

# Integrating Intellectual Property Rights and Development Policy



## Commission on Intellectual Property Rights

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# Integrating Intellectual Property Rights and Development Policy

**Report of the Commission on Intellectual Property Rights**

London September 2002

**Commission on  
Intellectual Property Rights**



# PREFACE

Clare Short, the Secretary of State for International Development, established the Commission on Intellectual Property Rights in May 2001. We are made up of members from a diversity of countries, backgrounds and perspectives. We have each brought very different viewpoints to the table. We incorporate voices from both developed and developing countries: from science, law, ethics and economics and from industry, government and academia.

I believe that it is a considerable achievement that there is so much that we have been able to agree on about our approach and our basic message. As our title implies, we consider that development objectives need to be integrated into the making of policy on intellectual property rights, both nationally and internationally, and our report sets out ways in which this could be put into practice.

Although appointed by the British Government, we have been given absolute freedom to set our own agenda, devise our own programme of work, and come to our own conclusions and recommendations. We have been given the opportunity and financial support to improve our understanding of the issues through commissioning studies, organising workshops and conferences, and visiting officials and affected groups throughout the world. We have been supported by a wonderfully capable Secretariat supplied by the DFID and the UK Patent Office, and we want to thank them especially.

We first met on 8-9 May 2001, and have held seven meetings since. All or some of us have visited Brazil, China, India, Kenya, and South Africa, and we have consulted with public sector officials, the private sector and NGOs in London, Brussels, Geneva, and Washington. We visited the Pfizer research facility in Sandwich. A list of the main institutions we have consulted appears at the end of the report. We have commissioned seventeen working papers and held eight workshops in London on various aspects of intellectual property. And we held a large conference in London on 21-22 February 2002 to ensure that we could hear questions and concerns from many perspectives. We regard these sessions as important parts of our work in their own right. They brought together a range of individuals with a view to facilitating dialogue and exploring the scope for moving some of the issues forward.

On behalf of all of us I want to thank all those people from all over the world, far too numerous to mention, who provided input to our discussions and who prepared working papers.

Our tasks were to consider:

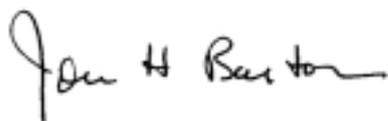
- how national IPR regimes could best be designed to benefit developing countries within the context of international agreements, including TRIPS;
- how the international framework of rules and agreements might be improved and developed – for instance in the area of traditional knowledge – and the relationship between IPR rules and regimes covering access to genetic resources;
- the broader policy framework needed to complement intellectual property regimes including for instance controlling anti-competitive practices through competition policy and law.

We decided early on not just to attempt to suggest compromises among different interest groups, but to be as evidence-based as possible. This has been challenging, for there is often limited or inconclusive evidence, but our Secretariat, extensive consultations, and the papers we commissioned, helped us in identifying the available evidence, which we then carefully evaluated.

We also recognised early on the importance of distinguishing nations (middle or low income) which have substantial scientific and technological capability from those which do not. We attempted to learn about the real impacts of intellectual property, both positive and negative, in each of these groups of nations. We chose to concentrate on the concerns of the poorest, both in low and middle income nations.

We all concur in this report. Our aim is practical and balanced solutions. In some cases we have adopted suggestions made by others but the responsibility for the conclusions is ours alone. We hope that we have fulfilled our task and that the report will be a valuable resource to all those engaged in the debate on how intellectual property rights might better serve to promote development and reduce poverty.

Finally I want to thank Clare Short, and the UK Department for International Development, for their foresight in creating the Commission on Intellectual Property Rights. I have been honoured to chair it. It has been an extraordinary experience for me, and for all of us on the Commission. We received a challenging remit. We greatly enjoyed our task and the opportunity to learn from one another and, in particular, from the many who have contributed to our work.



JOHN BARTON  
Chairman

# FOREWORD

There are few concerned with IP who will find that this report makes entirely comfortable reading. No greater compliment can be paid to Professor Barton and his team of Commissioners. Nor can there be any greater indication of the foresight and courage of Clare Short, the UK Secretary of State for International Development, in creating the Commission and setting its terms of reference in the first place.

Perhaps there is something about the era we live in that has encouraged blind adherence to dogma. This has affected many walks of life. It certainly has affected the whole area of intellectual property rights. On the one side, the developed world side, there exists a powerful lobby of those who believe that all IPRs are good for business, benefit the public at large and act as catalysts for technical progress. They believe and argue that, if IPRs are good, more IPRs must be better. On the other side, the developing world side, there exists a vociferous lobby of those who believe that IPRs are likely to cripple the development of local industry and technology, will harm the local population and benefit none but the developed world. They believe and argue that, if IPRs are bad, the fewer the better. The process of implementing TRIPS has not resulted in a shrinking of the gap that divides these two sides, rather it has helped to reinforce the views already held. Those in favour of more IPRs and the creation of a “level playing field” hail TRIPS as a useful tool with which to achieve their objectives. On the other hand those who believe that IPRs are bad for developing countries believe that the economic playing field was uneven before TRIPS and that its introduction has reinforced the inequality. So firmly and sincerely held are these views that at times it has appeared that neither side has been prepared to listen to the other. Persuasion is out, compulsion is in.

Whether IPRs are a good or bad thing, the developed world has come to an accommodation with them over a long period. Even if their disadvantages sometimes outweigh their advantages, by and large the developed world has the national economic strength and established legal mechanisms to overcome the problems so caused. Insofar as their benefits outweigh their disadvantages, the developed world has the wealth and infrastructure to take advantage of the opportunities provided. It is likely that neither of these holds true for developing and least developed countries.

It is against that background that the Secretary of State decided to set up the Commission and ask it to consider, amongst other things, how national IPR rights could best be designed to benefit developing countries. Inherent in that remit was the acknowledgement that IPRs could be a tool which could help or hinder more fragile economies. The Commissioners themselves represent as impressive a cross-section of relevant expertise as one could wish. They have consulted widely. This report is the result. It is most impressive.

Although the terms of reference have required the Commission to pay particular regard to the interests of developing countries, it has done this without ignoring the interests and arguments of those from the other side. As it states, higher IP standards should not be pressed on developing countries without a serious and objective assessment of their development impact. The Commission has gone a long way to providing such an assessment. This has produced a report which contains sensible proposals designed to meet most of the reasonable requirements of both sides.

However, the production of a series of workable proposals is not enough by itself. What is needed is an acceptance and will to implement them. Once again, in this respect the Commission is playing a major role. This is not the report of a pressure group. The Commission was set up to offer as impartial advice as possible. Its provenance and makeup should encourage all those to whom it is directed to take its recommendations seriously.

For too long IPRs have been regarded as food for the rich countries and poison for poor countries. I hope that this report demonstrates that it is not as simple as that. Poor countries may find them useful provided they are accommodated to suit local palates. The Commission suggests that the appropriate diet for each developing country needs to be decided on the basis of what is best for its development, and that the international community and governments in all countries should take decisions with that in mind. I very much hope this report will stimulate them to do so.

A handwritten signature in black ink, appearing to read "Hugh Laddie". The signature is written in a cursive style with a horizontal line underneath.

SIR HUGH LADDIE  
UK High Court Patents Judge

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# OVERVIEW

## INTRODUCTION

The Millennium Development Goals recognise the crucial importance of reducing poverty and hunger, improving health and education, and ensuring environmental sustainability. The international community has set itself the target of reducing the proportion of people in poverty by half by 2015, along with associated specific targets for improving health and education and environmental sustainability.

It is estimated that in 1999 nearly 1.2 billion people lived on less than \$1 a day, and nearly 2.8 billion people on less than \$2 per day.<sup>1</sup> About 65% of these are in South and East Asia, and a further 25% in sub-Saharan Africa. There were an estimated 3 million deaths from HIV/AIDS in 2001, 2.3 million of them in sub-Saharan Africa.<sup>2</sup> Tuberculosis (TB) accounts for nearly 1.7 million deaths worldwide.<sup>3</sup> On present trends, there will be 10.2 million new cases in 2005.<sup>4</sup> There are also over 1 million deaths annually from malaria.<sup>5</sup> In 1999 there were still 120 million children not in primary school. Sub-Saharan Africa has the lowest current enrolment rate at 60%.<sup>6</sup>

It is our task to consider whether and how intellectual property rights (IPRs) could play a role in helping the world meet these targets – in particular by reducing poverty, helping to combat disease, improving the health of mothers and children, enhancing access to education and contributing to sustainable development. It is also our task to consider whether and how they present obstacles to meeting those targets and, if so, how those obstacles can be removed.

Some argue strongly that IPRs are necessary to stimulate economic growth which, in turn, contributes to poverty reduction. By stimulating invention and new technologies, they will increase agricultural or industrial production, promote domestic and foreign investment, facilitate technology transfer and improve the availability of medicines necessary to combat disease. They take the view that there is no reason why a system that works for developed countries could not do the same in developing countries.

Others argue equally vehemently the opposite. IP rights do little to stimulate invention in developing countries, because the necessary human and technical capacity may be absent. They are ineffective at stimulating research to benefit poor people because they will not be able to afford the products, even if developed. They limit the option of technological learning through imitation. They allow foreign firms to drive out domestic competition by obtaining patent protection and to service the market through imports, rather than domestic manufacture. Moreover, they increase the costs of essential medicines and agricultural inputs, affecting poor people and farmers particularly badly.

In assessing these opposing arguments, it is important to remember the technological disparity between developed and developing countries as a group. Low and middle income developing countries account for about 21% of world GDP,<sup>7</sup> but for less than 10% of worldwide research and

development (R&D) expenditure.<sup>8</sup> The OECD countries spend far more on R&D than India's total national income.<sup>9</sup> Almost without exception, developing countries are net importers of technology.

It is essential to consider the diversity of developing countries in respect of their social and economic circumstances and technological capabilities. Altogether more than 60% of the world's poor live in countries that have significant scientific and technological capabilities, and the great majority of them live in China and India. China and India, along with several other smaller developing countries, have world class capacity in a number of scientific and technological areas including, for instance, space, nuclear energy, computing, biotechnology, pharmaceuticals, software development and aviation.<sup>10</sup> By contrast, 25% of poor people live in Sub-Saharan Africa (excluding South Africa), mainly in countries with relatively weak technical capacity.<sup>11</sup> It is estimated that in 1994 China, India and Latin America together accounted for nearly 9% of worldwide research expenditure, but sub-Saharan Africa accounted for only 0.5% and developing countries other than India and China only about 4%.<sup>12</sup>

Thus developing countries are far from homogeneous, a fact which is self-evident but often forgotten. Not only do their scientific and technical capacities vary, but also their social and economic structures, and their inequalities of income and wealth. The determinants of poverty, and therefore the appropriate policies to address it, will vary accordingly between countries. The same applies to policies on IPRs. Policies required in countries with a relatively advanced technological capability where most poor people happen to live, for instance India or China, may well differ from those in other countries with a weak capability, such as many countries in sub-Saharan Africa. The impact of IP policies on poor people will also vary according to socio-economic circumstances. What works in India, will not necessarily work in Brazil or Botswana.

## BACKGROUND

Over the last twenty years or so there has been an unprecedented increase in the level, scope, territorial extent and role of IP right protection.<sup>13</sup> Manifestations of this include:

- The patenting of living things and materials found in nature, as opposed to man-made products and processes more readily recognisable to the layman as inventions
- The modification of protection regimes to accommodate new technologies (particularly biotechnology and information technology), such as the EU Biotechnology Directive<sup>14</sup> or the Digital Millennium Copyright Act (DMCA) in the United States (US)
- The extension of protection into new areas such as software and business methods, and the adoption in some countries of new *sui generis* regimes for semiconductors and databases
- A new emphasis on the protection of new knowledge and technologies produced in the public sector
- The focus on the relationship between IP protection and traditional knowledge,<sup>15</sup> folklore and genetic resources
- The geographical extension of minimum standards for IP protection through the TRIPS agreement (see Box O.1), and of higher standards through bilateral and regional trade and investment agreements
- The widening of exclusive rights, extension of the duration of protection, and strengthening of enforcement mechanisms.

The concerns about the operation of the intellectual property system and the extension of IPRs are not confined to their application to developing countries. There are currently two prominent enquiries in the US, one by the National Academies of Science and one by the Department of Justice and the Federal Trade Commission, looking at this important question.<sup>16</sup> These concerns centre on the rapid increase in patent applications in the US in recent years (a more than 50% increase in the last five years), and the perception that many more patents of "low quality" and broad scope are being issued. A fear is commonly expressed that too many patents have been and may be granted

## Box O.1 The World Trade Organisation and the TRIPS Agreement

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)<sup>17</sup> emerged from the Uruguay Round of trade negotiations completed in 1994. The Final Act of these negotiations created the World Trade Organisation (WTO) and set out rules – the WTO Agreements including TRIPS – with which members of the WTO have to comply. A dispute settlement system was also streamlined to resolve trade disputes between WTO Members. The WTO, as of January this year, has 144 Members, accounting for over 90% of world trade. Over 30 further countries are negotiating membership.

TRIPS requires all WTO Members to provide minimum standards of protection for a wide range of IPRs including copyright, patents, trademarks, industrial designs, geographical indications, semiconductor topographies and undisclosed information. In doing so, TRIPS incorporates provisions from many existing IP international agreements such as the Paris and Berne Conventions administered by the World Intellectual Property Organisation (WIPO). TRIPS however also introduces a number of new obligations, particularly in relation to geographical indications, patents, trade secrets, and measures governing how IP rights should be enforced.

A special body, the Council for TRIPS (commonly known as the TRIPS Council), on which each WTO Member is represented, was established to administer the operation of the TRIPS. The TRIPS Council is responsible for reviewing various aspects of TRIPS as mandated in the agreement itself and also as requested by the biennial WTO Ministerial Conference.

Among the issues raised by TRIPS that have provoked the most discussion are:

- whether the objective set out in Article 7 that IPRs should contribute to the transfer of technology is achievable, particularly in respect of developing country members of the WTO.
- the perceived tensions between Article 8 which allows countries to adopt measures necessary to protect public health, and to prevent abuses of IP rights, provided they are TRIPS consistent, and other requirements in the agreement. These include the requirements to provide patent protection for pharmaceutical products, limitations on the conditions for issuing of compulsory licences (Article 31) and on the scope of provisions providing exceptions to patent rights (Article 30).
- the requirement to protect test data against “unfair commercial use” in Article 39.
- the justification for providing additional protection for geographical indications for wines and spirits, (Article 23) and whether this additional protection should also be extended to cover other or all geographical indications.
- the extent to which patents should be allowed on inventions relating to living forms, for example microorganisms (Article 27.3(b)), and the requirement to provide IP protection for plants. In that context, the compatibility of TRIPS with agreements such as the Convention on Biological Diversity (CBD) has been raised.
- the cost of meeting the requirements of TRIPS for many developing and least developed WTO Members in relation to the administration of IP rights and their effective enforcement.

TRIPS took effect on 1 January 1995. WTO Members considered as developed countries were given one year to comply whilst developing countries and transition economies were given until 1 January 2000 although for developing countries required to extend product patent protection to new areas such as pharmaceuticals, a further five years was provided before such protection had to be introduced. Least Developed Countries (LDCs)<sup>18</sup> are expected to enact TRIPS by 2006 although the Doha Ministerial Declaration on the TRIPS Agreement and Public Health allowed them a further 10 years in respect of pharmaceutical products.

Where there are disputes over the interpretation of TRIPS and its implementation by national laws, members may bring cases to the WTO’s Disputes Settlement Body (DSB) to resolve. To date there have been 24 cases involving TRIPS, where the disputes procedures have been invoked. Of these 23 were brought by developed country members, and one by Brazil. Sixteen were disputes between developed countries, seven were cases brought by developed against developing countries, and one by Brazil against the US. Of the 24, ten have been settled by mutual agreement, seven were decided by panels set up under the procedure, and seven are still pending.

in respect of developments of minor importance. For instance, in the pharmaceutical industry this can have the effect of prolonging monopolies on valuable therapies. Patents may also be granted in some jurisdictions over biological materials on the grounds that they have been isolated from nature, if a possible function or utility is identified. The extent to which such practices affect competition by making it more difficult for rival inventors to sell competing products, or more expensive for consumers to buy them, is a matter of concern and growing debate. Considerable debate also exists about their effect on research, particularly in software and biotechnology, where patents taken at an early stage in the research process may be an obstacle to downstream research and commercialisation.

In a seminal article, the biologist Garrett Hardin<sup>19</sup> coined the phrase “tragedy of the commons” to explain how common resources tended to be overutilised in the absence of rules for their use. The proliferation of IPRs, particularly in areas such as biomedical research, has suggested the possibility of “a different tragedy, an “anticommons” in which people underuse scarce resources because too many owners can block each other...more intellectual property rights may lead paradoxically to fewer useful products for improving human health.”<sup>20</sup> Companies may now incur considerable costs, in time and money, determining how to do research without infringing other companies’ patent rights, or defending their own patent rights against other companies. This gives rise to a question as to whether the substantial costs involved in patent searching, analysis and litigation are a necessary price to pay for the incentives offered by the patent system, or whether ways can be found to reduce them.

The issues are not confined to patents. In the US, the term of copyright has extended in the last century from 28 years (renewable for a further 28 years) under the 1909 Copyright Act to 70 years after the death of the author, or 95 years from publication (in line with European practice). The question is whether this extension of protection can credibly be regarded as enhancing the incentives for future creation, or whether it is more about enhancing the value of existing creations. In 1998, Congress passed the Digital Millennium Copyright Act (DMCA) which, *inter alia*, forbids the circumvention of technological protection (i.e. encryption). In Europe, the Database Directive requires all Member States to provide *sui generis* protection for any collection of data arranged in a systematic way, whether the data itself is original or not. So far the US has not followed this approach. Increasingly there is concern that protection, under the influence of commercial pressures insufficiently circumscribed by considerations of public interest, is being extended more for the purpose of protecting the value of investments than to stimulate invention or creation.

We think that the concerns about the impact of IP in the US and other developed countries are important for developing countries as well. But we consider that, if anything, the costs of getting the IP system “wrong” in a developing country are likely to be far higher than in developed countries. Most developed countries have sophisticated systems of competition regulation to ensure that abuses of any monopoly rights cannot unduly affect the public interest. In the US and the EU, for example, these regimes are particularly strong and well-established. In most developing countries this is far from being the case. This makes such countries particularly vulnerable to inappropriate intellectual property systems. We consider that developing countries can seek to learn from the experience of developed countries in devising their own intellectual property systems suitable to their particular legal system and economic situation.

Apart from the impact of local intellectual property rules internally in a developing country, there are also indirect impacts of the developed country intellectual property system on developing countries. In the digital age, restrictions on access to materials and data on the Internet affect everyone. Scientists in developing countries, for instance, may be prevented from gaining access to protected data, or have insufficient resources to do so. Research on important diseases or new crops affecting developing countries, but carried out in developed countries, may be hampered or

promoted by the IP system. The IP regime in developed countries may provide powerful incentives to do research of particular kinds which mainly benefit people in developed countries, diverting intellectual resources from work on problems of global significance. Practice in developed countries may allow knowledge or genetic resources originating in developing countries to be patented without prior arrangements for sharing any benefits from commercialisation. In some cases developing country exports to developed countries may be restricted as a result of such protection.

Equally important for developing countries is the continuing trend towards the global harmonisation of IP protection. The movement towards harmonisation is not new – it has been going on for over 100 years. However the TRIPS agreement, that entered into force, subject to specified transitional periods, in 1995 (see Box O.1) has made minimum standards of IP protection mandatory for WTO members. But TRIPS is only one element of international harmonisation. There are continuing discussions in WIPO aimed at further harmonisation of the patent system, which may supersede TRIPS. Moreover, bilateral or regional trade and investment agreements between developed and developing countries often include mutual commitments to implement IP regimes that go beyond TRIPS minimum standards. Thus there is sustained pressure on developing countries to increase the levels of IP protection in their own regimes, based on standards in developed countries.

We have also been struck by the inconclusive and contested nature of much of the economic research devoted to elucidating the impact of IPRs, even in relation to the developed world. There is much that is uncertain, and given the nature of the subject, may remain so. The impact of IPRs is very often contingent on particular circumstances and context. Many academic observers, for this reason, remain determinedly ambivalent as to whether the social benefits of IPRs exceed their costs. Typical of these is the following example:

“It is almost impossible to conceive of any existing social institution {the patent system} so faulty in so many ways. It survives only because there seems nothing better to do.”<sup>21</sup>

In the case of developing countries, several recent reports by international agencies have commented on the likely impact of the globalisation of IP protection on developing countries.<sup>22</sup> All of these reports reflect to varying extents a concern that heavy costs may be incurred, but that the benefits for many countries are less easy to identify.

## OUR TASK

We take the setting up of our Commission to be evidence that the British government is sensitive to these concerns. In that light our fundamental task is to consider whether the rules and institutions of IP protection as they have evolved to date can contribute to development and the reduction of poverty in developing countries.

Our starting point is that some IP protection is likely to be appropriate at some stage for developing countries, as it has been historically for developed countries. There is no doubt that it can make an important contribution to research and innovation in developed countries, particularly in industries such as pharmaceuticals and chemicals. The system provides the incentive for individuals and companies to invent and develop new technologies that may benefit society. But incentives work differently according to whether there is a capacity to respond to them. And, by conferring exclusive rights, costs are imposed on consumers and other users of protected technologies. In some cases, protection means that potential consumers or users, who are unable to pay the prices charged by IP owners, are deprived of access to the innovations the IP system is intended to make available. The balance of costs and benefits will vary according to how rights are applied and economic and social circumstances. Standards of IP protection that may be suitable for developed countries may cause greater costs than benefits when applied in developing countries which must

rely in large part on knowledge or products embodying knowledge generated elsewhere to satisfy basic needs and foster their development.

## The Nature of Intellectual Property Rights

Some see IP rights principally as economic or commercial rights, and others as akin to political or human rights. The TRIPS agreement treats them in the former sense, while recognising the need to strike a balance between the rights of inventors and creators to protection, and the rights of users of technology (Article 7 of TRIPS). The Universal Declaration of Human Rights has a broader definition recognising “the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author”, balanced by “the right...to share in scientific advancement and its benefits.”<sup>23</sup> The crucial issue is to reconcile the public interest in accessing new knowledge and the products of new knowledge, with the public interest in stimulating invention and creation which produces the new knowledge and products on which material and cultural progress may depend.

The difficulty is that the IP system seeks to achieve this reconciliation by conferring a private right, and private material benefits. Thus the (human) right to the protection of “moral and material interests” of “authors” is inextricably bound up with the right to the private material benefits which result from such protection. And the private benefit to the creator or inventor is derived at the expense of the consumer. Particularly where the consumer is poor, this may conflict with basic human rights, for example, the right to life. And the IP system, as manifested in TRIPS, does not allow – except in rather narrow ways - discrimination between goods essential to life or education, and other goods such as films or fast food.

We therefore consider that an IP right is best viewed as one of the means by which nations and societies can help to promote the fulfilment of human economic and social rights. In particular, there are no circumstances in which the most fundamental human rights should be subordinated to the requirements of IP protection. IP rights are granted by states for limited times (at least in the case of patents and copyrights) whereas human rights are inalienable and universal.<sup>24</sup>

For the most part IP rights are nowadays generally treated as economic and commercial rights, as is the case in TRIPS, and are more often held by companies rather than individual inventors. But describing them as “rights” should not be allowed to conceal the very real dilemmas raised by their application in developing countries, where the extra costs they impose may be at the expense of the essential prerequisites of life for poor people.

Regardless of the term used for them, we prefer to regard IPRs as instruments of public policy which confer economic *privileges* on individuals or institutions solely for the purposes of contributing to the greater public good. The *privilege* is therefore a means to an end, not an end in itself.

Thus in terms of assessing the value of IP protection, it may be compared to taxation. Hardly anybody claims that the more taxation there is, the better. However, there is a tendency among some to treat more IP protection as self-evidently a good thing. More taxation might be desirable if it delivers public services that society values more than the direct and indirect cost of taxation. But less can also be beneficial, for instance if excessive taxation is harming economic growth. Moreover, economists and politicians spend much time considering whether the structure of the tax system is optimal. Are heavy social security taxes harming employment? Are particular tax breaks serving their intended purpose, or merely subsidising their recipients to do what they are already doing? Is the effect of the tax system on the distribution of income desirable from a social point of view?

We think there are very analogous questions for intellectual property. How much of it is a good thing? How should it be structured? How does the optimal structure vary with sectors and levels of development? Moreover, even if we get the level and structure of protection right, to balance the

incentive to invention and creation against the costs to society, we also have to worry about the distribution of gains.

## Equitable Sharing of Benefits and Costs

The immediate impact of intellectual property protection is to benefit financially those who have knowledge and inventive power, and to increase the costs of access to those without. This is obviously relevant to the distribution of gains between developed and developing societies. Even if there were economic gains to the world as a whole from extending protection, on which there is some debate, the distributional consequences for income may not accord with our sense of equity. In the majority of developing countries, with weak scientific and technical infrastructures, the benefits in the form of the stimulus to domestic innovation will be muted, but they will still face the costs arising from the protection of (mainly foreign) technologies. Thus the costs and the benefits of the system as a whole may not be fairly distributed.

If most developing countries do not have a strong technological base which could benefit from IP protection, they do have genetic resources and traditional knowledge, which have value both to them and to the world at large. These are not necessarily IP resources in the sense that they are understood in developed countries, but they are certainly resources on the basis of which protected intellectual property can be, and has been, created. This raises a number of difficult issues as to whether and how these resources should interact with, and be valued by, the “modern” IP system, the extent to which these resources and knowledge require their own protection (not just in the IP sense), and how commercial benefits derived from these resources should be equitably shared.

The Internet also offers enormous opportunities for access to information required by developing countries, in particular scientists and researchers, whose access to printed media may be limited by lack of resources. But there is a concern that forms of encryption (or “digital rights management”), designed to counter widespread copying, will make material less accessible than is now the case with printed media. Such trends endanger the concept of “fair use”<sup>25</sup> (and similar doctrines) as it applies now to printed works, and at the extreme may provide the equivalent of perpetual copyright protection, by technological rather than legal means.

## How Should Intellectual Property Policy be Made?

When there is so much uncertainty and controversy about the global impact of IPRs, we believe it is incumbent on policy makers to consider the available evidence, imperfect as it may be, before further extending property rights in scope or territorial extent.

Too often the interests of the “producer” dominate in the evolution of IP policy, and that of the ultimate consumer is neither heard nor heeded. So policy tends to be determined more by the interests of the commercial users of the system, than by an impartial conception of the greater public good. In IPR discussions between developed and developing countries, a similar imbalance exists. The trade ministries of developed nations are mainly influenced by producer interests who see the benefit to them of stronger IP protection in their export markets, while the consumer nations, mainly the developing countries, are less able to identify and represent their own interests against those of the developed nations.

Thus we recognise that the rules and practices of intellectual property, and how they evolve, are the product of political economy. Developing countries - and in particular poor consumers of products which may be protected by IP rights - negotiate from a position of relative weakness. There is a fundamental asymmetry in relationships between developed and developing countries, based ultimately on their relative economic strength.

The negotiations on TRIPS in the Uruguay Round are but one example. Developing countries accepted TRIPS not because at the time the adoption of intellectual property protection was high on their list of priorities, but partly because they thought the overall package offered, including the reduction of trade protectionism in developed countries, would be beneficial. Now many of them feel that the commitments made by developed countries to liberalise agriculture and textiles and reduce tariffs, have not been honoured, while they have to live with the burdens of the TRIPS agreement. The agreement on a new “development” WTO Round at Doha last year recognises that this bargain, between developed and developing countries, needs to be made explicit and meaningful.

The difficulty for developing countries in this context is that they are “second comers” in a world that has been shaped by the “first comers”. And because of that, it is a very different world from that in which the “first comers” developed. It is a cliché to say that we live in an age of globalisation, when the world economy is becoming more integrated. It is an article of faith in the international community that integration on appropriate terms into the world economy is a necessary condition for development. The question from our point of view is what are the appropriate terms for that integration in the field of IPRs. Just as the now-developed countries moulded their IP regimes to suit their particular economic, social and technological circumstances, so developing countries should in principle now be able to do the same.

We therefore conclude that far more attention needs to be accorded to the needs of the developing countries in the making of international IP policy. Consistent with recent decisions of the international community at Doha and Monterrey, the development objectives need to be integrated into the making of IP rules and practice. At Monterrey in March 2002, governments welcomed “the decisions of the World Trade Organization to place the needs and interests of developing countries at the heart of its work programme”. They also acknowledged the concerns of developing countries, including:

“the lack of recognition of intellectual property rights for the protection of traditional knowledge and folklore; the transfer of knowledge and technology; the implementation and interpretation of the Agreement on Trade-Related Aspects of Intellectual Property Rights in a manner supportive of public health...”<sup>26</sup>

We believe this is a satisfactory but partial agenda. There is far more that needs to be thought about and done in considering the impact of the existing system upon developing countries. It is our contention that intellectual property systems may, if we are not careful, introduce distortions that are detrimental to the interests of developing countries. Very “high” standards of protection may be in the public interest in developed countries with highly sophisticated scientific and technological infrastructures (although we note, as above, that this is controversial in several respects), but this does not mean the same standards are appropriate in all developing countries. In fact we consider that developed countries should pay more attention to reconciling their own perceived commercial self-interest, with their own interest in the reduction of poverty in developing countries.

To achieve that end, so far as possible developing countries should not be deprived of the flexibility to design their IP systems that developed countries enjoyed in earlier stages of their own development, and higher IP standards should not be pressed on them without a serious and objective assessment of their development impact. We need to ensure that the global IP systems evolve so that they may contribute to the development of developing countries, by stimulating innovation and technology transfer relevant to them, while also making available the products of technology at the most competitive prices possible. We need to make sure that the IP system facilitates, rather than hinders, the application of the rapid advances in science and technology for the benefit of developing countries.

We hope our report will make a contribution by defining an agenda for making the global IPR system, and the institutions in that system, work better for poor people and developing countries.

We have identified a number of key issues for developing countries which we deal with in the following chapters:

- What can we learn from the economic and empirical evidence about the impact of IP in developing countries? Does the historical experience of developed countries hold any lessons for developing countries today? How can technology transfer to developing countries be facilitated? (Chapter 1)
- How does the IP system contribute to the development of medicines that are needed by poor people? How does it affect the access of poor people to medicines and their availability? What does this imply for IP rules and practices? (Chapter 2)
- Can IP protection on plants and genetic resources benefit developing countries and poor people? What sort of systems should developing countries consider for protecting plant varieties while safeguarding farmers' rights? (Chapter 3)
- How could the IP system contribute to the principles of access and benefit sharing enshrined in the Convention on Biological Diversity (CBD)? Can it help to protect or promote traditional knowledge, biodiversity and cultural expressions? Can the extension of Geographical Indications<sup>27</sup> (GIs) benefit developing countries? (Chapter 4)
- How does copyright protection affect developing countries' access to knowledge, technologies and information that they need? Will IP or technological protection affect access to the Internet? How can copyright be used to support creative industries in developing countries? (Chapter 5)
- How should developing countries frame their own legislation and practice on patents? Can developing countries frame their legislation in ways that might avoid some of the problems that have occurred in developed countries? What would be the best position for developing countries in relation to patent harmonisation? (Chapter 6)
- What sort of institutions do developing countries need to administer, enforce and regulate IP effectively and how can these be established? What complementary policies and institutions are necessary, in particular in relation to competition? (Chapter 7)
- Are the international and national institutions involved in IPRs as effective as they could be in serving the interests of developing countries? (Chapter 8)

<sup>1</sup> World Bank (2001) *“Global Economic Prospects and the Developing Countries 2002: Making Trade Work for the World’s Poor”*, World Bank, Washington DC, p.30.

Source: <http://www.worldbank.org/prospects/gep2002/full.htm>

<sup>2</sup> UNAIDS & WHO (2001) *“Aids Epidemic Update”*, UNAIDS/WHO, Geneva.

Source: [http://www.unaids.org/worldaidsday/2001/Epiupdate2001/Epiupdate2001\\_en.pdf](http://www.unaids.org/worldaidsday/2001/Epiupdate2001/Epiupdate2001_en.pdf)

<sup>3</sup> WHO (2001) *“Global Health Report 2001”*, WHO, Geneva. Statistical Annex, Table 2. *“Deaths by cause, sex and mortality stratum in WHO Regions, estimates for 2000”*.

Source: <http://www.who.int/whr/2001/main/en/pdf/annex2.en.pdf>

<sup>4</sup> World Bank Data. Source: [http://www.developmentgoals.org/Hiv\\_Aids.htm](http://www.developmentgoals.org/Hiv_Aids.htm)

<sup>5</sup> WHO (2001).

<sup>6</sup> World Bank Data. Source: <http://www.developmentgoals.org/Education.htm>

<sup>7</sup> World Bank Data. Source: <http://www.worldbank.org/data/databytopic/GDP.pdf>. In this report, we define developing countries as those classified by the World Bank as low income, lower middle income and upper middle income. Source: <http://www.worldbank.org/data/countryclass/classgroups.htm>

<sup>8</sup> See note 12 below.

<sup>9</sup> OECD Expenditure in 1999 was \$553 billion. OECD (2001) *“OECD Science, Technology and Industry Scoreboard 2001 - Towards a knowledge-based economy”*, OECD, Paris.

Source: <http://www1.oecd.org/publications/e-book/92-2001-04-1-2987/A.2.htm>. India’s national income was \$440 billion. World Bank Data.

Source: <http://www.developmentgoals.org/Data.htm>

- <sup>10</sup> One measure of technological capability is the number of US patents taken out annually. Those developing countries which were granted over 50 US patents in 2001 included: China 266, India 179, South Africa 137, Brazil 125, Mexico 87, Argentina 58, Malaysia 56. China (Taiwan) received 6545 and Korea 3763 but these are not developing countries on the World Bank classification.  
Source: [http://www.uspto.gov/web/offices/ac/ido/oeip/taf/cst\\_all.pdf](http://www.uspto.gov/web/offices/ac/ido/oeip/taf/cst_all.pdf)
- <sup>11</sup> This region received a total of only 10 US patents in 2001.  
Source: [http://www.uspto.gov/web/offices/ac/ido/oeip/taf/cst\\_all.pdf](http://www.uspto.gov/web/offices/ac/ido/oeip/taf/cst_all.pdf)
- <sup>12</sup> In 1994, China accounted for 4.9% of global R&D expenditure, India and Central Asia for 2.2%, Latin America for 1.9%, the Pacific and South East Asia 0.9% (excludes newly industrialised countries) and sub-Saharan Africa 0.5%. UNESCO (1998) "World Science Report 1998", UNESCO, Geneva, pp.20-21.  
Source [http://www.unesco.org/science/publication/eng\\_pub/wsr98en.htm](http://www.unesco.org/science/publication/eng_pub/wsr98en.htm)
- <sup>13</sup> See Box O.1
- <sup>14</sup> Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, *Official Journal L 213*, 30 July 1998, p.13-21.  
Source:[http://europa.eu.int/smartapi/cgi/sga\\_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31998L0044 &model=guichett](http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31998L0044 &model=guichett)
- <sup>15</sup> See Glossary for definition.
- <sup>16</sup> One enquiry is currently ongoing at the US National Academies ([http://www7.nationalacademies.org/step/STEP\\_Projects\\_IPR\\_Phase\\_II\\_Description.html](http://www7.nationalacademies.org/step/STEP_Projects_IPR_Phase_II_Description.html)). The other enquiry is being undertaken by the US Federal Trade Commission (FTC) and the Department of Justice (DOJ) on the relationship between intellectual property and competition policy. The speech of the Chairman of the FTC on 15 November 2001, "*Competition and Intellectual Property Policy: The Way Ahead*", sets out concisely current concerns. Source: <http://www.ftc.gov/speeches/muris/intellectual.htm>
- <sup>17</sup> The full text of the TRIPS Agreement can be found at: [http://www.wto.org/english/docs\\_e/legal\\_e/27-trips.pdf](http://www.wto.org/english/docs_e/legal_e/27-trips.pdf)
- <sup>18</sup> The least developed countries are 49 classified as such by the UN. Of these 30 are currently WTO members. For details see: <http://www.unctad.org/en/pub/ldcprofiles2001.en.htm>
- <sup>19</sup> Hardin, G. (1968) "The Tragedy of the Commons" *Science*, vol. 162, pp. 1243-1248.
- <sup>20</sup> Heller, M. & Eisenberg, R. (1998) "Can Patents Deter Innovation? The Anticommons in Biomedical Research", *Science*, vol. 280, pp.698-701. Source: <http://www.sciencemag.org/cgi/content/full/280/5364/698>
- <sup>21</sup> Jewkes, J., Sawers, D. & Stillerman, R. (1959) "*The Sources of Invention*", St Martins Press, New York, p.255.
- <sup>22</sup> These include: UNCTAD (1996) "*The TRIPS Agreement and Developing Countries*", UNCTAD, Geneva; UNDP (2001) "Human Development Report 2001", UNDP, Geneva. Source: <http://www.undp.org/hdr2001/>; World Bank (2001), Chapter 5; and Bystrom, M. & Einarsson, P. mimeo (2001) "*TRIPS: Consequences for Developing Countries: Implications for Swedish Development Cooperation*", SIDA, Stockholm.  
Source: <http://www.grain.org/docs/sida-trips-2001-en.PDF>
- <sup>23</sup> United Nations (1948) "*Universal Declaration of Human Rights*", UN, Geneva, Article 27.  
Source: <http://www.un.org/Overview/rights.html>
- <sup>24</sup> UN Sub-Commission on the Promotion and Protection of Human Rights (2001) "*Intellectual Property Rights and Human Rights*", UN, Geneva, p.6, paragraph14, Document No. E/CN.4/Sub.2/2001/12.  
Source: [http://www.unhchr.ch/Huridocda/Huridoca.nsf/\(Symbol\)/E.CN.4.Sub.2.2001.12.En?Opendocument](http://www.unhchr.ch/Huridocda/Huridoca.nsf/(Symbol)/E.CN.4.Sub.2.2001.12.En?Opendocument)
- <sup>25</sup> See Glossary for definition.
- <sup>26</sup> Monterrey Consensus, March 2002. Source: <http://www.un.org/esa/ffd/aac257L13-E.doc>
- <sup>27</sup> See Glossary for definition.

## INTELLECTUAL PROPERTY AND DEVELOPMENT



### INTRODUCTION

Intellectual property is a form of knowledge which societies have decided can be assigned specific property rights. They have some resemblance to ownership rights over physical property or land. But knowledge is much more than intellectual property. Knowledge is embodied in people, in institutions and in new technologies in ways that have long been seen as a major engine of economic growth.<sup>1</sup> Alfred Marshall, the “father” of modern economics, thought so in the 19th Century.<sup>2</sup> With recent scientific and technical advances, particularly in biotechnology and information and communications technologies (ICTs), knowledge has become to an even greater degree than before the principal source of competitive advantage for both companies and countries. Trade in high technology goods and services which are knowledge-intensive, and where IP protection is most common, tends to be among the fastest-growing in international trade.<sup>3</sup>

In developed countries, there is good evidence that intellectual property is, and has been, important for the promotion of invention in some industrial sectors, although the evidence as to exactly how important it is in different sectors is mixed. For example, evidence from the 1980s indicates that the pharmaceutical, chemical and petroleum industries were predominant in recognising that the patent system was essential to innovation.<sup>4</sup> Today, one would need to add biotechnology and some components of information technology. Copyright has also proven essential for the music, film and publishing industries.

For developing countries, like the developed countries before them, the development of indigenous technological capacity has proved to be a key determinant of economic growth and poverty reduction. This capacity determines the extent to which these countries can assimilate and apply foreign technology. Many studies have concluded the most distinctive single factor determining the success of technology transfer is the early emergence of an indigenous technological capacity.<sup>5</sup>

But developing countries vary widely in the quality and capacity of their scientific and technical infrastructures. A commonly used indicator of technological capability is the extent of patenting activity in the US and through international applications through the Patent Cooperation Treaty (PCT).<sup>6</sup> In 2001, less than 1% of US patents were granted to applicants from developing countries, nearly 60% of which were from seven of the more technologically advanced developing countries.<sup>7</sup> In the PCT, developing countries accounted for under 2% of applications in 1999-2001, with over 95% of these applications coming from just five countries: China, India, South Africa, Brazil and Mexico.<sup>8</sup> In these countries patent applications, although small, are growing faster than PCT applications generally. PCT applications grew by nearly 23% between 1999 and 2001, but the share of these countries in the total increased from 1% in 1999 to 2.6% in 2001. As we have seen R&D expenditure is heavily concentrated in developed countries, and in a few of the more technologically advanced developing countries. Few developing countries have been able to develop a strong indigenous technological capability. This means that it is difficult either for them to develop their own technology, or to assimilate technology from developed countries.

The crucial question is whether or not the extension of IP regimes assists developing countries in obtaining access to such technologies, and whether and how intellectual property right protection might help developing countries to achieve economic and social development and to reduce poverty. In this chapter we examine:

- The rationale for IP protection
- Its use historically in developed and developing nations
- The available evidence on the impact of IP on developing countries
- The role IP might have in facilitating the transfer of technology to developing countries.

### Box 1.1 What are Intellectual Property Rights?

Intellectual property (IP) rights are the rights awarded by society to individuals or organisations principally over creative works: inventions, literary and artistic works, and symbols, names, images, and designs used in commerce. They give the creator the right to prevent others from making unauthorised use of their property for a limited period. IP is categorised as Industrial Property (functional commercial innovations), and Artistic and Literary Property (cultural creations). Current technological developments are blurring, to some extent, this distinction, and some hybrid *sui generis* systems are emerging.

#### Industrial Property

**Patents:** A patent is an exclusive right awarded to an inventor to prevent others from making, selling, distributing, importing or using their invention, without license or authorisation, for a fixed period of time (TRIPS stipulates 20 years minimum from filing date). In return, society requires that the patent applicant disclose the invention in a manner that enables others to put it into practice. This increases the body of knowledge available for further research. As well as sufficient disclosure of the invention, there are three requirements (although details differ from country to country) that determine the patentability of an invention: novelty (new characteristics which are not “prior art”),<sup>9</sup> non-obviousness (an inventive step not obvious to one skilled in the field), and utility (as used in the US) or industrial applicability (as used in the UK). Utility models are similar to patents, but in some countries confer rights of shorter duration to certain kinds of small or incremental innovations.

**Industrial Designs:** Industrial designs protect the aesthetic aspects (shape, texture, pattern, colour) of an object, rather than the technical features. TRIPS requires that an original design be eligible for protection from unauthorised use by others for a minimum of 10 years.

**Trademarks:** Trademarks provide exclusive rights to use distinctive signs, such as symbols, colours, letters, shapes or names to identify the producer of a product, and protect its associated reputation. In order to be eligible for protection a mark must be distinctive of the proprietor so as to identify the proprietor's goods or services. The main purpose of a trademark is to prevent customers from being misled or deceived. The period of protection varies, but a trademark can be renewed indefinitely. In addition many countries provide protection against unfair competition, sometimes by way of preventing misrepresentations as to trade origin regardless of registration of the trademark.

**Geographical Indications:** Geographical Indications (GIs) identify the specific geographical origin of a product, and the associated qualities, reputation or other characteristics. They usually consist of the name of the place of origin. For example, food products sometimes have qualities that derive from their place of production and local environmental factors. The geographical indication prevents unauthorised parties from using a protected GI for products not from that region or from misleading the public as to the true origin of the product.

**Trade Secrets:** Trade secrets consist of commercially valuable information about production methods, business plans, clientele, etc. They are protected as long as they remain secret by laws which prevent acquisition by commercially unfair means and unauthorised disclosure.

### Artistic and Literary Property

**Copyright:** Copyright grants exclusive rights to the creators of original literary, scientific and artistic works. Copyright only prevents copying, not independent derivation. Copyright protection begins, without formalities, with the creation of the work, and lasts (as a general rule) for the life of the creator plus 50 years (70 years in the US and EU). It prevents unauthorised reproduction, public performance, recording, broadcasting, translation, or adaptation, and allows the collection of royalties for authorised use. Computer programs are protected by copyrights, as software source and code have been defined as a literary expression.

### *Sui Generis* systems

**Integrated Computer Circuits:** A specific *sui generis* form of protection for design of integrated computer circuits. As the inventive step is often minimal and originality is the only requirement, the minimum period of protection under TRIPS is 10 years.

**Plant Breeders' Rights:** Plant breeders' rights (PBRs) are granted to breeders of new, distinct, uniform and stable plant varieties. They normally offer protection for at least fifteen years (counted from granting). Most countries have exceptions for farmers to save and replant seeds, and for the use of protected materials for further breeding.

**Database Protection:** The EU has adopted legislation to provide *sui generis* protection in respect of databases, preventing unauthorised use of data compilations, even if non-original. Exclusive rights to extract or utilize all or a substantial part of the contents of the protected database are granted.

# THE RATIONALE FOR IP PROTECTION

## Introduction

Intellectual property creates a legal means to appropriate knowledge. A characteristic of knowledge is that one person's use does not diminish another's (for example, reading this report). Moreover the extra cost of extending use to another person is often very low or nil (for example, lending a book or copying an electronic file). From the point of view of society, the more people who use knowledge the better because each user gains something from it at low or no cost, and society is in some sense better off. Economists therefore say that knowledge has the character of a *non-rival public good*.<sup>10</sup>

The other aspect of knowledge, or products embodying knowledge, is the difficulty - often intrinsic - of preventing others from using or copying it. Many products, incorporating new knowledge, can be easily copied. Probably most products, with sufficient effort, can be copied at a fraction (albeit not necessarily small) of the cost it took to invent and market them. Economists refer to this latter characteristic as contributing to *market failure*. If a product takes considerable effort, ingenuity and research, but can be copied easily, there is unlikely to be a sufficient financial incentive from society's point of view to devote resources to invention,

## Patents

Patents are one way of addressing this market failure. By conferring temporary market exclusivities, patents allow producers to recoup the costs of investment in R&D and reap a profit, in return for making publicly available the knowledge on which the invention is based. However, someone else can only put that knowledge to potential commercial use with the authorisation of the patentee. The costs of investment in R&D and the return on that investment are met by charging the consumer a price based on the ability to exclude competition.

Protection is therefore a bargain struck by society on the premise that, in its absence, there would be insufficient invention and innovation. The assumption is that in the longer run, consumers will be better off, in spite of the higher costs conferred by monopoly pricing, because the short term losses to consumers are more than offset by the value to them of the new inventions created through additional R&D. Economists take the view that the patent system improves dynamic efficiency (by stimulating technical progress) at the cost of static efficiency (arising from the costs associated with monopoly).

This rationale for patent protection is relatively straightforward, but it is dependent on a number of simplifying assumptions that may not be borne out in practice. For instance, the optimal degree of patent protection cannot be accurately defined. If protection is too weak, then the development of technology may be inhibited through insufficient incentives for R&D. If too much protection is conferred, consumers may not benefit, even in the long run, and patentees may generate profits far in excess of the overall costs of R&D. Moreover, further innovation based on the protected technology may be stifled because, for instance, the length of the patent term is too long or the scope of the protection granted is too broad.

The length of the monopoly granted is one determinant of the strength of patent protection. Another is the scope of the patent. A broad patent is one that allows a right that goes considerably beyond the claimed invention itself. For example, a patent which claims a gene might only specify one use of that gene. But, under certain approaches to the scope of protection, the patentee will also have the rights to uses of the genetic information other than those disclosed in the patent, including those discovered later by someone else. Broad patents can tend to discourage subsequent innovation by other researchers in the general area of the patent. In contrast, narrow claims will encourage others to 'work around' the patent, offering less restriction on related research by others. They may also tend to create stronger rights which are less vulnerable to challenge in the courts.<sup>11</sup> The licensing policy pursued by the patentee will also have an important effect on the dissemination of new technologies, and the extent to which further research is affected by the granted rights.

The optimal degree of protection (where the social benefits are judged to exceed the social costs) will also vary widely by product and sector and will be linked to variations in demand, market structures, R&D costs and the nature of the innovative process. In practice IPR regimes cannot be tailored so precisely and therefore the level of protection afforded in practice is necessarily a compromise. Striking the wrong compromise - whether too much or too little - may be costly to society, especially in the longer term.

One underlying assumption is that there is a latent supply of innovative capacity in the private sector waiting to be unleashed by the grant of the protection that the IP system provides. That may be so in countries where there is substantial research capacity. But in most developing countries local innovation systems (at least of the kind established in developed countries) are weak. Even where such systems are stronger, there is often more capacity in the public than the private sectors.<sup>12</sup> Thus, in such contexts, the dynamic benefit from IP protection is uncertain. The patent system may provide an incentive but there may be limited local capacity to make use of it. Even when technologies are developed, firms in developing countries can seldom bear the costs of acquisition and maintenance of rights and, above all, of litigation if disputes arise.

Economists are also now very aware of what they call *transactions costs*. Establishing the infrastructure of an IPR regime, and mechanisms for the enforcement of IP rights, is costly both to governments, and private stakeholders. In developing countries, where human and financial resources are scarce, and legal systems not well developed, the opportunity costs of operating the system effectively are high. Those costs include the costs of scrutinising the validity of claims to patent rights (both at the application stage and in the courts) and adjudicating upon actions for infringement. Considerable costs are generated by the inherent uncertainties of litigation. These costs too need to be weighed against the benefits arising from the IP system.

Thus the value of the patent system needs to be assessed in a balanced way, acknowledging that it has both costs and benefits, and that the balance of costs and benefits is likely to differ markedly in diverse circumstances.

Amongst academics, notably economists, IPRs have generally been viewed critically. Such rights necessarily involve restrictions on competition which may be to the detriment of consumers and the freedom of trade, and the question is whether these costs are outweighed by the incentives for research and invention. The quotations in Box 1.2 below reflect well the ambivalence that is widely expressed about the effects of the IP system in developed countries, and its impact on developing countries. This ambivalence has tended to strengthen as the IP system has embraced new technologies.

