UNCTAD/ICTSD Capacity Building Project on

Intellectual Property Rights and Sustainable Development

Intellectual Property Rights and Development

Policy Discussion Paper

[Draft*]

UNCTAD

10 September 2002

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EXPLANATORY NOTE

The paper has been prepared as part of a Project on TRIPS and Development Capacity Building sponsored by the Department of International Development (DFID UK). It is being implemented by the United Nations Conference on Trade and Development (UNCTAD) secretariat (Project Number INT/OT/1BH) and the International Centre for Trade and Sustainable Development (ICTSD). The broad aim of the Project is to improve the understanding of TRIPS-related issues among developing countries and to assist them in building their capacity for ongoing as well as future negotiations on intellectual property rights. Other activities undertaken as part of the Project include production of a Resource Book aimed mainly at negotiators and policy-makers from developing countries. This will provide a step-by-step elaboration of the issues pertinent to the on-going as well as future negotiations in TRIPS and intellectual property related matters in general.

EXECUTIVE SUMMARY

IPRs and development: the key issues

This paper aims to inform and encourage policy discussion on the impact of intellectual property rights on development with particular focus on the the World Trade Organization's Agreement on Trade-related Aspects of Intellectual Property Rights ('the TRIPS Agreement'), which seeks to establish enforceable universal minimum (and high) standards of protection and enforcement for virtually all the most important IPRs. The paper is meant to be an easily readable and accessible document that can help generate a better understanding of the key issues regarding the TRIPS Agreement and development among a range of national authorities and broad range of stakeholders.

Intellectual property rights (IPRs) are legal and institutional devices to protect creations of the mind such as inventions, works of art and literature, and designs. They also include marks on products to indicate their difference from similar ones sold by competitors. IPRs presently consist of the following: patents, copyright and related rights, industrial designs, trademarks, trade secrets, plant breeders' rights, geographical indications, and rights to layout-designs of integrated circuits. Of these, patents, copyright and trademarks are arguably the most economically significant.

IPRs have never been more economically and politically important or controversial than they are today. Patents, copyrights, trademarks and geographical indications are frequently mentioned in discussions and debates on such diverse topics as human rights, public health, agriculture, education, trade, industrial policy, biodiversity management, biotechnology, information technology, the entertainment and media industries, and increasingly the widening gap between the income levels of the developed countries and the developing, and especially least-developed, countries. There is no doubt that an understanding of IPRs is indispensible to informed policy making *in all areas of human development.*

Opinions vary widely. At one end of the political spectrum are those who believe that strong IPR protection and enforcement is indispensable for a modern economy, and the stronger the better. At the other end are those who suspect that IPRs, useful as they could be, are in practice just another device by which the rich make themselves richer and the poor poorer, and may even be unnecessary to foster innovation anyway. Most critics are not anti-IPR at all, but are nonetheless sceptical of many of the claims deployed to justify ever stronger protection, especially when the changes advocated are to be globalized so that all trading nations of the world must accept them.

In fact, as this paper explains, IPRs are tools for economic and cultural development that should contribute to the enrichment of society through (a) the widest possible availability of new and useful goods, services and technical information that derive from inventive activity, and (b) the highest possible level of economic activity based on the production, circulation and further development of such goods, services and information. These objectives are supposed to be achieved because owners can seek to exploit their legal rights by turning them into commercial advantages. The possibility of attaining such advantages, it is believed, encourages innovation and creativity. But after a certain period of time, these legal rights are extinguished and the now unprotected inventions and works can be freely used by others. Nevertheless, *balancing the interests of creators, users of intellectual property and the public through the design of IPR systems is not just a matter of economic calculation but is an inherently political exercise.*

IPRs, like other regulatory systems, are not static but dynamic. During recent decades, there has been a tendency for protectable subject matter to be widened, for new rights to be created, and for the basic features of IPRs to be standardized. Consequently, national IPR regimes throughout the world are becoming increasingly held to harmonized minimum standards of protection, though these standards remain a long way from uniform law. Are these trends necessary responses to technological change? Possibly. Yet there is no reason to assume that the appropriate response should *always* be to strengthen existing rights, reduce or eliminate exceptions, or to create new ones. Such approaches may indeed be necessary in certain cases where the IPR systems available are inappropriate for new types of creative work or become inadequate for protecting existing types because, for example, new technologies make mass-copying easier. In other cases, weakening rights might be a more appropriate response to some instances of technological change. For example, in some industries there may be a fall in the average life-cycles of new products, and in others, average research and development costs for an industry might decline. And it is possible that overprotection might stifle innovation just as underprotection may constitute an insufficient inducement to innovate. In fact, exceptions and limitations to IPRs perform an important function in striking the right balance between the needs and interests of owners, users and the public. How to define these exceptions and limitations is in itself a major development issue. More fundamentally, as this paper shows, it is far from self-evident that the existence of strong IPR protection is a precondition for the transformation of developing country economies into developed ones, while it may help in some areas.

But the concerns about IPRs are not just to do with designing IPR systems that further national developmental objectives. IPRs are considered by many people actually to be harmful. Specifically, critics have argued that IPRs - or at least the way they are currently contoured - have such deleterious effects as raising the prices of essential drugs to levels that are too high for the poor to afford; limiting the available of educational materials for developing country school and university students; legitimising the piracy of traditional knowledge; and undermining the self-reliance of resource-poor farmers. Understandably, debates on these issues are polarized and emotional. However, policy makers need to be able to separate out the truth from the propaganda so that they can design IPR laws and policies that best meet the needs of the people they represent and negotiate effectively in future agreements.

Unfortunately, *it is impossible with any certainty to calculate the long-term impacts of TRIPS on developing countries and their populations*. It is possible that ultimately every country will benefit. But this is pure speculation. We can be certain, though, that developing and least-developed countries *will* incur short-terms costs in the form of administration and enforcement, and rent transfers, and that these will outweigh the benefits. The cost-benefit balance will vary widely from one country to another, but in many cases the costs will be extremely burdensome. According to the World Bank's *Global Economic Prospects and the Developing Countries 2002* study:

> If TRIPS were fully implemented, rent transfers to major technology-creating countries – particularly the United States, Germany, and France – in the form of pharmaceutical patents, computer chip designs, and other intellectual property, would amount to more than $20 billion.

Stated baldly, this means that TRIPS represents a $20 billion plus transfer of wealth from the technology importing nations – many of which are developing countries – to the technology exporters – few if any of which are developing countries – that may or may not be outweighed by future gains.

Developing country members of the WTO no longer have the policy options and flexibilities developed countries had in using intellectual property rights (IPRs) to support their national development. The TRIPS Agreement imposes minimum, relatively high, standards, which all WTO

members must follow. Recent World Bank estimates suggest that the costs of adopting these standards, just in terms of financial transfers from developing to developed countries through royalties and licence fees, will be extremely high. While benefits are also likely, such as through increased direct foreign investment, these are likely to take longer to accrue and their scale is difficult to predict. The dynamic efficiencies of stronger and more effective IPR systems may more than make up for the administrative and enforcement costs, as might increased direct foreign investments. Whether or not this turns out to be true, the costs must be borne before the benefits accrue and, for least-developed countries especially, these are likely to be particularly onerous.

Major policy issues remain, however. These include the question of whether, given their resources, balance of commitments and national interests, least-developed countries would be best to seek postponement of their obligation to implement TRIPS – as they are entitled to do under WTO rules. For developing countries issues arise about how best to interpret the flexibilities believed to be in TRIPS to best meet the food, health, education and other needs of their peoples. In the longer term, there is the bigger question of how, in the light of experience, TRIPS might be amended to best meet the development requirements and circumstances of a diverse range of countries.

Structure of the paper

This paper consists of three parts – a fourth on drawing together policy issues for different countries and sectors is planned and will be written in the light of feedback from this draft and a range of consultative meetings.

Part 1 consists of two chapters. Chapter 1 is an introduction to intellectual property rights, which explains how and why they came into being and have developed over time, how economists justify their existence, and why they are increasingly important in today's global economy. One of the most important conclusions of the chapter is that historically the scope and strength of intellectual property protection has tended to vary according to the level of economic and technological development of individual countries. Another key finding is that IPRs are designed to balance conflicting aims and interests in order to most effectively achieve certain public policy goals. But striking such a balance is likely to be very difficult for policy makers.

Chapter 2 presents the key features of the framework of the global intellectual property regulatory system and the international institutions that form its core. The most important of these institutions are the World Trade Organization (WTO) and the World Intellectual Property Organization (WIPO). The WTO Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS Agreement) is of special importance in that it seeks to establish enforceable universal minimum (and high) standards of protection and enforcement for virtually all the most important IPRs such as patents, copyrights and trademarks. The chapter explains how the TRIPS Agreement was negotiated, the purpose of the Agreement, and its main features.

Part 2 of the paper deals at some length with the key development issues for which intellectual property rights have relevance. These are as follows:

- Human rights
- Health
- Food, agriculture and biodiversity
- Traditional knowledge, folklore and cultural property
- Education
- IPRs and new technology, with specific reference to biotechnology and information and

communication technologies
- Technology transfer and foreign direct investment
- Administrative and institutional challenges for developing countries, especially relating to enforcement of TRIPS and setting up the administrative structures

These chapters should make clear, first, that IPRs have an effect on the lives of everybody, and secondly, that whatever development objectives developing countries may wish to pursue, IPRs have the potential to support them but also to undermine them. Unfortunately, there is a lack of reliable information upon which policy decisions in this area need to be based. Second, important international negotiations covering IPR issues also take place in forums and agreements that do not deal primarily with IPRs at all. Perhaps the most important of these are the Convention on Biological Diversity and the International Treaty on Plant Genetic Resources of the Food and Agriculture Organization of the United Nations. These are also described in Part 2.

Part 3 looks into the new development in international IPR regulation. Chapters 11 and 12 focus on recent TRIPS-related developments at the WTO, new treaty development and harmonization. Chapter 12 should make it clear that the WTO and TRIPS are by no means the only forums and agreements promoting the standardization and/or harmonization of IPR rules throughout the world. Others agreements include WIPO conventions, regional treaties and institutions, and regional and bilateral free trade agreements. Policy makers need to be aware of all of these forums, agreements and processes so as to develop coordinated and appropriate responses to ensure that national sustainable development interests are pursued as effectively as possible.

PART ONE:
INTELLECTUAL PROPERTY RIGHTS IN THE GLOBAL ECONOMY

CHAPTER I: INTRODUCTION

Intellectual property rights have never been as much in the news as they are today. Several issues have attracted controversy. For example, drug companies have been accused of taking advantage of their patent rights by charging exorbitant prices for life-saving medicines such as AIDS drugs. Indigenous peoples and advocacy groups supporting their rights condemn corporate 'biopirates' for making money out of their knowledge and claiming patent rights for 'inventions' essentially identical to knowledge acquired from tribal healers. Concerns are raised that patenting plants, animals, genes and gene fragments is not only unethical but may also be stifling innovation. Many developing countries complain about the pressure they feel is being imposed on them to introduce western-style IPR regimes before they think they are ready for them, and worry that this situation places them at a serious disadvantage in an era of rapid technological change. And while the global trend is towards ever stronger intellectual property right protection, increasingly determined efforts are made to oppose this process.

What are intellectual property rights?

Intellectual property rights (IPRs) are legal and institutional devices to protect creations of the mind such as inventions, works of art and literature, and designs. They also include marks on products to indicate their difference from similar ones sold by competitors. Over the years, the rather elastic IPR concept has been stretched to include not only patents, copyright, industrial designs and trademarks, but also trade secrets, plant breeders' rights, geographical indications, and rights to layout-designs of integrated circuits. Of these, patents, copyright and trademarks are arguably the most significant in terms of their economic importance, their historical role in the industrialization of Europe and North America, and their current standing as major pillars of the international law of intellectual property rights.

Patents provide inventors with legal rights to prevent others from using, selling or importing their inventions for a fixed period. Applicants for a patent must satisfy a national patent-issuing authority that the invention described in the application is new, susceptible of industrial application (or merely 'useful' in the United States), and that its creation involved an inventive step or would be unobvious to someone skilled in the art represented by the claimed invention.

Copyright gives authors legal protection for various kinds of literary and artistic work. Copyright law protects authors by granting them exclusive rights[1] to sell copies of their work in whatever tangible form (printed publication, sound recording, film, etc.) is being used to convey their creative expressions to the public. In theory, legal protection covers the expression of the ideas contained, not the ideas themselves. In practice, information may also be protected, as when copyright is extended to cover new types of work such as software programs and databases. The right usually lasts for the life of the author plus 50 years, though in some jurisdiction this has been extended recently to 70 years.

Trademarks are marketing tools used to support a company's claim that its products or services are authentic or distinctive compared with similar products or services of competitors. They usually consist of a distinctive design, word, or series of words placed on a product label. It some jurisdictions

sounds and smells can also be protected as trademarks. Normally trademarks can be renewed indefinitely, though this is likely to be subject to continued use. The trademark owner has the exclusive right to prevent third parties from using identical or similar marks in the sale of the same classes of goods or services, and thereby confuse customers.

What are intellectual property rights for?

Traditionally, IPRs – especially patents and copyright – have been justified on both consequentialist and rights-based grounds. These are not mutually exclusive since some arguments contain elements of both.[2]

The consequentialist justification is that when inventors, authors or artists have an exclusive right to reproduce and sell their works, society benefits in consequence. This proposition is based on two assumptions. First, it assumes that such a right encourages inventors to invent, authors to write and artists to paint. Second, it presupposes that the greater the quantity of inventions and creative works eventually released into the public domain, the more the public benefits through economic or cultural enrichment, or enhanced quality of life. Thus advocates of this justification tend to argue that IPRs are *incentives* that encourage creative endeavour.

According to rights-based justifications for IPRs, property in intellectual works is primarily a matter of justice rather than of public policy. IPR laws exist to define and enforce the property rights but are not the source of these rights, since to enjoy a property right over one's creative work is a human right.[3] According to such a view unauthorized use of somebody's invention or creative work is an unfair – and therefore illegal – intrusion on the creator-proprietor's freedom to benefit from its use without interference. This justification does not of course apply so easily to those many cases where IPRs are owned by companies and not individuals.

Consequentialist justifications have inspired national IPR laws and policy making far more than rights-based ones.[4] For example, the original role of the United States patent and copyright systems were to implement Article 1 Section 8 of the U.S. Constitution, which empowers Congress 'to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.' U.S. IPR law, then, was not founded on a natural rights justification of intellectual property ownership. Rather, the granting of exclusive rights *for limited times* was regarded as being beneficial for the country in terms of scientific and cultural progress.

IPRs, then, exist primarily to benefit society. But this does not tell us much about the ends that IPRs are meant to serve nor how these ends ought to be achieved. In general terms, IP rights – especially patents – are tools for economic advancement that should contribute to the enrichment of society through (i) the widest possible availability of new and useful goods, services and technical information that derive from inventive activity, and (ii) the highest possible level of economic activity based on the production, circulation and further development of such goods, services and information. In pursuit of these aims, inventors are able to protect their inventions through a system of property rights – the patent system. Once acquired, the owners then seek to exploit their legal rights in the marketplace. The possibility of attaining commercial benefits, it is believed, encourages invention and innovation.[5] But after a certain period of time, these legal rights are extinguished and the now unprotected inventions are freely available for others to use and improve upon. Enhancing the society's capacity to generate such useful goods, services and information by itself is one means for achieving such ends (and may, it could be argued, be a sufficient end in itself). But it is not the only means. After all, these could also be imported, and legal incentives could be created for such importation, as they were in the past.

Philosophy is not enough to explain why we have IPRs, except in general terms. Economics is helpful not only for identifying the specific problems that IPRs are meant to solve, but also for helping policy makers to design IPR systems so that they fulfil their intended objectives. In economic terms, patents and copyright are primarily intended to resolve market failure. The central issue is that economically-useful knowledge or culturally-enriching works are likely not only to be expensive to produce and market but difficult to control in a competitive market. Therefore, in the absence of any regulations to prevent free-riding, those capable of providing such knowledge or works are likely to be discouraged not only from investing in its production but also from publicly disclosing it. Thus, intellectual property rights, especially patents, are often portrayed by economists as a kind of regulatory response to the failure of the free market by itself to achieve optimal resource allocation for invention. According to such a perspective, 'patents are designed to create a market for knowledge by assigning proprietary rights to innovators which enable them to overcome the problem of non-excludability while, at the same time, encouraging the maximum diffusion of knowledge by making it public.'[6]

This explanation for patents assumes that knowledge is a public good. This notion was nicely articulated by Thomas Jefferson who wrote in a letter that the 'peculiar character' of an idea is that 'the moment it is divulged, it forces itself into the possession of everyone, and the receiver cannot dispossess himself of it', and also that 'no one possesses the less, because every other possesses the whole of it'. He then went on to explain that 'he who receives an idea from me, receives instruction himself without lessening mine; as he who lights his taper at mine receives light without darkening me'.

Patents are temporary exclusionary rights. Such rights can be converted into market monopolies if the invention so protected results in a commercial product. The public goods explanation for patents posits that the possibility of acquiring such rights encourages both investment in invention and the research and development needed to turn inventions into marketable innovations. Information about the invention as revealed in the patent and by the invention itself is, into the bargain, diffused throughout the economy. In this context, it is helpful to conceive of a patent as a contract between the holder and the government on behalf of the citizenry. The holder receives an exclusive right over his or her invention in exchange for the payment of fees and – which is much more important – for disclosing the invention for others to learn from. Without a patent, the inventor would have no incentive to disclose it. This would be a loss for society if such lack of protection left the inventor with no alternative but to keep it secret. Such an alternative is a feasible option in several technological fields including biotechnology. But it is also true that many kinds of product would upon examination readily betray the invention that brought it into existence.

As for the creation of markets for knowledge, it might be useful here to explain why these are considered beneficial and how patents are thought to bring them into being. The explanation relates to the common situation that many patent holders are poorly placed to exploit their invention in the marketplace. Take the case of a creative but small company lacking the funds to develop and commercialize new products based upon its inventions. If such products are desirable for consumers, failure to commercialize would be a loss for society. But if the company owns a patent, a wealthier company may wish to license or buy the patent secure in the knowledge that the invention is legally protected. And if the invention were kept secret, how would bigger companies know about it? The disclosure of patent information makes it possible for prospective users to find inventions of interest and then to approach their owners.

However, several studies[7] caution against assuming that innovations are necessarily discrete and independent. In reality, they tend to be cumulative and dependent.[8] Moreover, reproducing them may depend on tacit knowledge which cannot easily be documented in written form, such as in a patent specification, and is therefore available only to the innovator. Also, as is sometimes pointed out, other

means of appropriation are not only possible but may be more effective in some cases than IPRs. These include marketing, customer support services, reputation, and the advantage that comes with being first to bring innovations to market.[9] The fact that intellectual works are not necessarily public goods makes it extremely difficult if not impossible to determine an optimal level of protection for achieving an optimal allocation of resources for inventive activities. The difficulty for policy makers is further compounded by the task of ensuring that protection is effective but not so strong as to unduly restrict the freedoms of follow-on innovators. It has also been suggested that while patents encourage disclosure of an invention, they may paradoxically also encourage secrecy. According to Paul David, 'although the disclosure of codified information is augmented by patent systems, so is the inducement to curtail the transmission of tacit knowledge that might reduce the commercial value of the patents that have been issued'.[10]

One of the reasons that patents are so controversial is that the IP incentive – as far as it actually works – functions by restricting use by others of the protected invention for a certain period. Yet follow-on innovation by others is more likely to happen if use is not restricted. Thus a balance between private control over the use of technical information and its diffusion needs to be struck. Where the line – in terms of the length, breadth and strength of protection – should be drawn is very difficult to determine but its ideal location will vary widely from one country to another. In countries where little inventive activity takes place, free access to technical information may well do more to foster technological capacity building than providing strong private rights over such information. In fact, technological capacity building may at certain stages of national development be best achieved by requiring foreign technology holders to transfer their technologies on generous terms rather than by trying to encourage domestic innovation by making strong legal rights available to all.[11] This suggests that some developing countries should be careful not to make the rights too strong until their economies are more advanced. Historical evidence indicates that several modern day developed countries, rightly or wrongly, took such a policy decision in the past.

The task of designing IPR systems to stimulate the development and dissemination of new technologies would be much easier if policy makers could predict the trajectory of their future development, especially in an era of rapid technological advance such as the present one. This is always difficult, but especially for developing countries, which lack the data necessary for designing patent systems that most efficiently stimulate the *long-term* development and dissemination of new welfare-enhancing products and technologies.

In short, patents and other IPRs are intended to balance different aims and interests in order to most effectively achieve certain public policy goals. Striking an optimum balance is extremely difficult. IPRs can be underprotective, but they can also be overprotective. It is important to understand, though, that balancing the interests of present and future creators, users of intellectual property and of the public is not just a matter of economic calculation – it is an inherently political exercise.

The discussion so far has focused on the economics of the patent and copyright system. Other IPRs, such as trademarks can also be justified on economic grounds but in different ways. Trademarks make products identifiable from similar products available in the market and encourage producers to strive to maintain the value of their marks. According to Keith Maskus 'trademark protection may be expected both to raise the average quality of products on the market and to generate further product differentiation'.[12] Thus, consumers and producers stand to benefit. But this view is not universally held. Concerns have been raised that trademarks (as with other IPRs) are often asserted in ways that intrude on the legitimate freedoms of other.[13]

A brief history of intellectual property rights

Like many other systems of economic regulation, intellectual property rights have a history going back centuries.[14] But the main IPRs like patents and copyright took their modern forms in the nineteenth century at a time when Europe and North America were in the midst of rapid industrialization.

Over the years, patents have been granted for a variety of public policy purposes such as to encourage the immigration of craftsmen, to reward importers of foreign technologies, to reward inventors in general, to create incentives for further inventive activity, to encourage the dissemination of new knowledge[15], and to allow corporations to recoup their investments in research and development. From a public policy perspective, each of these justifications is as legitimate as the others. Which is most appropriate for a country depends largely on its economic circumstances. Historically and even today, the way patents have been justified in different countries has depended on the level of industrial development – and also to whom one speaks. Nonetheless, as with other forms of intellectual property (especially copyright), justice-based arguments for stronger and better enforced rights are also frequently deployed, and such claims can carry strong moral force. After all, many people would consider it just as immoral for somebody to copy an inventor's useful new gadget and claim it as his or her own as to similarly misappropriate somebody's new novel, song or painting.

One of the earliest patent laws was the 1624 English Statute of Monopolies. Its true purpose was to prohibit monopolies rather than to promote invention,[16] and the government intended the law to encourage foreign craftsmen to settle in the country.[17] Monopoly grants were banned *except* 'the true and first inventor or inventors' of 'any manner of new manufactures within this realm' as long as 'they be not contrary to the law, nor mischievous to the state, by raising prices of commodities at home, or hurt of trade, or generally inconvenient'. Such inventors could acquire up to 14 years' monopoly protection. Strict novelty was not required since courts interpreted the purpose of granting patents as being to introduce new trades to England whether or not they were 'novel' elsewhere in the world.[18] It should be noted in this context that at this time England was less advanced technologically than both France and the Netherlands.[19] The Statute was amended several times but remained in force until 1977 when Britain adopted the standards of the European Patent Convention including its requirement of absolute (i.e. global) novelty.[20]

The 1836 United States Patent Act[21] was arguably the first modern patent law. It required all applications to be examined by the government patent office for novelty and usefulness. Although this law did not discriminate between U.S. and foreign inventors with respect to the examination or the extent of rights granted, foreign applicants had to pay much higher fees, especially if they were British. Such discrimination was abolished in 1861 for nationals of countries whose laws were non-discriminatory towards Americans.

The German Patent Act[22] of 1877 was also an examination system.[23] In common with most countries today, it was possible to except inventions deemed contrary to public order or morality. Patenting of inventions regarding luxuries, medicines, articles of food, or chemical products was prohibited.

Some European countries managed without a patent law for much of the nineteenth century. Switzerland had a patent system only from 1799 to 1802[24], not re-establishing it until 1888. The Netherlands prohibited patents from 1869 until 1912.[25]

As with patents, copyright's origin is Renaissance Italy, although the most famous early copyright law is probably the English Statute of Anne of 1710.[26] Early copyright law was associated with the interests of domestic printers rather than authors. While its intent was both to prevent unauthorized

printing, reprinting and publishing of books and writings and to encourage 'learned men to compose and write useful books', the Statute of Anne was primarily the outcome of a campaign by an association of printers (the Company of Stationers) to reassert its control over the English book trade, rather than a law to uphold the rights of authors. Nonetheless, for the first time in a statute, it did recognize that authors could be proprietors of their works.[27] This law provided a time-limited right to print and reprint books whose titles were entered in the register book of the Company of Stationers. According to the economic historian, Paul David[28], 'copyright law, from the beginning, has been shaped more by the economics of publication than by the economics of authorship'. Nevertheless, copyright law in continental Europe displayed much more concern for the artistic integrity of authors than did the Anglo-American copyright regulations.[29] The time limitation, as with patents, reflects the need to balance the rights of publishers and authors with the interests of the community.

As with patent law, it is not until the nineteenth century that copyright law took its modern form. During this century, the protection term increased, the law began to accumulate a wider range of subject-matters, and international agreements began to proliferate with the result that national standards became more harmonized, and opportunities to secure stronger protection of creative works in more countries were greatly enhanced. These trends have continued. With respect to subject-matters, for example, U.K. copyright law had by 1988[30] been stretched to include literary and dramatic works (including computer programs), musical works, artistic works, sound recordings, films, broadcasts, cable programmes, typographical arrangements, and computer-generated works. And protection was not only economic in nature, but – following continental tradition and the requirements of the Berne Convention for the Protection of Literary and Artistic Works – included authors' moral rights. Moral rights include the right of authors to be identified as such (the 'right of paternity'), and to object to having their works altered in ways that would prejudice their reputation ('the right of integrity').

Historically, national copyright laws have generally been less friendly towards the interests of foreigners than have patent laws. This is because while granting rights to foreigners was sometimes considered to benefit the country by encouraging the introduction of protected technologies, allowing foreigners to protect their literary and artistic works does not provide such obvious economic advantages.[31] For example, for many years United States copyright law contained a so-called 'manufacturing clause' which originally required all copyrighted literary works to be printed in the country. This was a protectionist measure intended to benefit American printers. Although the clause was weakened over the years it remained on the statute books until as late as 1986.

Most countries that experienced industrial revolutions during the nineteenth century had patent systems. But Switzerland and Holland were exceptions to this general rule. What can be concluded from this? While it is likely to be true that patent systems did indeed stimulate the development and diffusion of new technologies that were the foundation for rapid industrial development[32], this does not prove they were indispensable. Since we cannot turn the clock back and re-run the nineteenth or twentieth centuries without a patent system there is much that we will never be sure of. But few if any of these early patent systems would come close to compatibility with the World Trade Organization's Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS Agreement), which seeks to establish enforceable universal minimum (and high) standards of protection and enforcement for virtually all the most important IPRs.[33] For one thing, they tended to be biased towards domestic inventors and users of foreign technologies. And for another, the rights given to holders were generally quite weak by modern standards. Nonetheless, one should not overstate the case that historical experience is relevant for today's policy makers. After all, the world has changed considerably in the last 100 years.

Contemporary debates and developments

The potential economic and social implications of IPRs are tremendous, and the stakes have never been higher than they are today. Increasing numbers of people have begun to recognise this. Consequently, despite their long history, public interest in IPRs world wide has reached unprecedented levels, and views on their effects differ quite radically. There are those who hold that strong IPR protection and enforcement is indispensable not only for the advanced industrialized economies but for developing and least-developed ones, too. While very few people favour the abolition of IPRs, there are many critics who believe that high levels of protection are generally a bad thing for any country, and are positively detrimental for poor countries. Others take a view in between, accepting that IPRs can enhance development by resolving market failures, but doubting that most developing and especially least-developed countries are ready to introduce strong levels of IPR protection as have been adopted by the developed economies.

Two recent closely-related developments are responsible for galvanizing the increasingly-heated debates on IPRs. The first development is the successful attempt of the United States, Europe and Japan, supported by business associations representing transnational corporations, to place IPRs on the GATT Uruguay Round agenda, and then to force through an agreement covering a wide-range of IPR standards going far beyond the original aim of preventing counterfeiting of trademarked goods and piracy of copyrighted works. Critical political and academic responses have focused on various issues, but mainly on the inherently protectionist motivation for setting minimum IPR standards at a high level as compared to the majority of countries[34], concern for the environment[35], the rights of indigenous peoples[36], the general interests of the developing countries[37], food security and the rights of farmers[38], access to technology, and on the high prices of life-saving drugs in developing countries.[39]

Second, the 'patenting life' controversy has, since the 1980s, stimulated a growth of critical literature which focuses on a number of aspects. These include:

- the moral significance of treating as property such 'inventions' as plants, animals, micro-organisms and – in some jurisdictions – functional or structural components of life-forms including gene sequences, proteins and cell cultures[40];
- the way that these patents appear to overturn some of the basic groundrules of patent law, such as that substances existing in nature are discoveries and cannot therefore be patented, that inventions must be fully disclosed, and that the rights to products are exhausted after the owners or authorised third parties have placed them on the market[41];
- the possibility that basic research may be discouraged when overly broad patent claims are allowed, which may also overlap with claims in other patents, and biotechnology research tools such as gene sequences are privatized through the patent system[42];
- that allowing 'life-form' patents supports the practice of 'biopiracy'[43]; and
- that patents on plants or some plant breeders' rights regulations infringe the basic right of farmers to freely dispose of harvested seed as they see fit including to sell it.[44]

While *national* IPR regulations (in some countries) have existed for two or more centuries, the history of intellectual property *at the international level* really began in the late nineteenth century with the formation in the 1880s of unions of mostly European countries for the protection of industrial property and literary and artistic works. Previously the only instruments for international protection had been based on bilateral commercial agreements involving mostly European countries.[45] The process of expanded international IPR regulation has continued since then to the extent that most countries of the world are now involved. During recent decades, the evolution of developed country IPR regimes has been characterized by three phenomena:

1. The widening of protectable subject matter

The parameters of protectable subject matter have been widened, and there has been a tendency to reduce or eliminate exceptions. Examples include the extension of copyright and patent protection to computer programs, the application of patent protection to cover business methods, life-forms, cell lines and DNA sequences, the removal of exclusions on product patents for drugs, and the extension of trademark protection in some countries to include sounds and smells.

2. The creation of new rights

Examples of new systems of rights created during the twentieth century include plant breeders' rights, rights to layout-designs of integrated circuits, and rights related to copyright such as performers' rights.

3. The progressive standardization of the basic features of IPRs

For instance, patent regulations increasingly provide 20-year protection terms; require prior art searches and examinations for novelty, inventive step or non-obviousness, and industrial application[46]; assign rights to the first applicant rather than the first inventor[47]; and provide protection for inventions in all industries and fields of technology.

These developments in IPR law, all of which began in Europe or North America, are spreading to the rest of the world, and at an accelerating pace. Two of the major driving forces have been the Paris and Berne Conventions. During the 1960s and 70s alone, 33 developing countries joined the Paris Convention for the Protection of Industrial Property, and 25 joined the Berne Convention for the Protection of Literary and Artistic Works. Consequently, national IPR regimes throughout the world are becoming increasingly held to harmonized minimum standards of protection. These, however, remain a long way from uniform law, a situation that some are hoping to remedy in the coming years.

It should not be assumed, though, that the developments referred to above were introduced gradually over time even in the developed world. In fact, many of the examples given above were introduced into national IPR regimes quite recently. For example, until the 1960s several West European countries (e.g. France, Belgium and Italy) still granted patents on the basis of registration.[48] Moreover, the bar to patentability of pharmaceutical products in several developed countries was lifted only in the 1960s or 70s.[49] And other important expansions in protectable subject matter are even more recent (e.g. the patenting of animals and DNA sequences, and the sui generis protection of integrated circuit layout-designs). And at the same time, a few developing countries moved in the reverse direction. For example, in the late 1960s and early 1970s Brazil and India passed laws to exclude pharmaceuticals as such from patentability (as well as processes to manufacture them in Brazil's case).

One could argue – as many do – that these trends are necessary responses to technological change. While there is probably much truth in this, there is no reason to suppose that the appropriate response should *always* be to strengthen existing rights, reduce or eliminate exceptions, or to create new ones. Such approaches may indeed be necessary in certain cases where the IPR systems available are inappropriate for new types of creative work[50] or become inadequate for protecting existing types because, for example, new technologies make mass-copying easier. In other cases, weakening rights might be a more appropriate response to some instances of technological change. For example, in some industries there may be a fall in the average life-cycles of new products, and in others, average research and development costs for an industry might decline.[51] And it is possible that overprotection might stifle innovation. More fundamentally – and this will be elaborated upon below – it is far from self-evident that the existence of strong IPR protection is a precondition for the transformation of

developing country economies into developed ones.

