goal in itself without questioning or at least discussing this assumption (Silberstein 1994:158). But most importantly the traditional, incentive-theoretical approach can only cover parts of the North-South dimensions in international patent regulations. Among other factors, the effects of world wide patent (and copyright) regulations on the culture, social structure and natural environment of non-western societies is neglected.

6 Patent Protection and Biotechnology

The controversial implications of a tightening of international patent regulations for the South can be perceived especially well in the polarised discussions over the TRIPs agreement in the biotechnological sector. For this reason the field of biotechnology and the linked questions of biodiversity, with their rising economic importance, are

useful as a focus for the more general strands of discussion described above.

World wide implementation of western models of intellectual property on the sector of biotechnology was one of the most disputed issues during the TRIPs negotiations.

There are two main reasons for that:

- There is no consent over the question of which processes and products are patentable.
- The attempt of renewing the regulations in the area of biotechnology touches on a conflict that goes on already for over 30 years regarding the rights to plant-genetic resources.

6.1 Patentability

Central to the debate about the patentability of biotechnology is the question whether biotechnological processes and products constitute as inventions and are thus patentable, or whether they are not rather to be treated as discoveries. For example, biotechnological (meaning microbiological and biochemical) processes are patentable, but classical methods of breeding plants are not, even though the goal of both of these methods, namely the breeding of more productive plant varieties, can be the same. The patentability is also in question in regards to products of biotechnological processes: Generally plant and animal species are not patentable.⁶ Genes, animal and plant cells, micro-

organism and plant components on the other hand may be patented, even though they were not transformed but only isolated.

Until now patent protection for altered plants and animals exists to some extent in Japan and Europe⁷, but particularly in the United States, where the first biotechnologically altered organism was patented in 1980. Since then large numbers of application for patents have been submitted and additionally, the frame for patentability has been widened (Knerr 1996:89). Currently the largest expansion has been caused by the TRIPs agreement, since all signatory states are now forced to either introduce a system of patenting regarding biotechnological processes and products or establish an efficient *sui generis* system or a combination of both (TRIPs art 27 III).

That the signatory countries have this choice can be seen as a success for the objections made by the developing countries against the northern countries' attempt to dictate patent regulations: The first TRIPs agreement still planned to make altered animals and plants patentable world-wide (McNally/Wheale 1996:224).

6.2 Property rights in the Agrarian Sector

The area of plant breeding, one of the main areas for the usage of biotechnology, has always been characterised by conflicts. The major disagreement occurs with regard to

⁶ All the same, patents for species have already been applied for and temporarily granted: Agracetus applied for a patent for transgenic cotton. If the patent had been granted all producers of genetically engineered cotton would have been forced to pay licence fees. Since this would have inhibited research too much, the patent was revoked (McNally/Wheale 1996:224).

⁷ Quite recently the European Union's Commission and the European Parliament after years of discussion finally reached agreement on a directive concerning the legal protection of biotechnological inventions. Apart from other issues, the Parliament insisted that animal races and plant varieties will be excluded from patentability and on a better definition of the farmer's privilege (Commission of the European Commission 1997).

the protection and the access to plant genetic resources, meaning the vegetative gene pool. Even if it is of importance in traditional cultivation in the form of cross-breeding, it is a central aspect of biotechnological research, since genes form the basic material of modern biotechnology.

Because of the specific use of plant genetic resources in the processes of modern biotechnology these genes, but also biological diversity⁸ in general, play a leading role. Added to that is the fact, that biological diversity on the one hand and biotechnological activities on the other are distributed most unevenly between the world's economic regions: Almost 90% of the biodiversity are located in the Asian and Latin American developing countries, mainly in the tropical rainforests. Biotechnology on the other hand is almost exclusively a domain of the developed countries. This distribution has temporarily been seen as a chance for the developing countries: They could receive modern technology in return for biodiversity (McNally/Wheale 1996:225).

Up to now, the conflict about plant genetic resources has been quite controversial because of the differing interests of northern and southern countries especially in the 1980s and led to several partially contradictory international regulatory attempts. The two most important regulations, the UPOV⁹ agreement signed 1961 and the

1983 Undertaking are typical for the opposing concepts. The UPOV is aimed at co-ordinating the legal regulations of its members by granting property rights to the breeders. This means that a grower, as a single identifiable person, is able to seek protection for a cultivated species that is new, uniform, stable and clearly distinct from other plant species. The breeder then is granted a temporal monopoly for the reproduction and trading of this protected species. Originally the UPOV agreement included the "farmers' privilege", which allows them to reuse seeds yielded by the harvest in the next season, and the "breeder's privilege". The latter allows breeders to develop their own variations from protected species and in turn apply for their protection if necessary. These privileges however have been abolished in the last change of the UPOV treaty in 1991.

UPOV's concept, which concentrates on the rights of the breeders and cultivators, came under heavy criticism by the developing countries especially during the conferences of the "Food and Agricultural Organization" (FAO) of the UN. The developing countries argued among other things, that the definition of what is a "protectable" species was formed by the North. The UPOV criteria did not cover traditional local races ("landraces") which were mainly cultivated in the South and thus, many of the Southern genetic assets were excluded from UPOV protection (Rembold/Swaminathan 1995:122).¹⁰ Another

⁸ Biodiversity includes the diversity of genes, species and eco-systems. For the breeding and cultivation of plants genetical diversity is of primary importance to allow the isolation and introduction of qualities of uncultivated into cultivated plants. For the pharmaceutical industry on the other hand, the diversity of species is of greater consequence, since it is hoped that new health-improving or health preserving substances could be discovered.