### Box 1.2 Conclusions on the Value of the IP System

Edith Penrose in "The Economics of the International Patent System" in 1951:

"Any country must lose if it grants monopoly privileges in the domestic market which neither improve nor cheapen the goods available, develop its own productive capacity nor obtain for its producers at least equivalent privileges in other markets. No amount of talk about the "economic unity of the world" can hide the fact that some countries with little export trade in industrial goods and few, if any, inventions for sale have nothing to gain from granting patents on inventions worked and patented abroad except the avoidance of unpleasant foreign retaliation in other directions. In this category are agricultural countries and countries striving to industrialise but exporting primarily raw materials...whatever advantages may exist for these countries...they do not include advantages related to their own economic gain from granting or obtaining patents on invention."<sup>13</sup>

Fritz Machlup concluded after studying the US patent system in 1958:

"If one does not know whether a system...is good or bad, the safest "policy conclusion" is to muddle through – either with it, if one has long lived with it, or without it, if one has lived without it. If we did not have a patent system, it would be irresponsible, on the basis of our present knowledge of its economic consequences, to recommend instituting one. But since we have had a patent system for a long time, it would be irresponsible, on the basis of our present knowledge, to recommend abolishing it. This last statement refers to a country such as the U.S. – not to a small country and not a predominantly non-industrial country, where a different weight of argument might well suggest another conclusion."<sup>14</sup>

And another leading economist, Lester Thurow, wrote in 1997:

"In a global economy, a global system of intellectual property rights is needed. This system must reflect the needs both of countries that are developing and those that have developed. The problem is similar to the one concerning which types of knowledge should be in the public domain in the developed world. But the Third World's need to get low cost pharmaceuticals is not equivalent to its need for low cost CDs. Any system that treats such needs equally, as our current system does, is neither a good nor a viable system."<sup>15</sup>

A prominent academic lawyer, Larry Lessig, said of the US in 1999:

"No doubt we are better off with a patent system than without one. Lots of research and invention wouldn't occur without the government's protection. But just because some protection is good, more isn't necessarily better...There is growing skepticism among academics about whether such state-imposed monopolies help a rapidly evolving market such as the Internet...The question economists are now asking is whether expanded patent protection will do any good. Certainly it will make some people very rich, but that's different from improving a market...Rather than unbounded protection, our tradition teaches balance and the dangers inherent in overly strong intellectual property regimes. But balance in IP seems over for now. A feeding frenzy has taken its place - not just in the field of patents, but in IP generally..."<sup>16</sup>

And Jeffrey Sachs, an eminent economist, said in 2002:

"...there is an opportunity to re-think the intellectual property rights regime of the world trading system vis-à-vis the world's poorest countries. In the Uruguay Round negotiation, the international pharmaceutical industry pushed very hard for a universal coverage of patent protection without considering the implications for the poorest countries. There is little doubt that the new IPR arrangements can make it more difficult for consumers in the poorest countries to access key technologies, as we've seen vividly in the case of essential medicines. The countries negotiating the new Doha round have already committed to re-examining the IPR issue in light of public health priorities, and they are wise to do so. It also may well be the case that the tightening of IPRs may slow the diffusion of technology to the world's poorest countries that has traditionally come through copying and reverse engineering. Those hallowed pathways of technological diffusion are increasingly being slowed, and the effects on the poorest countries may be unduly hindered. This is an area for close observation, policy attention, and continuing research."<sup>17</sup>

## Copyright

The rationale for copyright protection is not dissimilar to that of patents, although historically greater weight has been given to the inherent rights of creative artists to receive fair remuneration for their works than to the incentive effects. Copyright protects the form in which ideas are expressed, not the ideas themselves. Copyright was and remains the basis for making the publishing of literary and artistic works an economic proposition by preventing copying. Unlike patents, copyright protection does not require registration or other formalities (although this was not always the case).

As with patents, the trade-off for society is between the incentive offered to creators of literary and artistic works and the restrictions this places on the free flow of protected works. But, unlike patents, copyright in principle protects the expression of ideas, and not the ideas as such, which may be used by others. And it only prevents the copying of that expression, not independent derivation. The central issue for developing countries concerns the cost of access to physical or digital embodiments of the protected works, and the approach taken to enforcement of copyright protection.

As with patents, there are normally exceptions in law where the rights of owners are moderated in the wider public interest, known in some countries as “fair use” provisions (for example in the US), as “fair dealing” in the UK tradition, and exceptions to the reproduction right in the European tradition.<sup>18</sup> It is the issue concerning the cost of access, and the interpretation of “fair use”, that is particularly critical for developing countries, made more so by the extension of copyright to electronic material, and to software.

Copyright protects works for much longer than patents but does not protect against independent derivation of the work in question. Under TRIPS copyright allows a minimum of fifty years after the death of the author, but most developed countries and several developing countries have increased this to 70 years or more. While the main reason for the extension of copyright has been pressure from the copyright industries (notably the film industry in the US), there is no clear economic rationale for copyright protection being so much longer than that for patents. Indeed, the rate of technical change has led in several industries to a shorter effective product life (for example, successive editions of software programmes) which point to longer copyright protection being redundant. The successive increases in the period of copyright protection have given rise to concern in some quarters. This year the US Supreme Court is hearing a case that challenges the 1998 Copyright Term Extension Act on the grounds that it violates the Constitution which specifies that protection must be for “limited Times”. In addition, it is asserted that an extension of protection granted for a work that already exists can have no incentive effect, and also violates the *quid pro quo* requirement in the Constitution that monopoly rights are provided in exchange for public benefits.<sup>19</sup>

As with patents, a key issue for developing countries is whether the gains to be elicited from the incentives provided by copyright outweigh the increased costs associated with the restrictions on use that flow from copyright. Although there are exceptions, such as India’s film or software industry, most developing countries are net importers of copyrighted material, just as they are net importers of technologies. Since copyright does not need registration or other formalities, once a country has copyright laws in place, the impact of copyright is more ubiquitous than in the case of patents. Software, textbooks, and academic journals are key items where copyright is a determining factor in pricing and access, and which are also essential ingredients in education and other spheres crucial to the development process. For instance, a reasonable selection of academic journals is far beyond the purchasing budgets of university libraries in most developing countries, and increasingly in developed countries as well.

The interaction of the Internet and copyright is an issue of particular and growing importance for developing countries. With printed media, there are provisions for “fair use” under copyright law, and the nature of the medium lends itself to multiple use either formally through libraries or

informally through borrowing and browsing (as may be done in a bookshop before deciding to purchase). With material accessed through the Internet, the technology allows encryption and other means to exclude potential users even from browsing, unless they have paid the relevant charge. While the “philosophy” of the Internet has hitherto been about free access, increasingly sites with material of value are moving towards charging for use, or limiting access in other ways. Further, the DMCA in the US and Europe’s Database Directive have provisions that go well beyond what is required under TRIPS, and are held by many users to have shifted the balance of protection too far in favour of investors and originators of collections of data.

Thus, as with patents, there is a need for balance. Too much protection by copyright, by other forms of IP protection, or by technology, may restrict the free flow of ideas on which the further progress of ideas and technology depends. For developing countries, affordable access to works essential for development such as educational materials and scientific and technical knowledge may be affected by unduly strong copyright rules.

## HISTORY

There are several lessons that we can learn from history, particularly from the experience of the developed countries in the 19th century, and the emerging economies of East Asia in the last century.

First, historically IP regimes have been used by countries to further what they perceive as their own economic interests. Countries have changed their regimes at different stages of economic development as that perception (and their economic status) has changed. For instance between 1790 and 1836, as a net importer of technology, the US restricted the issue of patents to its own citizens and residents. Even in 1836, patents fees for foreigners were fixed at ten times the rate for US citizens (and two thirds as much again if one was British!). Only in 1861 were foreigners treated on an (almost wholly) non-discriminatory basis. In his Annual Report for 1858, the US Commissioner of Patents noted:

“It is a fact, as significant as it is deplorable, that of the 10,359 inventions shown to have been made abroad during the last twelve months, but forty-two have been patented in the US. The exorbitant fees exacted of the foreigner, and the severity of the offensive discrimination established to his prejudice, afford a sufficient explanation of the result...it might well be concluded that the government of this country regarded an invention made beyond the seas as something intrinsically dangerous, if not noxious, the introduction of which it is morally just and politically wise to burden with taxation, just as you would thus burden the importation of some foreign poisonous drug. There is a loftier view of this question, and one deemed more in harmony with the progressive spirit of the age -- a view which hails the fruits of the inventive genius, in whatever clime matured, as the common property of the world, and gives them cordial welcome as the common blessings of the race to whose amelioration they are devoted.”<sup>20</sup>

Until 1891, US copyright protection was restricted to US citizens but various restrictions on foreign copyrights remained in force (for example, printing had to be on US typesets) which delayed US entry to the Berne Copyright Convention until as late as 1989, over 100 years after the UK. It is for this reason that some readers may remember purchasing books which had on the cover the words: *“For copyright reasons this edition is not for sale in the U.S.A.”*

Until the adoption of the Paris Convention (on protecting industrial property) in 1883, and its 1886 Berne counterpart (on literary and artistic works) countries’ ability to tailor the nature of their regimes to their own circumstances was unconstrained. Even then, the rules of these Conventions exhibited considerable flexibility. The Paris Convention allowed countries to exclude fields of technology from protection and to determine the length of protection afforded under patents. It also permitted revocation of patents, and compulsory licences<sup>21</sup> to remedy abuses.

Secondly, numerous countries have at times exempted various kinds of invention in certain sectors of industry from patent protection. Often the law has restricted patents on products confining protection to processes for their production. Typically these sectors have been foodstuffs, pharmaceuticals and chemicals, based on the judgement that no monopoly should be granted over essential goods, and that there is more to be gained by encouraging free access to foreign technology, than by potentially stimulating invention in domestic industry. This approach was adopted by many countries which are now developed in the 19th Century, and for some until late in the 20th Century, and also in the East Asian countries (such as Taiwan and Korea) until relatively recently. However, TRIPS now forbids discrimination in the grant of patent protection in respect of different fields of technology.

Thirdly, intellectual property, and patents in particular, have often been politically contentious. Between 1850 and 1875, a debate raged in Europe, both in academic and political circles, on whether the patent system was a blight on free trade principles or the best practical means of stimulating inventions. John Stuart Mill took the latter view:

“...an exclusive privilege, of temporary duration is preferable [as a means of stimulating invention]; because it leaves nothing to anyone’s discretion; because the reward conferred by it depends upon the invention’s being found useful, and the greater the usefulness, the greater the reward; and because it is paid by the very persons to whom the service is rendered, the consumers of the commodity.”

In essence, this remains the case for the system today – a relatively inexpensive way (at least for governments, in so far as they are not purchasers of the goods) to provide an incentive for invention with a reward proportionate to the use subsequently made of it.<sup>23</sup>

Opposition to patent protection was advanced on various grounds but was summed up in the words of the Economist in 1851:

“The privileges granted to inventors by patent laws are prohibitions on other men, and the history of inventions accordingly teems with accounts of trifling improvements patented, that have put a stop, for a long period, to other similar and much greater improvements...The privileges have stifled more inventions than they have promoted...Every patent is a prohibition against improvements in a particular direction, except by the patentee, for a certain number of years; and, however, beneficial that may be to him who receives the privilege, the community cannot be benefited by it...On all inventors it is essentially a prohibition to exercise their faculties; and in proportion as they are more numerous than one, it is an impediment to the general advancement...”<sup>24</sup>

Again, this clearly illustrates a theme that recurs in current discussions. If the system protects one set of inventions, can it avoid deterring those who seek to make improvements upon the first?

Foreshadowing the debates concerning TRIPS, the 19th Century argument was also related to the free trade controversy in that the patent system, by conferring monopolies, was seen by some as a contravention of free trade principles. Moreover there was self-interest at work. In Switzerland in the 1880s, industrialists did not want a patent law because they wished to continue to use the inventions of foreign competitors. This opposition was maintained in spite of the fact that the Swiss were enthusiastic patentees in other countries themselves. And because Switzerland had low tariffs, they feared that those competitors would take out patents in Switzerland and then drive out Swiss competition under their protection.

Switzerland did eventually adopt a patent law, with various exclusions and safeguards, not because most Swiss thought there was any net benefit to be had from allowing foreign patents, but because Switzerland came under intense pressure, particularly from Germany, to do so and did not wish to invite retaliation from other countries.<sup>25</sup> Safeguards adopted included provisions for compulsory working<sup>26</sup> and compulsory licensing which enabled the government to enforce production in

Switzerland by one means or another, if it so desired. In addition, chemicals and textile dyeing were excluded from patent protection. Elsewhere in Europe the proponents of the patent system also largely won the argument, just as the free trade movement waned in the face of the Great Depression in Europe. Only in Holland did the movement against patents wholly succeed, and from 1869 until 1912 no patents were issued there.<sup>27</sup>

Fourthly, the best examples in the recent history of development are the countries in East Asia which used weak forms of IP protection tailored to their particular circumstances at that stage of their development. Throughout the critical phase of rapid growth in Taiwan and Korea between 1960 and 1980, during which their economies were transformed, both countries emphasised the importance of imitation and reverse engineering<sup>28</sup> as an important element in developing their indigenous technological and innovative capacity. Korea adopted patent legislation in 1961, but the scope of patenting excluded foodstuffs, chemicals and pharmaceuticals. The patent term was only 12 years. It was only in the mid-1980s, particularly as a result of action by the US under Section 301 of its 1974 Trade Act, that patent laws were revised, although they did not yet reach the standards to be set under TRIPS. A similar process took place in Taiwan. In India, the weakening of IP protection in pharmaceuticals in its 1970 Patent Act<sup>29</sup> is widely considered to have been an important factor in the subsequent rapid growth of its pharmaceutical industry, as a producer and exporter of low cost generic medicines<sup>30</sup> and bulk intermediates.<sup>31</sup>

The general lesson history shows us is that countries have been able to adapt IPR regimes to facilitate technological learning and promote their own industrial policy objectives. Because policies in one country impinge on the interests of others, there has always been an international dimension to debates on IP. The Paris and Berne Conventions recognised this dimension, and the desirability of reciprocity, but allowed considerable flexibility in the design of IP regimes. With the advent of TRIPS, a large part of this flexibility has been removed. Countries can no longer follow the path adopted by Switzerland, Korea or Taiwan in their own development. The process of technological learning, and of progressing from imitation and reverse engineering to establishing a genuine indigenous innovative capacity, must now be done differently from in the past.

## THE EVIDENCE ABOUT THE IMPACT OF IP

### The Context

Analysis of the available evidence on the impact of IPR regimes on developing, or developed countries, is a complex task. As noted above, we do not wish to focus on IPRs as an end in themselves, but on how they can contribute to development and the reduction of poverty. We believe that a prerequisite for sustainable development in any country is the development of an indigenous scientific and technological capacity. This is necessary to allow countries to develop their own process of technological innovation, and to enable them to absorb effectively technologies developed abroad. It is obvious that the development of such capacity is dependent on a large number of elements. It requires an effective education system, particularly at the tertiary level, and a network of supporting institutions and legal structures. It also requires the availability of financial resources, both public and private, to pursue technological development. There are many other factors that contribute to what are often known as “national systems of innovation”.

Viewed this way, the issue is whether IPRs can contribute to promoting effective national systems of innovation *in principle* and, given the wide existing variations in the indigenous scientific and technological capacity, how they can do so effectively *in practice*, taking account of the circumstances in particular countries. Moreover, since we are not just interested in the dynamic effect of IPRs in promoting innovation, but also the costs that IP protection imposes on society, particularly on poor people, we need to take account of these costs in considering the evidence and the value of any given IP system.

Much of the evidence about IPRs is either indirect or based on proxy measures. We cannot measure directly a country's capacity for innovation (for example, we might commonly use R&D expenditures or innovations-related expenditures as a proxy). Nor can we directly measure the strength of patent protection in a country (although indices have been compiled using a mixture of proxies). The use of econometrics, which attempts to isolate the independent effect of IPRs on economic variables, is often contested, particularly as to whether it demonstrates association rather than causation. For instance, some authorities argue that the absence of IP protection encourages technology transfer and technological learning (through copying and imitation). Others argue that IP protection is a mechanism which encourages technology transfer from abroad through direct investment or licensing, and the indirect effects are an effective means of technological learning. Determining where the truth lies can be difficult for policymakers.

## Redistributive Impact

Developing countries, taken as a whole, are net importers of technology, most of which is supplied by the developed countries. Organisations in developed countries own the overwhelming proportion of patent rights worldwide. Econometric models have been constructed to estimate what would be the global impact of applying the TRIPS agreement (i.e. globalising minimum standards for IP protection). The latest estimate, by the World Bank, suggests that most developed countries would be the major beneficiaries of TRIPS in terms of the enhanced value of their patents, with the benefit to the US estimated at an annual \$19 billion. Developing countries, and a few developed ones, would be the net losers. The country sustaining the largest loss in the study by the World Bank was Korea (\$15 billion). Not too much should be read into the exact value of these figures, which depend on a number of debateable assumptions, but it can safely be said that the effect of applying patent rights globally will be to benefit very considerably the holders of patent rights, mainly in developed countries, at the expense of the users of protected technologies and goods in developing countries. Between 1991 and 2001, the net US surplus of royalties and fees (which mainly relate to IP transactions) increased from \$14 billion to over \$22 billion.<sup>33</sup> In 1999, figures from the World Bank indicate a deficit for developing countries for which figures are available of \$7.5 billion on royalties and licence fees.<sup>34</sup>

## Growth and Innovation

That the extension of IPRs would tend to benefit the developed countries is not surprising and explains why pressure was applied by industry in developed countries for the adoption of TRIPS. But the calculations above only consider the cost side of the IPR equation for developing countries. If IPRs are to benefit developing countries that benefit will need to come through promoting invention and technological innovation, and thereby enhancing growth.

At the country level, there appears to be little economic research on developing countries that directly links the IPR regime to domestic innovation and development. An approach common to Germany, and the East Asian countries (including China), was the introduction of easily obtained utility models (or petty patents), which combined a lower standard of inventiveness, with registration rather than examination, and a shorter protection period.<sup>35</sup> When introduced in Germany, in 1891, these provided for three years of protection (renewable for a further three years) and by the 1930s, twice as many utility patents as examined patents were granted.<sup>36</sup> Studies of Japan's patent system in the period 1960-1993 have suggested that utility models were more important than patents in stimulating productivity growth.<sup>37</sup> There is also some evidence relating innovation in particular sectors in Brazil and the Philippines to the availability of such utility models.<sup>38</sup> In Japan, the evidence suggests that a system of "weak" protection based on utility models and industrial designs facilitated incremental innovation by small enterprises, and the absorption and diffusion of technology. This was associated, as in Taiwan and Korea, with an absence of patent protection for chemical and pharmaceutical products. Japan introduced protection for the latter only in 1976.<sup>39</sup>

There is more evidence about the impact of patent protection in developed countries. It appears to indicate that large firms consider patent protection of considerable importance in particular sectors (for example pharmaceuticals) but that in many sectors they are not considered important determinants of innovation.<sup>40</sup> Moreover, patents seem to be hardly used by small and medium enterprises in most sectors in many developed countries, as a means of promoting their innovation, or as a source of useful technical information. An important exception is the biopharmaceutical sector where companies often view their patent portfolios as their most important business asset.<sup>41</sup> A recent large study in the UK concluded that “formal IP regimes are applicable only to a small proportion of business activity, such as large manufacturing companies.” Other informal methods of protection, and of obtaining technical information, were generally more effective for SMEs.<sup>42</sup>

The crucial question from our point of view is to what extent IPRs promote growth. The evidence we have reviewed does not suggest strong direct effects on economic growth in developing countries.<sup>43</sup> One recent study found that the more open (to trade) an economy, the more likely it was that patent rights would affect growth. According to this calculation in an open economy, stronger patent rights might increase growth rates by 0.66% per annum.<sup>44</sup> But there is some debate about causation because both openness to trade and the strength of the IPR regime tend to increase in any case with per capita income.

Other evidence suggests that the strength of patent protection increases with economic development, but that this does not occur until quite high levels of per capita income. Indeed, prior to the recent global strengthening of IP laws, there was a reasonably consistent observed relationship between the strength of IP rights and per capita income. At low levels of income, protection is quite high (reflecting past colonial influences) but then falls to a low point of weak protection at an income of about \$2000 (at 1985 prices) per capita. This low point is maintained until a per capita income of nearly \$8000 when the strength of protection begins to increase again. This association is not necessarily causal but it does indicate that until relatively high levels of per capita income, IPR protection is not a high priority in developing country policy.<sup>45</sup>

Maybe the simplest evidence of the impact of the IP system is how much it is used, particularly by nationals. The propensity to take out patents will reflect some judgement as to the benefits, albeit private rather than social benefits. In sub-Saharan Africa in 1998 (excluding South Africa), 35 patents were granted to residents compared to 741 for non-residents. By contrast in Korea, 35900 patents were issued to residents, compared to 16990 to non-residents. In the US, the corresponding figures were 80292 and 67228.<sup>46</sup>

The main conclusion seems to be that for those developing countries that have acquired significant technological and innovative capabilities, there has generally been an association with “weak” rather than “strong” forms of IP protection in the formative period of their economic development. We conclude therefore that in most low income countries, with a weak scientific and technological infrastructure, IP protection at the levels mandated by TRIPS is not a significant determinant of growth. On the contrary, rapid growth is more often associated with weaker IP protection. In technologically advanced developing countries, there is some evidence that IP protection becomes important at a stage of development, but that stage is not until a country is well into the category of upper middle income developing countries.<sup>47</sup>

## Trade and Investment

Although the direct impact on growth is difficult to discern, much effort has been devoted to establishing the impact of changing IPR rights on trade and foreign investment. We do not find some of this work very helpful to our study. Much of it does not address the impact of IP rights on developing countries, but focuses instead on the question of how developed country exports and investment may be affected by strengthening IP rights in developing countries. These two approaches are not the same.

For instance, some studies show that stronger patent rights in developing countries would significantly increase imports from developed countries (or indeed other developing countries).<sup>48</sup> The argument is that some imports are a form of technology transfer (for example, high technology machinery imports have an independent impact on productivity). But strengthening IPRs is also particularly effective in increasing imports of low technology consumer items and is associated with the decline of indigenous industries based on imitation.<sup>49</sup> This effect is clearly a mixed blessing for a developing country. It may be that there is access to more high technology imports previously withheld for lack of IP protection but the costs may be very substantial in terms of lost output and employment, or even retarded growth. This issue is now a very real one in countries such as China. These studies also imply that countries with little technological capacity may experience reduced imports because the patent laws have the effect of increasing import prices on average, and hence reduce import capacity. Countries in the past have protected themselves against the possible adverse effects of increased imports on domestic industry through provisions relating to compulsory working of patents, as Switzerland did in the 19th century.

As regards the analyses of the impact on foreign investment, we have similar reservations. There is a considerable literature which discusses the extent to which stronger IPRs influence foreign investment, licensing behaviour and the transfer of technology. Much of this literature reaches only tentative conclusions, because of weaknesses in data or methodology.<sup>50</sup> Many of the studies pose the question, partly for reasons of data availability, in terms of how strengthening patents rights in developing countries will affect the investment, production and licensing behaviour of US multinationals in developing countries. For instance, one of the conclusions reached in a recent study, but it is typical of others working with similar datasets, is as follows:

“...these results suggest that if an average developing country were to strengthen its patent index by one unit, local sales of US affiliates would rise by...about 2% of average annual sales...a one-unit increase in the patent index of the average developing economy would raise the asset stock of US multinational affiliates by...about 16% of average asset stock.”<sup>51</sup>

For policymakers in a developing country, the framework and questions might be rather different. He or she would want to know, if IPRs were strengthened, whether that would be likely to affect economic growth, employment, investment and R&D in the private sector, access to foreign technology, the domestic innovation process, and exports (as well as imports). There is a paucity of studies that directly address these issues of critical importance to policymakers in developing countries, let alone reach definitive conclusions on the impact of IPRs.

What is clear from the literature is that strong IP rights alone provide neither the necessary nor sufficient incentives for firms to invest in particular countries. If this was the case, then large countries with high growth rates but weak IPR regimes would not have received large foreign investment inflows in the past and even now. This includes many of the East Asian and Latin American economies which have received the bulk of such flows.<sup>52</sup> If the question is addressed in terms of what factors are most important in determining foreign investment, it is quite common for IPRs to be omitted altogether. For instance, recent reports from international institutions and bodies on investment flows almost entirely fail to mention IPRs as a factor. These include, for instance, the World Bank’s report on Global Development Finance 2002,<sup>53</sup> and the Zedillo report on Financing for Development.<sup>54</sup> Similarly, a recent draft World Bank report on improving India’s investment climate makes no mention at all of the role of IPRs.<sup>55</sup>

As we have noted, there is some evidence that for particular industries (such as chemicals) and for particular activities (such as R&D) IPRs may be a significant factor in the decision by firms to invest.<sup>56</sup> But the investment decision is contingent on many factors. For most low technology industries, of the kind that less technologically advanced developing countries are likely to attract, IPRs are unlikely to be a relevant factor in the investment decision. Where technologies are more

sophisticated, but relatively easy to copy, then IPRs may be – though not necessarily - a significant factor in investment decisions if a country has both the scientific capacity to copy and a sufficiently large market to justify the costs of patenting and enforcement and other relevant factors are favourable. In other cases, however, the introduction of IP protection has been associated, as noted above, with an increase in imports, rather than investment in local production. Finally, in high technology industries and for countries with sophisticated technological capabilities, technology owners may opt to license their technologies, protected by the IP regime, rather than invest directly in production. Thus strong rights may deter investment flows but facilitate technology transfer under licensing, which we return to in the next section.

We conclude from the existing studies the following:

- There is some evidence that trade flows into developing countries are influenced by the strength of IP protection, particularly for those industries (often high technology) that are “IPR sensitive” (for example, chemicals and pharmaceuticals), but the evidence is far from clear.
- These flows may contribute to productive capability. But they may also be at the expense of domestic output and employment in local “copying” and other industries. Developing countries with no or weak technological infrastructure, may be adversely affected by the higher prices of importing IP protected goods.
- The evidence that foreign investment is positively associated with IP protection in most developing countries is lacking.
- For more technologically advanced developing countries, IPRs may be important to facilitate access to protected high technologies, by foreign investment or by licensing.
- Achieving the right balance may be difficult for some countries such as India or China where some industries have the potential to benefit from IP protection, but the associated costs for industries that were established under weak IP regimes as well as consumers are potentially high.
- Most of the evidence concerning the role of IP in trade and investment relates to those developing countries which are more technologically advanced. For other developing countries, we conclude that any beneficial trade and investment effects are unlikely to outweigh the costs at least in the short and medium term.

## TECHNOLOGY TRANSFER

In a sense, the crucial issue in respect of IP is not whether it promotes trade or foreign investment, but how it helps or hinders developing countries to gain access to technologies that are required for their development. If a supplier of foreign technology licenses production to a domestic firm, rather than itself establishing manufacturing locally, less foreign investment will have been attracted. However, the overall result may be more beneficial to the domestic economy because of the indirect contribution to domestic technological capabilities. If high technology imports increase as a result of strengthening IP regimes, a transfer of technology may be achieved (for example, as embodied in capital goods), but there is no guarantee that the domestic economy will be capable of absorbing that technology as a basis for further innovation. Therefore the transfer of technology may not be sustainable. Rather, as we have seen, some countries may use weak IP regimes as a means of gaining access to foreign technologies and developing them using reverse engineering, thereby enhancing indigenous technological capacity. The implementation of TRIPS now restricts the ability of developing countries to follow this path.

But the determinants of effective technology transfer are many and various. The ability of countries to absorb knowledge from elsewhere and then make use and adapt it for their own purposes is also of crucial importance. This is a characteristic that depends on the development of local capacity through education, through R&D, and the development of appropriate institutions without which even technology transfer on the most advantageous terms is unlikely to succeed. The effective

transfer of technology also often requires the transfer of “tacit” knowledge, which cannot be easily codified (for example, as in patent disclosures or instruction manuals). This is why even the best-designed programmes to foster national capacity for research which are funded by donors have not always been successful. Since many technologies of interest to developing countries are produced by organisations from developed countries, the acquisition of technology requires the ability to negotiate effectively based on an understanding of the particular area of technology. This process requires a determined approach on the part of the recipient of technology to acquire the necessary human capital and the appropriate institutions. Countries such as Korea started at a low level of technological expertise forty years ago, comparable to many low income countries today, but have now become innovators in their own right.

This aspect of the process of technology transfer is largely in the hands of developing countries themselves. But this does not mean that developed countries, or international policies more generally, cannot facilitate or hinder the process. The TRIPS agreement recognises in Article 7 that IPRs should contribute to the “transfer and dissemination of technology” but also, in Article 8, that measures may need to be taken to prevent the abuse of IPRs including practices that “adversely affect the international transfer of technology.” Article 40 includes provisions to prevent anti-competitive practices in contractual licenses. And Article 66.2 obliges developed countries to provide incentives to their enterprises and institutions to promote technology transfer to least developed countries (LDCs) in order to “enable them to create a sound and viable economic base”. These provisions in TRIPS reflect some of the provisions in the draft International Code of Conduct on Technology Transfer, on which negotiations between developed and developing countries failed in the 1980s.<sup>57</sup>

Since then, the global economy has changed. Notably, economic policies around the world have shifted from import substitution and directed industrialisation behind high tariff barriers towards open market policies which emphasise the benefits to be gained through low tariffs, global competition and a less directive role for governments in economic development. The so-called knowledge-based industries, and trade in high technology products, have grown apace. The importance of R&D has increased and product life cycles have shortened. In this liberalised and competitive environment, firms in developing countries can no longer compete on the basis of importing “mature” technologies from developed countries and producing them behind tariff barriers. Firms are more wary of transferring technology in ways that may increase the competition they face.

Thus the problem is not so much now about obtaining more or less mature technologies on fair and balanced terms, but of accessing the sophisticated technologies that are required to be competitive in today’s global economy. TRIPS has strengthened the global protection offered to suppliers of technology, but there is no international framework to ensure that the transfer of technology takes place within a competitive framework which minimises the restrictive technology licensing practices with which the Code was concerned.

We are uncertain as to how this gap in the international framework could best be filled. Recommencing discussions on a Code of Conduct is not a viable option in the changed environment. But we do think encouraging and assisting them to build their own competition law regimes could better serve the interests of developing countries. The development of a framework for international competition policy has been discussed for some time in the WTO. We understand the reluctance of developing countries to embark down this path, but the development of national competition laws and effective international cooperation could act as a counterbalance to the aspects of the TRIPS agreement which have the effect of restricting competition globally, and inhibiting technology transfer in certain circumstances.

As regards TRIPS, the evidence suggests that the provisions in Article 66.2 have been ineffective. Developed countries do not appear to have taken additional measures to encourage technology transfer by their firms and institutions. Moreover, the fact that the article applies only to LDCs seems unduly restrictive. As noted above, these are likely to be countries for the most part with the least absorptive capacity. We do not therefore consider that Article 66.2 is the most appropriate way to address the entire issue of technology transfer to developing countries. Moreover some of the IPR provisions used historically to facilitate technology transfer, such as the use of compulsory working, have been significantly diluted under TRIPS. Since technology is mostly in private hands and TRIPS is principally concerned with the protection of IPRs, rather than technology transfer, we are unsure as to whether TRIPS, rather than the WTO more generally, is the right focus for a discussion on technology transfer.

We therefore welcome the establishment of the Working Group on Trade and Technology Transfer which will report to the WTO Ministerial Conference next year.<sup>58</sup> We suggest this includes consideration of whether the TRIPS agreement could be made to work better as one mechanism to promote technology transfer, and what measures might be desirable to ensure that the IPR system promotes, and does not hinder, technology transfer. However, we see the range of complementary measures that will be required to promote technology transfer as equally important.

Although most applied technology is privately owned, it is important to remember the extent to which public spending on basic and applied research supports the process of technological development. Developed country public research spending now often has the explicit objective of enhancing international competitiveness and increasingly, the results of such research may be patented, as we discuss in Chapter 6. Not only is research funding often tied to nationals, perhaps understandably, but also the benefits of such research may be restricted to nationals. For instance the law in the US restricts for the most part the licensing of publicly financed technologies to nationals, a policy for which the scientific and economic logic is less clear.<sup>59</sup>

**Much of the technology transfer agenda goes well beyond our brief but we think the following measures need to be seriously considered:**

- **Appropriate incentive policies in developed countries to promote technology transfer, for instance tax breaks for companies that license technology to developing countries.**
- **Establishment of effective competition policies in developing countries.**
- **Making more public funds available to promote indigenous scientific and technological capability in developing countries through scientific and technological cooperation. For instance, supporting the proposed Global Research Alliance<sup>60</sup> between developing and developed country research institutions.**
- **Commitments to ensure that the benefits of publicly funded research are available to all.**
- **Commitments to ensure open access to scientific databases.**

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<sup>1</sup> The exact role of knowledge and technical change has been a matter of debate amongst economists, but this is the dominant view. For a non-technical discussion of the debate see World Bank (1999) *World Development Report 1998/99: Knowledge for Development*, World Bank, Washington DC, pp.18-22.

Source: <http://www.worldbank.org/wdr/wdr98/>

<sup>2</sup> World Bank (1999), p.20.

<sup>3</sup> Maskus, K. (2000a) *Intellectual Property Rights in the Global Economy*, Institute for International Economics, Washington DC, pp.73-79.

<sup>4</sup> Mansfield, E. (1986) *Patents and Innovation*, Management Science, vol. 32:2, pp.173-81.

<sup>5</sup> Radovesic, S. (1999) *International Technology Transfer and Catch-up in Economic Development*, Elgar, Cheltenham, p.242. Also Saggi, K. (2000) "Trade, Foreign Direct Investment and International Technology Transfer: A Survey", World Bank, Washington DC

Source: [http://www1.worldbank.org/wbiep/trade/papers\\_2000/saggiTT-fin.pdf](http://www1.worldbank.org/wbiep/trade/papers_2000/saggiTT-fin.pdf), and Rosenberg, N. (1982)

"*Inside the Black Box; Technology and Economics*", Cambridge University Press, Cambridge.

<sup>6</sup> See Glossary for explanation of the PCT.

<sup>7</sup> Those developing countries which were granted over 50 US patents in 2001 included: China 266, India 179, South Africa 137, Brazil 125, Mexico 87, Argentina 58, Malaysia 56. China (Taiwan) received 6545 and Korea 3763 but these are not developing countries on the World Bank classification. Our count is that 1560 US patents were granted to developing countries on the World Bank list, out of total grants of 184057 in 2001. Source: [http://www.uspto.gov/web/offices/ac/ido/oeip/taf/cst\\_all.pdf](http://www.uspto.gov/web/offices/ac/ido/oeip/taf/cst_all.pdf)

<sup>8</sup> Information provided to us by WIPO. 4816 applications in 1999-2001 were from these five countries out of total developing country applications of 5014. Total applications were 268918 in 1999-2001. Korea (4622) and Singapore (640) were also major applicants.

<sup>9</sup> See Glossary for definition.

<sup>10</sup> Stiglitz, J. "Knowledge as a Global Public Good", in Kaul, I. Grunberg, I. & Stern, M. (eds) (1999) "*Global Public Goods in the 20th Century: International Cooperation in the 20th Century*", Oxford University Press, Oxford.

<sup>11</sup> We discuss these issues at greater length in Chapter 6.

<sup>12</sup> The experience of the "emerging" economies such as Korea is that initially the public sector takes the lead but then, as the private sector becomes more innovative, it tends to predominate. Thus in Korea the most US patents are taken out by the private sector, in particular in electronics. In India, the public sector is still predominant, but there are signs of increased patenting activity in the private sector. For instance, in 2001, two of India's leading pharmaceutical companies were granted 11 patents in the US, compared to 58 for India's Council of Scientific and Industrial Research.

Source: [http://www.uspto.gov/web/offices/ac/ido/oeip/taf/asgstd/inx\\_stc.htm](http://www.uspto.gov/web/offices/ac/ido/oeip/taf/asgstd/inx_stc.htm)

<sup>13</sup> Penrose, E. (1951) "*The Economics of the International Patent System*", The John Hopkins Press, Baltimore, pp.116-117.

<sup>14</sup> Machlup, F. (1958) "*An Economic Review of the Patent System*", US Government Printing Office, Washington DC, p.80.

<sup>15</sup> Thurow, L. (1997) "Needed: A New System of Intellectual Property Rights", *Harvard Business Review*, Sept.-Oct. 1997, p.103. Source: [http://harvardbusinessonline.hbsp.harvard.edu/b01/en/hbr/hbr\\_home.jhtml](http://harvardbusinessonline.hbsp.harvard.edu/b01/en/hbr/hbr_home.jhtml)

<sup>16</sup> Lessig, L. (1999) "The Problem with Patents", *Industry Standard*, 23 April 1999.

Source: <http://www.thestandard.com/article/display/0,1151,4296,00.html>

<sup>17</sup> Sachs, J. "The Global Innovation Divide", in Jaffe, A., Lerner, J. and Stern, S. eds. (forthcoming) "*Innovation Policy and the Economy: Volume 3*", MIT Press, Cambridge MA. Source:

<http://www.nber.org/books/innovation3/>

<sup>18</sup> See Glossary for definition.

<sup>19</sup> The Brief for the Petitioners summarises their case as follows: "These repeated blanket extensions of existing copyright terms exceed Congress's power under the Copyright Clause, both because they violate the "limited Times" requirement and because they violate this Court's "originality" requirement. They violate the "limited Times" requirement, first, because terms subject to repeated, blanket extensions are not "limited"; second, because a term granted to a work that already exists does not "promote the Progress of Science"; and third, because the grant of a longer term for already existing works violates the Copyright Clause's quid pro quo requirement—that monopoly rights be given in exchange for public benefit in return."

Source: <http://eol.law.harvard.edu/openlaw/eldredvashcroft/supct/opening-brief.pdf>

<sup>20</sup> Source: <http://www.myoutbox.net/poar1858.htm>

<sup>21</sup> See Glossary for definition.

<sup>22</sup> Machlup, F. & Penrose, E. (1950) "The Patent Controversy in the Nineteenth Century". *The Journal of Economic History*, vol. 10:1, p.20.

<sup>23</sup> Although patent examiners and others might question whether the award of a patent leaves "nothing to anyone's discretion."

<sup>24</sup> Machlup & Penrose (1950), p.24.

<sup>25</sup> Penrose (1951), pp. 120-124.

<sup>26</sup> Compulsory working provided an obligation of various kinds under patent law to ensure that patented goods were manufactured domestically, rather than imported into the country where the patent was granted.

<sup>27</sup> Schiff, E. (1971) "*Industrialisation Without National Patents: The Netherlands 1869-1919, Switzerland, 1850 – 1907*", Princeton University Press, Princeton.

<sup>28</sup> See Glossary for definition.

<sup>29</sup> The Act provided, inter alia, for only process protection (for a period of seven years) in food, drugs and chemicals. This allows patented drugs to be reverse engineered, provided a different process is used in manufacture.

<sup>30</sup> See Glossary for definition.

- <sup>31</sup> Kumar, N. (2002) "Intellectual Property Rights, Technology and Economic Development: Experiences of Asian Countries", Commission on Intellectual Property Rights Background Paper 1b, Commission on Intellectual Property Rights, London, pp.27-35.  
Source: <http://www.iprcommission.org>
- <sup>32</sup> World Bank (2001a) "Global Economic Prospects and the Developing Countries 2002: Making Trade Work for the World's Poor", World Bank, Washington DC, p. 133.  
Source: <http://www.worldbank.org/prospects/gep2002/>
- <sup>33</sup> US Department of Commerce, Bureau of Economic Analysis, various publications.
- <sup>34</sup> World Bank (2001b) "World Development Indicators 2001", World Bank, Washington DC, Table 5.11.  
Source: <http://www.worldbank.org/data/wdi2001/>
- <sup>35</sup> See Glossary for definition of the terms used in this sentence.
- <sup>36</sup> Khan, Z. (2002) "Intellectual Property and Economic Development: Lessons from American and European History", Commission on Intellectual Property Rights Background Paper 1a, Commission on Intellectual Property Rights, London. p.16. Source: <http://www.iprcommission.org>
- <sup>37</sup> Maskus, K. & McDaniel, C. (1999) "Impacts of the Japanese Patent System on Productivity Growth". *Japan and the World Economy*, vol. 11, pp.557-574.
- <sup>38</sup> Dahab, S. (1986) "Technological Change in the Brazilian Agriculture Implements Industry", Unpublished PhD dissertation, Yale University, New Haven; and Mikkelsen, K. (1984) "Inventive Activity in Philippines Industry", Unpublished PhD dissertation, Yale University, New Haven.
- <sup>39</sup> This draws on Maskus and McDaniel (1999) and Kumar (2002).
- <sup>40</sup> Mansfield (1986).
- <sup>41</sup> Thomas, S. "Intellectual Property in Biotechnology SMEs", in Blackburn, R. (ed.) (in press) "Intellectual Property and Innovation Management in Small Firms", Routledge, London.
- <sup>42</sup> Conclusions of ESRC Intellectual Property Research Programme.  
Source: <http://info.sm.umist.ac.uk/esrcip/background.htm>
- <sup>43</sup> See discussion in Kumar (2002), p.6 and in Maskus (2000a), p.169.
- <sup>44</sup> Gould, D. & Gruben, W. (1996) "The Role of Intellectual Property Rights in Economic Growth", *Journal of Development Economics*, vol. 48, pp 323-350.
- <sup>45</sup> See discussion in Maskus (2000a), pp.102-109.
- <sup>46</sup> WIPO Statistics. Source: <http://www.wipo.int>
- <sup>47</sup> With per capita incomes between \$2976 and \$9205 in 2001, the World Bank's upper middle income group of developing countries. Source: <http://www.worldbank.org/data/countryclass/countryclass.html>
- <sup>48</sup> Maskus, K. & Penubarti, M. (1997) "How Trade-Related Are Intellectual Property Rights?" *Journal of International Economics*, vol. 39, pp. 227-248; and Smith, P. (1999) "Are Weak Patent Rights a Barrier to US Exports?", *Journal of International Economics*, vol. 48, pp.151-177.
- <sup>49</sup> Maskus (2000a), p.113.
- <sup>50</sup> Discussions of this literature are in Maskus (2000a), pp.119-142; and Kumar (2002), pp.11-18.
- <sup>51</sup> Maskus (2000a), p.131.
- <sup>52</sup> Maskus, K. (2000b) "Intellectual Property Rights and Foreign Direct Investment", Policy Discussion Paper No. 0022, University of Adelaide, Adelaide, pp.2-3. Source: <http://www.adelaide.edu.au/CIES/0022.pdf>
- <sup>53</sup> One passing mention while describing the agreement at Doha in World Bank (2002) "Global Development Finance 2002", World Bank, Washington DC. Source: <http://www.worldbank.org/prospects/gdf2002/>
- <sup>54</sup> UN General Assembly paper A/55/1000, June 26 2001. IPRs are mentioned but not in the discussion of private capital flows or foreign direct investment.
- <sup>55</sup> World Bank/Confederation of Indian Industries (2002) "Improving the Investment Climate in India" Draft, World Bank Group, Washington DC.  
Source: [http://www.worldbank.org/wbi/corpgov/core\\_course/core\\_pdfs/roger\\_india.pdf](http://www.worldbank.org/wbi/corpgov/core_course/core_pdfs/roger_india.pdf)
- <sup>56</sup> Mansfield, E. (1994) "Intellectual Property Protection, Foreign Direct Investment, and Technology Transfer", International Finance Corporation Discussion Paper 19, IFC, Washington DC.  
Source: <http://www.ksg.harvard.edu/dvc/ifcintellprop.pdf>
- <sup>57</sup> The history and current implications are reviewed in Patel, S., Roffe, P. & Yusuf, A. (2001) "International Technology Transfer: The Origins and Aftermath of the United Nations Negotiations on a Draft Code of Conduct", Kluwer Law International, The Hague.
- <sup>58</sup> See: [http://www.wto.org/english/tratop\\_e/dda\\_e/dohaexplained\\_e.htm#technologytransfer](http://www.wto.org/english/tratop_e/dda_e/dohaexplained_e.htm#technologytransfer)
- <sup>59</sup> The National Institutes of Health (NIH) in the US has recently proposed a policy to vest the worldwide IP rights derived from foreign research collaborators in the US Government, except in the collaborator's own country. Source: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-039.html>
- <sup>60</sup> Source: <http://www.research-alliance.net>

## HEALTH



### INTRODUCTION

#### The Issue

The impact of intellectual property rules and practices on the health of poor people in developing countries has generated substantial controversy in recent years. Although this predated TRIPS, and featured prominently in the TRIPS negotiations, impetus has been added by the coming into force of TRIPS,<sup>1</sup> and the dramatic rise in the incidence of HIV/AIDS, particularly in developing countries. For the developed countries, the pharmaceutical industry was one of the main lobbyists for the global extension of IP rights.<sup>2</sup> For developing countries, a major concern was how the adoption of intellectual property regimes would affect their efforts to improve public health, and economic and technological development more generally, particularly if the effect of introducing patent protection was to increase the price and decrease the choice of sources of pharmaceuticals.

We are aware of the importance of effective patent protection for the industry most directly involved in discovering and developing new pharmaceuticals. Indeed, without the incentive of patents it is doubtful the private sector would have invested so much in the discovery or development of medicines, many of which are currently in use both in developed and developing countries. The pharmaceutical industry in developed countries is more strongly dependent on the patent system than most other industrial sectors to recoup its past R&D costs, to generate profits, and to fund R&D for future products. Successive surveys have shown that the pharmaceutical companies, more than any other sector, think patent protection to be very important in maintaining their R&D expenditures and technological innovation.<sup>3</sup> The industry understandably takes a close interest in the global application of IPRs, and generally resists the contention that they constitute a major barrier to access or a deterrent to development in developing countries. For instance, Sir Richard Sykes, the former Chairman of GSK, said in March this year:

“Few would argue with the need for IP protection in the developed world, but some question whether it is appropriate to extend its coverage to the developing world, which the TRIPS agreement is gradually doing. As I have said, IP protection is not the cause of the present lack of access to medicines in developing countries. At Doha last November, WTO members agreed to defer TRIPS implementation for the least developed countries until 2016. I do not believe that TRIPS will prevent other developing countries like Brazil and India from obtaining access to the medicines they need. On the other hand, I firmly believe that these countries have the capacity to nurture research-based pharmaceutical industries of their own, as well as other innovative industries, but this will only happen when they provide the IP protection that is enshrined in TRIPS. TRIPS needs to be recognised as an important industrial development tool for developing countries.”<sup>4</sup>

That said, we are also fully aware of the concerns expressed by, and on behalf of, developing countries about the impact that such rights may have in those countries, particularly on prices of pharmaceuticals. If prices are raised, this will fall especially hard upon poor people, particularly in the absence of widespread provision for public health as exists in most developed countries. Thus others from many developing countries, and the NGO community, have argued the opposite:

“Why do developing countries object so strongly to TRIPS? Its essential flaw is to oblige all countries, rich and poor, to grant at least 20 years' patent protection for new medicines, thereby delaying production of the inexpensive generic substitutes upon which developing-country health services and poor people depend. And there is no upside: the increased profits harvested by international drug firms from developing-world markets will not be ploughed back into extra research into poor people's diseases - a fact some companies will in private admit.”<sup>5</sup>

Our starting point in this analysis is that healthcare considerations must be the main objective in determining what IP regime should apply to healthcare products. IP rights are not conferred to deliver profits to industry except so that these can be used to deliver better healthcare in the long term. Such rights must therefore be closely monitored to ensure that they do actually promote healthcare objectives and, above all, are not responsible for preventing poor people in developing countries from obtaining healthcare.

## Background

A spur to much of the recent debate has been the HIV/AIDS pandemic, although the issue of access to medicines in developing countries goes much wider. It is particularly important not to allow the debate in this area to be influenced unduly by the HIV/AIDS experience, dramatic though it is. Apart from HIV/AIDS, which is the biggest single cause of mortality in developing countries, TB and malaria claim almost as many lives. Together all three diseases claimed nearly six million lives last year, and led to debilitating illness for millions more.<sup>6</sup> In addition, there are a number of less common diseases which are collectively important. These include, for instance, measles, sleeping sickness, leishmaniasis and Chagas disease.<sup>7</sup>

Each group of diseases presents different problems in respect of the development of cures and treatments, and the economics of the R&D process. For diseases prevalent in the developed world as well as developing countries, such as HIV/AIDS, cancer or diabetes, research in the private or public sector in the developed world may produce treatments that are also appropriate to the developing world. For these diseases, one would expect that the promise of strong IP protection in the developed world would act as a major incentive for investment in R&D. But it should be noted that some strains of HIV/AIDS in Africa, for example, are different from those in developed countries, so different treatments may need to be devised.

Where appropriate treatments already exist, access to them depends on affordability, and the availability of the health service infrastructure to support delivery. We regard the cost of pharmaceutical products as an important concern in developing countries because most poor people in developing countries pay for their own drugs, and state provision is normally selective and resource-constrained. This is generally not the case in the developed world where costs are

mainly met by the state or through insurance schemes. Even so the cost of drugs is a controversial political issue in developed countries, for governments and for patients not covered by effective state or insurance schemes.<sup>8</sup> In developing countries, inadequacy of the infrastructure is an important problem, and may mean that even inexpensive medicines are not used, or that they may be misused and contribute to the emergence of drug resistant pathogens or a virus.

Again, HIV/AIDS provides a helpful illustration of the issues. The treatment of HIV with anti-retrovirals (ARVs), or drugs to treat opportunistic infections associated with the disease, raises the affordability issue acutely. The minimum annual costs of ARV therapies, even at deeply discounted or generic prices which do not cover R&D costs, far exceed the annual health expenditure per capita of most developing countries. Current per capita health expenditures in low income developing countries average \$23 per year, but the most inexpensive ARV triple therapies are now just over \$200 per year.<sup>9</sup> Thus, without extra funding for medicines and health delivery services, treatment for all those requiring it will remain unaffordable even at the cheapest generic prices. The World Health Organisation (WHO) estimates that fewer than 5% of those who require treatment for HIV/AIDS are receiving ARVs. Only about 230,000 of the 6 million estimated to be in need of such treatment in the developing world actually receive it, and nearly half of these people live in Brazil.<sup>10</sup>

Similar questions about affordability arise for treatments of other diseases. For example, TB and malaria are for the most part prevalent in developing countries, although there is a resurgence of TB in the developed world. It also needs to be remembered that TB is the leading cause of death among HIV-infected people, and about one third of them are co-infected with TB.<sup>11</sup> For these diseases, and for diseases exclusive to the developing world, the issue is both how to mobilise resources for R&D from the private and public sectors for new medicines, and having developed them to ensure access for those that need them.

The latter point is one of the most crucial questions concerning healthcare in developing countries. How can the resources necessary to develop new drugs and vaccines for diseases that predominantly affect developing, rather than developed, countries be generated when the ability to pay for them is so limited? Even when there is a developed country market from which these resources can be recovered through high prices, how can the affordability of these drugs in developing countries be secured? How can conflicts between the two objectives – covering R&D costs and minimising consumer costs – be resolved? As with technological development more generally, does the IP system have a role to play in stimulating the capacity of developing countries themselves to develop and produce drugs that they or other developing countries need?

This is the context in which we need to consider the role that IPRs could play in helping to address these dilemmas. It is not for us to consider in any depth the wide range of factors that affect the health of poor people or the quality of health services in developing countries. These have been discussed at some length in the recent report of the WHO Commission on Macroeconomics and Health (CMH).<sup>12</sup> The CMH concluded that a large injection of additional public funds into health services, infrastructure and research was required to address the health needs of developing countries. It took the view that patent protection offered little incentive for research on developing country diseases, in the absence of a significant market.<sup>13</sup> As regards access to medicines, it favoured coordinated action to establish a system of differential pricing<sup>14</sup> in favour of developing countries backed up, if necessary, by the more extensive use of compulsory licensing.<sup>15</sup>

Those conclusions are relevant for our current task. It is our role to indicate in greater detail how changes in intellectual property rules and practices could contribute to better health for poor people, while being fully aware that such changes have to be complemented by the range of actions suggested by the CMH.

We do this by considering three main questions:

- How does the intellectual property system contribute to the development of drugs and vaccines that are needed by poor people?
- How does the intellectual property system affect the access of poor people to drugs and availability?
- What does this imply for intellectual property rules and practices?

## RESEARCH AND DEVELOPMENT

### Research Incentives

It is estimated that less than 5% of the money spent worldwide on pharmaceutical R&D is for diseases that predominantly affect developing countries.<sup>16</sup> Pharmaceutical research by the private sector is driven by commercial considerations and if the effective demand in terms of market size is small, even for the most common diseases such as TB and malaria, it is often not commercially worthwhile to devote significant resources to addressing the needs. In 2002, the world drug market is valued at \$406 billion, of which the developing world accounts for 20%, and low income developing countries very much less.<sup>17</sup> In many pharmaceutical companies, research objectives are set by reference to threshold returns. We were given to understand that the large pharmaceutical companies are unwilling to pursue a line of research unless the potential outcome is a product with annual sales of the order of \$1 billion. Given that private companies have to be primarily responsible to their shareholders, this necessarily leads to a research agenda led by the market demand in the markets of the developed world, rather than by the needs of poor people in the developing world, and thus a focus mainly on non-communicable disease.