Why intellectual property is trade-related

The commercial importance of IPRs has grown considerably, especially since the 1970s. Those national economies in which most IPR-holding corporations are concentrated have experienced a transformation in the composition of their export trade in manufactures. Since 1970, for most developed countries the contribution of advanced technologies to economic performance in terms of manufacturing value-added and exports has increased substantially (Table 1).

One reason for this situation is the incessant and increasing pressure on businesses and national economies to be competitive. This puts a premium on innovation and creativity aimed at developing new products and services and at differentiating existing ones from those of competitors. Perhaps the most important of these advanced technologies are information and communications technology (ICT) and those based upon the applied life sciences. Both have multiple industrial applications and are of interest to companies operating in a wide range of product and service markets. So in addition to the commercial interests responsible for innovating in these fields, such as software, telecommunications, pharmaceutical and biotechnology companies, many other business sectors deploy these technologies including producers and providers of computers and other electronic goods, music, television programmes, films, printed works and financial services to name a few.

Technological change creates new opportunities for private appropriation, but also poses new challenges. One of these challenges is the threat of free-riding, which certain new technologies may facilitate. IP protection helps to maximize these opportunities while minimizing the risks. This is why many companies operating in all the above sectors hold large intellectual property portfolios protecting products and services developed through the deployment of these technologies. Indeed, for such businesses, the high market value of their goods and services may be due largely to such IPR-protectable intangible inputs as technical knowledge and artistic creativity or attributes like reputation and distinctiveness. Such businesses assert these rights with great determination. After all, developing, applying and benefiting commercially from such inputs and attributes can involve enormous research and development (R&D) and marketing expenditures. Moreover, despite the knowledge-rich corporations' market dominance, they are also highly vulnerable. While the marginal cost of manufacturing such goods as software packages, compact disks and videos is extremely low, so is the marginal and fixed cost of copying them. Multiple reproduction of these goods is possible with low cost equipment and minimal (if any) technical know-how. In countries where IPR such as patents, copyrights and trade marks are unavailable or enforcement is weak, imitators can quickly and inexpensively copy these products and sell them at home and in other countries where effective IPR protection is also weak. Similarly plant breeding companies can find their non-hybrid plant varieties being sold without their consent. Even though entry barriers for generic drug firms are higher in that competent chemists need to be hired and bulk production will require more expensive equipment than for, say software and compact disk piracy, the free-riding problem that research-based drug companies face is also potentially serious.

Table 1: Share of high-technology goods in manufacturing value-added and exports in selected high-income economies

	Value added		*Exports*	
	1970	**1994**	**1970**	**1993**
Australia	8.9	12.2	2.8	10.3
Canada	10.2	12.6	9.0	13.4
France	12.8	18.7	14.0	24.2
Germany	15.3	20.1	15.8	21.4
Italy	13.3	12.9	12.7	15.3
Japan	16.4	22.2	20.2	36.7
United Kingdom	16.6	22.2	17.1	32.6
United States	18.2	24.2	25.9	37.3

Source: World Bank (1999:24)

As for technology ownership, a similar story of developed country – especially U.S. – interest in high levels of IPR protection can be inferred from the relevant statistics. It is not only IPR-protected *products*, *technologies* and *services* that are major exports of developed countries like the United States; it is also the *rights* themselves in the form of licences to use patented processes, techniques and designs, copyrights, trademarks and franchises. According to Michael Ryan[52]: 'U.S. multinational manufacturing enterprises increasingly transfer intellectual property internationally through the industrial processes that they sell abroad. Exports, as measured by royalties and licensing fees, amounted to about U.S.$27 billion in 1995, while imports amounted to only U.S.$6.3 billion. At least U.S.$20 billion of the exports are transactions between U.S. firms and their foreign affiliates.'[53] This balance of payments surplus is far higher than for any other country.

Interestingly, most of the major industrialized countries do not have a balance of payments surplus for royalties and licence fees. According to International Monetary Fund figures for 1995[54], the United Kingdom is one of the few which also enjoyed a surplus. But it was far smaller than that of the U.S. (U.S.$1.71 bill. compared with U.S.$20.66 bill.). Countries with sizeable deficits included not only large developing countries like India (U.S.$-68 million [1992 figure]) and Brazil (U.S.$-497 mill.), but major economic and technological powers like Japan (U.S.$-3.35 bill.) and Germany (U.S.$-2.66 bill.). This is likely to puzzle many non-economists, especially considering the heavy corporate research and development commitments which are well-known features of the private sectors of the latter two countries. But there is a simple explanation. This is that 'German and Japanese firms exploit their technological advantage mainly through exports, whilst U.S. and U.K. forms rely much more on direct foreign investment, which results in a higher volume of measured royalty income.'[55] So Germany and Japan have just as much reason as the U.S. and U.K. to favour strong and enforceable IPR protection in overseas markets, if not for identical reasons.

Such figures give some impression of the static gains and losses to different countries of intellectual property protection and of the extent to which their interests are likely to vary. But clearly they do not tell the whole story, and more work is needed, not only to estimate static gains (and possible losses), but also the projected dynamic efficiency gains of strong IPR protection, especially for developing countries.

CHAPTER II: THE GLOBAL IPR ARCHITECTURE

The architecture of the global IPR regime has become increasingly complex, and includes a diversity of multilateral agreements, international organizations, regional conventions and instruments, and bilateral arrangements. In summary the international law of intellectual property in its present form consists of three types of agreement. These are multilateral treaties, regional treaties or instruments, and bilateral treaties. Of these, the agreements that affect the greatest number of countries are the TRIPS Agreement, and some of the multilateral treaties administered by the World Intellectual Property Organization (WIPO), a specialized United Nations agency located in Geneva. One of WIPO's main objectives is 'to promote the protection of intellectual property throughout the world through cooperation among States and, where appropriate, in collaboration with any other international organization'.[56]

Multilateral treaties

Most of these agreements are administered by the (WIPO), and are of three types:

i. *The standard setting treaties*, which define agreed basic standards of protection for the different IPRs, and also typically require national treatment. These include the 1883 Paris Convention for the Protection of Industrial Property, the 1886 Berne Convention for the Protection of Literary and Artistic Works, and the 1961 Rome Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations. Important non-WIPO treaties of this kind include UNESCO's 1952 Universal Copyright Convention, the 1961 International Convention for the Protection of New Varieties of Plants (the UPOV[57] Convention), and the World Trade Organization-administered TRIPS Agreement.

ii. *The global protection system treaties*, which facilitate filing or registering of IPRs in more than one country. These include the 1970 Patent Cooperation Treaty, and the 1891 Madrid Agreement Concerning the International Registration of Marks.

iii. *The classification treaties*, which 'organize information concerning inventions, trademarks and industrial designs into indexed, manageable structures for easy retrieval'.[58] One example is the 1971 Strasbourg Agreement Concerning the International Patent Classification.

Regional treaties or instruments

Examples of these kinds of agreement include the 1973 European Patent Convention, the 1998 European Community Directive on the Legal Protection of Biotechnological Inventions, the 1982 Harare Protocol on Patent and Industrial Designs within the Framework of the African Regional Industrial Property Organization, and the 2000 Andean Community Common Regime on Industrial Property. Some of these, such as Chapter 17 of the North American Free Trade Agreement, are components of trade agreements rather than stand-alone IPR treaties.

Bilateral agreements

Specifically, these include those bilateral agreements that deal with IPRs as perhaps one of several issues covered. A recent example is the 2000 Free Trade Agreement between the United States and Jordan, but there are many others (see Chapter 14).

While it sounds contradictory to suggest that *regional* agreements are part of the *global* architecture (or for that matter bilateral agreements), such instruments are extremely important. First, their

membership may be quite large, covering 20 or more countries. Second, it is possible that novel provisions in such agreements could subsequently be globalized through their incorporation into new multilateral agreements.[59] Third, developing countries may be required to introduce provisions that go beyond what TRIPS requires such as extending patents to new kinds of subject matter and eliminating certain exceptions. Fourth, regional agreements might stipulate that contracting parties should accede to certain international conventions. The third and fourth points also apply to bilateral agreements.

The emergence of TRIPS

Many developing countries have been ambivalent if not hostile to TRIPS from the beginning. Nonetheless, in 1986 developing country members of the General Agreement on Tariffs and Trade (GATT) accepted the Punta del Este Declaration, whose apparently quite limited aspirations were primarily to 'clarify GATT provisions' relating to IPRs and counterfeit goods, and to 'develop a multilateral framework of principles, rules and disciplines dealing with international trade in counterfeit goods' (see Box 1). By 1989, the situation changed radically with developing countries dropping their earlier resistance to a substantive agreement on IPRs that would ultimately form a package of agreements covering various trade issues such as agriculture, textiles and services.

Box 1: The Punta del Este Declaration – provisions on IPRs

D. Subjects for Negotiations

Trade-related aspects of intellectual property rights, including trade in counterfeit goods

In order to reduce the 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, the negotiations shall aim to clarify GATT provisions and elaborate as appropriate new rules and disciplines.
Negotiations shall aim to develop a multilateral framework of principles, rules and disciplines dealing with international trade in counterfeit goods, taking into account work already underway in GATT.

These negotiations shall be without prejudice to other complementary initiatives that may be taken in the World Intellectual Property Organization and elsewhere to deal with these matters.

On the face of it, this is puzzling especially when we consider that a certain number of relatively industrialized developing countries had reformed their IP systems a decade earlier in order to facilitate imitation by their domestic firms.[60] Why did developing countries, many of which seem to be as dubious today as they were in 1986 about the trade-relatedness of IPRs, agree to abide by such a comprehensive agreement setting high minimum standards of protection and enforcement?

There are two plausible ways to interpret the behaviour of developing countries. Both of these emphasize the important role of pro-IPR business associations and lobby groups as well as the power of certain developed countries to threaten and punish developing countries for being uncooperative on intellectual property rulemaking and enforcement. The first is that they were willing to accept the whole WTO package of agreements out of a conviction that the benefits of the other Uruguay Round agreements would outweigh the economic and social costs of TRIPS. In short, TRIPS was a loss but the WTO package was a net gain. Alternatively, developing countries might have considered TRIPS and the WTO agreements as a whole to be unsatisfactory, but had little choice but to accept it since the carrot of improved access to developed country markets was irresistible, and the stick of strengthened trade barriers and even unilateral sanctions expected to result from a refusal to raise IPR

standards was to be avoided at all costs. Accordingly, the establishment of the WTO was welcome because they expected (over-optimistically as it turned out) that it would insulate them from the aggressive unilateralism being adopted by some developed countries.

Box 2 presents two different ways to explain the diplomacy that led to the agreement between developed and developing countries to enter into negotiations on IPRs at the GATT.

Box 2: TRIPS and developing countries: coercion or contract?

According to one scholar, Peter Gerhart[61], there are two possible ways of accounting for the agreement between the United States and the developing countries to cooperate on the issue of intellectual property rights at the GATT when the latter countries saw no initial need to resolve the issue.

The 'coercion story' in the words of Gerhart 'portrays the United States as systematically threatening to close its borders to countries that would not agree to minimum intellectual property standards'. In other words it was the prospect of continued access to the U.S. market that led developing countries to agree to TRIPS rather than the conviction that adopting new standards of IPR protection would benefit their economies.

The 'contract story' 'emphasizes that the United States, Europe, and Japan 'bought' TRIPS not by agreeing to keep their markets open (which is the dynamic behind the coercion story) but by agreeing to liberalize their markets further'. So developing countries accepted TRIPS in exchange for promises 'to reduce barriers to trade in agricultural and textile goods, *and to limit the future use of unilateral threats by the industrial countries*'.[62]

Gerhart concludes that the truth probably lies somewhere in between a combination of these two stories.

'Trade-related' intellectual property rights: from WIPO to GATT

The first attempt to frame IPRs as a trade-related issue was made by a group of trademark-holding firms organized as the Anti-Counterfeiting Coalition, which unsuccessfully lobbied for the inclusion of an anti-counterfeiting code in the 1973-79 GATT Tokyo Round.[63] Nonetheless, this initiative attracted the interest of the United States and the European Community in drafting such a code and in gaining support for doing this from a few other countries.

Following the lead set by the U.S. trademark industries, the copyright, patent and semiconductor industries also decided during the early 1980s to frame the relative (and sometimes absolute) lack of effective IPR protection in overseas markets as a trade-related issue *and* a problem for the U.S. economy that the government ought to respond to. So by the time the contracting parties of the GATT met in Punta del Este to launch another trade round, U.S. corporations had forged a broad cross-sectoral alliance and developed a coordinated strategy.

For those seeking high standards of IPR protection and enforcement throughout the world by way of the GATT, the strategy had three advantages. First, if successful the strategy would globalize these standards much more rapidly than could be achieved through the WIPO-administered conventions. This is first because it allowed for the possibility of including all the main IPRs in a single agreement (which could also incorporate by reference provisions of the major WIPO conventions), and secondly because once it was agreed that the Uruguay Round agreements had to be accepted as a package (i.e. a 'single undertaking'), countries could not opt out of any one of them and be a member of the new World Trade Organization. Second, the GATT already had a dispute settlement mechanism.[64] WIPO has no enforcement or dispute settlement mechanisms except through the treaties that it administers,

and these treaties do not provide much recourse for countries concerned about the non-compliance of other parties. Third, the broad agenda of the Uruguay Round provided opportunities for linkage-bargain diplomacy that WIPO, with its exclusive focus on IPRs, did not allow. Hard bargaining by the U.S., Europe and Japan on IPRs could thus be linked to concessions in such areas as textiles and agriculture, where exporting countries in the developing world were eager to achieve favourable agreements.[65]

The reason why the United States was predisposed to identifying the interests of these groups with the national interest is closely linked to a feeling of declinism experienced by the political elites during the 1980s. In large part this was due to increasing competition in various high-technology sectors from other countries, especially Japan, that the U.S. had hitherto dominated, and manufacturing generally from low-wage rapidly industrialising economies like South Korea, Taiwan and China. These countries' enhanced competitiveness was perceived largely to be due to their unfair trade, investment and industrial policies (including intellectual property and technology licensing regulations). The U.S. was especially concerned about these countries' trade and industry policies. These allegedly protected domestic markets for local firms, while helping these countries to export their goods in massive quantities to the U.S. and consequently to enjoy sizeable trade surpluses. A related complaint was that these countries were condoning what was seen as blatant and widespread intellectual property piracy.

The support of European and Japanese business was necessary for any proposal on IPRs at Punta del Este to succeed. Consequently, United States business interests under the umbrella of the Intellectual Property Committee (IPC) forged an alliance with their European and Japanese counterparts: the Union of Industrial and Employers' Confederations of Europe (UNICE) and Keidanren.

Even so, it is not only developing country governments that are dissatisfied with TRIPS. Many firms, including the pharmaceutical transnationals, were unhappy about the compromises and concessions achieved by developing countries such as the transition periods. Neither were the life science businesses satisfied with the compromises between the US and Europe which resulted in language that among other things permitted exclusions on the patenting of plants and animals. And many developed countries would like TRIPS to be revised in order to better accommodate technological advances since the conclusion of the Uruguay Round.[66] It is not surprising, then, that the US Congress has not renounced Special 301, and reserves the USTR's right to initiate bilateral negotiations with countries whose IPR standards may be TRIPS-compatible but still lower than those of the United States.[67]

For further reading on the TRIPS Agreement, Annex I provides details of some of the comprehensive and most current published works.

What is TRIPS for?

While the original purpose of an agreement on IPRs at the Uruguay Round was to prevent the trade in 'counterfeit goods' (see Box 3 for a clarification of this and related terms), the resulting agreement turned out to be much more ambitious than this[68] (see Annex II for key issues and salient features of the Agreement). Since it is very difficult to judge the success of the agreement or evaluate its future prospects without a clear idea of its objectives, this section of the chapter seeks to identify the official goals of the TRIPS Agreement.

Box 3: Copying IPR-protected goods and service: fair following or free riding?[69]

TRIPS provides the following definitions of counterfeit trademark goods and pirated copyright goods[70]:

'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;

'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.

'Counterfeiting' and 'piracy' are normally considered to be both morally wrong and illegal. Yet in countries where products do not have IPR protection, either because such protection has not been applied for or because it is unavailable anyway, the production and domestic circulation of such goods by others do not constitute IPR infringements. Therefore if counterfeiting and piracy are illegal by definition, these words do not apply to such acts.

The task then for those seeking to reduce opportunities for free-riding by eradicating the copying of valuable products and marks is threefold: first, to ensure that legal means are available so that as much copying as possible can be classed as illegal counterfeiting or piracy; second, to bind as many countries as possible to the legal obligation to provide such means; and third, to make these laws enforceable. In most countries, the laws are in place but often they are not enforced.

This is not to say that free-riding or imitation are always wrong. Indeed, imitating is not necessarily the same as slavish duplication of other people's creative achievements, and may even be creative in itself. According to Kim and Nelson, 'imitation ranges from illegal duplicates of popular products to truly creative new products that are merely inspired by a pioneering brand'.[71] Distinct imitations may include 'knockoffs or clones, design copies, creative adaptations, technological leapfrogging, and adaptation to another industry'.[72] In fact, history shows that becoming good at imitating through, for example, reverse engineering, is a vital stage in the process of becoming innovative.

Copying CDs and misappropriation of trademarks provides no scope for learning at all. Moreover, if it is too easy to profit from uncreative imitation, there is unlikely to be much incentive to innovate. But the situation may be quite different for products whose manufacture requires the application of complex processes whose operation and adaption to local conditions may well require high levels of knowledge and skill.

The preamble affirms the desire of member states 'to tak[e] into account the need to promote effective and adequate protection of intellectual property rights', while 'recognizing the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives'. 'Effective' implies enforceable. But whether IPR protection is 'adequate' depends largely on what the systems of rights are supposed to achieve.

Dealing with counterfeiting is clearly considered as important. Its main importance lies in the fact that the trade in counterfeit goods is what makes intellectual property most clearly trade-related. The preamble indicates that members recognise 'the need for a multilateral framework of principles, rules and disciplines dealing with international trade in counterfeit goods'.

And yet, the objectives as stated in Article 7 make no reference to the eradication of counterfeiting. Rather, TRIPS is explicitly aimed at promoting public policy objectives, the nature of such objectives presumably being left to national governments, though technological development is given priority.

Article 7 states that 'the protection and enforcement of intellectual property right should':

- contribute to the promotion of technological innovation; and
- to the transfer and dissemination of technology

and be:

- to the mutual advantage of producers and users of technological knowledge;
- in a manner conducive to social and economic welfare
- to a balance of rights and obligations

Evidently, TRIPS is not only supposed to establish effective legal remedies to prevent unauthorized copying, but also to stimulate technological advancement. TRIPS thus appears to give greater priority to economic development than to the eradication of the trade in counterfeit goods, which was the original idea of having such an agreement. Moreover, a balance needs to be struck so that the interests of the public, the producers, and of the users of technological knowledge are all promoted and in ways that enhance social and economic welfare.

In addition, Article 8.1 allows member states implementing their IPR regulations to 'adopt measures necessary to protect human health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development'. These measures are not obligatory but, again, they highlight the socio-economic welfare implications of IPRs. On the other hand, the proviso that such measures be consistent with the provisions of TRIPS appears to narrow their possible scope quite considerably.

National treatment and most-favoured-nation

By virtue of Article 3, members accept the principle of national treatment, i.e. that each country must treat nationals of other members at least as well as it treats its own nationals. In other words, IPR protection and enforcement must be non-discriminatory as to the nationality of rights holders. This principle is in fact well established in international law, dating back to the nineteenth century.[73]

National treatment should be contrasted with the principle of reciprocity, according to which rights or concessions are available only to foreigners from countries that provide the same rights or concessions. Foreigners from other countries are unable to avail themselves of protection according to this principle. The United States applied the principle of reciprocity rather than national treatment when it enacted its 1984 Semiconductor Chip Protection Act, as did the European Union with its 1996 Directive on the Legal Protection of Databases.[74] Application of the reciprocity principle to IPR regulation is clearly contrary to the TRIPS Agreement.

Article 4 upholds the principle of most-favoured-nation. This means that any concession granted by one member to another must be accorded to all other members 'immediately and unconditionally'. So if country A agrees to take special measures to prevent the copying of the products of a company from country B, but turns a blind eye when the company is from country C, D or E, such inconsistency of treatment will violate this principle. Although this principle of international law dates back in history TRIPS is the first multilateral IPR treaty that refers to it.

Transitional arrangements

All countries must have applied Articles 3 (National Treatment), 4 (Most-Favoured-Nation Treatment) and 5 (Multilateral Agreements on Acquisition or Maintenance of Protection) within one year of the entry into force of the WTO Agreement. But the developing countries and the former centrally-planned socialist states were allowed a period of five years from the date of entry into force of the WTO Agreement to apply the full provisions of TRIPS i.e. 1 January 2000. But developing country members that are required to extend patent protection to areas of technology not hitherto covered in their laws are permitted to delay such extension until 1 January 2005. The least-developed countries are allowed until 1 January 2006 to apply TRIPS in full. Upon request to the Council for TRIPS, they may also be granted further extentions of this period. The 2001 Doha Declaration on the TRIPS Agreement and Public Health allows least-developed countries to delay implementation of patent protection for pharmaceutical products and legal protection of undisclosed test data submitted as a condition of approving the marketing of pharmaceuticals until 1 January 2016. Countries that have joined the WTO since then are required also to comply with these deadlines.

Table 2: Main dates in the application of the TRIPS Agreement

Final Act of the results of the Uruguay Round	14.04.1994
Entry into force of the WTO Agreement	01.01.1995
Special arrangements for pharmaceuticals and agricultural chemical products not protected in a member country as of the date of entry into force of the Agreement (Art.70.8-9)	
a) Means for filing applications	01.01.1995
b) Criteria for patentability (to be applied as of the time that the patent protection has become available in the country in question)	01.01.1995
c) Exclusive marketing rights for five years (to be applied once all conditions of Article 70.9 are met	01.01.1995
Entry into force of TRIPS Agreement (Art.65.1)	01.01.1996
National treatment principles applicable to all countries	01.01.1996
Most-favoured-nation treatment applicable to all countries (Art.4)	01.01.1996
Review of issue of patentability of plants and animals other than micro-organisms (Art.27.3(b))	01.01.1999
Transitional arrangement for developing countries (Art. 65.2)	01.01.2000
Transitional arrangement for economies in transition, but only if conditions of article 65.3 are met	01.01.2000
Review and amendment by Council of TRIPS Agreement (Art.71.1)	2000 $\Rightarrow \Rightarrow$
Transitional arrangement for developing countries concerning product patent protection – to technologies not previously protected by product patents (Art. 65.4)	01.01.2005
Transitional arrangements for least developed countries (Art. 66.1)	01.01.2006
Transitional arrangements for least developed countries concerning patent protection for pharmaceutical products and legal protection of undisclosed test data submitted as a condition of approving the marketing of pharmaceuticals (Declaration on the TRIPS Agreement and Public Health)	01.01.2016

Source: UNCTAD 1996:35 (with update)

Institutional arrangements: final provisions

Article 68 (Council for Trade-Related Aspects of Intellectual Property Rights) sets out the role of the WTO Council for TRIPS. The Council is responsible for:

- monitoring the operation of TRIPS, and in particular members' compliance;
- affording members the opportunity to consult on matters relating to trade-related IPRs;
- assisting members in the context of dispute settlement procedures; and
- carrying out other duties assigned to it by the members.

The Council is scheduled to review the implementation of TRIPS at two-year intervals from the expiration of the transitional period referred to in Article 65.2 (i.e. 1 January 2000). Article 71.1 states in addition that 'the Council may also undertake reviews in the light of any relevant new developments which might warrant modification or amendment of this Agreement'.

PART TWO:
IPRS AND ECONOMIC AND SOCIAL DEVELOPMENT: THE ISSUES

CHAPTER III: HUMAN RIGHTS

Conventionally, IPRs tend to be seen as primarily an economic or legal issue, embodied in the rights to 'ownership' and thus exclusive use of inventions and creative works. But it can also be argued that there is also a broader 'human rights' dimension, illustrated by the fact that the right of authors to the 'moral and material interests' resulting from their scientific, literary and artistic productions is recognised in the 1948 Universal Declaration of Human Rights. The declaration implies, therefore, agreement by the international community of nations that a right to intellectual property is a human right, which is vested in individual 'authors' (including inventors). The existence of such a moral interest implies that an author's right to prevent others from appropriating or otherwise interfering with his or her work emerges from the very fact that the author is responsible for the work's creation. The right to a material interest suggests that where commercial use is made of the work, the author should be compensated.

The Anglo-American legal tradition places much less emphasis on the moral rights of authors than does that of continental Europe, especially France where moral rights are perpetual. It is noteworthy that while U.K. copyright law extends moral rights to authors, these can be waived with the author's consent.

The principle that an intellectual right is also a basic human right became legally-binding when Article 15.1 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), which came into force in 1976, includes the right of everyone 'to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author' (15.1(c)) This right is balanced with the right also 'to take part in cultural life' (15.1(a)) and 'to enjoy the benefits of scientific progress and its applications' (15.1(b)).

Three important points about the implications of this covenant for international debates on IPR law need to be made. First, sub-paragraphs 15.1(a) and 15.1(b) affirm that the general public has a legitimate interest in intellectual productions and a right to benefit from them. Policy makers are therefore required under this agreement to strike a balance between the interests of 'authors' and those of the wider society.

Second, as we saw earlier, governments drawing up patent and copyright regulations are in practice usually motivated more by the expectation of positive economic consequences than by considerations of morality. In other words, while they may agree with the moral principle that authors should receive an appropriate reward from society for their efforts, their prime concern is a more practical one, albeit also consistent with the ICESCR: that IPRs should contribute to the scientific, cultural and economic enrichment of society.

Third, in the modern world 'authors' – including, for example, researchers who work for private corporations – often assign copyrights and patents to their employers (or publishers). According to the ICESCR, they must receive benefits to compensate for this.

In August 2000, the Sub-Commission on the Promotion and Protection on Human Rights of the

United Nations Commission on Human Rights adopted a resolution on 'Intellectual Property Rights and Human Rights', which was partly spurred by the initiative of the World Intellectual Property Organization to hold a panel discussion on Intellectual Property and Human Rights in 1998.[75] While the resolution has no legal status it has attracted a great deal of attention to this issue. The 'actual or potential conflicts' referred to in the resolution are:

- impediments resulting from the application of IPRs to the transfer of technology to developing countries;
- the consequences of plant breeder's rights and the patenting of genetically modified organisms for the enjoyment of the basic right to food;
- the reduction of control by communities (especially indigenous communities) over their own genetic and natural resources and cultural values, leading to accusations of 'biopiracy'; and
- restrictions on access to patented pharmaceuticals and the implications for the enjoyment of a basic right to health.

The resolution requested that the WTO take fully into account the obligations of member states under the international human rights conventions to which they are parties during its ongoing review of TRIPS.

In August 2001, the Sub-Commission considered two reports on the relationship between intellectual property rights and human rights in general, and on the impact of TRIPS on human rights.[76] One of those reports, the report of the UN High Commissioner for Human Rights, examined the implications of the TRIPS Agreement on the right to health, looking specifically at the case of providing HIV treatments in Brazil. The High Commissioner noted that the right to health includes an obligation on states to provide affordable essential drugs according to the WHO list. Consequently, the implementation of the TRIPS Agreement, consistent with human rights obligations, could require States, in certain cases, to issue compulsory licenses over drugs. The Brazilian Government's use of flexibilities under the TRIPS Agreement as negotiating tools was considered consistent with Brazil's human rights obligations. In response to the reports, another resolution was adopted which essentially reiterated the Sub-Commission's view that actual or potential conflict exists between the implementation of the TRIPS Agreement and the realization of economic, social and cultural rights. It requested that the U.N. High Commissioner for Human Rights seek observer status with the WTO for the ongoing review of TRIPS. The resolution also stressed the need for adequate protection of the traditional knowledge and cultural values of indigenous peoples, and emphasised the Sub-Commission's concern for the protection of the heritage of indigenous peoples.[77] Whether these concerns are justified – and if so to what extent – the resolution passed by the commission does not state that IPRs *per se* conflict with human rights. Rather it is suggested that problems lie in the *implementation* of a particular international agreement, namely TRIPS.

The TRIPS Agreement does not itself explicitly refer to human rights. But, as was explained earlier, it does acknowledge that a balance needs to be struck between the interests of producers and users, both to ensure that each side benefits, and to enhance social and economic welfare more widely. According to the Sub-Commission, human rights obligations should take priority over economic agreements. But whether TRIPS should be revised in consequence of this is likely to be opposed by many governments in future trade rounds or meetings of the Council for TRIPS, at least until there is greater clarity concerning the alleged points of potential conflict between intellectual and human rights than there is at present.

CHAPTER IV: HEALTH

In the last few years, increasing attention has been centred on the relationship between patents and the availability and price of essential drugs. In particular, a number of governments and health and development non-governmental organizations (NGOs) have condemned pharmaceutical companies for taking advantage of their patent monopolies in two ways. First, by charging high prices for treatments for diseases that heavily affect poor people that are unable to afford them. Second, by putting pressure on developing country governments to prevent the local manufacture or importation of cheaper copied versions of the drugs produced in countries where either they cannot be patented or where the patents are not respected.

Many of these issues have been brought to the fore by the current HIV/AIDS pandemic. This is now one of the most serious public health crises the world is facing. Africa is the most severely affected continent. Millions of infected people there are destined to die in the next few years unless they can be treated with anti-retroviral drugs. Yet in many developing countries, a tiny proportion of HIV/AIDS sufferers receives these treatments.[78]

High prices for AIDS drugs are not the only factor limiting patients' access to them. Poor people often live far away from clinics and hospitals. Also, many countries are short of medical practitioners trained to prescribe anti-AIDS drugs to patients in the appropriate combinations and dosages. Nonetheless, high prices obviously have a profound impact on the ability of poor people to acquire them. And, at least in principle, patent monopolies can place the companies holding them in a strong position to set prices at high levels.

One widely-suggested solution is either for a local firm to be allowed under some specific circumstance to copy the patent 'recipe', or for the government to import drugs placed on the market more cheaply elsewhere. Such competition would lead to price reductions. The research-based pharmaceutical corporations claim that to do so would be unfair since it enables generic companies to free-ride on their expensive research and development. They also argue that patents are absolutely essential for them to remain in the highly expensive business of discovering and developing new drugs. Several surveys do support the view that pharmaceuticals is one of the few industrial sectors in which patents are effective means to capture returns from R&D.[79] The corporations are also concerned that if such copying is allowed, these counterfeit drugs will be exported to developed country markets where corporations make most of their profits. And they point out that 95 per cent of drugs on the World Health Organization essential drugs list can be legally copied either because the patents have expired or because they had never been patented. Critics counter that the welfare implications of having 5 percent of these drugs on-patent is still extremely serious, and that the WHO's list does not include every drug that could reasonably be classed as 'essential' anyway. In fact, it is partly the relative cheapness of the drugs listed that makes them 'essential' and thus worthy of inclusion.

TRIPS provides a safeguard in that use of a patent's subject matter without the patent holder's authorization in exchange for royalties (often referred to as compulsory licensing) is permitted even without prior negotiation 'in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use'. And TRIPS also specifies that this must be 'predominantly for the supply of the domestic market'. However, compulsory licensing in general is not necessarily a panacea. In cases where prior authorization from the patent owner is required (as is normally the case but not in national emergencies), negotiations can be complicated and take a long time to conclude. Second, the patent specification may not provide sufficient information to copy the drug. In fact, with some drugs the most efficient manufacturing process is protected as a trade secret

or by a separate patent, which may even be owned by a different company. Third, many countries may lack chemists who can do the copying, and licensees may not necessarily be able to profitably sell the drug at a much lower price than that of the patent-holding firm. However, the very possibility of compulsory licensing tends to strengthen the bargaining position of governments even if it is rarely used. It is also compatible with TRIPS for purchasers of drugs sold abroad to import them into a country where they are patented as long as the original sale of the drugs was legal. This is known as parallel importation.