⁹ UPOV: Union internationale pour la Protection des Obtentions Végétales

¹⁰ Landraces are characterized by the fact, that they are well known and have been used for a long time. Even today landraces are still planted, though large parts were wiped out during and by the green revolution. One of the most critical aspects of the lack of effective protection mechanism for landraces results from the fact that landraces themselves often form the initial basis for biotechnological research.

criticism touches the behaviour of Western companies and the activities of the mostly Northern controlled "international" agrarian research institutes. Very often they would use the genetic resources of the South for the development of new species without paying, but then in turn they would expensively sell the resulting seeds to the developing countries. The developing countries as a matter of fact received no compensation for the supply of genetic resources.

The differing positions of the North and the South led to the adoption of the "International Undertaking on Plant Genetic Resources" that has been negotiated under the roof of the FAO. The Undertaking though has no binding power in terms of international law. The Undertaking stresses, that all plant genetic resources (including those of species resulting from conservation and cultivation) constitute a common heritage of mankind and should thus be preserved and freely available. The developing countries should furthermore be enabled to use their diversity on their own (Margulies 1993:328).

Additionally, in a revised version of the undertaking the concept of farmers' rights was brought into the debate by developing countries.¹¹ Farmers' rights cede to the farmers a collective right of ownership, since they did not only preserve the plant genetic resources throughout times, but also put them at everyone's disposal (Flitner 1995:197). The Convention on Biological Diversity, signed in Rio 1992, addresses this North-South controversy. It draws a reciprocity between genetic resources (from the South) and biotechnol-

ogy (from the North) and provides for a fair share of profits coming out of the use of biodiversity. The convention, however, remained unclear about the relation between keeping or strengthening of patent protection and the free exchange of technologies and genetic resources (Flitner 1995:242).

6.3 Patenting Biotechnology: An Ambivalent Assessment

As in most other sectors, the global introduction of patents in the field of biotechnology is mainly discussed on the grounds of the profit-incentive thesis for patent protection that was mentioned above. It is assumed that patent or similar protection in the field of biotechnology will intensify independent biotechnological research and development in the developing countries. Furthermore, a transfer of technology from the North to the South can be expected, from which the developing countries would benefit (Moufang 1995:118). Another positive aspect would be increasing incentives to improve protection of biodiversity, which can be regarded as the basic input of the biotechnological industry.

Since the South with its richness in biodiversity as well as the North with its biotechnology would have "something to offer" to one another, a profitable exchange of biotechnology and biodiversity for both sides can be expected. This reciprocal relationship between biotechnology and biodiversity is most often illustrated with the example of the Costa Rican private institute INBio and the US company Merck: INBio provides Merck with biochemical extracts of plants, insects and micro-organisms from domestic nature reserves, which Merck is allowed to patent and exploit exclusively. In return, Merck pays the amount of 1.1 million US\$ for a

¹¹ This term, which was discussed at the second conference of the Commission of Plant Genetic Resources in 1983 for the first time, was not established in the Undertaking until 1989 (Flitner 1995:197).

period of two years. Additionally Merck guarantees a share of the license fees earned from the patent-contracts to INBio. INBio in turn then promised to pay half of the fees to national parks (Flitner 1995:253). Preservation of nature would thus be a result of patent protection.

Critics of the patenting of biotechnology would not share these expectations. They doubt that there will be a transfer of technology between North and South, since the transnational biotechnological companies would not be willing to export capital intensive technologies if there is no direct profit in doing so.

However, the main point is that only those new types of breded plants or inventions would be patentable that suffice the criteria dictated by the North. Indigenous or local knowledge and types of plants derived from that could thus not gain any patent protection, since a single breeder could seldom be pinpointed, the cultivation would be developed over decades and the property rights were traditionally collective (Shiva 1996:122).

The TRIPs agreement is further criticised for failing to offer regulations for the remuneration or compensation of those that preserve biodiversity (Mugabe et al. 1996:10). It is also faulted for the fact, that indigenous populations may be excluded from the utilisation of traditionally used plants by the patent regulations: Indian farmers for example protested against the patenting of an insecticide obtained from the seeds of the Neem tree, since they feared to be excluded from using this tree, known to them for centuries. They also feared a sharp increase in prices for products derived from the Neem tree which would hinder them from using Neem products, even if the patent was not valid in India itself (Sharma 1995:11).

Finally TRIPs could lead to a accumulation of patents and by this promote market concentration (Knerr 1995:89), since today the development of transgenic plants always touches various patents.

6.4 *Sui Generis* System as an Alternative?

Since the connection between patent regulations and biotechnology poses a special problem for the developing countries, the WTO countries have agreed to allow for the introduction of a *sui generis* system as an alternative to patenting. These *sui generis* laws have to be established by January 2000, a review of the *sui generis* option will be in 1999 (Seiler 1998). For many industrialised countries this in turn means, that the UPOV agreements for the protection of plant species - including biotechnologically developed ones - will be converted into action.