Regardless of the intellectual property regime prevailing in developing countries, in reality there is little commercial incentive for the private sector to undertake research of specific relevance to the majority of poor people living in low income countries. Accordingly, little such work is done by the private sector. Total pharmaceutical R&D in the private sector has more than doubled in the last decade to an estimated \$44 billion in 2000.<sup>18</sup> Exactly what proportion of this is directed to diseases afflicting mainly developing countries is difficult to determine. However it has been estimated that of 1393 drugs approved between 1975 and 1999, only 13 were specifically indicated for tropical diseases.<sup>19</sup> Where diseases are common to both developed and developing countries, the picture is different. Thus, there is significant private sector R&D on HIV/AIDS. This contrasts with the limited work on tuberculosis and malaria, and virtually none on diseases such as sleeping sickness.<sup>20</sup> As regards HIV/AIDS, there are now 64 approved drugs in the US for treatment of the disease and opportunistic infections, and 103 in development.<sup>21</sup>

In the case of the public sector, such as the National Institutes of Health (NIH) in the US or Medical Research Councils (MRCs) in other developed countries, the situation is little different because their research priorities are principally determined by domestic considerations. Public sector spending on health research was estimated to be \$37 billion in 1998, of which \$2.5 billion was spent in low and middle income developing countries.<sup>22</sup> In 2001 the US National Institutes of Health (NIH) alone accounted for over \$20 billion.<sup>23</sup> In addition, charitable foundations are estimated to have spent \$6 billion. The WHO's Special Programme for Research and Training in Tropical diseases (known as TDR) receives only about \$30 million annually. The exact proportion of public sector spending on diseases relevant to developing countries has not been authoritatively estimated, but seems unlikely to be higher than 10%.<sup>24</sup> This situation is now being addressed through the WHO, the Global Forum for Health Research, the initiative of Médecins Sans Frontières (MSF) on drugs for neglected diseases, additional funding by foundations and the development of several public-private partnerships to address specific diseases.<sup>25</sup> But the overall level of funding for these new efforts is still very modest in relation to the scale of the problem and global R&D expenditure of about \$75 billion, and the outcome uncertain.

So what role does IP protection play in stimulating R&D on diseases prevalent in developing countries? All the evidence we have examined suggests that it hardly plays any role at all, except for those diseases where there is a large market in the developed world (for example, diabetes or heart disease). There is some weak evidence related to an increase in indicators of research activity in malaria since TRIPS was agreed, but the relation between cause and effect is not at all clear.<sup>26</sup> The heart of the problem is the lack of market demand sufficient to induce the private sector to commit resources to R&D. Therefore, we believe that presence or absence of IP protection in developing countries is of at best secondary importance in generating incentives for research directed to diseases prevalent in developing countries.

Thus this research may be inadequate in quantity because of inadequate effective demand from developing countries where the disease is heavily concentrated. Moreover research, particularly on vaccines, may require tackling characteristics of diseases specific to developing countries, where the solution for the developed world may not address the problem in the developing world. For example, the majority of HIV vaccines are being developed for genetic profiles of subtype B, prevalent in developed countries, but most AIDS sufferers in developing countries are types A and C. Vaccine research for HIV is also particularly scientifically challenging because of the way the virus evades the body's natural immune responses, and the way it mutates.<sup>27</sup> Malaria vaccine research is also challenging, because of the size and diversity of the malaria parasite, and the complexity of its mutations.<sup>28</sup> Thus, for the private sector, vaccine research is a high risk/low return investment, particularly in relation to disease types prevalent in developing countries. The market tends to undervalue the social returns from vaccines, more than is the case for treatments.<sup>29</sup> In the case of malaria, the market demand is dominated by prophylaxis for travellers from developed countries, rather than vaccines which would be of greater relevance to sufferers in the developing world.

In respect of TB, where there are an estimated eight million people in developing countries that have the disease, no new class of anti-TB drug has been developed for over 30 years. Current treatments require drug courses of 6 months or more. A drug that produced the same effect in two months could have a dramatic impact in helping to control the disease globally. The scientific challenge of producing such a medicine is significant because of the characteristics of the disease.<sup>30</sup> A recent report by the Global Alliance for TB Drug Development has estimated that based on market demand (both private and public, including from developed countries) there might in fact be a respectable financial rate of return on the estimated cost of developing a new and improved drug. Nevertheless it is still not considered that IP protection, and favourable economics, will induce investment without considerable public sector involvement.<sup>31</sup> The current business model of the research-based pharmaceutical companies is such that research expenditure and profit generation are dependent on the sales of a few "blockbuster" drugs (normally with sales in excess of \$1 billion per annum), which help finance the high percentage of failures in the R&D process.<sup>32</sup> But these companies have the freedom to pursue promising avenues wherever they may lead (for example, treatment for a disease or condition not previously envisaged). The economics of research for a specific treatment for a particular disease have to be very favourable to induce significant research effort.

Some, such as Sir Richard Sykes above, have argued that providing IP protection in developing countries with significant scientific and technical skills will help to increase the amount of research devoted to developing country diseases. Evidence on this is lacking because most of the relevant countries have only just introduced TRIPS-compliant laws, or are yet to do so. But we see no reason why firms with research capability in developing countries should respond to global IP and market incentives significantly differently from those based in developed countries. There is some evidence for this behaviour from firms in countries such as India.<sup>33</sup> The reality is that private companies will devote resources to areas where an optimal return can be made. Moreover, widely supported moves to establish differential pricing would reduce margins to reward R&D in developing countries, further undermining any incentive for additional research on developing country diseases.

In short we do not think that the globalisation of IP protection will make a significant contribution to increasing R&D expenditure by the private sector relevant to the treatment of diseases that particularly affect developing countries. The only feasible way to do this is by increasing the quantity of international aid resources devoted to such R&D. The CMH recommended an additional \$3 billion annually to be spent on R&D through a new Global Health Research Fund, existing mechanisms and public-private partnerships.<sup>34</sup>

How increased publicly funded research should be directed requires careful consideration. It should not act as a form of subsidy to the existing pharmaceutical industry, although the industry certainly has an important part to play. The opportunity should be taken to build up the capacity of developing countries themselves to undertake R&D on treatments for those diseases which particularly affect them. In the technologically more advanced developing countries, such research can be highly cost-effective. For instance, General Electric has established its second largest R&D Centre in the world in India, employing about 1000 PhDs and 27 other global firms set up R&D centres in India between 1997 and 1999.<sup>35</sup> Thus research could be conducted with the active participation of selected research institutions and companies in developing countries, taking advantage of the human resources available in such countries and lower R&D costs. The institutional structure of for such funding also needs thought. The CGIAR<sup>36</sup> network of agricultural research institutes (which we discuss in Chapter 3) is one model. More promising in this context might be a network of public-private partnerships in developing countries, taking advantage of the concentration of research resources in public sector institutions but also the opportunity to build research capacity in the private sector. In particular the arrangements for intellectual property arising from such research need to be such that access by the poor to the products of research is ensured as much as possible.

**Public funding for research on health problems in developing countries should be increased. This additional funding should seek to exploit and develop existing capacities in developing countries for this kind of research, and promote new capacity, both in the public and private sectors.**

Although IP may not have much to contribute in generating additional research relevant to poor people, it is clear to us that there are important issues about the impact of the patent system on the research process. While patent protection provides an incentive for R&D, the patenting of intermediate technologies (particularly gene-based ones) required in the research process may actually create disincentives for researchers in terms of accessing, or unwittingly infringing patents on, technologies they need.<sup>37</sup> This is an area where patent practices in the developed world can impinge directly on what research is done for people in the developing world, and there are implications for the type of patent regimes that developing countries adopt. The IP arrangements in public-private partnerships also give rise to important questions of managing IP to benefit poor people. We consider these questions in Chapter 6.

## ACCESS TO MEDICINES FOR POOR PEOPLE

The purpose of patents, as we have noted, is to provide a temporary monopoly to rights holders as a stimulus to inventions and their commercialisation. However, it should also be noted that the monopoly right provided by a patent normally only excludes others from making, using or selling that particular invention. It does not prevent competition from other drugs, patented or not, that address the same medical conditions. Nevertheless, other things being equal there is a presumption that the producer of a patented product, through the ability to exclude copies, will attempt to earn a monopoly profit and charge higher prices than would otherwise be the case. That, indeed, is the basis of the system. The bargain with society is precisely that the benefits to society generated by the extra innovation induced (for example, a lifesaving drug which might not exist but for the patent system) should exceed the extra cost of the product.

Given that in developing countries most people are poor and that patent protection can increase prices, it is necessary to examine with particular care the arguments put forward by some that

patents in developing countries are not likely significantly to affect access to pharmaceuticals subject to patent protection. There are two grounds on which this argument is made. First, because patents are not always sought in some – especially smaller - developing countries, they cannot be a significant problem in accessing medicines. Secondly, even if they are sought, either this is not a determining factor in pricing or there are other overriding factors that prevent access to drugs by the poor.

## Prevalence of Patenting

It is true that, although patent protection for pharmaceutical products is available in most developing countries, multinational companies have not patented their products in all of them. This is normally the case for countries with small markets and limited technological capacity. Companies may take the view that it is not worth the expense of obtaining and maintaining protection when the potential market is small, and the risk of infringement low. For instance, a recent study in 53 African countries found that the extent of patenting of 15 important antiretroviral drugs was 21.6% of the possible total.<sup>38</sup> In 13 countries there were no patents on these medicines at all. The conclusion was drawn that, because the patenting rate was so small, patents “generally do not appear to be a substantial barrier to...treatment in Africa today”, although it was recognised that there would be an issue when TRIPS came into force for all WTO members.<sup>39</sup>

Although the overall prevalence of patents found in the study is relatively low in aggregate, it is perhaps surprising that it is not lower, given the very low treatment rates, small markets, and the fact that few countries are capable of producing generic copies. The prevalence of patents is very much higher in countries where there is a substantial market, and technological capacity. Thus in South Africa (which alone counts for over 17% of Africa’s HIV cases) 13 of the 15 drugs are patented. There are 6-8 patents for these drugs in Botswana, Gambia, Ghana, Kenya, Malawi, Sudan, Swaziland, Uganda, Zambia and Zimbabwe, which together account for another 31% of HIV cases in sub-Saharan Africa.<sup>40</sup>

The industry points out that the prevalence of patenting is very much lower, or nil, for a wide range of drugs to treat other diseases. Until the latest revision this year, less than 5% of the drugs on the WHO Essential Drugs List were patented.<sup>41</sup> An industry survey indicated that 94% of countries surveyed had no patents on TB and malaria drugs, and no country has patents on all the relevant drugs for these diseases.<sup>42</sup> There were no patents at all on drugs for trypanosomiasis or diarrhoeal diseases. The argument advanced by industry is that even where there is no patent protection, the drugs are still not available.<sup>43</sup> For instance, even where vaccines are available for various common diseases and cheap (for example, less than \$1 for a polyvalent vaccine), WHO’s Expanded Programme of Immunisation (EPI), in spite of undoubted successes, still fails to reach many children who could benefit.

This is of course true, but it does not follow that the patent system has no adverse effects. Even if patents do not exist for particular products and countries, the patent system may still have an effect on access to medicines. Most low income developing countries have to rely on imports for their supplies. The existence of patents in potential supplier countries may allow the patentee to prevent supplies being exported to another country, particularly through controls on distribution channels. This is another reason why companies may selectively patent in countries such as South Africa because it is a potential supplier to its poorer neighbours in the rest of Southern Africa (or indeed elsewhere). At present, importing countries where there is no patent protection have the option of importing supplies from generic companies, principally in India, because India need not have pharmaceutical product protection until 2005. But thereafter, under TRIPS, new drugs and those for which patent applications were submitted after 1994 will be patentable, and the opportunity for these imports will diminish correspondingly over time. However, it should be noted that all existing drugs produced as generics in India or elsewhere will continue to be available for export provided, of course, they are not patented in the importing country. We return to this issue below in our discussion of policy options.

## Patents and Prices

The importance of prices of medicines to poor consumers in developing countries is perhaps obvious. But it is worth emphasising that if a sick person has to pay more for a pharmaceutical product as a result of a patent, it means that he or she will have less to spend on other essentials of life such as food or shelter. Alternatively, foregoing the medicine because it is unavailable or unaffordable may result in long term ill health, or death. That is why it is essential to consider the impact of the introduction of an IP regime on prices, while recognising that prices are affected by many factors. These include purchasing power, competition and market structure, responsiveness of demand to price and government price controls and regulations.

It is particularly difficult to observe directly and isolate the impact of introducing patents in developing country markets. In part we have to rely on econometric models to simulate the impact of introducing patent protection, and in part the experience of developed countries where generic producers compete with research-based ones.

### *Developed Countries*

There is extensive evidence from developed countries that prices fall quite steeply as soon as drugs go off patent, assuming there are generic competitors. The price fall seems to be greater the more generic competitors enter the market. Governments can encourage price reductions by facilitating the early entry of generic producers into the market. For instance, the 1984 Drug Price Competition and Patent Term Restoration Act in the US (known as the Hatch-Waxman Act) did precisely that, resulting in the share of generics in prescriptions dispensed rising from 19% in 1984 to 47% in 2000.<sup>44</sup> In other developed countries, such as the UK, the generic share of the market is often much higher. Pharmaceutical companies have also brought or defended expensive court actions to delay or prevent generic entry and to protect or extend a monopoly on a best selling drug.<sup>45</sup> Correspondingly, we must remember that generic producers are governed by market incentives just as the research-based industry, and that it is necessary to encourage competition within the generic industry if lower drug prices are to be achieved. A recent study in the US found that prices fall when generic competition enters the market but at least five generic competitors are necessary to push prices down to a minimum.<sup>46</sup> The number of competitors entering the market, and the speed with which they do so, will depend on the expected profits. A crucial finding is that the full benefits of competition will only be felt at quite large market sizes – in smaller markets fewer generic firms will consider the market worth entering and prices to consumers will be higher. This is very relevant to the position of developing countries, as discussed below.

### *Developing Countries*

Developing countries can also limit the costs of the patent system for their population by facilitating generic entry and generic competition. But in most cases their options are severely limited by the small size of their markets and lack of indigenous technological, productive and regulatory capacity. It is this lack of capacity to create a competitive environment for both patented and generic products that makes the existence of patents more contentious than in developed markets with greater capacity to enforce a strongly pro-competitive regulatory environment.

International comparisons show that copies of drugs patented elsewhere are much cheaper in markets which do not offer patent protection. The Indian market, where there is no product protection, is the lowest priced in the world. One of our studies indicated that for 12 drugs covering a range of conditions US prices range from four to 56 times the price of equivalent formulations in India, and yet still a large number of people in India cannot obtain access to them.<sup>47</sup>

However, studies of multinational company pricing policies (mainly for ARVs) indicate that until recently there was remarkably little correlation between the price of the same drug and a country's

per capita income. This correlation is expected on theoretical grounds because companies should be able to make more profits by charging low prices in low income markets and high prices in high income markets (known as differential pricing), than by charging a uniform global price. But prices have appeared to vary more or less randomly between countries. Some developing countries paid more than US prices and some less. At best there was a very weak relationship between wholesale drug prices and per capita income.<sup>48</sup> The actual price to the patient is complicated by import duties, local tariffs, taxes and wholesaler profits.<sup>49</sup>

In the last two years this situation may have changed somewhat as some companies have drastically lowered prices offered in response to international pressure, principally from NGOs, and potential competition from generic manufacturers, particularly from India. For instance, between July 2000 and April 2002 the annual cost of a branded triple therapy ARV combination fell from over \$10000 to just over \$700 for selected groups of consumers. By then the lowest generic price for this combination had fallen to \$209.<sup>50</sup>

But to estimate the impact of introducing patent regimes anew in developing countries, it is necessary to use econometric models. There is a small but growing literature, that relates almost entirely to lower and middle income developing countries which already have significant pharmaceutical industries. This literature demonstrates that the introduction of patent regimes into such developing countries has, or is predicted to have, the effect of raising prices. The estimates range widely depending on the drugs and countries being considered – from 12% to over 200%, but even the lower estimates imply very substantial costs for consumers.<sup>51</sup> The range of estimates is indicative of the degree of uncertainty about the dynamic effect of introducing patents, and suggests that the outcome will be very much determined by market structure and demand, in particular the degree of competition.

There is also considerable evidence that consumption of medicines is sensitive to price. One study in Uganda estimated that reducing the price of an ARV triple therapy from \$6000 per annum to \$600 per annum would increase the demand for treatment from 1000 to 50000 patients if associated with relatively modest investments in treatment infrastructure (of \$4-6 million).<sup>52</sup> Another study, also in Uganda, indicated that price cuts arising from discounts by brand name companies, further lowered by the import of generic equivalents, increased the number of patients being treated threefold between 2000 and 2001.<sup>53</sup> A global econometric study estimated that the effect of eliminating patents in a cross-section of developing countries would be to increase access to ARVs by 30%, albeit from the very low existing level.<sup>54</sup>

The impact of introducing patent systems is likely to be most strongly felt in the group of countries that have developed strong generic industries, with a degree of competition that has kept prices low. There is evidence from some countries that the introduction of patents (for example in Italy in 1978) or strengthening the regime, as in Canada in the 1990s, by increasing the market power of foreign multinationals, will result in the consolidation and restructuring of the domestic industry. This may entail significant costs to the consumer by reducing the degree of competition in the market and increasing imports. Whether these costs may be offset by other benefits (for example, a boost to local research) is much debated. In Italy and Canada, two developed countries, the evidence is mixed.<sup>55</sup> In Italy multinational companies took over many local companies, exports of generic drugs declined and imports of patented drugs increased. There was little evidence of increased R&D. In Canada, there is evidence of a significant rise in R&D, partly as a result of a deal struck with the multinational manufacturers and tax credits allowed under the Income Tax Act (1987), but R&D is focused on preclinical and clinical trials and improvement of manufacturing processes rather than on the development of new molecules.<sup>56</sup> In both countries price controls were used to limit price increases on patented products.

In developing countries with strong generic industries, the outlook is also uncertain. On the one hand, manufacturers of mainly generic drugs are likely to be adversely affected by the introduction of patent protection, and also consumers and governments who will need to pay more for drugs

that receive patent protection. On the other hand, producers who are developing a research capability, or who may be able to obtain licences from multinational companies, may perceive benefits from patent protection. These conflicting impacts explain why the introduction of patent protection in India is so controversial. Sections of the Indian pharmaceutical industry support the introduction of patent protection, and are gearing up their research in anticipation of its introduction, while other sections strongly oppose it. And, of course, it is controversial with consumer groups and NGOs.

More generally, as the TRIPS agreement is implemented, the supply of generic copies of new drugs will be prevented. At present, the threat of international competition from generic suppliers of copies of patented drugs is a restraining factor on the prices that can be charged in countries with no patent regimes, and to a lesser extent in countries with patent regimes where there is a credible threat of compulsory licensing. When all producer countries have patent laws, generics will increasingly be limited to older off-patent drugs. This will be no different from the current situation in developed countries, but developing countries will still find it difficult to afford new on-patent medicines. Means will need to be found, within the patent system and outside it, to generate the competitive environment that will help to offset the adverse price effect of patents on developing country consumers. We consider below some of the measures that need to be considered to ensure that the patent system supports a country's right to protect human health and to promote access to medicines, in line with the Doha Declaration on TRIPS and Public Health (hereafter Doha Declaration – see Box 2.1).

## Other Factors Affecting Access

It is argued, for instance by the pharmaceutical industry, that the most important constraints to access to medicines in developing countries, are not patent protection but the lack of spending on healthcare in developing countries, and the absence of a suitable health infrastructure to administer medicines safely and efficaciously. Improper administration may contribute to the development of drug resistance, apart from being ineffective. In the case of HIV, where the virus mutates readily, wide distribution of ARVs without the development of adequate infrastructure may contribute to the emergence of drug resistance.<sup>57</sup> It is also argued that generic versions of patented drugs may be of sub-standard quality, or even hazardous.<sup>58</sup>

A report by the US pharmaceutical industry association says:

“Handicapped by limited financial resources, these nations’ ability to contain AIDS and address a host of other killer diseases is compromised by inadequate infrastructure, cultural barriers to care, and mismanaged health care systems. Some developing countries also are hampered by political leadership that lacks the will to confront or even acknowledge their nation’s health care needs.”<sup>59</sup>

Other than patents, there are a number of factors that affect drug prices, such as tariffs and other forms of indirect taxation.<sup>60</sup> It can appear perverse to complain about the price impact of patents, while ignoring other policies under national control that have a similar effect. Thus it is important that national tax systems operate in a way that supports public health policies, just as the patent system should.

In order to help allay concerns about delivery mechanisms for AIDS drugs, the WHO has this year produced the first treatment guidelines for using ARVs in poor settings and issued a list of manufacturers and products (including eleven ARVs) which meet WHO quality standards as suppliers to UN agencies. The list currently includes both producers of patented products and a number of generic versions of these products including, so far, two Indian suppliers. In addition the WHO has included for the first time twelve ARVs for the treatment of AIDS (two were already there but for the treatment of mother-to-child transmission) on its Essential Drugs List.<sup>61</sup>

There is much debate about the comparative relevance of patents and other factors in determining access to medicines. We consider it important that all these factors are addressed. But we also do not consider that there is a real trade-off between improving IP arrangements to pursue the objectives of public health and addressing the issues of policy, infrastructure and resources for the same objectives. Both need to be pursued, and pursuing one has no bearing on one's ability to pursue the other. One of the participants at our conference said:

"...I would like to discourage the Commission from arriving at the conclusion in this debate {that it is all} about infrastructure and resources. If that is the conclusion, I think you will have what the title says: "People are Poor". So don't make recommendations that people are poor because we know that. We are trying to solve their problems, not to tell them that they are poor."<sup>62</sup>

**Countries need to adopt a range of policies to improve access to medicines. Additional resources to improve services, delivery mechanisms and infrastructure are critical. Other macroeconomic policies need to be in harmony with health policy objectives. But so also does the IP regime. Countries need to ensure that their IP protection regimes do not run counter to their public health policies and that they are consistent with and supportive of such policies.**

## POLICY IMPLICATIONS

### National Policy Options

#### *The Context*

The context of our discussion of the policy implications is the Doha Declaration agreed at the WTO Ministerial Meeting in Doha in November 2001 (see Box 2.1). Ministers clarified that TRIPS should not prevent countries from taking measures to protect public health. They confirmed that, within the terms of the agreement, compulsory licences could be granted on grounds determined by member countries. Moreover, domestic demand could be supplied by parallel imports (governed in legal terms by what is known as the "exhaustion of rights" doctrine).<sup>63</sup> They recognised that a special problem existed for countries with insufficient manufacturing capacity in making use of compulsory licensing, and instructed the TRIPS Council to find a solution by the end of this year. Members also agreed to exempt least developed countries from implementing, applying or enforcing pharmaceutical product and test data protection<sup>64</sup> until 2016. The TRIPS Council confirmed this decision on 27 June 2002. The Council at the same time approved a waiver that would exempt LDCs from having to provide exclusive marketing rights for any new drugs in the period when they do not provide patent protection. The latter waiver, now approved by the General Council of WTO, has to be reviewed annually by the Ministerial Conference of WTO (or the General Council between Ministerial meetings) until it terminates.

The premise of our recommendations is that for most developing countries any benefits in terms of the development of new treatments for diseases that afflict them will be, at best, long term, while the costs of implementing a patent system are both real and immediate. Thus we concentrate on measures within the IP system that will reduce to a minimum the prices of drugs, while maintaining their availability. As noted above, we have not found evidence to suggest such measures will diminish the incentives for research on diseases specific to developing countries, because it is the lack of demand rather than the IP system which is the determining factor. But we recognise that, because we are entering uncharted waters, continuing research will be necessary to establish how much TRIPS implementation in practice affects both research incentives and access, particularly in the longer term.

## Box 2.1 Doha WTO Ministerial Declaration on TRIPS and Public Health

Adopted on 14 November 2001

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, TB, malaria and other epidemics.
2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.
3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.
4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:
  - a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.
  - b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.
  - c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, TB, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
  - d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.
6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.
7. We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

## Differential Pricing

As we have noted, differential pricing in principle should be an economically rational way for global companies to maximise their profits on products that are sold in both low and high income markets.<sup>65</sup> It should also be a way of ensuring that poorer people obtain less expensive products.

There are several initiatives aimed at facilitating a global system of differential pricing. As noted above, there are many other factors unrelated to IPRs that affect the prices and availability of medicines. In establishing a differential pricing system, which would allow low prices in developing countries to coexist with higher prices in developed countries, there are two important factors:

- Markets with different price levels must be segmented so that low priced medicines cannot enter higher priced markets. This means controlling exports and imports of relevant products.
- Pricing decisions in higher priced markets, where these are set or influenced by government policy, must not be made by reference to prices in the low priced markets.

The second factor does not involve IP considerations, but represents a political problem in many developed countries because of the existing variation in prices of pharmaceuticals, even between developed countries, and the pressure on the budgets of patients, insurance schemes and the state to meet ever rising bills for patented drugs.

But the tools of the IP system, including parallel imports and compulsory licensing, are likely to play an essential part in underpinning differential pricing and market segmentation. In order to ensure an effective operation of a differential pricing system, national laws in developing countries should retain the right for the government to admit parallel imports and to issue compulsory licences.

We are also aware of recent price reductions and of the number of special schemes operated by some companies, sometimes in cooperation with international agencies, to provide heavily discounted or free drugs and, in conjunction with local government and NGOs, supportive infrastructure to ensure delivery to the patient. These offers generally apply only to purchasers who are governments, NGOs, aid organisations or private sector employers, not commercial suppliers of medicines. These are all welcome contributions to improving access to medicines in developing countries.<sup>66</sup> But there is also the need to seek more broad-based solutions, which are also sustainable, to the serious public health problems that are being addressed. That is why continued efforts are required to make differential pricing effective.

## Parallel Imports

In principle, it is undesirable for there to be restrictions upon the free movement of products once placed on the market by a manufacturer. But in practice, and strictly for the purpose of ensuring that lower priced products can be supplied to, and only to, those who need the lower prices, it may be necessary to derogate from that general principle. Therefore an important component in establishing a system of differential pricing is that markets need to be segmented to prevent low priced products undermining high priced markets. For that purpose, it is essential that developed countries put in place effective mechanisms that prevent parallel importing of medicines. This is already broadly the case for the US and the EU, but appears not to be so for Japan.<sup>67</sup>

**Developed countries should maintain and strengthen their legislative regimes to prevent imports of low priced pharmaceutical products originating from developing countries.**

However, to secure the segmentation of markets, it would also be desirable for developing countries to act to prevent exports to developed countries of drugs that are part of a donation or differential pricing scheme. It is especially important to avoid product diversion from those patients for whom the medicine is intended. But, recognising limitations in their capacity for enforcement,

the primary burden of segmentation between developed and developing countries will realistically need to rest with developed countries.

Developing countries should not eliminate potential sources of low cost imports from other developing or developed countries. In order to be an effective pro-competitive measure in a scenario of full compliance with TRIPS, parallel imports should be allowed whenever the patentee's rights have been exhausted in the foreign country. Since TRIPS allows countries to design their own exhaustion of rights regimes (a point restated at Doha), developing countries should aim to facilitate parallel imports in their legislation.

## Compulsory Licensing

As noted above, the result of implementing TRIPS will be to curtail the supply of generic copies of patented products. This will remove an important element in restraining and reducing the prices of patented products in developing countries. Providing effective legislation and procedures for compulsory licensing may have an important role to play in maintaining a pro-competitive IPR policy in the new environment. We do not regard compulsory licensing as a panacea, but rather as an essential insurance policy to prevent abuses of the IP system.

Although TRIPS allows compulsory licensing (as clarified in the Doha Declaration), subject to certain procedures and conditions, developing countries have yet to use it. Ironically, it is the developed countries that have been the most active users of compulsory licensing (not only in the pharmaceutical field) for a number of purposes, including importantly in anti-trust cases in the US. Canada used compulsory licensing extensively in the pharmaceutical field from 1969 until the late 1980s. This resulted in prices of licensed drugs being 47% lower than in the US in 1982.<sup>68</sup> The UK also used compulsory licensing until the 1970's, including for important drugs such as Librium and Valium. More recently in 2001, the US Secretary for Health and Human Services (HHS), publicly envisaged the possibility of procuring generic equivalents prior to his negotiations with Bayer (the patentee) on the purchase of the drug Cipro to deal with the consequences of anthrax attacks although, in the end, agreement was reached with Bayer.<sup>69</sup>

Developing countries have not used the system for a number of reasons. First, it requires an administrative and legal infrastructure that is absent in many developing countries. Secondly, developing countries have feared that sanctions might be threatened, bilaterally or multilaterally. Thirdly, compulsory licensing has to be "predominantly for the domestic market". Fourthly, the word compulsory refers to the **legitimate** limitation of patent owner rights by a government. The actual producer of the licensed drug manufactures voluntarily and for profit (at least in the case of a private sector licensee). Thus the licensee must have the know-how to reverse engineer and manufacture the drug without the cooperation of the patent owner, and must also foresee a sufficiently large market to justify the costs of investment and manufacture and adequate remuneration to the patentee. If these conditions are not fulfilled, the threat of a compulsory licence will not be credible.

The threat of compulsory licensing has been successfully used by Brazil in the pursuit of its National STD/AIDS Programme (see Box 2.2). As a result of its research capability, and the development of public sector manufacturing capacity, Brazil has been able to use the threat of compulsory licensing in negotiations with pharmaceutical companies. This includes an ability to use estimates of its own production costs under compulsory licensing when negotiating prices with patentees. But there are relatively few developing countries which are in the same position as Brazil, so the threat will lack credibility in most developing countries unless they are able to rely on imports from countries with the requisite capacity.

## Box 2.2 The Brazilian National STD/AIDS Programme (NSAP)

The primary mission of the Brazilian National STD/AIDS Programme (NSAP) is to make HIV/AIDS medications available free of charge to all citizens who need them through the national public health care system. NSAP was initiated in the early 1990s and the treatment of HIV/AIDS patients was made a legal obligation in 1996. With the assistance of HIV/AIDS NGOs, there has been a major reorganisation of the national public health services network for drug distribution, AIDS testing and care. There are now hundreds of Drugs Dispensing Units across the country.

NSAP now supplies anti-retroviral drugs to currently nearly 105,000 of Brazil's estimated 600,000 HIV/AIDS patients. It has now reduced the number of cases of HIV and mortality among AIDS victims to half what was predicted in the early 1990s. Hospital admissions have decreased by 80 percent since 1996. So, although the NSAP is expensive (the total annual cost is about US\$500m out of a total health budget of US\$10bn), the costs avoided due to reduced illness, hospitalisation and other impacts of HIV/AIDS are beginning to balance the budget. The Brazilian Ministry of Health estimates that in 2001, the final cost of NSAP, incorporating reduced morbidity expenditure, was negative (a net saving of US\$50m).<sup>70</sup>

Of the total cost of the programme, \$300 million is spent on AIDS drugs. The cost of acquiring the antiretroviral drugs has reduced recently, as the Ministry of Health/NSAP develops local production in the public sector - establishing national laboratories, and tools to negotiate with multinational companies, including the threat of compulsory licensing. Far-Manguinhos (part of the Oswaldo Cruz Foundation - FIOCRUZ) is the main government drug producer, developing the technology that provides the country with low-cost anti-retroviral drugs. The institute already produces seven of the 15 medicines used in the antiretroviral cocktail offered in Brazil. None of these drugs are patented in Brazil. The prices of these drugs, when developed for local production, fell by an average of 72.5% between 1996 and 2000. In 1999, 47% of antiretrovirals were produced in Brazil but accounted for only 19% of total expenditures. Thus 81% of expenditure was on ARVs purchased from multi-national companies.

Because Far-Manguinhos has the technical capacity to reverse engineer patented drugs, and can estimate realistic production costs, the Health Ministry is in a strong bargaining position for negotiating price reductions with foreign producers, backed up by the credible threat of compulsory licensing. In 2001 the Health Minister used this approach with Roche and Merck for their drugs Nelfinavir and Efavirenz, eventually negotiating price reductions of 40 to 70%.

While Brazil's programme has been widely acclaimed as a possible model for other countries, it needs to be noted that the cost of the programme amounts to nearly \$5000 per annum per treated person, or \$800 for each HIV infected person, or \$3 for every person in Brazil. Thus Brazil has prioritised the treatment of HIV/AIDS. This is affordable for Brazil because it is a relatively affluent developing country, and because in proportionate terms it has a low rate of HIV infection. Moreover, its technical know-how allows the Ministry of Health to negotiate price reductions effectively. As noted above, it may be an investment that pays for itself in reduced mortality and morbidity. But the initial investment in this type of programme may not be affordable in poorer countries with much higher rates of HIV infection, without external assistance. For such nations, their weak technological capacity will also be a constraint in the absence of effective means of compulsory licensing as proposed in Doha.

## National Arrangements for Compulsory Licensing

An important barrier to compulsory licensing in developing countries is the absence of straightforward legislative and administrative procedures to put it into effect. Because legal systems in most developing countries are overburdened, it would be most appropriate to legislate for a quasi-judicial and independent administrative system for implementation of compulsory licensing. The essential elements would include:

- straightforward, transparent and fast procedures
- procedures for appeals that do not suspend the execution of the licence
- legislation that fully exploits the flexibilities in TRIPS for determining the grounds for compulsory licensing, as well as for non-commercial use by government, including production for export (see below)
- clear, easy to apply, and transparent guidelines for setting royalty rates (which may vary).

There is much to be learnt from the experience of developed countries, particularly Canada, which seems to have had the most comprehensive programme. Canada set a more or less universal royalty rate of 4%, for which an early precedent was set in an important test case. US practice has varied considerably from very low rates to quite high, depending on court judgements. Developing countries will need to develop rules and procedures adapted to their own circumstances for setting royalty rates, but the implication of other countries' experience is that royalty rates need not be very high.

Developing countries also need to consider adopting in this context strong provisions on government and non-commercial use. This is different from compulsory licensing but has a similar effect in the public health sector. Again, many developed (and developing) countries have such provisions in their laws. In Commonwealth countries these derive from the British 1883 Act, which has been retained in current law.<sup>71</sup> These powers are quite sweeping and do not specify closely particular circumstances in which they can be used. For instance, in New Zealand:

“...any Government Department ...may make, use, exercise and vend any patented invention for the services of the Crown and anything done by virtue of this subsection shall not amount to an infringement of the patent concerned.”<sup>72</sup>

**Developing countries should establish workable laws and procedures to give effect to compulsory licensing, and provide appropriate provisions for government use.**

### Compulsory Licensing for Countries with Insufficient Manufacturing Capacity

Paragraph six of the Doha Declaration directs the TRIPS Council to develop an expeditious solution to the problem faced by certain countries not having sufficient manufacturing capacity in the pharmaceutical sector. It defines the problem as the inability of these countries to use compulsory licensing to obtain needed pharmaceuticals from a producer located in their territory. A compulsory licence ordinarily could be used for this purpose - the country could authorise through a compulsory licence a domestic producer to produce the product within its territory, or an importer to procure from elsewhere. The countries identified as having this problem, however, cannot turn to a domestic producer for products under this approach, and would need to rely on a producer from another country.

We agree that it is important to get the interpretation or amendment of TRIPS right, bearing in mind the longer term scenario when patent protection will apply to countries that can currently produce and export generic copies of patented drugs. The ultimate need is to create a pro-competitive solution for the market in patented drugs in developing countries after TRIPS is fully in force which allows expeditious procurement of drugs in a sustainable manner at the lowest

possible cost. This applies whether we are considering the direct procurement of patented drugs where there are a range of therapeutic substitutes, or about procurement under compulsory licensing.

Compulsory licensing needs to be viewed as a means to an end. The end in this case is to help achieve the lowest possible cost of medicines in developing countries in order to facilitate access. The only point of compulsory licensing in this context is if it will help to achieve this. As noted above, aside from the legal and administrative aspects, compulsory licensing will only be effective if the compulsory licensee sees the possibility of a reasonable return from his investment while also supplying at a significantly lower price than the patentee (or his licensee).

While there are now several countries, particularly those with significant domestic markets, with the capacity to produce copies of drugs cheaply, this will become more difficult after 2005. There will be no incentive, as now, for manufacturers in these countries to reverse engineer newly patented drugs and take the other steps necessary for manufacture and sale (including obtaining regulatory approval), because the domestic market would be closed. Thus the ready supply of generic substitutes for patented drugs now available will gradually disappear. Potential compulsory licensees would therefore have to charge a price closer to full economic cost (including start-up and manufacturing costs) as compared to the possibility of providing off-the-shelf generics at prices where start-up costs have already been amortised to some extent on the domestic market. Moreover, if the necessary investment is only triggered by the availability of a compulsory licence, there will inevitably be long delays before the drug actually reaches the intended patients.<sup>73</sup> In addition, there is some evidence that reverse engineering of new medicines is intrinsically more difficult in biopharmaceuticals than in traditional process chemistry.

This suggests that, without special arrangements, the possibility of compulsory licensing being a vehicle for price reductions will be more limited than at present, even in the few technologically advanced developing countries. For most countries, the only feasible supplier may be the patentee (or his licensee).

We therefore see the problem identified at Doha as being as much economic as legal. A quasi-legal solution as may be identified in the TRIPS Council is necessary, but is by no means sufficient to solve the problem we have outlined. In particular the quasi-legal solution is less likely to be effective the more compulsory licensing is hedged around with restrictions. Such restrictions reduce the likelihood that such licensing can be an effective bargaining tool for developing countries negotiating prices with patentees – it can be effective only if the compulsory licensing alternative is a viable economic proposition.

### *Legal Aspects*

In this section we consider and comment on the various proposals put forward by different countries and groups of countries to address the WTO resolution of the problem identified in paragraph 6 of the Doha Declaration. This revolves around the substance of Articles 28 (Rights Conferred), Article 30 (Exceptions to Rights Conferred) and Article 31(f) of TRIPS, where Article 31 deals with “Other Use Without Authorisation of the Right Holder”. Article 31(f) provides that a compulsory licence must be “predominantly for the supply of the domestic market of the Member authorising such use.”

Countries with no or insufficient manufacturing capacity cannot therefore issue a compulsory licence to a domestic manufacturer, or to one overseas because patents are territorial. At present they could issue a compulsory license to an importer, who could source the supply from a generic manufacturer in a country where the product is not patented. After 2005, this option will not be possible for drugs that are patented in the supplier country.

The practical effect of this provision is to render the compulsory licensing provisions practically worthless for the very countries which are likely to need it most – namely the poorest. With limited domestic manufacturing capacity, there is no one to invoke those provisions in those countries. This is plainly unsatisfactory and the Doha Declaration rightly recognised that a swift solution should be found to this problem.

There are a number of interpretative problems raised by the Doha Declaration, a few of which we note in passing. The Declaration notes that countries are free to determine the grounds on which compulsory licences are granted (paragraph 5b), and the right to determine what constitutes a “national emergency or other circumstances of extreme urgency” (paragraph 5c). The latter provision reflects the shortcut in procedures allowed in these circumstances in Article 31(b) of TRIPS. Thus paragraph six refers to procedures for compulsory licensing in the pharmaceutical sector needed to address “public health problems...especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics” (paragraph 1).<sup>74</sup> It does not, as sometimes assumed, refer only to compulsory licensing in situations of emergency or urgency. Nor is it limited to a particular type of disease.

It also needs to be clarified which countries have no or insufficient manufacturing capacity. Again we think this requires an economic interpretation. If production of a needed medicine is technically possible but extremely costly, there is no point in issuing a domestic compulsory licence. If the objective is affordable access to medicines of appropriate quality and quantity, then the solution should allow production in the most economically viable manner, whether domestically or overseas. Developing countries generally favour an interpretation of “manufacturing capacity”, that takes account of economic criteria (for example, whether the capacity is such that economic production is possible in the envisaged circumstances), and place emphasis on a country’s ability to decide the criteria on a product by product basis. Developed countries, with one exception, suggest that criteria for defining this should be drawn up, without defining what these might be.<sup>75</sup>

Since the Declaration also allows LDCs not to apply pharmaceutical patents until 2016, countries that take advantage of this provision will not be able to issue compulsory licences, nor will any country where a patent has not been taken out. At present, such countries may be able to import cheaper supplies from other countries without patents on the relevant products, but again this situation will change after 2005. Thus paragraph six, while referring specifically to compulsory licensing, is clearly intended to address this wider context of action to address the affordability and accessibility of medicines, particularly in developing and least developed countries.

The Declaration does not specify which countries may act as suppliers to the countries in question. In order to maximise competition, and achieve the lowest prices possible, applying no restriction on which WTO members may act as suppliers would seem to be the logical market-based solution. For the same reasons, countries seeking a licence should logically seek out the most competitive compulsory licensee, wherever they might be located. Developing countries favour having the ability to import from suppliers in any country. One developed country favours the possibility of import from developed countries, but the EU has no fixed views and the US favours supply from developing countries only, as does the research-based pharmaceutical industry.

Five main solutions have been proposed to the problem mentioned in paragraph six of the Declaration which we examine in turn.

*The Amendment of Article 31 of TRIPS.* Article 31(f) could be deleted. However this may be regarded as altering the sense of the Agreement for compulsory licensing other than in relation to public health problems. The alternative is an amendment which would make a clearly demarcated exception to the restriction imposed by Article 31(f) covering compulsory licensing needed to address public health problems envisaged in the Declaration. Such an amendment to TRIPS would be very time-consuming and require ratification by national governments. An interim or provisional solution, such as a declaration of intent, and temporary waiver or moratorium on dispute settlement, could be provided to cover the period until any amendment is ratified. But many

countries, both developed and developing may be reluctant to re-open TRIPS at all, because of the risk of other aspects of the agreement being opened up for renegotiation at the same time. Assuming a solution was found, it would then be necessary for a potential exporting country to delete the “predominantly” clause from its own legislation and to make sure that the grounds for compulsory licensing accorded with those envisaged in the Declaration. In the final stage compulsory licences would need to be invoked and paid for in both the importing and exporting countries, if there is a patent in both. The exporting country would need to be prepared, in any case, to issue a compulsory licence for the benefit of the importing country.

Developing countries have suggested a number of options for resolving the problem including the revision of Article 31 or deletion of Article 31(f), so as to ensure Article 31(f) would not apply to any laws, measures and administrative regulations including compulsory licences, adopted to protect public health and in particular to ensure affordable access to pharmaceutical products. Other developing countries note that under Article 31(f) there would be a need to issue compulsory licences in both the importing and exporting country which would be administratively burdensome. The EU favours the specific amendment to Article 31(f) described above. The US does not favour an amendment to 31(f), but a moratorium on dispute settlement proceedings to achieve the same effect.

*Interpretation of Article 30.* Article 30 provides for limited exemptions to patent rights that do not conflict with the normal exploitation of the patent. Under this proposed solution no amendment is required to TRIPS, nor a compulsory licence in the exporting country. One claimed advantage is that it would allow exports to countries where no patents exist on the relevant medicine. All that would seem to be required is an “authoritative interpretation” under Article IX of the WTO agreement, adopted by three quarters of WTO Members. This would clarify that an exception under patent rights to allow export in the circumstances envisaged in the Declaration is legitimate. National legislation in the exporting country would then need to be amended to ensure that the envisaged exception is incorporated. One issue with this proposed solution is whether the “Doha exception” would be compatible with the conditions of Article 30. An interpretation of this Article in a recent Disputes Settlement Panel<sup>6</sup> suggested that the “limited exceptions” should be interpreted narrowly. This was in the context of justifying Canada’s provision of an exception for early working by potential competitors for the purposes of obtaining regulatory approval. There is a case to be made that an exception, as suggested here, is “limited” to particular circumstances as defined in the Declaration. It could also be said that it does not “unreasonably conflict” with the normal exploitation of the patent, being for export at low prices, provided the “legitimate interests” of the patentee are safeguarded (for example, preventing diversion to other markets). Moreover, the legitimate interests of third parties (people suffering from diseases in developing countries) would need to be weighed appropriately against those of the patentee. For the most part the very different circumstances applying here, as contrasted to those in the Canada case, means this WTO case law is of limited relevance.

Some developing countries particularly favour the Article 30 solution, noting that it solves the problem of double remuneration under Article 31, and removes the need for a compulsory licence in the exporting country. In terms of administrative procedures they feel it is the least burdensome option. It should also be noted that activist NGOs think the Article 30 option is preferable to other options.

*Moratorium or Waiver.* An alternative is the proposal for a moratorium or waiver for exports in the “Doha circumstances”. Advocates argue that a waiver is the most expeditious solution noting that it could provide legal security and still avoid the need for either amendment or authoritative interpretation of the TRIPS agreement. The conditions for a waiver could be set out in advance to define the circumstances in which they would apply. Obviously there would be a need to set these out very clearly and unambiguously to the satisfaction of all WTO members. This has not yet been attempted and clarity may inevitably be compromised in negotiations on the criteria.

The WTO Ministerial Council would have to agree the criteria under which Members may be exempted from complying with the provisions of the TRIPS Agreement. Both in the case of a

moratorium and a waiver, however, interested parties may only invoke protection under the Agreement if national legislation has been changed to implement the exemption to the 31(f) requirement.<sup>77</sup> If national legislation is not changed, a patentee may still make a case in national courts in spite of the fact that a WTO waiver or moratorium applies. It also needs to be remembered that a waiver requires regular review by the Ministerial Conference/General Council if granted for a period of more than one year.

The EU have suggested that a waiver (or moratorium) might be necessary while the amendment they propose to 31(f) is agreed. Some developing countries have suggested that that a waiver (or moratorium) would not amount to a sustainable and legally predictable solution. By contrast the US has suggested that a waiver or moratorium is more likely to achieve an expeditious, workable, transparent, sustainable and legally certain solution. We also understand that the pharmaceutical industry supports a proposal on these lines.

*Non-Justiciability.* The proposal for a non-justiciability option would achieve much of the Article 30 approach by a different means. It would operate in a similar manner to the position of TRIPS on the exhaustion of rights (paragraph six of TRIPS). By authoritative interpretation or amendment of the Agreement, it would be decided that settlement disputes under TRIPS would not be used in relation to exports undertaken as envisaged in the Declaration. However, it is unclear exactly how this proposal would be implemented.

*Export by a Nation with a Compulsory Licence.* A final option, which is not in the hands of the WTO, is that countries which have the capacity to reverse engineer and manufacture, and large local markets for the required medicines, may issue compulsory licences in accordance with their own legislation. In that case, a proportion of the supplies manufactured could be offered for export to countries in need (on the basis of a compulsory licence for import if necessary) in a manner that did not breach Article 31(f). A compulsory licence can also be granted to remedy anti-competitive practices (Article 31(k)), and in this case the restriction on exports would not apply. But this option depends on the supplying country having legitimate grounds for issuing a compulsory licence in the first place, on its having a large enough market that exports constitute less than half of total production, and on its willingness to export.

**The choice between these options will be worked out politically, but we strongly emphasise our concern that whatever the legal solution adopted by the WTO is, it should proceed upon the following principles. First, it should be quickly and easily implementable with a view to a long term solution. Second, the solution should ensure that the needs of poor people in developing countries without manufacturing capacity are given priority. Third, it should seek to ensure that conditions are established to provide potential suppliers the necessary incentive to export medicines that are needed**

### *Economic Aspects*

Whatever means are utilised to achieve the objectives at Doha, developed countries will require safeguards to prevent leakage of product from the intended recipient to other markets, and to ensure that production is only for export to the affected country, not for domestic sale. They may also require actions through WTO to ensure all Members are fully informed of the nature of the transaction in a transparent manner. Whatever safeguards are finally agreed upon, the crucial issue is that the economics of supply to one particular country with a limited market may be insufficient to attract potential generic suppliers. Moreover, if prices offered under compulsory licensing are to be as low as possible, then there should be competition between more than one supplier at the point of ordering, if not for the actual supply. To allow therefore for economies of scale, and a degree of competition, it is important that small markets are grouped together as much as is possible.

An obvious solution is for groups of countries with the similar needs for essential drugs to group together. International institutions, such as WHO or the Global Fund to Fight AIDS, Tuberculosis and

Malaria (GFATM) may also have an essential role to play in facilitating and financing group purchases of medicines from both brand and generic manufacturers.

**A way needs to be found to reconcile the nature of the solution adopted with the objective of providing medicines of the appropriate quality at the lowest possible cost. If that cannot be achieved, the legal solution will have little practical reality. Nor will the option of compulsory licensing be effective as a negotiating tool.**

## Developing Country Legislation

The main way that developing countries can use IPRs to address public health issues is to ensure that their legislation provides for appropriate standards and practices. What is appropriate will vary according to country circumstances and level of development. For instance, countries with well developed R&D capability, or with particular strengths in, say, biotechnology, may want to have “stronger” protection than countries that are almost entirely users of other countries’ technology.

Developing countries should not feel compelled, or indeed be compelled, to adopt developed country standards for IPR regimes. They might be overwhelmed if they did so. The number of new chemical entities approved for use by the US Food and Drug Administration (FDA) declined to 27 in 2000, compared to about 60 in 1985.<sup>78</sup> But the number of patents granted in the main patent class for new drug compositions (424) was 6730 in 2000.<sup>79</sup> The great majority of patents are granted not for new therapeutic compounds, but relate to variations in production processes, new formulations or crystalline forms, new combinations of known products, and new uses of known drugs. In the period 1989-2000, 153 of the 1035 new drug approvals by the FDA were reported to be for drugs that contained new active ingredients and offered significant clinical improvement. A further 472 drugs were classified as being modestly innovative.<sup>80</sup>

**The underlying principle should be to aim for strict standards of patentability and narrow scope of allowed claims, with the objective of:**

- **limiting the scope of subject matter that can be patented**
- **applying standards such that only patents which meet strict requirements for patentability are granted and that the breadth of each patent is commensurate with the inventive contribution and the disclosure made**
- **facilitating competition by restricting the ability of the patentees to prohibit others from building on or designing around patented inventions**
- **providing extensive safeguards to ensure that patent rights are not exploited inappropriately.**

All this would help to ensure that patenting rules as far as possible limit the scope for patenting that serves more to protect markets, and exclude competition, than promote local R&D. Moreover loose patenting standards and practices, as noted above, can actually inhibit innovation by impeding research by others. Because, under TRIPS, it is not possible to discriminate between different fields of technology, we deal with the application of these principles in more detail in Chapter 6.

However, specific to pharmaceuticals, most developing countries should as a minimum take up the possibility allowed by TRIPS<sup>81</sup> of excluding diagnostic, therapeutic and surgical methods for treatments of humans or animals from patentability, as well as new uses of known products (which, in essence, are equivalent to therapeutic methods). Since most developing countries are not in a position to develop such methods, they will have nothing to gain by not exploiting this flexibility. Of course, the few developing countries with research capabilities in these areas may wish to have such protection, but we should note that most developed countries also exclude these areas from patentability. We would also suggest that developing countries think very carefully about diluting this exception by relaxing the concept of novelty and allowing patent claims for essentially first or subsequent medical uses of known chemical compounds as has been done in a number of

developed and developing countries.<sup>82</sup> Again, developed countries may consider that the incentive for research justifies allowing such claims, but for most developing countries with limited research capabilities we consider that the costs are likely to outweigh the benefits.