As an alternative some have offered voluntarily to sell their drugs at heavily reduced prices in some markets. For example, Merck has offered to sell its anti-AIDS drugs at non-profit making prices[80], and Bristol-Myers Squibb at below cost. According to critics, though, while this is a positive development, many such revised price offers are still no lower than they would be if copying were permitted. Some corporations, though, have gone further by donating drugs. For example, Boehringer Ingelheim has offered to donate one of its drugs free of charge for five years to developing country mother-to-child AIDS transmission prevention programmes. But helpful as price reductions and donations are, they do not provide a long-term solution to the lack of access problem.

The corporations have been pressuring governments not to import drugs from countries producing generic versions. South Africa found itself subjected to extremely heavy pressure both diplomatically and in the courts when it passed amendments to its Medicine and Related Substances Control Act. A recent World Bank report describes the legislation's contentious IPR-related provisions: 'The amendments permit the health minister to revoke pharmaceutical patent rights in South Africa if he deems the associated medicines to be too expensive. They further empower the minister to order compulsory licensing if the patentee engages in abusive practices, defined basically as a failure to sell a drug in adequate amounts to meet demand, or a refusal to license the product on reasonable terms so that domestic firms may meet demand. They also permit parallel importation (imports of original or generic versions without the authorization of the South African patent holder) of drugs, and allow the health minister to override regulatory decisions concerning the safety and registration of medicines. The law requires pharmacists to employ generic substitution (prescribe generic versions of patented drugs) unless the doctor or patient forbids it, sets limits on pharmacy markup rates, and bans in-kind inducements from drug manufacturers to physicians.' According to the World Bank, 'while it may be a heavy dose of regulation, South Africa's law is probably consistent with TRIPS'.[81] But this was not a view shared by some developed countries which pressured South Africa to repeal the legislation. In 1999, a South African association of multinational pharmaceutical corporations initiated legal proceedings against the national government to have the legislation overturned. In early 2001, the case was dropped in the face of heavy criticism within and outside the country and most probably a realisation by the plaintiffs that they were unlikely to win the case anyway.

While relaxing the international patent rules that restrict the manufacture and sale of generic versions of patented drugs is arguably the best possible IPR-related measure to enhance their availability to the poor, this would require agreement by the international community which may never come. In the meantime, other measures may be available to widen access to treatments for diseases that affect the poor. These include not only the price cuts and donations some companies are already offering, but also tax incentives to encourage research on diseases that most seriously affect poor people, and a global fund to pay for such research, or to purchase essential drugs and supply them for free or at heavily-discounted prices. Of course, these depend on the willingness of companies and governments. Developing country governments cannot depend on such measures but need to take full advantage of the opportunities that may be gleaned from a careful reading of the TRIPS Agreement, including the language dealing with objectives (Article 7), principles (Article 8), exhaustion of rights (Article 6), and unauthorized use (Article 31).

While this is an issue that arouses strong emotions, governments, corporations, United Nations agencies and NGOs appear, at least in their public statements, to be committed to finding mutually-agreeable solutions. One possible solution is to set prices for drugs in developing countries that are more sensitive to widely varying abilities to pay for them.

At the same time, however, pharmaceutical companies warn that anything that significantly undermines the current global patent regime risks does little to encourage commercial investment in research on diseases affecting the poor. As it is, the World Health Organization has estimated that only 4.3 percent of pharmaceutical research and development expenditure is targeted at those health problems mainly concerning low and middle income countries, such as malaria and tuberculosis.[82] According to James Orbinski, President of the International Council of Médicins sans Frontières, while 95 percent of active TB cases occur in developing countries, no new drugs for the disease have been developed since 1967.[83] But it is hard to assess the validity of such arguments. A great deal of pharmaceutical research is targeted at discovering and developing treatments for diet-related health concerns of affluent societies such as obesity and high cholesterol, for dealing with trivial ailments like baldness, and for treating chronic problems such as high blood pressure that do not cure patients but that need to be taken continually for many years. Whether stronger patent rights will shift research investments towards malaria and TB remains to be seen.

Apart from this controversy, it is important to be aware that pharmaceutical companies often use patents and also trademarks in attempts to restrict competition in some cases beyond the 20-year patent duration. pharmaceutical companies use patents (and also trademarks) strategically in order to restrict competition in some cases for several years beyond the 20-year patent duration. 'Evergreening' or 'line extensions' are terms used to refer to the use of IPRs in order to extend the monopoly or at least the market dominance of a drug beyond the life of the original patent protecting it. Drug companies will often try to stretch out their exclusive rights over successful drugs for as long as possible, especially when they are heavily dependent on a small number of such highly profitable products (or even just one). For example, firms might seek to obtain patents on new delivery methods for the drug, on reduced dosage regimens, or on new versions of the active compound or combinations that are more effective or that produce fewer side-effects than the original substance. Another tactic that may be possible in the case of drugs that are metabolized by the body and thereby transformed into another substance that directly causes the therapeutic effect, is to patent also this latter chemical.[84] Doubtless, companies other than the owner of the patent protecting the original substance will also seek to acquire such patents. But in many cases these firms will prefer to license their patents to the first company, since the latter already enjoys the monopoly position and is therefore better placed to make commercial use of them. In addition, pharmaceutical companies, like those in other industries, use patents for a range of strategic purposes such as creating broad zones of exclusion around their inventions, preventing other companies from exploiting their own patents, and enhancing bargaining positions in cross-licensing deals.

Companies also use trademark law to extend their market power beyond the patented drug's expiry date.[85] [86]Patented drugs are usually marketed under their brand name rather than the generic name. Since generic producers cannot use this name, it is often very difficult for them to promote their alternative product effectively. Therefore, physicians may continue to prescribe the branded product even if it is more expensive than the generic version. In fact, in many countries physicians may not even know that alternatives exist.

It is important in this context to point out that the global market for pharmaceuticals is increasingly competitive, albeit also highly concentrated at the level of therapeutic groups. The quantity of new chemical entities has declined in recent years[87] and many of the drugs entering the market are similar to existing ones in terms of their chemical structures and therapeutic effects. These are often referred

to disparagingly as 'me-too drugs'. In order to make big profits from these drugs, companies must be prepared to spend large sums of money on marketing. We can get an idea of how much is at stake when we consider that 'drugs with annual sales of some $45 billion are set to go off patent between 2001 and 2005'.[88] Companies that are excessively dependent on one or two highly profitable drugs nearing the end of their patent lives, but lack the security of having a large portfolio of potential best-sellers in the pipeline have become vulnerable to takeovers. This situation has resulted in a consolidation in the industry. Clearly, evergreening has its limits as a business strategy. It may be a panacea for a weak product pipeline, but it is certainly not a cure.

Finally, it should be understood that even without patents it would still be difficult for many poor people to acquire cures for the illnesses that disproportionately afflict them. 80 percent of the population of the developing world cannot afford to buy pharmaceuticals. Even in India, where pharmaceutical products cannot be patented (and will not have to until 2005), and with a large generic drug sector that has a lot of expertise in medicinal chemistry, the figure is only 10 percent lower than the developing country average.[89]

The Doha Declaration on the TRIPS Agreement and Public Health

WTO Members meeting in Doha for the November 2001 Ministerial Conference adopted a declaration intended to address the public health problems faced by the developing and least-developed countries. The declaration consists of seven paragraphs. The most important one is probably the fifth, which clarifies the freedoms all WTO Members have with respect to compulsory licensing, their determination of what constitutes a national emergency or other circumstances of extreme urgency, and exhaustion of rights. Thus, the declaration reaffirms the right to use to the full the provisions in TRIPS allowing each member 'to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted'. The declaration explicitly mentions that public health crises 'relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency'. Moreover, WTO members are free to establish their own regime for exhaustion of intellectual property rights. This is important because it means that if national laws indicate that patent rights over drugs are exhausted by their first legitimate sale, countries can then import drugs legally purchased in countries where they are sold at a lower price.

Box 4: Patents on HIV/AIDS drugs: do they affect access?

Defenders of the position that patents do not hinder access to essential medicines in Africa have been pointing to a recently-published study by Amir Attaran of Harvard University and Lee Gillespie-White of the International Intellectual Property Institute, a Washington-based organization.[90] The paper provided data on the extent of patent protection throughout Africa of fifteen anti-AIDS drugs, which showed that few of these were patented all that widely anywhere in the continent except a few countries like South Africa. This finding suggested to the authors that 'patents and patent law are not a major barrier to treatment access in and of themselves'.

But others have argued that while the study's data are probably accurate as far they go, the study does not make a convincing case that patents do not obstruct treatment access in Africa. Five organizations, Consumer Project on Technology, Essential Action, Oxfam, Treatment Access Campaign and Health Gap distributed a joint statement rebutting the Attaran and Gillespie-White paper and several other campaigners added criticisms of their own which were distributed on a listserve called IP Health. Another response was circulated by the South African activist group Treatment Action Campaign.

There were three main criticisms. First, anti-retroviral (ARV) drug patent coverage tends to be quite comprehensive in countries that have high populations and/or relatively high incomes, *and* large numbers of HIV/AIDS sufferers. These include South Africa, Kenya and Zimbabwe. According to the above-mentioned rebuttal statement 'the 23 countries in Sub-Saharan Africa that have 4 or more ARV products on patent have 53 percent of the HIV+ patients and 68 percent of the Region GDP. The 20 Sub-Saharan countries that have patents on 6 or more ARV products have 46 percent of the patients and 56 percent of the region's GDP'.[91] Second, effective treatment is based on the use of combinations of drugs. If only one ingredient in the 'cocktail' is protected and sold at a monopoly price, the whole regime will be too expensive for most patients. Third, generic producers need to make profits like any other business. If they cannot sell in the major national markets or are only allowed to make one or two components of a combination therapy regime, they cannot easily achieve the economies of scale to make a profit.

One matter the declaration left unresolved is whether governments can only grant a compulsory license to a domestic manufacturer. Since TRIPS stipulates that unauthorised use of a patent shall be 'predominantly for the supply of the domestic market' it can be argued that awarding a license to a foreign manufacturer would be illegal. This is an important issue because many poor countries lack the capacity to manufacture the HIV/AIDS treatments and would therefore need to import them from countries like India, an important supplier of cheap generic drugs. To make the situation even more difficult, India is required by the terms of TRIPS to introduce product patents on drugs from 2005. Normally patents prevent not just the unauthorised sale of protected products but also their manufacture. Therefore, even if a poor country granted a compulsory license to an Indian generic firm, if the drug were protected by a patent, the licensee would presumably need permission from the domestic patent owner to make the drug .

However, paragraph six acknowledges that countries lacking the capacity to produce drugs will find it difficult to make effective use of compulsory licensing. In response, the declaration instructs the TRIPS Council 'to find an expeditious solution to this problem and to report to the General Council before the end of 2002'.

CHAPTER V: FOOD, AGRICULTURE AND BIODIVERSITY

Food, agriculture and biodiversity as IPR-related issues are closely related. They are also the subject of three very important international agreements whose coverage overlaps to a significant degree. These are: (i) the UPOV Convention, which is administered by an intergovernmental organization closely linked to WIPO, the International Union for the Protection of New Varieties of Plants (UPOV); (ii) the FAO International Treaty on Plant Genetic Resources for Food and Agriculture, which has not yet entered into force; and (iii) the Convention on Biological Diversity.

The international law of plant genetic resources and intellectual property rights

The UPOV Convention

UPOV provides a framework for IPR protection of plant varieties. The existence of the UPOV Convention can be attributed largely to two organizations: the International Association for the Protection of Industrial Property (AIPPI) and the International Association of Plant Breeders (ASSINSEL). Both organizations shared the strategic view that the complex and uncertain situation in Europe needed to be dealt with at the international level.

Delegates at the 1952 AIPPI Congress, partly at the urging of ASSINSEL, discussed the issue of plant varieties. There was general agreement that plant varieties should be protected in some way. But the Congress could not reach a consensus on the means of protection, as AIPPI failed also to do at its 1954 Congress. One of the main reasons was that some of the patent lawyer members of AIPPI opposed the patenting of plant varieties on the grounds that doing so would stretch basic patent law concepts like inventiveness to the point of undermining the credibility of the patent system.[92]

In response, ASSINSEL's members decided at their own Congress in 1956 to abandon the patent route and to call for an international conference to consider the possibility of developing a new international instrument for protecting plant varieties. ASSINSEL requested the French government to organize what became the International Conference for the Protection of New Varieties of Plants. The Conference, which comprising delegations from most West European countries, met during the period 1957 and 1961 to negotiate what became the UPOV Convention.

The Convention was signed in Paris in 1961 and entered into force in 1968. It was revised in 1972, 1978 and 1991. The 1978 Act entered into force in 1981, and the 1991 Act in 1998. The convention established the International Union for the Protection of New Varieties of Plants, which is based in Geneva. Until recently, the overwhelming majority of UPOV members were in developed countries. This reflect the fact that in many developing countries, especially in Africa, private sector involvement in plant breeding and seed supply has been quite limited. Moreover, in many of these countries traditional communities are responsible for much of the plant breeding and seed distribution, as they have been for centuries. Consequently, until recently there would have been few domestic beneficiaries of a PBR system, especially if state involvement in breeding was also quite limited. However, while many developing countries are exploring the possibility of developing their own PBR systems, the number of such countries joining UPOV is increasing. As of 7 January 2002, there were 50 states parties of which 21 were developing countries or economies in transition. The main reason for this trend is Article 27.3 (b) of TRIPS which requires WTO members to provide protection for plant varieties by patents, a sui generis system, or a combination of these (see below). But it is also true that some developing countries have agreed to join UPOV because bilateral free trade agreements with the

United States and the European Union require them to do so (see below). In this context, it is worth mentioning that TRIPS does not refer to UPOV, but the UPOV system is the only sui generis system for plant varieties that exists in international law. Alternative models have been developed but these remain to be tested in the real world, since they have not yet been implemented anywhere.[93]

To be eligible for protection, the plant variety must be novel, distinct, stable, and uniform (in UPOV 1991) or homogeneous (in UPOV 1978). To be novel, the variety must not have been offered for sale or marketed, with the agreement of the breeder or his successor in title, in the source country, or for longer than a limited number of years in any other country. To be distinct, the variety must be distinguishable by one or more characteristics from any other variety whose existence is a matter of common knowledge. To be considered as stable, the variety must remain true to its description after repeated reproduction or propagation.

UPOV 1978 defines the scope of protection as the breeder's right to authorize the following acts: 'the production for purposes of commercial marketing; the offering for sale; and the marketing of the reproductive or vegetative propagating material, as such, of the variety'.[94] There is no reference in the 1978 version to the right of farmers to re-sow seed harvested from protected varieties for their own use (often referred to as 'farmers' privilege'). The Convention establishes minimum standards such that the breeder's prior authorization is required for at least the three acts mentioned above. Thus, countries that are members of the 1978 Convention are free to uphold farmers' privilege or eliminate it. Most of them uphold it, either explicitly or by default. UPOV 1991 extends protection from at least 15 years to a minimum of 20 years. This later version is silent on the matter of double (i.e. both patent and PBR) protection whereas the earlier version stated that 'member states may not protect varieties by both patent and special rights'. Even so, many countries expressly forbid the patenting of plant varieties, including most European countries.

The right of breeders both to use protected varieties as an initial source of variation for the creation of new varieties and to market these varieties without authorization from the original breeder (the 'breeders' exemption') is upheld in both versions. One difference is that the 1991 version states that rights extend also to varieties which are *essentially derived* from the protected variety.

With respect to farmers' privilege, the 1991 version is more specific. Whereas the scope of the breeder's right includes production or reproduction and conditioning for the purpose of propagation[95], governments can use their discretion in deciding whether to uphold the farmers' privilege. Article 15 provides for an optional exception that allows parties 'within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder, [to] restrict the breeder's right in relation to any variety in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting, on their own holdings, the protected variety or a[n essentially derived] variety'. In effect, this means that parties to UPOV 1991 can continue to uphold the farmers' privilege as long their national PBR system provides for it. If the national PBR legislation of UPOV 1991 parties is silent about farmers' privilege, this presumably means there is no farmers' privilege and farmers cannot re-sow harvested seed even on their own farms.

At present the strength of the farmer's privilege varies quite widely. France has no farmers' privilege at all, while the U.S. until the law was changed in 1994 allowed farmers even to sell protected seed as long as their 'primary farming occupation is the growing of crops for sale for other than reproductive purposes'.

The Table below compares UPOV 1978, 1991, and patents to clarify their similarities and differences.

Table 3: Comparison of main provisions of UPOV 1978/1991 and patent law

Provisions	UPOV 1978	UPOV 1991	Patent law under TRIPS
Protection coverage	Plant varieties of nationally defined species	Plant varieties of all genera and species	Inventions
Requirements	Novelty Distinctness Homogeneity Stability Variety denomination	Novelty Distinctness Uniformity Stability Variety denomination	Novelty Inventive step (or nonobviousness) Industrial application Enabling disclosure
Protection term	Min. 15 years from issue (Min. 18 years for vines and trees)	Min. 20 years from issue (Min. 25 years for vines and trees)	Min. 20 years from filing
Protection scope	*Minimum scope:* Producing for purposes of commercial marketing, offering for sale and marketing of propagating material of the variety.	*Minimum scope:* Producing, conditioning, offering for sale, selling or other marketing, exporting, importing, stocking for above purposes of propagating material of the variety. Plus, some acts in relation to harvested material if obtained through an unauthorized use of propagating material and if the breeder has had no reasonable opportunity to exercise his right in relation to the propagating material.	*In respect of the product:* Making, using, offering for sale, selling, or importing. *In respect of a process:* Using the process; doing any of the above-mentioned acts in respect of a product obtained directly by means of the process.
Breeders' exemption	Yes.	Yes. Plus, *essentially derived* varieties cannot be exploited in certain circumstances without permission of holder of rights in the protected initial variety.	Up to national laws. But likely to be limited to scientific and/or experimental use.
Farmers' privilege	In practice: Yes	Up to national laws	Up to national laws[96]
Prohibition of double protection	Any species eligible for PBR cannot be patented	No	Up to national laws

Based upon Wijk et al. 1993 with modifications.

PBRs are justified on the basis that they encourage investment in plant breeding, the argument being that without legal protection there would be little incentive to breed new conventionally-bred varieties of plants, especially of crops such as wheat and rice that usually self-pollinate, and therefore remain genetically homogeneous through several generations. This is because breeders cannot otherwise legally prevent farmers and rival companies from selling second generation seed (except perhaps through contracts).

The evidence suggests that the introduction of PBRs in Europe and North America has led to increased private investment in plant breeding overall but that this increase has been modest and targeted at a small number of crop species.[97] But even with PBRs, much breeding effort continues to focus on crops like maize that are relatively easy to hybridize, rather than on self-pollinating crops bred through the more traditional crossing and selecting methods which result in varieties that can be protected by PBRs. The attraction for farmers is that the first generation of hybrid seed is extremely productive. The drawbacks are that the 'hybrid vigour' does not extend to harvested seed, which does not even breed true to type. Farmers must consequently buy fresh seed for each planting season. This is a major benefit for the seed companies, which is why they invest so much in hybrid breeding.

The Food and Agriculture Organization of the United Nations and the International Treaty on Plant Genetic Resources for Food and Agriculture

During the 1980s the FAO became the principle battleground of what became known as 'the seed wars'.[98] The main bone of contention was that the free exchange principle was being abused by the developed countries since: (a) most of the world base crop collections were held in the developed world even though most of the accessions had come from the developing world; and (b) while folk varieties were treated as being the common heritage of humankind, plant breeders in the developed countries were securing IPR protection for their own varieties.

At the 1981 FAO biennial conference, a resolution called for the drafting of a legal convention. In 1983, the over-ambitious demand for a convention was replaced by a call for a non-binding 'undertaking', and for the creation of a new FAO Commission on Plant Genetic Resources (CPGR) where governments could meet for discussion and monitor what became known as the International Undertaking on Plant Genetic Resources. By the mid-1980s, over 100 countries agreed to the IUPGR, including many developed countries that would not have signed a binding convention. The first meeting of the Commission took place in 1985, and it is now the largest FAO commission with 161 members plus the European Union.

The objectives of the IUPGR were 'to ensure the safe conservation and promote the unrestricted availability and sustainable utilization of plant genetic resources for present and future generations, by providing a flexible framework for sharing the benefits and burdens.'

The Farmers' Rights concept was included in the IUPGR from 1989 – in response to the developed countries' insistence on excluding IPR-protected plant varieties from application of the common heritage principle.[99] 'Farmers' Rights' is not an IPR as such, but it is frequently suggested as a principle that could be implemented as a compensation or benefit-sharing mechanism. Officially Farmers' Rights is an attempt to acknowledge 'the contribution farmers have made to the conservation and development of plant genetic resources, which constitute the basis of plant production throughout the world'. Resolution 5/89 defined Farmers' Rights as 'rights arising from the past, present and future contributions of farmers in conserving, improving and making available plant genetic resources particularly those in the centres of origin/diversity. Those rights are vested in the international community, as trustees for present and future generations of farmers, and supporting the

continuation of their contributions as well as the attainment of overall purposes of the International Undertaking' [on Plant Genetic Resources].

In May 1992 the Conference for the Adoption of the Agreed Text of the Convention on Biological Diversity adopted Resolution 3 on 'The Interrelationship Between the Convention on Biological Diversity and the Promotion of Sustainable Agriculture'. This recognised the need 'to seek solutions to outstanding matters concerning plant genetic resources within the Global System for the Conservation and Sustainable Use of Plant Genetic Resources for Food and Sustainable Agriculture, in particular: (a) Access to *ex situ* collections not acquired in accordance with this Convention; and (b) The question of farmers' rights.[100]

The following year, CPGR Resolution 93/1 called for the IUPGR to be revised in harmony with the CBD. To this end, the Commission, now called the Commission on Genetic Resources for Food and Agriculture (CGRFA), held a series of negotiations to revise the International Undertaking. Protracted discussions progressed, albeit slowly, at several extraordinary sessions of the CGRFA, and at a series of contact group meetings convened by the Chair of the CGRFA.

These negotiations were finally concluded in November 2001, when a text for the revised Undertaking was adopted and then converted into a legally-binding treaty.

Recognising both the sovereign rights and the inter-dependence of countries over their PGRFA, the International Treaty establishes a multilateral system that aims to facilitate access and benefit-sharing (ABS). ABS is to be regulated principally by means of a standard material transfer agreement (MTA), which will apply also to transfers to third parties and to all subsequent transfers.

One of the most controversial parts of the Treaty is Article 12.3(d), which states that 'recipients shall not claim any intellectual property or other rights that limit the facilitated access to the plant genetic resources for food and agriculture, or their genetic parts and components, in the form received form the Multilateral System'. Such an undertaking is to be provided in the standard MTA adopted to regulate the facilitated access. Japan and the United States both opposed this language and abstained from the vote on the adoption of the Treaty.

What exactly is the issue here? In some legal jurisdictions, it is possible to patent DNA sequences and chemical substances that have been isolated from plant material without any structural modification. Therefore a patent holder could restrict – subject to possible research exemptions – use of the protected sequence or compound by others, and even access if the patent covered the method of isolation. To some developed countries, allowing such patents is necessary to encourage innovation and disclosure of the 'invention'. But to many developing countries (and even some developed countries), they legitimise misappropriation of resources to which they have sovereign rights, and are contrary to the spirit of an international agreement that emphasises exchange rather than appropriation.

The Treaty does not define Farmers' Rights. Article 9 states that national governments are responsible for realising these rights as they see fit, and the Treaty refers to three measures that governments should take to protect and promote them. These are: '(a) protection of traditional knowledge relevant to plant genetic resources for food and agriculture; (b) the right to equitably participate in sharing benefits arising from the utilization of plant genetic resources for food and agriculture; and (c) the right to participate in making decisions, at the national level, on matters related to the conservation and sustainable use of plant genetic resources for food and agriculture. While none of these is necessarily IPR-related, the last paragraph of Article 9 points out that 'Nothing in this Article shall be interpreted to limit any rights that farmers have to save, use, exchange and sell farm-saved

seed/propagating material, subject to national law and as appropriate.' Since many countries have not yet extended IPR protection for plants or plant varieties, governments might decide to follow the example of India, whose recently-passed PBR legislation upholds these latter rights to the full.

The Convention on Biological Diversity and the Conference of the Parties

The Convention on Biological Diversity (CBD), which entered into force in 1993[101], has as its three objectives 'the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources'. Intellectual property rights and particularly patents are considered to be most relevant to the third of these objectives, that of fair and equitable benefit sharing.

Agreeing a text acceptable to governments of the biodiversity-poor industrialised world and of the biodiversity-rich developing countries turned into an unexpectedly long, difficult and contentious process. Some developing countries, initially Malaysia and India, complained that it was unfair for influential conservation organisations and developed country governments to expect them to protect their forests and forgo the economic benefits from selling timber or converting them to other uses. These countries argued vociferously that a quid pro quo for biodiversity preservation was fair and necessary. Realising the potential economic value of their biodiversity wealth and needing to improve their scientific, technological and financial capacities to exploit it, their position was that they had the right to set conditions on those seeking *their* resources including the fair and equitable sharing of benefits such as the transfer of technology and financial resources. Needless to say, perhaps, developed countries and transnational corporations wanted as few restrictions and conditions as possible on access to biological resources.

While the position of these developing countries seems very reasonable, it introduced some major difficulties. First, although not directly stated, the CBD's language is based on an inherent assumption that the main users of genetic resources are pharmaceutical and biotechnology firms. It is important to underline here that the rights and responsibilities in relation to access and benefit sharing arise in connection with *genetic resources* rather than the broader term *biological resources*. Second, the emphasis on national sovereignty and the authority of governments to regulate access suggests that bilateral negotiations are to be the normal means by which biodiversity-rich but technologically poor countries can benefit fairly from the commercial use of resources acquired from them.

What is wrong here? First, the pharmaceutical corporations are primarily interested in pharmacologically active biochemical substances that do not contain DNA and are therefore not genetic resources. Biotechnology firms, it is true are interested in genes, and not just therapeutic proteins. But these latter businesses are generally small, short of cash and have no products to sell or license (except patents). There is nothing to stop governments from extending their ABS regimes to cover biochemical resources, and some of them do, but the choice of terminology seems to reflect a lack of realism which the second problem makes apparent. This is that no country is completely self sufficient in plant genetic resources for food and agriculture, not even countries like Brazil and India. In fact, these resources have generally been exchanged quite openly, and it is in the interests of all countries, as well as farmers and plant breeders, that this situation should continue. This is why countries generally exercise their national sovereignty rights in a way that places few access restrictions on this category of biological resources, and why the new FAO International Treaty establishes a multilateral system of germplasm exchange. In other words, the CBD promotes bilateral agreements between providers and users of resources for which a multilateral approach is more mutually beneficial, and also encourages countries to withhold access to resources that should probably be circulated freely for the benefit of all countries.[102] And even if governments extend their

ABS regulations to cover biological resources, their bargaining position is not all that strong. The same resources may exist in two or more countries. Also, natural product research is one of several competing approaches to drug discovery. In this context it is worth bearing in mind that chemists have created 10 million new molecules since the nineteenth century, and also that nowadays they can make 25,000 variants of the same molecule.[103] So as long as companies have plenty of lead compounds to investigate, bioprospecting may not be as important as many people think. Third, there is surprisingly little information on the economic potential of in situ genetic resources. Yet, designing an appropriate ABS regulatory regime without having any idea of how much the resources are likely to be worth means founding it on guesswork and assumptions that may be completely false.

The relationship between intellectual property rights and the CBD tends to be treated as most relevant to the regulation of access to genetic resources, and the development of measures to ensure fair and equitable benefit sharing with states and the holders of traditional knowledge. The most important parts of the Convention here are Articles 15 and 8(j). Article 15 recognises the sovereign rights of States over their natural resources and their authority to determine access to genetic resources, and that access, where granted, shall be on mutually agreed terms and subject to prior informed consent of the provider party. Article 8(j) requires parties to "respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices".

In spite of this, intellectual property is only explicitly referred to in the context of technology transfer, which is supposed to be one of the main kinds of benefit for provider countries to receive.[104] Article 16 on access to and transfer of technology requires parties to the Convention to undertake to provide and/or facilitate access and transfer of technologies to other parties under fair and most favourable terms. The only technology referred to is biotechnology, but Article 16 is concerned with any technologies 'that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment". Recognising that technologies are sometimes subject to patents and other IPRs, access to such technologies must be "on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights'.[105] Clearly this is nothing for the life science industries to feel too concerned about. Indeed, the clause beginning "adequate and effective protection" was specifically to establish a link with the draft TRIPS Agreement, which also used this language as did the final version.

Paragraph 16.5 is a little more controversial, requiring the parties to cooperate to ensure that patents and other IPRs 'are supportive of and do not run counter to' the CBD's objectives. This reflects the profound disagreement during the negotiations between those who believed that IPRs conflict with the CBD's objectives and others that saw no contradiction. While the language does not seem particularly threatening, life science firms in the United States were nonetheless unhappy with the CBD's coverage of IPRs and with the Convention more generally, and persuaded President Bush that it was not in America's best interests to sign it. Although the US did so a few years later, it remains one of the few countries in the world not to have ratified it.[106]

To review implementation of the CBD, the Conference of the Parties (composed of all Contracting Parties) meets periodically (usually biannually). IPRs are most frequently discussed in deliberations on such topics as access to genetic resources, benefit sharing, and the knowledge innovations and practices of indigenous and local communities, and not so much transfer of technology.

At the Sixth Meeting of the Conference of the Parties, which took place in The Hague in May 2002, the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization were officially adopted. The Guidelines, which are intended to be used when developing and drafting legislative, administrative or policy measures on ABS and contracts, have a number of provisions relating to IPRs. Parties with genetic resource users under their jurisdiction are suggested to consider adopting 'measures to encourage the disclosure of the country of origin of the genetic resources and of the origin of traditional knowledge, innovations and practices of indigenous and local communities in applications for intellectual property rights'.[107] As means to implement the CBD provision that benefit sharing be upon mutually agreed terms, two elements to be considered as guiding parameters in contracts and as basic requirements for mutually agreed terms are that 'provision for the use of intellectual property rights include joint research, obligation to implement rights on inventions obtained and to provide licences by common consent', and 'the possibility of joint ownership of intellectual property rights according to the degree of contribution'.[108] COP Decision VI/24, to which the Bonn Guidelines were annexed, also called for further information gathering and analysis regarding several matters including:

- Impact of intellectual property regimes on access to and use of genetic resources and scientific research;
- Role of customary laws and practices in relation to the protection of genetic resources and traditional knowledge, innovations and practices, and their relationship with intellectual property rights;
- Efficacy of country of origin and prior informed consent disclosures in assisting the examination of intellectual property rights application and the re-examination of intellectual property rights granted;
- Feasibility of an internationally recognized certification of origin system as evidence of prior informed consent and mutually agreed terms;
- Role of oral evidence of prior art in the examination, granting and maintenance of intellectual property rights.

Key issues: food security, genetic erosion and trade

Food security

An adequately nutritious diet is essentially for all people throughout their lives. In addition, people need to earn a living. In many developing countries the majority of the population lives on the land, cultivating food and other crops for both subsistence and exchange. One of the biggest issues raised by current debates on IPRs – particularly in the context of their impact on developing countries – is the consequences that legislation protecting such rights may have for food security. The term 'food security' here applies to more than just ensuring that an adequate amount of food is cultivated or available through the market. It also embraces the question of whether people can afford to buy enough food to satisfy their basic nutritional requirements. If not – as is frequently the case throughout the developing world – one can argue that food security is lacking.

What is the connection with IPRs? In the developed world, plant breeders have generally sought IPR protection for new plants – including new foodstuffs – through the system known as plant breeders' rights (PBRs). Plant biotechnologists, on the other hand, tend to use the patent system. The point at issue is whether the international acceptance of common standards of PBRs through the International Convention for the Protection of New Varieties of Plants, commonly known as the UPOV Convention[109], initially developed to meet the conditions in the advanced industrialized countries (see Box 4), and of patents on plants may have the effect of undermining the food security of communities

in developing countries. Some NGOs argue that they may do this in three ways: (i) by encouraging the cultivation of a narrow range of genetically-uniform crops including non-food cash crops, with the possible consequences that people's diets will become nutritionally poorer and crops will be more vulnerable to outbreaks of devastating diseases; (ii) by limiting the freedom of farmers to acquire seeds they wish to plant without payment to breeders, and thereby impoverishing them further; and (iii) by restricting the free circulation of plant genetic resources, which is generally considered essential for the development of new plant varieties.