At closer inspection the UPOV however fails to distinguish itself from patent regulations, because, since the farmer's and breeder's privileges have been abolished the protection of plant species is nearly as strict as it would be with patent laws. Since the UPOV regulations pose no real alternative to patent laws, several developing countries search for an alternative *sui generis* system. Supported by non-governmental organisations (NGOs) they aim to develop a *sui generis* system, which pays much more attention to the concept of farmers' rights. It is, in fact, doubtful whether such alternative systems can indeed be developed and whether they would work effectively. It is furthermore unclear if the developed countries would accept such an alternative system, that stresses farmers' rights, as sufficient to the obligations the TRIPs agreement poses on the signatory member states.

7 From Multilateral Trade Policy to Multifunctional Patent Policy?

The TRIPs Agreement is a crucial step towards the implementation of globally binding patenting standards in general as well as for the sector of biotechnology. Even if some critics regard a turning back to be desirable, this matter of concern can be judged as politically unrealistic, especially in the light of economic globalisation and current technological developments.

In our view this leads to the question whether any theoretical and political approaches are available in order to more comprehensively account for the North-South dimension of patent regulations than the innovation oriented theory alone is able to. For this purpose it seems advisable to widen the "profit-incentive" argument for patent protection, to include other arguments as well and to question the western concept of patentability.

7.1 Arguments for Patent Systems

According to the natural-law argument for a patent system the protection of individual property rights by the state constitutes a civil right.¹² The "natural-rights thesis" of patent protection is thus based on individualism and (implicitly) builds on the concept of a market style economy, which is characterised by private property of the means of production. Even though the universalisation of these values and principles remains disputable, they offer, though with some reservations, a ground to legitimate

certain standards for the international protection of intellectual property. However, it appears especially problematic, that the initial distribution of knowledge, which poses a central issue for the North-South discussion, is seen as an exogenous date in the concept of "natural law" and deduced theories. Apart from that, the "natural-law approach" leaves little room for thoughts about general welfare issues, which are of prime importance in development politics.

The "profit-incentive approach" to the patent system which encompasses the conflict between patent protection and free competition is able to bridge some of these gaps. Its findings translate into the limited duration of patent protection and into the restriction of intellectual property rights as soon as they lead to uncompetitive business practices. Though this approach is limited to innovative activities in the technological sense. If the community of states were interested in granting intellectual property rights to those other categories of knowledge, that add to the common good and are possibly not directly commercially exploitable by the "discovering" or "preserving" persons (e.g. biodiversity), the "reward thesis" would offer a possible reason for this: The assigned right holders would share in the profits that result from the subsequent utilisation of the respective product they preserved.

7.2 The Western Concept of Patentability

The criteria of the technological invention is aimed towards activities that can be found in industrialised or transition countries and increasingly in emerging economies as well, but rarely appear in the remaining developing countries. Smaller, less technologically demanding mechanical inventions, as they can be more frequently

¹² Politicians in the US have in times gone so far as to call the violation of intellectual property rights a human rights issue (Neue Zürcher Zeitung, Oct. 7th 1988:16).

found in the developing countries are not protected under the TRIPS agreement, even though the model of "petty patents" would have been available (Ullrich 1989:153). The natural and cultural wealth of many developing countries is furthermore seldom "new" and can thus hardly be invented, but at best be discovered, as has been exemplified with the discussion on landraces and farmers' rights. Finally many cultural and natural goods are characterised by the fact that they are neither private property nor in strict terms commercially exploitable. Instead they often resemble public goods. But to this it must be added that the lack of clear cut property rights and of commercial exploitability of a (material or immaterial) good could be removed by a definite assignment of property rights. In other words, the question, whether or not a certain category of knowledge falls under the system of intellectual property protection is not merely a technical, but foremost a political issue.

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Annex

AGREEMENT ON TRADE-RELATED
ASPECTS OF INTELLECTUAL
PROPERTY RIGHTS
(selected provisions)

PART I GENERAL PROVISIONS
AND BASIC PRINCIPLES

PART II STANDARDS CONCERNING
THE AVAILABILITY, SCOPE
AND USE OF INTELLECTUAL
PROPERTY RIGHTS

PART III ENFORCEMENT OF
INTELLECTUAL PROPERTY
RIGHTS

PART IV ACQUISITION AND
MAINTENANCE OF
INTELLECTUAL PROPERTY
RIGHTS AND RELATED
INTER-PARTES PROCEDURES

PART V DISPUTE PREVENTION AND
SETTLEMENT

PART VI TRANSITIONAL
ARRANGEMENTS

PART VII INSTITUTIONAL
ARRANGEMENTS; FINAL
PROVISIONS

Members,

Desiring to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade;

Recognizing, to this end, the need for new rules and disciplines concerning:

- (a) the applicability of the basic principles of GATT 1994 and of relevant international intellectual property agreements or conventions;
- (b) the provision of adequate standards and principles concerning the availability, scope and use of trade-related intellectual property rights;
- (c) the provision of effective and appropriate means for the enforcement of trade-related intellectual property rights, taking into account differences in national legal systems;
- (d) the provision of effective and expeditious procedures for the multilateral prevention and settlement of disputes between governments; and
- (e) transitional arrangements aiming at the fullest participation in the results of the negotiations;

Recognizing the need for a multilateral framework of principles, rules and disciplines dealing with international trade in counterfeit goods;

Recognizing that intellectual property rights are private rights;

Recognizing the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives;

Recognizing also the special needs of the least-developed country Members in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base;

Emphasizing the importance of reducing tensions by reaching strengthened commitments to resolve disputes on trade-related intellectual property issues through multilateral procedures;

Desiring to establish a mutually supportive relationship between the WTO and the World Intellectual Property Organization (referred to in this Agreement as "WIPO") as well as other relevant international organizations;

Hereby agree as follows:

PART I

GENERAL PROVISIONS AND BASIC PRINCIPLES

Article 1

Nature and Scope of Obligations

1. Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement

in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.