**Most developing countries, particularly those without research capabilities, should strictly exclude diagnostic, therapeutic and surgical methods from patentability, including new uses of known products.**

We also deal here with two issues which particularly affect the pharmaceutical sector, and the production of generic drugs.

### *Bolar Exception*

In the US, the Drug Price Competition and Patent Term Restoration Act of 1984 overturned a landmark court decision (*Roche versus Bolar*, 1984) by introducing, inter alia, what is now known as the “Bolar Exception” (or “early working exception”). This makes it legal for a generic producer to import, manufacture and test a patented product prior to the expiry of the patent in order that it may fulfil the regulatory requirements imposed by particular countries as necessary for marketing as a generic. The WTO legality of this exception was confirmed in 2000 by the dispute settlement case brought by the EU against Canada.<sup>43</sup> For developing countries this is very important, particularly if they are actual or potential producers of generics, in order to ensure that lower priced generics can reach the market as soon as a patent expires. Even if they are not likely to be potential producers in the foreseeable future, it would be prudent to include the exception in their legislation. For instance, a foreign company may need to conduct trials for the purpose of gaining regulatory approval. Of 63 developing countries whose legislation we examined only eight specifically included a Bolar exception, although others may also allow “early working” under general exceptions to exclusive rights (covered by equivalent wording to Article 30 in TRIPS).<sup>84</sup>

**Developing countries should include an appropriate exception for “early working” to patent rights in their legislation, which will accelerate the introduction of generic substitutes on patent expiry.**

### *Marketing Approval*

Another important step in marketing a generic drug is the need to meet regulatory requirements for that purpose. TRIPS provides in Article 39.3 an obligation on countries to protect against unfair commercial use of confidential data (for example, trials data) on new chemical entities submitted by companies to obtain approval for marketing new drugs from the regulatory agency (such as the FDA in the US).

The rationale for this is the “considerable effort” invested in the compilation of this data. Pharmaceutical companies understandably argue that it is unfair if the product of possibly millions of dollars of clinical trials and other investigations is made available to competitors who thereby avoid the need for comparable expenditure in order to obtain marketing approval. Against this it is argued, from the public health point of view, that such data should be in the public domain because they contain important medical information not available elsewhere and that excessive secrecy has undesirable effects (for example, the data might be usefully reanalysed to understand side-effects only detected after marketing). Moreover, from a societal point of view, it makes no sense for a potential generic competitor to repeat very expensive tests if the biopharmaceutical equivalence of their version of the drug can be reliably demonstrated. Data exclusivity can be a barrier to generic entry irrespective of whether the drug was patented, or the patent period has expired.

TRIPS does not require the imposition of data exclusivity, as such, on these test data, only protection against unfair commercial use. The EU, however, has rules that confer exclusivity on such data for a period of six to ten years, and is considering moving to ten years. This means, inter alia, that the

health authorities cannot rely on such data to approve other applications without the originators' consent. In the US, similar protection is applicable for five years.

In the light of the above, we take the view that developing countries should protect test data against unfair commercial use in order to protect the legitimate interests of the originators of data and their "considerable effort." But TRIPS allows considerable freedom in how this may be done.

**Countries may allow health authorities to approve equivalent generic substitutes by "relying on" the original data. Developing countries should implement data protection legislation that facilitates the entry of generic competitors, whilst providing appropriate protection for confidential data, which may be done in a variety of TRIPS-compatible ways. Developing countries need not enact legislation the effect of which is to create exclusive rights where no patent protection exists or to extend the effective period of the patent monopoly beyond its proper term.**

## **Doha Extension for Least Developed Countries**

The Doha Declaration (paragraph seven) instructed the TRIPS Council to allow least developed countries to defer introduction of patent protection for pharmaceutical products and protection of confidential test data until at least 2016. We applaud the intention behind this paragraph, but it also creates and highlights a number of anomalies.

At least 70% of the population in LDCs are in countries that provide pharmaceutical patent protection, and 27 of the 30 LDCs in Africa also provide it. These countries would need to amend their legislation to remove protection on pharmaceuticals to take advantage of this extension. It may well be in their interest to do so in view of the length of the extension granted. We presume, however, that amendments to legislation may not be retrospective and thus current patents would remain valid.

Further, certain countries will be constrained in amending their laws by bilateral or multilateral agreements. For instance the 12 LDC members of OAPI (three are not least developed) would need to agree on a revision to the Bangui Treaty which governs OAPI. Similarly, others may be bound by bilateral agreements which do not allow for this course of action.

For countries that have not yet implemented IP protection, we question whether it makes sense to implement the whole IP protection regime in 2006, except for pharmaceutical protection. Since pharmaceuticals account for a significant proportion of all patent applications (for example, 50 % of patents issued by ARIPO in 1994-1999 were related to pharmaceutical products),<sup>85</sup> it is even harder to justify the financial and human resources necessary for implementing an IP regime in these countries only for non-pharmaceutical sectors. Article 66.1 of TRIPS provides that the TRIPS Council may grant extensions to the transition period for LDCs taking account of their "special needs and requirements...their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base". It is not therefore very logical to grant an extension for one sector on the grounds of public health to a specific future date, when the criteria under TRIPS for granting extensions are far more broadly based.

**Those LDCs which already provide pharmaceutical protection should consider carefully how to amend their legislation to take advantage of the Doha Declaration. Consistent with our analysis elsewhere, the TRIPS Council should review the transitional arrangements for LDCs, including those applying to join the WTO, in all fields of technology.**

- <sup>1</sup> USTR launched investigations (under Section 301 of the Trade Act) into the failure of countries to provide adequate IP protection to pharmaceutical products in Brazil (1987), Argentina (1988) and Thailand (1991). Source: [http://www.ustr.gov/html/act301.htm#301\\_52](http://www.ustr.gov/html/act301.htm#301_52)
- <sup>2</sup> Ryan, M. (1998) *Knowledge Diplomacy: Global Competition and the Politics of Intellectual Property*, Brookings Institution, Washington DC, pp.67-72. Source: <http://brookings.nap.edu/books/0815776535/html/>
- <sup>3</sup> Review of the evidence in Scherer, F.M. (2001) "The Patent System and Innovation in Pharmaceuticals", *Revue Internationale de Droit Economique*, (Special Edition, "Pharmaceutical Patents, Innovations and Public Health"), pp.109-112
- <sup>4</sup> Presentation by Sir Richard Sykes at Royal Institute of International Affairs, London, 14 March 2002.
- <sup>5</sup> Oxfam (2001) *Priced Out of Reach*, Oxfam Briefing Paper No. 4, Oxfam International, Oxford. Source: <http://www.oxfam.org.uk/policy/papers/priced/priced.html>
- <sup>6</sup> WHO (2002) "Infectious Disease Report 2002", WHO, Geneva. Source: <http://www.who.int/infectious-disease-report/2002/framesintro.html>
- <sup>7</sup> Médecins sans Frontière (2001) *Fatal Imbalance: The Crisis in Research and Development for Drugs for Neglected Diseases*, MSF, Brussels. Source: <http://www.msf.org/source/access/2001/fatal/fatal.pdf>
- <sup>8</sup> See, for instance, "Courting Trouble" *The Economist*, 8 June 2002. Source: <http://www.economist.com/>
- <sup>9</sup> Commission on Macroeconomics and Health (2001) *Macroeconomics and Health: Investing in Health for Economic Development*, WHO, Geneva, p.56. Source: <http://www3.who.int/whosis/menu.cfm?path=whosis,cmh&language=english>; and Médecins sans Frontière (2002) *Untangling the Web of Price Reductions: A Pricing Guide for the Purchase of ARVs for Developing Countries*, MSF, Geneva. Source: <http://www.who.int/medicines/organization/par/edl/access-hivdrugs.shtml>
- <sup>10</sup> WHO Press Release (WHO/58), 9 July 2002. Source: [www.who.int/inf/en/pr-2002-58.html](http://www.who.int/inf/en/pr-2002-58.html)
- <sup>11</sup> See UNAIDS (2002) *Report on the Global HIV/AIDS Epidemic 2002*, UNAIDS, Geneva, p.151. Source: <http://www.unaids.org/barcelona/presskit/report.html>
- <sup>12</sup> Commission on Macroeconomics and Health (2001)
- <sup>13</sup> Commission on Macroeconomics and Health (2001), p.77
- <sup>14</sup> See Glossary for definition.
- <sup>15</sup> Commission on Macroeconomics and Health (2001), pp.86-91
- <sup>16</sup> Commission on Macroeconomics and Health (2001), p.79, and footnote 103 for a discussion of various estimates.
- <sup>17</sup> MSF (2001), p. 16
- <sup>18</sup> Scrips Pharmaceutical R&D Compendium 2000. Source: [www.inpharm.com/intelligence/largesize/cmr020801a.gif](http://www.inpharm.com/intelligence/largesize/cmr020801a.gif). But note estimates vary. The estimate from this source for 1998 is \$38 billion, while the Global Forum for Health Research estimates \$30.5 billion in 1998. Global Forum for Health Research (2002) *The 10/90 Report on Health Research 2001-2002* Global Forum for Health Research, Geneva, p. 107. Source: <http://www.globalforumhealth.org/pages/index.asp>
- <sup>19</sup> Trouiller, P. et al (2002) "Drug Development for Neglected Diseases: a Deficient Market and a Public Health Policy Failure" *The Lancet*, vol. 359, pp.2188 – 94. Source: <http://www.thelancet.com>
- <sup>20</sup> MSF (2001), p. 12.
- <sup>21</sup> Pharmaceutical Research and Manufacturers of America (2001) *PhRMA Industry Profile 2001*, PhRMA, Washington DC, p.16.
- <sup>22</sup> Global Forum for Health Research (2002), p.107.
- <sup>23</sup> Global Forum for Health Research (2002), p.107.
- <sup>24</sup> MSF (2001), p. 21. It is unlikely that more than \$1.2 billion is spent on top of the \$2.5 billion recorded for low and middle income developing countries.
- <sup>25</sup> These include the Medicines for Malaria Venture (MMV), the Global Alliance for TB Drug Development GATB, the International Aids Vaccine Initiative (IAVI) the proposed Medicines for Leishmaniasis and Trypanosomiasis Initiative (MLT), amongst others.
- <sup>26</sup> Lanjou, J. & Cockburn, I. (2001) "New Pills for Poor People? Empirical Evidence after GATT", *World Development*, vol. 29:2, pp.265-289.
- <sup>27</sup> See UNAIDS (2002), p.105.
- <sup>28</sup> The Malaria Vaccine Initiative (MVI) is another public private partnership. The complexities of research are explained at: <http://www.malariavaccine.org/mal-vac2-challenge.htm>. See also Clark, A. (2002) "Population Genetics: Malaria Varorium" *Nature* 418, pp.283-285. Source: [http://www.nature.com/cgitaf/Dynapage.taf?file=/nature/journal/v418/n6895/full/418283a\\_fs.html](http://www.nature.com/cgitaf/Dynapage.taf?file=/nature/journal/v418/n6895/full/418283a_fs.html)

- <sup>29</sup> Kremer, M. & Snyder, C. (2002) *"The Revenue Consequences of Vaccines versus Drug Treatments"*, draft working paper, p.3. Source: [http://www.iaen.org/files.cgi/6913\\_vaccines\\_snyder.pdf](http://www.iaen.org/files.cgi/6913_vaccines_snyder.pdf)
- <sup>30</sup> The bacillus can lie dormant and undetected in the body for several months or years.
- <sup>31</sup> The Global Alliance for TB Drug Development (2001) *"The Economics of TB Drug Development"*, The Global Alliance for TB Drug Development, New York. Source: [http://www.tb Alliance.org/pdf/rpt\\_per.PDF](http://www.tb Alliance.org/pdf/rpt_per.PDF)
- <sup>32</sup> The industry points out that a successful new medicine can take 10-15 years to discover and develop and that perhaps only three out of ten new medicines make a good return. Each drug may cost \$500-800 million to develop. These figures, however, are contentious. For the industry view, see for instance: <http://www.phrma.org/publications/publications/primer01>
- <sup>33</sup> Kettler, H. (2002) *"Using Innovative Action to Meet Global Health Needs through Existing Intellectual Property Regimes"*, Commission on Intellectual Property Rights Background Paper 1a, Commission on Intellectual Property Rights, London, pp.24-26. Source: <http://www.iprcommission.org>
- <sup>34</sup> Commission on Macroeconomics and Health (2001), p.85
- <sup>35</sup> Foreign pharmaceutical companies are reported to be reluctant to increase R&D because of the absence of product protection on pharmaceuticals. On the other hand there is evidence of increasing investment in recent years to take advantage of India's skilled researchers. For instance, AstraZeneca has recently set up a Research Centre in Bangalore to research TB, inter alia. See, for instance, Kumar, N. (2002) *"Intellectual Property Rights, Technology and Economic Development: Experiences of Asian Countries"*, Commission on Intellectual Property Rights Background Paper 1b, Commission on Intellectual Property Rights, London, p.35. Source: <http://www.iprcommission.org>. Also see *Express Pharma Pulse*, 2 May 2002. Source: <http://www.expresspharmapulse.com/20020502/story3.shtml>
- <sup>36</sup> The Consultative Group on International Agricultural Research, coordinated by a Secretariat in the World Bank. Source: <http://www.cgiar.org/>
- <sup>37</sup> See, for instance, Advisory Committee on Health Research (2002) *"Genomics and World Health"*, WHO, Geneva, p.138. Source: [http://www3.who.int/whosis/genomics/genomics\\_report.cfm](http://www3.who.int/whosis/genomics/genomics_report.cfm)
- <sup>38</sup> Attaran, A. & Gillespie-White, L. (2001) *"Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment In Africa"*, *JAMA*, vol. 286:15. Source: <http://jama.ama-assn.org/issues/v286n15/ffull/jsc10222.html>
- <sup>39</sup> Attaran, A. & Gillespie-White, L. (2001), p.1891.
- <sup>40</sup> See UNAIDS (2002), pp.189-201.
- <sup>41</sup> IFPMA Press Release, Geneva, 20 December 2001. Source: [www.ifpma.org/pdfifpma/CMH%20report-news%20release.pdf](http://www.ifpma.org/pdfifpma/CMH%20report-news%20release.pdf). Although patent status is not a consideration in selecting medicines for the list, the total cost of treatment and cost-effectiveness are criteria for inclusion so some therapeutically important patented medicines may be omitted on these grounds. The criteria are at: <http://www.who.int/medicines/organization/par/edl/procedures.shtml#4>
- <sup>42</sup> In large part the absence of patents also indicates the absence of recent research on these diseases. See Trouiller, P. et al (2002).
- <sup>43</sup> Pharmaceutical Research and Manufacturers of America (2002) *"Health Care in the Developing World"*, PhRMA, Washington DC. Source: <http://world.phrma.org/ip.access.aids.drugs.html>
- <sup>44</sup> Pharmaceutical Research and Manufacturers of America (2001), p.61.
- <sup>45</sup> For instance, GSK is currently involved in litigation in the US to establish the validity of patents on its drug Augmentin which expire in 2017 and 2018. Generic producers are seeking to enter the market after the expiration of the first patents on the drug in 2002. The patent on its biggest selling drug, Paxil, was recently partially overturned in the High Court in London. See *"GSK Suffers from Paxil Patent Ruling"* *Financial Times*, 13 July 2002. Source: <http://www.ft.com>. For a roundup on patent litigation in the pharmaceutical industry, see *"Pharma Sector Loses its Defensive Edge"*, *Investors Chronicle*, 19 June 2002. Source: <http://investorschronicle.ft.com/IC/home>
- <sup>46</sup> Reiffen, D. & Ward, M. (2002) *"Generic Drug Industry Dynamics"*, US Federal Trade Commission Working Paper 248. Source: <http://www.ftc.gov/be/workpapers/industrydynamicsreiffenwp.pdf>
- <sup>47</sup> Kumar, N. (2002), p.28.
- <sup>48</sup> Scherer, F. M. & Watal, J. (2001) *"Post-TRIPS Options for Access to Patented Medicines in Developing Countries"*, Commission on Macroeconomics and Health Background Paper, p.45. Source: <http://www.icrier.res.in/pdf/schrerwatal62.PDF>
- <sup>49</sup> Scherer, F. M. & Watal, J. (2001), p.45.
- <sup>50</sup> MSF (2002), p.6.
- <sup>51</sup> Fink, C. (2000) *"How Stronger Patent Protection in India Might Affect the Behaviour of Transnational Pharmaceutical Industries"*, World Bank Policy Research Paper No. 2352, World Bank, Washington DC. Source: [http://wbln0018.worldbank.org/research/workpapers.nsf/0/5d9b67dfa0777405852568e80065f3c4/\\$FILE](http://wbln0018.worldbank.org/research/workpapers.nsf/0/5d9b67dfa0777405852568e80065f3c4/$FILE)

- [E/wps2352.pdf](#); and Watal, J. (2000) "Pharmaceutical Patents, Prices and Welfare Losses: A Simulation Study of Policy Options for India under the WTO TRIPS Agreement", *The World Economy*, vol. 23:5, pp.733-752.
- <sup>52</sup> "Continent in Crisis", Report by McKinsey & Company on increasing access to ARVs in Uganda, 2000.  
Source: <http://www.mckinsey.com/firm/people/feature/uganda/main/index.asp>
- <sup>53</sup> Oxfam (2002) "Generic Competition, Price and Access to Medicines" Oxfam Briefing Paper No. 26, Oxfam, Oxford. Source: <http://www.oxfam.org.uk/policy/papers/26generic/26generic.html>
- <sup>54</sup> Borrell, J-R. & Watal, J. (2002) "Impact of Patents on Access to HIV/AIDS Drugs in Developing Countries", CID Working Paper No. 92, Centre for International Development, Harvard University, Cambridge MA, p.5.  
Source: <http://www2.cid.harvard.edu/cidwp/092.pdf>
- <sup>55</sup> See Scherer, F.M. (2001), pp.116 -118 for a review of the experience in Canada and Italy.
- <sup>56</sup> In Canada, 16.1% of total R&D in 2001 was directed towards basic research; 44.1% to clinical trials, 7.9% to improvement in manufacturing processes, 7.9% to preclinical studies, and 24% to drug regulation submissions, bioavailability studies and Phase IV clinical trials. Patented Medicines Prices Review Board (2002) "Annual Report 2001", PMPRB, Ottawa, p. 28.  
Source: [http://www.pmprb-cepmb.gc.ca/english/06\\_e/06ann01\\_e.htm](http://www.pmprb-cepmb.gc.ca/english/06_e/06ann01_e.htm)
- <sup>57</sup> Trachtenberg, J. & Sande M. (2002) "Emerging Resistance to Nucleoside Reverse Transcriptase Inhibitors: A Warning and a Challenge", *JAMA* 288:2, pp.239-241.  
Source: <http://jama.ama-assn.org/issues/v288n2/ffull/jed20035.html>
- <sup>58</sup> See, for instances "India's Plague: Cheaper drugs may help millions who have AIDS – but how many will they hurt?" *The New Yorker*, 17 December, 2001. Source: <http://www.newyorker.com/>
- <sup>59</sup> Pharmaceutical Research and Manufacturers of America (2002).
- <sup>60</sup> See, for instance, Report on the East African Access to Essential Medicines Conference "Improving Access to Essential Medicines in East Africa: Patents and Prices in a Global Economy", organised by Médecins Sans Frontières (MSF) and Health Action International (HAI), Nairobi, 15-16 June 2000.  
Source: <http://www.haiweb.org/mtgs/nairobi200006.html>
- <sup>61</sup> See WHO Press Release No. 19, 20 March 2002 and No.28, 22 April 2002.  
Source: <http://www.who.int/inf/en/index-pr-2002.html>
- <sup>62</sup> Presentation given by Sisule Musungu at the Session on Medicines, Commission on Intellectual Property Rights Conference, London, 21-22 February 2002. Source: <http://www.iprcommission.org>
- <sup>63</sup> See Glossary for definition of the terms in this sentence.
- <sup>64</sup> See discussion on protecting test data below for explanation.
- <sup>65</sup> The theoretical case for this is more complex than indicated, being dependent on relative demand elasticities. There is a good discussion in Scherer and Watal (2001), pp.45-49.
- <sup>66</sup> These are usefully documented for HIV/AIDS drugs in MSF (2002), pp.11-15.
- <sup>67</sup> Maskus, K. (2000) "Intellectual Property Rights in the Global Economy", Institute for International Economics, Washington DC, p. 210.
- <sup>68</sup> Scherer and Watal (2001), p. 28.
- <sup>69</sup> The HHS told us: "The United States may procure items without first obtaining a license, so long as it pays 'reasonable and entire compensation.' There was no need for the Secretary to exercise this power. The Secretary was able to negotiate an historic agreement with Bayer that ensured an unprecedented production of Cipro. When negotiations with Bayer were pending, the Secretary did make it clear that if he needed authority to procure generics, he would ask Congress. Offering to work with Congress on a matter of such importance is hardly the same as 'threatening' a company. The Secretary acted properly and with deliberation in the matter of Bayer's Cipro patent." Personal communication from Dr Stuart Nightingale of HHS, 10 February 2002.
- <sup>70</sup> UNAIDS (2002), p.145
- <sup>71</sup> Presentation by Christopher Garrison, Legal Advisor to MSF, at MSF, CPTech, OXFAM and HAI conference, "Implementation of the Doha Declaration on the TRIPS Agreement and Public Health: Technical Assistance – How to Get it Right", Geneva, 28 March 2002.
- <sup>72</sup> Section 55(1) of Patents Act. Source: <http://www.piperpat.co.nz/patlaw/crown.html#s55>
- <sup>73</sup> This draws heavily on Engelberg, A. (2002) "Implementing the Doha Declaration - A Potential Strategy for Dealing with Legal and Economic Barriers to Affordable Medicines".  
Source: <http://www.cptech.org/ip/health/pc/engelberg.html>
- <sup>74</sup> This includes non-commercial governmental use, which is regulated in Article 31 of TRIPS with other compulsory licences.
- <sup>75</sup> The views of countries/groups here and in the rest of this section are drawn from the WTO Secretariat note, 11 July 2002, summarising statements and papers submitted by members (WTO Document No. IP/CW/363). Source: <http://docsonline.wto.org/DDFDocuments/t/IP/CW363.doc>

- <sup>76</sup> “Canada – Patent Protection Of Pharmaceutical Products”, WTO Document No. WT/DS114/R.  
Source: <http://docsonline.wto.org/DDFDocuments/t/WT/DS/114R.DOC>
- <sup>77</sup> In the case of a moratorium, moreover, another Member may not bring a case against the Member benefiting from it, but a patent owner could request a national court to apply the treaty obligation that the Member would still be obliged to comply with (unlike in the case of a waiver, where the obligation itself is suspended).
- <sup>78</sup> “The Odyssey Continues: Charting a path towards Pharma 2010”, presentation given by Simon Hughes, PwC Consulting, at the DIA Euro Meeting, Barcelona, March 2001.  
Source: <http://www.pwcconsulting.com/us/pwccons.nsf/viewwebpages/PharmalandTIndustry#Odyssey>
- <sup>79</sup> USPTO website. Source: [www.uspto.gov](http://www.uspto.gov)
- <sup>80</sup> NIHCM (2002) “Changing Patterns of Pharmaceutical Innovation”, NIHCM, Washington DC.  
Source: <http://www.nihcm.org/innovations.pdf>
- <sup>81</sup> TRIPS Article 27 3 (a). Source: [http://www.wto.org/english/tratop\\_e/trips\\_e/t\\_agm0\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm)
- <sup>82</sup> Such first and further use type claims are accepted in the EU and a number of developing countries including those in ARIPO and OAPI. See for example ARIPO patent No. AP868 and OAPI patent No. OA09495.
- <sup>83</sup> “Canada – Patent Protection Of Pharmaceutical Products”, WTO Document No. WT/DS114/R.  
Source: <http://docsonline.wto.org/DDFDocuments/t/WT/DS/114R.DOC>
- <sup>84</sup> Thorpe, P. (2002) “Implementation of the TRIPS agreement by Developing Countries”, Commission on Intellectual Property Rights Background Paper 7, Commission on Intellectual Property, London, p.20.  
Source: <http://www.iprcommission.org>
- <sup>85</sup> Thorpe (2002), p.8



## AGRICULTURE AND GENETIC RESOURCES



### INTRODUCTION

#### Background

The importance of the agricultural sector in developing countries as a source of food, incomes, employment and often foreign exchange cannot be overstated. As much as good health, a productive and sustainable agricultural sector is critical to achieving economic growth and poverty reduction. About three quarters of the world's poor people live and work in rural areas.<sup>1</sup> Apart from its direct role in sustaining incomes and employment, the role of agriculture, and in particular technological change in agriculture, in stimulating overall economic growth has been much discussed by economists and policymakers. Raising productivity in agriculture can directly increase the incomes and employment levels of the majority of poor people dependent on agriculture. It can also help to reduce food prices (relatively or absolutely) for poor people in both rural and urban sectors.

Historically agriculture has been seen, sometimes controversially, as a source of food, labour and finance to supply a growing urban and industrial sector on which sustained growth in incomes will depend. Achieving this transition usually depends on achieving productivity increases if food prices are not to rise, and stifle both industrial growth and poverty reduction. In developed countries changes in technology and institutions in the agricultural sector are regarded as having been instrumental in the industrial revolution.

In developing countries, technical progress traditionally occurred through a process of on-farm experimentation, selection and adaptation of traditional landraces<sup>2</sup> of crops. Subsequently this was supplemented by purposive breeding of new varieties of crops, mainly through crossing varieties with desirable characteristics. This process of research was largely conducted in the public sector by national research institutes, supported by a network of international research institutes, for the last

thirty years under the umbrella of the Consultative Group on International Agricultural Research (CGIAR). It was this network which led to the Green Revolution of the 1960s, based initially on high yielding semi-dwarf varieties of rice and wheat. In spite of criticisms of its environmental and distributional impact, this technology is widely credited with having had a favourable impact on nutrition, employment and incomes, albeit mainly in the areas of developing countries capable of reasonably assured irrigation. Subsequently, further breeding efforts have tried, but with less success, to extend these technologies to new crops and to rainfed and dryland areas.

More recently, significant changes have occurred in both the technology and the structure of research in agriculture. First, the advent of biotechnology, and in particular genetic engineering, in the last twenty years has vastly expanded the possibilities of what can be achieved in agricultural research (for example, introducing new genetic traits in plants). Secondly, while public investment in public research, at least through the CGIAR, has tended to stagnate in recent years, investment by the private sector has gone up rapidly.<sup>3</sup> Market forces have increasingly guided the direction and purpose of additional research spending.

## Intellectual Property Rights in Agriculture

Historically, systems for the protection of intellectual property were applied principally to mechanical inventions of one kind or another, or to artistic creations. The assignment of IPRs to living things is of relatively recent origin in developed countries. Vegetatively propagated plants were first made patentable in the US only in 1930. And the protection of plant varieties (or plant breeder's rights - PBRs), a new form of intellectual property, only became widespread in the second half of the 20th Century. Thus systems for the protection of plants derive from the economic structure and circumstances of agriculture that prevailed in developed countries in this period. That such systems came into being reflected the growing interest of private breeders in protecting their intellectual property. Farmers have traditionally replanted, exchanged or sold seed from the previous years' crop which means that breeders have difficulty in recouping the investments made in improved varieties through repeat sales. Patents or PBRs normally impose restrictions on farmers' ability to sell grown seed (and in some cases to reuse it) and thus enhance the market for the breeder's seed. Even in the developed countries, reuse of seeds remains quite common although for many crops annual purchase is now the rule. In developing countries the majority of farmers reuse, exchange or sell informally to neighbours, and annual purchase of new seed is relatively rare in most countries.

With the adoption of the TRIPS Agreement, developing countries have been obliged to adopt protection of plant varieties, by patents or by other means, without any serious consideration being given to whether such protection would be beneficial, both to producers and consumers, or its possible impact on food security. As with medicines, a crucial issue is whether and how intellectual property protection can help promote research and innovation relevant to the needs of developing countries and poor people. And we also need to ask how IP protection affects the cost and access of farmers to the seeds and other inputs they need.

If the aim of plant variety protection is to provide incentives to breeders, one of the questions that arises is how the contribution of farmers to the conservation and development of plant genetic resources should be recognised and preserved. Until formal breeding programmes were introduced, varietal and cultural improvements depended on a process of selection and experimentation by farmers. Formal breeding programmes have since utilised those varieties and knowledge in order to develop improved varieties of higher productivity, or with other desirable characteristics. The question is whether this contribution of farmers to conservation and innovation should be either protected or rewarded. Building on the principles embodied in the Convention on Biological Diversity (CBD), which we discuss in the next chapter, the new International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) seeks to establish principles for facilitating access to plant genetic resources and establishing fair and equitable mechanisms of benefit sharing.

In this chapter, we address the following questions:

- Can intellectual property protection on plants and genetic resources help to generate the technologies required by farmers in developing countries?
- Will IP protection affect the access of farmers to technologies they need?
- How could the intellectual property system contribute to the principles of access and benefit sharing enshrined in the CBD and the ITPGRFA?

## PLANTS AND INTELLECTUAL PROPERTY PROTECTION

### Introduction

Under TRIPS, countries may exclude from patentability plants and animals and essentially biological processes for producing them, but not microorganisms. And they are required to apply some form of protection, either by patents or a *sui generis* system to plant varieties.

There are many legal complexities about definitions arising from the wording of TRIPS, such as the exact meaning of a plant variety, a “microorganism” or an essentially biological process. But it is important to note here that TRIPS does not mention whether or not genes should be patentable, whether derived from plants, humans or animals. The issue raised by TRIPS is what constitutes an invention in relation to genetic material. For instance, should genetic material identified in nature be patentable on the grounds that isolating and purifying it differentiates it from an unpatentable discovery? This is a matter for national legislation. The only specific requirement, other than for microorganisms, is that plant varieties be protected.

Some people object altogether to the patenting of life forms on ethical grounds, considering that the private ownership of substances created by nature is wrong, and inimical to cultural values in different parts of the world. The sequencing of the human genome also raises specific concerns. We recognise these concerns, which we discuss further in Chapter 6 in the context of designing patent systems. The ethical and legal issues in respect of patenting DNA are discussed in a recent report of the Nuffield Council on Bioethics.<sup>4</sup> Our task here is to consider the practical and economic consequences of patenting in agriculture and how this affects the livelihoods of poor people and the implications for policy.

Intellectual property protection can be conferred in relation to plant materials in a number of ways:

- The US model of plant patents, which are distinct from normal (utility) patents
- Through allowing normal patents on plants or parts thereof, such as cells
- Through patenting plant varieties as is the practice in the US and in few other countries (for example, not in the EU)
- Through applying a *sui generis* form of plant variety protection (PVP), such as plant breeders’ rights (as in the EU or the US) or other modalities
- Through allowing patents on DNA sequences, and gene constructs including the gene, plants transformed with those constructs, the seed and progeny of those plants.

In addition, patents are widely used to protect the technologies which are employed in research on plant genomics.<sup>5</sup>

Apart from the use of patents and PVP, the intellectual property in plants can be appropriated by technological means. For instance, crops such as commercial hybrid<sup>6</sup> maize cannot be reused if hybrid yield and vigour are to be maintained. This characteristic of some hybrids confers a natural form of protection by which seed companies can more readily capture a return on their investment through repeat seed sales. By contrast, other types of seed variety can be replanted each year without deterioration in yield, so that farmers may replant their own seed without repurchasing.

The Green Revolution varieties were of this nature, which is one reason why they were so successful. It is only more recently that hybrid varieties of rice and then wheat have been developed. Genetic Use Restriction Technologies (known as GURTs) is a term used to describe different forms of controlling the action of genes in plants. The so-called “terminator” technology, which would render the seed sterile so that it is not physically possible to grow a second crop,<sup>7</sup> is well known but other characteristics can also be controlled, either for agronomic or commercial reasons. The effect of technological protection is similar to that of IP protection, but possibly cheaper and certainly more effective in the sense that it is self-enforcing.

## Research and Development

As compared to medical research, there is a great deal more agricultural R&D undertaken by, and of relevance to, developing countries. For instance it is estimated that in 1995, total expenditure by the public sector on agricultural research in developing countries, although unevenly distributed, amounted to \$11.5 billion (at 1993 international dollar values) compared to the \$10.2 billion spent in developed countries.<sup>8</sup> The great majority of research is conducted in the more technologically advanced developing countries in Asia and Latin America. Moreover, research expenditures by these countries grew at 5-7% annually between 1976 and 1996, while they stagnated in Africa.<sup>9</sup> By contrast, of worldwide private research expenditure totalling \$11.5 billion, only \$0.7 billion is attributable to developing countries.

This means that, globally, about one third of all agricultural R&D is spent in developing countries in marked contrast to the maximum of 5% estimated for health research for developing countries. Three points should be noted here. First, global R&D<sup>10</sup> on agriculture is only a little more than half that estimated for health R&D. Secondly, there is almost twice as much agricultural R&D in the public sector as the private sector. In medicine, expenditure by the private sector is proportionately larger, as we have seen. Thirdly, and partly as a result, the developing countries are relatively better served in the case of agricultural research.

Nevertheless current trends give cause for concern. Although the CGIAR spends only about \$340 million per year, its role is strategically important. For instance, the CGIAR centres played a crucial role in the Green Revolution and now act as the guardian of the world’s largest collection of genetic resources of relevance to developing countries, which is the major source of crop improvements for the future. But funding for the CGIAR system, which is provided by the donor community, has fallen in real terms since 1990<sup>11</sup> and this threatens both its research effort and its ability to maintain its gene banks, or assist developing countries in maintaining their own collections. Indeed the FAO and CGIAR have launched an endowment specifically to ensure that these genetic materials across the world can be properly maintained.<sup>12</sup> While funding from the aid donor community is stagnating, the private sector is the dynamic element in agricultural R&D, but little of its effort is of direct relevance to poor farmers in developing countries.

## The Impact of Plant Variety Protection

In this section we examine the evidence on the impact of plant variety protection (PVP) in developed and developing countries and what PVP systems might have to offer developing countries.

Most of the evidence relating to the impact of patent or plant variety protection on research is from developed countries, and even that is quite sparse. Before IP protection was introduced, private sector breeding initiatives focused on hybrid varieties, particularly of maize in the US, because inherent in these varieties is an element of “technological protection”. In the US a study from the 1980s suggested there was no evidence that total R&D activity had increased as a result of the introduction of PVP, although it appeared to have had some impact on soya beans, and perhaps wheat.<sup>13</sup> The latter crops also accounted for the majority of PVP certificates issued. There was also evidence that PVP was used as a marketing strategy for product differentiation and that it had contributed to the large number of mergers that took place in the seed industry. But the evidence

is inconclusive, in particular because of the difficulty in isolating the effect of protection from other ongoing changes. Even now research spending on hybrid crops as a share of sales continues to exceed that on non-hybrid crops, which are the principal object of PVP.<sup>14</sup> A recent study found that PVP on wheat in the US had not contributed to increased investment in private sector wheat breeding, but may have done so in the public sector. Nor had it contributed to an increase in yields. But the share of wheat acreage sown to private varieties had increased markedly, reinforcing the suggestion that the main impact of PVP was as a marketing tool.<sup>15</sup>

A major study conducted in middle income developing countries<sup>16</sup> found little evidence of an increased range of plant material available to farmers or increased innovation as a result of PVP protection. Access to foreign genetic material had improved, but its use was sometimes subject to restrictions, for example on exports. Generally speaking, commercial farmers and the seed industry were perceived as the principal beneficiaries. Poor farmers had not benefited directly from protection, but could potentially be adversely affected by restrictions on seed saving and exchange in the future.

Under TRIPS, developing countries may choose an “effective *sui generis*” PVP system. A major decision is to identify a system that is suitable to their particular agricultural and socio-economic circumstances. The UPOV Convention (see Box 3.1) is one system which they may adopt, based on the legislation introduced in Europe and the US. A consideration is that it provides a ready made legislative framework, but a disadvantage is that it was designed with the commercialised farming systems of the developed countries in mind. There are therefore concerns expressed about the application of the UPOV model in developing countries, some of which apply to any form of PVP.

The criteria for awarding a PVP certificate involve lower thresholds than the standards required for patents. There are requirements for novelty and distinctness, but there is no equivalent of non-obviousness (inventive step) or utility (industrial applicability). Thus, PVP law allows breeders to protect varieties with very similar characteristics, which means the system tends to be driven by commercial considerations of product differentiation and planned obsolescence, rather than genuine improvements in agronomic traits.<sup>17</sup> Developing countries might consider raising the threshold, in particular so that protection is only given for significant or important innovations with particular characteristics that are deemed socially beneficial (for example, yield increases, or traits of nutritional value). Thus the criteria for distinctness may be strengthened, and also criteria formulated defining utility in terms of the objectives of agricultural policy. Alternatively, countries may decide to retain lower standards for certain categories of plant in order to facilitate access by nascent domestic breeding industries to PVP protection from which may flow commercial and export benefits.

Similarly, the requirement for uniformity (and stability) in UPOV type systems excludes local varieties developed by farmers that are more heterogeneous genetically, and less stable. But these characteristics are those that make them more adaptable and suited to the agro-ecological environments in which the majority of poor farmers live. Again it would be open to developing countries to devise systems that would offer protection for varieties that meet criteria suited to the circumstances and crops on which poor farmers depend. But such criteria may be difficult to devise, and the system costly to operate. And governments may consider that extending such a system would not play a positive role in the development of their farming systems.

Another concern is about the criterion for uniformity. While proponents argue that PVP, by stimulating the production of new varieties, actually increases biodiversity, others claim that the requirement for uniformity, and the certification of essentially similar varieties of crops, will add to uniformity of crops and loss of biodiversity. Of course this concern goes wider than PVP. Seed legislation in many countries imposes strict uniformity requirements, sometimes stricter than PVP legislation. Moreover similar concerns have arisen in respect of greater uniformity arising from the success of Green Revolution varieties, leading to greater susceptibility to disease and loss of on-field biodiversity. But, as plant breeding becomes an increasingly private sector activity, and new varieties displace traditional varieties on a large scale, there is the crucial issue of how genetic resources are to be conserved and maintained for possible future use, whether in fields or in “gene banks.”<sup>18</sup>

There may also be a need to differentiate standards of protection between different kinds of crop. For instance, countries with significant commercial and export sectors might adopt UPOV-type standards for the relevant crops in those sectors to encourage innovation and commercialisation. But they might adopt other standards for food crops grown by farmers to protect their practices of saving, trading and exchanging seeds, and informal systems of innovation. For instance, in Kenya PVP rights seem to have been predominantly applied for by the foreign-owned commercial exporters of flowers and vegetables to underpin commercialisation and exporting. This may be beneficial to the expansion of Kenya's export industries and commercial agriculture, and indirectly to poor people. PVP may facilitate the availability of new varieties in Kenya (which might have been withheld in the absence of protection) but appears to play little part in stimulating local research. The system has not appeared to be very relevant to the direct concerns of Kenya's poor farmers and the crops they grow.

### **Box 3.1. Union Internationale pour la Protection des Obtentions Végétales/ International Union for the Protection of New Varieties of Plants (UPOV)**

The internationally recognised agreement on PVP protection is UPOV. The UPOV Convention dates from 1961, and has been revised thrice subsequently. Apart from South Africa, the first developing countries to join UPOV were Uruguay and Argentina in 1994, when there were 26 members in total. Since 1994, 24 further developing countries have joined UPOV. Although TRIPS only specifies that there should be a *sui generis* regime, UPOV has been an obvious choice as it provides an off-the shelf solution to developing such legislation. In addition, pressure has been put on various countries to join UPOV in the context of bilateral trade agreements (for instance, the recently concluded Vietnam-US trade agreement obliges both parties to be members of UPOV, of which the US is already a member).

The purpose of the UPOV Convention is to ensure that the member States of the Union acknowledge the achievements of breeders of new plant varieties, by making available to them exclusive property right, on the basis of a set of uniform and clearly defined principles.

As UPOV has been revised successively (1978 and 1991), the scope and length of protection has been extended. The minimum period of protection increased to 20 years (25 years for vines and trees) in the 1991 version (from 15 and 20 previously). Unlike patents, the criteria for protection do not involve an inventive step as such. Rather, to be eligible, varieties must only be distinctive, uniform and stable (DUS in the jargon) and novel (in terms of prior commercialisation).

The 1978 Act allowed breeders to use protected varieties as a source for new varieties, which could then be protected and marketed themselves. The 1991 Act has preserved the breeders' exception, but the right of the breeder extends to varieties which are "essentially derived" from the protected variety, which cannot be marketed without the permission of the holder of the original variety.

The 1978 Act provided the breeder with protection in respect of production for the sale of seed, its offer for sale and its commercialisation (Article 5 (1)) and it therefore implicitly allowed farmers to replant and exchange the seed (although this right is not spelt out). The 1991 Act is more restrictive of the rights of farmers. The right of the breeder now extends to production or reproduction, in addition to the marketing of propagated or harvested material (Article 14 (1)). This is mitigated by an optional farmers' exception which allows "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 [an essentially derived variety]." (Article 15 (2)).<sup>19</sup>

Thus developing countries should consider basing their PVP legislation on a realistic appreciation of how it could benefit their agricultural development and food security, taking account also of agriculture's role in generating exports, foreign exchange and employment. In particular they need to consider possible modifications to the UPOV model to adapt it to their circumstances.<sup>20</sup> A number of countries have passed or are considering legislation which incorporates elements described above.<sup>21</sup>

An important aspect of *sui generis* systems is the scope of the farmers' exception. Unlike patents, PVP legislation generally allows an exception, as in UPOV 1978, which permits farmers to reuse on their own holding harvested seeds without the permission of the rightsholder. In the US, this exception was expanded to allow limited sale of harvested crops for seed purposes to other farmers. And, in the developing world, in the absence of legal rules, farmers exchange and sell their seeds informally. As we have noted, this is a practice which is still very widespread amongst poor farmers in developing countries, and even still common in developed countries. These systems of sale and exchange are an important mechanism by which farmers have traditionally selected and improved their own varieties, and the restriction of this right may impede this process of improvement. Although UPOV (1991) permits nations to allow farmers to reuse their own crop for seed purposes on their own holdings, it does not allow for informal sale or exchange. In contrast, TRIPS only requires that there should be some form of IP protection for plant varieties, and does not define in any way the exceptions that may be provided to the rights of owners of protected varieties.

Thus countries and organisations have experimented with a number of alternatives in this area. For instance, the OAU (now the African Union) has produced model legislation which it recommends African countries adapt in their own legislation. This provides for the right to save, use, multiply and process farm-saved seed, but not to sell it on a commercial scale.<sup>22</sup> The Indian government, which has recently decided to seek admission to UPOV, has incorporated in its PVP legislation (2002) a clause (39 (1) (iv)) that states:

"a farmer shall be deemed to be entitled to save, use, sow, re-sow, exchange, share or sell his farm produce including seed of a variety protected under this Act in the same manner as he was entitled to before the coming into force of this Act:

Provided that the farmer shall not be entitled to sell branded seed of a variety protected under this Act."<sup>23</sup>

The breeders' exception under PVP also differs from patent law in that breeders may, without authorisation, use a protected variety as the basis for breeding another variety (which itself may then gain protection). Thus PVP provides less protection than patents, and as we have argued little incentive for research, but correspondingly is less restrictive of incremental follow-on innovation than patents. Again developing countries are free to choose exactly what exceptions they provide. At one extreme, PVP could be conferred as a superior kind of seed certificate or seal giving the holder the sole rights to sell seed with this seal. But there would be no rights to protect subsequent use or sale of the seed, as long as it was not sold under the certificate. This right would be superior to a trademark or seed certificate, but would not restrict subsequent reuse of harvested material in any way. Such a system might be a way to tailor the PVP system to the needs of poor farmers, but it would offer less incentive for breeders.<sup>24</sup>

## The Impact of Patents

Patents on plant varieties, as such, are only allowed in the US, Japan and Australia, and are most frequent in the US. The 1930 US Act introduced a special kind of Plant Patent for vegetatively propagated materials, but in the US standard utility patents can also now be granted on plant varieties. Patents are the strongest form of intellectual property protection in the sense that they normally allow the rightsholder to exert the greatest control over the use of patented material by limiting the rights of farmers to sell, or reuse seed they have grown, or other breeders to use the

seed (or patented intermediate technologies) for further research and breeding purposes. However, patent law can provide for exceptions similar to those in PVP systems. For example, the EU Biotechnology Directive, while not permitting the patenting of plant varieties, provides for a farmer's exception where a patent on genetic material would otherwise prevent reuse on the farm. It also contains a provision for compulsory licensing, subject to certain conditions, where a breeder's use of material would otherwise infringe the patent right.<sup>25</sup>

In the US, the patenting of plant varieties is particularly important because, with appropriate claims in the patent, the holder of the patented variety can prevent others from using it for breeding purposes. This is a significant difference from PVP. Proving that a new variety meets the criteria for patentability is more difficult and more costly than obtaining plant variety protection, where the criteria for protection are lower. Patent protection is also frequently obtained through a broad patent which claims the gene, the vector or carrier for effecting the transformation and so on, which may cover a number of potential varieties or crops incorporating the gene. For practical purposes this may have the same effect as patenting the whole plant, because the patent normally extends to "all material...in which the product is incorporated".<sup>26</sup>

Whatever the incentives provided by patenting, market forces will tend to direct research efforts by the private sector to where there is the most substantial potential return. However, in contrast to medicines, there is the potential for companies to become attracted to crops that are widely grown in developing countries. The investment costs are correspondingly lower than for medical research, and the potential markets correspondingly larger. For instance rice, where the value of production in India alone exceeds that of the US maize market, has hitherto been a crop where breeding has been the preserve of the national or international public sector (principally the CGIAR). Since then the private sector has become increasingly interested in rice research. Monsanto and Syngenta have worked on sequencing the rice genome of two major rice varieties. The number of patents relating to rice issued annually in the US has risen from less than 100 in 1995 to over 600 in 2000.<sup>27</sup>

So far about 80% of trials of transgenic crops have occurred in developed countries, where three quarters of the world's GM crops are grown. The breeding strategies of the multinationals have been naturally oriented to the needs of developed world markets, and the commercial sectors of middle income developing countries (for example, Brazil, Argentina or China). The development of genetic traits such as herbicide tolerance has been determined principally by the search for commercial advantage, rather than for characteristics useful to poor farmers in developing countries. But companies are introducing GM varieties which, although controversial both in developed and developing countries, are considered by some developing countries to be of potential benefit to them (for example, the Bt gene which confers insect resistance).<sup>28</sup> Bt Cotton or Bt maize is now grown in at least five developing countries, and other countries may be interested, if they can resolve environmental concerns. For instance, India has recently approved the planting of Bt Cotton. Companies have also donated technologies of relevance to developing countries (for example, through royalty free licences), including those related to vitamin A enriched rice (Golden Rice) and cassava. Some companies have published scientific articles based on their genomic research, but have aroused controversy by not depositing the raw data in public databanks. Negotiations about the deposit in public databanks have been complicated by the companies' desire to limit access to components of data with the greatest potential commercial value.<sup>29</sup>

Thus there is the potential for agricultural technologies developed by the private sector to spill over to the benefit of the commercial sectors in developing countries. But if the Green Revolution which was developed and applied with public sector funding failed to reach effectively poor farmers living in agro-ecologically diverse rainfed environments, it is apparent that biotechnology-related research led by the private sector will be even less likely to do so. For that, more public sector research specifically oriented to such farmers will be required. In 1998, the CGIAR system spent \$25 million on such research compared to the \$1.26 billion invested by Monsanto.<sup>30</sup>

Apart from the problem of incentives for research relevant to poor farmers, there is evidence that patents, and to some extent PVP, have played a part in the major consolidation of the global seed and agricultural input industries. The consolidation appears to be driven by technological change, with an objective of vertical and horizontal integration so that the appropriability of investment in research can be maximized through better control of distribution channels, including those of complementary agricultural inputs (such as herbicides).

Companies acquire patent rights to protect their own investment in research, and to prevent the encroachment of others. But by the same token, other companies' patent rights can impede one's own research. For instance, there are several hundred overlapping patent rights for the Bt technology, and at least four companies obtained patents that cover Bt-transformed maize.<sup>31</sup> Recently, Syngenta filed two law suits in the US against a number of its competitors alleging infringement of several of its patents relating to this technology, although the companies involved have been using these technologies, and selling seeds incorporating them, for several years.<sup>32</sup> Cross licensing,<sup>33</sup> or strategic alliances, can also be used as mechanisms to overcome problems of conflicting patents,<sup>34</sup> but merger or acquisition may be the most effective means of obtaining the freedom to use required technologies in a particular field of research. All of these approaches, not just the last, reduce competition. And the major multinational agrochemical companies, with their growing control over essential proprietary technologies, also represent a formidable barrier to the entry of innovative start-ups.<sup>35</sup> In the 1980s, the university and public sector accounted for 50% of the total of granted US patents relating to Bt. By 1994, independent biotechnology companies and individuals held 77%, but by 1999 the big six companies (which became five with the merger of the agricultural arms of AstraZeneca and Novartis to form Syngenta) held 67%. Moreover, the growing control of these companies was demonstrated by the fact that 75% of their Bt patents in 1999 had been obtained by the acquisition of smaller biotechnology and seed companies.<sup>36</sup>

In developing countries, there is evidence of similar trends with an extremely rapid process of merger and acquisition by the multinational companies. For instance, in Brazil, following the introduction of plant variety protection in 1997 (but presumably also related to the expected permission to grow GM crops), Monsanto increased its share of the maize seed market from 0% to 60% between 1997 and 1999. It acquired three locally based firms (including Cargill as the result of an international deal), while Dow and Agrevo (now Aventis) also increased their market share by acquisition. Only one Brazilian-owned firm remained with a 5% market share.<sup>37</sup> This trend appears widespread in developing countries.<sup>38</sup>

Thus, the speed of concentration in the sector raises serious competition issues. There are considerable dangers to food security if the technologies are overpriced to the exclusion of small farmers, or there is no alternative source of new technologies, particularly from the public sector. Further, the increase in concentration, and the conflicting patent claims when both the public and private sectors have patented plant technologies, may have had an inhibiting effect on research. In the private sector the response has been alliances or acquisitions, but a problem for the public sector is how to access the technologies they need to undertake research without infringing IP rights and, if they develop new technologies, the terms on which they may be made available. A recent review published by the US Department of Agriculture concludes that "whether the current intellectual property regime is stimulating or hampering research is unclear."<sup>39</sup> We return to this subject in Chapter 6.

## Conclusion

Thus developing countries have possibly three options for meeting their obligation to protect plant varieties under TRIPS. They may adopt one or a combination of the following:

- UPOV style legislation based on the 1978 or 1991 Convention (although they may now only join the 1991 Convention)
- Another form of *sui generis* system, including or not landraces
- Patents on plant varieties

Our reservations about the possible impact of patents apply not just to patents on plant varieties but also to plants and animals in general. At present there appears to be little evidence that providing patent protection for biotechnology-related inventions is really in the interests of the majority of developing countries which have little or no capability in this technology. We would therefore recommend that maximum use be made of the possibilities under TRIPS of excluding such inventions from patent protection. Even where TRIPS requires patent protection to be available, for example in respect of microorganisms, there is still scope for developing countries to restrict the scope of protection. In particular, in the absence of any universally recognised definition of what constitutes a “microorganism”, developing countries remain free to adopt a credible definition that limits the range of material covered.<sup>40</sup>

**Developing countries should generally not provide patent protection for plants and animals, as is allowed under Article 27.3(b) of TRIPS, because of the restrictions patents may place on use of seed by farmers and researchers. Rather they should consider different forms of *sui generis* systems for plant varieties.**

**Those developing countries with limited technological capacity should restrict the application of patenting in agricultural biotechnology consistent with TRIPS, and they should adopt a restrictive definition of the term “microorganism.”**

Countries that have, or wish to develop, biotechnology-related industries may wish to provide certain types of patent protection in this area. If they do so, specific exceptions to the exclusive rights, for plant breeding and research, should be established. The extent to which patent rights extend to the progeny or multiplied product of the patented invention should also be examined and a clear exception provided for farmers to reuse seeds.