One consequence of TRIPS is that WTO member countries – including developing countries – must provide IPR protection for plant varieties, either in the form of patents, or through a 'sui generis' (i.e. of its own kind) system. In principle, the sui generis provision allows countries to develop their own system for protecting plants. In practice, the UPOV Convention is likely to be the most widely used model, as it is the only plant variety protection system that exists in international IPR law.

But concern has been raised that the UPOV system was drawn up mainly by European countries, and is designed to accommodate the specific characteristics of the capital-intensive large-scale commercial agricultural systems that generally prevail in that continent. As a result, it is often argued, the system is unsuitable for most developing countries.[110] Among such critics, the current system of IPR protection for plants has raised concerns over their impact on food security in three areas.

(a) UPOV and research priorities. The first of these is that PBRs generally do not encourage breeding related to minor crops with small markets. This is because the returns on their research investment will be quite small. Rather, they encourage breeding targeted at major crops with significant commercial potential. Moreover, protected varieties of plants may not even be food crops. In Kenya, for example, about half the protected new varieties are foreign-bred roses cultivated for export (see Box 5).

In fact, many resource-poor farmers cultivate minor food crops that enable them to meet the nutritional needs of rural communities much better than if major crops such as wheat, rice and maize alone are cultivated. In the hills and valleys of Nepal, for example, villages may grow more than 150 crop species and plant varieties.[111]

It is conceivable, then, that PBRs may contribute to a trend whereby traditional diverse agro-ecosystems, containing a wide range of traditional crop varieties, are replaced with monocultures of single agrochemical-dependent varieties, with the result that the range of nutritious foods available in local markets becomes narrower. Admittedly this trend is a global phenomenon whose beginning predates the introduction of PBRs. Nevertheless it is one that the existence and increasingly widespread use of PBRs may indirectly encourage. On the other hand, there is nothing to stop developing countries from encouraging research on such minor crops that are important for local communities, either by providing strengthened IPR protection for such species, or through non-IPR-related measures.

Box 5: Is UPOV beneficial for developing countries? the case of Kenya

When Kenya's Seeds and Plant Varieties Act entered into force in 1975, it became one of the first developing countries to provide plant breeders rights in national legislation. The act, which is largely modelled on the UPOV Convention (and on the counterpart UK legislation[112]), required protected varieties to be sufficiently distinguishable; sufficiently varietal pure; sufficiently uniform or homogenous; and stable in their essential characteristics. In addition to these requirements, 'the agro-ecological value [of the variety] must surpass, in one or more characteristics, that of existing varieties according to results obtained in official tests.'

However, the PBR section of the act could not be implemented until the 1990s when the Seeds and Plant Varieties (Plant Breeders' Rights) Regulations were passed (in 1994), and the Plant Breeders' Rights Office was established (in March 1997).

According to the Registrar of the Plant Breeders' Rights Office, Evans Sikinyi[113], most of the 200 plus applications have so far come from foreigners[114], and these are mostly for horticultural varieties with roses constituting about half the total. The public sector, which produces most new varieties in Kenya, has shown little interest in seeking protection. While new firms are starting up, given the amount of time it takes to breed new varieties[115], it is likely to be several more years until any increased private sector breeding activity is reflected in a rise in the number of applications.

But when it comes to research priorities, one of the (two) PBRO staff members warns that: 'PBR introduction is likely to weaken research on crop varieties that are less economic such as traditional food crops … The main threat lies in the anticipated displacement of some of the food security crops for cash crop/high value crops. The anticipated shift of research priorities will bring a problem in technology development and transfer for resolving food shortage problems and hence may destabilize food security.'[116] This scenario is plausible. Yet if income from the sale of higher value crops benefits the poor, the system may nonetheless be beneficial on balance even for the poor.

It is too early to say whether the system is a success or a failure, or how far the Kenyan experience would be repeated in other developing countries. At the present time, the most useful role the PBR system plays is probably that of encouraging the transfer of foreign-bred varieties to Kenya. This is necessary for those products heavily dependent on foreign breeding material and which are cultivated largely for export. Perhaps the most important of these are cut flowers.[117]

(b) UPOV and the interests of poor farmers. The second issue is that in most developing countries, a large proportion of the population depends on agriculture for employment and income. Many of these farmers are small-holders for whom seed saving, across-the-fence exchange and replanting are common practices. This is especially in countries – such as many of those in Africa – where neither the public or private sectors play a significant role in producing or distributing seed. Although the UPOV system allows on-farm replanting, its rules restrict farmers' freedom to buy seed from sources other than the original breeders.

Seed companies argue in response that farmers do not have to purchase PBR-protected seed just because it is available. They point out that the farmers are free to continue cultivating non PBR-protected seed – including traditional local varieties – if they so wish. Therefore their basic freedoms are unaffected by PBRs. While this is likely to be true, folk varieties are often disparaged and may be excluded from government-approved seed lists.[118]

Wherever the truth lies, the 'sui generis' clause in TRIPS does give governments a certain amount of freedom to tailor their PBR systems to address such concerns. Thus while, as we saw earlier, an increasing number of developing countries are joining UPOV, some countries are devising alternative

PBR systems that aim in part to strengthen food security. They do this, for example, by allowing farmers to acquire PBR-protected seed from any source and requiring protected varieties to display qualities that are genuinely superior to existing varieties.

The Indian parliament has recently passed legislation that would maintain the freedom to save, sell and exchange all produce of a protected variety (Box 6), and the Organization of African Unity has developed a model law for the consideration of member governments, known as the African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources (Box 7). In both cases, at least as much importance is attached to the interests of farmers as to those of breeders.

(c) IPRs and the availability of genetic resources for breeding. Plant breeders and other supporters of UPOV tend to stress the necessity of being able to freely access genetic material including that which is IPR protected. This is why the UPOV Convention contains such a broad breeders' exemption. Patent law tends to have a much narrower research exemption which is often limited to non-commercial scientific or experimental use. Moreover, while a PBR-protected plant variety is covered by a single title, plant-related biotechnological inventions are likely to be protected by a patents and in some cases several patents. The patents may cover not just plants, but also genes and DNA sequences. The effect of patents is to restrict access to the patented 'products'. It has been argued that 'locking up' genetic resources with patents is a bad thing because innovation in plant breeding is cumulative and depends on being able to use as wide a stock of material as possible. It was to deal with this concern that the FAO International Treaty introduced a number of provisions as were laid out above. However, apart from patents, the restrictions on access to breeding material may have other causes than IPRs. For one thing, some countries have chosen to except certain categories of plant genetic resources they consider to be strategically important from the multilateral system to be set up under the International treaty. Also, some developing countries have been exercising their rights under the CBD to regulate access to their genetic resources and in doing so have restricted their free flow. This may well be detrimental to long-term food security even in their own countries.

But beyond these issues about how specific intellectual property rights privatise genetic material needed for breeding is the association of IPRs with the privatisation of agricultural research, the shrinkage of non-proprietarian public sector research, and the increased concentration of ownership of breeding material, research tools and technologies in the hands of a small number of giant corporations.[119] Not only does this trend reduce the free circulation of breeding material, but it can also make public policy making aimed at enhancing food security harder to put into practice. This is because it is much more difficult for governments to influence the public institutions they partly or wholly fund than private companies.[120]

Box 6: The Indian Protection of Plant Varieties and Farmers' Rights Act

In response to TRIPS, the Indian government chose the sui generis option by drafting the Protection of Plant Varieties and Farmers' Rights Act, which was recently passed by parliament. The main objectives are: (i) to stimulate investments for research and development both in the public and the private sectors for the development of new plant varieties by ensuring appropriate returns on such investments; (ii) to facilitate the growth of the seed industry in the country through domestic and foreign investment which will ensure the availability of high quality seeds and planting material to Indian farmers; and (iii) to recognise the role of farmers as cultivators and conservors [sic] and the contribution of traditional, rural and tribal communities to the country's agrobiodiversity by rewarding them for their contribution through benefit sharing and protecting the traditional rights of farmers.

While sharing similarities with UPOV 1978, additional provisions are included to protect the interests of public sector breeding institutions and the farmers. For example, the bill upholds 'the right of a farmer to save, use, exchange, share *or sell* his farm produce of a [protected] variety' except 'in case where the sale is for the purpose of reproduction under a commercial marketing arrangement'.

The Act appears to reflect a genuine attempt to implement TRIPS in a way that supports the specific socio-economic interests of all the various producer groups in India, from private sector seed companies to public corporations and research institutions, and resource poor farmers.

Box 7: The African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources

In March 1998, the Scientific, Technical and Research Commission of the Organization of African Unity (OAU/STRC) task force on community rights and access to biological resources met to develop a Draft Model Legislation on Community Rights and Access to Biological Resources as a basis for national legislation and an Africa-wide convention. In June that year, governmental delegates at the OAU Ministerial Meeting in Ouagadougou agreed to recommend that member governments *inter alia:* give due attention as a matter of priority to the need for regulating access to biological resources, community knowledge and technologies and their implication for intellectual property rights as entrenched in the international trade regime of the TRIPS Agreement.

The draft was further developed and expanded by experts from East and Southern African countries meeting in June 1999 in Lusaka, Zambia. Seeking to implement in an appropriate way for the African continent CBD Articles 8(j), 15(1) and 15(2), the FAO International Undertaking on Plant Genetic Resources, and the TRIPS requirement that plant varieties be protected under an IPR system, the result was a much more substantial document titled the African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources.

The Model's main aim is to ensure the conservation, evaluation and sustainable use of biological resources, including agricultural genetic resources, and knowledge and technologies in order to maintain and improve their diversity as a means of sustaining the life support systems. But there are 11 specific obligations in total which cover recognition of the rights of local communities and breeders, regulation of access to biological resources and community knowledge and technologies, promotion of benefit sharing mechanisms, and various others relating to participation, community rights, capacity-building, conservation and sustainable use of plant genetic resources, agricultural sustainability, and food security.

The African Model Legislation is particularly ambitious in its treatment of traditional knowledge, innovations, practices and technologies. It adopts two terms: community rights and Farmers' Rights. Community rights include the rights of communities (a) to their knowledge, innovations, practices and technologies, as well as to collectively benefit from their utilisation, and to use them in the conservation and sustainable use of biodiversity, and (b) to exercise their collective rights as legitimate custodians and users of their biological resources, and to collectively benefit from their use. The State recognises and protects these rights as they are enshrined and protected under the norms, practices and customary law of the concerned local and indigenous communities. According to Article 26, Farmers' Rights include the right to: (a) the protection of their traditional knowledge relevant to plant and animal genetic resources; (b) obtain an equitable share of benefits arising from the use of plant and animal genetic resources; (c) participate in making decisions, including at the national level, on matters related to the conservation and sustainable use of plant and animal genetic resources; (d) save, use, exchange and sell farm-saved seed/propagating material of farmers' varieties; (e) use a new breeders' variety protected under this law to develop farmers' varieties, including material obtained from genebanks or plant genetic resource centres; and (f) collectively save, use, multiply and process farm-saved seed of protected varieties.

Genetic erosion: an IPR-related issue?

It is sometimes argued that IPRs have implications for biodiversity. Concerns raised about this tend to focus on the fact that the UPOV PBR rules require individual plant varieties to be genetically uniform. The mass-cultivation of uniform varieties based on a narrow range of breeding material can result in outbreaks of devastating diseases. This happened with the potato crop in Ireland in the 1840s, and the United States in the 1960s and 1970s with wheat and maize respectively.[121] Of course, many such disease outbreaks predated the introduction of PBRs to the affected countries. Despite this, critics argue that PBRs encourage the genetic uniformity that can potentially increase the dangers of such outbreaks occurring.

But concerns extend also to the agribusiness field more generally, some two important questions emerge. In this context, two questions need to be addresses: do intellectual property rights encourage the spread of monocultural agriculture consisting of genetically-uniform varieties? And if so, does this cause erosion of agro-biodiversity? Perhaps one of the most plausible criticisms of IPRs is that they encourage centralized research as opposed to research tailored to local environmental and socio-economic conditions. According to one commentator, the prevailing policy framework for the use of genetic resources for food and agriculture favours 'centralized crop breeding and the creation of uniform environmental conditions, and discourages agro-ecological research or local breeding tailored to local conditions.' IPRs enhance incentives to develop seeds that will have a large potential demand. To ensure maximum demand for their products, the seed companies will tend to focus their research on commonly utilized high-value crops and develop varieties that can be cultivated as widely as possible. To do so means either breeding through selection of genes for maximum adaptability, or introducing the new seeds while also promoting farming practices that reduce environmental heterogeneity. The biodiversity-erosive effects of this IPR-supported bias towards centralized crop breeding programmes are: (i) decreased crop diversity; (ii) decreased spatial genetic diversity; (iii) increased temporal genetic diversity; and (iv) increased use of external inputs.

Dwijen Rangnekar of London University has sought to push the discussion forward by taking a historical/institutional analysis of the relationship between plant breeders' rights and genetic uniformity. He reaches the interesting conclusion that such IPRs *do* in fact encourage plant breeding based upon existing material already in scientific use, while providing 'juridical legitimization to the breeding of genetically uniform varieties'.[122]

However, the the erosion of biodiversity will not necessary result from the spread of monocultural systems. If a monocultural system produces higher yields per harvest and/or more harvests per year compared to a more polycultural agro-ecosystem it replaced, pressure to open up biodiverse ecosystems to cultivation *may* be reduced as a consequence (though the opposite result is also possible too). It is important also to point out though that this trend in crop breeding dates back to when the Green Revolution began, and earlier still in some countries. The varieties most commonly associated with the Green Revolution were developed by public crop breeding institutions, not corporations. On the face of it, this suggests that this may not be an IPR-related problem at all.

Increasing trade in agricultural produce through geographical indications

For the many developing countries that are important commercial producers of agricultural goods, food security is far from being the only agricultural issue. They are also likely to want to generate wealth through the increased commercialisation of such goods. Geographical indications (GIs) may provide support for such an aspiration, at least for certain products. GIs are defined in the TRIPS Agreement as 'indications which identify a good as originating in the territory of a Member, or a

region or locality in that territory, where a given quality, reputation, or other characteristic of the good is essentially attributable to its geographical origin'. According to David Vivas[123], the GI concept embraces the following elements:

- GIs identify goods, they do not apply to services;
- GIs do not protect ideas or procedures, they simply identify and differentiate products in the market;
- the good must be identified by a geographical name;
- the identification corresponds to a territory, region or locality. The geographical origin has to exist in reality or has to identify its origin;
- there must be a special link between the origin and the quality, reputation or special characteristics.

According to TRIPS, WTO Members are required to 'provide the legal means for interested parties to prevent: (a) the use of any means in the designation or presentation of a good that indicates or suggests that the good in question originates in a geographical area other than the true place of origin in a manner which misleads the public as to the geographical origin of the good; [and] (b) any use which constitutes an act of unfair competition …'

To some experts, the geographical indications section of TRIPS can potentially provide gains for developing countries. Indeed, geographical indications seem especially appropriate for the produce of small-scale producers and cultivators. This is because when countries adopt such an IPR, they implicitly accept 'the underlying philosophy of the distinctiveness of local and regional products', and also that 'globalization of … artisanally-based principles' inherent to geographical indications 'counters the standardization of products which is normally considered the outcome of the internationalization of the agro-food industries [and] assists small family firms to resist the industrialization and corporatization of production'.[124]

For several developing countries, then, geographical indications could provide some solid gains and have real potential in terms of developing and exploiting lucrative markets for natural products including those manufactured by resource-poor farming communities. But they are useless without good standards of quality control and marketing, and up-to-date information on markets including foreign ones if the products are to be exported. At present the potential of geographical indications for developing countries is speculative because this type of IPR has hardly been used outside Europe. To illustrate the potential of geographical indications, it is interesting to consider whether this type of IPR or trademarks could be used to protect two well-known products: kava (Box 8) and basmati rice.

Box 8: Could kava be protected as a geographical indication?[125]

Kava, or *Piper methysticum*, is a shrub that is cultivated widely throughout the islands of the South Pacific, providing cash income to small farmers. Numerous cultivars of kava exist. Most of the kava produced is consumed domestically, but increasing amounts are also sent overseas for burgeoning herbal medicine markets. Kava is the fifth fastest growing herbal product in the U.S. mass market, with growth during the year up to July 1998 of 473%.[126] As a result of increased foreign demand, market prices for raw and processed kava have increased dramatically.

Current prices for kava destined for North American and European markets are reportedly in the neighbourhood of US$ 5-10/pound, or $11-22/kg.[127] A typical price for a kava product in the U.S. retail market, in contrast, is $12-20 for a bottle with a total stated kava content of 60 grams. Clearly, there is room for kava producers to capture additional value through processing of the commodity into end use products, which would be a logical accompaniment to labelling of consumer products indicating geographical origin.

Kava appears a strong candidate for geographical indications such as appellations of origin. The four key elements needed for appellations of origin appear to be present: distinctive varieties (nearly 120); variation in yield of dry matter and kavalactones; different production methods (such as organic and multi-cropping); and processing methods (e.g. sun-drying). [128] However, to establish a basis for a geographical indication, there must be a showing of distinctive qualities of kava grown by traditional methods in traditional growing areas.

At a regional Kava Symposium held in Fiji in October 1998, participants felt that the first step towards developing geographic indications to 'protect' their kava resource is accurate characterisation of existing germplasm. Once these steps have been undertaken, the 'Original Vanuatu Kava' could be defined as including morphotypes 'x', chemotypes 'y', and genotypes 'z'. The 'Original Fijian Kava' could be defined on similar criteria. All of these kava types taken together could be denominated as the 'Original Pacific Kava.' A catalogue might be published to describe the existing 120 distinct varieties. The Kava Forum Secretariat is continuing to explore such an approach, taking into account systems such as the AOC employed in France, or the system used to distinguish between California, Korean, and Chinese ginseng. [129]

Certification marks, collective marks and geographical indications all have the potential to encourage sustainable use, by increasing benefits captured at a local level and rewarding wise management. Perhaps most important, the cooperative development of such marks enables producers to establish shared standards for sustainable management, and to monitor and enforce compliance with those standards. This is an essential step in avoiding destructive competition in which producers harvest resources as cheaply and quickly as possible to maximise short-term profits at the expense of the long-term sustainability of their resources.

Box 9: Can basmati rice be protected by a geographical indication?[130]

Basmati rice is a long-grained aromatic rice variety cultivated in areas of Northern India and Pakistan. Basmati is exported to North America and Europe and commands a high price on account of its high quality. Two corporations in France and the United States have been actively appropriating the high reputation of basmati rice and are in this way threatening a lucrative market for India and Pakistan.

A food company called Establissements Haudecoeur La Courneuve has been granted two French trademarks using the word 'Basmati': 'Riz Long Basmati' and 'Riz Long Basmati Riz du Monde'[131], and a US company called RiceTec has for several years been selling rice in the US and the Middle East under the name 'Texmati'.[132]

Further outrage in India and Pakistan was provoked when it was revealed in early 1998 that RiceTec had been awarded a US patent entitled *Basmati Lines and Grains*. Among the various claims are for "novel rice lines, whose plants are semi-dwarf in stature, substantially photoperiod insensitive, high yielding and produce rice grains comprising characteristics and qualities similar or superior to those of good quality basmati rice grains produced in India and Pakistan".

The Indian government decided to respond in two ways. The first was to challenge the validity of the patent. This was partially successful in that all but 5 of the 20 claims were either withdrawn by RiceTec or revoked by the US Patent and Trademark Office. The second was to pass legislation on geographical indications. Given that TRIPS does not require a WTO member to protect geographical indications unless they are protected in their country of origin, this was necessary. But will it help? Most probably India cannot challenge use of the name 'Texmati', which connotes Texas more strongly than it does the Indian subcontinent. But what about the name 'basmati'? Success would depend upon rejection of any claims that basmati is a generic term, and acceptance of the argument that basmati is a variety of rice made distinctive, not only by its inherent qualities, but also by its geographical origin *and* local know-how. The taste and quality of basmati rice, but above all its reputation (since these are to some extent subjective attributions), *must* be inextricably linked to its place of origin. If consumers in countries where basmati is sold *do not* associate basmati rice with the Indian subcontinent, then 'basmati' is no more than a generic term for a type of long-grained fragrant rice.[133] But one of the major difficulties is that basmati is not a geographical expression *per se*. In addition, Pakistan and India disagree on the meaning of 'basmati'. According to Pakistan, authentic basmati must be grown in Punjab. India argues that the exact location is not so important as long as it is cultivated in the foothills of the Himalayas.

Curiously, the Indian government, which seemed to be most concerned about the patent appeared to make no attempt to use the existing regulations to protect the basmati name in the United States. Instead this was left to two US NGOs and an Indian one, which together unsuccessfully petitioned the US Department of Agriculture and the Federal Trade Commission to preserve the basmati name for certain varieties of aromatic rice grown in India and Pakistan (and also basmine rice for aromatic rice from Thailand).

Such legal challenges notwithstanding, the best way for basmati rice growers to increase exports and secure good prices is not through litigation but effective marketing, and this will surely benefit from the availability in India and Pakistan of either a geographical indication system or certification trademarks. These could do much to protect and enhance the reputation of basmati rice and facilitate international protection from competitors that would unfairly exploit this reputation.

CHAPTER VI: TRADITIONAL KNOWLEDGE (TK), FOLKLORE AND CULTURAL PROPERTY

The economic value of TK and folklore

TK plays an important role in the global economy. Traditional peoples and communities are responsible for the discovery, development and preservation of a tremendous range of medicinal plants, health-giving herbal formulations, and agricultural and forest products that are traded internationally and generate considerable economic value. TK is also used as an input into modern industries such as pharmaceuticals, botanical medicines, cosmetics and toiletries, agriculture and biological pesticides. In most cases, virtually all the value added is captured by corporations that can harness advanced scientific, technological and marketing capabilities.

Attempts have been made to estimate the contribution of TK to modern industry and agriculture. For pharmaceuticals, the estimated market value of plant-based medicines sold countries in 1990 was $61 billion.[134] That many of these would have used TK leads in their product development is borne out by biochemist Norman Farnsworth's[135] estimate that of the 119 plant-based compounds used in medicine worldwide, 74 per cent had the same or related uses as the medicinal plants from which they were derived.

There are no reliable estimates of the total contribution of traditional crop varieties (landraces) to the global economy. However, a study on the use and value of landraces for rice breeding in India[136] calculated that rice landraces acquired from India and overseas contributed 5.6 per cent, or $75 million, to India's rice yields. Assuming that landraces contribute equally to other countries where rice is cultivated, the global value added to rice yields by use of landraces can be estimated at $400 million per year.

But accurately estimating the full value of TK in monetary terms is impossible, first because TK is often an essential component in the development of other products, and secondly because, most TK-derived products never enter modern markets anyway.[137] In any case, a great deal of TK is likely to have cultural or spiritual value that cannot be quantified in any monetary sense.[138]

Who owns TK and folklore?

The fact that TK is being so widely disseminated and commercially exploited with such a small proportion of the benefits flowing back to provider peoples and communities raises the question of ownership. Who owns TK according to traditional peoples and communities? And who owns TK according to most national legal systems and the international IPR regime?

Many commentators argue that traditional peoples and communities are often characterized by a strong sharing ethos with respect to their knowledge and resources. There is a great deal of truth in this, but this does not mean that every*thing* is shared with every*body*. The anthropological literature reveals that such concepts as ownership and property rights – or at least close equivalents to them – also exist in most, if not all, traditional societies.[139] But to assume that there is a generic form of collective intellectual property rights ignores the intricacies and sheer diversity of traditional proprietary systems. According to a Canadian indigenous peoples' organization, the Four Directions Council:[140] 'Indigenous peoples possess their own locally-specific systems of jurisprudence with respect to the classification of different types of knowledge, proper procedures for acquiring and sharing knowledge, and the rights and responsibilities which attach to possessing knowledge, all of

which are embedded uniquely in each culture and its language.'

Nonetheless, IPR regulators and courts dealing with IPR disputes have hardly ever paid any heed to customary law nor seen any reason why they should do so.[141] In most countries all TK anywhere in the world that has not been kept secret is generally treated as being the intellectual property of nobody. Therefore it can be used freely by anybody who acquires it.

The case of the United States, however, requires that this generalisation be qualified. According to U.S. patent law, undocumented knowledge held only in foreign countries does not form the state of the relevant art.[142] Although an applicant is not allowed to receive a patent if 'he did not himself invent the subject matter sought to be patented'[143], there are concerns that this loophole sometimes allows people to copy such undocumented foreign knowledge and claim they have come up with a new invention. The notorious patent on the use of turmeric powder for wound healing granted to the University of Mississippi Medical Center may be an example of this.[144] The patent provoked considerable anger in India because such use of turmeric was common knowledge there. Yet the Indian government agency that challenged the patent had to do more than persuade the US Patent and Trademark Office that this was true. It had to provide published documentation. Because it was able to do so the patent was revoked.[145] Yet the patent should never have been granted in the first place.

It could be argued that many such erroneously granted patents do little harm beyond wasting the time of patent examiners. But some may well be harmful. A good example appears to be a US patent on a field bean cultivar called "Enola" (Box 10).

Box 10: The "Enola" bean patent

In 1999, the US Patent and Trademark Office granted a patent on a field bean cultivar dubbed "Enola" by the inventor, an entrepreneur called Larry Proctor. Controversially, Proctor's Colorado USA-based company Pod-Ners has been using the patent to block the sale of imported beans with the same colour as the ones described in the patent. This would include various traditional bean varieties. The patent claims not only a certain yellow-coloured *Phaseolus vulgaris* bean seed, plants produced by growing the seed as well as all other plants with the same physiological and morphological characteristics include, but also the breeding methods employed. Two things are extraordinary about this patent. The first is many bean cultivars exist and the specification provides no evidence that none of these cultivars possess the same characteristics falling within the patent's rather broad claims.[146] The second is that Mr Proctor employed conventional crossing and selecting breeding methods that are in no way novel. This prevents others from using the bean *and* other beans with similar characteristics in their own breeding programmes. None of this would necessarily matter if the owner had not decided to assert the patent aggressively. Soon after receiving the patent, Proctor sued a company called Tutuli that had been importing Mexican yellow bean cultivars called mayocoba and peruano from that country since 1994, and with customs inspectors disrupting supplies Tutuli began to suffer financially as did Mexican farmers that had been selling their beans to this firm. His company has since then filed lawsuits against various other small bean companies and farmers.[147] The patent is being challenged by the International Center for Tropical Agriculture (CIAT), which holds the largest collection of bean varieties and claims that six of its 260 yellow bean accessions very closely resemble enola and may well fall within its claims. CIAT's Director, Dr Joachim Voss reportedly called the patent "both legally and morally wrong" and claimed to have 'solid scientific evidence that Andean peasant farmers developed this bean first, together with Mexico.'[148] The Mexican government has also condemned the patent. But according to one report, the patent owner will get his revenge on Mexico is he loses: 'Proctor warns that if his patent is reversed he'll flood the Mexican market with beans, depressing an already-weak bean price'.[149]

However strictly patent offices seek to apply the novelty and non-obviousness criteria, patent office staff in some jurisdiction are known to have insufficient time or resources to conduct thorough prior art searches and examinations. It is noteworthy, that the World Intellectual Property Organization is

seeking ways to deal with this problem by improving accessibility of published TK through databases.

Protecting TK and folklore through the IPR system

The following question now arises: can IPRs such as copyright, patents and trade secrets be used for the protection of TK?

Copyright

At the international level, the idea of applying copyright law to protect intangible cultural expressions including those of traditional peoples and communities dates back to the 1960s. The term commonly applied to such manifestations of culture was not TK but folklore, or 'expressions of folklore'.[150]

The possibility of protecting folklore by means of copyright was raised at the Diplomatic Conference of Stockholm in 1967 for the revision of the Berne Convention. While the issue was not fully resolved, the following provisions were included in the Stockholm Act of the Convention and retained in the most recent revision, adopted in Paris in 1971:

> In the case of unpublished works where the identity of the author is unknown, but where there is every ground to presume that he is a national of a country of the Union, it shall be a matter for legislation in that country to designate the competent authority which shall represent the author and shall be entitled to protect and enforce his rights in the countries of the Union (Article 15.4[a]).
>
> Countries of the Union which make such designation under the terms of this provision shall notify the Director General [of WIPO] by means of a written declaration giving full information concerning the authority thus designated. The Director General shall at once communicate this declaration to all other countries of the Union. (15.4[b]).

Over the years many traditional peoples and communities have condemned the unauthorized reproduction of their fixed and unfixed cultural expressions such as artistic works, handicrafts, designs, dances, and musical and dramatic performances. Not only do outsiders frequently neglect to ask permission to do so, but also fail to acknowledge the source of the creativity, and even pass off productions and works as authentic expressions or products when they are not. Yet, they find it difficult to prevent such practices. Could the copyright provisions of TRIPS provide a solution?

In Australia, Aboriginal artists have on a few occasions successfully sued on the basis of copyright infringement.[151] Copyright law is also being used by the Dene of Canada, as well as several other indigenous groups worldwide, to control use by others of compilations of their TK. In theory, then, more and more peoples and communities will be able to avail themselves of copyright protection as countries increase their compliance with the levels of enforcement required by TRIPS.

Despite these successes, copyright law has some fundamental limitations in the folklore context. First, whereas copyright requires an identifiable author, the notion of authorship is a problematic concept in many traditional societies. Second, copyright has a time limit: for folkloric expressions that are important elements of people's cultural identity, it would be more appropriate to have permanent protection. Third, copyright normally requires works to be fixed. However, among some traditional groups, folkloric expressions are not fixed, but are passed on orally from generation to generation. This normally excludes such expressions from eligibility for copyright protection.

Taking the first limitation, it is sometimes argued that IPRs, and copyright law especially, unduly emphasize the role of individuals in knowledge creation and consequently fail to reward those

knowledgeable communities and collaborators that provided the intellectual raw material that formed the true basis for the copyrighted work or patented invention.[152] In other words, creative expressions and collective innovations such as those of traditional communities are ineligible for protection yet may legally be treated as free inputs for industrial R&D and the copyright industries. According to this view, then, copyright law is more likely to be used to undermine the interests of traditional peoples and communities than to promote them. This is probably true. But this is not a reason to discount copyright completely, since it is not essential to name an author to acquire copyright protection. Indeed, the copyright industries have – with the help of supportive copyright legislation – devised ways of making authors disappear. This can be achieved by, for example, taking advantage of the work for hire doctrine, according to which authors give up their rights to works in exchange for an agreed remuneration, and – in the U.K. – requiring authors to waive their moral rights. So a community or organization representing it could likewise hold copyright over a work originating in that community whether or not there is an identifiable author.

Turning to the second limitation, copyrights have time limits and most people would probably agree that it is a good thing they do. But for many traditional peoples and groups certain expressions and works are central to their cultural identity and should therefore never be fully released into the public domain, at least not to the extent that others would be free to do whatever they like with them. This is not to say that copyright protection should therefore be permanent for culturally significant expressions and works, but that copyright law should not be seen as the appropriate approach for each and every kind of cultural work.

Regarding the third limitation, copyright normally protects works but not unfixed expressions. Since communities often do not have the means of recording their cultural expressions, they cannot acquire copyright protection. However, this bar to protection can be removed with the will to do so. Several countries have incorporated protection of folkloric expressions into their national copyright laws. These include Tunisia (1967), Bolivia (1968), and Kenya (1975).[153] Given the way copyright has been transformed to, for example, treat computer programs as literary works, it hardly seems radical to extend copyrightable subject matter to unfixed cultural expressions or even to create a new IPR based on copyright for such an end.[154] But the most powerful actors in international IPR negotiations are still resistant to the idea of modifying international copyright rules to more effectively protect folklore.[155] And to date, proposals to reform TRIPS to protect TK have paid little attention to copyright.

Unfixed cultural expressions can to a limited extent also be protected under performers' rights in cases where performances have been fixed without the authorization of the original performers. TRIPS partially incorporates the 1961 Rome Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations, allowing performers to prevent the recording and reproduction of their performance on a phonogram, and the broadcast and public communication of a live performance.[156] But neither the Rome Convention or TRIPS makes any reference to folklore. However, the 1996 WIPO Performances and Phonograms Treaty defines 'performers' as 'actors, singers, musicians, dancers, and other persons who act, sing, deliver, declaim, play in, interpret, or otherwise perform literary or artistic works or *expressions of folklore*'.[157] It is possible that a future revision of TRIPS will incorporate this treaty. Nonetheless, the scope of protection is quite narrow.