2. For the purposes of this Agreement, the term "intellectual property" refers to all categories of intellectual property that are the subject of Sections 1 through 7 of Part II.

3. Members shall accord the treatment provided for in this Agreement to the nationals of other Members.¹³ In respect of the relevant intellectual property right, the nationals of other Members shall be understood as those natural or legal persons that would meet the criteria for eligibility for protection provided for in the Paris Convention (1967), the Berne Convention (1971), the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits, were all Members of the WTO members of those conventions.¹⁴

¹³ When "nationals" are referred to in this Agreement, they shall be deemed, in the case of a separate customs territory Member of the WTO, to mean persons, natural or legal, who are domiciled or who have a real and effective industrial or commercial establishment in that customs territory.

¹⁴ In this Agreement, "Paris Convention" refers to the Paris Convention for the Protection of Industrial Property; "Paris Convention (1967)" refers to the Stockholm Act of this Convention of 14 July 1967. "Berne Convention" refers to the Berne Convention for the Protection of Literary and Artistic Works; "Berne Convention (1971)" refers to the Paris Act of this Convention of 24 July 1971. "Rome Convention" refers to the International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations, adopted at Rome on 26 October 1961. "Treaty on In-

Any Member availing itself of the possibilities provided in paragraph 3 of Article 5 or paragraph 2 of Article 6 of the Rome Convention shall make a notification as foreseen in those provisions to the Council for Trade-Related Aspects of Intellectual Property Rights (the "Council for TRIPS").

Article 2

Intellectual Property Conventions

1. In respect of Parts II, III and IV of this Agreement, Members shall comply with Articles 1 through 12, and Article 19, of the Paris Convention (1967).

2. Nothing in Parts I to IV of this Agreement shall derogate from existing obligations that Members may have to each other under the Paris Convention, the Berne Convention, the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits.

Article 3

National Treatment

1. Each Member shall accord to the nationals of other Members treatment no less favourable than that it accords to its own nationals with regard to the protection¹⁵ of intellectual property, subject to

lectual Property in Respect of Integrated Circuits" (IPIC Treaty) refers to the Treaty on Intellectual Property in Respect of Integrated Circuits, adopted at Washington on 26 May 1989. "WTO Agreement" refers to the Agreement Establishing the WTO.

¹⁵ For the purposes of Articles 3 and 4, "protection" shall include matters affecting the availability, acquisition, scope, maintenance and enforcement of intellectual property rights as well as those matters affecting the use of intellectual

the exceptions already provided in, respectively, the Paris Convention (1967), the Berne Convention (1971), the Rome Convention or the Treaty on Intellectual Property in Respect of Integrated Circuits. In respect of performers, producers of phonograms and broadcasting organizations, this obligation only applies in respect of the rights provided under this Agreement. Any Member availing itself of the possibilities provided in Article 6 of the Berne Convention (1971) or paragraph 1(b) of Article 16 of the Rome Convention shall make a notification as foreseen in those provisions to the Council for TRIPS.

2. Members may avail themselves of the exceptions permitted under paragraph 1 in relation to judicial and administrative procedures, including the designation of an address for service or the appointment of an agent within the jurisdiction of a Member, only where such exceptions are necessary to secure compliance with laws and regulations which are not inconsistent with the provisions of this Agreement and where such practices are not applied in a manner which would constitute a disguised restriction on trade.

Article 4

Most-Favoured-Nation Treatment

With regard to the protection of intellectual property, any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and

property rights specifically addressed in this Agreement.

unconditionally to the nationals of all other Members. Exempted from this obligation are any advantage, favour, privilege or immunity accorded by a Member:

(a) deriving from international agreements on judicial assistance or law enforcement of a general nature and not particularly confined to the protection of intellectual property;

(b) granted in accordance with the provisions of the Berne Convention (1971) or the Rome Convention authorizing that the treatment accorded be a function not of national treatment but of the treatment accorded in another country;

(c) in respect of the rights of performers, producers of phonograms and broadcasting organizations not provided under this Agreement;

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

Article 5

Multilateral Agreements on Acquisition or Maintenance of Protection

The obligations under Articles 3 and 4 do not apply to procedures provided in multilateral agreements concluded under the auspices of WIPO relating to the acquisition or maintenance of intellectual property rights.

Article 6

Exhaustion

For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.

Article 7

Objectives

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Article 8

Principles

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade

or adversely affect the international transfer of technology.

PART II

STANDARDS CONCERNING THE AVAILABILITY, SCOPE AND USE OF INTELLECTUAL PROPERTY RIGHTS

SECTION 1: COPYRIGHT AND RELATED RIGHTS

Article 9 - Article 14 (...)