The continuing review of Article 27.3(b) of TRIPS should also preserve the right of countries not to grant patents for plants and animals, including genes and genetically modified plants and animals, as well as to develop *sui generis* regimes for the protection of plant varieties that suit their agricultural systems. Such regimes should permit access to the protected varieties for further research and breeding, and provide at least for the right of farmers to save and plant-back seed, including the possibility of informal sale and exchange.

Because of the growing concentration in the seed industry, public sector research on agriculture, and its international component, should be strengthened and better funded. The objective should be to ensure that research is oriented to the needs of poor farmers; that public sector varieties are available to provide competition for private sector varieties; and that the world’s plant genetic resource heritage is maintained. In addition, this is an area in which nations should consider the use of competition law to respond to the high level of concentration in the private sector.

# ACCESS TO PLANT GENETIC RESOURCES AND FARMERS' RIGHTS

## Introduction

As noted above, a major issue of importance to the future of agricultural research is the conservation of genetic resources held in fields and in national and international collections, along with guaranteed access for researchers on terms that recognise the contribution made by farmers in the developing world in conserving, improving and making available these resources.

The foundation for international action to ensure the conservation, use and availability of plant genetic resources was the FAO Undertaking on Plant Genetic Resources agreed in 1983. Subsequently, the concept of Farmers' Rights<sup>41</sup> arose in debates in the FAO where it was recognised that there was an imbalance between the IP rights afforded to breeders of modern plant varieties and the rights of farmers who were responsible for supplying the plant genetic resources from which such varieties were mainly derived. A second concern was the consistency between making available plant genetic resources as the common heritage of mankind, and the taking out of private IP rights on varieties derived from them.

In 1989 the FAO agreed to recognise these concerns by incorporating Farmers' 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" in the Undertaking.<sup>42</sup> Farmers' Rights were to be implemented through an International Fund for Plant Genetic Resources, which would finance relevant activities, particularly in developing countries. Subsequently the FAO agreed that "Plant Breeders' Rights, as provided for under UPOV...are not incompatible with the International Undertaking," a choice of words that reflected the continuing ambivalence felt by some developing countries about the underlying consistency between the Undertaking and UPOV.<sup>43</sup>

Following the agreement of the CBD in 1992, it was on this basis that the process of transforming the Undertaking into the Treaty (ITPGRFA), finally agreed in 2001, was undertaken.<sup>44</sup> The ITPGRFA has the specific objective of facilitating access to plant genetic resources held by contracting parties, and those in international collections, for the common good, recognising that these are an indispensable raw material for crop genetic improvement, and that many countries depend on genetic resources which have originated elsewhere. This represents an implementation of the CBD principles taking account of the specific characteristics of plant genetic resources. Most varieties now in existence, in particular those derived from public breeding programmes, contain genetic material from many sources, often derived from genetic material in gene banks, which themselves may have diverse origins.

The ITPGRFA also recognises the contribution of farmers in conserving, improving and making available these resources, and that this contribution is the basis of Farmers' Rights. It does not limit in any form whatsoever rights that farmers may enjoy under national law to save, use, exchange and sell farm-saved seed. It also sets out the right to participate in decision making about, and to derive fair and equitable benefits from, the use of these resources (see Box 3.2).

## Farmers' Rights

The ITPGRFA leaves it entirely up to national governments to implement Farmers' Rights (paragraph 9.2). Thus, implementing specific Farmers' Rights is not an international obligation like that imposed under provisions in TRIPS.

The rationale for Farmers' Rights combines arguments about equity and economics. Plant breeders and the world at large benefit from the conservation and development of plant genetic resources undertaken by farmers, but farmers are not recompensed for the economic value they have

contributed. Farmers' Rights may be seen as a means of providing incentives for farmers to continue to provide services of conservation and maintenance of biodiversity. As noted, the protection of plant varieties contains an inherent tendency to encourage uniformity and reduce biodiversity, to which the traditional practices of farmers are an essential counterweight. Farmers should be supported in recognition of the economic value they conserve, which is not recognised in the market system, and is to some extent threatened by technical change and the extension of plant breeders' protection. Moreover, the extension of intellectual property protection does carry the risk of restricting farmers' rights to reuse, exchange and sell seed, the very practices which form the basis of their traditional role in conservation and development.

Farmers' Rights are not an intellectual property right, but they need to be viewed as an important counterbalance to the rights accorded to breeders in the formal sector under PVP or patents. However, defining how to implement these rights at national level is complex, as we discuss in the next chapter in the context of CBD. The Treaty provides for a financing mechanism to be set up, financed by contributions and the share of the proceeds of commercialisation, which will enable the implementation of agreed plans and programmes for farmers "who conserve and sustainably utilise plant genetic resources for food and agriculture."<sup>45</sup>

### Box 3.2 Farmers' Rights In ITPGRFA (Article 9)

9.1 The Contracting Parties recognize the enormous contribution that the local and indigenous communities and farmers of all regions of the world, particularly those in the centres of origin and crop diversity, have made and will continue to make for the conservation and development of plant genetic resources which constitute the basis of food and agriculture production throughout the world.

9.2 The Contracting Parties agree that the responsibility for realizing Farmers' Rights, as they relate to plant genetic resources for food and agriculture, rests with national governments. In accordance with their needs and priorities, each Contracting Party should, as appropriate, and subject to its national legislation, take measures to protect and promote Farmers' Rights, including:

- (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.

9.3 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.

## The Multilateral System

Under the Treaty, countries have agreed to provide facilitated access to plant genetic resources from an agreed list of crops listed in an annex, which are important for food security. By signing the Treaty, governments agree to put such resources under their direct control into the “Multilateral System”. They will also encourage institutions, not under their direct control, to do likewise. Of particular importance is the large collection of genetic material of interest to developing countries under the aegis of the CGIAR, but there are of course many national collections of worldwide importance in both developed and developing countries, as well as the store of genetic diversity in farmers’ fields.

With regard to IPRs, the potentially contentious part of the treaty is that referring to the protection of resources accessed from the Multilateral System. As finally agreed the Treaty states:

“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 or components, in the form received from the Multilateral System;”<sup>46</sup>

This wording is inevitably a diplomatic compromise, reflecting a desire on the part of many developing countries to avoid a limitation on access being imposed by the grant of IP rights, and of some developed countries to allow patenting of genetic material according to existing criteria applied nationally. The crucial words “in the form received” mean that material received cannot be patented *as such*, but they do allow patents to be taken out on modifications (however defined) to that material.

The compromise wording clearly excludes the patenting of seeds as obtained from a seed bank. But the extent to which patents can be taken out on a gene isolated from that material is controversial. During the negotiation of the Treaty, some countries were of the opinion that this article should be read as precluding such patenting. Others thought that the isolated form of a gene (for which a function has also been determined) is different than the “form received” and, hence, should be patentable. Thus the wording raises the important general issue of what are the appropriate rules for patenting genetic material, both for developed and developing countries. This revolves around the nature of the inventive step required for patenting, the nature of the claims for the invented use of that material, and the extent to which those claims might limit use of the underlying genetic material. We discuss this further in Chapter 6.

The Treaty has also established an important principle in that any user of material will sign a standard Material Transfer Agreement (MTA),<sup>47</sup> to be devised by the Governing Body of the Treaty, which will incorporate the conditions for access agreed in the Treaty (paragraph 12.3) and provide for benefit sharing of the proceeds of any commercialisation arising from the material through a Fund established under the Treaty. This significantly goes beyond the provisions of CBD in suggesting a concrete mechanism for benefit sharing, based on multilateral rather than bilateral arrangements.

**Developed and developing countries should accelerate the process of ratification of the FAO International Treaty on Plant Genetic Resources for Food and Agriculture and should, in particular, implement the Treaty’s provisions relating to:**

- **Not granting IPR protection of any material transferred in the framework of the multilateral system, in the form received.**
- **Implementation of Farmers’ Rights at the national level, including (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 utilisation of plant genetic resources for food and agriculture; (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.**

- <sup>1</sup> IFAD (2001) *"Rural Poverty Report 2001 - The Challenge of Ending Rural Poverty"*, IFAD, Rome, pp. 14-15.  
Source: <http://www.ifad.org/poverty/>
- <sup>2</sup> See Glossary for definition.
- <sup>3</sup> See next section
- <sup>4</sup> See Nuffield Council on Bioethics (2002) *"The Ethics of Patenting DNA: A Discussion Paper"*, Nuffield Council on Bioethics, London, pp.21-23.  
Source: <http://www.nuffieldbioethics.org/filelibrary/pdf/theethicsofpatentingdna.pdf>
- <sup>5</sup> See Glossary for definition.
- <sup>6</sup> See Glossary for definition.
- <sup>7</sup> This technology has not been commercially implemented yet.
- <sup>8</sup> Pardey, P. & Beintema, M. (2001) *"Slow Magic: Agricultural R&D a Century After Mendel"* International Food Policy Research Institute, Washington DC, p. 10. Source: <http://www.ifpri.cgiar.org/pubs/fps/fps36.pdf>. Note that these figures are based on purchasing power parity exchange rates which the authors consider a more accurate reflection of relative magnitudes. In ordinary \$ terms, the developed country share is considerably higher (69% rather than 44%, see p.5).
- <sup>9</sup> Pardey, P. & Beintema, M. (2001), p.4
- <sup>10</sup> For data on health-related R&D, see Commission on Macroeconomics and Health (2001) *"Macroeconomics and Health: Investing in Health for Economic Development"*, WHO, Geneva, footnote 103, p.124.  
Source: [http://www3.who.int/whosis/cmh/cmh\\_report/e/report.cfm?path=cmh,cmh\\_report&language=english](http://www3.who.int/whosis/cmh/cmh_report/e/report.cfm?path=cmh,cmh_report&language=english)
- <sup>11</sup> Pardey, P. & Beintema, M. (2001), p.8.
- <sup>12</sup> Speech by Geoffrey Hawtin at World Food Summit, 13 June 2002.  
Source: [http://www.fao.org/worldfoodsummit/top/detail.asp?event\\_id=12899](http://www.fao.org/worldfoodsummit/top/detail.asp?event_id=12899)
- <sup>13</sup> Butler L. & Marion, B. (1985) *"The Impacts of Patent Protection on the US Seed Industry and Public Plant Breeding"*, Food Systems Research Group Monograph 16, University of Wisconsin, Madison.
- <sup>14</sup> Shoemaker, R. et al (2001) *"Economic Issues in Biotechnology"*, ERS Agriculture Information Bulletin No. 762, USDA, Washington DC, p. 36.
- <sup>15</sup> Alston, J. & Venner, R. (2000) *"The Effects of the US Plant Variety Protection Act on Wheat Genetic Improvement"*, EPTD Discussion Paper No. 62, International Food Policy Research Institute, Washington DC.  
Source: <http://www.grain.org/docs/eptdp62.pdf>
- <sup>16</sup> Van Wijk, J. & Jaffe, W. (1995) *"Impact of Plant Breeders Rights in Developing Countries"* Inter-American Institute for Cooperation on Agriculture, San Jose, and University of Amsterdam.
- <sup>17</sup> Rangnekar, D. (2002) *"Access to Genetic Resources, Gene-based Inventions and Agriculture"*, Commission on Intellectual Property Rights Background Paper, 3a, Commission on Intellectual Property Rights, London, p.39. Source: <http://www.iprcommission.org>
- <sup>18</sup> Louwaars, N. & Marrewijk, G. (1996), *"Seed Supply Systems in Developing Countries"*, Technical Centre for Agricultural and Rural Cooperation, Wageningen Agricultural University, Wageningen, p. 99.
- <sup>19</sup> UPOV 1978. Source: <http://www.upov.int/eng/convntns/1978/pdf/act1978.pdf>. UPOV 1991.  
Source: <http://www.upov.int/eng/convntns/1991/pdf/act1991.PDF>
- <sup>20</sup> IPGRI has produced a useful document which discusses the issues developing countries should consider in adopting sui generis regimes. IPGRI (1999) *"Key Questions for Decisionmakers: Protection of Plant Varieties under the WTO TRIPS Agreement"*, IPGRI, Rome.  
Source: [http://www.ipgri.cgiar.org/publications/pubsurvey.asp?id\\_publication=41](http://www.ipgri.cgiar.org/publications/pubsurvey.asp?id_publication=41).  
A more detailed review we have drawn on here is Leskien, D. & Flitner, M. (1997) *"Intellectual Property Rights and Plant Genetic Resources: Options for a Sui Generis System"*, Issues in Genetic Resources No. 6, IPGRI, Rome.  
Source: [http://www.ipgri.cgiar.org/publications/pubfile.asp?ID\\_PUB=497](http://www.ipgri.cgiar.org/publications/pubfile.asp?ID_PUB=497)
- <sup>21</sup> See, for instance, the GRAIN website. Source: <http://www.grain.org/publications/nonupov-en.cfm>
- <sup>22</sup> "African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders and for the Regulation of Access to Biological Resources", Organisation of African Unity, 2000, Article 26.  
Source: <http://www.grain.org/publications/oau-model-law-en.cfm>
- <sup>23</sup> "Protection of Plant Varieties and Farmer's Rights Act", Government of India, 2000.  
Source: <http://www.grain.org/brl/pvp-brl-en.cfm>
- <sup>24</sup> This idea comes from Leskien and Flitner (1997).
- <sup>25</sup> Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, Official Journal L 213, 30 July 1998, pp.13-21, (Articles 11 and 12).  
Source: [http://europa.eu.int/smartapi/cgi/sga\\_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31998L0044](http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31998L0044)

&model=guichett. These provisions were implemented in the UK in 2002.

See: <http://www.patent.gov.uk/about/ippd/notices/biotech.htm>

<sup>26</sup> See Directive 98/44EC, Article 9 (and also Article 8).

<sup>27</sup> Barton, J. & Berger, P. (2001) "Patenting Agriculture", *Issues in Science and Technology*, Summer 2001, p.4. Source: [www.nap.edu/issues/17.4/p\\_barton.htm](http://www.nap.edu/issues/17.4/p_barton.htm)

<sup>28</sup> The potential benefits and risks of GM crops for developing countries are discussed in Nuffield Council on Bioethics (1999) "*Genetically Modified Crops: The Ethical and Social Issues*" Nuffield Council on Bioethics, London, Chapter 4. Source: <http://www.nuffieldbioethics.org/filelibrary/pdf/gmcrop.pdf>

<sup>29</sup> See, for instance, Normile, D. (2002) "Syngenta Agrees to Wider Release" *Science*, vol. 296, pp.1785-1787.

Source: <http://www.sciencemag.org/cgi/content/full/296/5574/1785b?ijkey=pUrgaGgEb0z7.&keytype=ref&siteid=sci>

<sup>30</sup> Pardey, P. & Beintema, M. (2001), p.19.

<sup>31</sup> Barton, J. & Berger, P. (2001) p.4.

Source: [http://www.syngenta.com/en/media/printer.asp?article\\_id=234](http://www.syngenta.com/en/media/printer.asp?article_id=234)

<sup>33</sup> See Glossary for definition.

<sup>34</sup> See, for instance, two recent agreements announced on 2/3 April 2002, between Monsanto and DuPont, and Monsanto and Ceres. Source: <http://www.monsanto.com/monsanto/media/02/default.htm>

<sup>35</sup> The big six companies were normally regarded as AstraZeneca, Aventis, Dow, DuPont, Monsanto, and Novartis, which became five in 2000 with merger of the agricultural arms of Novartis and AstraZeneca.

<sup>36</sup> De Janvry, A., Graff, G., Sadoulet, E. & Zilberman, D. (2000) "*Technological Change in Agriculture and Poverty Reduction*" University of California, Berkeley. Concept paper for WDR on Poverty and Development 2000/2001, pp.6-7. Source: <http://www.worldbank.org/poverty/wdrpoverty/background/dejanvry.pdf>

<sup>37</sup> Wilkinson, J. & Castelli, P. (2000) "*The Internationalisation of Brazil's Seed Industry: Biotechnology, Patents and Biodiversity*", ActionAid Brazil, Rio de Janeiro, p.49. Source: <http://www.actionaid.org.br/e/pdf/seed.pdf>

<sup>38</sup> Byerlee, D. & Fischer, K. (2001) "Accessing Modern Science: Policy and Options for Agricultural Biotechnology in Developing Countries", *IP Strategy Today*, No. 1, p.2.

Source: <http://www.biodevelopments.org/ip/ipst1hr.pdf>

<sup>39</sup> Shoemaker, R. et al (2001), p.37.

<sup>40</sup> Genes are not microorganisms and neither, under a narrow definition, are cell lines although, for example, the UK Patent Law considers the latter to be microorganisms. See UK Patent Office Manual of Patent Practice Section 1.40. See also, Adcock, M. & Llewelyn, M. (2000) "*Microorganisms, Definitions and Options under TRIPS*", Occasional Paper 2, QUNO, Geneva.

<sup>41</sup> See Glossary for definition.

<sup>42</sup> IUPGR Resolution 5/89. Source: <http://www.mtnforum.org/resources/library/iupgr91a.htm>

<sup>43</sup> IUPGR Resolution 4/89

<sup>44</sup> Text of the ITPGR. Source: <http://www.fao.org/ag/cgrfa/IU.htm>

<sup>45</sup> ITPGRFA Article 18.5

<sup>46</sup> ITPGRFA Article 12.3 d)

<sup>47</sup> A contractual agreement between the supplier and recipient of material setting out the conditions governing the transfer.



## TRADITIONAL KNOWLEDGE AND GEOGRAPHICAL INDICATIONS



### INTRODUCTION

Human communities have always generated, refined and passed on knowledge from generation to generation. Such “traditional” knowledge<sup>1</sup> is often an important part of their cultural identities. Traditional knowledge has played, and still plays, a vital role in the daily lives of the vast majority of people. Traditional knowledge is essential to the food security and health of millions of people in the developing world. In many countries, traditional medicines provide the only affordable treatment available to poor people. In developing countries, up to 80% of the population depend on traditional medicines to help meet their healthcare needs.<sup>2</sup> In addition, knowledge of the healing properties of plants has been the source of many modern medicines. As we note in Chapter 3, the use and continuous development by local farmers of plant varieties and the sharing and diffusion of these varieties and the knowledge associated with them play an essential role in agricultural systems in developing countries.

Only recently, however, has the international community sought to recognise and protect traditional knowledge. In 1981, WIPO and UNESCO adopted a model law on folklore. In 1989 the concept of Farmers’ Rights was introduced by the FAO into its International Undertaking on Plant Genetic Resources and in 1992 the Convention on Biological Diversity (CBD) highlighted the need to promote and preserve traditional knowledge.<sup>3</sup> In spite of these efforts which have spanned two decades, final and universally acceptable solutions for the protection and promotion of traditional knowledge have not yet emerged.

The CBD also set out principles governing access to genetic resources and the knowledge associated with them, and the sharing of benefits arising from such access. We therefore consider the relationship between the IP system and the access and benefit sharing principles of the CBD in the context of both knowledge, traditional or otherwise, and genetic resources.

We also consider here, although it is largely a separate issue, whether Geographical Indications (GIs) have a role to play in promoting development, and the issues relevant to developing countries in the current discussions on this issue in the TRIPS Council.

Thus in this chapter we examine the following questions:

- What is the nature of traditional knowledge and folklore and what do we mean by its protection?
- How can the existing IP system be used to protect and promote traditional knowledge?
- What modifications of the IP system might improve its protection?
- How can the IP system support the principles of access and benefit sharing enshrined in the Convention on Biological Diversity (CBD)?
- Is the protection of Geographical Indications important for developing countries?

### Box 4.1 Biopiracy

There is no accepted definition of “biopiracy.” The Action Group on Erosion, Technology and Concentration (ETC Group) defines it as “the appropriation of the knowledge and genetic resources of farming and indigenous communities by individuals or institutions seeking exclusive monopoly control (usually patents or plant breeders’ rights) over these resources and knowledge.”

The following have been described as “biopiracy”:

- The granting of ‘wrong’ patents.** These are patents granted for inventions that are either not novel or are not inventive having regard to traditional knowledge already in the public domain. Such patents may be granted due either to oversights during the examination of the patent or simply because the patent examiner did not have access to the knowledge. This may be because it is written down but not accessible using the tools available to the examiner, or because it is unwritten knowledge. A WIPO led initiative to document and classify traditional knowledge seeks to address some of these problems.
- The granting of ‘right’ patents.** Patents may be correctly granted according to national law on inventions derived from a community’s traditional knowledge or genetic resources. It could be argued this constitutes “biopiracy” on the following grounds:
  - Patenting standards are too low. Patents are allowed, for instance, for inventions which amount to little more than discoveries. Alternatively, the national patent regime (for example, as in the US) may not recognise some forms of public disclosure of traditional knowledge as prior art.<sup>4</sup>
  - Even if the patent represents a genuine invention, however defined, no arrangements may have been made to obtain the prior informed consent (PIC)<sup>5</sup> of the communities providing the knowledge or resource, and for sharing the benefits of commercialisation to reward them appropriately in accordance with the principles of the CBD.

# TRADITIONAL KNOWLEDGE

## Background

A number of cases relating to traditional knowledge have attracted international attention. As a result, the issue of traditional knowledge has been brought to the fore of the general debate surrounding intellectual property. These cases involve what is often referred to as “biopiracy” (See Boxes 4.1 and 4.2). The examples of turmeric, neem and ayahuasca illustrate the issues that can arise when patent protection is granted to inventions relating to traditional knowledge which is already in the public domain. In these cases, invalid patents were issued because the patent examiners were not aware of the relevant traditional knowledge. In another example, a patent was granted on a plant species called Hoodia. Here, the issue was not whether the patent should or should not have been granted, but rather on whether the local people known as the San, who had nurtured the traditional knowledge underpinning the invention, were entitled to receive a fair share of any benefits arising from commercialisation.

Partly as a result of these well known cases, many developing countries, holders of traditional knowledge, and campaigning organisations are pressing in a multitude of fora for traditional knowledge to be better protected. Such pressure has led, for example, to the creation of an Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore in WIPO. The protection of traditional knowledge and folklore is also being discussed within the framework of the CBD and in other international organisations such as UNCTAD, WHO, FAO and UNESCO.<sup>6</sup> In addition, the Doha WTO Ministerial Declaration highlighted the need for further work in the TRIPS Council on protecting traditional knowledge.<sup>7</sup>

## The Nature of Traditional Knowledge and the Purpose of Protection

How can traditional knowledge be defined? Whilst the vast majority of the knowledge is old in the sense that it has been handed down through the generations, it is continually refined and new knowledge developed, rather as the modern scientific process proceeds by continual incremental improvement rather than by major leaps forward. One of the speakers at our conference suggested that the term “folklore” be replaced by the more appropriate “expressions of culture” which represents living, functional traditions, rather than souvenirs of the past. Whilst most traditional knowledge and folklore is passed on orally, some of it, such as textile designs and Ayurveda medicinal knowledge, is codified. The groups that hold traditional knowledge are very diverse: individuals, groups or groups of communities may all be custodians. Such communities might be indigenous to the land or descendants of later settlers. The nature of the knowledge is also diverse: it covers, for example, literary, artistic or scientific works, song, dance, medical treatments and practices and agricultural technologies and techniques.

Whilst a number of definitions for traditional knowledge and folklore have been put forward, there is no widely acceptable definition for either of them. It is not only the broad scope of traditional knowledge that has confounded the debate so far. There is also some confusion about exactly what is meant by “protection” and its purpose. It should certainly not be equated directly with the use of the word “protection” in its IP sense. In its report on a series of fact-finding missions, WIPO<sup>8</sup> sought to summarise the concerns of traditional knowledge holders as follows:

- concern about the loss of traditional life styles and of traditional knowledge, and the reluctance of the younger members of the communities to carry forward traditional practices
- concern about the lack of respect for traditional knowledge and holders of traditional knowledge
- concern about the misappropriation of traditional knowledge including use of traditional knowledge without any benefit sharing, or use in a derogatory manner
- lack of recognition of the need to preserve and promote the further use of traditional knowledge.

## Box 4.2 Controversial Patent Cases involving Traditional Knowledge and Genetic Resources

### Turmeric

Turmeric (*Curcuma longa*) is a plant of the ginger family yielding saffron-coloured rhizomes used as a spice for flavouring Indian cooking. It also has properties that make it an effective ingredient in medicines, cosmetics and as a colour dye. As a medicine, it is traditionally used to heal wounds and rashes.

- In 1995, two Indian nationals at the University of Mississippi Medical Centre were granted US patent no. 5,401,504 on "use of turmeric in wound healing".
- The Indian Council of Scientific and Industrial Research (CSIR) requested the US Patent and Trademark Office (USPTO) to re-examine the patent.
- CSIR argued that turmeric has been used for thousands of years for healing wounds and rashes and therefore its medicinal use was not novel.
- Their claim was supported by documentary evidence of traditional knowledge, including an ancient Sanskrit text and a paper published in 1953 in the Journal of the Indian Medical Association.
- Despite arguments by the patentees, the USPTO upheld the CSIR objections and revoked the patent.

**Observations:** The turmeric case was a landmark case as it was the first time that a patent based on the traditional knowledge of a developing country had been successfully challenged. The legal costs incurred by India in this case have been calculated by the Indian Government to be about at US \$10,000.

### Neem

Neem (*Azadirachta indica*) is a tree from India and other parts of South and Southeast Asia. It is now planted across the tropics because of its properties as a natural medicine, pesticide and fertilizer. Neem extracts can be used against hundreds of pests and fungal diseases that attack food crops; the oil extracted from its seeds is used to treat colds and flu; and mixed in soap, it is believed to offer low cost relief from malaria, skin diseases and even meningitis.

- In 1994 the EPO granted European Patent No. 0436257 to the US Corporation W.R. Grace and USDA for a "method for controlling fungi on plants by the aid of a hydrophobic extracted neem oil".
- In 1995 a group of international NGOs and representatives of Indian farmers filed a legal opposition against the patent.
- They submitted evidence that the fungicidal effect of extracts of neem seeds had been known and used for centuries in Indian agricultural to protect crops, and thus was the invention claimed in EP257 was not novel.
- In 1999 the EPO determined that according to the evidence "all features of the present claim have been disclosed to the public prior to the patent application... and [the patent] was considered not to involve an inventive step".
- The patent was revoked by the EPO in 2000.

### Ayahuasca

For generations, shamans of indigenous tribes throughout the Amazon Basin have processed the bark of *Banisteriopsis caapi* to produce a ceremonial drink known as "ayahuasca". The shamans

use ayahuasca (which means "vine of the soul") in religious and healing ceremonies to diagnose and treat illnesses, meet with spirits, and divine the future.

An American, Loren Miller obtained US Plant Patent 5,751 in June 1986, granting him rights over an alleged variety of *B. caapi* he had called "Da Vine". The patent description stated that the "plant was discovered growing in a domestic garden in the Amazon rain-forest of South America." The patentee claimed that Da Vine represented a new and distinct variety of *B. caapi*, primarily because of the flower colour.

The Coordinating Body of Indigenous Organizations of the Amazon Basin (COICA) – an umbrella organisation representing over 400 indigenous groups – learned of the patent in 1994. On their behalf the Center for International Environmental Law (CIEL) filed a re-examination request on the patent. CIEL protested that a review of the prior art led that Da Vine was neither new nor distinct. They argued also that the granting of the patent would be contrary to the public and morality aspects of the Patent Act because of the sacred nature of *Banisteriopsis caapi* throughout the Amazon region. Extensive, new prior art was presented by CIEL, and in November 1999, the USPTO rejected the patent claim agreeing that Da Vine was not distinguishable from the prior art presented by CIEL and therefore the patent should never have been issued. However, further arguments by the patentee persuaded the USPTO to reverse its decision and announce in early 2001 that the patent should stand.

**Observation:** Because of the date of filing of the patent, it was not covered by the new rules in the US on *inter partes* re-examination. CIEL were therefore unable to comment on the arguments made by the patentee that led to the patent being upheld.

## Hoodia Cactus

The San, who live around the Kalahari Desert in southern Africa, have traditionally eaten the Hoodia cactus to stave off hunger and thirst on long hunting trips. In 1937, a Dutch anthropologist studying the San noted this use of Hoodia. Scientists at the South African Council for Scientific and Industrial Research (CSIR) only recently found his report and began studying the plant.

In 1995 CSIR patented Hoodia's appetite-suppressing element (P57). In 1997 they licensed P57 to the UK biotech company, Phytopharm. In 1998, the pharmaceutical company Pfizer acquired the rights to develop and market P57 as a potential slimming drug and cure for obesity (a market worth more than £6 billion), from Phytopharm for up to \$32 million in royalty and milestone payments.

On hearing of possible exploitation of their traditional knowledge, the San People threatened legal action against the CSIR on grounds of "biopiracy." They claimed that their traditional knowledge had been stolen, and CSIR had failed to comply with the rules of the Convention on Biodiversity, which requires the prior informed consent of all stakeholders, including the original discoverers and users.

Phytopharm had conducted extensive enquiries but were unable to find any of the "knowledge holders". The remaining San were apparently at the time living in a tented camp 1500 miles from their tribal lands. The CSIR claimed they had planned to inform the San of the research and share the benefits, but first wanted to make sure the drug proved successful.

In March 2002, an understanding was reached between the CSIR and the San whereby the San, recognised as the custodians of traditional knowledge associated with the Hoodia plant, will receive a share of any future royalties. Although the San are likely to receive only a very small percentage of eventual sales, the potential size of the market means that the sum involved could

still be substantial. The drug is unlikely to reach the market before 2006, and may yet fail as it progresses through clinical trials.

**Observations:** This case would appear to demonstrate that with goodwill on all sides, mutually acceptable arrangements for access and benefit sharing can be agreed. The importance of intellectual property in securing future benefits appears to have been recognised by all parties including the San.

Another source more succinctly classified these and other possible reasons for protecting traditional knowledge as:

- equity considerations – the custodians of traditional knowledge should receive fair compensation if the traditional knowledge leads to commercial gain
- conservation concerns – the protection of traditional knowledge contributes to the wider objective of conserving the environment, bio-diversity and sustainable agricultural practices
- preservation of traditional practices and culture – protection of traditional knowledge would be used to raise the profile of the knowledge and the people entrusted with it both within and outside communities
- prevention of appropriation by unauthorised parties or avoiding “biopiracy”
- promotion of its use and its importance to development.<sup>9</sup>

A single solution can hardly be expected to meet such a wide range of concerns and objectives. The type of measures required to prevent misappropriation may not be the same, indeed may not be compatible, with those needed to encourage the wider use of traditional knowledge. A multiplicity of complementary measures will almost certainly be required, many of which will be outside the field of intellectual property. Indeed, underlying the debate may be a much bigger issue such as the position of indigenous communities within the wider economy and society of the country in which they reside, and their access to or ownership of land they have traditionally inhabited. In that sense, concerns about the preservation of traditional knowledge, and the continued way of life of those holding such knowledge, may be symptomatic of the underlying problems that face these communities in the face of external pressures.

However, we intend to limit our consideration to how the intellectual property system might help address these concerns. Much has already been written on this subject and many international organisations, in particularly WIPO, have started to consider whether the existing system of intellectual property has a role to play or whether new forms of protection will be required.

## Managing the Debate on Traditional Knowledge

As noted above, a large number of bodies including WIPO, the CBD, UNCTAD and WTO are discussing the protection of traditional knowledge. These debates have rightfully focused on understanding the issue rather than on developing international norms. Only with a deeper understanding and greater practical experience at national or regional level would it be realistic to develop an international system of protection for traditional knowledge. It is essential that all of the agencies considering the issue work together to avoid unnecessary duplication and to ensure that the debate includes as many different views as possible. In this respect it has been suggested to us that an organisation such as WIPO, which deals exclusively with intellectual property matters, may not be the most appropriate forum to consider traditional knowledge in all its aspects.<sup>10</sup> We believe however that no single body is likely to have the capacity, expertise or resources to handle all aspects of traditional knowledge. Indeed it is our view that a multiplicity of measures, only some of them IP-related, will be necessary to protect, preserve and promote traditional knowledge.

There is much to gain at this early stage by considering the issue in a number of fora, while ensuring coherent approaches are developed and that effort is not duplicated.

## Making Use of the Existing IP System to Protect and Promote Traditional Knowledge

Examples are emerging which illustrate how the current intellectual property system can be utilised to commercialise traditional knowledge or prevent its misuse. For example, Aboriginal and Torres Strait Islander artists in Australia have obtained a national certification trademark.<sup>11</sup> Like any other trademark, this certification mark or Label of Authenticity is intended to help promote the marketing of their art and cultural products and deter the sale of products falsely claiming to be of Aboriginal origin.

In recent surveys of the existing protection of traditional knowledge and folklore, a number of countries have provided further examples of how IP tools have been utilised to promote and protect traditional knowledge and folklore.<sup>12</sup> These include the use of copyright protection in Canada to protect tradition-based creations including masks, totem poles and sound recordings of Aboriginal artists; the use of industrial designs to protect the external appearance of articles such as head dresses and carpets in Kazakhstan and the use of geographical indications to protect traditional products such as liquors, sauces and teas in Venezuela and Vietnam.

The ability to extend the life of trademarks indefinitely and the possibility of collective ownership of such rights suggest that they may be especially suitable for protecting traditional knowledge. This is also the case with geographical indications, which may be used to protect traditional products or crafts if particular characteristics of such products can be attributed to a particular geographical origin. However, trademarks and geographical indications can only prevent the use of the protected marks or indications; they do not protect the knowledge, or the technologies embracing that knowledge, as such.

Other IP rights, especially those requiring some form of novelty or those with fairly limited periods of protection, seem less appropriate for protecting traditional knowledge. Nevertheless it is clear from these surveys, and indeed other research, that existing IPRs do have a role to play in protecting traditional knowledge. Whether that role is a significant one remains to be seen. Experience elsewhere would suggest that the impact may not be great, not least because of the high cost of obtaining and enforcing rights. If the majority of small companies in developed countries have found the intellectual property system, particularly the patent system, to be unattractive,<sup>13</sup> then it seems unlikely that local communities in developing countries, or individuals within such communities, will derive much benefit.

## *Sui Generis* Protection of Traditional Knowledge

Some countries have already decided that the existing intellectual property system is not, on its own, adequate to protect traditional knowledge. A number of these have enacted or are in the process of enacting *sui generis* systems of protection.<sup>14</sup>

The Philippines has enacted legislation, and is considering further provisions,<sup>15</sup> giving indigenous communities rights over their traditional knowledge. These rights extend to controlling access to ancestral lands, access to biological and genetic resources and to indigenous knowledge related to these resources. Access by other parties will be based on the prior informed consent (PIC) of the community obtained in accordance with customary laws. Any benefits arising from genetic resources or associated knowledge will be equitably shared. The legislation however seeks to maintain the free exchange of biodiversity among local communities. The law also seeks to ensure that indigenous communities are able to participate at all levels of decision-making.

Whilst the primary objectives of these pieces of legislation is to recognise, protect and promote the rights of communities and indigenous people, including those relating to biological resources and associated traditional knowledge, they also recognise the potential for exploiting these resources. However, Guatemalan law also seeks to preserve and promote the wider use of its traditional knowledge by placing expressions of national culture, including for example medicinal knowledge and music, under the protection of the state.<sup>16</sup> Such expressions cannot under the law be sold or be subject of any remuneration. Thus, different types of models are being developed at the national level, seeking to adapt legislation and practice to local needs.

A particularly important question is the extent to which any form of protection recognises the customary laws under which the knowledge evolved. Countries such as Bangladesh, and organisations such as the AU,<sup>17</sup> are considering *sui generis* legislation that provides community-based rights over biological resources and associated traditional knowledge and are seeking to give increased recognition to the cultural and customary practices of communities. The *sui generis* system of protection in the Philippines also takes account of customary laws.

The Australian Federal Court has considered the relevance of customary Aboriginal laws and practices in a case of copyright infringement. Although the Court found that it was not able to “recognise the infringement of ownership rights of the kind which reside under Aboriginal law in the traditional owners of the dreaming stories and the imagery such as that used in the artworks of the present applicants,” it did take into account the harm suffered by the aboriginal artists in their cultural environment when considering damages.<sup>18</sup> Whilst such decisions give some degree of recognition to customary laws, they obviously do not go as far as some would like. In our consultations on this subject several people called for greater recognition of customary laws.<sup>19</sup>

Recognition of customary laws, whether they are specifically related to traditional knowledge or not, raises issues beyond the scope of this report. We believe nevertheless that customary laws relating to traditional knowledge should be respected and, if possible, recognised more widely. Further work to meet these objectives, as for example recently mandated by the 6th Conference of the Parties of the CBD, should be supported.<sup>20</sup>

Whether these national systems as they evolve will have sufficient common characteristics to enable the development of an international *sui generis* system remains to be seen. We recognise that there is continuing pressure for the establishment of an international *sui generis* system, as recently articulated by the G15 Group of developing countries.<sup>21</sup>

**With such a wide range of material to protect and such diverse reasons for “protecting it”, it may be that a single all-encompassing *sui generis* system of protection for traditional knowledge may be too specific and not flexible enough to accommodate local needs.**

As we have discussed already, the ability to protect, promote and exploit traditional knowledge does not necessarily depend on the presence of IP rights. Bringing together, for example, local innovators and entrepreneurs may be much more relevant. Whatever measures are put in place or whatever tools are utilised, exploitation is likely to raise the profile of traditional knowledge and local innovation within communities and encourage greater involvement by younger members of the community. This is especially likely to happen if tangible economic returns are generated. However it is important to remember that not all holders of traditional knowledge would want to see their knowledge exploited in this way. A participant in one of our expert workshops, a Kechuan Indian from Peru, made this point to the Commission. For many local communities, he explained, the concept of wealth is completely different to that found in the western world. For such communities, the imperative is to be able to ensure that their traditional knowledge and the customary laws governing it are preserved and respected, rather than to obtain monetary compensation. He also noted that there was already probably an unrealistic expectation among traditional knowledge holders of the possible economic value of their knowledge. Such expectations are of course raised as a result of high profile cases such as the Hoodia example (Box 4.2).

## Misappropriation of Traditional Knowledge

The nature of traditional knowledge is such that more of it is transmitted orally than written down. This poses particular problems when parties not authorised by the holder of that knowledge seek to obtain IPRs over it. In the absence of any accessible written record, a patent examiner in another country is unable to access documentation that would challenge the novelty or inventiveness of an application based on traditional knowledge. The only option for an aggrieved party, be it the holders of the knowledge, or someone representing them, is to challenge the patent during the granting process or after grant, where national laws permit. For instance, this is what the Indian Government achieved by overturning the patents on basmati (see Box 4.5 below) and turmeric in the US.

The presence of administrative or quasi-judicial patent opposition or re-examination procedures has facilitated the overturning of these patents. In the absence of such procedures it would have been necessary to instigate proceedings before the relevant court with the inherent cost and time implications. Even with such procedures, it is extremely difficult and costly for developing countries to monitor and challenge IPRs issued all around the world. We suggest later in this chapter a possible way of assisting countries to monitor patents granted on inventions consisting of, or developed from, acquired biological material and associated knowledge.

### Box 4.3 Traditional Knowledge Digital Library (TKDL) – An Indian View

In 1999, following the ultimately successful, but expensive, Indian challenge of the turmeric and basmati patents granted by USPTO, it was agreed that the Indian National Institute of Science Communication (NISCOM) and the Department of Indian System of Medicine and Homoeopathy (ISM&H) would collaborate to establish a Traditional Knowledge Digital Library (TKDL).

The TKDL project is initially targeting Ayurveda (a traditional Indian system of medicine), and proposes to document the knowledge available in public domain (the existing Ayurveda literature) in digitised format. Information from about 35,000 Slokas (Versus & Prose) and formulations will be inputted on a database, and it is expected that the web site will have approximately 140,000 Ayurveda pages. The data will be made available in several international languages (English, Spanish, German, French, Japanese and Hindi).

The Traditional Knowledge Resource Classification (TKRC) is an innovative, structured classification system that has been designed to facilitate the systematic arrangement, dissemination and retrieval of the information in the traditional knowledge DL. The TKRC is based on the International Patent Classification system (IPC), with the information classified under section, class, subclass, group and subgroup for the convenience of its use by the international patent examiners. But it provides greater definition of traditional knowledge information by expanding one IPC group (i.e. AK61K35/78 related to medicinal plants) into about 5000 subgroups.

The TKDL will give legitimacy to existing traditional knowledge, and by ensuring ease of retrieval of traditional knowledge-related information by patent examiners will hopefully prevent the granting of patents, such as the turmeric and neem cases discussed above which claim subject matter already in the public domain.

Work on such libraries is also being pursued in WIPO where a specialized Task Force including representatives from China, India, the USPTO, and the EPO are examining how such libraries can be integrated into the existing search tools used by patent offices.

Patent applications claiming traditional knowledge already in the public domain should not be granted. The problem is that the knowledge tends not to be documented, or if it is, it is unlikely to be easily accessible to a patent examiner. In particular, information on traditional knowledge is not likely to be found in the type of patent-based information that patent offices rely most on when assessing novelty and inventiveness. To address this problem, WIPO and a number of developing countries led by India and China are seeking to develop traditional knowledge digital libraries (see Box 4.3). These digital libraries will not only detail in writing considerable amounts of traditional knowledge already in the public domain, but will do so taking into account international classification standards (the WIPO International Patent Classification (IPC) system) so that the data will be easily accessible to patent examiners.

WIPO is also examining the extent to which information on traditional knowledge is already available on the Internet. Initial findings from WIPO indicate that the amount of traditional knowledge-related information available is substantial and growing. However, much of it is not in a form that would make it either searchable or useable by patent examiners.<sup>22</sup>

The greater documentation of traditional knowledge may not only be of value in preventing the granting of unwarranted patents but also, more importantly, it may contribute to the preservation, promotion and possible exploitation of traditional knowledge. In this respect it is crucial that the documentation process does not prejudice possible IPRs in the material being documented. India's National Innovation Foundation provides an example of an attempt to address these issues.<sup>23</sup> One of the concerns raised by both WIPO, and a number of developing countries, about many of the databases unearthed by WIPO was whether the information had been recorded with the prior informed consent of the holders of the knowledge. During discussions in WIPO on the documentation of traditional knowledge, differences were also evident among developing countries as to the type of data that could or should be included in any databases. Some countries, for example, argued that such databases are appropriate only for information that was already publicly available in a codified form. Others indicated that traditional knowledge that had not yet been codified could also be included.

**Digital libraries of traditional knowledge should, as soon as it is practical, be incorporated into the minimum search documentation lists of patent offices therefore ensuring that the data contained within them will be considered during the processing of patent applications. Holders of the traditional knowledge should play a crucial role in deciding whether such knowledge is included in any databases and should also benefit from any commercial exploitation of the information.**

Traditional medicine is an area that has the potential to be quite well documented. In Lao People's Democratic Republic, for example, the Government established the Traditional Medicines Resource Centre (TRMC) which is working with local healers to document details of all traditional medicines with a view to promoting a sharing of practices within Laos. The TRMC is also collaborating with the International Co-operative Biodiversity Group (ICBG) in efforts to discover prospective medicinal products. Any benefits, profits or royalties realised from plants and knowledge recovered during the collaboration will be shared with all the communities involved.<sup>25</sup>

IPRs clearly may have a role in exploiting products based on traditional medicine. But the primary objective must be to promote the application of this knowledge to improve human health, rather than to generate income. Indeed it would be unfortunate if the objective of benefit sharing based on commercialisation resulted only in a few people getting richer at the price of restricting access to medicines needed particularly by the poor. The WHO Traditional Medicine Strategy for 2002-2005 clearly bring out the public health objective.<sup>26</sup> Lessons learnt from this exercise and other similar initiatives should be freely shared and technical assistance provided to assist other countries managing initiatives relating to documentation.

It must however be recognised that much traditional knowledge will continue to be undocumented. The concept of absolute novelty whereby any disclosure including **through use**, anywhere in the world, is sufficient to destroy the novelty of an invention therefore remains a necessary safeguard. Without this safeguard, patents could continue to be granted for traditional knowledge that is already in the public domain, albeit not through written disclosure. Some countries do not include use outside their country as “prior art.”

**Those countries that only include domestic use in their definition of prior art, should give equal treatment to users of knowledge in other countries. In addition, account should be taken of the unwritten nature of much traditional knowledge in any attempts to develop further the patent system internationally.**

For some communities the granting of IPRs such as patents over their knowledge can cause great offence. Although provisions exist in most countries to prevent the granting of IPRs on moral grounds, it is questionable whether intellectual property offices will be able to apply them in respect of small indigenous communities. For example, moral grounds for rejecting trademark applications have existed for some time in New Zealand but it has now been considered necessary to define more clearly the scope of this provision. The amendment under consideration would prevent the registration of a trademark where, on reasonable grounds, the use or registration of the mark is likely to offend a significant section of the community, including the Maori.<sup>27</sup> Such measures as this, together with the greater use of searchable databases of traditional knowledge already in the public domain should go some way to preventing the issuing of IP rights on material that is not novel, obvious or likely to cause offence.

However, as we have noted, there is a second group of patents and indeed other IPRs that cause concern. These are rights which essentially meet the usual criteria for patentability or protection but which nevertheless:

- are based on, or consist of, material obtained illegally or without the consent of the holder of the material
- do not fully recognise the contribution made by others to the invention either in terms of ownership of the rights, or in the sharing of any benefits accruing from the commercialisation of the patented invention.

These concerns do not apply just to patents relating to traditional knowledge although, in light of the CBD, the most contentious patents in this area are likely to be those relating to biological resources and/or traditional knowledge associated with such resources. In the Hoodia case, the concern was essentially not about whether the patents should have been granted, but about whether the San would receive a fair share of the benefits of commercialisation. We address possible ways of providing a more equitable balance in such cases below.

## ACCESS AND BENEFIT SHARING

### Background

As we have seen, one of the main issues in the debate on traditional knowledge is the relationship between intellectual property protection and the ownership and rights pertaining to the knowledge on which the intellectual property right has been based. The context of our discussion of this issue is to consider also how to promote the objectives related to benefit sharing and prior informed consent set out in the CBD. Since the international community, albeit with some important exceptions, has ratified both TRIPS and the CBD there is an obligation to ensure that they reinforce, rather than contradict one another

## Convention on Biological Diversity (CBD)

The Convention, which was agreed in 1992, seeks to promote the conservation of biodiversity and the equitable sharing of benefits arising out of the utilisation of genetic resources.<sup>28</sup> It asserts the sovereign rights of nations over their national resources, and their right to determine access according to national legislation with the aim of facilitating the sustainable use of these resources, promoting access and their common use. It notes that access to genetic resources should be on the basis of prior informed consent, and on mutually agreed terms that provide fair and equitable sharing of the results of R&D and the benefits of commercialisation and utilisation.<sup>29</sup> It also calls for the fair and equitable sharing of the benefits derived from the use of traditional knowledge.<sup>30</sup>

In respect of intellectual property, the CBD states that access and transfer (of genetic resources) should be consistent with the “adequate and effective protection of intellectual property rights.” Governments should put in place policies to ensure that, particularly for developing countries, access to genetic resources takes place on mutually agreed terms. It notes that patents and other IPRs may have an influence on implementation of the Convention, and governments should co-operate (subject to national and international law) in order to ensure that such rights are supportive of and do not run counter to the CBD’s objectives.<sup>31</sup>

The Governing Body of the CBD has now agreed guidelines on access and benefit sharing as a guide to countries when drafting national legislation.<sup>32</sup> But countries face difficult decisions, both practical and conceptual, in putting benefit sharing into practice. First, the resources in question are often not “owned” by anyone in particular, but are the heritage of one or more communities, which are not necessarily cohesive, or all living in one country. Secondly, while some genetic resources can be traced to very specific areas and habitats, in other cases they comprise components from many countries, in which case benefit-sharing arrangements will be totally impractical. Thirdly, because of the diversity of national circumstances or indeed those within nations in relation, for example, to their cultural, economic or institutional conditions, it is very difficult to devise legislation and practices which cover that diversity in ways that facilitate implementation of such measures. Indeed, care will be necessary to ensure that legislation and practices that seek to give effect to the CBD do not in fact unnecessarily restrict or discourage the legitimate use of genetic resources, whether with a view to commercialisation or in terms of scientific research. There is some evidence that the tightening of restrictions in some countries has hindered the access of biologists studying genetic resources.<sup>33</sup>

While recognising these difficulties, our focus is on how intellectual property rules might need to be modified in both developed and developing countries, to provide support for access and benefit sharing. Many argue that since TRIPS says nothing about the CBD, nor the CBD about TRIPS, there can be no conflict between the two agreements. Moreover it is argued, TRIPS supports the CBD in that patenting often engenders commercialisation which generates the benefits that are a prerequisite to any benefit sharing arrangement. Others have countered this argument by pointing out that since patenting based on the use of genetic resources is allowed under TRIPS, (subject to meeting patentability criteria), this does not support the objectives of the CBD because the criteria for patentability do not include prior informed consent or mutually agreed terms for benefit sharing. While the CBD asserts national sovereignty over genetic resources, there is nothing in TRIPS to provide support to these CBD objectives. Foreign companies may obtain private rights derived from national resources, but TRIPS is silent on obligations set out by the CBD.

Nevertheless even those, mainly from industry, who argue there is no conflict between the CBD and TRIPS, broadly support the underlying principles of the CBD. In particular, since the CBD asserts the principle that nations have sovereignty over their natural resources, those industries that are interested in making use of genetic resources need to ensure that prospecting activities take place on the basis of prior informed consent, and agreements on benefit sharing. If they ignore these principles, then any access to these resources may not be legitimate.

Given the understandable difficulties faced by developing countries in formulating and enforcing laws on access and benefit sharing, we take the view that developed and developing countries should do more to ensure their IP systems help to promote the objectives of the CBD, and to promote the underlying mutuality of interest that should exist between the providers of genetic resources, mainly in developing countries, and the users who are mainly based in developed countries.

## Disclosing the Geographical Origin of Genetic Resources in Patent Applications

One suggestion is that applicants for IP rights which consist of, or are developed from, genetic resources should identify the source of these resources and provide proof that they were acquired with the prior informed consent of the country from which they were taken. Examples of countries who have introduced such requirements into their law are given in Box 4.4.

The territorial nature of patents means that the requirements referred to above apply only in respect of patents issued in those particular countries or regions. For example, they do not have any bearing on patents issued in the US or Japan. This, it is argued, justifies a more international solution to this issue.

A requirement in all patent laws for the patent applicant to disclose the source of origin of the genetic resources and evidence of prior informed consent would, it is argued, increase transparency and, simply by providing information, assist in the enforcement of any access and benefit sharing agreements. It might also bring to light cases similar to the Hoodia example.

Opponents argue that seeking to counter illegal access or unauthorised use through patent law does not address instances where patenting is not involved. Moreover, introducing such a requirement only in respect of genetic resources and associated knowledge, would discriminate against other cases where patents may have been obtained as the result of illegal or unauthorised activities. It is also argued that this would lead to more legal uncertainty and create “serious difficulties in practice” since it is “often not clear where a biological sample originated.”<sup>34</sup> Even if the immediate source of material is known, this may not be the original source, especially where material is obtained, as is very common, from *ex situ* collections that have been built up over many years.