Apart from these theoretical difficulties, there are practical obstacles, too. For example, the entity wishing to assert its copyright – or indeed to claim any other IPR – must have a legal personality. Such collective groups as rural communities and smaller groups within communities rarely have the status of being juristic persons according to the national legal system.[158]

Patents

Michael Blakeney of London University notes that 'the expression 'Traditional Knowledge' … accommodates the concerns of those observers who criticize the narrowness of 'folklore'. However, it significantly changes the discourse. Folklore was typically discussed in copyright, or copyright-plus terms. Traditional knowledge, would be broad enough to embrace traditional knowledge of plants and animals in medical treatment and as food, for example. In this circumstance the discourse would shift from the environs of copyright to those of patent law and biodiversity rights.'[159]

But can patent law actually provide promising solutions? This question may be addressed by considering the most commonly-expressed objections to the patent approach and assessing their validity. The main objections are as follows: (i) TK is collectively-held and generated while patent law treats inventiveness as an achievement of individuals; (ii) patent applicants must supply evidence of a single act of discovery; (iii) patent specifications must be written in a technical way that examiners can understand; and (iv) applying for patents and enforcing them once they have been awarded is prohibitively expensive.

Taking the first objection, it is often asserted that because TK is collectively held and generated, patent law is fundamentally incompatible. This is because patents require that an individual inventor be identifiable. Yet while TK is merely part of the public domain, a new and non-obvious modification to this knowledge achieved by an individual or identifiable group can be the subject of a patentable invention.

This particular argument against the compatibility of IPRs is persuasive in the copyright context but does not fit the patent situation so easily. In the late nineteenth century, large research-based corporations were already finding the heroic inventor paradigm to be rather inconvenient. They much preferred to treat invention as a collective and routinized corporate endeavour in which individual flashes of genius were unnecessary. Through their lobbying efforts patent law and doctrine began to accommodate the collective notion of inventorship from as early as the 1880s, first in Germany and then elsewhere. This suggests that the collective nature of TK production and ownership need not be a bar to the acquisition of a patent. It certainly has not been for corporations. Nonetheless, the requirement to name inventors remains, and this is likely to be a serious obstacle in many cases.

As to the second objection, while there need be no demonstrable 'flash of genius', patent specifications must nonetheless provide evidence of an inventive step or an act that would not be obvious to one skilled in the art. Applying the same criteria to TK would exclude much, but by no means all, of it from patentability. This is not only because it is difficult to identify a specific act of creation in the area of TK, but also because such acts may have taken place in the distant past. This point should not be over-stated. Many anthropologists have demonstrated that TK in many societies is evolutionary, dynamic and adaptive.

Turning to the third objection, it would be extremely difficult for a shaman or indigenous group to describe their knowledge to a patent attorney in a way that would enable the latter to complete a patent specification on their behalf. While a useful characteristic of a plant or animal may be well-known to such an individual or group, the inability to describe the phenomenon in the language of chemistry or molecular biology would make it almost impossible to apply for a patent even if the fees could be afforded, which is unlikely.[160]

This is a situation that a company can take advantage of. Patent rules in most countries require a company to do more than describe the mode of action or the active compound to acquire a patent. Minimally, it would probably need to come up with a synthetic version of the compound or a purified extract. But in the absence of a contract or specific regulation, the company would have no requirement to compensate the communities concerned.

Finally, the lack of economic self-sufficiency of many traditional communities, the unequal power relations between them and the corporate world, and the high cost of litigation, would make it very difficult for them to protect their IPRs through the patent system. The costs of preparing and prosecuting a patent application, and of periodically renewing the patent after it has been granted, are well beyond the financial means of most communities. Even though patent fees in some jurisdictions may be reduced for small and medium-sized enterprises, using the patent system is still likely to be prohibitively expensive.

On the face of it, the use of patent law has some genuine possibilities. Among the options that might be considered are: (a) for traditional peoples, communities or their representative organizations to apply for patents; (b) for them to share ownership with companies who would apply on their behalf; or (c) for companies to file patents but with community members named as inventors with contractual rights to be compensated.

Nevertheless, most traditional peoples and communities seem to be fundamentally opposed to patents, and few if any are rushing to patent offices to submit their applications, or are likely to in the future. There are various reasons why traditional peoples and communities are sceptical that patent law can be utilized to further their interests. Some of these are practical while others are more fundamental.

The main practical difficulty that deters them from filing patents is the expense of doing so, which includes payments to the patent attorney hired to complete the application, and the filing, prosecution and renewal fees. Legally enforcing the patent against infringers is likely to be even more expensive. Moreover, patents with overly broad claims encompassing non-original products or processes are sometimes mistakenly awarded. Due to poverty, few if any indigenous groups could mount legal challenges to patents on the grounds that their knowledge or, say, landraces, have been fraudulently or erroneously claimed.

Supporters of patents argue that you cannot 'patent traditional knowledge'. While patent law generally supports such a defence, 'the state of the art' is to some extent subjective, especially from a cross-cultural perspective. To give a recent example, *Phyllanthus amarus*, a medicinal plant used in India for treating various ailments including jaundice, was discovered in tests to show effectiveness against viral hepatitis-B and E. Subsequently, the Fox Chase Cancer Center was awarded a U.S. patent for a pharmaceutical preparation comprising an extract of the plant.[161] [162] While the invention was sufficiently new, useful and non-obvious to be patentable, Indian ayurvedic healers are unlikely to be as impressed as the Patent and Trademark Office examiner who granted the patent.

While patent law has been contoured in ways that tend to be highly supportive of corporate interests, the demands of traditional peoples and communities are rarely if ever taken into account when patent regulations are reformed.[163] To traditional peoples and communities this is unjust. It can be argued that a democratic IP system should take into account a wider set of interests including those of TK holders.

Undisclosed information (trade secrets)

While the sharing of knowledge is common in many traditional societies, healers and other specialist knowledge-holders as well as clans and lineage groups are likely to have knowledge that they will not wish to share with anybody. Conceivably, a considerable amount of TK could be protected under trade secrecy law.

An experimental project based in Ecuador and supported by the InterAmerican Development Bank is currently trying to protect TK as trade secrets. The project, 'transforming traditional knowledge into trade secrets', aims to enable traditional peoples and communities to benefit from bioprospecting through effective trade secret protection of their knowledge.[164] An NGO called Ecociencia is documenting the botanical knowledge of the participating indigenous groups, and registering it in closed-access databases. Checks are made to see whether each entry is not already in the public domain and whether other communities have the same knowledge. If an entry is not in the public domain, the community or communities with the knowledge have a trade secret. The trade secret can then be disclosed to companies with benefit sharing guaranteed by a standardized contract. These benefits would then be distributed among the trade secret-holding communities and the Ecuadorian government. So far the database contains 8,000 entries provided by six participating indigenous groups. 60 percent of the uses appear so far not to have been disclosed through publications. Already, three companies have expressed interest in accessing the database.[165]

So as developing countries implement the TRIPS section on undisclosed information, the possibility exists for trade secrecy to be deployed as a means to protect TK and to realize its commercial potential for the benefit of the knowledge holders and their communities.

As for the other IPRs, Table 4 sets out the advantages and disadvantages of each one of them.

Table 4: Advantages and disadvantages of various IPRs for local communities[166]

Advantages	Disadvantages
• *Patents* • Can safeguard knowledge legally • Available in most countries	• Limited term of protection • Applications expensive and require legal advice • Protect knowledge of individual inventors, not collective knowledge of communities • Difficult and expensive to defend
Utility models • Can safeguard knowledge legally • More traditional knowledge may be protected than under patent • Compared with patents, less-expensive application procedure and shorter and less-stringent examination	• Available only in a few countries • No international agreements to facilitate application in different countries • Shorter period of protection than patents
Breeders' rights • Less expensive than patents • Communities may have very large numbers of folk varieties (landraces)	• Folk varieties do not usually meet eligibility criteria
Copyright • Easy to obtain (no registration requirement) • Long period of protection	• Protects expression of ideas, but not knowledge itself • Protection period not indefinite • Subject matter must be in a physical form
Trademarks • Can protect collective knowledge • Inexpensive compared to patents • Indefinite protection period, although may have to be renewed periodically • May attract more customers to products of indigenous traders and trading organisations	• Does not protect knowledge per se
Trade secrets • Can protect traditional knowledge with commercial application • Can protect more knowledge than the other IPR types • Can be traded for economic benefits by contract • Inexpensive to protect	• Does not protect knowledge from reverse engineering and independent discovery
Geographical indications • Can protect collective knowledge • Inexpensive • Indefinite protection period • May attract more customers to products of indigenous traders and trading organisations	• Does not protect knowledge per se
Neighbouring rights (such as performers' rights) • Can protect folkloric performances	• Protection is limited in time • Protection only covers certain types of unauthorised use

International negotiations on protection of TK and folklore

The development of legal measures to protect TK and/or folklore has become an integral part of the work of several inter-governmental organizations. These include the WTO, WIPO, the CBD, the United Nations Conference on Trade and Development (UNCTAD), and the World Health Organization (WHO).

The World Trade Organization

Traditional knowledge has become an especially important concern for many developing countries in their negotiations on TRIPS. On 6 August, 1999, two important documents were submitted to the General Council. One of these, from the Permanent Mission of Venezuela,[167] proposed that the next review of TRIPS inter alia should 'establish on a mandatory basis within the TRIPS Agreement a system for the protection of intellectual property, with an ethical and economic content, applicable to the traditional knowledge of local and indigenous communities, together with recognition of the need to define the rights of collective holders.'[168]

The other, from the African Group of countries[169] proposed that in the sentence on plant variety protection in Article 27.3(b) 'a footnote should be inserted stating that any sui generis law for plant variety protection can provide for [inter alia]: (i) the protection of the innovations of indigenous farming communities in developing countries, consistent with the Convention on Biological Diversity and the International Undertaking on Plant Genetic Resources.' This communication, which attracted considerable civil society organization support worldwide, also warned that 'by mandating or enabling the patenting of seeds, plants and genetic and biological materials, Article 27.3(b) is likely to lead to appropriation of the knowledge and resources of indigenous and local communities.'

A more detailed proposal for a legal framework on TK was submitted to the General Council on October 12, 1999 by the governments of Bolivia, Colombia, Ecuador, Nicaragua, and Peru.[170] Specifically, the document proposed that the WTO establish a mandate in a future trade round with three purposes: (a) To carry out studies, in collaboration with other relevant international organizations, in order to make recommendations on the most appropriate means of recognizing and protecting traditional knowledge as the subject matter of intellectual property rights. (b) On the basis of the above-mentioned recommendations, initiate negotiations with a view to establishing a multilateral legal framework that will grant effective protection to the expressions and manifestations of traditional knowledge. (c) To complete the legal framework envisaged in paragraph (b) above in time for it to be included as part of the results of this round of trade negotiations.

The continued interest in this issue among many developing countries is borne out by the fact that WTO member states agreed at the 2001 Doha Ministerial Conference 'to examine the relationship between TRIPS and the CBD, and the protection of traditional knowledge and folklore' (see below).

The World Intellectual Property Organization

In 1998, WIPO established a new unit called the Global Intellectual Property Issues Division (now called the Traditional Knowledge Division). The purpose of this new Division was to identify and respond to the new challenges for the intellectual property system of globalisation and rapid technological change. As part of this mandate, the Division sought to identify potential new beneficiaries of IPRs, including traditional peoples and communities. The Division researches and explores various issues including protection of traditional knowledge, innovations and creativity, and protection of folklore. During 1998 and 1999 WIPO embarked on nine fact-finding missions in various parts of the world on traditional knowledge, innovations and culture to investigate the needs

and expectations of TK holders bearing in mind the possible use of existing IPRs to protect their knowledge, innovations and culture. In addition, WIPO held four regional consultations on protection of expressions of folklore, jointly with UNESCO. Since 2000, the TKD has sought to go beyond identifying and investigating the issues involved and finding out the views of TK holders by addressing basic conceptual problems and testing practical solutions. The emphasis of its work has shifted towards such activities as pilot projects on the use of existing IPRs to protect TK, exploration of customary law and its relationship with the formal intellectual property system, and training and awareness-raising programmes for the benefit of TK holders.

For the 26th Session of the WIPO General Assembly from September 25 - October 3 2000, the WIPO Secretariat prepared a paper (*Matters concerning intellectual property and genetic resources, traditional knowledge and folklore*.[171] The paper invited member states to consider the establishment of an Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. This proposal was approved by the General Assembly, and the first meeting of the Committee took place in Spring 2001. A second meeting was held in December 2001. At IGC-2, the Committee agreed that WIPO should continue its work to establish model IPR clauses for contractual agreements regulating access and benefit sharing, possibly including the development of a database of such clauses to help guide negotiations. Approval was also given to continuation of WIPO's work on the IPR aspects of documenting public domain traditional knowledge, the aim of which is to ensure that patent examiners are able to prevent cases where patents whose claims extend to traditional knowledge are improperly awarded. Towards the end of the meeting, several developing countries proposed, without objections from other participating countries, that WIPO should produce a document providing elements for model sui generis protection for traditional knowledge.[172] This was presented and discussed at IGC-3 in June 2002. At the latter meeting, differences arose regarding the need for, scope and nature of the legal protection. Some delegations felt that a legally binding international sui generis system for the protection of TK was premature or even unnecessary. In contrast, many developing countries supported an international treaty and considered this to be an urgent priority. With respect to the scope of protection, while some developing countries supported the idea of an agreement that would encompass both TK and folklore, others cautioned that it would be better to keep these separate, perhaps with TK being confined to knowledge that is associated with genetic resources. Nonetheless, developing countries supporting the unified approach tended to agree with those favouring the separation of TK and folklore that the scope of protection should reflect the holistic nature of these concepts. Other dissented, feeling that this would lead to practical difficulties. Regarding the elements of the sui generis system, several suggestions were made, including incorporating such norms and principles as human rights, unfair competition and moral rights. Views, however, differed on the extent to which the system should resemble existing IPRs, such as patents, trademarks and geographical indications. These deliberations will continue at IGC-4 in December 2002.

The Convention on Biological Diversity

As mentioned earlier, the CBD explicitly acknowledges the role of traditional knowledge, innovations and practices in biodiversity conservation and sustainable development, as well as the need to guarantee their protection, whether through IPRs or other means. Article 8 (j) requires the parties to 'respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote the wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.'

In terms of implementation, in May 1998, the Conference of the Parties to the CBD at its 4th meeting recognized[173] "the importance of making intellectual property-related provisions of Article 8 (j) and related provisions of the Convention on Biological Diversity and provisions of international agreements relating to intellectual property mutually supportive, and the desirability of undertaking further cooperation and consultation with the World Intellectual Property Organization (WIPO)." The Parties agreed to establish an "ad hoc open-ended inter-sessional working group" to address the implementation of Article 8 (j) and related provisions to be composed of Parties and observers including, in particular, representatives of indigenous peoples and local communities. The mandate of the working group includes the following items: "to provide advice on the application and development of legal and other appropriate forms of protection for the knowledge, innovations and practices of indigenous and local communities"; and "to develop a programme of work, based on the structure of the elements in the Madrid report".

The working group had its first meeting in March 2000. Based upon its recommendations, COP 5, which took place two months later, extended the mandate of the working group and adopted a programme of work. The second meeting took place in February 2002. One specific area of difference was that of TK databases. Some governments believe they can prevent patents being improperly awarded for 'inventions' that are essentially identical to TK. Databases could help patent examiners – who must screen applications so only those describing novel and inventive discoveries may receive legal protection – to filter out spurious inventions. Indigenous groups in attendance proposed that databases be maintained locally and under the control of indigenous and local communities. They and other groups also opposed the registration of TK without the holders' consent. India is a keen supporter of international TK databases because of concerns about biopiracy, including recent cases of Indian TK being the subject of patents held in the US and Europe, such as the patenting of turmeric powder as a wound-healing agent and of basmati rice. Many developing countries, however, are closer to indigenous organisations, worrying that international databases may encourage biopiracy rather than prevent it.

Another controversial issue is that of harmonising CBD provisions on TK protection with patent law. NGOs, indigenous groups and some developing country governments, including India, have been proposing that patent applicants be required – where applicable – to disclose the source of biological material forming the subject matter of their inventions. Some proposals have gone further than this by suggesting (a) that applicants be required to provide evidence that national authorities regulating access to genetic resources had consented to the use of the relevant resources, and (b) that traditional community members whose knowledge was used in the development of an invention had also given their prior informed consent to the application and been guaranteed a share of any benefits arising from the patent. Such measures are unpopular, though with certain developed countries.

An interesting feature of the Working Group meeting is that while TK holding representatives and most developing countries agreed on several key issues such as their shared suspicion of international TK databases, basic differences remain. For indigenous groups, TK protection is a rights-based issue, while many governmental representatives regard it as a matter of international equity or national development. The same divide exists in other intergovernmental forums in which TK protection is debated. Indigenous peoples' organisations and TK holders sometimes suspect that the subject is being used by their governments to secure trade advantages that will be of no benefit to them. They see particular irony in a situation in which governments of countries where indigenous peoples are victims of human rights abuses are among those calling for protection of TK as a matter of justice in international trade. In the event, the Working Group made several recommendations for the 6th Conference of the Parties to the CBD, which took place in The Hague in April 2002. COP-6 Decision VI/10 inter alia "invited Parties and Governments, with the approval and involvement of indigenous and local communities representatives, to develop and implement strategies to protect traditional

knowledge, innovations and practices based on a combination of appropriate approaches, respecting customary laws and practices, including the use of existing intellectual property mechanisms, *sui generis* systems, customary law, the use of contractual arrangements, registers of traditional knowledge, and guidelines and codes of practice".

Other institutions and forums

In 2000, UNCTAD began its work on TK by holding an Expert Meeting on National Experiences and Systems for the Protection of Traditional Knowledge, Innovations and Practices. The Meeting, which was requested by the member states, resulted in a Report intended to reflect the diversity of views of experts.[174] The Report was taken up in February 2001 by UNCTAD's Commission on Trade in Goods and Services, and Commodities. Based upon this report, the Commission adopted recommendations directed at governments, to the international community, and to UNCTAD.[175] The recommendations to the international community are as follows:

> The issue of protection of TK has many aspects and is being discussed in several forums, in particular the CBD Working Group on the Implementation of Article 8(j) and Related Provisions, the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore and the WTO (both the TRIPS Council and the Committee on Trade and Environment). Therefore, continued coordination and cooperation between intergovernmental organizations working in the field of protection of TK should be promoted. The Commission makes the following recommendations at the international level:
> (a) Promote training and capacity-building to effectively implement protection regimes for TK in developing countries, in particular in the least developed among them;
> (b) Promote fair and equitable sharing of benefits derived from TK in favour of local and traditional communities;
> (c) Encourage the WTO to continue the discussions on the protection of TK;
> (d) Exchange information on national systems to protect TK and to explore minimum standards for internationally recognized sui generis system for TK protection.

WHO's involvement in TK relates to the organisation's work on traditional medicine and in response to requests from its members to cooperate with WIPO, UNCTAD and other international organisations to support countries in improving their awareness and capacity to protect knowledge of traditional medicine and medicinal plants, and securing fair and equitable sharing of benefits derived from them. Pursuant to this undertaking, WHO held an Inter-regional Workshop on Intellectual Property Rights in the Context of Traditional Medicine in Bangkok in December 2000. The Workshop produced a list of recommendations including the following:

- Ways and means need to be devised and customary laws strengthened for the protection of traditional medicine knowledge of the community from biopiracy.
- Traditional knowledge which is in the public domain needs to be documented in the form of traditional knowledge digital libraries in the respective countries with the help of WHO to WIPO's work in this area. Such information needs to be exchanged and disseminated through systems or mechanisms relating to intellectual property rights.
- Governments should develop and use all possible systems including the sui generis model for traditional medicine protection and equitable benefit sharing.
- Countries should develop guidelines or laws and enforce them to ensure benefit sharing with the community for commercial use of traditional knowledge.
- Efforts should be made to utilize the flexibility provided under the TRIPS Agreement with a

view to promoting easy access to traditional medicine for the health care needs of developing countries.

CHAPTER VII: EDUCATION

One way that copyright law seeks to strike a balance between the rights of the owners and the public interest is to allow – within certain limits – unauthorized copying of protected works for educational or other non-commercial purposes. This is called fair use or fair dealing. However, there are concerns that as part of the tendency towards strengthened copyright protection, fair use will be one of the casualties. Either it will be restricted further, or it might even be eliminated altogether with the help of technological restrictions on access. Information technology provides both opportunities and threats for the copyright industries that include the publishing industry, the main supplier of educational content. It sometimes appears, though, that these industries would prefer to emphasize the threats when lobbying governments to reform the law to accommodate technological changes.

As for developing countries whose public education systems are dependent upon foreign publications, price is obviously a very important determinant of access. And academic journals such as the many titles published by the large transnational publishing houses tend to be very expensive. While private schools and colleges may be able to afford imported copyright-protected texts and distribute them to all the students, the public education system may not. There educators may be tempted to encourage or turn a blind eye to the copying of such texts by students, schools and colleges. This creates a difficult dilemma for developing countries: should they clamp down on copyright infringers but allow textbook prices to be prohibitively high for most students and educational institutions? Or should they allow copying with impunity but risk being threatened with trade sanctions by the governments of the copyright-owning publishing companies if they fail to enforce copyright?

In an interview for a U.K. Commission on Intellectual Property Rights study[176], Denise Nicholson, Copyright Services Librarian at the University of the Witwatersrand in South Africa, highlighted a number of copyright-related issues she faces which are likely to be experienced by other universities throughout the developing world. These include the following: (i) getting copyright clearance may impose a heavy administrative burden; (ii) obtaining permission directly from publishers for works excluded from or not mandated to the Rights Organisation is time-consuming, expensive (payable in foreign currency) and difficult; (iii) translating from one language to another causes problems. In some developing countries many languages may be spoken, and permission normally has to be sought for all translations; (iv) public domain material such as government documents are not easily accessible and must often be reproduced from published versions of the documents which involves having to get copyright clearance and paying high copyright fees; (v) obtaining permission to transfer print into other formats, e.g. onto CDs, websites, etc. creates problems as publishers are reluctant to give permission, or they charge exorbitant fees; (vi) using material from multimedia or online resources for educational and other programmes creates problems as users do not always know where to obtain permission. Often no response is received or strict conditions are applied and high levies are charged for use of the material; (vii) medical lecturers, for example, wishing to use anatomical diagrams from websites or wanting to scan them into other formats, cannot do this without going through the whole process of getting permission, which is often not given or is levied with high copyright costs. In many instances, rural medical personnel do not have access to computers, etc. and their only source of information is programmes prepared and provided by medical institutions and academic teaching hospitals; (viii) copyright fees for electronic databases are usually incorporated in the subscription fee. However, each database has its own contract and conditions as to what can and cannot be copied, which makes it difficult for users and library staff to know how to respond.

The Berne Convention for the Protection of Literary and Artistic Works offers some support for developing countries in this regard. The 1971 Paris Act of the Convention contains an Appendix which provides – subject to just compensation to the right owner – 'for the possibility of granting non-exclusive and non-transferable compulsory licensing in respect of (i) translation for the purpose of teaching, scholarship or research, and (ii) reproduction for use in connection with systematic instructional activities, of works protected under the Convention'.[177] However, the Annex's provisions are complicated, laden with restrictions and qualifications, and therefore difficult to put into practice. Consequently, it has only rarely been used.[178] Indeed, only eight developing countries are currently availing themselves of the two options. Another country has adopted option (ii) alone. Clearly other solutions must be found.

CHAPTER VIII: IPRs AND NEW TECHNOLOGIES

This part of the chapter considers the IPR-related aspects of two technological fields with considerable strategic and economic importance in today's global economy, and for which IPRs play an especially important part: biotechnology and ICT.

Biotechnology

Biotechnology and the genomics revolution

According to a report by the United States Office of Technology Assessment (1989): 'biotechnology, broadly defined, includes any technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants or animals, or to develop micro-organisms for specific uses.'

This definition is rather broad and would embrace what some experts refer to as the first, second and third generation biotechnologies. The first generation includes traditional technologies like beer brewing and bread making, and the second begins with the microbiological applications developed by Louis Pasteur culminating in the mass production by fermentation of the antibiotics. Tissue culture and modern plant and animal breeding also fall within this 'generation'. The third generation biotechnologies or 'the new biotechnologies' include recombinant DNA ('gene splicing'), hybridoma technology[179], and genomics.[180]

Most government funding and commercial activity so far has been in the area of health biotechnology. The types of product being developed include so-called 'biopharmaceuticals' such as genetically-engineered therapeutic proteins and vaccines. Other common types of product are diagnostic kits for diseases linked to genetic defects. Health biotechnology is not only used to develop new types of drug but also to enhance the efficiency of the drug discovery process. In fact, this has become the main objective of health biotechnology research. According to one commentator: 'partly … due to the high costs of production, using genetic engineering to make human proteins is currently seen to be a minor use in pharmaceuticals. The major use of genetic engineering is to improve the efficiency of the drug discovery process, in combination with a better understanding of the workings of the body. Combining that knowledge implies that pharmaceuticals can be more directly designed to do certain things.'[181]

Agricultural biotechnology is the second most important biotechnology field in the United States and Europe. Much of this research is geared towards the development of new seed products with introduced traits providing mainly agronomic benefits such as disease resistance, pest resistance, herbicide tolerance, and also extended shelf-life of harvested produce. Little of the research has been directed so far at improving output quality for the benefit of consumers, although this situation is beginning to change. This is one important reason why genetically-modified (GM) crops are so controversial in Europe: the perception among many people is that consumers are expected to accept the unknown risks of consuming GM products and bear the consequences should something go wrong. Yet, unlike genetically-engineered pharmaceuticals, these products provide no additional benefits for the public, as they would if they were cheaper or more nutritious. Unlike the healthcare case, there are few agricultural DBFs, even in the U.S.

Of the two fields, healthcare products tend to be more commercially attractive. This is because they have potentially much higher returns, and because demand tends to be much less cyclical. Most of the remaining biotechnology companies provide industrial or environmental products and services such as industrial enzymes and pollution diagnostics.

The 'biotechnology industry' is not a discrete industrial sector. Rather, there are dedicated biotechnology firms (henceforth 'DBFs') that do nothing but biotechnology, and other companies, universities and public research institutes that do biotechnological work but do not specialize in it. The biotechnology and genomics revolutions have created completely new commercial opportunities, and spawned four types of business. These are (i) the technology providers who manufacture the DNA sequencing machines and other equipment (e.g. Applied Biosystems and Amersham Biosciences); (ii) the information providers (e.g. Incyte and Celera) that collect and organize sequencing information; (iii) the research firms, consisting mainly of the DBFs that generally do the upstream research but lack the resources or the ambition to do the downstream product development and marketing; and (iv) the health, agricultural and industrial biotechnology firms. These include the larger vertically integrated DBFs (e.g. Amgen and Genentech), and much longer established businesses, which are mostly pharmaceutical, chemical and life science corporations. These business types are not necessarily discrete. For example, while Incyte and Celera are essentially information providers, Millennium Pharmaceuticals and Human Genome Sciences are also involved in drug discovery and development..

As with other science-based sectors, the road leading from basic research to product development is long, winding, and has many branches, some of which may be short cuts but are mostly dead ends. It is also very expensive to use especially as journey's end approaches. And the companies best equipped to carry a product to the end of the road are not necessarily the most competent to start the journey.

This situation provides both obstacles and opportunities for business. For new start-up firms it is hugely difficult for them to transform themselves into biopharmaceutical corporations. The opportunities lie in the fact that as the big firms concentrate on their core competences they outsource more and more tasks that may be essential elements of the R&D process. Therefore niches are created that new small and medium-sized science-based firms can occupy profitably. As the cost of gene sequencing falls, it is likely that barriers to entry will fall as well. Therefore, we can expect some highly specialized small genomics firms to spring up in the coming years, mainly from universities, and not just in developed countries.

Arguably, biotechnology patents encourage such a diversification of business activity by stimulating the foundation of small but highly-innovative firms and then by helping them to survive and remain independent. It has always been crucial to have access to large amounts of investment capital just to stay in business. Patent portfolios are the main magnet for outside investors – which also include larger science-based firms – and the larger the portfolio, the greater the interest from investors. In common with other industries, patents also become a form of currency in inter-firm transactions: 'few products can be developed, tested, approved by regulatory agencies, and on the markets in time to generate enough cash to save most biotechnology companies. For many companies, the patent becomes the product – the product that can be dangled before the investment community for more funds, or the product that can literally be sold to other companies'.[182] Research decisions in many companies can depend as much, if not more, on the advice of patent lawyers as the opinions of the scientists. Naturally, companies have a strong interest in securing patents that encompass the broadest possible scope and whose claims are drawn in ways that seek to anticipate future scientific developments.

But from the view of the public interest, there is a danger in the increasing dis-integration of the genomics innovation chain. For new DBFs that provide genetic information to the drug development firms, what they sell are to them final products but to their customers further down the chain are mere research tools. In order to protect these 'products' – and to secure funding to produce further ones – the DBFs have a strong incentive to privatize their information through IPRs. But since the

development of future commercial products such as therapeutic proteins or genetic diagnostic tests often requires the use of multiple gene fragments, an increasing number of which are being patented, companies intending to develop such products will need to acquire licences from other patent holders. In doing so, they will incur large (and possibly prohibitive) transaction costs. To return to the road metaphor, the danger is that more and more tollgates will be installed making the journey ever more expensive and excluding more and more potential travellers. So not only is the product development race becoming a relay race with more and more runners, but each runner is being forced to pay for the privilege of receiving the baton from the previous runner. The question is, will this slow down innovation and lead to fewer products on the market than would otherwise be available? And if so, how should the regulation of innovation through intellectual property protection be recontoured in response?

To date much if not most of the basic research in biotechnology and genomics have been financed and conducted by governments, universities and private foundations. But private sector investment has increased in recent years, especially in the United States. The U.S. pioneered commercial biotechnology. There are various reasons for this but two important ones are the considerable amount of related state-funded basic research that had already been conducted by the universities and government agencies, and the large quantities of venture capital funds.

While the U.S. system has been relatively effective at turning new discoveries made by public sector and university researchers into commercial products, Europe and Japan have been less successful in putting together the downstream linkages from fundraising for basic research all the way to commercialization. However, since the 1980s the European Community countries and Japan have been preoccupied with catching up with the US. Both the European Commission and the member governments have sought to stimulate biotechnology R&D through industrial policy and more business-friendly product and IPR regulation. So far they have been only partly successful, raising the question of whether developing countries can succeed no matter how carefully their IPR systems are designed.

Biotechnology and developing countries

Developing countries vary considerably according to the capacity of their research institutions and businesses to generate biotechnological inventions. M.R. Bhagavan of the Swedish International Development Cooperation Agency[183] divides developing countries according to their science and technology (S&T) capacities. Thus, these countries are members either of the ‘strong’, ‘medium’ or ‘weak’ South. The Strong South includes such countries as Brazil, China, India and Mexico, which are moving into high-technology fields such as the third-generation biotechnologies. The Medium South includes Indonesia, Malaysia and Argentina, while the Weak South consists of most other countries which are as technologically dependent on the developed countries as they were before decolonization.

Several developing countries, including India, China, Brazil and Cuba, have adopted third generation biotechnologies. India is perhaps the most advanced developing country in terms of scientific capabilities, including the life sciences. However, the overwhelming bulk of biotechnology applications even in these countries are of the earlier generations such as fermentation and tissue culture. While health biotechnology is more important than agro-biotechnology in the United States and Europe, agro-biotechnology has been prioritized by many developing country governments, such as India and Kenya. This is largely due to the dependence of most emerging national economies on the viability of agricultural sectors for food security and employment, and in many cases, foreign exchange and political stability.

Given the likelihood that sequencing and analysing human, animal, plant and microbial genomes will take less and less time and money, one can anticipate a lowering of barriers to entry. This increases the possibility that a few developing countries like India, China and Brazil will become sources of innovations in this field in the coming years. It is perfectly feasible, then, to envisage a time in the near future when a developing country like India will not just be a recipient of gene technologies and products but will be a provider to global markets as well.

It is frequently argued that biotechnology has nothing to offer developing countries. This view tends to be founded upon three convictions: first, that transnational corporations are aggressively promoting inappropriate and potentially dangerous genetic modification technologies in countries where biosafety regulations either do not exist or cannot easily be enforced; second, that traditional natural products like cocoa and vanilla, upon which some countries are heavily dependent, may be displaced by laboratory-produced substitutes; and third that because genetically-modified (GM) crops are bad for developing countries, then so is biotechnology.