SECTION 2: TRADEMARKS

Article 15 - Article 21 (...)

SECTION 3: GEOGRAPHICAL INDICATIONS

Article 22 - Article 24

SECTION 4: INDUSTRIAL DESIGNS

Article 25 - Article 26

SECTION 5: PATENTS

Article 27

Patentable Subject Matter

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.¹⁶ Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. 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.

3. 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 micro-organisms, and essentially biological

¹⁶ For the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively.

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. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

Article 28

Rights Conferred

1. A patent shall confer on its owner the following exclusive rights:

(a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing¹⁷ for these purposes that product;

(b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

Article 29

Conditions on Patent Applicants

1. Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.

2. Members may require an applicant for a patent to provide information concerning the applicant's corresponding foreign applications and grants.

Article 30

Exceptions to Rights Conferred

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

Article 31

Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use¹⁸ of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the

¹⁷ This right, like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6.

¹⁸ "Other use" refers to use other than that allowed under Article 30.

government, the following provisions shall be respected:

- (a) authorization of such use shall be considered on its individual merits;
- (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;
- (c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semiconductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;
- (d) such use shall be non-exclusive;
- (e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;
- (f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;
- (g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;
- (h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;
- (i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
- (j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
- (k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and

(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

Article 32

Revocation/Forfeiture

An opportunity for judicial review of any decision to revoke or forfeit a patent shall be available.

Article 33

Term of Protection

The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.¹⁹

Article 34

Process Patents: Burden of Proof

1. For the purposes of civil proceedings in respect of the infringement of the rights of the owner referred to in paragraph 1(b) of Article 28, if the subject matter of a patent is a process for obtaining a product, the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process. Therefore, Members shall provide, in at least one of the following circumstances, that any identical product when produced without the consent of the patent owner shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process:

(a) if the product obtained by the patented process is new;

(b) if there is a substantial likelihood that the identical product was made by the process and the owner of the patent has been unable through reasonable efforts to determine the process actually used.

2. Any Member shall be free to provide that the burden of proof indicated in paragraph 1 shall be on the alleged infringer only if the condition referred to in subparagraph (a) is fulfilled or only if the condition referred to in subparagraph (b) is fulfilled.

3. In the adduction of proof to the contrary, the legitimate interests of defendants in protecting their manufacturing and business secrets shall be taken into account.

¹⁹ It is understood that those Members which do not have a system of original grant may provide that the term of protection shall be computed from the filing date in the system of original grant.

SECTION 6: LAYOUT-DESIGNS (TOPOGRAPHIES) OF INTEGRATED CIRCUITS

Article 35

Relation to the IPIC Treaty

Members agree to provide protection to the layout-designs (topographies) of integrated circuits (referred to in this Agreement as "layout-designs") in accordance with Articles 2 through 7 (other than paragraph 3 of Article 6), Article 12 and paragraph 3 of Article 16 of the Treaty on Intellectual Property in Respect of Integrated Circuits and, in addition, to comply with the following provisions.

Article 36

Scope of the Protection

Subject to the provisions of paragraph 1 of Article 37, Members shall consider unlawful the following acts if performed without the authorization of the right holder:²⁰ importing, selling, or otherwise distributing for commercial purposes a protected layout-design, an integrated circuit in which a protected layout-design is incorporated, or an article incorporating such an integrated circuit only in so far as it continues to contain an unlawfully reproduced layout-design.

Article 37

Acts Not Requiring the Authorization of the Right Holder

1. Notwithstanding Article 36, no Member shall consider unlawful the performance of any of the acts referred to in that Article in respect of an integrated circuit incorporating an unlawfully reproduced layout-design or any article incorporating such an integrated circuit where the person performing or ordering such acts did not know and had no reasonable ground to know, when acquiring the integrated circuit or article incorporating such an integrated circuit, that it incorporated an unlawfully reproduced layout-design. Members shall provide that, after the time that such person has received sufficient notice that the layout-design was unlawfully reproduced, that person may perform any of the acts with respect to the stock on hand or ordered before such time, but shall be liable to pay to the right holder a sum equivalent to a reasonable royalty such as would be payable under a freely negotiated licence in respect of such a layout-design.

2. The conditions set out in subparagraphs (a) through (k) of Article 31 shall apply *mutatis mutandis* in the event of any non-voluntary licensing of a layout-design or of its use by or for the government without the authorization of the right holder.

Article 38

Term of Protection

1. In Members requiring registration as a condition of protection, the term of protection of layout-designs shall not end before the expiration of a period of 10 years counted from the date of filing an application for registration or from the first commercial exploitation wherever in the world it occurs.

²⁰ The term "right holder" in this Section shall be understood as having the same meaning as the term "holder of the right" in the IPIC Treaty.

2. In Members not requiring registration as a condition for protection, layout-designs shall be protected for a term of no less than 10 years from the date of the first commercial exploitation wherever in the world it occurs.

3. Notwithstanding paragraphs 1 and 2, a Member may provide that protection shall lapse 15 years after the creation of the layout-design.

SECTION 7: PROTECTION OF UNDISCLOSED INFORMATION

Article 39 (...)