It is difficult to judge how real any such uncertainty would be. Where a company is interested in a particular genetic resource it seems likely that it would endeavour to discover as much information about that material as possible because of its relevance to its possible utility (for example, how local populations use it). In such cases it is likely that the geographical origin of the resource will be known. In other cases it may be more difficult to establish the precise geographical origin of an individual sample. Nevertheless it seems unlikely, especially for samples obtained after 1992, that some information on the geographical source of a particular sample is not available. Under the terms of the CBD any benefits are to be shared with the country providing the resource irrespective of whether the resource actually originated in that country.<sup>35</sup> The ITPGRFA, as we have seen, provides a different mechanism for plant genetic resources of diverse origin.

One of the stated objectives for requiring disclosure of source of origin and prior informed consent is to encourage compliance with the access and benefit sharing principles of the CBD. However, other mechanisms and incentives exist which may address this objective. Failure to obtain authorisation to access or use material may, for example, lead to court action under the doctrine of misappropriation or breach of contract. But seeking recompense in this way is time-consuming and costly, and of limited use for many holders of traditional knowledge. In addition, the stigma of being identified as a “bio-pirate” may also be an incentive for organisations to ensure the probity of their activities. Known violators of the CBD may be denied future access to material. Such a sanction has already been considered in Bangladesh.<sup>36</sup> Suppliers of material may collectively agree

to supply only to organisations prepared to disclose in any patent applications that they might file full details of any access contracts. It is possible that these incentives alone may be sufficient. Companies and organisations that use or supply biological material or traditional knowledge have already adopted or are considering adopting codes of conduct covering CBD-related activities.<sup>37</sup>

Nevertheless, we believe that it is important to recognise the force of the CBD, even if only a few countries have implemented specific access and benefit sharing legislation. We conclude therefore that where a country has established a clear legal framework governing access to biological material and/or traditional knowledge then that country should be able to take action where IPRs are granted over material or knowledge which was acquired illegally from that country.

#### Box 4.4 Examples of Patent Legislation incorporating Disclosure of Origin

**India:** Section 10 (contents of specification) of the Patents Act 1970 as amended by the Patents Second Amendment Act (2002) provides that the applicant must disclose the source and geographical origin of any biological material deposited in lieu of a description. Also Section 25 (opposition to grant of patent) as amended allows for opposition to be filed on the ground that “the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention”.

**Andean Communities:** Andean Decision 486 provides in Article 26 that applications for patents shall be filed with the competent national office and shall contain:

- h) a copy of the contract for access, if the products or processes for which a patent application is being filed were obtained or developed from genetic resources or by products originating in one of the Member Countries;
- i) if applicable, a copy of the document that certifies the license or authorization to use the traditional knowledge of indigenous, African American, or local communities in the Member Countries where the products or processes whose protection is being requested were obtained or developed on the basis of the knowledge originating in any one of the Member Countries, pursuant to the provisions of Decision 391 and its effective amendments and regulations;

**Costa Rica:** Biodiversity Law 7788 Article 80 (Obliged prior consultation) states that “Both the National Seed Office and the Registers of Intellectual and Industrial Property are obliged to consult with the Technical Office of the Commission (for the Management of Biodiversity) before granting protection of intellectual or industrial property to innovations involving components of biodiversity. They must always provide the certificate of origin issued by the Technical Office of the Commission and the prior informed consent. Justified opposition from the Technical Office will prohibit registration of a patent or protection of the innovation.”

**Failure to provide the necessary information in any of the cases referred to above could lead to the failure of the application or revocation of the patent.**

**Europe:** Recital 27 of Directive 98/44 on the legal protection of biotechnological inventions provides that the patent application should where appropriate, include information on the geographical origin of biological material if known. But this is entirely voluntary, as it is without prejudice to the processing of patent applications or the validity of rights arising from granted patents.

Indeed we would go further in supporting the objectives of the CBD by arguing that no person should be able to benefit from any IP rights consisting of, or based on, genetic resources or associated knowledge obtained in an illegal manner, or used in an unauthorised way. Those organisations currently considering this issue should examine what measures may be possible within the existing international framework to meet this objective. As well as the possibility of refusing applications or invalidating rights, we would suggest that consideration also be given to declaring such IPRs unenforceable.<sup>38</sup> Such a sanction is already available in the US under the doctrines of “unclean hands” and inequitable conduct, whereby a court will refuse to enforce a patent until the patentee has cleaned his hands or remedied any inequitable conduct or fraud. In interpreting these doctrines the courts have indicated the paramount interest is to ensure that patents issue from “backgrounds free from fraud or other inequitable conduct”.<sup>39</sup> The US Supreme Court has noted also that

“A court of equity acts only when and as conscience commands; and if the conduct of the plaintiff be offensive to the dictates of natural justice, then, whatever may be the rights he possesses, and whatever use he may make of them in a court of law, he will be held remediless in a court of equity”.<sup>40</sup>

**The principle of equity dictates that a person should not be able to benefit from an IP right based on genetic resources or associated knowledge acquired in contravention of any legislation governing access to that material. In such cases the burden should generally lie with the complainant to prove that the IP holder has acted improperly. However, a precursor for any action is knowledge of the wrong. It is to assist in this respect that we believe that a disclosure requirement of the type discussed above is necessary.**

All countries should provide in their legislation for the obligatory disclosure of information in the patent application of the geographical source of genetic resources from which the invention is derived. This requirement should be subject to reasonable exceptions as, for example, where it is genuinely impossible to identify the geographical source of material. Sanctions, possibly of the type discussed above, should be applied only where it can be shown that the patentee has failed to disclose the known source or where he has sought to deliberately mislead about the source. This issue should be considered by the Council for TRIPS, in the context of paragraph 19 of the Doha Ministerial Declaration.

Consideration should also be given to establishing a system whereby patent offices examining patent applications which identify the geographical source of genetic resources or traditional knowledge pass on that information, either to the country concerned, or to WIPO which may act as a depository for patent-related information on alleged “biopiracy.” Through these measures it will be possible to monitor more closely the use and misuse of genetic resources

## GEOGRAPHICAL INDICATIONS

### Background

At the beginning of this chapter we consider the relevance of geographical indications for protecting traditional knowledge. However, geographical indications have a much wider application and for some countries constitute one of the most important categories of intellectual property. This is reflected in the TRIPS Agreement.

### Geographical Indications and TRIPS

The negotiations on the geographical indication section of the TRIPS Agreement were among the most difficult.<sup>41</sup> This stemmed from clear divisions between the main proponents of the TRIPS Agreement – the US and EU. In addition, as has been borne out in the subsequent discussions in the

TRIPS Council, divisions also exist among other developed countries and among developing countries. The final text of the agreement reflects these divisions and, in mandating further work, recognises that agreement could not be reached in a number of important areas.

The outcome was that the current text of TRIPS provides a basic standard of protection, and a higher standard specifically for wines and spirits. The inclusion of this higher standard does not refer to the unique characteristics of wines and spirits, but was rather a compromise reached in negotiations. This imbalance in protection has led to demands for additional protection from a number of countries including India, Pakistan, Kenya, Mauritius and Sri Lanka.<sup>42</sup> Other countries, such as Argentina, Chile, and Guatemala argue that extending the additional protection to other products would impose extra financial and administrative burdens on all WTO Members and that these would outweigh any trade benefit. They believe that such burdens would fall most heavily on developing countries.

In the absence of a reliable economic assessment, it is difficult to evaluate the merits of both sets of arguments. They also, of course, reflect differences in perceived economic interest between both developed and developing countries. A few countries, for example Egypt and Paraguay, have already indicated that the additional protection for geographical indications for wines and spirits will be made available under their national laws for other products.<sup>43</sup> It will be interesting to see whether providing such comprehensive additional protection leads to significant additional costs or benefits, in the absence of international recognition.

## Multilateral Register of Geographical Indications

As well as providing increased protection for geographical indications on wines and spirits, TRIPS also requires negotiations to be undertaken in the TRIPS Council concerning the establishment of a multilateral register of geographical indications for wines. The Doha Ministerial Conference extended this mandate to negotiate the establishment of a system that includes spirits. The purpose of the register has not been clearly defined. As noted below, groups of countries differ in their views. Some wish to use it as a full international register that would oblige all member countries to provide protection to geographical indications meeting the requirements for registration. Others want it as a voluntary system of registration and source of information.

To date, three different proposals for a multilateral register have been presented. The EU envisages a register that has an effect on all WTO Members irrespective of whether or not they have any geographical indications included on the register.<sup>44</sup> Any WTO Member wishing to challenge the inclusion of a geographical indication in the register is required to notify the country concerned and enter into negotiations with a view to resolving the disagreement. The Hungarian proposal provides that where one WTO Member has successfully challenged the inclusion of a geographical indication on certain specified grounds, then that geographical indication will not need to be protected by other WTO Members.<sup>45</sup> In both of these proposals, inclusion of a geographical indication in the register would constitute a presumption of eligibility for protection under any legal means provided for protecting geographical indications in any WTO Member.

By contrast, the joint proposal from the US, Canada, Chile and Japan provides a system of registration that is binding only on those seeking to participate in the system.<sup>46</sup> Participating members would make use of the register when, for example, examining trademark applications containing or consisting of a geographical indication. Non-participating WTO Members would be encouraged to make similar use of the register. Negotiations on the register are, according to the recent Doha WTO Ministerial Conference, to be completed by the next Conference in Mexico in 2003.

The TRIPS Council Secretariat has already begun to shed some light on how a number of WTO Members, including some developing countries, have met their obligations under TRIPS.<sup>47</sup> The vast majority of countries from which information has been obtained provide specific legislation

covering geographical indications although it is unclear whether this legislation stems directly from the TRIPS Agreement or was already in place to meet, for example, bilateral commitments.

The administrative burden in giving effect to new legislation for those countries without current protection would not appear that great. This is because TRIPS does not currently require any formal national registration system for geographical indications, and the burden and costs of compelling enforcement therefore falls on the holders of the geographical indication, not the government. As mentioned below, however, the costs of ensuring compliance with quality standards and promoting and enforcing geographical indications abroad may be significant.

### **Box 4.5 Geographical Indications: The Basmati Case**

Basmati is a variety of rice from the Punjab provinces of India and Pakistan. The rice is a slender, aromatic long grain variety that originated in this region and is a major export crop for both countries. Annual basmati exports are worth about \$300m, and represent the livelihood of thousands of farmers.

The “Battle for Basmati” started in 1997 when US Rice breeding firm RiceTec Inc. was awarded a patent (US5663484) relating to plants and seeds, seeking a monopoly over various rice lines including some having characteristics similar to Basmati lines. Concerned about the potential effect on exports, India requested a re-examination of this patent in 2000. The patentee in response to this request withdrew a number of claims including those covering basmati type lines. Further claims were also withdrawn following concerns raised by the USPTO. The dispute has however moved on from the patent to the misuse of the name “Basmati.”

In some countries the term “Basmati” can be applied only to the long grain aromatic rice grown in India and Pakistan. RiceTec also applied for registration of the trademark ‘Texmati’ in the UK claiming that “Basmati” was a generic term. It was successfully opposed, and the UK has established a code of practice for marketing rice. Saudi Arabia (the world’s largest importer of Basmati rice) has similar regulations on the labelling of Basmati rice.

The code states that “the belief in consumer, trade and scientific circles [is] that the distinctiveness of authentic Basmati rice can only be obtained from the northern regions of India and Pakistan due to the unique and complex combination of environment, soil, climate, agricultural practices and the genetics of the Basmati varieties.”

But in 1998 the US Rice Federation submitted that the term “Basmati” is generic and refers to a type of aromatic rice. In response, a collective of US and Indian civil society organizations filed a petition seeking to prevent US-grown rice from being advertised with the word “Basmati”. The US Department of Agriculture and the US Federal Trade Commission rejected it in May 2001. Neither considered the labeling of rice as “American-grown Basmati” misleading, and deemed “Basmati” a generic term.

The problem is not just limited to the US; Australia, Egypt, Thailand and France also grow basmati type rice and may take the lead from the US and officially deem “basmati” a generic term.

The name “Basmati” (and the Indian and Pakistani export markets) can be protected by registering it as a Geographical Indication. However, India and Pakistan will have to explain why they did not take action against the gradual adoption of generic status of basmati over the last 20 years. For example, India did not lodge a formal protest when the US Federal Trade Commission formally declared “basmati” generic.

## The Economic Impact of Geographical Indications

In considering positions to take on the discussions on both the multilateral register and the possible extension of the scope of protection, it is important that developing countries consider carefully the potential costs and benefits. Indeed as we have suggested elsewhere, we believe that comprehensive economic impact assessments need to be undertaken before any new IP-related obligations are introduced for developing countries.

The economic consequences for a developing country are difficult to assess. The main economic benefit of geographical indications would be to act as a quality mark which will play a part in enhancing export markets and revenues. But increased protection, particularly applied internationally, may adversely affect local enterprises which currently exploit geographical indications that may become protected by another party. Thus there will be losses to countries producing substitutes for goods that become protected by geographical indications. A proliferation of geographical indications would tend to reduce their individual value.

It has also been suggested that geographical indications may be of particular interest to a number of developing countries who might have, or might be able to achieve, a comparative advantage in agricultural products and processed foods and beverages.<sup>48</sup> For these countries, seeking and enforcing protection for geographical indications abroad may have economic gains. However the costs involved in such actions, especially enforcement, might be prohibitively high. In addition, prior to seeking protection abroad, it is necessary both to develop and protect the geographical indication in the country of origin. Resources may need to be deployed to ensure that the required quality, reputation or other characteristics of the product covered by the geographical indication are developed and maintained. Effort will also be needed to ensure that the geographical indication does not become an accepted generic term, freely useable by all (see Box 4.5).

In our view it is far from clear whether these countries will be able to gain significantly from the application of geographical indications. By way of example, the Lisbon Agreement, which is an international system of protection administered by WIPO for the protection of appellations of origin, was agreed in 1958.<sup>49</sup> To date only 20 countries (seven of which are developed) have acceded to the agreement, and as of 1998, 766 appellations of origin are protected under the agreement, of which European countries hold 95%.

Even taking into account the well documented weaknesses in the Lisbon Agreement, such as the lack of an appropriate exception for geographical indications that had become generic, that make it unattractive to both developed and developing countries alike, the level of interest, even for those developing countries who deemed it worthwhile to join, seems very limited.<sup>50</sup>

Within the framework of the discussions in the WTO on a multilateral register, it has been proposed that more consideration should be given, inter alia, to the likely cost of introducing the type of register proposed by the EU.<sup>51</sup> A similar call for this type of analysis was made by a number of developing countries during recent discussions in WIPO.<sup>52</sup> However the necessary support to take it forward was not forthcoming from some of the same countries now pressing for such work in the WTO. We, like others, believe only with this type of analysis will developing countries, particularly low income ones, be able to take informed positions on the continuing debates on geographical indications, especially within the WTO.<sup>53</sup>

**Further research should be undertaken, as a matter of urgency, by a competent body, possibly UNCTAD, to assess in respect of developing countries:**

- the actual or likely costs of implementing existing geographical indications provisions under TRIPS
- what role geographical indications could play in the development of these countries

- the likely costs and benefits of extending the current additional protection for wines and spirits to other products
- the costs and benefits of the various proposals put forward for establishing a multilateral register of geographical indications.

<sup>1</sup> For the remainder of this chapter, references to “traditional knowledge” should be assumed to cover folklore also, unless indicated otherwise.

<sup>2</sup> WHO Fact Sheet No. 271, June 2002.

Source: <http://www.who.int/medicines/organization/trm/factsheet271.doc>

<sup>3</sup> Article 8j of CDB provides that “Members should 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”.

Source: <http://www.biodiv.org/convention/articles.asp>

<sup>4</sup> See Glossary for definition.

<sup>5</sup> See Glossary for definition.

<sup>6</sup> For more information of the various ongoing debates, see for example “*The State of the Debate on TK*”, Background note prepared by the UNCTAD secretariat for the International Seminar on Systems for the Protection and Commercialisation of traditional knowledge, in particular traditional medicines, 3-5 April 2002, New Delhi.

Source: [http://www.unctad.org/trade\\_env/test1/meetings/delhi/statedebateTK.doc](http://www.unctad.org/trade_env/test1/meetings/delhi/statedebateTK.doc)

<sup>7</sup> Paragraph 19 of Doha WTO Ministerial Declaration (WTO Document No. WT/MIN(01)/DEC/1) adopted on 14 November 2001, calls for the TRIPS Council to examine the issue of protection of traditional knowledge and folklore.

Source: [http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_e.doc](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.doc)

<sup>8</sup> WIPO (1999) “*Intellectual Property Needs and Expectations of traditional knowledge Holders*”, WIPO Report on Fact-Finding Missions 1998-1999, WIPO, Geneva (Publication Number 768E).

Source: <http://www.wipo.int/globalissues/tk/report/final/index.html>

<sup>9</sup> Correa, C. (2001) “*Traditional Knowledge and Intellectual Property*”, QUNO, Geneva.

Source: <http://hostings.diplomacy.edu/quaker/new/doc/tkcol3.pdf>

<sup>10</sup> Minutes of the Commission on Intellectual Property Rights Workshop on Traditional Knowledge, 24 January 2002.

Source: <http://www.iprcommission.org>

<sup>11</sup> Source: <http://www.niaaa.com.au/label.html>

<sup>12</sup> WIPO Reviews of Existing Intellectual Property Protection of TK (WIPO Document No. WIPO/GRTKF/IC/3/7) 25 March 2002.

Source: [http://www.wipo.org/eng/meetings/2002/igc/doc/grtkfic3\\_7.doc](http://www.wipo.org/eng/meetings/2002/igc/doc/grtkfic3_7.doc) and Folklore (WIPO Document No. WIPO/GRTKF/IC/3/10) 25 March 2002.

Source: [http://www.wipo.org/eng/meetings/2002/igc/doc/grtkfic3\\_10.doc](http://www.wipo.org/eng/meetings/2002/igc/doc/grtkfic3_10.doc).

<sup>13</sup> McDonald, S. (2001) “*Exploring the hidden costs of Patents - notes of a talk given at Quakers House Geneva 16 May 2001*”, QUNO Occasional Paper 4, QUNO, Geneva. Source:

<http://hostings.diplomacy.edu/quaker/new/doc/OP4.pdf>

<sup>14</sup> Sui generis system of protection is a distinct system tailored or modified to accommodate the special characteristics of traditional knowledge or folklore. Sui generis systems of protection are already provided in areas such as the protection of plant varieties (UPOV system) and protection of databases (EC Directive 96/9/EC, 11 March 1996).

Source: [http://www.eurogeographics.org/WorkGroups/WG1/eu\\_directive.pdf](http://www.eurogeographics.org/WorkGroups/WG1/eu_directive.pdf).

<sup>15</sup> The Indigenous Peoples Rights Act of 1997, Republican Act No. 8371.

Source: <http://www.grain.org/docs/philippines-ipra-1999-en.pdf>, and The Community Intellectual Rights Protection Act 1994 Senate Bill No. 1841 (still pending).

Source: <http://www.grain.org/docs/philippines-cirpa-1994-en.pdf>

<sup>16</sup> Cultural Heritage Protection National Law (No. 26-97, as amended in 1998) as explained in WIPO Document No. WIPO/GRtraditional knowledge F/IC/3/7.

Source: [http://www.wipo.org/eng/meetings/2002/igc/doc/grtkfic3\\_7.doc](http://www.wipo.org/eng/meetings/2002/igc/doc/grtkfic3_7.doc)

<sup>17</sup> “*African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources*”, OAU Model Law, 2000. Source:

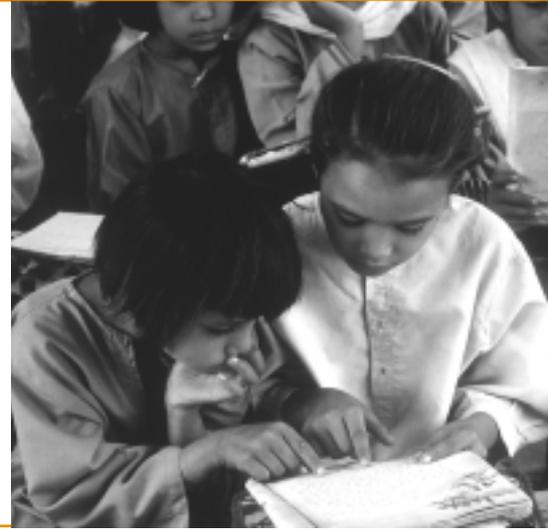
<http://www.grain.org/publications/oau-model-law-en.cfm>

- <sup>18</sup> Milpurrru and others v. Indofurn Pty Ltd and others (1995) 30 IPR 209
- <sup>19</sup> Minutes of the Commission on Intellectual Property Rights Workshop on Traditional Knowledge, 24 January 2002.  
Source: <http://www.iprcommission.org>
- <sup>20</sup> Sixth Meeting of the Conference of the Parties to the Convention on Biological Diversity, The Hague, Netherlands, 7-19 April 2002. Decision VI/24 C 3(b) requests further consideration of the role of customary laws and practices in relation to the protection of genetic resources and traditional knowledge, innovations and practices, and their relationship with IPRs.  
Source: <http://www.biodiv.org/decisions/default.asp?lg=0&m=cop-06&d=24>
- <sup>21</sup> Joint Declaration G-15 Experts Meeting on Science and Technology, "Sustainable Use of Biodiversity, traditional knowledge and Protection Systems", 3-5 April 2002, Caracas.  
Source: <http://www.mct.gov.ve/g15/declaracionbioingles.htm>
- <sup>22</sup> Inventory of existing online databases containing traditional knowledge documentation data (WIPO Document No. WIPO/GRtraditional knowledge F/IC/3/6 - May 10, 2002).  
Source: [http://www.wipo.org/eng/meetings/2002/igc/doc/grtkfic3\\_6.doc](http://www.wipo.org/eng/meetings/2002/igc/doc/grtkfic3_6.doc)
- <sup>23</sup> As an example the National Innovation Foundation in India seeks to obtain the PIC of local innovators and traditional knowledge holders before disseminating their innovations or knowledge to third parties. Modalities for benefit sharing are also agreed.  
Source: <http://www.nifindia.org/benefit.htm>
- <sup>24</sup> WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Third Session, June 2002, Geneva.  
Source: [http://www.wipo.int/eng/meetings/2002/igc/index\\_3.htm](http://www.wipo.int/eng/meetings/2002/igc/index_3.htm)
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Source: <http://www.cs.org/publications/CSQ/244/riley.htm>
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Source: [http://www.who.int/medicines/library/trm/trm\\_strat\\_eng.pdf](http://www.who.int/medicines/library/trm/trm_strat_eng.pdf)
- <sup>27</sup> For discussion on the Trademark Bill see:  
<http://www.ruddwatts.com/newsroom/publications/ip/newtrademarksbill2001.asp>
- <sup>28</sup> CBD Article 1
- <sup>29</sup> CBD Article 15
- <sup>30</sup> See note 3 above.
- <sup>31</sup> CBD Article 16
- <sup>32</sup> Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilisation.  
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- <sup>35</sup> CBD Article 2
- <sup>36</sup> Article 13(3) Biodiversity and Community Knowledge Protection Act of Bangladesh, draft text proposed by the National Committee on Plant Genetic Resources, 29 September 1998.  
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Source: <http://docsonline.wto.org/DDFDocuments/t/IP/C/W308R1.doc>
- <sup>43</sup> WTO Document No. IP/C/W/278/Add.1  
Source: <http://docsonline.wto.org/DDFDocuments/t/ip/c/w278a1.doc> and IP/C/W/231  
Source: <http://docsonline.wto.org/DDFDocuments/t/ip/c/w231.doc>
- <sup>44</sup> WTO Document No. IP/C/W/107/Rev.1.  
Source: <http://docsonline.wto.org/DDFDocuments/t/ip/c/w107R1.doc>
- <sup>45</sup> WTO Document No. IP/C/W/255.  
Source: <http://docsonline.wto.org/DDFDocuments/t/ip/c/w255.doc>
- <sup>46</sup> WTO Document No. IP/C/W/133/Rev.1.  
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## COPYRIGHT, SOFTWARE AND THE INTERNET



### INTRODUCTION

Any serious enquiry into the subject of IP and development has to consider the crucially important role of copyright and the copyright-based industries (including publishing, film, television, radio, music and now computer software too) in the production and dissemination of knowledge and knowledge-based products. These industries supply the intellectual “raw material” for science and innovation, as well as for education and instruction in general, and they have helped bring about dramatic increases in productivity through aiding the creation of information-based products like desk-top publishing software, electronic mail or sophisticated scientific computer databases. Moreover, the copyright-based industries have developed into a huge source of wealth and employment creation in the knowledge-based global economy. In the US, for example, their overall combined value has increased at such a rapid rate in the last twenty or thirty years, that together they currently contribute more than \$460 billion to US gross domestic product and sold almost \$80 billion in exports in 1999.<sup>1</sup>

For developing countries this provides both enormous opportunities and challenges:

“The creation and ownership of knowledge products are of increasing importance because of the centrality of information and knowledge to post-industrial economies. The concept of copyright, originally intended to protect authors and publishers of books, has broadened to include other knowledge products such as computer programs and films... Copyright has emerged as one of the most important means of regulating the international flow of ideas and knowledge-based products, and will be a central instrument for the knowledge industries of the twenty-first century. Those who control copyright have a significant advantage in the emerging, knowledge-based global economy. The fact is that copyright ownership is largely in the hands of the major industrialized nations and of the major multimedia corporations placing low per capita income countries as well as smaller economies at a significant disadvantage.”<sup>2</sup>

The legal protection of copyright dates back to the 1700s with the Statute of Anne, and at the end of the 19th century it was enshrined in the Berne Convention. Although the language of the Convention suggests a paradigm for the protection of the rights of authors and artists, in many cases copyright belongs not to individuals but to the firms that employ them. Indeed, copyright is an essential element in the business model of publishers, television and record companies, and software producers because they grant their owners exclusive rights, *inter alia*, over the reproduction and distribution of protected works. The new information and communication technologies (ICTs), and in particular the Internet enable unauthorised creation of unlimited, perfect and costless copies of protected works, as well as their almost instantaneous and worldwide distribution. This poses an unprecedented challenge to copyright law. Some believe the future will see copyright become of far less importance as industries switch to technology-based protection, in the form of encryption and anti-circumvention measures, supplemented by contract law and *sui generis* forms of IP protection for databases.

We believe that copyright-related issues have become increasingly relevant and important for developing countries as they enter the information age and struggle to participate in the knowledge-based global economy. Of course, some developing countries have long standing concerns that copyright protection for books and learning materials, for example, may make it harder for them to achieve their goals in education and research. These were prominently expressed at the 1967 Stockholm Conference of the Berne Convention and remain valid today.

Copyright deserves special attention now not only because millions of poor people still lack access to books and other copyrighted works, but because the last decade has seen rapid advances in information and communication technologies, transforming the production, dissemination and storage of information. This has been accompanied by a strengthening of national and international copyright protection. Indeed, it was largely these technological changes that led the copyright-based industries in the developed countries to lobby for TRIPS and the WIPO Copyright Treaty, as well as the *sui generis* protection system for databases established by the EU in 1996. These trends are likely to have both positive and negative aspects for developing nations and it is important to understand how they impact on such countries, particularly the poor.

The crucial issue for developing countries is getting the right balance between protecting copyright and ensuring adequate access to knowledge and knowledge-based products. It is the cost of access, and the interpretation of “fair use” or “fair dealing” exemptions that are particularly critical for developing countries, made more so by the extension of copyright to software and to digital material. These issues need to be addressed to ensure developing countries have access to important knowledge-based products as they seek to bring education to all, facilitate research, improve competitiveness, protect their cultural expressions and reduce poverty.

In this chapter we consider the following issues:

- How important is copyright as a stimulus to cultural and other industries in developing countries?
- How does copyright affect developing countries as consumers of products from abroad, particularly educational material, including via the Internet?
- What should developing countries do about enforcement of copyright?
- How does copyright on software affect developing countries?

## COPYRIGHT AS A STIMULUS TO CREATION

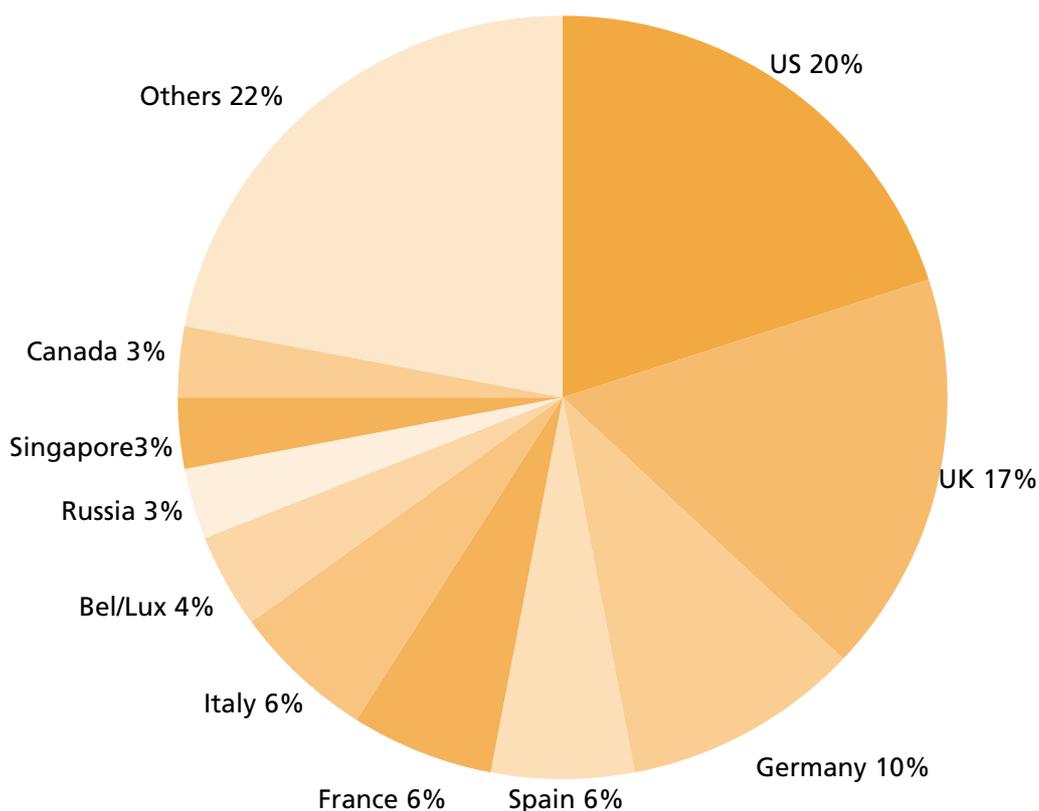
As agencies such as WIPO, UNESCO and the World Bank have pointed out, it is important that developing countries develop mechanisms to protect and benefit from the commercial exploitation of their own past and present creative works. On this view, copyright can play an important role in the development of cultural industries in developing countries by ensuring rewards through

exclusive rights over copying and distribution.<sup>3</sup> In Chapter 4, we discuss the issues relating to protection of traditional knowledge in developing countries and much of that is also relevant here, in so far as such knowledge and creativity may be protectable under copyright.

From a global perspective, the direct rewards from copyright protection are largely directed to the publishing, entertainment and software industries in Europe and North America. As Figure 5.1 below shows, the US, UK, Germany, Spain, France and Italy between them produced nearly two thirds of global exports of books in 1998. But, in some instances, copyright-based industries in developing countries are also flourishing and obtaining a share of these rewards.

Perhaps the most famous case is the Indian software industry. Between 1994-95 and 2001-02, the industry's gross earnings expanded from \$787 million to \$10.2 billion (a large proportion of which were software exports, which grew in value during the period from \$489 million to \$7.8 billion) and by March 2002, the software and services sector employed about 520,000 workers.<sup>4</sup> And certainly there is a wealth of creative talent in developing countries – such as the musicians in Mali and Jamaica or the traditional artists in Nepal – which could be harnessed to generate more wealth for emerging economies. But this will only happen if there is a local infrastructure for cultural industries, for example for publishing and recording. Currently many writers and musicians in developing countries (particularly in Africa) have to rely on foreign publishers or record companies.

**Figure 5.1 The Top Book Exporting Countries by Market Share, 1998**



Source: UNESCO (2000a)

At the same time, whilst there are success stories like India's software industry, there are also developing countries who have provided copyright protection as members of the Berne Convention for decades (such as Benin or Chad which joined in 1971) and have not seen significant increases in their national copyright-based industries or in the level of copyright-protected works being created by their people.

The evidence suggests, therefore, that the availability of copyright protection may be a necessary but not a sufficient condition for the development of viable domestic industries in the publishing, entertainment and software sectors in developing countries. Many other factors are important for the sustained development of such copyright-based industries. Taking the publishing industry in Africa as an example, factors such as the unpredictability of textbook purchasing by governments and donors, weak management skills in local firms, high costs for printing equipment and paper, and poor access to finance are likely to continue to act as very severe constraints in many countries for the foreseeable future.<sup>5</sup>

Moreover, given the small market size of many developing countries, the availability of copyright protection may be most significant from a commercial standpoint in export markets rather than domestically, notwithstanding the fact that authors and companies from developing countries may face insurmountable costs when action to enforce their rights in such markets is required. Of course, in larger developing countries like India, China, Brazil or Egypt, copyright protection in the domestic market is clearly of considerable importance to national publishing, film, and music and software industries. Although, as we have noted, during the 19th century the US sought to aid the development of its domestic publishing industry by not recognising the rights of foreign copyright holders.

## Collecting Societies

In order to realize the potential benefits of copyright, some developing countries have established collective management societies, which represent the rights of artists, authors and performers and collect royalties from licensing copyrighted works held in their inventories. At present, only a minority of developing countries has followed this approach and there are quite different views on the merits of the establishment of collective management societies. WIPO and some donor agencies actively advocate and support them, as do some developing country governments (for example, in the Caribbean). Copyright-based industry groups in developed countries also argue that the establishment of Reprographic Rights Organisations in developing countries would facilitate wider provision of access to protected works through photocopying at rates suited to the local market.

On the other hand, some commentators argue that although such organisations in developing countries may collect royalties for local authors and artists, they are likely to collect far more for foreign rights holders from developed countries who may often dominate the market place for copyrighted works. For example, in South Africa, where the balance is likely to be more favourable than in lower income developing countries, its Dramatic, Artistic and Literary Rights Organisation (DALRO) distributed a total of approximately €74,000 to national rights holders, of which approximately €20,000 were received from foreign collecting societies; whilst over the same period it distributed approximately €137,000 to foreign rights holders.<sup>6</sup> It is also important to recognise that collective management organisations can potentially wield significant market power and may act in an anti-competitive manner. This is particularly of concern in developing countries with weak institutional capacities and regulatory frameworks.

Ultimately, developing countries will have to make their own judgements on the benefits of establishing collective management organisations. In developing countries with large markets for the products of their copyright-based industries, domestically and abroad, establishing these institutions may bring financial benefits for copyright holders. In other countries, the net benefits to the citizens of the country as opposed to foreign nationals means it may be difficult to justify the costs. In any event, it would seem to be imperative that the full costs of establishment and operation of such agencies in developing countries are demonstrated transparently from the outset

and that these are borne by copyright holders as the direct beneficiaries. Moreover, collective management organisations should probably not be created unless properly functioning specialist copyright and competition tribunals can be established in parallel.

Although the potential benefits from the development of copyright-based industries in some developing countries may be enticing in some cases, it is hard not to conclude from looking at the evidence from the developing world overall that the negative impacts of stronger copyright protection are likely to be more immediate and significant for the majority of the world's poor. Today, there is an enormous "knowledge gap" between the richest and the poorest countries. As the World Bank has noted:

"If knowledge gaps widen, the world will be split further, not just by disparities in capital and other resources, but by the disparity in knowledge. Increasingly, capital and other resources will flow to those countries with the stronger knowledge bases, reinforcing inequality. There is also the danger of widening knowledge gaps within countries, especially developing ones, where a fortunate few surf the World Wide Web while others remain illiterate. But threat and opportunity are opposite sides of the same coin. If we can narrow knowledge gaps and address information problems ... it may be possible to improve incomes and living standards at a much faster pace than previously imagined."<sup>7</sup>

In the long term, stronger copyright protection may help to stimulate local cultural industries in developing countries if other conditions affecting the success of such industries are also met. But in the short to medium term, it is likely to reduce the ability of developing countries and poor people to close this gap by getting the textbooks, scientific information and computer software they need at affordable cost.

## **WILL COPYRIGHT RULES ALLOW DEVELOPING COUNTRIES TO CLOSE THE KNOWLEDGE GAP?**

In theory, international copyright rules should be able to deal with problems of access because they provide room for countries to include exemptions and relaxations of copyright in certain circumstances under their national laws. So, for example, Articles 9 and 10 of the Berne Convention permit countries to allow limited copying of protected works without permission for certain purposes defined in national legislation such as teaching, research and private use, so long as these do not interfere with the normal exploitation of the work by the copyright owner (see Box 5.1).

At the 1967 Stockholm conference of the Berne Convention, developing countries argued for additional flexibilities within international copyright rules because of their needs for mass education. The conference produced a Protocol that allowed developing countries to provide a reduced term of protection of 25 years together with compulsory licensing for translations into local languages and, most controversially, for any protected use for educational, scientific or research purposes. But the Stockholm Protocol was never ratified because of a lack of consensus between developed and developing countries. Eventually, in Paris in 1971, agreement was reached on a watered down set of exemptions for developing countries, essentially allowing limited compulsory licensing of works for translation into local languages. These are set out in an Appendix to the Convention, but it has been of very little direct benefit to developing countries, as shown by the fact that only a handful of developing countries have ever included the special provisions in their national law.<sup>8</sup>

A central question is whether the exemptions and limitations within the existing framework of international rules allow developing countries to set the right balance in protecting copyright whilst addressing their special development needs. There are certainly grounds for doubt. As one distinguished international copyright expert has put it:

“Where a developing country decides to enter international copyright relations it will generally find that a perceptible gap remains between what is needed to satisfy its requirements [for education and transfer of knowledge] and the standard of protection demanded by a multilateral instrument such as the Berne Convention.”<sup>9</sup>

In fact, our consultations with stakeholders and reading of the evidence suggests that the issues are most serious in relation to access to education materials where demand is not met by the local publishing industries or donor-financed programmes; and in relation to access to computer software, a pre-requisite for access to information and for competitiveness in the global economy. The arrival of the digital era provides great opportunities for developing countries in accessing information and knowledge. The development of digital libraries and archives, Internet-based distance learning programmes, and the ability of scientists and researchers to access sophisticated on-line computer databases of technical information in real time are just some examples. But the arrival of the digital era also poses some new and serious threats for access and dissemination of knowledge. In particular, there is a real risk that the potential of the Internet in the developing world will be lost as rights owners use technology to prevent public access through pay-to-view systems.

### Box 5.1 “Fair Use” and “Fair Dealing” in the Digital Era

As part of the balance between the exclusive rights of authors, artists and other creators on the one hand, and the social goal of wide dissemination of knowledge on the other, international copyright rules allow countries to place limits on the right to prevent unauthorised use and reproduction in certain prescribed circumstances. For example, article 9, paragraph 2 of the Berne Convention states *“It shall be a matter for legislation in the countries of the Union to permit the reproduction of such works in certain special cases, provided that such reproduction does not conflict with a normal exploitation of the work and does not unreasonably prejudice the legitimate interests of the author.”*

Accordingly, national copyright laws in most countries incorporate exceptions for copying for personal use, research, education, archival copying, library use and news reporting, based on principles of ‘fair dealing’, or in the US, the doctrine of ‘fair use’. The scope, strength and flexibility of these exceptions vary widely between countries and regions, in part due to differing national jurisprudence, but generally focus on the following conditions:

- The purpose and character of the use – copying must be for private, non-commercial purposes. Only single or a small number of copies may be reproduced.
- The proportion of the work that is copied – copies should be made only of parts of the work. Complete works may be copied only where originals are not available on the market.
- Copies of hard copy works may typically be produced only by reprographic processes. There is also some freedom to make copies of electronic works as, for example, for time-shifting of TV programs or archiving of computer software.
- If there are exemptions for the benefit of libraries and archives, those institutions must be accessible to the public and act in a non-commercial way.
- The legitimate interest of the right-holder must be taken into account – the effect on the potential market for the work.

The development and diffusion of digital technology, however, now permits unauthorised creation of unlimited, perfect and costless copies, and the almost instantaneous and worldwide distribution of protected works. The copyright industries are responding by using digital technology, in the form of encryption technologies and anti-circumvention measures, supplemented by contract law and *sui generis* forms of databases protection. Critics argue that these measures effectively restrict “fair use”, and may reduce the ability of teachers, students, researchers and consumers to access information, particularly in developing countries. On this view, new approaches are needed to ensure that appropriate “fair use” exceptions can be preserved in this digital context.<sup>10</sup>

## COPYRIGHT-BASED INDUSTRIES AND COPYING OF PROTECTED WORKS

As we note at the beginning of this chapter, copyright-based industries such as publishing and computer software play a major part in the global knowledge-based economy, and the products and services they provide have a central role in facilitating innovation and social and economic development in general. The success of these industries is reflected by their tremendous growth, which has generated millions of high-paying jobs and billions in revenues, including in some developing countries. The computer software industry is also a highly important source of innovation in its own right and its members argue that they have produced dramatic gains in the performance and functionality of many commercial software products in the last decade or so while prices have remained stable or even fallen.

Representatives from these industries have stressed to us the importance of copyright laws and strong protection against unauthorised copying to encourage investments in creativity and innovation, as well as in product and technological development. The scale of these investments in developing creative works and bringing them to market is certainly considerable. For example, according to the Publishers' Association there are around 600,000 books currently in print in UK. This is a hugely valuable knowledge resource for innovative industries and society at large. And of course, industries must be able to recoup these investments to pay for new generations of knowledge-based products. So, for example, the computer software industry argues that charging licence fees for its products allows companies to generate revenues to fund future R&D.

The prevention of unauthorised copying has always been the principal objective behind the development of international copyright rules and this remains the case. Unauthorised copying of copyrighted works (usually described rather more pejoratively as "piracy" by copyright holders) has a long history and remains an international phenomenon, occurring in both the developed and the developing world. The US, for example, justified its persistent refusal to grant copyright protection to foreign authors during the 19th century on the grounds that this was a necessity to meet the nation's needs for knowledge and enlightenment. And interestingly, although industry claims that current rates of unauthorised copying are highest in some developing countries and transition economies,<sup>11</sup> the biggest financial losses to rights holders still occur in developed countries, because their market size is so much bigger.<sup>12</sup> The arrival of the digital era has created the fear for the copyright-based industries that they may be able to sell "only one copy" of a new e-book, DVD movie, music CD, or computer programme before it is illegally copied, as a perfect replica at no cost, and may be distributed seamlessly worldwide through computer networks and the Internet.

In the past, however, the evidence shows that weak levels of copyright enforcement have had a major impact on diffusion of knowledge and knowledge-based products in certain cases, such as computer software, throughout the developing world. Indeed, it is arguably the case that many poor people in developing countries have only been able to access certain copyrighted works through using unauthorised copies available at a fraction of the price of the genuine original product. We are therefore concerned that an unintended impact of stronger protection and enforcement of international copyright rules as required, *inter alia*, by TRIPS will be simply to reduce access to knowledge products in developing countries, with damaging consequences for poor people.

Responding to this concern, representatives from the copyright-based industries point to the special initiatives they are undertaking for developing countries, such as donation schemes and low price "budget" editions of books and computer programmes for cost-sensitive users, as the way forward rather than any weakening of international copyright rules and/or enforcement measures in the developing world. For example, the publishing industry is now supporting an expanding number of initiatives aimed at improving affordable access to books and journals in developing countries and establishing partnerships with publishers in less developed countries to encourage the

development of local publishing industries.<sup>13</sup> Likewise, in the computer software industry, a leading software company is making several of its software products available to South Africa's 32,000 public schools at no charge, thereby helping South African students and teachers become IT-proficient, while helping to build its future markets.

But ultimately commercial companies are responsible to their shareholders. They are not charities, nor are they intended to be. Companies therefore think it is the responsibility of governments from developed countries and development agencies to meet developing countries' requirement for subsidised access to affordable copyrighted works in order to address their needs for education and transfer of knowledge. As noted in a report presented to the UK Parliament in 1977 and by a recent decision of the UK Copyright Tribunal no one has yet suggested that the makers of notebooks, compasses or rulers should supply them to educational establishments free of charge.<sup>14</sup> So why should the copyright-based industries tolerate widespread unauthorised copying of their books, journals, computer software or scientific databases?

We have considered these arguments carefully. We recognise the value of the voluntary initiatives being undertaken by industry for developing countries and think more could be done in this area. More generally, we are not convinced from our observation in different developing countries that, even from the rightsholder's perspective, the pricing of products is optimal. To the extent that copying, particularly on a commercial scale, is driven by the ratio of the selling price to the cost of producing copies, there must be scope for the use of more differential pricing in developing countries that would either be revenue-neutral or even revenue-enhancing for producing industries. The fact that publishers are prepared to support various schemes for low or no cost access for institutions in developing countries for on-line publications indicates that they recognise there is scope for differential pricing, with suitable safeguards. Whilst we fully accept that copyright holders have a right to appropriate returns from their investments just as other industries, we believe that from the wider public policy perspective, ultimately it is just as important to ensure that people in developing countries have better access to knowledge, as it is to ensure they have access to other essential inputs for development such as food, water and medicines. It is not clear to us that publishers, and software producers, have got the balance right in facilitating access in developing countries in ways that are consistent with their obligations to shareholders.

**Publishers, both of hard copy and on-line books and journals, and software producers should review their pricing policies to help reduce unauthorised copying and to facilitate access to their products in developing countries. Initiatives being undertaken by publishers to expand access to their products for developing countries are valuable and we encourage an expansion of such schemes. The extension of free on-line access initiatives for developing countries to cover all academic journals is a good example of what could be done.**

## COPYRIGHT AND ACCESS

### Educational Materials

In recent years, there has been a welcome expansion of primary and secondary education in developing countries, and aid has been concentrated rightly in these sectors. Whilst there are still major challenges in achieving "Education for All", developing countries and their donor partners are making significant progress.<sup>15</sup> Access to books and reading materials at primary and secondary levels in some countries has also improved. This is the result of increased levels of public expenditure on primary education and international book donation programmes, such as Book Aid International. And importantly, in some countries, it is also because local publishing industries, albeit often at an embryonic stage, are able to produce low cost schoolbooks and reading materials.<sup>16</sup>

However, access to books and learning materials is still a real problem in many developing countries. In 1999, research by the Association for Development of Education in Africa (ADEA), a

consortium of donors and developing countries, revealed that shortages of relevant, low cost books for use inside and outside school continue to undermine the provision of good quality education. Indeed, the conclusions of ADEA's research present a very depressing picture:

“Uneven access to teaching and learning materials, inadequate provision of reading materials for the development of vital literacy skills and unacceptable pupil/book ratios continue to predominate. African publishers continue to be at a disadvantage in an economic context that tends to favour the import of books from abroad at the expense of those published in-country.”<sup>17</sup>

But access to books and materials is important for other parts of the education system as well. Developing countries need educated people such as doctors, nurses, lawyers, scientists, researchers, engineers, economists, teachers and accountants. Without people skilled in these professions and a system of life-long learning and education, developing countries will be less able to absorb new technologies, generate innovation, and compete in the global knowledge economy. For example, even if developing countries can obtain cheap medicines they will still need trained doctors and nurses to administer them properly in order to save lives.

However, in many developing countries, particularly in Sub-Saharan Africa, the tertiary education sector has sunk to levels where it may soon no longer be able to provide minimum levels of teaching and research – and this at a time of growing demand for admissions for undergraduates.<sup>18</sup> With many developing countries already spending a significant proportion of GNP on education, they may be unable to find the additional resources required simply to maintain current levels of tertiary enrolments, let alone improve quality. Clearly, copyright is not the only issue with the weak tertiary infrastructure but high prices of books and materials and limited access to Internet-based resources are still important parts of a worsening crisis.

In the tertiary sector, the evidence indicates that access to books and other materials for education and research remains a critical problem in many developing countries, particularly the poorest. Most developing countries remain heavily dependent on imported textbooks and reference books, as this sector is often not commercially feasible for struggling local publishers to enter. The prices of such books are beyond the means of most students.

## Libraries

University libraries should play a key role in supporting research and ensuring access to copyrighted books, journals and on-line materials for poor students in developing countries, but they are typically in a very poor state. Donor agencies have provided funding to modernise and re-stock libraries in a number of countries, including providing Internet connectivity and photocopying facilities.<sup>19</sup> More of this assistance is urgently needed. But donors' systems are just too slow and bureaucratic to enable libraries to maintain up-to-date textbook collections. Generally, the situation for university libraries in the poorer developing countries remains very bleak,<sup>20</sup> particularly in Africa, as a recent UNESCO report noted:

“The downturn in the economic fortunes of African countries during the last decade or so has had a devastating effect on the quality of library services in academic institutions, virtually all of which are publicly funded. Most of them can no longer afford to buy new books, and large proportions of periodical subscriptions have been cancelled. With a corresponding inability to switch to the new information technologies, African university libraries in particular, and African academics in general, face a dim future indeed.”<sup>21</sup>

Our consultations have also found that for better-resourced university libraries in developing countries, such as South Africa, there are sometimes serious problems in having to obtain copyright clearance and pay royalties for materials needed by teachers and students. And the evidence we have reviewed indicates that even these better-funded libraries have had to reduce their subscriptions to academic journals dramatically due to the high costs of maintaining up to date

collections. Indeed, even well resourced libraries in developed countries are experiencing extreme difficulty in continuing to stock the full range of journals their academics and students expect. In developed countries the rapid increase in subscription prices for academic journals, and ongoing consolidation in the publishing industry has fuelled an active debate on how researchers can maintain access to the materials they need, and the development of alternative models of on-line publishing such as BioMed Central.<sup>22</sup>

But developing countries also need to be allowed greater freedom to relax international copyright rules to meet their educational and research needs. As we have noted, delegates at the Stockholm conference proposed a package of such amendments to the Berne Convention in 1967. Developed countries rejected these proposals because they were considered to place too radical limitations on copyright protection. Examining the evidence 30 years later, it is clear to us that the special provisions for developing countries that were added to the Berne Convention in 1971, as set out in the Appendix, have not been effective. Further reforms are therefore needed, and different measures may be more or less important in meeting the specific needs in individual countries. As one commentator has put it:

“In some cases, access to scientific journals and books at subsidized prices for a limited period would help greatly. In others, local publishers with limited markets need easy and inexpensive access to foreign books in order to translate them into the local language. In a different context, permission to reprint books from the industrialised countries in the original language is needed to serve an indigenous population literate in English or French but unable to pay the high cost of imported books. And for some countries, most of the elements of an indigenous publishing industry are missing and there is a need to build it up from scratch. Copyright may not be the key element in all of these circumstances, but it does play a role.”<sup>23</sup>

**In order to improve access to copyrighted works and achieve their goals for education and knowledge transfer, developing countries should adopt pro-competitive measures under copyright laws. Developing countries should be allowed to maintain or adopt broad exemptions for educational, research and library uses in their national copyright laws. The implementation of international copyright standards in the developing world must be undertaken with a proper appreciation of the continuing high level of need for improving the availability of these products, and their crucial importance for social and economic development.**

## COPYRIGHT AND COMPUTER SOFTWARE

As others have noted, there is a digital divide between the developed countries and the developing world. In the knowledge-based global economy, computer technologies are an essential requirement for accessing and using information, accelerating technology transfer and boosting the growth of productivity. At the same time, computer software products are perhaps the most heavily protected of all forms of knowledge-based products. Under the TRIPS Agreement, computer programmes now qualify for copyright protection just as any other literary work, as well as for other forms of IP protection, including by patents in some nations, such as the US.