Supporters of biotechnology are likely to counter that whether or not transnational life-science corporations are guilty and to what extent, there are no scientific reasons why GM crops cannot be designed with the needs and interests of poor farmers and consumers in mind. Moreover, most second and third generation biotechnologies are not capital intensive compared to most other advanced technological fields.[184] Therefore, entry barriers need not be prohibitively high, although success would probably still depend on there being adequate capacities in all the related disciplinary fields including fermentation science and chemical engineering, and a conducive institutional environment.

Intellectual property rights

It is only after a country has a critical mass of trained life-science technicians that inventorship in the life sciences can take place on any scale, and only once this stage has been reached can a patent system be of benefit to a country by rewarding and encouraging further invention. While a few developing countries may perhaps be reaching this critical mass, domestic research institutions and businesses in developing countries are unlikely to be heavy users of patent systems at least in the short term.

But the truth of this proposition provides no definitive answer to the question of whether these countries should offer broad and strong patent protection in the field of biotechnology or to take a TRIPS *de minimis* approach that excludes plants and animals, defines 'micro-organism' narrowly, and opts for a sui generis alternative to patents for plant varieties. While many developing countries will prefer to opt for the latter approach, at least for the time being, it is worth pointing out that if biotechnological inventions are well protected, developing countries could conceivably benefit even if there are few if any domestic patents applicants. This would depend on whether foreign firms are encouraged to transfer technologies to those countries or to establish R&D facilities there because of the existence of IPRs. But at this stage we simply cannot be sure that strong IPR protection will make this happen. One complicating factor is that such business decisions depend on a range of factors of which intellectual property is just one.

Developing countries need first to determine to what extent and how they wish to harness biotechnology for their economic development and then to design an IPR regime that supports the objectives they decide to pursue. The TRIPS Agreement gives them quite a lot of choice in terms of how they prefer to define a patentable invention in the context of biotechnology. Since discussing the first task is beyond the scope of this paper, this section discusses how TRIPS deals with the IPR protection of biotechnological inventions and how the relevant provisions may be interpreted.

TRIPS makes no reference at all to biotechnology, but the section of the Agreement dealing with IPR protection of life-forms is Article 27.3(b), which allows members to exclude from patentability 'plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof.'

This means that with respect to *products*, plants and animals may be excluded from patentability. As regards *processes*, essentially biological processes for the production of plants or animals may also be excluded. But patents *must* be available for micro-organisms as *products* and for non-biological and microbiological *processes* for producing plants or animals. Patent protection need not be available for plant varieties but an effective IPR system is still obligatory. This may be an UPOV-type plant variety right system, an alternative system yet to be devised, or some combination of systems (see Table xx). Drawing distinctions between micro- and macro- biological processes is by no means easy, especially in the biotechnology age. Therefore, different jurisdictions are likely to draw the line in different places according to how these terms are understood in specific cases.[185]

Table 4: Article 27.3(b) – a summary of its provisions

WTO Members may exclude from patent protection:	**WTO members must provide protection for:**
Plants	Microorganisms (by patents)
Animals	Non-biological processes (by patents)
Essentially biological processes for the production of plants or animals	Microbiological processes (by patents)
Plant varieties	Plant varieties (by an IP system which may be patents, a sui generis alternative, or a combination)

Much of the language is difficult and open to conflicting interpretations. For example, it remains an open question whether an application relating to a genetically-engineered plant would necessarily include plant varieties within its scope or not. This is important because in some jurisdictions, plants can be patented but plant varieties cannot. In others neither can but there may be a separate IPR system exclusively for plant varieties.

Since the language follows quite closely that of the European Patent Convention, it may be useful to see how the European Patent Office (EPO), which allows plants to be patented but not plant varieties, has addressed this complex issue. In 1995, the Technical Board of Appeal of the EPO[186] determined that a claim for plant cells *contained in a plant* is unpatentable since it does not exclude plant varieties from its scope. This implied that transgenic plants *per se* were unpatentable because of the plant variety exclusion. But in December 1999, the Enlarged Board of Appeal of the EPO declared that 'a claim wherein specific plant varieties are not individually claimed is not excluded from patentability under Article 53(b), even though it may embrace plant varieties', but that 'plant varieties containing genes introduced into an ancestral plant by recombinant gene technology are excluded from patentability'.[187] Of course, other WTO Members do not have to follow this interpretation.

Even words like 'micro-organisms' can be interpreted differently from one legal jurisdiction to another. According to the EPO, for example, 'micro-organism' 'includes not only bacteria and yeasts, but also fungi, algae, protozoa and human, animal and plant cells, i.e. all generally unicellular organisms with dimensions beneath the limits of vision which can be propagated and manipulated in a laboratory. Plasmids and viruses are also considered to fall under this definition.' This seems rather

over-expansive since it is not at all obvious that a single cell from a multi-cellular organism is itself an organism even if it has been cultured in a laboratory. There is no reason why developing countries should not define the term in a narrower sense if they should consider it advantageous to do so.

TRIPS makes no reference to genes or DNA sequences. Does this mean that WTO Members are required to allow these to be patented? This is not easy to answer. On the one hand, one could argue – as geneticists generally do – that DNA is merely a chemical. Consequently, complementary DNA (cDNA) sequences, which are produced in the laboratory and differ from their naturally-occurring counterparts in that certain sections of the molecule are 'edited out', should be patentable subject to fulfillment of the novelty, inventive step and industrial applicability requirements.

The alternative view, which many geneticists subscribe to, is that the deletion of non-protein coding DNA is not inventive enough to deserve the reward of a patent. Why? Because a claimed cDNA molecule is likely to be obvious to somebody 'skilled in the art' who knew the sequence of its naturally-occurring equivalent. This is because techniques for isolating and purifying DNA sequences are well-known and no longer require a great deal of skill to use. But what if nobody knew about the naturally-occurring equivalent? Such a claim should still arguably fail for the lack of an inventive step on the basis of the techniques employed being routine.

To a large extent, the patenting of DNA sequences and genes depends on how policy makers and the courts decide how the law should define novelty or interpret the term if it is not explicitly defined. For example, most developed countries' patent laws and their courts allow 'purified' or 'isolated' DNA sequences to be patented as long as a credible use is disclosed. Other jurisdictions may prefer to raise the novelty standards so that purification or isolation of a naturally-occurring substance is insufficient to demonstrate novelty.

It has also been argued that allowing patents on genes and gene fragments is inadvisable because, for the reasons given earlier, it is likely to raise the cost of doing research. Objections to such patents have also been raised on moral or religious grounds, as have patents on plants, animals and other life-forms.[188]

Such objections notwithstanding, the extent of patenting relating to DNA has increased tremendously in the last two decades. According to Giles Stokes of Derwent Information, '[DNA] sequences first began appearing in patents in 1980, just 16 sequences all year. By 1990 that figure had risen to over 6,000 sequences. Throughout the 1990s the growth in the patenting of sequences expanded exponentially, and this looks set to continue. In 2000 over 355,000 sequences were published in patents, a 5000 percent increase over 1990'[189]

Article 27.3(b) was to be reviewed by the Council for TRIPS in 1999. In fact, the review is still going on. Many countries have submitted proposals concerning how the review should be conducted and suggesting changes to the language of the sub-paragraph. At the present time, though, it does not seem as if there will be any agreement to revise the text.

Box 11: Patenting natural substances

TRIPS requires micro-organisms to be patentable, while plant variety rights must come under some kind of IPR system but not necessarily patents. But what about genetic and biochemical resources? Must these also be patentable? Since they are not expressly excluded, patents must be made available for these subject to the conditions that they be new, involve an inventive step and be capable of industrial application. Presumably these requirements mean that resources existing in nature cannot be patented. But is this correct?

In Europe and North America, which have the most experience in the patenting of apparently natural substances, there has never been any kind of blanket exclusion of certain types of invention on the basis that because they were not 100 per cent human-made they cannot be patented. For example, adrenaline was first patented in 1903, and insulin in 1923. Shortly after the Second World War Merck was granted patents on two products extracted from a micro-organism called *Streptomyces griseus*: the antibiotic streptomycin and vitamin B12. While there was a general assumption that living things could not be invented, patents were occasionally granted in some countries on plants and micro-organisms. The United States even had a plant patent system from as early as 1930. But for most of the 20th century the legal situation in Europe and North America was uncertain. From the 1970s, though, things became clearer as the scope of patent protection was extended not just to micro-organism products but micro-organisms themselves followed later on by plants and animals. As for DNA sequences they started appearing in patent applications in about 1980.

How can such products, some of which are obviously discoveries, be protected by patents as if they are inventions? The technical explanation is that patent law treats them as if they are chemical substances, and these have been patentable for at least 150 years. It is well established in the patent laws of Europe and North America that while you cannot claim as an invention something as it occurs in nature, it is possible to do so if you extract it from nature and thereby make it available for industrial utilisation for the first time. This argument may not always convince a patent examiner or a court, though. But you almost certainly will if you change the substance or life-form in some way such as by adding something to it (e.g. a gene), subtracting something from it (i.e. purifying it), mixing it with something else to create a new or synergistic effect, or structurally modifying it so that it differs in an identifiable manner from what it was before. It also appears to be possible in some jurisdictions to get a patent on a natural substance by simply being the first to describe it in the language of biochemistry. Thus the South African Council for Scientific Research has a patent on certain compounds found in a plant called the hoodia which is used by the Bushmen as an appetite suppressant and which the Council hopes will form the basis of a successful anti-obesity treatment. The patent may well provide the first biochemical description of how the plant produces its commercially promising effect, but the intended use of the plant would hardly be considered as novel by the Bushmen. According to the European Patent Convention's standards, though, the Council has a legitimate claim. The European Patent Office Guidelines for Examination state that: 'if a substance found in nature has first to be isolated from its surrounding and a process for obtaining it is developed, that process is patentable. Moreover, if the substance can be properly characterised either by its structure, by the process by which is it obtained or by other parameters … and it is "new" in the absolute sense of having no previously recognised existence, then the substance per se may be patentable'.

Information and communication technologies (ICT)

Electronic information-processing and communication is the other technological field in which tremendous advances have been achieved in a very short time. Like biotechnology, information technology has multiple industrial applications. The main sources of innovation in ICT are the software, hardware, semiconductor and telecommunications industries.

But other types of business are involved in the ICT sector that have an interest in intellectual property regulation including those that do not themselves innovate in this particular field, such as those which use ICT to provide content to consumers. For example, the copyright industries have benefited

tremendously from ICT, by cutting the cost of doing business and increasing the availability of their products to the public.

On the Internet such businesses can be divided into:

- The World Wide Web browsers. This sector is essentially a duopoly, since virtually all computers use either Microsoft's Internet Explorer or Netscape's Navigator or Communicator.
- The Internet service providers (ISPs), which enable users to access the Internet. These include companies like America On Line (AOL), Compuserve, and telecommunications companies.
- The content providers which make information and creative works available on the Internet. These include publishing and media companies, non-profit organizations, universities and individuals.
- The content creators. These include authors and entertainment companies. Sometimes these are also providers.
- E-commerce businesses. These include dedicated e-commerce firms (e.g. Amazon.com) and those using e-commerce in addition to more conventional means of selling goods and services to the public. These businesses have increased their presence in recent years.

Content providers tend to take a hard line on intellectual property rights, favouring protection as strong as, if not stronger than, the levels of copyright protection available to businesses operating in the more conventional environments such as print. Creators often take a similar position, but not all of them. For example, academics are likely to be more interested in circulating their work as widely as possible than in IPRs as long as they receive personal acknowledgment.

On the other hand, ISPs generally have little reason to favour strong copyright protection of Internet content, especially given the possibility of finding themselves held liable for the copyright infringements of their users. But this situation may change if other ISPs follow the example of one of the biggest, America On Line, which owns Netscape and has recently merged with Time Warner to form AOL Time Warner. This new corporation is therefore not just an ISP but also a large-scale provider and creator of content.

ICT and developing countries

Stated baldly, very little innovation in the field of ICT takes place in most developing countries. Therefore, many such countries may be more concerned with access than with the promotion of innovation. In this context it is important to be aware that in several ICT-related businesses such as software, hardware, semiconductors and telecommunications, and Internet service providers, the markets tend to be highly concentrated. This has not been the case so far with Internet content, but this situation may begin to change. Therefore innovative start-up firms based in developing countries may find it difficult to grow. And while software and hardware products are often manufactured in developing as well as developed countries, the companies that design and sell the products capture most of the value by far. Few such companies exist in the developing world.

Intellectual property rights

While there is nothing new in patenting telecommunications technologies or copyrighting books and motion pictures, the ICT revolution has pushed the boundaries of the IPR system in a number of different ways and has the potential to push them still further. For example, though software programs are arguably no more than a long sequence of binary-coded instructions to a computer, copyright law nowadays treats them as if they are literary works. In the United States, programs are now patentable as well. There are two types of software-related intellectual product that may be regarded as an invention in

some jurisdictions: 'a) computer programs that produce a technical effect within the computer or on other hardware components; and b) computer programs that produce technical effects different from those described in (a), entailing changes in the state of physical matter such as effects on equipment applied to a specific industrial task.'[190] In the U.S. it is possible to obtain patents for both types. In Europe, programs are not patentable officially, although patents on type (b) inventions have been granted.

The semiconductor manufacturers came up with a different approach to the software industry. They deemed existing IPRs to be unsuitable for the protection of their chip designs and successfully lobbied for a *sui generis* system, first in the United States and now globally through the TRIPS Agreement. The U.S. legislation, passed in 1984, is known as the Semiconductor Chip Protection Act (SCPA). To a large extent, the SCPA provided the model for the 1989 WIPO Treaty on Intellectual Property in Respect of Integrated Circuits (Washington Treaty). The agreed text of the Treaty was a disappointment for the main semiconductor-producing countries. So while it was incorporated by reference into TRIPS, modifications were made that strengthened the rights provided.

As for digital information, views on the applicability of IPRs vary from the opinion of those who believe that IPRs are completely inappropriate, to others who hold that IPRs have evolved over time and that it is nothing new for them to accommodate new technologies even while there may be problems at first. Among the former are those who believe that 'information wants to be free'[191], and that attempting to use them only holds up technological development while intruding on freedom of expression. Many, if not most, others hold to a view somewhere in between.[192]

It is important to bear in mind that software and database producers use copyright law not only to protect expressions but also to block access to information. For example, software developers in the United States can copyright the code of their programs without having to fully disclose it. Additional protection can be secured by keeping the source code secret (and thereby protecting it under trade secrecy law), and through restrictive licenses.

Developing countries are required under TRIPS to protect software under copyright law and semiconductor designs under the *sui generis* system in accordance with Articles 35-37. However, TRIPS does not explicitly state that they have to allow the patenting of programs, although they may be required to do so under the terms of bilateral free trade agreements, such as the one between the United States and Jordan. It is possible to argue that since patents must be available for all fields of technology, protection must be extended to computer programs. But this may not necessarily be the case. The European Patent Convention expressly disallows the patenting of computer programs. The reason is that legal protection of inventions requires evidence of a technical contribution to the state of the art. Computer programs *as such* are not considered to meet this requirement. But in spite of this, the European Patent Office and national patent offices in Europe have so far granted thousands of patents for computer-implemented inventions, including over 20,000 by the EPO alone.[193]

The two 1996 'Internet treaties', i.e. the WIPO Copyright Treaty (WCT) and the WIPO Performers and Phonograms Treaty (WPPT) are particularly important since they attempt to meet the challenge of a new and rapidly expanding field of mass communication, i.e. the Internet. While the Internet was clearly becoming a promising new medium for making intellectual works available to the public, concerns were raised that in the digital environment opportunities for large-scale counterfeiting were massively increased. Moreover, copyright enforcement was also highly problematic because members of the public and competitors could access Internet content from virtually anywhere in the world. There were also concerns that technological barriers to copying could never be totally secure, which is why content providers are not only developing ever more sophisticated technological barriers to copying but are keen to prevent the production, use and dissemination of technologies aim at, or are merely capable of, circumventing these barriers.

But while these concerns motivated certain WIPO member states to lobby for new norms to address these problems, a quite different concern was also raised at the 1996 diplomatic conference at which the above treaties were negotiated and adopted. This other concern was that the creation of new norms, if driven purely by the interests of content producers, could lead to overprotection, thereby upsetting the mutually beneficial balance between the interests of (a) the public, (b) the content producers, who are likely to be copyright owners of such content, and (c) the content access providers, such as Internet Service Providers and libraries. Because many of the delegates accepted the need to address this matter, the agreed texts of the two treaties are generally considered to reflect a reasonable balance between the different interests involved.

The treaties evidence the continuing role of WIPO in the development of new IPR norms which, among other things, seek to accommodate new technological advances. They are also important in that the U.S. and the European Union have suggested that TRIPS be revised to incorporate these two treaties. In fact, the U.S. is actively encouraging other countries to sign and ratify these treaties through, for example, bilateral trade agreements containing such a requirement.[194]

CHAPTER IX: TECHNOLOGY TRANSFER AND FOREIGN DIRECT INVESTMENT

According to Pedro Roffe of UNCTAD *formal* private-sector[195] technology transfer 'is a commercial operation that takes place through firm-to-firm arrangements and involves flows of knowledge, be they embodied in goods (as in the sale of machinery and equipment) or in the form of ideas, technical information and skills (through licensing, franchising or distribution agreements). Technology transfer can take place at arm's length, as in the case of the export of capital equipment or of licensing agreements between unaffiliated firms, or it can be internalized through the transfer of new production techniques within a transnational corporation, between affiliate firms.'[196] Informal technology transfers can also take place on a large scale and in those countries in the early stages of industrialisation these may be far greater in number than formal ones.[197] By definition, informal transfers are not based on any monetary transactions or legal agreements. If IPRs exist to create markets for knowledge, such transfers presumably do not depend at all on the existence of intellectual property protection. The rest of this chapter deals with formal transfers.

There are several formalized means of transferring technologies, which include foreign direct investment (FDI), joint ventures, wholly owned subsidiaries, licensing, technical-service arrangements, joint R&D arrangements, training, information exchanges, sales contracts, and management contracts.[198] Of these FDI in some form or another is the main channel for technology transfer flows.[199]

The relationship between levels of IPR protection and the volume and direction of inward technology flows is highly complex and is likely to involve a great many factors whose relative importance will vary widely from one country to another. Theoretically, it seems logical to assume that IPR availability would be a prerequisite for the international transfer of new technologies, *at least those that can easily be copied*. One would expect companies to be reluctant to lose control over technologies that may have cost them millions of dollars to develop *in countries where domestic firms can adopt the technologies and produce goods that will compete with those of the technology owners.*[200] Accordingly, the only way that companies would feel encouraged to transfer proprietary technologies is where IPR protection is strong enough for them to charge licence fees high enough to reflect the costs of innovation, or alternatively by means of FDI or joint ventures where they maintain more control over these technologies.[201] According to Keith Maskus of the World Bank,[202] in countries with strong IPR protection and enforcement, transnational corporations are likely to favour technology licensing agreements and joint ventures. In countries with weak IPRs, FDI would be the favoured business strategy in overseas markets.[203]

In this context, it is important to understand that a great deal of formal international 'technology transfer' takes place not between but *within* companies. Given that these companies continue to control access to the technologies, it seems reasonable to question whether such transactions are genuine technology transfers of the kind that would result in widespread adoption in developing countries. It is also worth noting that some companies are alleged to adopt fraudulent accounting practices when declaring the cost of such transactions for tax evasion purposes.

However, a counter-argument can be made that the *overall* effect of IPRs will inhibit technology transfers. The views of the critics who argue that IPRs inhibit technology transfer and reinforce North-South inequalities can be summarized as follows:

As an intervention in the free market, patents restrict the number of people who could otherwise freely make, use, sell or import the protected products and processes. This enables owners to maintain high prices, avoiding a situation where the price of their products or processes is driven down towards the

marginal cost of reproduction. Foreign patent owners can use their legal rights either to block access to their technologies or to charge license fees that are too high for domestic firms. If so, one might argue that the best ways for developing country governments to help domestic firms and public institutions to acquire technologies might be to weaken patent rights such as by allowing compulsory licensing on licensee-friendly terms.

This may not be the case, though. It is important to understand that reading a patent specification is unlikely to be sufficient to gain access to a technology. There are three reasons for this. First, patents do not necessarily disclose the invention to the extent that a person skilled in the art could manufacture it. Undisclosed tacit knowledge is often essential for reproducing an invention. Also, 'in the public domain' is not synonymous with 'freely available'. According to Stuart Macdonald of Sheffield University: 'Legal fiction maintains that all the information needed to re-create the invention is contained in the patent specification. The fact is that the specification is forced to refer again and again to other information, information that is in the public domain, which means that it is available somewhere but must be acquired from these sources before the information in the specification can be used. Much of this information will be tacit and uncodified information [i.e. know-how].' Moreover, 'the information contained in patent specifications is available only to those who consult them directly, or who pay others more adept at arcane classifications and the language of lawyers to do so.'[204] [205] Second, the possibility to take commercial advantage of information disclosed in expired patents may be precluded by multiple overlapping IPR portfolios. For example, companies sometimes apply for further patents or use trademarks or copyright protection as means to extend the life of a monopoly beyond the expiry date of the original patent. Third, many developing countries lack the institutional capacity to adopt and adapt new technologies.

As for the geography of patent ownership, this is heavily skewed in favour of the North. Patent Cooperation Treaty statistics for 1998 and 2000 show that despite the increased developing country membership of recent years, the vast majority of PCT applications continue to be filed by companies based in North America, Western Europe or Japan (Table 5). Since such companies are the main users of the patent system, in the short term at least, they will be the major beneficiaries of new patent laws in developing countries. And given the economic power of these companies it may be more difficult than ever for developing countries to negotiate favourable terms for technology. Peter Drahos suggests a worst-case scenario[206]: 'if it turns out that the global market in scientific and technological information becomes concentrated in terms of the ownership of that information it might also be true that the developmental paths of individual states become more and more dependent upon the permission of those intellectual property owners who together own most of the important scientific and technological knowledge.'

What is the empirical evidence concerning the links between stronger IPRs, investment flows, R&D and technology transfers? In fact, the data produced so far are hardly conclusive and suggests that FDI decisions may depend on a host of factors including the general investment climate. A study by Maskus[207] claimed some evidence of a positive correlation, while conceding that IPRs are one of several factors that may facilitate technology transfers, and also that strengthening IPRs will involve unavoidable costs[208] as well as benefits for developing countries.[209] A World Bank study was even more cautious and recommended further research before firm conclusions could be made.[210] Evidence from Turkey[211] found that the banning of pharmaceutical patents appeared to have no significant effects on levels of FDI, technology transfers or domestic innovation. Similarly, a study on Brazil, taking manufacturing industry as a whole, found no evidence that FDI levels were greatly affected by patent protection.[212] On the other hand, Edwin Mansfield's well-known (1994) study based on interviews with intellectual property executives of U.S. corporations in several industrial sectors indicated that a large proportion of respondents from the chemical and pharmaceuticals industries claimed that their FDI decisions *were* affected by the levels of IPR protection available.

Table 5: Geographical origin of Patent Cooperation Treaty patent applications filed in 1998 and 2000 (from figures published on WIPO Website)

Region	Country of origin	No. patents filed 1998	No. Patents filed 2000	% of total 1998	% of total 2000
North America	USA	28,356	38,171	42.3	42.0
	Canada	1,315	1,600	2.0	1.8
Total North America		*29,671*	*39,771*	*44.3*	*43.8*
Western Europe/EU	Germany	9,112	12,039	13.6	13.2
	UK	4,383	5,538	6.5	6.1
	France	3,322	3,601	5.0	4.0
	Sweden	2,554	3,071	3.8	3.4
	Netherlands	2,065	2,587	3.1	2.8
	Switzerland	1,293	1,701	1.9	1.9
	Finland	1,092	1,437	1.6	1.6
	Italy	925	1,354	1.4	1.5
	Denmark	624	789	0.9	0.9
	Austria	421	476	0.6	0.5
	Norway	394	470	0.6	0.5
	Others	1,101	1,463	1.6	1.6
Total Western Europe/EU		*27,286*	*34,526*	*40.7*	*38.0*
East Asia and China	Japan	6,098	9,402	9.1	10.3
	South Korea	485	1,514	0.7	1.7
	China	322	579	0.5	0.6
Total East Asia & China		*6,905*	*11,495*	*10.3*	*12.6*
Eastern Europe	Russia	429	590	0.6	0.7
	Others	402	627	0.6	0.7
Total Eastern Europe		*831*	*1,217*	*1.2*	*1.3*
Australasia	Australia	1,048	1,627	1.6	1.8
	New Zealand	178	264	0.3	0.3
Total Australasia		*1,226*	*1,891*	*1.9*	*2.1*
Total Middle East		*707*	*925*	*1.1*	*1.0*
Total Rest of Asia		*146*	*473*	*0.2*	*0.5*
Total Latin America/ Caribbean		*209*	*252*	*0.3*	*0.3*
Total Africa		*26*	*398*	*<0.1*	*0.4*
Total applications		***67,007***	***90,948***	***100.0***	***100.0***

In short, much uncertainty remains as to the effects of IPRs on technology transfers to developing countries. But there is empirical evidence to suggest that the effect of IPRs on technology transfer depends on the level of development of a country, the specific technological fields involved, and the behaviour and absorptive capacity of individual firms.[213] Accordingly, TRIPS is likely to benefit some countries, harm others, and make no difference elsewhere. But bearing in mind the highly concentrated market structures of some industries, it is possible that the bargaining power of all developing countries and their companies is likely to be weak and getting weaker still, especially the smaller countries that are unlikely to be an important market for the technology-owning firms. Yet the situation is not entirely bleak. There is some evidence from Africa to suggest a certain willingness of transnational corporations to share technologies on concessional terms.[214] But often this is only as long as domestic companies do not produce competing products for sale in that market or abroad.

CHAPTER X: NATIONAL ENFORCEMENT AND ADMINISTRATION CHALLENGES

TRIPS places much emphasis on enforcement. With respect to the general enforcement obligations, procedures must be available that 'permit effective action against any act of infringement of IPRs'.[215] They must be fair, equitable and not unnecessarily complicated, costly or time-consuming.[216] The judicial authorities must be granted the power to require infringers to pay damages adequate to compensate the right holder for the injury suffered due to the infringement.[217] Members are required to provide for criminal procedures and penalties 'at least in cases of wilful trademark counterfeiting or copyright piracy on a commercial scale'.[218] Remedies may include imprisonment and/or monetary fines. Such remedies may also be applied in other cases of IPR infringement if done 'wilfully and on a commercial scale'. Members are not required to put in place a judicial system for enforcing IPRs separate from that for the enforcement of law in general.[219] Moreover, TRIPS creates no obligation to shift resources away from the enforcement of law in general towards the enforcement of IPRs. Nonetheless, resource-poor countries may face a difficult dilemma when determining how to allocate the scarce resources they have.

The dynamic efficiencies of stronger and more effective IPR systems may more than make up for the administrative and enforcement costs. Whether or not this turns out to be true, the costs must be borne before the benefits accrue and, for least-developed countries especially, these are likely to be particularly onerous. In addition, since regulators and courts are likely to lack experience in dealing with IPR-related matters, financial and appropriate technical assistance will be desperately needed in many poor countries.

The tables below should make this point apparent. The first table gives details of a few World Bank-financed capacity-building projects including their costs. The second table provides a list of reforms needed by developing country WTO members with the estimated costs involved.

One serious problem needing to be addressed is that many developing countries lack sufficient qualified examiners to handle a high volume of patent applications. Therefore, national patent offices accumulate large backlogs of unexamined applications, especially in the most advanced technological fields. A number of solutions are possible. One is to join with neighbouring countries to set up a regional patent system. Another is to conduct only cursory examinations or to opt for a registration system without any examinations. If this happened, though, the quality of issued patents could become very poor. A thirs possibility is to accept search and examination reports from other patent offices.

Table 6: Sample of IPR-related projects World Bank with costs

Country	Project description	Cost
Brazil, 1997-2002	Train staff administering IPR laws – component of Science and Technology Reform project	$4.0 million
Indonesia, 1997-2003	Improve IPR regulatory framework – component of Information Infrastructure Development project	$14.7 million
Mexico, 1992-96	Established agency to implement industrial property laws – component of Science and Technology Infrastructure project	$32.1 million

Source: Finger and Schuler 1999.

Table 7: Prospective estimates of IPR reform in selected developing countries

Country	Reforms needed	Cost
Bangladesh	Draft new laws, improve enforcement	$250,000 one-time plus $1.1 million annually
Chile	Draft new laws, train staff administering IPR laws	$718,000 one-time plus $837,000 annually
Egypt	Train staff administering IPR laws	$1.8 million
India	Modernize patent office	$5.9 million
Tanzania	Draft new laws, develop enforcement capability	$1.0-1.5 million

Source: UNCTAD 1996

PART THREE:
NEW DEVELOPMENTS IN INTERNATIONAL IPR REGULATION

As was mentioned early, IPRs are dynamic regulatory systems. In addition to TRIPS, two other developments are affecting the evolution of IPR law at the international and national levels: (1) new treaty development; and (2) harmonization. Taking the first development, since the TRIPS Agreement entered into force a number of new multilateral IPR treaties have been negotiated and adopted. Harmonization of substantive IPR law is coming about in two ways. The first is through bilateral treaties between developed and developing countries which tend to require standards of protection to be on the same level as the developed country party and with narrowed-down exceptions. The second is through international and bilateral technical cooperation. There are concerns that such cooperation does not fully take into account the development needs of beneficiary countries nor the flexibilities allowed to them under TRIPS.[220] Another emerging force for harmonization in the area of patent law is WIPO's draft Substantive Patent Law Treaty.

In sum, harmonization is likely to entail making the patent systems of the world more like each other using those of the technologically most advanced countries as the models. The effects of developments (1) and (2) overlap in the sense that both are raising the floor of minimum IPR standards above the level of the TRIPS Agreement and are therefore 'TRIPS plus'. The implications for developing countries are two-fold. First, their options are being *rapidly* narrowed. Second, because they have to be aware of related developments taking place in a wide range of forums and know where their national interest lies with respect to each one, the development of coherent, effective and sustainable policies and negotiating strategies on IPRs is becoming harder than ever before. Ensuring consistency between the positions adopted at the multilateral, regional and bilateral levels, and with national IPR regulations is an enormous challenge and a tall order for any country. In the case of developing countries and least developing countries, it might constitute an impossible endeavour.

Part 3 presents the various forums and agreements promoting the standardization and/or harmonization of IPR rules throughout the world. These include WIPO conventions, regional treaties and institutions, and regional and bilateral free trade agreements.

CHAPTER XI: TRIPS-RELATED DEVELOPMENTS AT THE WTO

In the future historians of trade law may point to 1999 as a year that marked a shift in the balance of power at the WTO. While the Quad countries (the U.S., E.U. member states, Japan and Canada) were still disproportionately powerful, developing countries became more proactive and assertive. More than half of the 250 proposals submitted to the WTO General Council during the preparations for the Seattle Ministerial Conference came from developing countries.[221] Of these 250 proposals, 15 were on TRIPS and 8 came from developing countries.[222] And while many factors contributed to the collapse of the Seattle Conference, criticisms by many developing countries that they were being excluded from key negotiations probably contributed to its failure to launch a new trade round or even to agree on a declaration at all.

At the November 2001 Doha Ministerial Conference, the WTO members agreed on the texts of three statement: the Ministerial Declaration, the Decision on Implementation-related Issues and Concerns, and the aforementioned Declaration on the TRIPS Agreement on Public Health. In the Ministerial Declaration, members agreed 'to negotiate the establishment of a multilateral system of notification and registration of geographical indications for wines and spirits by the Fifth Session of the

Ministerial Conference'. With respect to the extension of the protection of geographical indications to products other than wines and spirits, it was agreed that issues related to this matter would be addressed in the Council for TRIPS. As its work programme including its reviews of Article 27.3(b) and of the implementation of the whole Agreement under Article 71.1, the Council was requested to examine the relationship between TRIPS and the CBD, and the protection of traditional knowledge and folklore. In a brief section on trade and transfer of technology, the Declaration expressed agreement on the establishment of a Working Group to examine 'the relationship between trade and transfer of technology, and of any possible recommendations on steps that might be taken within the mandate of the WTO to increase flows of technology to developing countries.' Clearly this is an IPR-related issue.

The Decision on Implementation-related Issues and Concerns reaffirmed the mandatory nature of Article 66.2 ('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'). The TRIPS Council was directed to establish 'a mechanism for ensuring the monitoring and full implementation of the obligations in question'.

TRIPS is clearly unfinished business. Many developed countries would like to progressively raise the standards. Some developing countries accept the agreement as it is and seek to construe its rules as creatively as possible. Others would like TRIPS to be revised to lower the standards.