SECTION 8: CONTROL OF ANTI-COMPETITIVE PRACTICES IN CONTRACTUAL LICENCES

Article 40

1. Members agree that some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology.

2. Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market. As provided above, a Member may adopt, consistently with the other provisions of this Agreement, appropriate measures to prevent or control such

practices, which may include for example exclusive grantback conditions, conditions preventing challenges to validity and coercive package licensing, in the light of the relevant laws and regulations of that Member.

3. Each Member shall enter, upon request, into consultations with any other Member which has cause to believe that an intellectual property right owner that is a national or domiciliary of the Member to which the request for consultations has been addressed is undertaking practices in violation of the requesting Member's laws and regulations on the subject matter of this Section, and which wishes to secure compliance with such legislation, without prejudice to any action under the law and to the full freedom of an ultimate decision of either Member. The Member addressed shall accord full and sympathetic consideration to, and shall afford adequate opportunity for, consultations with the requesting Member, and shall cooperate through supply of publicly available non-confidential information of relevance to the matter in question and of other information available to the Member, subject to domestic law and to the conclusion of mutually satisfactory agreements concerning the safeguarding of its confidentiality by the requesting Member.

4. A Member whose nationals or domiciliaries are subject to proceedings in another Member concerning alleged violation of that other Member's laws and regulations on the subject matter of this Section shall, upon request, be granted an opportunity for consultations by the other Member under the same conditions as those foreseen in paragraph 3.

PART III

ENFORCEMENT OF INTELLECTUAL
PROPERTY RIGHTS

SECTION 1: GENERAL OBLIGATIONS

Article 41

1. Members shall ensure that enforcement procedures as specified in this Part are available under their law so as to permit effective action against any act of infringement of intellectual property rights covered by this Agreement, including expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements. These procedures shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse.

2. Procedures concerning the enforcement of intellectual property rights shall be fair and equitable. They shall not be unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays.

3. Decisions on the merits of a case shall preferably be in writing and reasoned. They shall be made available at least to the parties to the proceeding without undue delay. Decisions on the merits of a case shall be based only on evidence in respect of which parties were offered the opportunity to be heard.

4. Parties to a proceeding shall have an opportunity for review by a judicial authority of final administrative decisions

and, subject to jurisdictional provisions in a Member's law concerning the importance of a case, of at least the legal aspects of initial judicial decisions on the merits of a case. However, there shall be no obligation to provide an opportunity for review of acquittals in criminal cases.

5. It is understood that this Part does not create any obligation to put in place a judicial system for the enforcement of intellectual property rights distinct from that for the enforcement of law in general, nor does it affect the capacity of Members to enforce their law in general. Nothing in this Part creates any obligation with respect to the distribution of resources as between enforcement of intellectual property rights and the enforcement of law in general.

SECTION 2: CIVIL AND
ADMINISTRATIVE PROCEDURES
AND REMEDIES

Article 42 - Article 49 (...)

SECTION 3: PROVISIONAL
MEASURES

Article 50 (...)

SECTION 4: SPECIAL
REQUIREMENTS RELATED TO
BORDER MEASURES²¹

Article 51

Suspension of Release by Customs Authorities

²¹ Where a Member has dismantled substantially all controls over movement of goods across its border with another Member with which it forms part of a customs union, it shall not be required to apply the provisions of this Section at that border.

Members shall, in conformity with the provisions set out below, adopt procedures²² to enable a right holder, who has valid grounds for suspecting that the importation of counterfeit trademark or pirated copyright goods²³ may take place, to lodge an application in writing with competent authorities, administrative or judicial, for the suspension by the customs authorities of the release into free circulation of such goods. Members may enable such an application to be made in respect of goods which involve other infringements of intellectual property rights, provided that the requirements of this Section are met. Members may also provide for corresponding procedures concerning the suspension by the customs authorities of the release of infringing goods destined for exportation from their territories.

Article 52 - Article 60 (...)

²² It is understood that there shall be no obligation to apply such procedures to imports of goods put on the market in another country by or with the consent of the right holder, or to goods in transit.

²³ For the purposes of this Agreement:

(a) "counterfeit trademark goods" shall mean any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation;

(b) "pirated copyright goods" shall mean any goods which are copies made without the consent of the right holder or person duly authorized by the right holder in the country of production and which are made directly or indirectly from an article where the making of that copy would have constituted an infringement of a copyright or a related right under the law of the country of importation.

SECTION 5: CRIMINAL PROCEDURES

Article 61

Members shall provide for criminal procedures and penalties to be applied at least in cases of wilful trademark counterfeiting or copyright piracy on a commercial scale. Remedies available shall include imprisonment and/or monetary fines sufficient to provide a deterrent, consistently with the level of penalties applied for crimes of a corresponding gravity. In appropriate cases, remedies available shall also include the seizure, forfeiture and destruction of the infringing goods and of any materials and implements the predominant use of which has been in the commission of the offence. Members may provide for criminal procedures and penalties to be applied in other cases of infringement of intellectual property rights, in particular where they are committed wilfully and on a commercial scale.

PART IV

ACQUISITION AND MAINTENANCE OF INTELLECTUAL PROPERTY RIGHTS AND RELATED *INTER-PARTES* PROCEDURES

Article 62

1. Members may require, as a condition of the acquisition or maintenance of the intellectual property rights provided for under Sections 2 through 6 of Part II, compliance with reasonable procedures and formalities. Such procedures and formalities

ties shall be consistent with the provisions of this Agreement.