Developing countries, of course, have a range of requirements for computer software applications in their industries, hospitals, schools and government offices. But most commonly, they need affordable access to off-the-shelf business software packages, such as word-processing, spreadsheet, e-mail and Internet browsing products. Companies in Europe and North America, with Microsoft being the major player, dominate the global market for these products. The software industries of developing countries, even in India, are mostly absent from the off-the-shelf, packaged computer programs sector.<sup>24</sup>

Copyright matters most in the computer software industry to the off-the-shelf business applications sector. Unlike bespoke software applications, these products have a mass market and can be easily

copied. Copyright protection enables companies to prevent copying, limit competition and charge monopoly prices for these products. In developing countries, this presents two main problems.

First, as there is currently widespread copying together with low local purchasing power in developing countries, there is a concern that stronger protection and enforcement could mean a more limited diffusion of such technologies. This may be a particular risk because the network effects of business applications tend to re-enforce the dominance of existing software producers. Examining the evidence, however, we conclude that this problem is not insurmountable for developing countries, if the right steps are taken. For example, governments and donor organisations could review their software procurement policies with a view to giving greater consideration to low cost business software products, including generic and open-source products that are widely available.<sup>25</sup>

The second problem is that where the source code of software is also protected, this may make it harder to adapt the products for local needs. It may also restrain competition in development of inter-operating applications, through follow-on innovation by reverse engineering. Under TRIPS, developing countries are permitted the flexibility to allow reverse engineering of software, so this problem may be avoided if national copyright laws are drafted appropriately. As another practical measure, more widespread use of the various open source software<sup>26</sup> products, where source code is made available unlike proprietary software, may be considered.<sup>27</sup> Alternatively, some in industry argue that with stronger copyright enforcement, closed source proprietary developers may be more willing to make source code available to software developers in developing countries.

It is clearly beyond our mandate to recommend what kind of policies developing countries should follow for procurement of computer software. For instance, whilst low cost or open source software may *a priori* offer cost and other advantages over proprietary software, many factors besides software license fees affect the total cost of an IT system such as customising the system to the user's specific needs, as well as servicing, and maintaining the system. That said, given the considerable needs which developing countries have for information and communication technologies and the limited funds which are available, it would seem sensible that governments and donors should certainly consider supporting programmes to raise awareness about low cost options, including open source software, in developing countries.

**Developing countries and their donor partners should review policies for procurement of computer software, with a view to ensuring that options for using low-cost and/or open-source software products are properly considered and their costs and benefits carefully evaluated. Developing countries should ensure that their national copyright laws permit the reverse engineering of computer software programmes beyond the requirements for inter-operability, consistent with the relevant IP treaties they have joined.**

## DELIVERING THE POTENTIAL OF THE INTERNET FOR DEVELOPMENT

There is reason to hope that the information technology revolution has the potential to increase access to information and knowledge in developing countries. Rapid advances in two key technologies – digital information storage/processing and satellite/optical fibre communications – are creating faster and cheaper ways of accessing and using knowledge around the world. The growth of the Internet is a prime example. In mid-1993, there were fewer than 200 websites on the Internet but by late 2000, there were 20 million; and the number of Internet users is expected to reach 1 billion by 2005, though most of these will still be in the developed countries (UNDP 2001). Table 5.1 shows the dramatic contrasts in Internet usage in developed, developing and least developed countries.

**Table 5.1 Internet Connectivity in the Developed and Developing World in 2000**

	Internet Users (millions)	Population (millions)	Internet Users per 10,000 people
<b>Developed Countries</b>	253.2	860	2944
<b>Developing Countries</b>	107.0	4500	238
<b>Least Developed Countries</b>	0.7	780	9
<b>Total</b>	<b>360.9</b>	<b>6140</b>	<b>588</b>

Source: ITU (2001), as quoted in Story (2002) Appendix 4

The growth of the Internet offers real opportunities for improving access and transfer of knowledge for developing countries. For example, the growing size and number of digital libraries creates unprecedented kinds of access to all published information anywhere in the world. In the future, developing countries may be able to build a national digital network to provide access to library resources from around the world to every remote village, as is being done in Australia.<sup>28</sup> Similarly, initiatives such as the African Virtual University (AVU) are showing the potential of the Internet as a tool and resource for distance learning in the developing world. Since its launch in 1997, more than 24,000 students in 17 African countries have completed semester-long courses in technology, engineering, business and the sciences through the AVU. It also provides students with access to an on-line digital library with over 1,000 full text journals and the AVU website currently receives more than 1 million hits per month.<sup>29</sup>

### Technological Restrictions

But there are also threats to access and diffusion of knowledge and technology from these technological changes. There is a growing trend within the publishing and software industries towards distribution of content on-line, together with access restrictions enforced by digital rights management systems, such as encryption technologies. This sophisticated form of technological protection rescinds traditional "fair use" rights to browse, share, or make private copies of copyrighted works in digital formats, since works may not be accessible without payment, even for legitimate uses. For developing countries, where Internet connectivity is limited and subscriptions to on-line resources unaffordable, it may exclude access to these materials altogether and impose a heavy burden that will delay the participation of those countries in the global knowledge-based society.

In terms of the relationship of this trend with IP rules and the potential of the Internet for development, there are three factors that have further significance for developing countries.

First, the WIPO Copyright Treaty establishes new rules that may soon become the international standard.<sup>30</sup> It clarifies copyright holders' exclusive rights over material in the on-line environment and specifically calls for countries to provide effective legal remedies against the circumvention of technological protection measures restricting types of access that are not authorised by the copyright holder or permitted in national law. As of April 2002, 35 countries had ratified the treaty, including Burkina Faso, Mali and Gabon. An important concern here is that developing countries will come under pressure, for instance in the context of bilateral agreements with developed countries (see Chapter 8), to accede to the WIPO Copyright treaty, or even to adopt stricter

prohibitions against circumvention of technological protection systems and effectively thereby reducing the scope of traditional “fair use” in digital media.

In the US, the Digital Millennium Copyright Act (DMCA) of 1998 enacted the WIPO Treaty but went beyond it. In particular it gave a strong boost to the use of technological protection by making it illegal to circumvent technological protection used by publishers, or to develop or distribute devices that do so. Such acts are illegal even for uses that would not hitherto have infringed on copyright (which is not the case with the WIPO treaty). This deeply compromises the principles of “fair use” which have been established under copyright, as also the principle of first sale. In the case of a book you are free to resell it to someone else – technological protection may prevent the equivalent digital act. Finally, technological protection is indefinite, whereas copyright is time limited (albeit the time seems to keep increasing).

Secondly, certain quarters of the “content” industries are calling for governments to enact legislation that require manufacturers of computer technology to build-in devices to prevent unauthorised copying of digital works. For example, Michael Eisner, chairman and chief executive of the Walt Disney company, asserted in a article in the Financial Times on 25 March 2002 that:

“We are now at a crossroads. The primary goal must be for the creators of content and the creators of computer technology to come together to agree on appropriate technologies to hinder the unauthorised duplication and transmission of copyrighted materials. The US government has an important role to play, by setting a reasonable deadline after which, if no progress has been made, it will step in to mandate technological standards to protect copyrighted works from unlawful exploitation.”

Thirdly, specifically in relation to scientific or technical electronic databases, it is possible that developing countries will be encouraged to adopt a special regime of IP protection, in addition to the limited protection already provided under TRIPS and the Berne convention (see Box 5.2). Such a *sui generis* protection regime was introduced in the 15 countries of the European Union in 1996.<sup>31</sup> Aided by the fact that the EU’s database regime only provides protection for foreigners on a reciprocal basis, similar proposals have been before the US congress for a number of years (for example, the draft Database Investment and Intellectual Property Anti-Piracy Act of 1996). The EU and the US also tabled proposals for an international treaty on database protection at the 1996 WIPO Diplomatic Conference.

Digitalisation and the potential for instant, low-cost global communication have opened tremendous new opportunities for the dissemination and use of scientific and technical databases in developing countries, as elsewhere in the world. Indeed, the ability to access existing databases and to extract and recombine selected portions of them for research has become a key part of the scientific process. However, commercially-owned private sector databases typically seek to control unauthorised access in order to maximise revenues from subscriptions, even when some of the data they contain may be in the public domain or collected through publicly funded research. Our central concern here, therefore, is that a strengthening of IP protection for databases at the international level, whilst encouraging more investment in new commercial database products and services, may at the same time greatly reduce the access of scientists and researchers in developing countries to the data they contain because they will often lack the financial means to pay for the necessary subscriptions.

It is clear that the issues surrounding access to information and knowledge over the Internet are still emerging. In some respects, they are of limited immediate importance in many developing countries, given these nations’ limited Internet connectivity. However, Internet issues are crucial to universities and scientific research in the developing world, and may soon be central to secondary and even primary education in developing nations since Internet access will be much less expensive than the construction and stocking of libraries. The Internet has remarkable potential for development and it is imperative that this is not lost.

## Box 5.2 IP Protection of Databases

IP protection of databases is a very important issue for science, research, innovation and creativity, given the global proliferation of computerised information services. Advances in information and communication technologies have made digital databases of factual information an essential resource for accelerating the growth of knowledge and for producing new discoveries. And the expansion of the Internet facilitates their wide dissemination and easy use. At the same time, the same technologies make unauthorised uses and wholesale misappropriation of these valuable databases relatively simple. The central issue here is, on the one hand, the balance between addressing concerns of database creators regarding the provision of incentives and protecting investment in new database products and services and, on the other, safeguarding customary access to the data they contain by users from the scientific, education and library communities.

In most countries, databases qualify for IP protection through trademark and copyright legislation (they may also be protected de facto through contracts between the users of the database and the service provider). However, protection for databases under copyright law is limited. The Berne Convention protects compilations or collections of works but is silent on the protection of collections of material other than works that are themselves copyrightable. In the famous 1991 case of *Feist Publications Inc. v. Rural Telephone Service Co.*, the US Supreme Court denied protection to a telephone directory on the grounds that the collecting of names, addresses and telephone numbers was not an original creative work.

Under the EU's *sui generis* regime, introduced in 1996, database creators have the right to prevent extraction of the whole or a substantial part of the contents of the database for a period of 15 years, although this term of protection is renewable whenever substantial change is made (for example, through adding more data). The argument that the EU's regime is designed to protect investment rather than original creative expression is supported by the fact that in order to gain protection, the creators need only show that they have made a "substantial investment" in developing the database.

More analysis needs to be undertaken about the best means of protecting digital content and the interests of rightsholders, whilst at the same time honouring principles that ensure adequate access and "fair use" for consumers. More specifically, policymakers need to gain a better understanding of the impacts of the trend towards on-line distribution and technological protection of content on developing countries. There is a possibility that much such material will be protected technologically or through contractual provisions that are imposed as a condition of accessing the material. And it is not clear how reasonable requirements of "fair use" will be guaranteed in such an environment.

Bearing in mind this considerable level of uncertainty, we conclude that it is premature at the present time for developing countries to be required to go beyond TRIPS standards in this area. We believe developing countries would probably be unwise to endorse the WIPO Copyright Treaty, unless they have very specific reasons for doing so, and should retain their freedom to legislate on technological measures. It follows that developing countries, or indeed other developed countries, should not follow the example of the DMCA in forbidding all circumvention of technological protection. In particular, we take the view that legislation such as the DMCA shifts the balance too far in favour of producers of copyright material at the expense of the historic rights of users. Its replication globally could be very harmful to the interests of developing countries in accessing information and knowledge they require for their development. Similarly we have concluded that the EU Database Directive goes too far in providing protection for assemblages of material and will restrict unduly access to scientific databases required by developing countries.

Users of information available on the Internet in the developing nations should be entitled to “fair use” rights such as making and distributing printed copies from electronic sources in reasonable numbers for educational and research purposes, and using reasonable excerpts in commentary and criticism. Where suppliers of digital information or software attempt to restrict “fair use” rights, by contract provisions associated with the distribution of digital material, the relevant contract provision may be treated as void. Where the same restriction is attempted through technological means, measures to defeat the technological means of protection in such circumstances should not be regarded as illegal. Developing countries should think very carefully before joining the WIPO Copyright Treaty and other countries should not follow the lead of the US and the EU by implementing legislation on the lines of the DMCA or the Database Directive.

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- <sup>1</sup> Story, A. (2002) *“Copyright, Software and the Internet”*, Commission on Intellectual Property Rights Background Paper 5, Commission on Intellectual Property Rights, London, p.11.  
Source: <http://www.iprcommission.org>
- <sup>2</sup> UNESCO (1998) *“World Information Report 1997/98”*, UNESCO, Paris, p.320.  
Source: [http://www.unesco.org/webworld/com\\_inf\\_reports/wirenglish/chap23.pdf](http://www.unesco.org/webworld/com_inf_reports/wirenglish/chap23.pdf)
- <sup>3</sup> See, for example, Oman, R (2000) *“Copyright – engine of development”*, UNESCO, Paris. Note that this is available on the Web as an e-book with an access fee of £10.67. This fee allows one to browse the book on-line but not print it out in hard copy. It is a good example of technological protection on the Internet.  
Source: <http://upo.unesco.org/ebookdetails.asp?id=3004>
- <sup>4</sup> The source of this data is the Indian National Association of Software and Service Companies (NASSCOM) [http://www.nasscom.org/it\\_industry/sw\\_industry\\_home.asp](http://www.nasscom.org/it_industry/sw_industry_home.asp)
- <sup>5</sup> Bgoya, W. et al (1997) *“The Economics of Publishing Educational Materials in Africa”*, Perspectives on African Book Development series, ADEA Working Group on Books and Learning Materials, London.  
Source: [http://www.adeanet.org/trans/Econ%20of%20publishing\\_ENG/Economic%20eng.pdf](http://www.adeanet.org/trans/Econ%20of%20publishing_ENG/Economic%20eng.pdf)
- <sup>6</sup> Story, A. (2002) p.53.
- <sup>7</sup> World Bank (1999) *“World Development Report 1998/99: Knowledge for Development”*, World Bank, Washington DC, p14. Source: <http://www.worldbank.org/wdr/wdr98/>
- <sup>8</sup> For a history of the Protocol and Appendix, see Ricketson, S. (1987) *“The Berne Convention for the Protection of Literary and Artistic Works: 1886-1986”*, Kluwer, London, Chapter 11.
- <sup>9</sup> Ricketson, S. (1987), p. 591
- <sup>10</sup> Correa, C. M. (2000) *“Fair Use in the Digital Era”*, UNESCO, Paris.  
Source: [http://webworld.unesco.org/infoethics2000/documents/paper\\_correa.rtf](http://webworld.unesco.org/infoethics2000/documents/paper_correa.rtf)
- <sup>11</sup> For example, the Business Software Alliance estimates computer software infringement levels of 97% and 94% in Vietnam and China respectively in 2000. Business Software Alliance (2001) *“Sixth Annual BSA Global Software Piracy Study”*, BSA. Source: <http://www.bsa.org/resources/2001-05-21.55.pdf>
- <sup>12</sup> For example, North America, Western Europe and Japan alone account for over 65% of global revenue losses from counterfeit computer software, Business Software Alliance (2001). It should be noted that the methodology of these studies has been criticised. The description indicates that they are based on the difference between estimated installed software and estimated legitimate supply, valued at the prices of legitimate supply. No reference is made to the fact that, in the absence of “piracy”, additional legitimate sales would necessarily have been much lower. On this basis, some have claimed these are very substantial overestimates of lost sales revenue.
- <sup>13</sup> The range and number of such initiatives makes it impossible to describe them all here, but perhaps the best known example is the WHO-sponsored Health Internet Access to Research Initiative (HINARI) offering free on-line access to 100 developing countries to around 1000 leading medical journals. For a more comprehensive listing of such access initiatives for developing countries see: [http://www.alpsp.org/http\\_dev.htm](http://www.alpsp.org/http_dev.htm) or <http://www.library.yale.edu/~license/develop.shtml>
- <sup>14</sup> Report of the committee to consider the law on Copyright and Designs under the chairmanship of Mr Justice Whitford (the Whitford Report), presented to the UK Parliament in 1977; UK Copyright Tribunal interim decision in *Universities UK v. CLA* September 2001  
Source: <http://www.patent.gov.uk/copy/tribunal/uukvcla.pdf>
- <sup>15</sup> See, for example, UNESCO (2001) *“Monitoring Report on Education for All”*, UNESCO, Paris.  
Source: [http://www.unesco.org/education/efa/monitoring/pdf/monitoring\\_report\\_en.pdf](http://www.unesco.org/education/efa/monitoring/pdf/monitoring_report_en.pdf)

- <sup>16</sup> Altbach, P. (1995) *Copyright and Development: Inequality in the Information Age*, Bellagio Publishing Network, Boston MA; and Bgoya, W. et al (1997).
- <sup>17</sup> The Association for Development of Education in Africa (ADEA) Working Group on Books and Learning Materials. Source: [http://www.adeanet.org/workgroups/en\\_wgblm.html](http://www.adeanet.org/workgroups/en_wgblm.html)
- <sup>18</sup> During the 1980s public expenditure per tertiary student in Sub-Saharan Africa dropped from \$6,300 to \$1,500 in real terms, and the 1990s have witnessed a further decline of an estimated 30%. Saint, W. (1999) *Tertiary Distance Education and Technology in Sub-Saharan Africa*, ADEA Working Group on Higher Education, Washington DC.
- <sup>19</sup> For example, according to UNESCO (1998), the World Bank granted a \$15.8m loan to the Senegal Government for the improvement of library services in the Cheikh Anta Diop University of Dakar.
- <sup>20</sup> For example, at the University of Dar es Salaam in Tanzania, classes of 100 students chasing one copy of a library textbook are common and the textbook collections are often two editions out of date. Rosenberg, D. (1997) *University Libraries in Africa: A Review of their Current State and Future Potential*, International African Institute, London.
- <sup>21</sup> UNESCO (1998), Chapter 4.
- <sup>22</sup> See "Journal Wars" *The Economist*, 10 May 2001.
- <sup>23</sup> Altbach, P. (1995), p.7
- <sup>24</sup> This situation is unlikely to change quickly. There are considerable non-IP related barriers that prevent software firms in developing countries from entering the off-the-shelf market at a significant level, at least for the short and medium term. These barriers include the small domestic market size in developing countries, which totals less than 5% of the global software market. OECD (2000) *Information Technology Outlook 2000*, OECD, Paris, p.67.  
Source: <http://www.oecd.org/dsti/sti/it/prod/it-out2000-e.htm>
- <sup>25</sup> To give one example, the "StarOffice" suite of business software, produced by Sun Corporation, is reportedly fully inter-operable with Microsoft's highly popular "Office" product and is available to download free of charge from the companies' website.
- <sup>26</sup> See Glossary for definition.
- <sup>27</sup> A famous example of open source software is "Linux", a Unix-like operating system for personal computers, developed at the University of Helsinki in 1991 and freely available. Linux is distributed with its source code under a "general public license".
- <sup>28</sup> Lyman, P. (1996) "What is a Digital Library? Technology, Intellectual Property, and the Public Interest", *Daedalus: Journal of the American Academy of Arts and Sciences*, vol. 125 No. 4, p. 12
- <sup>29</sup> For more information, see [www.avu.org](http://www.avu.org)
- <sup>30</sup> The WIPO Diplomatic Conference in December 1996 led to the adoption of two new treaties, the "WIPO Copyright Treaty" (Source: <http://www.wipo.org/eng/diplconf/distrib/94dc.htm>) and the "WIPO Performances and Phonograms Treaty" (Source: <http://www.wipo.org/eng/diplconf/distrib/95dc.htm>) dealing respectively with the protection of authors and the protection of performers and phonogram producers.
- <sup>31</sup> EC Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the Legal Protection of Databases. Source: <http://europa.eu.int/ISPO/infosoc/legreg/docs/969ec.html>

## PATENT REFORM



### INTRODUCTION

In its original “modern” conception the patent system was, in the words of the American Constitution, “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”. The purpose was to stimulate invention, by rewarding inventors with a right to exclude others from the use of their invention, where the reward should relate to the usefulness of the invention to society. The disclosure of information in the patent was also seen as stimulating technical progress.

Over time, the emphasis has shifted towards viewing the patent system as a means of generating the resources required to finance R&D and to protect investments. Since the patent system offers a standard level of protection in all the fields it covers, there can be no direct link between the value of the right granted for a particular invention and the costs incurred in R&D. There may be a link between the value of the monopoly and its social utility, if the demand in the market is taken as a reliable indicator of the latter. But, for developing countries in particular, this is far from being the case. The patent system cannot stimulate inventions that are useful to society if the potential beneficiaries cannot pay for them, or someone else is not prepared to pay on their behalf.

As we noted in the Overview, there are concerns about the way the system has evolved which apply to developed countries as well as developing countries. These relate in particular to the application of the patent system to the new generation of technologies, particularly in the life sciences and information technology. The development of biotechnology has been accompanied by the more widespread patenting of living things, whose patentability was confirmed in the US by the Supreme Court case of *Diamond versus Chakrabarty* in 1980.<sup>1</sup> Similarly the development and growing sophistication of information and communications technology has been accompanied by the extension of patenting to computer software in the US.

This extension to new technologies, has been accompanied by greater use of the patent system. In the US, and to a lesser extent worldwide, the number of patents granted has been rapidly rising. Between 1981 and 2001, the number of patents granted in the US has increased from 71000 to over 184000, an increase of 159%. In the last five years the rise has accelerated, the number of patents granted has increased by over 50%, compared to an increase of under 14% in the previous five years. This increase appears to reflect growth in the intensity of patenting (for example, per dollar spent on research), rather than a 50% increase in the number of inventions. In the 1990s, US R&D expenditures increased in real terms by nearly 41%, while patents granted rose by over 72% in the decade to 2001.<sup>2</sup>

The patent system is designed as a tool to provide an incentive to technical progress. The effectiveness with which it can do this will depend on the fit between the nature of the incentive and the processes by which technological development takes place. But whereas the patent system has uniform criteria to judge patent applications, the pattern of technical progress may vary significantly in different fields. The patent system fits best a model of progress where the patented product, which can be developed for sale to consumers, is the discrete outcome of a linear research process. The safety razor and the ballpoint pen are examples, and new drugs also share some of these characteristics.

By contrast in many industries, and in particular those that are knowledge-based, the process of innovation may be cumulative, and iterative, drawing on a range of prior inventions invented independently, and feeding into further independent research processes by others.<sup>3</sup> Knowledge evolves through the application of many minds, building often incrementally on the work of others. Sir Isaac Newton modestly wrote a long time ago: "If I have seen further it is by standing on the shoulders of giants."<sup>4</sup> Moreover much research consists of the relatively routine development of existing technologies. For instance, gene sequencing, formerly a labour intensive manual technique, is now a fully automated process, involving little creativity. The development of software is very much a case of building incrementally on what exists already. Indeed, the Open Source Software Movement depends precisely on this characteristic to involve a network of independent programmers in iterative software development on the basis of returning the improved product to the common pool.

In practice, it is often difficult to distinguish between "discrete" and "incremental" or "cumulative" research processes, because research is carried out in so many ways and there is often a serendipitous element. But for the most part, the "cumulative" model now seems to fit more research than the "discrete" model. A patent system, which evolved with the latter concept in mind, may not be optimal for the former. Thus, as Merges and Nelson point out:

"Ultimately it is important to bear in mind that every potential inventor is also a potential infringer. Thus a "strengthening" of property rights will not always increase incentives to invent; it may do so for some pioneers, but it will also greatly increase an improver's chances of becoming enmeshed in litigation... When a broad patent is granted...its scope diminishes incentives for others to stay in the invention game, compared again with a patent whose claims are trimmed more closely to the inventor's actual results. This would not be undesirable if the evidence indicated that control of subsequent developments by one party made subsequent inventive effort more effective. But the evidence, we think, points the other way."<sup>5</sup>

The crucial issue here is the extent to which the patent system as it has now evolved in the developed world, and which the developing world is being pressed to adopt, will provide appropriate incentives for invention. One of the fundamental dilemmas here is the large number of patents on technologies that may be outputs of one research process, but are possible inputs into one or several downstream processes. One example is the issue of patenting "research tools."<sup>6</sup>

In concert with the expansion of patenting in the private sector, public research institutions have been accelerating the transfer of the technologies that they develop by patenting. In the US, this approach was encouraged by the introduction of the Bayh-Dole Act in 1980, and the policy has since spread to other developed countries and, increasingly, to the more technologically advanced developing countries. Patents awarded annually to US universities have increased nearly tenfold, from less than 350 in the 1970s to over 3000 in 2000. The share of patents granted to academics in the US has increased from 0.5% to 2% of the total over the same period. This policy, according to some, has stimulated a flow of inventions from universities and promoted their commercialisation, to the wider economic benefit of society. For others, it raises concerns about the possible restriction of access to research findings or their utilisation by others; the possible distortion of research priorities in the public sector, and as to whether the increase in patenting is a valid indicator of the acceleration of technology transfer. We consider what these concerns about the patent system in developed countries mean for developing countries.

First, in order to avoid the possibility of encountering similar problems to the developed world, developing countries should try to devise patent systems to take account of their particular economic and social circumstances. Both patent offices and legislatures in developing countries need be fully aware of the commercial and social impact of the approach they take in devising and implementing patent policy. The more technologically advanced developing countries may wish to adopt systems that provide extensive patent protection as incentives for R&D. On the other hand, they would also wish to avoid those aspects of the system which could provide disincentives to R&D, in particular follow-on innovation. They would wish to avoid resources being diverted to litigation and disputes about patents of doubtful validity, and rent-seeking<sup>8</sup> behaviour amongst rights holders of doubtful social benefit. Such systems would need to have adequate safeguards to ensure a competitive environment, and to minimise costs for consumers. Because much of the scientific and technological expertise in developing countries is concentrated in the public sector, there will need to be careful consideration of the implications of patenting by research institutions and universities. Countries which have a weak scientific and technological infrastructure will have less reason to adopt extensive patent protection, given that most of their technology is imported.

Secondly, a very difficult issue concerns how the interests of developing countries should be reconciled with the current pressures to harmonise the international patent system with the standards of the developed countries. This issue is raised by both the increase in the number of patent applications which is imposing heavy demands on the resources of many patent offices, and the recognition that there is considerable duplication of effort in the system, particularly with regard to the need to submit multiple applications for a single invention in different jurisdictions. Such duplication could be avoided by harmonising differences in standards and criteria in search and examination procedures. For some, the ultimate goal is an international patent, valid throughout the world and based on a single application process. But if, as we argue, developing countries should be encouraged to devise patent systems that suit their individual circumstances and objectives, which themselves will vary according to their stage of development, how should developing countries then proceed?

The crucial questions for developing countries which arise from the discussion above are:

- How should developing countries frame their patent legislation and practice? What measures can developing countries adopt in general to minimize the possible adverse effects of patenting regimes?
- Should developing countries encourage their public sector research institutions to patent their inventions?
- To what extent does the patent system inhibit research relevant to developing countries? Is the patenting of research tools a problem for developing countries?
- What would be the optimal approach for developing countries to take in relation to patent harmonisation?

# THE DESIGN OF PATENT SYSTEMS IN DEVELOPING COUNTRIES

## Introduction

We believe that in considering the design of their patent systems, developing countries should adopt a pro-competitive strategy that, as one observer suggests, is tilted towards second comers rather than distant patentees.<sup>9</sup> This is especially important in those areas of technology such as pharmaceuticals and agriculture where, as we have already considered, the cost of providing strong protection is likely to be greatest. Such a pro-competitive strategy is best realised by seeking to restrict the scope of patent protection provided.

This should be achieved, within the constraints of international and bilateral obligations, by:

- limiting the scope of subject matter that can be patented
- applying standards such that only patents which meet strict requirements for patentability are granted and that the breadth of each patent is commensurate with the inventive contribution and the disclosure made
- facilitating competition by restricting the ability of the patentees to prohibit others from building on or designing around patented inventions
- providing extensive safeguards to ensure that patent rights are not exploited inappropriately
- considering the suitability of other forms of protection to encourage local innovation.

We consider below how these objectives can be put into practice.

Historically, as we have seen, countries have adapted their patent regimes to encourage, discourage or more often prohibit patents in certain areas of technology. The advent of TRIPS, with its requirement for a more consistent approach to different fields of technology,<sup>10</sup> has reduced the options available to patent legislators. Nevertheless drafters of patent legislation still have a significant array of tools, even if some of them have been blunted by TRIPS. Numerous books and texts detailing the range of options available under TRIPS have been produced.<sup>11</sup> In the following paragraphs we describe some of these options and consider their relevance to the type of pro-competitive patent regime that we recommend for the majority of developing countries. We also consider how some of the recommendations relating to patent policy made in the preceding chapters on health and agriculture can be implemented.

## Scope of Patentability

### *Patentable Inventions*

TRIPS requires that “patents shall be available for any inventions, whether products or processes, in all fields of technology provided they are new, involve an inventive step (non obvious) and are capable of industrial application (useful).”<sup>12</sup> It does not however define the term “invention”, nor does it prescribe how the three criteria for patentability are to be defined. Indeed we would note that it is not uncommon for different courts in Europe, even when applying identical law, to come to different conclusions on whether a patent is or is not obvious. There is therefore ample scope for developing countries to determine for themselves how strictly the common standards under TRIPS should be applied and how the evidential burden should be allocated.

Developed and developing countries have historically provided that certain things do not constitute inventions for the purpose of patent protection. Included in these are those set out, for example, in Article 52 of the European Patent Convention (EPC):

- a) discoveries, scientific theories and mathematical methods;
- b) aesthetic creations;
- c) schemes, rules and methods for performing mental acts, playing games or doing business, and programmes for computers;
- d) presentations of information.

Article 52(4) of the EPC also provides that methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application. Article 53(b) of the EPC provides that patents shall not be granted for plant or animal varieties or essentially biological processes for the production of plants and animals

Even though subsequent EPO practice and jurisprudence have to some extent diluted the scope of these Articles,<sup>13</sup> it would seem entirely reasonable for most developing countries to adopt this list of exclusions as a minimum. Indeed we have already gone further by concluding in Chapter 3 that developing countries should not generally make patent protection available for all plants and animals.<sup>14</sup> A number of developing countries have also sought to limit further what constitutes a patentable invention. For example, the Common Industrial Property Regime of the Andean Pact countries provides that the following shall not be considered as inventions:

“Any living thing, either complete or partial, as found in nature, natural biological processes, and biological material, as existing in nature, or able to be separated, including the genome or germ plasm of any living thing.”<sup>15</sup>

Similar provisions can be found in the legislation of Brazil and Argentina. We consider further below the question of what rules should apply to the patentability of genetic material.

### *Excluding Inventions on Moral or Ethical Grounds*

The debate surrounding patent protection for certain inventions particularly those covering biological material is clearly about more than economics. For a significant number of people, in both developed and developing countries, the idea of patenting living organisms is morally wrong. This is often associated with the view that living things should not be patented because they can, by definition, only be discovered, not invented. In recent discussions within Europe on the protection to be afforded to biotechnological inventions, groups opposing patents on “life” were actively involved.<sup>16</sup> The final text of the resulting EC Directive<sup>17</sup> made some provision for excluding certain groups of inventions<sup>18</sup> from patent protection on moral grounds but it still allowed patents on plants and animals and genetic material. A similar debate in a developing country where domestic economic interests favouring patents on living things are likely to be weaker and where cultural and religious values often differ, might lead to a different outcome. In such a case a decision to deny patents on ethical grounds might be made for inventions claiming genetic material such as human genes. However, an exclusion of this type would be sustainable on the basis of the morality exception of Article 27.2 of TRIPS only if the prevention of the “commercial exploitation” of the invention denied a patent is deemed necessary. It is therefore debatable whether the exclusion can be applied while at the same time permitting the sale or other commercial exploitation of the invention.

Some ethical concerns about gene-based technologies may extend only to the possibility of someone claiming a monopoly over the technology, rather than to its commercial exploitation. In which case seeking an exclusion from patent protection may best be achieved by a strict application of the criteria for patentability. These include, as we have discussed above, clearly defining what constitutes a patentable invention as opposed to an unpatentable discovery, and ensuring that the concepts of novelty, inventive step and industrial utility are properly applied. We recognise that, in practice, the distinction between a discovery and an invention can be difficult to define, and this is a continuing challenge to legislators.

Issues of morality may also arise in respect of patents other than those in the biotechnology field. For example, the UK and Kenya have recently decided to reject, on moral grounds, patents on landmines.

## Patentability Standards

### *Novelty, Inventive Step and Utility Requirements*

In Chapter 4 we recommend that an absolute standard of **novelty** be provided such that the prior art against which novelty is judged includes disclosure through use anywhere in the world. Also, in Chapter 2, we caution against developing countries simply taking over from the comparatively recent European jurisprudence the counter-intuitive notion that a product may be regarded as new, if a new use is identified for it. Such an approach is not required by TRIPS and different views can reasonably be taken of whether it is desirable to extend protection in this way, which developing countries will wish to consider with care.

In certain jurisdictions, disclosure of an invention by the inventor in the period, usually 12 months, preceding the filing of a patent for that invention will not destroy the novelty of that patent. This **grace period**, which may be limited to disclosure only at internationally recognised exhibitions or may cover any disclosure, is intended to allow the patentee to seek backing or test the market for his invention. However, in the absence of any international harmonisation on grace periods, an inventor risks losing patent rights in a jurisdiction not recognising grace periods because of disclosure in one that does. For those developing countries having few prospective patentees, there may therefore be little to gain from providing a grace period.

At present an invention is typically considered to be **inventive** if it is not obvious to a person skilled in the art.<sup>19</sup> Some would argue that this standard as it is now applied, for example by the USPTO or the EPO, is too low resulting in a proliferation of patents for trivial inventions which may not contribute to the over-riding objective of the patent system which is the advancement of science for public benefit.

We are not aware of any significantly higher standard being applied currently elsewhere. However, there are examples of higher standards being applied in the past. For example, in the first half of the 20th Century, the US applied a “flash of creative genius” standard which would probably render the majority of patents currently issued invalid.

For developing countries, the currently prevalent low standard of inventive step raises two concerns. The first is that as applied in developed countries, it could hinder research of importance to developing countries. The second concern is that developing countries would be expected to apply a similar standard in their own regimes. We would urge developing countries to think carefully before doing so and to explore whether a different higher standard is more desirable. One suggestion that has been made would be to require the patent applicant to demonstrate that the proposed invention reflects a standard of inventiveness higher than that which is normal in the industry involved.<sup>20</sup> The objective of any standard should be to ensure that routine increments to knowledge, involving minimal creative input, should not generally be patentable.

Developing countries will need to consider the possible impact of any higher standard of inventive step on the ability of domestic enterprises to protect their own innovations. We return to this issue when we consider the importance of second tiers of protection such as utility models.

The requirement that the invention has an **industrial application** (or **utility** in the US) is perhaps the only patentability requirement to have been made more stringent in recent times. This has arisen essentially because of the difficulty of determining whether certain biotechnology-related inventions, such as those covering genes or proteins, really have any industrial application. Often

any such application is not evident from the invention itself. The USPTO has recently provided guidance on how utility should be assessed in cases involving DNA sequences.<sup>21</sup> In such cases, utility can be established only if the patent application discloses a specific, substantial and credible utility. Such a requirement is now to some extent also being applied by the EPO.<sup>22</sup> It is to be hoped that this new standard will prevent patents being granted on inventions for which only a speculative application is disclosed, but it may be that it does not go far enough and the impact of the new Guidelines will therefore need to be closely monitored.

**Developing countries providing patent protection for biotechnological inventions should assess whether they are effectively susceptible to industrial application, taking account of the USPTO guidelines as appropriate.**

### *Disclosure Requirement*

The contract with society for the granting of a patent is that a limited monopoly period will be awarded in return for which the applicant will fully disclose his invention. The extent of the disclosure considered necessary to satisfy the applicant's part of the contract varies amongst countries. In some countries including the US, the applicant is required not only to fully disclose his invention in a manner that would enable another party to put it into practice, but must also disclose the **best mode** for doing so. The sanction for non-compliance is usually the loss of the patent.

**Developing countries should adopt the best mode provision to ensure that the patent applicant does not withhold information that would be useful to third parties.**

A further issue relating to disclosure concerns the possible requirement to disclose the source of any biological material used in the invention which we discuss in Chapter 4.

The relationship between the extent of the disclosure and the scope or breadth of protection sought is another important issue. Patent regimes typically require that the invention be disclosed in the patent application in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. The claims made should also be supported by the description of the invention. The standard applied in the UK, for instance, is that a fair statement of claim is one which is not so broad that it goes beyond the invention nor yet so narrow as to deprive the patent applicant of a just reward for the disclosure of his invention.<sup>23</sup> The UK Courts have also recently stated that the disclosure must be sufficient to enable all aspects of the claimed invention to be performed, and the disclosure of a single manner of putting the invention into practice will not always be sufficient.<sup>24</sup>

But what is meant by a broad claim? Take the example of an inventor of a new compound for the treatment of headaches. She discloses the potential use for her compound in her patent application, but her claims extend beyond that use to the compound itself, and all its potential uses. During the life of the patent, someone else establishes that the compound is also useful in treating heart disease. Is it right that the patentee can then prevent the compound being used, without her authorisation, for purposes she had not foreseen? Are such broad claims really justified on the basis of limited disclosure?

Patent laws in developed countries have typically justified this type of broad claiming on the basis that the inventor has made available to others two things: the compound itself and the first use of it. Whilst the issue of the breadth of claims is a generic one, it arises particularly in relation to the patenting of genes. As noted above, some take the view that an isolated gene (even when one or more of its functions have been determined) should not be patentable because it pre-exists in nature and would constitute a discovery rather than an invention. However, if a country opts for allowing patents over genes, it is crucial to define the possible

scope of protection. At present, if a researcher isolates a gene and is granted a patent, for example, for the use of that gene as a diagnostic for a particular disease, depending upon the precise wording of the claim and the approach that the local law takes to interpretation of the patent, she may be able to assert rights over all uses of that gene, including those as yet undiscovered. Given that the isolation and identification of a gene is now a more routine procedure since the human and other genomes have been sequenced, the researcher stands to gain a level of protection which is considerably greater than her contribution. Moreover, because it is difficult for others to 'invent around' a gene, the researcher may be able to exercise a powerful monopoly.

A recent report on DNA patents, after considering the issue in detail, suggested that "consideration be given to the concept of limiting the scope of product patents that assert rights over naturally-occurring DNA sequences to the uses referred to in the patent claims, where the grounds for inventiveness concern the use of the sequence only and not the derivation or elucidation of the sequence itself".<sup>25</sup> This would lead to the researcher being awarded only the rights to the uses that she has set out in the specification, and not all uses.

This issue is as relevant to developing countries as it is to developed countries. Therefore we suggest that developing countries conduct their own investigation into ways of ensuring that the scope of patent claims in their own jurisdictions are consistent with the disclosure. Developing countries might also wish to press for consideration of this issue within WIPO, possibly as part of the ongoing discussions on greater patent harmonisation.

**If developing countries allow patents over genes as such, regulations or guidelines should provide that claims be limited to the uses effectively disclosed in the patent specification, so as to encourage further research and commercial application of any new uses of the gene.**

But measures to address the issue about breadth, as noted, extend beyond gene patents and should encompass broad patents in all fields of technology. While TRIPS forbids discrimination in terms of fields of technology, it is also desirable from a more general perspective to ensure that broad claims do not unfairly hamper research and competition in any field.

### *Applying the Standards*

We have so far suggested that developing countries should consider adopting higher standards of patentability than those currently provided in many developed countries. But it is not sufficient just to incorporate these standards in the legislation. It is necessary also to apply them. In Chapter 7 we address the issues relating to capacity, such as the scarcity of qualified personnel, which might constrain a developing country from implementing an effective patent policy. We also consider the type of measures, such as contracting out the examination of patents, which might be used to address some of these problems. We also discuss the possibility of re-registering patents granted elsewhere, although with such a solution it will be necessary to ensure that sufficiently high standards are applied when examining the patent.

Whatever type of system is adopted, it might be appropriate for developing countries to consider providing some form of low cost opposition or re-examination procedure.<sup>26</sup> In Chapter 4 we highlight the value of such procedures in overturning invalid patents covering known traditional knowledge. The type of opposition or re-examination procedure that a developing country might consider adopting could be a hybrid of the types of system currently available in some developing countries, the US and in Europe. For example, a system that allows an opposition to be made before grant, and the patent to be challenged at any point during the patent term through an administrative type procedure on the basis of any question relating to patentability, might be desirable.

When undertaking the examination of patent applications, developing countries should seriously consider requiring the applicant to disclose all relevant information concerning other

corresponding applications filed elsewhere for the invention. Developing countries should also consider supplementing the judgement of patent examiners by inviting other available experts to comment on patent applications. In Brazil, applications for pharmaceutical-related patents are passed for evaluation to the Ministry of Health who may be in a better position to comment on, for example, the inventiveness of the claimed invention.

## Exceptions to Patent Rights

In Chapter 2, we recommend that developing countries introduce the so-called “Bolar exception” to patent rights to facilitate early entry of generic competition in the pharmaceutical field. We have also suggested that providing an international exhaustion regime (i.e. permitting parallel imports of patented products) may be beneficial for developing countries. Such exceptions are however not the only ones that developing countries should consider. Most European countries, for example, provide that certain acts, such as those done for private and non-commercial purposes or those relating to experimentation on the subject matter of the patent (including for commercial purposes) shall not be considered infringements of a patent. The intent behind these exceptions, which is equally relevant for developing countries, is to encourage further innovation by enabling others to build on or design around the patented invention.

A further exception that already exists in a few developing countries provides freedom to use patented inventions for teaching purposes. Justification for such an exception might come from the copyright field where “fair use” of copyrighted works for educational purposes is well established. Indeed with the growing encroachment of patents into areas previously the sole domain of copyright, for example computer programmes, the relevance of an educational exception in the patent field may increase.

## Providing Safeguards in a Patent Policy

We have so far considered the requirements to obtain a patent and possible limitations to the rights of the patentee. We now consider tools for ensuring that such rights are not used in an inappropriate manner. We consider many of these issues in some detail in Chapter 2, but supplement them here.

### *Compulsory Licensing and Government Use*

In cases in which it is considered that the patentee is acting in an inappropriate manner then governments can intervene to remedy the situation. Such intervention could emanate from the general competition regime, or from within the patent system itself. The possibility of governments using, or allowing other third parties to use, a patented invention without the consent of the patentee is well established in patent law, and in TRIPS, as we note in Chapter 2. TRIPS prescribes a number of conditions that must be met in cases of such “unauthorised” use, but it does not prescribe the grounds on which such use can be authorised. Developing countries can therefore develop their own grounds for authorising compulsory licensing, or other exceptions to the rights of patentees (such as Crown or Government Use in developed countries). In considering introducing or revising legislation, they could seek guidance from the patent laws in other countries. For example, the US has used compulsory licensing in more than 100 antitrust cases.<sup>27</sup> The UK provides that compulsory licences may be granted on the following grounds:

- that the demand for the patented product in the UK is not being met on reasonable terms
- that the exploitation in the UK of any other patented invention, which involves an important technical advance of considerable economic significance, is prevented or hindered
- that the establishment or development of commercial or industrial activities in the UK is unfairly prejudiced.

Of course developing countries are not obliged to follow what countries such as the UK have done. Other grounds already adopted by developing countries include “public interest” and failure by a third party to obtain a licence under reasonable terms.<sup>28</sup> Brazil and other countries<sup>29</sup> have provided, or are considering providing, that a compulsory licence can be granted in cases where the demand for the patented invention is being met essentially through importation. As we note in Chapter 1, this type of measure was used by developed countries in the 19th and 20th centuries to limit the potential damage to domestic industry from issuing patents to foreigners. Questions arise however about the compatibility of this measure with TRIPS which makes patent rights enjoyable without discrimination as to whether the product is imported or domestically produced.<sup>30</sup> Developed countries, including the UK, have generally removed this provision from their statutes on the basis of their own interpretation of the TRIPS Agreement.

Ideally the mere possibility of having a compulsory licence issued should be enough to encourage the patentee to alter his behaviour. We note in Chapter 2 that this is only likely to be the case where the threat is a credible one in terms of there being a potential licensee capable of supplying the patented product economically at a lower price than the patentee.

An extensive use of compulsory licensing in developing countries is unlikely given the procedural complexities of the system. We nevertheless believe that an effective and credible compulsory licence system, as we recommend in Chapter 2, is an essential part of any patent policy. This is especially so for countries lacking a coherent or effective general competition policy.

### *Disputes about Patent Ownership*

During our visit to Kenya we were made aware of the controversy surrounding a patent relating to an HIV vaccine filed by the Medical Research Council (MRC) in the UK. In particular, there were concerns that the contribution made by researchers at the University of Nairobi towards the invention claimed in this patent had not been adequately recognised. Partly as a result of the public pressure surrounding this case, an agreement was reached whereby the MRC, the University of Nairobi and the International Aids Vaccine Initiative (IAVI) would jointly own this particular patent and any future patents involving this particular development.<sup>31</sup> In the absence of such an agreement, the researchers from Kenya would have had to consider instigating legal action to obtain any just entitlement that they had to the patent or to any benefits accruing from its possible exploitation.

Most, if not all, patent laws presume that the person filing the application for the patent is entitled to be granted a patent. For example, under UK patent law, an applicant who does not claim to be the inventor is required to state his entitlement to the patent. Patent offices do not as a rule make any attempt to question *prima facie* statements relating to entitlement or inventorship, although a third party may initiate a challenge both before and after a patent is granted. To succeed with a claim, the third party must show that he is either the inventor or co-inventor of the patented invention or that he has a right to it by virtue of an agreement or operation of law. The burden of proof almost invariably rests on the person making the claim.

It has been suggested that there may be some benefit to be gained by the introduction of a requirement for applicants to demonstrate how they have achieved an invention in cases where the route to the invention might not be immediately obvious (for instances in some cases claiming biological material).<sup>32</sup> Such a requirement, which appears to be allowable under TRIPS, differs from the current requirement to describe how to put the invention into practice.<sup>33</sup> Whilst a more proactive role in investigating issues of entitlement may place an additional burden on already overworked patent offices, we do nevertheless believe that this suggestion is worthy of further study.

## Encouraging Domestic Innovation

Many of the suggestions that we have made in this chapter reflect the fact that nationals of low income developing countries file very few patent applications. This should not be taken to indicate that there is no innovative activity in these countries; the problem is rather that the current patent system does not provide a suitable means for protecting their efforts. One possible reason for this situation is that the types of inventions being made may not possess the necessary level of inventiveness. Another important reason is the complexity and cost of acquiring rights, especially in foreign markets and, above all, of enforcing such rights in courts.

Many countries, both developed and developing, have recognised the need to protect the inventions, which result from what might be termed a “sub-patentable” type of innovation, and have therefore introduced a second tier of patent-like protection. Such systems are usually referred to as **utility model** or **petty patent** systems.<sup>34</sup> In comparison with the normal patent system, utility model or petty patent systems typically require a lower level of inventive step, provide a shorter period of protection and, in not being subject to any substantive examination prior to grant, are cheaper to obtain.<sup>35</sup>

Such characteristics are intended to make the system more attractive to small and medium size enterprises (SMEs) which typically have neither the desire nor the capacity to use the normal patent system. The type of innovative activity in such organizations may be more focused on relatively small incremental improvements to existing products rather than the development of completely new products. Such improvements, whilst not necessarily having the level of inventiveness for normal patent protection, do nevertheless contribute to technological advancement and should be encouraged. They are most likely to be beneficial for products, such as mechanical products, of a type likely to be produced domestically. They certainly should not be used as a substitute for normal patents (where we are recommending a raising of standards).

Evidence on how successful utility model systems have been in encouraging innovation in developing countries is hard to find.<sup>36</sup> During our visit to Kenya we were advised that the level of interest amongst Kenyan companies in their recently introduced utility model system had been disappointingly low. In other developing countries this is also the case. Figures compiled by WIPO show that in Argentina only 38 utility models were registered in 2000 and in Vietnam only 32.

Apart from those systems in current use, various other proposals have been suggested to encourage sub-patentable or incremental innovation. One of these is based on the provision of a right to a small royalty when the invention is used by others, but would not allow the prohibition of that use. This approach seeks to provide a reward for innovation, while reducing effects which might discourage follow-on innovation. But the administrative and enforcement requirements of such a system need to be tested to assess its practicality in developing countries.<sup>37</sup>

**Rather than diluting the patentability standards to capture the incremental type of innovations that predominate in many developing countries, lawmakers and policy makers in these countries should consider the establishment of utility model protection for stimulating and rewarding such innovations. Further research would seem desirable to assess the precise role that utility model protection, or other systems with similar objectives, might play in developing countries.**

A further type of protection is available in some countries<sup>38</sup> to allow a patentee to obtain protection for improvements that he makes to his own invention. These **improvement patents** or **certificates of addition** which typically expire at the same time as the patent on the initial invention, are intended to cover improvements that do not possess the necessary level of inventiveness that would allow them to be the subject of a separate independent application. The legal uncertainty that might arise if a patentee is allowed to extend the effective scope of his protection at any point in the life of the patent may deter other inventors from building on or designing around the patented invention. A

patent system providing such improvement patents in parallel with a relatively high level of inventive step could however possibly prevent the unjust extension of the duration of patent protection that sometimes results when separate patents for relatively minor improvements are allowed.

## Conclusions

In summary, we set out here, including recommendations from other chapters, the elements of a pro-competitive model of patent law which developing countries may consider. These are summarised in Box 6.1.

### Box 6.1 Summary of Recommendations Relating to the Patent System

#### Developing Countries\*

- Exclude totally from patentability diagnostic, therapeutic and surgical methods for the treatment of humans and animals
- Exclude from patentability plants and animals and adopt a restrictive definition of microorganisms
- Exclude from patentability computer programs and business methods
- Avoid patenting of new uses of known products
- Avoid using the patent system to protect plant varieties and where possible, genetic material
- Provide for international exhaustion of patent rights
- Provide an effective compulsory licensing system and adequate government use provisions
- Provide broadest possible exceptions to patent rights including adequate research exemption exception and an explicit "Bolar exception"
- Apply strict standards of novelty, inventive step and industrial application or utility (consider higher standards than currently applied in developed countries)
- Make use of strict patentability and disclosure requirements to prevent unduly broad claims in patent applications
- Provide a relatively low cost opposition or re-examination procedure
- Provide means to prevent the granting or enforcement of patents comprising biological material or associated traditional knowledge obtained in contravention of access legislation or the provisions of the CBD
- Consider providing alternative forms of protection to encourage sub-patentable type local innovation.

#### Developed and Developing Countries

- Apply an absolute standard of novelty such that any disclosure anywhere in the world can be considered prior art
- Take greater account of traditional knowledge when examining patent applications
- Provide for the obligatory disclosure of information in the patent application of the geographical source of biological materials from which the invention is derived.

#### Least Developed Countries

- Delay providing protection for pharmaceutical products until at least 2016. Those who currently provide protection for such products should seriously consider amending their legislation.