On the one hand, developed countries have softened their stance and have decided to focus for the time being on implementation of the existing standards rather than seeking to raise them further (though some of these countries have been actively promoting their preferred interpretations of these existing standards). And while many countries have failed to meet the built-in implementation deadlines, such as the requirement to provide protection for plant varieties by 2000, they are not being challenged at the WTO for this at the present time.

On the other, the U.S. and E.U. have responded by encouraging developing countries to raise their IPR standards *beyond* those required by TRIPS *outside of the WTO*, such as through bilateral treaties. A good example of such a bilateral agreement is the 2000 Agreement Between the United States of America and the Hashemite Kingdom of Jordan on the Establishment of a Free Trade Area, which requires patents to be available for any invention in all fields of technology without including the exception from Article 27.3(b) of TRIPS. Jordan must also join UPOV. In addition, a supplementary memorandum of understanding requires Jordan allow the patenting of business methods and computer-related inventions. While one must assume that the Jordanian government felt it was a good agreement for the country, such patents are highly controversial in the U.S. and Europe. In addition, the U.S. and the E.U. continue to pressure countries with 'inadequate' IPR standards by threatening to remove trade concessions.

CHAPTER XII: NEW TREATY DEVELOPMENT AND HARMONIZATION

Since TRIPS entered into force, WIPO has provided a forum for the development of new IPR treaties. Most notable among these are the 1996 Internet treaties', i.e. the WIPO Copyright Treaty (WCT) and the WIPO Performers and Phonograms Treaty (WPPT). In 2000, the Patent Law Treaty (PLT) was also adopted at a Diplomatic Conference. The PLT was intended to harmonize certain patent procedures but steered clear of matters relating to substantive patent law. However, WIPO has recently drafted a Substantive Patent Law Treaty that the organization's Standing Committee on the Law of Patents is currently debating.

In terms of patent law, the draft Substantive Patent Law Treaty has the potential to harmonize national and regional patent laws almost completely. While the SPLT initiative may never go much further than defining key terms such as prior art, novelty and inventive step, Shozo Uemura, WIPO's Deputy Director-General recently suggested as a future possibility 'the establishment of basic principles regulating an ideal global patent system, according to which a patent granted in a civil procedure would have effect in different countries, and it would co-exist with existing national patent systems'.[223] Obviously, any such system would have to provide agreed standards on the scope of patentable subject matter. And as recent history shows, what the US, EU and Japan agree upon the rest of the world is likely to have to accept.

Away from the Geneva-based intergovernmental agencies, bilateral and regional-level negotiations have been concluded and are also ongoing that have the objective of raising national IPR standards to the level of TRIPS and even beyond. Some of the resulting agreements have required developing countries to promise they will introduce TRIPS standards before the expiry of the transitional periods, and even to introduce higher standards of protection than TRIPS requires. Often such commitments are embedded in free trade agreements. The table below provides details of agreements, which have *inter alia* required developing countries to implement Article 27 of TRIPS in ways that go beyond the required minimum standards.

According to Peter Drahos, there is a good reason why such agreements are becoming common, at least those which have the United States as one of the parties.[224] This is that the developing countries are becoming more effective negotiators at the TRIPS Council and have successfully blocked moves to push standards beyond those that the present text of the Agreement requires.

Table 8: Bilateral and regional agreements securing commitments to TRIPS-plus standards for IPRs on life*

Proponent North	Counterpart South	Type of agreement	Date	TRIPS-plus provisions
AFRICA & MIDDLE EAST				
EU	ACP (Cotonou Agreement)	trade	2000	must patent biotech inventions[225]
EU	Morocco	trade	2000	must join UPOV and Budapest by 2004[226]
EU	Palestinian Authority	trade	1997	'highest international standards'[227]
EU	South Africa	trade	1999	must patent biotech inventions; highest international standards; must undertake to go beyond TRIPS[228]
EU	Tunisia	trade	1998	must join UPOV and Budapest by 2002; 'highest international standards'[229]
US	Jordan	trade	2000	must implement and join UPOV within one year and partially implement Budapest; no exclusions for plants and animals from patent law[230]
US	Sub-Saharan Africa (AGOA)	trade	2000	trade benefits gauged on extent to which countries go beyond TRIPS[231]
ASIA & PACIFIC				
EU	ACP (Cotonou Agreement)	trade	2000	must patent biotech inventions
EU	Bangladesh	trade	2001	must make best effort to join UPOV by 2006[232]
Switzerland	Vietnam	IPR	1999	must join UPOV by 2002[233]
US	Cambodia	trade	1996	must join UPOV[234]
US	Korea	IPR	1986	must join Budapest[235]
US	Mongolia	trade	1991	no exclusions for plants and animals from patent law[236]
US	Singapore	trade	under negotiation	see US-Jordan[237]
US	Sri Lanka	IPR	1991	no exclusions for plants and animals from patent law[238]
US	Vietnam	trade	2000	must implement and make best effort to join UPOV; must provide patent protection on all forms of plants and animals that are not varieties as well as inventions that encompass more than one variety[239]
LATIN AMERICA & CARIBBEAN				

Proponent North	Counterpart South	Type of agreement	Date	TRIPS-plus provisions
EU	ACP (Cotonou Agreement)	trade	2000	must patent biotech inventions
EU	Mexico	trade	2000	must join Budapest within three years; highest international standards[240]
US	Andean countries (ATPA)	trade	1991	trade benefits gauged on extent to which countries go beyond TRIPS[241]
US	Caribbean countries (CBTP)	trade	2000	trade benefits gauged on extent to which countries go beyond TRIPS[242]
US	Ecuador	IPR	1993	must conform with UPOV if no patents on plant varieties[243]
US	Nicaragua	IPR	1998	must join UPOV; no exclusion for plants and animals from patent law[244]
US	Trinidad & Tobago	IPR	1994	must implement and make best effort to join UPOV[245]
US and Canada	Latin America (FTAA/ALCA)	trade	under negotiation	US negotiating position is no exclusions for plants and animals from patent law; actual negotiating text contains many proposals to implement UPOV[246]
US and Canada	Mexico (NAFTA/ TLCAN)	trade	1994	Had to implement and join UPOV within two years[247]

We only present the highly prescriptive trade and IPR agreements from those bilateral treaties surveyed. Omitted from the table in particular are the 1,000 bilateral investment treaties concluded between developed and developing countries, which may eventually be classed as TRIPS-plus pending further research and discussion. Source: Genetic Resources Action International (2001).

PART FOUR:
SUMMARY OF MAIN FINDINGS AND CONCLUSIONS

[TO BE DRAFTED]

ANNEX I: USEFUL PUBLICATIONS ON TRIPS

Blakeney, M. Trade Related Aspects of Intellectual Property Rights: A Concise Guide to the TRIPs Agreement. London, Sweet & Maxwell, 1996.

This book provides a comprehensive textual analysis of the TRIPS Agreement. The first part details the background of TRIPS including its evolution, and introduces the key concepts and institutions of the global IPR system. The second part of the book comprises an in-depth analysis of the whole agreement.

Beier, F.-K. and G. Schricker, eds. From GATT to TRIPS. Weinheim, VCH, 1997.

This book constitutes a comprehensive survey over, and insight into the TRIPS Agreement, from the general rules and special provisions to the obligations of the Member States with regard to the enforcement of the various rights and settlement of disputes. The book also deals with the adoption of the Agreement's provisions into national law, particularly within the framework of the European Community.

Correa, C.M. Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options. London, New York, Penang, Zed Books & Third World Network, 2000.

The author explores the TRIPS Agreement's implications for developing countries. These relate to the future of R&D, their access to advanced technology, commercial exploitation of their natural resources and the welfare effects. He focuses on information technologies, integrated circuits and digital information, and also the conservation and sustainable use of genetic resources for food and agriculture. Correa also indicates some TRIPS-compatible policy options.

Correa, C.M. and A.A. Yusuf, eds. Intellectual Property and International Trade: The TRIPS Agreement. London, The Hague and Boston, Kluwer Law International, 1998.

This work offers a framework for understanding the background, principles and complex provisions of the TRIPS Agreement. It highlights the context in which it was elaborated and adopted, and explains the manner in which it is to be interpreted and applied. The book further analyses the new standards established under TRIPS. Finally, the work aims to stimulate further discussions and analysis in this area of growing importance to international law and international economic relations, particularly in respect of the possibilities offered by TRIPS, the legislative latitudes it leaves its member states and the loose ends that may need to be addressed at national or international level in the future.

Gervais, D. The TRIPS Agreement: Drafting History and Analysis. London, Sweet & Maxwell, 1998.

This guide to the TRIPS Agreement consists of two parts. The first part is a summary of the negotiations themselves including the informal sessions. The second provides information on how to interpret the text of the Agreement, and includes texts of earlier versions and a commentary with each Article of the final version. The purposes of the commentary is to explain the underlying issues, any link with other provisions of the Agreement or of other relevant agreements, the possible impact of other GATT rules or principles of international IPR law, and where this is useful, to point out possible divergencies of views of arguments that may surface in the application of the Agreement.

Maskus, K.E. Intellectual Property Rights in the Global Economy. Washington DC, Institute for International Economics, 2000.

This book provides a comprehensive economic assessment of the effects of stronger IPRs through the TRIPS Agreement. The author presents findings on the potential effects of stronger global IPRs, including likely impacts on foreign direct investment, technology transfer, and pricing under enhanced market power.

United Nations Conference on Trade and Development. The TRIPS Agreement and Developing Countries. New York & Geneva, United Nations, 1996.

This is a study on the financial and other implications of TRIPS on developing countries. Part one assesses the economic implications of TRIPS, focusing on market-related costs and benefits, as well as the direct costs stemming from implementation. It also summarizes the results of selected country case studies carried out for the purpose of this study. Part two deals with the main disciplines covered by TRIPS. It highlights the principal provisions of each of these, its main economic and legal implications, general issues arising from its implementation and the costs involved in implementing the specific discipline. A section containing summaries of the main findings and conclusions of the study and the key issues that might require further consideration is presented. The section also explores the role that international organizations can play in assisting developing countries in their efforts to implement TRIPS.

Watal, J. Intellectual Property Rights in the WTO and Developing Countries London, The Hague and Boston, Kluwer Law International, 2001.

The implementation of TRIPS with its enormous effect on national and global strategies for healthcare, agriculture, and the environment, among other crucial sectors of the world economy is clearly among the most critical projects currently under way in the field of international relations. This book, written by a former TRIPS negotiator for India, assesses the benefits and pitfalls of TRIPS compliance for developing countries. She explains how TRIPS was negotiated at the Uruguay Round, how various countries have implemented it so far, how the WTO monitors compliance, how the WTO dispute settlement process has worked to date in matters involving TRIPS, and how it is likely to deal with new issues that arise. Most importantly, she explains how developing countries can interpret TRIPS to their best advantage, and how to ensure that the "constructive ambiguity" that characterizes the agreement remains flexible.

ANNEX II: KEY ISSUES AND SALIENT FEATURES OF THE TRIPS AGREEMENT

Scope (Art. 1)	Copyright and related rights; trademarks; geographical indications; industrial designs; patents; layout designs of integrated circuits; undisclosed information.
General obligations/basic principles	
National treatment (Art. 3)	Requires all Members to treat nationals of other countries no less favourably than their own nationals on all matters concerning IPRs, subject to certain exceptions already provided in conventions/treaties related to IPRs.
Most-favoured-nation treatment (Art. 4)	Advantages, privileges granted by a Member to the nationals of any other country should be extended unconditionally to the nationals of all other Members.
Exhaustion of intellectual property rights (Art. 6)	For the purposes of dispute settlement, nothing in the Agreement shall be used to address the issue of exhaustion of IPRs, provided there is compliance with national treatment and most-favoured-nation treatment.
Basic objectives and principles (Arts. 7 & 8)	The protection and enforcement of IPRs should contribute to the promotion of technological innovation and to the transfer and dissemination of technology. They should also contribute 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. The Agreement allows members to 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. At the same time, appropriate measures can be taken in order to prevent the abuse of IPRs or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.
Standards	
Copyright and related rights	
Relation to the Berne Convention (Art. 9)	All members are required to comply with the substantive provisions of the Bern Convention except for the obligation on moral rights. Eligible works must be protected on the basis of their expression as a literary work, not on the basis of ideas, procedures, methods of operation or mathematical concepts as such.
Protection of computer programs and compilation of data (Art. 10)	Computer programs are protected (for the normal period of literary works, if the term is calculated on the basis of the life of the author plus). Compilations of data are also protected under the Agreement.

Rental rights (Art. 11)	Members shall provide to authors the rights to authorize or to prohibit the commercial rental of their works or to the public and for cinematographic works unless commercial rental has led to widespread copying which is materially impairing the reproduction rights.
Protection of performers, producers of phonograms & broadcasting organizations (Art. 14)	Specific provisions are introduced for the protection of performers and the term of protection is extended (50 years) (as compared to the Rome Convention).
Trademarks	
Protection of service marks (Arts. 15 & 16)	Provides equal treatment to trade and service marks. Under certain circumstances also provides protection against use of dissimilar goods and services. No cancellation for reason of non-use (if use required to maintain a registration).
Protection of well-known marks (Art. 16)	Well-known marks must be protected even when not used in a country. In determining whether a trademark is well known, the knowledge of the trademark in the relevant sector of the public is to be taken into account (Art. 16.2).
Elimination of restrictions on use of trademarks (Art. 20)	Use of trademarks is not to be encumbered by special requirements, such as use with another trademark.
Geographical indications	
Geographical names (Art. 22)	Provides means to prevent use of geographical direct or indirect names from misleading the public as to the true origin of the good or which constitutes an act of unfair competition.
Additional protection (Arts. 23 & 24)	With regard to wines and spirits, protection must be provided even where there is no threat of the public being misled as to the true origin of the good. A multilateral system of notification and registration will be established for wines eligible for protection.
Industrial designs	
Term of protection (Arts. 25 & 26)	For industrial designs, a protection of at least 10 years is required. Special provisions on textile designs which leave each Member to decide whether to provide protection through copyright law or industrial design law.
Patents	
Scope of protection (Art. 27)	Protection should be available for any inventions, whether products of processes, in all fields of technology Inventions that threaten public order or morality need not be patented, provided

	the commercialization of such inventions is also prohibited. Most biotechnological inventions must also be protected, but plants and animals and essentially biological processes for the production of plants and animals (excluding micro-organisms and micro-biological processes) may be exempted from patent protection.
Non-discrimination (Art. 27.1)	The Agreement requires non-discrimination in the granting of patents and the enjoyment of rights in relation to the field of technology, the place of invention and whether patented products are imported or locally produced.
Term of protection (Art. 33)	The duration of protection must not be less than 20 years from the date of filing application.
Other uses without authorization of the patentholder (Art. 31)	In principle, no restrictions are placed on granting compulsory licensing and government use of patents. However, these practices must respect a number of conditions to prevent patent-holders' rights being undermined. Authorization of such use should be considered on its individual merits. The detailed conditions for granting these authorizations are listed in the Agreement.
Process patents (burden of proof) (Art. 34)	Reversal of the burden of proof in civil proceedings relating to infringements of process patent is to be established in certain cases.
Plant varieties (Art. 27)	Plant varieties, including seeds, must be protected through patent or alternative sui generis means.
Layout designs of integrated circuits (Arts. 35-37)	Substantive provisions of the Washington Treaty must be respected with a number of additional obligations: scope of protection includes not only the protected chip, but also articles incorporating it. Term of protection must be 10 years. An 'innocent infringer' must be free from liability, but once he has received notice of infringement, he is liable to pay a reasonable royalty.
Undisclosed information and test data (Art. 39)	
Protection of trade secrets	Undisclosed information (or trade secrets) must be protected against acquisition, use or disclosure in a manner contrary to honest commercial practices. To benefit from such protection, information must be secret, have commercial value owing to such secrecy, and have been subject to reasonable steps to keep them secret.
Protection of test data	Test data provided by a company in order to gain marketing approval for pharmaceutical and agricultural chemical products, must be protected against unfair commercial use; they must also

	be protected against disclosure, except where necessary to protect the public or unless steps are taken to ensure that the data are protected against unfair commercial use.
Anti-competitive practices in contractual licences (Art. 40)	
Licensing practices	The Agreement recognizes that countries may specify in their domestic legislation the commercial licensing practices that constitute an abuse of intellectual property protection, and take steps to address these through appropriate measures.
Consultations among members	Members must cooperate with each other, including through the provision of information, in investigations of alleged abuse of intellectual property rights that have international dimensions.
Enforcement	
General obligations (Art. 41)	Members must provide effective means of action for any right holder, foreign or domestic, to secure the enforcement of his/her rights, while at the same time preventing abuse of the procedures.
Procedures (Arts. 43-50)	The Agreement specifies procedures for civil and judicial action, including means to produce relevant evidence. Civil remedies that must be available must include injunctions, damages and destruction of infringing goods or disposal of these outside the channels of commerce. Provisional measures must be available to prevent infringing activity and to preserve relevant evidence. Judicial authorities must have the authority to adopt provisional measures inaudita altera parte.
Customs cooperation	Right holders must have the means to obtain the cooperation of the customs authorities in preventing imports of pirated copyright and counterfeit trademark goods.
Criminal procedures (Art. 61)	Criminal procedures and penalties must be available in case of wilful trademark-counterfeiting or copyright piracy on a commercial scale.
Indemnification of the defendant (Art. 48)	Compensation for the abuse of enforcement measures are specified, including payment of defendant expenses, which include appropriate attorney's fees.
Acquisition and maintenance of IPRs (Art. 62)	Procedures or formalities for obtaining intellectual property rights should be fair, reasonably expeditious, not unnecessarily complicated or costly, and generally sufficient to avoid impairment of the value of other commitments.

Dispute settlement (Arts 63 & 64)	The new WTO dispute settlement procedures will apply to the TRIPS Agreement.
Faster procedures	Dispute settlement procedures will be faster than in the GATT because of time limits at each stage of the process. There is no scope for interested parties to block the process of the adoption of recommendations of panels.
Transitional arrangements (Art. 65)	One-year transitional period for all countries to apply the Agreement.
Developing countries	Developing countries can delay application of the Agreement for another four years, except for national treatment and MFN obligations. These countries are entitled to an additional five-year period for introducing product patents in areas of technology (pharmaceuticals and agricultural chemicals) that are not protected at the date of application of the Agreement. This 10-year delay in the implementation of these provisions should be seen in conjunction with Art. 70.8 of the Agreement which provides, in respect of pharmaceutical and agricultural chemical products, the following arrangements: any member who does not make available, as of 1 January 1995, patent protection for the pharmaceutical and agricultural chemical inventions must accept the filing of applications for patents for such inventions (establishment of a 'mailbox' for patent applications claiming such product patents), and must do so from 1 January 1995, even if it is a country which may delay the application of the Agreement, as indicated above. Once the Agreement becomes applicable in that country, it must take a decision in respect of the application (either reject it or grant a patent) but, in doing so, it must apply (retroactively) the criteria of patentability as laid down in the Agreement. If its decision is to grant a patent, that patent will be available for the remainder of the term (Art. 70, para. 8). However, an 'exclusive marketing right' (for a period of five years) must be granted concerning the invention which is the subject matter of the application if, after 1 January 1995, in another country a patent application has been filed and a patent granted for that product and marketing approval obtained in such other Member (Art. 70, para. 9).
Least developed countries	Least developed countries are entitled to delay application of the Agreement, except for national treatment and MFN until 1 January 2006. However, they are also covered by the requirement to protect all pharmaceutical inventions made after the entry into force of WTO.
Technical cooperation (Art. 67)	The Agreement calls upon developed country members to provide technical and financial assistance in favour of developing country members on mutually agreed terms and conditions.

Source: UNCTAD 1996:8-11

ENDNOTES

[1] Though in some cases the rights may be restricted by statutory licenses.

[2] For example, the view that IPRs are *rewards* for inventors and artists for their contribution to the public good.

[3] And this is recognised in the international law of human rights. Article 15.1 of the International Covenant on Economic, Social and Cultural Rights requires state parties 'to recognize the right of everyone … to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.'

[4] This generalization holds in spite of the continental tradition of 'authors' rights' (as opposed to Anglo-American copyright), which suggest the predominance of natural rights over utilitarianism.

[5] Invention and innovation are not interchangeable words. Invention is the first step in the development of a marketable new product or process. Innovation comes afterwards. Joseph Schumpeter's well-known definition of innovation (or what he calls 'carrying out new combinations') comprises '(1) The introduction of a new good …. (2) The introduction of a new method of production … which need by no means be founded upon a discovery scientifically new…. (3) The opening of a new market …. (4) The conquest of a new source of supply of raw materials …. (5) The carrying out of the new organization of any industry …' (Schumpeter 1983[1934]:66). Innovation connotes newness but it is possible to argue that an innovation for one company or national economy may not necessarily be innovative to another. Ernst et al (1998, in Mytelka and Tesfachew 1998:1-2) make this point when they define innovation as 'the process by which firms master and implement the design and production of goods and services that are new to them, irrespective of whether or not they are new to their competitors – domestic or foreign.'

[6] Geroski, P. (1995), 'Markets for technology: knowledge, innovation and appropriability', in P. Stoneman (ed.), *Handbook of the Economics of Innovation and Technological Change*, Oxford and Malden: Blackwell:97.

[7] e.g Merges, R.P., and R.R. Nelson (1990), 'On the complex economics of patent scope', *Columbia Law Review* 90:839-916; Scotchmer, S. (1991), 'Standing on the shoulders of giants: cumulative research and the patent law', *Journal of Economic Perspectives* 5 (1):29-41.

[8] Menell, P.S. (1994), 'The challenges of reforming intellectual property protection for computer software', *Columbia Law Review* 94 (8):2644-2654.

[9] See Levin, R.C., A.K. Klevorick, R.R. Nelson, and S.G. Winter (1987), 'Appropriating the returns from industrial research and development', *Brookings Papers on Economic Activity*, 783-820.

[10] David, P.A. (2002), 'The political economy of public science', in H. Lawton-Smith (ed.), *The Regulation of Science and Technology*, Basingstoke and New York: Palgrave.

[11] This point applies to those developing countries that have attained a reasonable capacity to adopt and benefit from such technologies. Countries with very limited capacity have little to gain from free access to advanced technologies.

[12] Maskus, K. (2000), *Intellectual Property Rights in the Global Economy*, Washington DC: Institute for International Economics.

[13] Klein, N. (2000), *No Logo*, London: Flamingo.

[14] See Braithwaite, J. and P. Drahos (2000), *Global Business Regulation*, Cambridge: Cambridge University Press.

[15] The idea that patent applicants should disclose their inventions and that the dissemination of technical information and not the finished product alone is the inventor's part of the 'bargain' was introduced into patent law from the late 18th century following an English legal decision (see Merges, R.P. (1997), *Patent Law and Policy: Cases and Materials* (second edition), Charlottesville: Michie Law Publishers:657).

[17] MacLeod, C. (1991), 'The paradoxes of patenting: invention and its diffusion in 18th and 19th century Britain, France, and North America', *Technology and Culture* 32 (4):885-911.

[18] Webster, T. (1844), Reports and Notes of Cases on Letters Patent for Inventions, London: Thomas Blenkarn:756-757.

[19] Cornish, W.R. (1999), *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights* (fourth edition), London: Sweet and Maxwell:111.

[20] See Bercovitz-Rodriguez, A. (1990), 'Historical trends in protection of technology in developed countries and their relevance for developing countries', Geneva: United Nations Conference on Trade and Development:2-3.

[21] Officially titled 'An act to promote the progress of useful arts, and to repeal all acts and parts of acts heretofore made for that purpose'.

[22] In German: Reichspatentgesetz.

[23] As opposed to a registration system.

[24] Dessemontet, F. (2000), *Intellectual Property Law in Switzerland*, The Hague, London and Bern: Kluwer Law International and Stämpfli:23.

[25] Schiff, E. (1971), Industrialization without Patents: The Netherlands, 1869-1912, Switzerland, 1850-1907, Princeton: Princeton University Press.

[26] Officially 'An act for the encouragement of learning, by vesting the copies of printed books in the author's or purchaser of such copies, during the times therein mentioned'.

[27] Rose, M. (1993), *Authors and Owners: The Invention of Copyright*, Cambridge and London: Harvard University Press:4; Sherman, B., and L. Bently (1999), *The Making of Modern Intellectual Property Law: The British Experience, 1760-1911*, Cambridge: Cambridge University Press:11-12.

[28] David, P. (1993), 'Intellectual property institutions and the panda's thumb: patents, copyrights, and trade secrets in economic theory and history', in M.B. Wallerstein, R.A. Schoen and M.E. Mogee (eds), *Global Dimensions of Intellectual Property Rights in Science and Technology*, Washington, DC: National Academy Press.

[29] Cornish op cit:343.

[30] By virtue of the Copyright, Designs and Patents Act 1988.

[31] Cornish op cit:48, 50.

[32] For well-researched and convincing evidence to support this view in the U.K. context, see Dutton, H.I. (1984), *The Patent System and Inventive Activity during the Industrial Revolution, 1750-1852*, Manchester: Manchester University Press.

[33] These are: copyright and related rights; trademarks; geographical indications; industrial designs; patents; layout-designs of integrated circuits; and protection of undisclosed information (trade secrets). Among the few IPRs excluded from TRIPS are utility models and plant breeders rights (although plant varieties must be protected whether through patents or an alternative system such as UPOV-style PBRs, or a combination thereof).

[34] e.g Almeida, P.R. de (1995), 'The political economy of intellectual property protection: technological protectionism and the transfer of revenue among nations', *International Journal of Technology Management* 10 (2/3):214-29; Bhagwati, J. (1998), *A Stream of Windows: Unsettling Reflections on Trade, Immigration and Democracy*, Cambridge: MIT Press.

[35] e.g. Cameron, J., and Z. Makuch (1995), 'The UN Biodiversity Convention and the WTO TRIPS Agreement: Recommendations to Avoid Conflict and Promote Sustainable Development', Gland: World Wide Fund For Nature; Yamin, F. (1995), The Biodiversity Convention and Intellectual Property Rights. Gland, Switzerland: World Wide Fund for Nature.

[36] e.g. Brush, S.B., and D. Stabinsky (eds) (1996), *Valuing Local Knowledge: Indigenous People and Intellectual Property Rights*, Washington DC and Covelo: Island Press; Greaves, T., (ed.) (1994),

Intellectual Property Rights for Indigenous Peoples: A Sourcebook, Oklahoma City: Society for Applied Anthropology; Posey, D.A., and G. Dutfield (1996), *Beyond Intellectual Property: Toward Traditional Resource Rights for Indigenous Peoples and Local Communities*, Ottawa: International Development Research Centre.

37 e.g. United Nations Development Programme (1999), *Human Development Report 1999*, New York and Oxford: UNDP and Oxford University Press.

38 The Crucible Group (1994), *People, Plants and Patents: The Impact of Intellectual Property on Trade, Plant Biodiversity, and Rural Society*, Ottawa: International Development Research Centre; Dutfield, G. (2000), *Intellectual Property Rights, Trade and Biodiversity: Seeds and Plant Varieties*, London: Earthscan Books; Mooney, P.R. (1996), *The Parts of Life: Agricultural Biodiversity, Indigenous Knowledge, and the Role of the Third System. Development Dialogue. Special Issue (1996:1–2)*, Uppsala: Dag Hammarskjöld Foundation; Shiva, V. (1996), 'Agricultural biodiversity, intellectual property rights and farmers' rights', *Economic and Political Weekly* (22 June): 1621-1631; Tansey, G. (1999), *Trade, Intellectual Property, Food and Biodiversity: Key Issues and Options for the 1999 Review of Article 27.3(b) of the TRIPS Agreement*, London: Quaker Peace and Service.

39 Oxfam (2001), *Patent Injustice: How World Trade Rules Threaten the Health of the Poor*, Oxford: Oxfam.

40 See Drahos, P. (1999), 'Biotechnology patents, markets and morality', *European Intellectual Property Review* 21 (9):441-449; Overwalle, G. van (ed.) (1998), *Octrooirecht, Ethiek en Biotechnologie/ Patent Law, Ethics and Biotechnology/ Droit des Brevets, Ethique et Biotechnologie*, Brussels: Bruylant; Sterckx, S. (ed.) (1997), *Biotechnology, Morality and Patents*, Aldershot: Ashgate.

41 e.g. Winter, G. (1992). 'Patent law policy in biotechnology'. *Journal of Environmental Law* 4 (2):167-187.

42 Heller, M.A., and R.S. Eisenburg (1998), 'Can patents deter innovation? the anticommons in biomedical research', *Science* 280:698-701.

43 'Biopiracy' is usually applied to the unauthorised commercial use of biological resources and/or associated traditional knowledge (TK) from developing countries, and sometimes also to the patenting of spurious inventions based on such knowledge or resources without compensation. E.g. Baumann, M., J. Bell, F. Koechlin, and M. Pimbert (eds) (1996), *The Life Industry: Biodiversity, People and Profits*, London: Intermediate Technology Publications.

44 e.g Verma, S.K. (1995), 'TRIPS and plant variety protection in developing countries', *European Intellectual Property Review* 17 (6): 281-289.

45 69 bilateral industrial property-related conventions to protect the rights of foreigners were signed between 1859 and 1883 (Ladas, S. (1930), *The International Protection of Industrial Property. Volume 1*, Cambridge: Harvard University Press:54-57). All parties to these conventions were either European, North American or Latin American, but the vast majority were European countries.

46 Albeit with some exceptions, even in Europe. France, the Netherlands and Switzerland do not require prior art searches.

47 The United States is the only country still to have a first-to-invent system (as opposed to first-to-file).

48 Robbins, L.J. (1961), 'The proposed new European patent', *The Patent, Trademark, and Copyright Journal of Research and Education* 5 (3):217-232. In France pharmaceutical patents were examined for novelty from 1960. Novelty examinations for other types of invention were phased in from 1968 (Lynfield, H.G. (1969), 'The new French patent law', *IDEA* 13 (2):201-210).

49 For example, France in 1960, Germany in 1968, Japan in 1976, Switzerland in 1977, Italy and Sweden in 1978, and Spain in 1992.

50 Such as integrated circuit layout-designs.

51 In this context it is noteworthy that for pharmaceuticals average periods for obtaining marketing authorization became shorter during the 1990s (see Panagariya, A. (1999), 'TRIPs and the WTO: an

uneasy marriage'. Mimeo).

52 Ryan, M.P. (1998), *Knowledge Diplomacy: Global Competition and the Politics of Intellectual Property*, Washington DC: Brookings Institution Press:2.

53 The United Nations Development Programme notes (op cit 1999:68) that 70 percent of total royalty and licence fee payments worldwide are between corporations and their overseas affiliates.

54 In Maskus, K.E. (1998), 'The role of intellectual property rights in encouraging foreign direct investment and technology transfer', *Duke Journal of Comparative and International Law* 9 (1):109-161.

55 Patel, P., and K. Pavitt (1995), 'Patterns of technological activity: their measurement and interpretation', in P. Stoneman (ed.), *Handbook of the Economics of Innovation and Technological Change*, Oxford and Malden: Blackwell:24.

56 Article 3, Convention Establishing the World Intellectual Property Organization. Signed at Stockholm on July 14, 1967.

57 The UPOV abbreviation is based on the French name of the organization.

58 http://www.wipo.int/treaties/index.html.

59 For example, some of the language of the European Patent Convention and of Chapter 17 of the North American Free Trade Agreement were incorporated into TRIPS. Having made this point, the national laws of some influential countries may also be used as sources of text to be incorporated into multilateral agreements, although such countries are likely to be few in number (and perhaps only the United States).

60 See Roffe, P. (2000), 'The political economy of intellectual property rights – an historical perspective', in J. Faundez, M.E. Footer and J.J. Norton (eds), *Governance, Development and Globalization: A Tribute to Lawrence Tshuma*, London, Blackstone Press:404-405.

61 Gerhart, P.M. (2000), 'Why lawmaking for global intellectual property is unbalanced', *European Intellectual Property Review* 22 (7):309-313.

62 Emphasis added.

63 Doremus, P.N. (1996), 'The externalization of domestic regulation: intellectual property rights reform in a global era', *Global Legal Studies Journal* 3 (2) (http://www.law.indiana.edu/glsj/vol3/no2/doremus.html).

64 Albeit a flawed one (see Jackson 1997:112-117).

65 Ryan op cit; Sell, S.K. (1998), *Power and Ideas: North-South Politics of Intellectual Property and Antitrust, Suny Series in Global Politics*, Albany: State University of New York Press.