2. Where the acquisition of an intellectual property right is subject to the right being granted or registered, Members shall ensure that the procedures for grant or registration, subject to compliance with the substantive conditions for acquisition of the right, permit the granting or registration of the right within a reasonable period of time so as to avoid unwarranted curtailment of the period of protection.

3. Article 4 of the Paris Convention (1967) shall apply *mutatis mutandis* to service marks.

4. Procedures concerning the acquisition or maintenance of intellectual property rights and, where a Member's law provides for such procedures, administrative revocation and *inter partes* procedures such as opposition, revocation and cancellation, shall be governed by the general principles set out in paragraphs 2 and 3 of Article 41.

5. Final administrative decisions in any of the procedures referred to under paragraph 4 shall be subject to review by a judicial or quasi-judicial authority. However, there shall be no obligation to provide an opportunity for such review of decisions in cases of unsuccessful opposition or administrative revocation, provided that the grounds for such procedures can be the subject of invalidation procedures.

PART V

DISPUTE PREVENTION AND SETTLEMENT

Article 63

Transparency

1. Laws and regulations, and final judicial decisions and administrative rulings of general application, made effective by a Member pertaining to the subject matter of this Agreement (the availability, scope, acquisition, enforcement and prevention of the abuse of intellectual property rights) shall be published, or where such publication is not practicable made publicly available, in a national language, in such a manner as to enable governments and right holders to become acquainted with them. Agreements concerning the subject matter of this Agreement which are in force between the government or a governmental agency of a Member and the government or a governmental agency of another Member shall also be published.

2. Members shall notify the laws and regulations referred to in paragraph 1 to the Council for TRIPS in order to assist that Council in its review of the operation of this Agreement. The Council shall attempt to minimize the burden on Members in carrying out this obligation and may decide to waive the obligation to notify such laws and regulations directly to the Council if consultations with WIPO on the establishment of a common register containing these laws and regulations are successful. The Council shall also consider in this connection any action required regarding notifications pursuant to the obligations under this Agreement stemming from the

provisions of Article 6ter of the Paris Convention (1967).

3. Each Member shall be prepared to supply, in response to a written request from another Member, information of the sort referred to in paragraph 1. A Member, having reason to believe that a specific judicial decision or administrative ruling or bilateral agreement in the area of intellectual property rights affects its rights under this Agreement, may also request in writing to be given access to or be informed in sufficient detail of such specific judicial decisions or administrative rulings or bilateral agreements.

4. Nothing in paragraphs 1, 2 and 3 shall require Members to disclose confidential information which would impede law enforcement or otherwise be contrary to the public interest or would prejudice the legitimate commercial interests of particular enterprises, public or private.

Article 64 *Dispute Settlement*

1. The provisions of Articles XXII and XXIII of GATT 1994 as elaborated and applied by the Dispute Settlement Understanding shall apply to consultations and the settlement of disputes under this Agreement except as otherwise specifically provided herein.

2. Subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994 shall not apply to the settlement of disputes under this Agreement for a period of five years from the date of entry into force of the WTO Agreement.

3. During the time period referred to in paragraph 2, the Council for TRIPS shall examine the scope and modalities for complaints of the type provided for under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994 made pursuant to this Agreement, and submit its recommendations to the Ministerial Conference for approval. Any decision of the Ministerial Conference to approve such recommendations or to extend the period in paragraph 2 shall be made only by consensus, and approved recommendations shall be effective for all Members without further formal acceptance process.

PART VI

TRANSITIONAL ARRANGEMENTS

Article 65 *Transitional Arrangements*

1. Subject to the provisions of paragraphs 2, 3 and 4, no Member shall be obliged to apply the provisions of this Agreement before the expiry of a general period of one year following the date of entry into force of the WTO Agreement.

2. A developing country Member is entitled to delay for a further period of four years the date of application, as defined in paragraph 1, of the provisions of this Agreement other than Articles 3, 4 and 5.

3. Any other Member which is in the process of transformation from a centrally-planned into a market, free-enterprise economy and which is undertaking structural reform of its intellectual property system and facing special problems in the

preparation and implementation of intellectual property laws and regulations, may also benefit from a period of delay as foreseen in paragraph 2.

4. To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, as defined in paragraph 2, it may delay the application of the provisions on product patents of Section 5 of Part II to such areas of technology for an additional period of five years.

5. A Member availing itself of a transitional period under paragraphs 1, 2, 3 or 4 shall ensure that any changes in its laws, regulations and practice made during that period do not result in a lesser degree of consistency with the provisions of this Agreement.

Article 66

Least-Developed Country Members

1. In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65. The Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period.

2. Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base.

Article 67

Technical Cooperation

In order to facilitate the implementation of this Agreement, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in favour of developing and least-developed country Members. Such cooperation shall include assistance in the preparation of laws and regulations on the protection and enforcement of intellectual property rights as well as on the prevention of their abuse, and shall include support regarding the establishment or reinforcement of domestic offices and agencies relevant to these matters, including the training of personnel.

PART VII

INSTITUTIONAL ARRANGEMENTS; FINAL PROVISIONS

Article 68

Council for Trade-Related Aspects of Intellectual Property Rights

The Council for TRIPS shall monitor the operation of this Agreement and, in particular, Members' compliance with their obligations hereunder, and shall afford Members the opportunity of con-

sulting on matters relating to the trade-related aspects of intellectual property rights. It shall carry out such other responsibilities as assigned to it by the Members, and it shall, in particular, provide any assistance requested by them in the context of dispute settlement procedures. In carrying out its functions, the Council for TRIPS may consult with and seek information from any source it deems appropriate. In consultation with WIPO, the Council shall seek to establish, within one year of its first meeting, appropriate arrangements for cooperation with bodies of that Organization.

Article 69

International Cooperation

Members agree to cooperate with each other with a view to eliminating international trade in goods infringing intellectual property rights. For this purpose, they shall establish and notify contact points in their administrations and be ready to exchange information on trade in infringing goods. They shall, in particular, promote the exchange of information and cooperation between customs authorities with regard to trade in counterfeit trademark goods and pirated copyright goods.

Article 70

Protection of Existing Subject Matter

1. This Agreement does not give rise to obligations in respect of acts which occurred before the date of application of the Agreement for the Member in question.

2. Except as otherwise provided for in this Agreement, this Agreement gives rise

to obligations in respect of all subject matter existing at the date of application of this Agreement for the Member in question, and which is protected in that Member on the said date, or which meets or comes subsequently to meet the criteria for protection under the terms of this Agreement. In respect of this paragraph and paragraphs 3 and 4, copyright obligations with respect to existing works shall be solely determined under Article 18 of the Berne Convention (1971), and obligations with respect to the rights of producers of phonograms and performers in existing phonograms shall be determined solely under Article 18 of the Berne Convention (1971) as made applicable under paragraph 6 of Article 14 of this Agreement.

3. There shall be no obligation to restore protection to subject matter which on the date of application of this Agreement for the Member in question has fallen into the public domain.

4. In respect of any acts in respect of specific objects embodying protected subject matter which become infringing under the terms of legislation in conformity with this Agreement, and which were commenced, or in respect of which a significant investment was made, before the date of acceptance of the WTO Agreement by that Member, any Member may provide for a limitation of the remedies available to the right holder as to the continued performance of such acts after the date of application of this Agreement for that Member. In such cases the Member shall, however, at least provide for the payment of equitable remuneration.

5. A Member is not obliged to apply the provisions of Article 11 and of para-

graph 4 of Article 14 with respect to originals or copies purchased prior to the date of application of this Agreement for that Member.

6. Members shall not be required to apply Article 31, or the requirement in paragraph 1 of Article 27 that patent rights shall be enjoyable without discrimination as to the field of technology, to use without the authorization of the right holder where authorization for such use was granted by the government before the date this Agreement became known.

7. In the case of intellectual property rights for which protection is conditional upon registration, applications for protection which are pending on the date of application of this Agreement for the Member in question shall be permitted to be amended to claim any enhanced protection provided under the provisions of this Agreement. Such amendments shall not include new matter.

8. Where a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27, that Member shall:

(a) notwithstanding the provisions of Part VI, provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed;

(b) apply to these applications, as of the date of application of this Agreement, the criteria for patentability as laid down in this Agreement as if those criteria were being applied on the date of filing in that

Member or, where priority is available and claimed, the priority date of the application; and

(c) provide patent protection in accordance with this Agreement as from the grant of the patent and for the remainder of the patent term, counted from the filing date in accordance with Article 33 of this Agreement, for those of these applications that meet the criteria for protection referred to in subparagraph (b).

9. Where a product is the subject of a patent application in a Member in accordance with paragraph 8(a), exclusive marketing rights shall be granted, notwithstanding the provisions of Part VI, for a period of five years after obtaining marketing approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter, provided that, subsequent to the entry into force of the WTO Agreement, a patent application has been filed and a patent granted for that product in another Member and marketing approval obtained in such other Member.

Article 71

Review and Amendment

1. The Council for TRIPS shall review the implementation of this Agreement after the expiration of the transitional period referred to in paragraph 2 of Article 65. The Council shall, having regard to the experience gained in its implementation, review it two years after that date, and at identical intervals thereafter. The Council may also undertake reviews in the light of any relevant new developments which

might warrant modification or amendment of this Agreement.

2. Amendments merely serving the purpose of adjusting to higher levels of protection of intellectual property rights achieved, and in force, in other multilateral agreements and accepted under those agreements by all Members of the WTO may be referred to the Ministerial Conference for action in accordance with paragraph 6 of Article X of the WTO Agreement on the basis of a consensus proposal from the Council for TRIPS.

such traffic in other goods and materials as is carried on directly or indirectly for the purpose of supplying a military establishment;

(iii) taken in time of war or other emergency in international relations; or

(c) to prevent a Member from taking any action in pursuance of its obligations under the United Nations Charter for the maintenance of international peace and security.

Article 72

Reservations

Reservations may not be entered in respect of any of the provisions of this Agreement without the consent of the other Members.

Article 73

Security Exceptions

Nothing in this Agreement shall be construed:

(a) to require a Member to furnish any information the disclosure of which it considers contrary to its essential security interests; or

(b) to prevent a Member from taking any action which it considers necessary for the protection of its essential security interests;

(i) relating to fissionable materials or the materials from which they are derived;

(ii) relating to the traffic in arms, ammunition and implements of war and to