66 Such as by incorporating by reference new WIPO treaties. For example, the United States and the European Union have been suggesting that TRIPS be revised to incorporate the 1996 WIPO Performances and Phonograms Treaty and the WIPO Copyright Treaty (Correa, C.M. (2000), *Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options*, London, New York and Penang: Zed Books and Third World Network:232).

67 See Drahos, P. (2001), 'BITs and BIPs: bilateralism in intellectual property', *Journal of World Intellectual Property* 4 (6): 791-808.

68 In fact, it was agreed to delete the reference to counterfeit goods from the title of the agreement.

69 See Reichman, J.J. (1996-97) 'From free riders to fair followers: global competition under the TRIPS Agreement', *New York Journal of International Law and Politics* 29: 11-93.

70 TRIPS Footnote 14.

71 Kim, L. and Nelson, R.R. (2000), 'Introduction', in L. Kim and R.R. Nelson (eds.), *Technology, Learning, and Innovation: Experiences of Newly Industrializing Economies*, Cambridge: Cambridge University Press.

[72] Kim and Nelson op cit, citing Schnaar, S. (1994), *Managing Imitation Strategy: How Later Entrants Seize Markets from Pioneers*, New York: Free Press.

[73] Evans, G.E. (1996), 'The principal of national treatment and the international protection of industrial property', *European Intellectual Property Review* 18 (3): 149-160:149-151.

[74] UPOV 1978 also contains a reciprocity provision.

[75] United Nations Commission on Human Rights - Sub-Commission on the Promotion and Protection of Human Rights (2000), 'Intellectual property and human rights' - Resolution 2001/21. [E/CN.4/SUB.2/RES/2000/7].

[76] United Nations Commission on Human Rights - Sub-Commission on the Promotion and Protection of Human Rights (2001a), 'Intellectual property rights and human rights. Report of the Secretary-General' [E/CN.4/Sub.2/2001/12]; United Nations Commission on Human Rights, Sub-Commission on the Promotion and Protection of Human Rights (2001b), 'The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights. Report of the High Commissioner' [E/CN.4/Sub.2/2001/13].

[77] United Nations Commission on Human Rights, Sub-Commission on the Promotion and Protection of Human Rights (2001c), 'Intellectual property and human rights' - Resolution 2001/21 [E/CN.4/SUB.2/RES/2001/21].

[78] Oxfam (2001) 'Cutting the cost of global health', Oxfam Parliamentary Briefing No. 16. February 2001.

[79] e.g. Levin et al op cit; Mansfield, E. (1986), 'Patents and innovation: an empirical study', *Management Science* 32(2): 173-181; Taylor, C.T., and Z.A. Silberston (1973), *The Economic Impact of the Patent System: The British Experience*, Cambridge: Cambridge University Press.

[80] Merck (2001), 'Merck & Co., Inc. announces significant reductions in prices of HIV medicines to help speed access in developing world', Press release 7 March 2001

[81] The World Bank (2001), *Global Economic Prospects and the Developing Countries 2002: Making Trade Work for the World's Poor*, Washington DC: The World Bank:138.

[82] World Health Organization (1996), 'Investing in health research and development: report of the ad hoc committee on health research relating to future intervention options', Geneva: Geneva.

[83] Orbinski, J. (2001), 'Health, equity, and trade: a failure in global governance', in G.P. Sampson (ed.), *The Role of the World Trade Organization in Global Governance*, Tokyo: United Nations University:230-231.

[84] Patenting targets chosen by companies to extend their monopolies on drugs may include the following: polymorphs (crystalline forms of the active compound); pharmaceutical forms (i.e. new ways of administering the active compound); selective inventions (elements selected from a group that were not specifically named in earlier patents claiming the group); analogy processes; combinations of known products; optical isomers; active metabolites; prodrugs (inactive compounds that produce active metabolites when introduced into the body); new salts of known substances; variants of existing manufacturing processes; and new uses for old products. See Correa, C.M. (2001), *Trends in Drug Patenting: Case Studies*, Buenos Aires: Corregidor:11-12.

[85] This is not a new practice. As early as 1919 the American Pharmaceutical Association complained about this form of monopolistic 'abuse' and accused the German chemical firms. At that time the Association favoured either compulsory licensing provisions or the abolition of product patents on medicinal chemicals that would cover any process to manufacture it (see American Pharmaceutical Association (1919), 'Report of the Committee on Patents and Trademarks of the American Pharmaceutical Association, August 1919', *Journal of the Patent Office Society* 2(1):76-82).

[86] In the case of 'old' compounds whose effectiveness against a particular disease may take many years to prove, trademarks may be the *only* form of IPR protection available. A good example is the anti-cancer drug taxol (see Goodman, J., and V. Walsh (2001), *The Story of Taxol: Nature and Politics in the Pursuit of an Anti-cancer Drug*, Cambridge: Cambridge University Press).

87 From 1969 to 1989 the number of new chemical entities launched per year on the world market fell from over 90 to under 40 (Chartered Institute of Patent Agents (CIPA) (1998), 'Briefing paper - patenting in the pharmaceutical industry - Supplementary Protection Certificates', London: CIPA).

88 Reuters (2001), 'AstraZeneca holds off rivals as U.S. patent on world's top drug dies', 6 October (http://www.economictimes.com/today/06worl11.htm).

89 Lanjouw, J. (1998), *The Introduction of Pharmaceutical Product Patents in India: 'Heartless Exploitation of the Poor and Suffering'? NBER Working Paper No. 6366*, Cambridge: National Bureau of Economic Research.

90 Attaran, A., and L. Gillespie-White (2001), 'Do patents for antiretroviral drugs constrain access to AIDS treatment in Africa?' *Journal of the American Medical Association* 286 (15):1886-1892.

91 Consumer Project on Technology, Essential Action, Oxfam, Treatment Access Campaign and Health Gap (2001), 'Comment on the Attaran/Gillespie-White and PhRMA surveys of patents on Antiretroviral drugs in Africa' - http://www.cptech.org/ip/health/africa/dopatentsmatterinafrica.html.

92 Bugos, G.E., and D.J. Kevles (1992), 'Plants as intellectual property: American practice, law, and policy in a world context', *Osiris* 7:75-104.

93 Such models include the Organization of African Unity's 'African model legislation for the protection of the rights of local communities, farmers and breeders, and for the regulation of access to biological resources', and the 'Convention of Farmers and Breeders', which was produced by an Indian advocacy group called Gene Campaign. Both were drafted in the late 1990s. Also, the Crucible Group produced a set of options for sui generis intellectual property laws for plant varieties (see Crucible II Group (2001), *Seeding Solutions. Volume 2. Options for National Laws Governing Control over Genetic Resources and Biological Innovations*, Ottawa, Rome and Uppsala: IDRC, IPGRI and Dag Hammarskjöld Foundation). India's recently-passed PBR legislation is unusual in that it diverges from the UPOV standards and may provide a suitable model for other developing countries.

94 Article 5.

95 Article 14.

96 Article 11 of the EU biotechnology inventions directive provides for farmers' privilege.

97 Rangnekar, D. (2002), 'Access to genetic resources, gene-based inventions and agriculture', London: Commission on Intellectual Property Rights.

98 See Kloppenburg Jr., J., and D.L. Kleinman (1987), 'Seed wars: common heritage, private property, and political strategy', *Socialist Review* 95: 6-41.

99 Halewood, M. (1999), 'Indigenous and local knowledge in international law: a preface to sui generis intellectual property protection', *McGill Law Journal* 44:953-996.

100 Food and Agriculture Organization (1993), 'Convention on Biological Diversity and related resolutions'. Commission on Plant Genetic Resources, Fifth session, Rome, 19-23 April 1993 [CPGR/93/Inf.3].

101 As of 7 January 20002, the CBD has 182 state parties plus the European Union.

102 See Charles, D. (2001), 'Seeds of discontent', *Science* 294:773-775.

103 Bensaude-Vincent and Stengers 1996:254-255.

104 Along with appropriate access to genetic resources and appropriate funding (Article 1).

105 Article 16.2.

106 Thailand is another notable non-Party.

107 Paragraph 16(d)(ii).

108 Paragraph 42(c) and (d).

109 The UPOV abbreviation is based on the French name of the organization.

110 See Gaia Foundation and GRAIN op cit.

[111] Riley, K.W. (1996), 'Decentralized breeding and selection: tool to link diversity and development', in L Sperling and M Loevinsohn (eds), *Using Diversity: Enhancing and Maintaining Genetic Resources On-farm*, New Delhi: International Development Research Centre.

[112] Sikinyi pers. comm. 2000.

[113] Pers. comm. 2000.

[114] According to Cullet, foreigners submitted 91 percent of the applications from 1997-1999 (Cullet, P. (2001), 'Plant variety protection in Africa: towards compliance with the TRIPS Agreement', *Journal of African Law* 45(1)).

[115] See Juma, C. (1989), *The Gene Hunters: Biotechnology and the Scramble for Seeds*, Princeton: Princeton University Press:153.

[116] Chirchir, N.J. (1997), 'Harmonization of plant breeders rights and policy in public research institutions in Kenya'. Policy paper prepared as part of the ACTS 'Training Course in Policy Analysis for Africa: Intellectual Property, Technology Transfer and the Convention on Biological Diversity', Jun. 16 – Nov. 26:17.

[117] Roozendaal, G. van (1994), 'Kenyan cut flower export blooming', *Biotechnology and Development Monitor* (21): 6-7.

[118] See Tripp, R. (1997), 'The structure of national seed systems', in R. Tripp (ed.) *New Seed and Old Laws: Regulatory Reform and the Diversification of National Seed Systems*, London: Intermediate Technology Publications on behalf of the Overseas Development Institute.

[119] See Herdt, R.W. (1999), 'Enclosing the global plant genetic commons'. Paper prepared for delivery at the China Center for Economic Research, May 24.

[120] It is true though that cash-strapped governments have to reduce their research expenditures out of necessity and the private sector can play a useful role in taking up the slack.

[121] Groombridge, B. (ed) (1992), *Global Biodiversity: Status of the Earth's Living Resources*, London: Chapman and Hall.

[122] Rangnekar, D. (2000), *Plant Breeding, Biodiversity Loss and Intellectual Property Rights. Economics Discussion Paper 00/5*, Kingston upon Thames: Kingston University - Faculty of Human Sciences.

[123] Vivas-Eugui, D. (2001), 'Negotiations on geographical indications in the TRIPS Council and their effect on the WTO Agricultural negotiations', *Journal of World Intellectual Property* 4(5): 703-728.

[124] Moran, W. (1993), 'Rural space as intellectual property', *Political Geography* 12(3): 263-277.

[125] Summarised from: Downes, D.R., Laird, S.A., (with contributions by G. Dutfield and R. Wynberg) (1999), 'Innovative mechanisms for sharing benefits of biodiversity and related knowledge case studies on geographical indications and trademarks'. Prepared for UNCTAD Biotrade Initiative.

[126] Brevoort, P. (1998), 'The booming U.S. botanical market: a new overview', *Herbalgram* (44).

[127] Field, M. (1998), 'Pacific kava', *Agence France Presse, International news*, March 20.

[128] Lebot, pers. comm.

[129] Lebot, pers. comm., 1998.

[130] Portions of this case study reflect the author's contribution to the following publication: Downes, D.R. and Laird, S.A. (in press) *Innovative Mechanisms for Sharing Benefits of Biodiversity and Related Knowledge: Case Studies on Geographical Indications, Trademarks and Databases*. UNCTAD, Geneva.

[131] The Economic Times (1998), 'India confronts basmati-pinching French', 4 July. (Internet edition http://www.economictimes.com/040798/04econ5.htm).

[132] Dasgupta, S. (1996), 'Ours and theirs', *Down to Earth* (July 15): 13-14.

[133] 'Basmati' is Hindi for 'the fragrant one'.

134 Principe, P. (1998), 'Economics and medicinal plants', in T.R. Tomlinson and O. Olayiwola Akerele (eds), *Medicinal Plants: Their Role in Health and Biodiversity*, Philadelphia: University of Pennsylvania Press.

135 Farnsworth, N. (1988), 'Screening plants for new medicines', in E.O. Wilson (ed.), *BioDiversity*, Washington DC: National Academy Press.

136 Evenson, R.E. (1996), 'Economic valuation of biodiversity for agriculture', in Pan American Health Organization (ed.), *Biodiversity, Biotechnology, and Sustainable Development in Health and Agriculture: Emerging Connections*, Washington DC: PAHO.

137 United Nations Conference on Trade and Development (2000), 'Systems and national experiences for protecting traditional knowledge, innovations and practices. Background note by the UNCTAD secretariat', Geneva: UNCTAD: 6.

138 See Posey, D.A. (ed.) (1999), *Cultural and Spiritual Values of Biodiversity*, Nairobi and London: United Nations Environment Programme and Intermediate Technology Publications.

139 See Cleveland, D.A. and Murray, S.C. (1997), 'The world's crop genetic resources and the rights of indigenous farmers', *Current Anthropology* 38(4): 477-496; Griffiths, T. (1993) 'Indigenous knowledge and intellectual property: a preliminary review of the anthropological literature'. Unpublished paper commissioned by Working Group on Traditional Resource Rights, Oxford.

140 Four Directions Council (1996), 'Forests, indigenous peoples and biodiversity'. Contribution of the Four Directions Council to the Secretariat of the Convention on Biological Diversity, Lethbridge: FDC.

141 A rare exception is a 1995 copyright case in Australia (Milpurruru versus Indofurn Pty. Ltd.). This case involved the unauthorized importation and sale by an Australian firm of carpets manufactured in Vietnam on which had been reproduced the designs of three living and five deceased Aboriginal artists. According to Blakeney this case 'establishe[d] the principle that where the unauthorized reproduction of such works involved a breach of copyright, customary Aboriginal laws on the subject may be taken into account in quantifying the damage which had been suffered'. See Blakeney, M. (1998), 'Communal intellectual property rights of indigenous peoples in cultural expressions', *Journal of World Intellectual Property* 1 (6): 985-1002.

142 A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States . . . 35 USC §102.

143 See 35 USC §102(f).

144 It is worth emphasising the words "may be". Many patents are granted that should not be and the problem seems largely due to the failure of the system to more efficiently enable examiners to identify novelty-destroying prior art published also in the U.S (see www.bustpatents.com).

145 Ganguli, P. (2001), *Intellectual Property Rights: Unleashing the Knowledge Economy*, New Delhi, Tata McGraw Hill:156.

146 In fact, Proctor indicated in his application for a Plant Variety Protection certificate on Enola (that was subsequently granted) that 'the yellow bean, Enola variety, is most likely a landrace from the [Mexican] azufrado-type varieties'. ETC Group (2001), 'Proctor's gamble', News Release: 17 December 2001.

147 ETC Group (2001), 'Proctor's gamble', News Release: 17 December.

148 In Pratt, T. (2001), 'Small yellow bean sets off international patent dispute, *New York Times* 20 March.

149 In Carlsen, L. (2001), 'Little, yellow … different?', www.latintrade.com/newsite/content/archives.cfm?TopicID=3&StoryID=1385.

150 For example, in 1982 the Model Provisions for National Laws on the Protection of Expressions of Folklore Against Illicit Exploitation and Other Prejudicial Actions were adopted by a Committee of Governmental Experts jointly convened by UNESCO and WIPO.

151 See Blakeney op cit.

152 See Boyle, J. (1996), *Shamans, Software, and Spleens: Law and the Construction of the Information Society*, Cambridge and London: Harvard University Press; Jaszi, P. and M. Woodmansee (1996), 'The ethical reaches of authorship, *The South Atlantic Quarterly* 95 (4):947-977.

153 WIPO op cit: 53. For more examples from Africa see Kuruk, P. (1999), 'Protecting folklore under modern intellectual property regimes: a reappraisal of the tensions between individual and communal rights in Africa and the United States', *American University Law Review* 48: 769-849.

154 This is not to suggest that computer programs are unworthy of protection, but that they are hardly works of literature in the strict sense.

155 See Reichman, J.H. (2000), 'The TRIPS Agreement comes of age: conflict or cooperation with the developing countries? *Case Western Reserve Journal of International Law* 32 (3):441-470. It may actually be quite difficult even for sympathetic western trade negotiators to understand why folklore is so important for people in developing countries. This is because folklore in western societies is no longer an integral part of most people's lives and is generally considered as archaic or quaint.

156 TRIPS Article 14.1.

157 Article 2 [emphasis added].

158 Barsh, R.L. (1999), 'Indigenous knowledge and biodiversity', in D.A. Posey (ed.), *Cultural and Spiritual Values of Biodiversity*, London and Nairobi: Intermediate Technology Publications and United Nations Environment Programme: 75.

159 See Blakeney, M. (1999), 'What is traditional knowledge? why should it be protected? who should protect it? for whom?: understanding the value chain' [WIPO Doc. WIPO/IPTK/RT/99/3].

160 Though it may be able to if it could describe a specific formulation, even in fairly non-technical terminology.

161 U.S. patent US4673575 (Composition, pharmaceutical preparation and method for treating viral hepatitis).

162 Shankar, D., A. Hafeel, A. and T.S. Suma (1999), 'Cultural richness of green pharmacy', *COMPAS Newsletter* (2):10-11.

163 A good example is the unwillingness of government policy makers to take seriously proposals that patent applications where appropriate should provide evidence of prior informed consent of indigenous peoples providing knowledge upon which applicants based their inventions. The European Union rejected such a proposal when drawing up the 1998 Directive on the Legal Protection of Biotechnological Inventions.

164 See Vogel, J.H. (1997), 'Bioprospecting and the justification for a cartel', *Bulletin of the Working Group on Traditional Resource Rights* (4):16-17.

165 Information provided by Dr Rocio Alarcon of Ecociencia in seminar at Oxford University, 7 Feb. 2001.

166 Adapted from Posey and Dutfield 1996.

167 World Trade Organization - General Council (1999e), 'Preparations for the 1999 Ministerial Conference. Proposals regarding the TRIPS Agreement (Paragraph 9(a)(ii) of the Geneva Ministerial Declaration). Communication from Venezuela' [WT/GC/W/282].

168 A more detailed proposal for a legal framework on TK was submitted two months later to the General Council by the governments of Bolivia, Colombia, Ecuador, Nicaragua, and Peru. World Trade Organization - General Council (1999f), 'Preparations for the 1999 Ministerial Conference. Proposal on protection of the intellectual property rights relating to the traditional knowledge of local and indigenous communities. Communication from Bolivia, Colombia, Ecuador, Nicaragua, and Peru'

[WT/GC/W/362].

169 World Trade Organization - General Council (1999g), 'Preparations for the 1999 Ministerial Conference. The TRIPS Agreement. Communication from Kenya on behalf of the African Group' [WT/GC/W/302].

170 [WT/GC/W/362].

171 World Intellectual Property Organization (2000), 'Matters concerning intellectual property and genetic resources, traditional knowledge and folklore. Document prepared by the Secretariat' [WO/GA/26/6].

172 World Intellectual Property Organization (2002), 'Elements of a sui generis system for the protection of traditional knowledge. Document prepared by the Secretariat' [WIPO/GRTKF/IC/3/8].

173 By virtue of Decision IV/9 on Implementation of Article 8 (j) and Related Provisions.

174 UNCTAD (2000), *Report of the Expert Meeting on National Experiences and Systems for the Protection of Traditional Knowledge, Innovations and Practices* [TD/B/COM.1/33; TD/B/COM.1/EM.13/3].

175 See http://www.unctad.org/en/special/c1dos5.htm

176 Story, A. (2002), 'Study on intellectual property rights, the Internet, and copyright', London: Commission on Intellectual Property Rights.

177 World Intellectual Property Organization (1998), *Intellectual Property Reading Material*, Geneva, WIPO:260-261.

178 Correa, C.M. (2000), *Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options*, London, New York and Penang: Zed Books and Third World Network.

179 Hybridoma cells result from the fusion of a type of cancer cell known as a myeloma with another antibody-producing cell. Hybridomas produce multiple antibodies of a highly specific type, which are called monoclonal antibodies. The technology has considerable potential in both diagnostics and therapeutics.

180 Genomics refers to the mapping, sequencing and analysis of the full set of genes (i.e. the genome) of different organisms or species. The human genome has always been the most interesting for governments and foundations, as well as for companies seeking to identify commercial applications from genomics.

181 McKelvey, M. (1996), *Evolutionary Innovations: The Business of Biotechnology*, Oxford: Oxford University Press:xxi.

182 Fowler, C. (1994), *Unnatural Selection: Technology, Politics, and Plant Evolution*, Yverdon: Gordon and Breach:173.

183 Bhagavan op cit:3-4.

184 The United Nations Development Programme's World Development Report 2001 ('Making New Technologies Work for Human Development') provides a discussion on the risks and potential of GM technologies in developing countries.

185 See Cornish op cit:226-227.

186 In Greenpeace v Plant Genetic Systems NV.

187 EPO Decision G 01/98 - http://www.european-patent-office.org/dg3/biblio/g980001ex1.htm.

188 See Bruce, D. and A. Bruce (1998), *Engineering Genesis - The Ethics of Genetic Engineering in Non-human Species*, London: Earthscan:223-244.

189 http://www.derwent.com/ipmatters/2001_01/genetics.html.

190 Correa op cit 2000:134.

191 e.g. Barlow, J.P. (1994), 'The economy of ideas: everything you know about intellectual property is wrong', *Wired* March.

[192] e.g. McManis, C.R. (1996), 'Taking TRIPS on the information superhighway: international intellectual property protection and emerging computer technology', *Villanova Law Review* 41 (1): 207-288; Samuelson, P. (1993), 'A case study on computer programs', in M.B. Wallerstein, R.A. Schoen and M.E. Mogee (eds), *Global Dimensions of Intellectual Property Rights in Science and Technology*, Washington, DC: National Academy Press.

[193] European Commission (2002), 'Proposal for a Directive of the European Parliament and of the Council on the patentability of computer-implemented inventions' [COM(2002) 92 final].

[194] See Correa, C.M. (2000), 'Reviewing the TRIPS Agreement, in United Nations Conference on Trade and Development, 'Elements of a positive agenda', in UNCTAD, *Positive Trade Agenda for Developing Countries: Issues for Future Trade Negotiations*, Geneva: UNCTAD.

[195] Governments are also involved in technology transfer. Informal and free-of-charge technology transfers are also possible.

[196] Roffe, P. (1999), 'Transfer of technology and competition policy in the context of a possible', in S. Picciotto and R. Mayne (eds), *Regulating International Business: Beyond Liberalization*, Basingstoke: Macmillan Press:151.

[197] Kim, L. (2002), The Protection of Intellectual Property Rights and Technology Transfer: A Developing Country View. Case Study for the ICTSD-UNCTAD Capacity Building Project on IPRs and Development.

[198] Mugabe, J. and Clark, N. (1996), 'Technology transfer and the Biodiversity Convention: issues of conservation and sustainable use', *Science, Technology and Development* 14 (3):1-31.

[199] Radosevic, S. (1999), *International Technology Transfer and Catch-up in Economic Development*, Cheltenham: Edward Elgar:28.

[200] It is not necessarily the case that technologies can easily be copied. Moreover, with technologies that can be copied, not all developing countries have the S&T capacity to take advantage. India and Brazil are much better placed than, say, Kenya or Burkina Faso to copy advanced foreign technologies.

[201] But having made this point, licensing agreements can also be quite restrictive with respect to the licensees' freedom to use and profit from the technologies.

[202] Maskus, K. (2000), *Intellectual Property Rights in the Global Economy*, Washington DC: Institute for International Economics:123.

[203] Similarly, Vishwarao suggests the possibility that gains for a developing countries from lack of IPR protection would be 'offset by strategic behavior by Northern firms who opt for technology transfer via subsidiary or monopoly production' (Vishwarao, S. (1994), 'Intellectual property rights and the mode of technology transfer', *Journal of Development Economics* 44: 381-402).

[204] The relevance of tacit knowledge goes further than merely casting doubt on the notion of patents as a reward for disclosing an invention. Even without patents, companies may enjoy a powerful position since those wishing to acquire tacit knowledge may have no alternative but to licence it from holding firms.

[205] This situation may be changing somewhat with patent databases being placed on the Internet.

[206] Drahos, P. (1997), 'States and intellectual property: the past, the present and the future', in D. Saunders and B. Sherman (eds), *From Berne to Geneva: Recent Developments in Copyright and Neighbouring Rights*, Brisbane: Australian Key Centre for Cultural and Media Policy and Impart Corporation.

[207] Maskus op cit 1998.

[208] In terms of legislation, administration and enforcement.

[209] See also United Nations Conference on Trade and Development (1996), *The TRIPS Agreement and Developing Countries*, New York and Geneva: United Nations; Finger, J.M. and Schuler, P. (1999), 'Implementation of Uruguay Round commitments: the development challenge'. Presented at the WTO/World Bank Conference on Developing Countries in a Millennium Round, WTO Secretariat, Geneva, 20-21 Sept.

[210] Primo Braga, C.A. and Fink, C. (1999), 'International transactions in intellectual property and developing countries'. Mimeo.

[211] Kirim, A.S. (1985), 'Reconsidering patents and economic development: a case study of the Turkish pharmaceutical industry', *World Development* 13 (2): 219-236.

[212] Kondo, E.K. (1995), 'The effect of patent protection on foreign direct investment', *Journal of World Trade* 29 (6): 97-122.

[213] Kim (2002).

[214] See Stokes, K. (1998), 'Intellectual property rights and the transfer of biotechnology to Zimbabwe'. Biopolicy International No. 20, Nairobi: ACTS Press.

[215] Article 41.1.

[216] Article 41.2.

[217] Article 45.1.

[218] Article 61.

[219] Article 41.5.

[220] See MSF, CPT, Oxfam International and HAI (2002), 'Conference report: implementation of the Doha Declaration on the TRIPS Agreement and public health: technical assistance – how to get it right', which raises this issue.

[221] See Ricupero, R. (2001), 'Rebuilding confidence in the multilateral trading system: closing the "legitimacy gap"', in G.P. Sampson (ed.), *The Role of the World Trade Organization in Global Governance*, Tokyo: United Nations University:40; Sampson, G.P. (2001), 'Overview', in G.P. Sampson (ed.), *The Role of the World Trade Organization in Global Governance*, Tokyo: United Nations University:8.

[222] United Nations Conference on Trade and Development (2000), 'Elements of a positive agenda', in UNCTAD, *Positive Trade Agenda for Developing Countries: Issues for Future Trade Negotiations*, Geneva: UNCTAD:13.

[223] Uemura, S. (2000), 'WIPO update: patent law harmonization and the grace period', *CASRIP Publication Series: Rethinking Intellectual Property* 6: 263-270.

[224] Drahos, P. (2002), 'Developing countries and international intellectual property standard-setting', London: Commission on Intellectual Property Rights:29.

[225] Partnership Agreement between the African, Caribbean and Pacific States and the European Community and its Member States, CE/TFN/GEN/23-OR, ACP/00/0371/00, 8.2.00. http://europa.eu.int/comm/trade/pdf/acp.pdf [Art 45]

[226] Euro-Mediterranean Agreement establishing an association between the European Communities and their Member States, of the one part, and the Kingdom of Morocco, of the other part, Official Journal of the European Communities (OJ) L 070 of 18 March 2000, p. 0002-0204. http://europa.eu.int/eur-lex/en/lif/dat/2000/en_200A0318_01.html [Annex 7, Art 1]

[227] Euro-Mediterranean Interim Association Agreement on trade and cooperation between the European Community, of the one part, and the Palestine Liberation Organization (PLO) for the benefit of the Palestinian Authority of the West Bank and the Gaza Strip, of the other part, Official Journal L 187 of 16 July 1997, p. 0003-0135. http://europa.eu.int/eur-lex/en/lif/dat/1997/en_297A0716_01.html [Title II, Art 33]

[228] Agreement on Trade, Development and Cooperation between the European Community and its Member States, of the one part, and the Republic of South Africa, of the other part, Official Journal L 311 of 4 December 1999 p. 0003-0297. http://europa.eu.int/eur-lex/en/lif/dat/1999/en_299A1204_02.html [Art 46]

[229] Euro-Mediterranean Agreement establishing an association between the European Communities and their Member States, of the one part, and the Republic of Tunisia, of the other part, Official Journal L

097 of 30 March 1998 p. 0002-0183. http://europa.eu.int/eur-lex/en/lif/dat/1998/en_298A0330_01.html [Annex 7]

230 Agreement Between the United States of America and the Hashemite Kingdom of Jordan on the Establishment of a Free Trade Area. http://192.239.92.165/regions/eu-med/middleeast/textagr.pdf [Art 4.1(b), Art 4.18, Art 4.21 and Art 4.29(b)].

231 Trade and Development Act of 2000. http://www.agoa.gov/agoa/agoatext.pdf [Sec B.211.5.b.ii]

232 Cooperation Agreement between the European Community and the People's Republic of Bangladesh on partnership and development, OJ C143 of 21 May 1999. [Art 4.5]

233 Abkommen zwischen dem Schweizerischen Bundesrat und der Sozialistischen Republik Vietnam über den Schutz des geistigen Eigentums und über die Zusammenarbeit auf dem Gebiet des geistigen Eigentums. http://www.admin.ch/ch/d/ff/2000/1521.pdf [Art 2 and Annex 1]

234 Agreement between the United States of America and the Kingdom of Cambodia on Trade Relations and Intellectual Property Rights Protection. http://199.88.185.106/tcc/data/commerce_html/TCC_Documents/CambodiaTrade.html [Art XI.1]

235 Record of Understanding on Intellectual Property Rights. http://199.88.185.106/tcc/data/commerce_html/TCC_2/KoreaIntellectual.html [Sec. B.6]

236 Agreement on Trade Relations between the Government of the United States of America and the Government of the Mongolian People's Republic. http://199.88.185.106/tcc/data/commerce_html/TCC_2/MongoliaTrade.html [Art 9(c)i]

237 The negotiating text is confidential but it is allegedly modeled on the US-Jordan bilateral trade agreement.

238 Agreement on the Protection and Enforcement of Intellectual Property Rights between the United States of America and the Democratic Socialist Republic of Sri Lanka. http://199.88.185.106/tcc/data/commerce_html/TCC_2/Sri_Lanka_Intellectual_Property/Sri_Lanka_Intellectual_Property.html (Sec 2c)

239 Agreement between the United States of America and the Socialist Republic of Vietnam on Trade Relations. http://usembassy.state.gov/vietnam/wwwhbta.html [Chpt II: Art 1.3 and Art 7.2(c)]

240 Economic Partnership, Political Coordination and Cooperation Agreement between the European Community and its Member States, of the one part, and the United Mexican States, of the other part, Official Journal L 276/45 of 28 October 2000. http://europa.eu.int/comm/trade/pdf/oj276_mex.pdf [Art 12.1]. Decision No 1/----- of the Joint Council. http://europa.eu.int/comm/trade/pdf/text_dec.pdf [Title IV, Art 36.2 and 36.4].

241 Andean Trade Preferences Act. http://www.mac.doc.gov/atpa/webmain/legislation1.htm [Sec 3202(d)9 and 3202(c)2b.ii]

242 US-Caribbean Trade Partnership Act of 2000. http://www.mac.doc.gov/CBI/Legislation/cbileg-00.htm [Sec B.211.5.b.ii]

243 Agreement between the Government of the United States of America and the Government of Ecuador Concerning the Protection and Enforcement of Intellectual Property Rights. http://199.88.185.106/tcc/data/commerce_html/TCC_Documents/EcuadorIntellectual.html [Art 6.1(c)]

244 Agreement between the Government of the United States of America and the Government of the Republic of Nicaragua Concerning Protection of Intellectual Property Rights. http://199.88.185.106/tcc/data/commerce_html/TCC_2/NicaraguaIPR.html [Art 1.2 and Art 7.2]

245 Memorandum of Understanding between the Government of the United States of America and the Government of Trinidad and Tobago Concerning Protection of Intellectual Property Rights. http://199.88.185.106/tcc/data/commerce_html/TCC_2/TrinidadTobago_Intellectual_Property/TrinidadTobago_Intellectual_Property.html (Art 1.2)

246 The US negotiating position as of early 2001: http://www.ustr.gov/regions/whemisphere/intel.html. Free Trade Area of the Americas, Draft Agreement, Chapter on Intellectual Property Rights,

FTAA.TNC/w/133/Rev.1, 3 July 2001. http://www.ftaa-alca.org/ftaadraft/eng/ngip_e.doc

[247] North America Free Trade Agreement, Chapter 17, Intellectual Property. http://www.mac.doc.gov/nafta/ch17.htm [Art 1701.2 and Annex 1701.3]