\* *These recommendations are considered relevant for the majority of developing countries. For those developing countries seeking to promote certain sectors of technology then a more selective approach may be desirable.*

# THE USE OF THE PATENT SYSTEM IN PUBLIC SECTOR RESEARCH

## Introduction

A major change in the developed world has been the encouragement of patenting in state-funded research institutions or universities. The Bayh-Dole Act in the US permitted universities to patent inventions based on federally funded research on the premise that this would facilitate the commercialisation of research, and hasten innovation. Subsequently, most of the developed world has pursued similar policies. In the more technologically advanced developing countries there is also considerable evidence of such patenting activity. In some developing countries international applications for patents (through the PCT) come increasingly from universities or spin-off companies. For example, in China in 2000, universities and scientific research institutes accounted for 13.2% of domestic patent applications.<sup>39</sup> And in May 2002, China announced that research institutes were to be encouraged to file patents relating to government-sponsored research.<sup>40</sup> In 2001, India's principal scientific organisation, the Council of Scientific and Industrial Research was the second largest PCT applicant from developing country institutions. Of the top 30 applicants from developing countries to the PCT, eight were from university or public sector research institutes.<sup>41</sup>

The theory underlying these policies is that patenting by public sector institutions and exclusive (or limited) licensing of technologies to the private sector increases the rate of commercial application of knowledge. Unless companies negotiate exclusive access to such technologies, it is argued, they would not have the incentive to invest the resources necessary to develop the technology into a marketable product. The opposing point of view contends that the interests of technology transfer and commercial application would be best served by the widest possible dissemination of knowledge through publication.

It is not really possible to say that either view is wholly wrong or right. Much depends on the individual situation. Traditionally, "basic" science was viewed as the main activity of the public/university sector and "applied" science the activity of the private sector. In the former, the incentives for scientific advance are the established systems of open disclosure, publication, peer review and promotion, and prestige associated with being first to make a discovery. In the latter the incentives and reward systems are commercial and financial, mediated by different forms of intellectual property protection. There was a symbiotic and finely balanced relationship between these two systems.<sup>42</sup> The university sector provided not only the scholarship to advance the progress of science but also the skilled people required by the private sector.

In the modern era, innovation has come to be seen as a more complex and interactive process. Throwing knowledge over university walls and hoping for the best is not now perceived as sufficient to encourage the application of that knowledge for economic and social benefit. Hence, the introduction of patents was seen as a means of changing the incentive structure in the public sector to address this deficiency. There has also been an erosion of the division, never very distinct, between basic and applied science. The development of biotechnology has resulted in some areas of basic science, such as genomics, being perceived as having potentially large commercial value. The combination of these two factors has resulted, particularly in the US, in a rapid increase in patenting by universities, particularly in the biomedical field.

## Evidence from the United States

So far, evidence from the US on the impact of the Bayh-Dole Act on technology transfer is inconclusive. Although, as noted, there has been a rapid expansion of patenting by universities, this alone does not demonstrate that commercialisation of inventions has increased. There is no firm evidence to indicate that researchers in US universities are producing more or better inventions than they would have done in the absence of Bayh-Dole or, if that is the case, that more of these inventions are being commercialised and applied. Supporters of Bayh-Dole point to the undeniable

increase not just in patenting, but also licensing income and the number of start-up companies spun off from universities. In 2000 it was estimated that the gross royalty income for universities in the US amounted to \$678 million, and that over 3000 start-up companies had been formed since 1980.<sup>43</sup> However, the increase in patenting and licensing activity can also be attributed to the growth of biotechnology, combined with the outcome of the Diamond versus Chakrabarty case, which would have contributed to an increase in patenting activity as universities conducted more research with commercial potential.<sup>44</sup> In addition, research funding, particularly from the NIH, greatly increased between 1980 and 2000. And R&D expenditure in US academic institutions rose by 150% in real terms between 1980 and 2000.<sup>45</sup> It is therefore difficult to determine the precise significance of the role of the Bayh-Dole Act in the expansion of patenting and, more importantly, whether or not it has increased technology transfer, and the application of technology, as compared to the counterfactual situation.

In the public sector, patenting and licensing activity can also provide both incentives and disincentives to the application of technologies. The incentive for commercialisation is predicated on the conferring of an **exclusive** licence to a commercial partner, on the basis that the exclusion of others provides the necessary incentive to the licensee to bear the risk of investing funds in development and commercialisation. But 50% of licences granted in the US in 2000 were **non-exclusive**.<sup>46</sup> To the extent that universities patent technology non-exclusively, there is arguably no technology transfer benefit because the numbers of those who can utilise the technology for further development is restricted by the licensing arrangement and the cost, as compared to simply publishing the results of research. But the incentive for further development and commercialisation, which is predicated on conferring an exclusive licence, is lost. Essentially, non-exclusive licensing is a tax on users of technology.<sup>47</sup> Exclusive licensing would appear to be important in developing early stage technologies which require considerable further development work. Against this, by its nature, the granting of an exclusive license involves “picking winners”. In some documented cases, the licensee has failed to commercialise a technology, which other potential developers might have been better placed to exploit. Where a university develops a “ready to use” technology for which there is an obvious demand, then it can clearly earn income from patenting but, equally, there is no additional technology transfer benefit since the technology would have been taken up by the private sector anyway.<sup>48</sup>

For universities which create new products and processes, patenting can provide a useful source of additional income, although this has to be offset against the substantial costs of running a technology transfer office, as well as the costs of patent application and maintenance. For example, in 1999 the University of California (UC) received a gross income of \$74 million from royalties and licence fees against gross expenses for the technology transfer office of \$24 million. Of the \$50 million “profit”, nearly \$30 million was returned to inventors at the university, and the resulting balance used to finance university research.<sup>49</sup> Of course, UC is one of the foremost research universities in the world, and the average financial returns from patenting and licensing in the US are much lower. It is estimated that new research funding from licence income in US universities amounted to only \$149 million in 1999, compared to total R&D expenditure in US academic institutions of \$30 billion in 2000.<sup>50</sup>

## Evidence from Developing Countries

In the US, there is a dearth of evidence on how, if at all, patenting by universities affects research priorities. In developing countries, there is even less since patenting activity is at such a low level. Nevertheless, we consider that there is considerable potential for tensions to arise between the need to secure intellectual property protection for the products of research institutions and the achievement of their wider social objectives, particularly those relating to the needs of poor producers.

In the absence of much published evidence, we use as an example one of the leading agricultural research institutes in the developing world which we visited, as a means of illustrating the set of

issues that developing countries will face in devising policies for the use of IP in publicly funded institutions. We were struck both by the vigour with which intellectual property protection was being introduced, and by the conscious effort being made to change the traditionally open culture of research. This change in policy envisages the protection of all assets produced by the Institute so that they can be licensed to earn revenue, or licensed free to small farmers participating in government programmes. While the institute's guidelines state that this policy should be implemented without sacrificing its social mission, they also make clear that not seeking protection will be the exception rather than the rule, and any exceptions must be considered by its intellectual property committee. Underlying this change in policy is also a requirement from the government to meet 30% of the total costs of the institution from non-government sources. There is also a more or less explicit emphasis on improving the overall competitiveness of the commercial and export agriculture through cooperation with agribusiness. In particular, the development of transgenic crops is a crucial area because large multinational companies own much of the proprietary technology required.<sup>51</sup>

It is obviously too early to judge exactly how this policy, introduced only recently, is likely to affect research output and priorities. We note there is a conscious emphasis given to the policy providing financial benefits to researchers, and to the institute as a whole, to provide incentives. However, we think it is very important in introducing such a major change in research incentives and culture to ensure that the social mission of a research institute is not compromised. The rationale for the Bayh-Dole Act was to promote faster technology transfer and application, rather than raise funds for public institutions and researchers. If the primary motive is financial, then the government may be tempted to reduce funding on the grounds that an institute has the capacity to generate alternative sources of funding. Alternatively, governments could offer to match additional funding generated through the licensing of IP. Either way, there is a danger that research priorities will adjust to focus on the largest potential markets which, in this case, will be the commercial agricultural sector, to the possible detriment of poorer farmers.

**Based on the above, we believe that there is a role for IP in public research institutions to promote the transfer and application of technologies. But it is important that:**

- **generating alternative sources of funding is not seen as the principal goal, which is rather to promote technology transfer.**
- **care be taken to ensure that research priorities, particularly as regards the technology requirements of the poor, be it in agriculture or health, are not distorted by the search for a larger licensing income.**
- **patenting and licensing should only be undertaken where it is judged necessary to encourage private sector development and the application of technologies.**
- **careful consideration be given to the need to take out "defensive" patents on important inventions, particularly for use as a bargaining tool where complementary technologies are owned by private sector entities and cross-licensing may be required to access those technologies.**
- **expertise in IP is developed in public sector institutions which traditionally have had none, but without losing sight of the objectives of public policy for research.**

# HOW THE PATENT SYSTEM MIGHT INHIBIT RESEARCH AND INNOVATION

## The Issues in Developed Countries

As the patent system has been applied to new fields of technology, we have seen that the primary issue is whether the balance between stimulating genuine invention of useful technologies, and protecting minor and intermediate technologies or processes that can hinder research by others can be attained. Many argue that the standards of patenting, particularly in the US, have been excessively lowered so that too many patents are issued for inventions that are trivial; or, because of pressures on patent examiners, too many patents are issued that will not prove valid in the courts if challenged.<sup>52</sup>

The problem in the US has been described thus:

"...our patent system, while surely a spur to innovation overall, is in danger of imposing an unnecessary drag on innovation by enabling multiple rights owners to "tax" new products, processes and even business methods. The vast number of patents currently being issued creates a very real danger that a single product or service will infringe on many patents. Worse yet, many patents cover products or processes already being widely used when the patent issued, making it harder for the companies actually building businesses and manufacturing products to invent around these patents. Add in the fact that a patentee can seek injunctive relief, i.e., can threaten to shut down the operations of the infringing company, and the possibility for "hold up" becomes all too real."<sup>53</sup>

This may lead to behaviour by companies or public institutions that appears perverse from a social point of view. Organisations may patent in order to prevent others gaining access to areas of research, or to ensure that other organisations cannot block their research. They may also develop patent portfolios as a bargaining tool, with which to obtain access to technologies owned by other companies, through cross licensing. This is particularly a feature of small high technology companies. We note in Chapter 3 the importance of this kind of strategy in the agricultural biotechnology sector, and the extent to which it could result in costly patent disputes and litigation, and have possible implications for competition and concentration.

The problem was well put recently by an executive from CISCO in a submission to the US Federal Trade Commission:

"So obtaining patents has become for many people and companies an end in itself, not to protect an investment in research and development, but to generate revenue through licensing ("holding up") other companies that actually make and sell products without even being aware of their patents. They try to patent things that other people or companies will unintentionally infringe and then they wait for those companies to successfully bring products to the marketplace. They place mines in the minefield. The people and companies...who file these patents and extract license fees from successful businesses play the patent system like a lottery...The long delays in the patent office work to their benefit by keeping the eventual coverage of their patents indefinite while others produce products. They benefit from the high cost of litigation by demanding license fees that are less than the cost of litigation, hoping that people will pay even if they don't infringe, or, if they do infringe, it will be too costly to change the product. This provides opportunities for contingency fee litigators, for licensing companies and consulting firms who claim to help people 'mine' their patent portfolios for patents that even they didn't know they had. It's hard to see how this contributes to the progress of science and the useful arts."<sup>54</sup>

Of course, it is argued by some that this situation is a price that needs to be paid for the incentive effect of patents and that licensing strategies can be pursued to mitigate the most serious adverse effects. However, while there may be debate about the scale of the problem, and the degree of inhibition on research incentives, our principal concern is that developing countries avoid where possible the creation of similar problems in their own IPR regimes.

The problem of research tools applies both in the public and private sectors. Research tools have been defined as embracing “the full range of resources that scientists use in the laboratory, while recognizing that from other perspectives the same resources may be viewed as “end products.”<sup>55</sup> In the public sector, these are seen as a problem particularly, for example, when one university wishes to access the patented technology of another for research, which some see as perverse when both are publicly funded. But this is a logical consequence of introducing patenting into the university arena. And the potential problem exists in all directions. Universities may wish to access private sector technologies, and vice versa. As we have seen, private sector companies may experience difficulties in accessing each others’ technologies which leads to a number of defensive strategies in an attempt to overcome them.

Recent research in the US suggests that, although there has been an increase in the patenting of research tools (such as gene sequences) required for drug discovery, it is not obvious that drug discovery has been substantially impeded.<sup>56</sup> Various strategies have been adopted to mitigate the potential problems. These include taking out licences on patents that may block research, inventing around patents, shifting to areas of research where there is more freedom to operate, moving research offshore, or simply infringing (or informally invoking a research exemption). Thus organisations have generally found a way around the problems. Nevertheless the transactions costs of undertaking research have been increased and delays incurred. Patents which prevent access need to be identified, negotiations held with relevant parties and licensing and legal costs incurred. However, adaptive changes have occurred in the institutional environment. As mentioned, the USPTO has issued new guidelines on patenting that raise the utility barrier for gene patents.<sup>57</sup> The NIH have also introduced new guidelines that are designed to mitigate problems in biomedical research.<sup>58</sup> The research referred to here concluded that, while there were social costs arising from research tools, these were unlikely to outweigh the positive incentive benefits from protection of research tools.<sup>59</sup>

## The Relevance to Developing Countries

Of course, this does not mean that it would not be desirable to reduce social costs arising from research tools if the benefits of the system are adversely affected. As we have noted above, developing countries can mitigate these problems by adopting an appropriate patent system, with limitations on the patenting of genes and appropriate exemptions for research. But this will not wholly address the problem. Much research relevant to developing countries may be carried out in developed countries, or in collaborative efforts with developed country researchers. In those circumstances, the rules applying in developed countries will be relevant.

While at the aggregate level the overall impact of patents on research tools may not be substantial, many research priorities relevant to developing countries are directed in relatively narrow fields of research where circumventing a problem created by research tools may be difficult. One example of this, which relates the general problem to that of developing countries is the patent on the CCR5 receptor that was subsequently identified as being important in transmission of the HIV/AIDS virus. We have also considered in some depth a case involving the use of patented DNA sequences for research on malaria. The Malaria Vaccine Initiative (MVI) has identified a particular protein antigen (MSP-1) which may be crucial to the development of an effective vaccine for malaria. The ownership of patents relating to this protein was investigated, uncovering some surprising findings:

- The patenting of the DNA sequences for the antigen is very complex. There are up to 39 patent families that are potentially relevant in developing the vaccine from MSP-1.
- At the early stage of research on MSP-1, patents were granted on the basis of science that subsequent research found to be unsound.
- The citing of prior art in many patent applications appears incomplete, so that it is difficult to relate one patent to another.
- On that basis, a number of the patent claims made may be invalid (which is only verifiable through legal means or re-examination). In general, the scope of claims made (which determines the potential for infringement) appear broader than they should be.<sup>60</sup>

## Box 6.2 The CCR5 Gene Patent

The US company Human Genome Sciences Inc. (HGS) isolated the CCR5 gene during its sequencing of the human genome. The company searched databases for homologues with known genetic sequences and concluded that they had found a gene belonging to the family of cell receptors, and applied for a patent.

In February 2000, HGS was issued US patent No. 6,025,154 for “Polynucleotides Encoding Human G-Protein Chemokine Receptor HDGMR10 (now called CCR5)”, which contained a broad claim covering the gene and all medical applications, such as therapies to block or enhance the receptor function.

Later, scientists from several academic centres (including the Aaron Diamond AIDS Research Centre and the National Institutes of Health) found that the CCR5 gene makes a receptor protein that the HIV virus uses to gain access into an immune cell.

The receptor is a membrane-spanning molecule found on the surface of cells in the immune system, binding them to the site of tissue damage or disease. The HIV virus takes advantage of these receptors to bind and gain access to the cell.

A certain CCR5 gene mutation, containing a 32-base pair deletion, causes a shift in the reading frame of the bases in the DNA sequence. This results in the receptor protein being severely truncated and unable to reach the cell surface, thus preventing the HIV virus from infecting the cells or slowing the rate of infection.

Individuals with the CCR5 gene mutation are much less vulnerable to HIV infection. The gene could be the means to identify a new class of treatment for HIV/AIDS patients, such as a drug that could block the receptor protein.

At the time when HGS isolated the CCR5 gene and applied for its patent, the company was unaware that the receptor was one of the entry points for the HIV virus into human cell. However, the broad scope of the patent claims means that HGS have rights over any use of the gene, thus enabling them to claim royalties through licensing contracts.

Although HGS has in fact already agreed to several licences for the use of the CCR5 receptor gene in research into new drugs, the example illustrates the possible dangers of granting patents on inventions which are in reality little more than discoveries in which the use claimed is merely speculative and based on an incomplete knowledge of the function of the gene.

Faced with such a situation, a commercial research organisation might decide to shift to another area of research. In the case of MVI (which was established with charity funding to accelerate the development of malaria vaccines), there is little choice but to seek to understand and manage the complexity, with the high transactions costs (both time and money) that this involves. In doing this, MVI has found that, although the malaria vaccine is unlikely to be of significant commercial value, holders of intermediate patents often put an unrealistically high value on their technologies. This can be addressed by assigning a share of royalties to intermediate patentees but this in turn creates a possible problem of “royalty stacking”, where the royalties that need to be paid to intermediaries may be excessive in relation to the royalties received on the final product.

In agriculture, similar problems have arisen. These have occurred mainly in the context of the CGIAR. The main problem has arisen in respect of accessing specific technologies that the CGIAR centres require to undertake research.<sup>61</sup> In several cases the central issue has concerned the terms on which the patent owners will provide licences. These include agreements which specify that a technology can be used for “research only” and “reach through” conditions that have implications for any new inventions which are developed through the application of the technology. In one case, a licence took several years to negotiate because the patent owner had provided an exclusive licence to one company. In another, the licensing terms demanded for access to a proprietary database of the genome of a rice variety were unacceptable. CGIAR has also experienced restrictions, or excessive costs, in accessing scientific databases it needs for its work. These problems have been exacerbated since the EU Database Directive came into force. Finally, there is the well known case of Golden Rice (see Box 6.3).

### Box 6.3 Golden Rice

Crops grown for subsistence or sold to poor consumers in developing countries are of little commercial interest to multinational companies, and there have been cases of companies granting royalty-free licences to agricultural research institutions in the public sector working with their patented technologies on behalf of poor farmers in the developing world. The Golden Rice case is a well known example.

Golden Rice contains enhanced levels of vitamin A. This has the potential to provide great benefit to health in developing countries where 100 million people (mainly children) suffer vitamin A deficiency (a condition which causes blindness). In August 1999, collaborating on a Rockefeller Foundation funded research project, scientists Ingo Potrykus (Swiss Federal Institute of Technology) and Peter Beyer (University of Freiburg) succeeded in inserting three genes – two from daffodils, one from a bacterium – into the rice genome so that beta carotene, the precursor of vitamin A, was expressed in rice grain.

However, according to a 2000 ISAAA report,<sup>62</sup> there were 70 process and product patents associated with the Golden Rice technology; the genes and methods used were the intellectual property of 32 companies and universities. The legal complexities of navigating this complex of patents, so that the rice could be further developed, tested and marketed, proved highly onerous for the scientists who, in May 2000, negotiated a deal with AstraZeneca (now part of Syngenta, the world's largest agricultural biotechnology company).

Syngenta acquired the rights to Golden Rice, allowing the company to exploit the commercial potential of the technology, and in return, agreed to allow distribution of the rice on a royalty-free basis to farmers who earn less than \$10,000 per year and live in developing countries. They then continued to collaborate throughout the year 2000, contacting the companies (including Bayer and Monsanto) holding patents key to the Golden Rice technology, to secure similar royalty-free licence ‘donations’.

However, in countries where a technology is not subject to local IP protection, anyone is free to use it, irrespective of whether it is for subsistence or commercial purposes and whether the technology has IP protection elsewhere. Further investigation of the IP rights surrounding the technology, indicates that most developing countries have few or no patents associated with Golden Rice.<sup>63</sup> Therefore researchers and farmers in these countries would have been free to develop, grow and sell Golden Rice without infringing IPRs or risking legal action anyway, regardless of the highly publicised licence donations of the multinationals. Of course, the story will be different for producers wishing to export to markets where the technology is subject to patent protection.

The case of Golden Rice also illustrates the prevalence of misunderstandings about the territorial nature of IP rights. Researchers in national or international research centres located in developing countries may worry unnecessarily about patents on technologies that are valid abroad, but which do not apply in the country where the centre is located. In some cases their concern may derive from a desire not to antagonise either suppliers of technology whose knowledge and skills may be needed, or developed country donors whom they may perceive as wishing to protect IP rights.

There are a number of continuing initiatives, which seek to identify the mutual self-interest of different parties in ways that minimise problems of access to protected technologies, and to lower transactions and other costs. Pharmaceutical companies, although greatly concerned about patents on their marketed products, are generally keen to avoid patenting of technologies which impinge on their research work. Thus, in 1999, ten large pharmaceutical companies and the U.K. Wellcome Trust established a consortium<sup>64</sup> to find and map 300,000 common SNPs.<sup>65</sup> This has generated a widely accepted, high-quality, extensive, publicly available map using SNPs as markers evenly distributed throughout the human genome, many of which will be used to locate targets for drug research. More recently, the International Genetics Consortium,<sup>66</sup> backed by a broad group of pharmaceutical companies, universities and foundations, has announced the building of a major facility to perform large-scale gene sequence expression on tissue samples, beginning with a major project on cancer. Again, the results will be made public.

A number of public-private partnerships (PPP) have developed IP strategies that seek to reconcile the interests of patent owners with the objective of making products available at affordable prices in the developing world. These usually involve contractual arrangements relating to any intellectual property that might be created. For instance, rights to commercialise in the developed world market may be assigned to a commercial partner in return for a royalty-free licence to the developing world for the PPP entity. Numerous other strategies can be considered to balance the objectives of the PPP entity against the need to provide meaningful incentives to the commercial partner. Considerable expertise in these areas has been developed, amongst others, by the Global TB Alliance, the International Aids Vaccine Initiative, and the Medicines for Malaria Venture.<sup>67</sup> A new institution, the Centre for the Management of Intellectual Property in Health Research and Development (MIHR), is being established which would seek to elaborate “best practices” in this field and provide training and support services.

In the agricultural field, there are two organisations offering similar support and information services in IP for biotechnology for the benefit of developing countries. CAMBIA in Australia is, inter alia, developing user-friendly databases which will allow researchers more easily to identify the relevant patents in their field of interest.<sup>68</sup> The International Service for the Acquisition of Agri-biotech Applications (ISAAA) is a not-for-profit organisation that aims to deliver the benefits of new agricultural biotechnologies to the poor in developing countries. It is sponsored by public and private sector institutions and has the objective of transferring and delivering appropriate biotechnology applications to developing countries and the building of partnerships between institutions in the South and the private sector in the North, and by strengthening South-South collaboration.<sup>69</sup> Proposals have been made for further initiatives to facilitate the acceleration of biotechnology research in agriculture.<sup>70</sup>

**There is a need for the further development of institutions and strategies such as these which will seek to facilitate the development and acquisition of technologies required for research relevant to developing countries, seek to use the opportunities offered by IP to best advantage, and also help resolve the difficulties associated with the proliferation of patents on research tools. We also consider it important that, in developing such initiatives, attention continues to be paid to opportunities to improve patent systems, in both developed and developing countries, to obviate some of the problems these initiatives are seeking to address. The rules of the game, as well as the way it is played, are both important considerations for developing countries.**

# INTERNATIONAL PATENT HARMONISATION

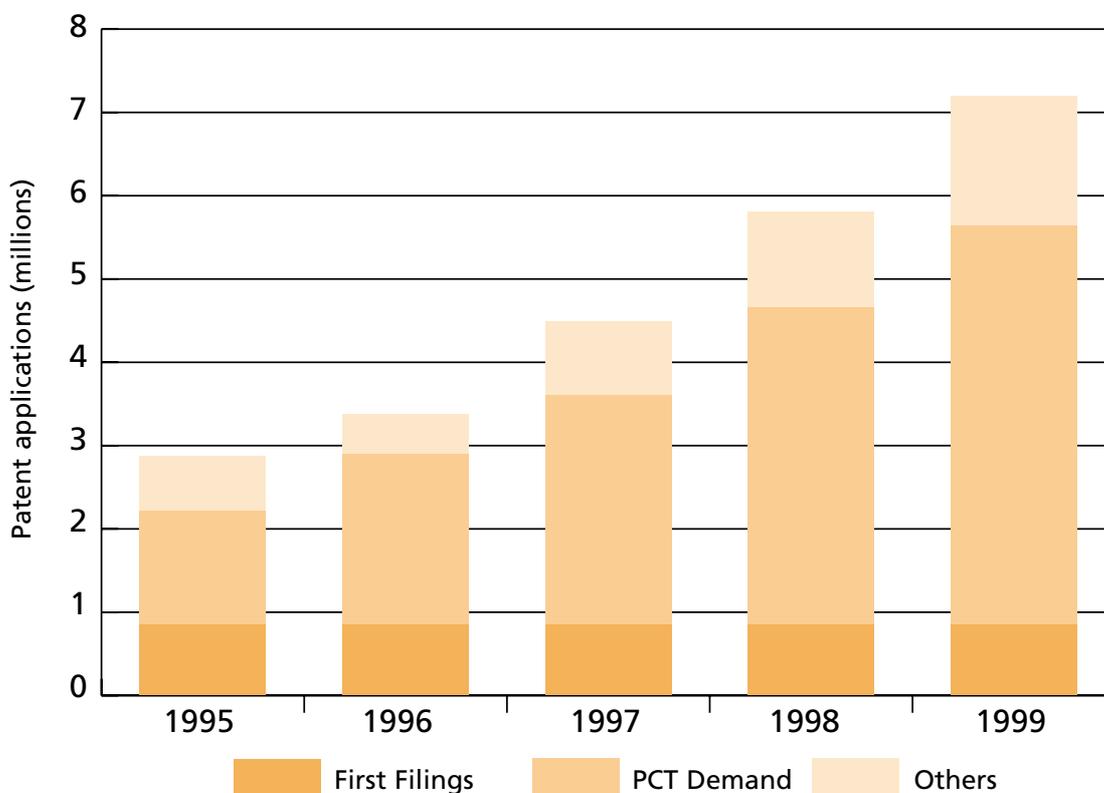
## Background

The growing internationalisation in trade coupled with the greater international harmonisation of patent laws and practices and the simplification of the application procedure under the PCT system has led to a rapid increase in the number of patent applications. The rise in demand shown in Figure 6.1 has continued into the 21st Century.

This surge in demand has led, unsurprisingly to an increase in the backlog of unprocessed patent applications in the patent offices and an increase in the time taken to obtain a patent. For instance, the average time in the Chinese Patent Office is now about 46 months, and similar to that in other large offices. In the short term, all the major patent offices are recruiting numbers of new patent examiners (the USPTO hired 460 new examiners in 2001 and is expecting to hire about 600 in 2002). Even where new examiners have been appointed, it is still unlikely that the patent system will satisfy the demands for quick and relatively inexpensive delivery of high quality patents.

In the short to medium term, it is likely that patent offices will begin to recognise work done by other offices on corresponding applications (applications essentially claiming the same subject matter). For example, if a patent is filed and searched in the US, then a corresponding filing at the EPO might not require a further search by the EPO but could instead rely on the search performed by the US. The advantages in terms of reduced cost to the applicant and less work for the offices makes such mutual recognition of work attractive to all.

**Figure 6.1 The Demand for Patent Rights Worldwide 1995-1999**



Reproduced from the EPO/JPO/USPTO Trilateral Website.  
Source: <http://www.jpo.go.jp/saikine/tws/tsr2000/graph3-1.htm>

At the WIPO Conference on the International Patent System in March 2002,<sup>71</sup> it was clear that the issue of mutual recognition was attracting greater attention. Comparisons of the quality of searches provided by the major offices are being undertaken and it seems inevitable that some form of mutual or unilateral (where a country decides simply to accept the results of a search performed by another office) recognition of searches between the major offices will occur soon. However, major differences in patentability requirements, especially in the high technology areas such as biotechnology and computer software, means that mutual recognition of examination reports amongst the major patent offices may require further harmonisation. Such harmonisation may also provide a small but important step towards the holy grail of some in the patent world, a single world patent valid anywhere in the world.

## WIPO Substantive Patent Law Treaty

Discussions on the further harmonisation of substantive patent law are currently in progress within WIPO and we have already had a foretaste of what might be the outcome of these discussions. In 1991, a substantive patent law treaty was almost agreed in WIPO. Whilst developing countries made a number of proposals during the negotiations, the final treaty was essentially a hybrid of the laws prevailing in a number of developed countries, in particular the US and the EU. As the delegate of one developing country noted, there was a paradox that through a harmonisation process, the majority of the countries were being asked to align their law with the provisions of a minority.

Failure of those negotiations was, however, followed closely by agreement on the text of the TRIPS Agreement that went a considerable distance in harmonising substantive patent law around the world. But even with TRIPS, differences remain between the patent laws in many countries, including between the US and EU. The new discussions in WIPO, which commenced in early 2001, are seeking to remove these differences. But what form is any treaty likely to take and how should developing countries approach these discussions?

Although discussions are at an early stage, it seems likely, based on the drafts already produced by WIPO<sup>72</sup> and indications from some of the leading nations, that any treaty will be based essentially on a first-to-file system<sup>73</sup> in combination with a suitable grace period. It is also possible that attempts will be made to remove a significant number of the flexibilities currently provided by TRIPS that we discussed above. For example, the treaty might seek to qualify what constitutes a patentable invention and how the requirements of novelty, inventive step and industrial application are to be determined.

Clearly for developing countries the concern must be to ensure that these flexibilities are not surrendered unless it can be shown it is in their interests to adopt new international rules further limiting their freedom to design appropriate IP policies. We have suggested above the sort of patent system that we believe would be appropriate to the interests of developing countries. Developing countries, as we explain in Chapter 7, face formidable obstacles in implementing patent systems. If they seek to adopt more strict patenting standards, the institutional and administrative problems are likely to prove even more burdensome.

**Developing countries should identify a strategy for dealing with the risk that WIPO harmonisation will lead to standards that do not take account of their interests. This could be done by seeking a global standard reflecting the recommendations of this report; it could be done by seeking continued flexibility in the WIPO standards; it could be done by rejection of the WIPO process if it appears that the outcome will not be in the interests of developing countries.**

But we believe many of our suggestions for improving the patent system also have relevance to developed countries, precisely because of the concerns about the system being overloaded with the processing of patent applications, a significant proportion of which would probably not be patentable under our proposed reforms.

The discussions on patent reform and harmonisation have so far concentrated on how to improve the efficiency of the current global patent system by streamlining procedures, eliminating duplication and pursuing harmonisation more generally.<sup>74</sup> But little thought has been given to the quality of patents issued, the resources tied up in enforcing and challenging patent rights, and the extent to which the benefits of the system in encouraging technical progress outweigh its economic, administrative and enforcement costs. The ever-expanding demand for patents is regarded as a right which has to be met by increasing the productivity of the granting process at the expense of a possible further reduction in quality. We believe that policy makers in both developed and developing countries should seek to tip the balance away from quantity and back towards quality. Fewer and better patents, which retain their validity in the courts, would in the longer term be the most efficacious way of both reducing the burden on the major patent offices and, more importantly, securing widespread support for the patent system.

<sup>1</sup> Although this was a landmark case, processes involving living organisms and isolated versions of natural products had been patented previously. Nuffield Council on Bioethics (2002) *"The Ethics of Patenting DNA: A Discussion Paper"*, Nuffield Council on Bioethics, London, pp.23-28.

Source: <http://www.nuffieldbioethics.org/filelibrary/pdf/theethicsofpatentingdna.pdf>

<sup>2</sup> National Science Foundation (2002) *"Science and Engineering Indicators 2002"*, NSF, Washington DC, Chapter 4, Appendix Table 4.6.

Source: <http://www.nsf.gov/sbe/srs/seind02/c4/c4s1.htm>. Patent data from USPTO.

Source: [www.uspto.gov](http://www.uspto.gov)

<sup>3</sup> This draws on Merges, R. & Nelson, R. (1990) "On the Complex Economics of Patent Scope", *Columbia Law Review*, vol. 90, pp.839-916. Source: <http://sp.uconn.edu/~langlois/E382/Scope.html>

<sup>4</sup> Letter to Robert Hooke, 5 February 1676

<sup>5</sup> Merges and Nelson (1990), p.916

<sup>6</sup> See Glossary for definition.

<sup>7</sup> National Science Foundation (2002) Chapter 5. Source: <http://www.nsf.gov/sbe/srs/seind02/c5/c5h.htm>

<sup>8</sup> Rent-seeking is a term used by economists to indicate how participants in markets may experience perverse incentives (from a social point of view) created by the "monopoly rents" resulting from various government interventions in the market. IPRs are one example of such an intervention. The seminal text is: Krueger, A (1974) *"The Political Economy of the Rent-Seeking Society,"* *American Economic Review*, 291-303 Vol. 64 (3) pp. 291-303.

<sup>9</sup> Reichman, J. (1997) "From Free Riders to Fair Followers: Global Competition under the TRIPS Agreement", *NYU Journal of International Law and Politics*, vol. 29.

Source: <http://www.nyu.edu/pubs/jilp/main/issues/29/b.html>

<sup>10</sup> See TRIPS Article 27(1). Source: [http://www.wto.org/english/tratop\\_e/trips\\_e/t\\_agm0\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm)

<sup>11</sup> For example UNCTAD (1996) "The TRIPS Agreement and Developing Countries", UNCTAD, Geneva, Doc. No. UNCTAD/ITE/1; Correa, C. (2000) *"Intellectual Property Rights, The WTO and Developing Countries"*, Zed Books, London & Third World Network, Penang; Heald, P. (2002) "Intellectual Property Strategies for Developing Countries: Flexibility, Leverage, and Self Help Within the Framework of the TRIPS Agreement" (mimeo).

<sup>12</sup> TRIPS Article 27(1).

<sup>13</sup> For example Article 54(5) of the EPC provides that the novelty requirement will not prevent the patenting of any substance or composition, comprised in the state of the art, for use in a method referred to in Article 52, paragraph 4, provided that its use for that method is not comprised in the state of the art. The Courts have further held that second and further medical uses of known compounds are also allowed. In reaching these decisions the Courts have taken "a special view of the concept of the state of the art", EPO Decision G83/0005.

Source: <http://www.european-patent-office.org/legal/epc/gdehtml/en/g583.htm>

<sup>14</sup> As allowed under TRIPS Articles 27(3)(b) and (a) respectively

<sup>15</sup> Article 15(b) of Decision 486 of the Common Intellectual Property Regime of Andean Community.

Source: <http://www.comunidadandina.org/ingles/treaties/dec/D486e.htm>

<sup>16</sup> We have received submissions on this subject from a number of NGOs who would like amendments to TRIPS as regards the patenting of living things.

- <sup>17</sup> Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, *Official Journal* L 213, 30 July 1998, p.13-21.  
Source: [http://europa.eu.int/smartapi/cgi/sga\\_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31998L0044&model=guichett](http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31998L0044&model=guichett)
- <sup>18</sup> Articles 5 and 6 of the EU Biotechnology Directive (EU Directive 98/44) restricts patenting relating to human and animal genetic material.
- <sup>19</sup> Article 56 EPC, 35USC S103. Under the EPC, a person skilled in the art is presumed to be an ordinary practitioner aware of what was common general knowledge in the art but who is incapable of inventive activity. Canadian practice refers to a person "skilled in the art but having no scintilla of inventiveness or imagination; a paragon of deduction and dexterity, wholly devoid of intuition; a triumph of the left hemisphere over the right." *Beloit Canada Ltd v Valmet OY* 1986, 8 CPR (3d) 289
- <sup>20</sup> Barton J. (2001) "Non-Obviousness" (work in progress).  
Source: <http://emlab.berkeley.edu/users/bhahall/ipconf/Barton901.pdf>
- <sup>21</sup> USPTO Utility Examination Guidelines Federal Register vol. 66 No 4 January 5, 2001.  
Source: <http://www.uspto.gov/web/offices/com/sol/notices/utilexmguide.pdf>
- <sup>22</sup> EPO Opposition Decision revoking EP0630405 (ICOS Corporation) 20 June 2001 (Unreported).
- <sup>23</sup> The UK Patent Office Manual of Patent Practice Section 14.143.  
Source: [http://www.patent.gov.uk/patent/reference/mpp/s14\\_16.pdf](http://www.patent.gov.uk/patent/reference/mpp/s14_16.pdf)
- <sup>24</sup> *Biogen Inc v Medeva plc* House of Lords [1997] RPC 1
- <sup>25</sup> Nuffield Council on Bioethics (2002) pp.73-74.
- <sup>26</sup> In Japan, any person may file an opposition against the grant of patent within six months of the date of publication of the grant. Before the EPO, the period for filing opposition begins after granting of the patent rights and lasts nine months. Before the USPTO a re-examination of a patent may be requested where significant questions of patentability arise at any time during the life of the patent. Pre grant opposition procedures exist in Indonesia under article 45 of their patent law (No. 14, 2001) and in the Andean Communities under article 42 of Decision 486, of 14 September 2000.
- <sup>27</sup> Scherer, F.M. (2001) "The Patent System and Innovation in Pharmaceuticals", *Revue Internationale de Droit Economique*, (Special Edition, "Pharmaceutical Patents, Innovations and Public Health"), p.119.
- <sup>28</sup> For example Articles 48 and 49 of the Chinese Patent Law 2000 provides that a compulsory licence may be granted to an entity who has made requests for authorization from the patentee of an invention to exploit his patent on reasonable terms and conditions and such efforts have not been successful within a reasonable period of time or where the public interest so requires.
- <sup>29</sup> Egypt draft law as notified to the WTO in document IP/CW/278  
Source: <http://docsonline.wto.org/DDFDocuments/t/IP/CW278.doc>; Jamaica's draft law as notified in IP/N/1/JAM/I/1  
Source: <http://docsonline.wto.org/DDFDocuments/t/IP/N/1/JAM/I1.doc>
- <sup>30</sup> A WTO DSP procedure (IP/D/23) that might have clarified the compatibility of a local working requirement with TRIPS was terminated before a panel was able to give an opinion.  
Source: <http://docsonline.wto.org/DDFDocuments/t/G/L/385.DOC>  
Source: <http://www.iavi.org/press/63/p20010824a.asp>
- <sup>31</sup> Source: <http://www.iavi.org/press/63/p20010824a.asp>
- <sup>32</sup> Correa, C. (forthcoming) "Protection and promotion of traditional medicine" South Centre, Geneva.
- <sup>33</sup> TRIPS Article 62 allows Members to require, as a condition of the acquisition of IP rights, compliance with reasonable procedures. In the WTO Dispute Settlement Case on Section 211 of the US Omnibus Appropriations Act, the panel noted that TRIPS does not prohibit Members from denying the registration of a trademark on the grounds that the applicant is not the owner of the trademark as defined in their respective domestic legal system (paragraph 8.56 of WTO Document No. WT/DS176/R). This would appear to apply equally in respect of patents.
- <sup>34</sup> WIPO currently identify 49 countries providing such protection.  
Source: [http://www.wipo.int/sme/en/ip\\_business/utility\\_models/where.htm](http://www.wipo.int/sme/en/ip_business/utility_models/where.htm)
- <sup>35</sup> In some jurisdictions, for example, Germany, the level of inventive step required to obtain a petty patent is the same as that for a full patent.
- <sup>36</sup> See Chapter 1.
- <sup>37</sup> Reichman, J. (2000) "Of Green Tulips and Legal Kudzu: Repackaging Rights in Subpatentable Innovation", *Vanderbilt Law Review*, vol. 53, pp.1743-1798.  
Source: <http://law.vanderbilt.edu/lawreview/vol536/reichman.pdf>
- <sup>38</sup> See for example Article 76 of the Brazilian Industrial Property Law No 9279/96 of 1996 as amended.  
Source: <http://www.inpi.gov.br/idiomas/conteudo/law.htm>
- <sup>39</sup> State Intellectual Property Office, China (2001) "Annual Report 2000", SIPO, and Beijing, p.29.  
Source: [http://www.sipo.gov.cn/sipo\\_English/gftx\\_e/ndbg\\_e/2000nb\\_e/nbbg\\_2000\\_e/12-1-b2-e.htm](http://www.sipo.gov.cn/sipo_English/gftx_e/ndbg_e/2000nb_e/nbbg_2000_e/12-1-b2-e.htm)

- <sup>40</sup> "Chinese Institutes 'can keep intellectual property'", Jia Hepeng, 21 May 2000.  
Source: <http://www.scidev.net>
- <sup>41</sup> Information provided by WIPO, derived from 2001 application statistics.
- <sup>42</sup> Dasgupta, P. and David, P. (1994) "Towards a New Economics of Science", *Research Policy*, vol. 23, pp.487-521
- <sup>43</sup> Association of University Technology Managers (2002) "AUTM Annual Survey FY 2000: Summary", AUTM, Northbrook IL. Source: <http://www.autm.net/surveys/2000/summarynoe.pdf>
- <sup>44</sup> Mowery, D. et al (2001) "The Growth of Patenting and Licensing by US Universities: An Assessment of the Effects of the Bayh-Dole Act of 1980", *Research Policy*, vol. 30, pp.99-119.  
Source: <http://www.sipa.columbia.edu/RESEARCH/Paper/99-5.pdf>
- <sup>45</sup> National Science Foundation (2002), Appendix Table 4.04.  
Source: <http://www.nsf.gov/sbe/srs/seind02/append/c4/at04-04.xls>
- <sup>46</sup> Association of University Technology Managers (2002), p.10
- <sup>47</sup> Colyvas, J. et al (2002) "How Do University Inventions Get into Practice", *Management Science*, vol. 48, p.67  
Source: <http://www.vannevar.gatech.edu/pdfs%20of%20publications/mans126.pdf>
- <sup>48</sup> Colyvas, J. et al (2002)
- <sup>49</sup> Annual Report 2000, University of California, Office of Technology Transfer.  
Source: <http://www.ucop.edu/ott/ttimport.html>
- <sup>50</sup> National Science Foundation (2002), Chapter 5, Text Table 5-25.  
Source: <http://www.nsf.gov/sbe/srs/seind02/c5/c5h.htm>
- <sup>51</sup> Sampaio, M. and Brito da Cunha, E. "Managing Intellectual Property in Embrapa: A Question of Policy and a Change of Heart", in Cohen, J. (ed.) (1999) "Managing Agricultural Biotechnology: Addressing Research Program Needs and Policy Implications", ISNAR/CABI, The Hague, pp.240-248.
- <sup>52</sup> See the submission of David Martin to Congress Round Table Discussion on 10 May 2001, where he claims that over 30% of US patents may share one or more claims with other patents.  
Source: [http://www.house.gov/judiciary/martin\\_051001.htm](http://www.house.gov/judiciary/martin_051001.htm)
- <sup>53</sup> Shapiro, C. "Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting", in Jaffe, A., Lerner, J. and Stern, S. eds. (2001) "Innovation Policy and the Economy: Volume 1", MIT Press, Cambridge MA, p.3.  
Source: <http://haas.berkeley.edu/~shapiro/thicket.pdf>
- <sup>54</sup> Testimony on 28 February, 2002. Source: <http://www.ftc.gov/opp/intellect/barrrobert.doc>
- <sup>55</sup> National Institutes of Health (1998) "Report of Working Group on Research Tools", NIH, Washington DC.  
Source: <http://www.nih.gov/news/researchtools/>
- <sup>56</sup> Walsh, J. et al (2000) "The Patenting of Research Tools and Biomedical Innovation", National Academies of Sciences, Washington DC. Source: [http://www7.nationalacademies.org/step/Walsh\\_et\\_al\\_paper.pdf](http://www7.nationalacademies.org/step/Walsh_et_al_paper.pdf)
- <sup>57</sup> USPTO Utility Examination Guidelines Federal Register vol. 66 No 4 January 5, 2001.  
Source: <http://www.uspto.gov/web/offices/com/sol/notices/utilexmguide.pdf>
- <sup>58</sup> National Institutes of Health (1998); NIH Guidelines for Implementation, 1999  
(Source: [http://ott.od.nih.gov/NewPages/RTguide\\_final.html#guide](http://ott.od.nih.gov/NewPages/RTguide_final.html#guide)).
- <sup>59</sup> Walsh, J. et al (2000) p.31
- <sup>60</sup> Presentation given by Greg Galloway (Falco-Archer) to the Commission on Intellectual Property Rights Conference, London, 21-22 February 2002; and presentation given by Melinda Moree (PATH) to the Commission on Intellectual Property Rights Workshop on Research Tools, London, 22 January 2002. Source: <http://www.iprcommission.org>
- <sup>61</sup> Examples taken from presentation by Victoria Henson-Appolonio at Commission on Intellectual Property Rights Workshop on Research Tools, London, 22 January 2002. Source: <http://www.iprcommission.org>
- <sup>62</sup> Kryder, R., Kowalski, S. & Krattinger, A. (2000) "The Intellectual and Technical Property Components of Pro-Vitamin A Rice (Golden Rice): A Preliminary Freedom-to-Operate Review", ISAAA Briefs No. 20, International Service for the Acquisition of Agri-biotech Application, New York.  
Source: [http://www.isaaa.org/publications/briefs/Brief\\_20.htm](http://www.isaaa.org/publications/briefs/Brief_20.htm)
- <sup>63</sup> Pardey, P. et al (2000) "South-North Trade, Intellectual Property Jurisdictions and Freedom to Operate in Agricultural Research on Staple Crops", EPTD Discussion Paper No. 70, International Food Policy Research Institute, Washington DC. Source: <http://www.ifpri.cgiar.org/divs/eptd/dp/papers/eptdp70.pdf>
- <sup>64</sup> The SNP Consortium Ltd. Source: <http://snp.cshl.org/>
- <sup>65</sup> SNP is short for single nucleotide polymorphisms. These are alterations in the basic building block of DNA (the single base pair) which may be connected to the causation of diseases, or other genetic variations.
- <sup>66</sup> The International Genetics Consortium. Source: <http://www.intgen.org/>
- <sup>67</sup> Wheeler, C. & Berkley, S. (2001) "Initial Lessons from public-private partnerships in drug and vaccine development", *Bulletin of the World Health Organisation*, vol. 79:8.

Source: <http://www.who.int/bulletin/pdf/2001/issue8/vol79.no.8.728-734.pdf>

<sup>68</sup> Center for the Application of Molecular Biology to International Agriculture (CAMBIA).

Source: <http://www.cambia.org/>

<sup>69</sup> International Service for the Acquisition of Agri-biotech Application (ISAAA). Source: <http://www.isaaa.org/>

<sup>70</sup> Krattiger, A. (2002) "Public-Private Partnerships for Efficient Proprietary Biotech Management and Transfer, and Increased Private Sector Investments", *IP Strategy Today*, No. 4.

Source: <http://binas.unido.org/binas/reviews/Krattiger.pdf>

<sup>71</sup> WIPO Conference on the International Patent System, Geneva, 25-27 March 2002.

Source: <http://patentagenda.wipo.int/meetings/2002/program/index.html>

<sup>72</sup> Draft Substantive Law Treaty prepared by the International Bureau of WIPO (WIPO Document No. SCP/7/3).

Source: [http://www.wipo.org/scp/en/documents/session\\_7/pdf/scp7\\_3.pdf](http://www.wipo.org/scp/en/documents/session_7/pdf/scp7_3.pdf)

<sup>73</sup> A first to file system awards a patent to the first person to file the patent application. The vast majority of countries already operate such a system. The US by contrast employs a first-to-invent system whereby the patent belongs to the first person to make the invention.

<sup>74</sup> See "Agenda for Development of the International Patent System", Memorandum of the Director General, WIPO, 6 August 2001 (WIPO Document No. A/36/14).

Source: [http://www.wipo.int/eng/document/govbody/wo\\_gb\\_ab/pdf/a36\\_14.pdf](http://www.wipo.int/eng/document/govbody/wo_gb_ab/pdf/a36_14.pdf)

## INSTITUTIONAL CAPACITY



### INTRODUCTION

Developing countries face formidable institutional challenges in implementing IP protection, as required by TRIPS. Since the majority of developing countries with limited technological and scientific capacity have little to gain in the medium term from implementing TRIPS obligations, a major concern must be to limit the human and resource cost of establishing IP regimes. At the same time, these nations need to ensure that their national IP regimes operate in the public interest and are effectively regulated. The more technologically advanced developing countries will also want to ensure that their IP regimes complement and enhance their broader policies for encouraging technological development and innovation.

The challenges include formulating appropriate policy and legislation; administering IPRs in line with international obligations; and enforcing and regulating IPRs in a pro-competitive manner appropriate to national levels of development. Of course, many of these IP-related institutional and policy challenges are common to all countries but they are especially acute for many developing countries. And, importantly, the economic and regulatory context in developing countries in which IP regimes are being revised, in line with TRIPS, is often quite different from that in developed countries.

Difficult choices are involved. Should a developing country, for want of its own resources, be satisfied with re-registering patents because they have been granted in a developed country? Or should it attempt to develop national capacity in the examination of patents, in order to apply the different standards of patentability that we suggest may be appropriate? Under current circumstances, this is a very difficult task for the IPR administration institutions in most developing countries.

In this chapter we consider:

- What are the requirements for making effective IP policy and legislation in developing countries?
- How should developing countries approach the implementation of IP policy and enforcement of IP rights?
- How can developed countries and international institutions provide effective technical assistance to developing countries?

## IP POLICY MAKING AND LEGISLATION

As the majority of developing countries, including LDCs, are either members of the WTO or in the process of becoming so, implementation of TRIPS requires changes in industrial property and copyright legislation. In some areas the changes will be relatively minor. In others, entirely new legislation is required. Many developing countries have already amended their IP legislation to comply with TRIPS and meet their January 2000 deadline. A much smaller number of LDCs have so far completed the legal and institutional reforms required to put TRIPS into practice. In addition to TRIPS, those countries not already members of international treaties such as the Paris and Berne Conventions may choose to join and this will require further legislative changes.

Developing countries also face choices about other IP-related reforms such as design of appropriate protection systems for plant varieties and plant genetic material; whether and how to protect traditional knowledge within the formal IP system; and how to regulate access and implement benefit sharing for national biological resources as envisaged under the CBD. Few countries have so far passed legislation in these areas. Quite apart from legislative or capacity issues, this may also reflect a lack of political consensus on which policies to adopt. In addition to amending IP-related legislation, developing countries also have to consider complementary reforms in related areas of the domestic regulatory environment, such as science and technology policy and anti-trust legislation.

### Integrated Policy Making

In many cases, developing countries face particular difficulties in developing a comprehensive and co-ordinated policy on IP, in what is, for many, a relatively new area of public policy.<sup>1</sup> The impetus for policy changes in IP typically comes from international agreements to which the country is signatory, without necessarily having a coherent idea of how they can be implemented nationally (for example, TRIPS or the CBD). Within government, IP is a classic “cross cutting issue” affecting the interests of several government departments who will have different positions which will need to be reconciled. Typically, industry groups and other civil society organisations with a particular interest or view on the matter will also lobby departments. Moreover, some foreign governments may exert formal or informal pressure where they see their interests as being at stake. Thus the policy making process is complicated.<sup>2</sup> Ideally, formulation of IP policy in a developing country would be based on a sound appreciation of how the IP system might be used to promote development objectives, derived from an analysis of the country’s industrial structure, modes of agricultural production, and healthcare and education needs. But the expertise and the evidence necessary to undertake that task is often in very short supply.

The reality in many developing countries is that institutional capacity is generally weak, and in particular there is a lack of experienced and well-qualified officials. In the majority of developing countries there is considerable dependence on technical assistance, in the form of draft laws, expert advice and commentary on new draft legislation, provided by WIPO and other bodies.<sup>3</sup> In the words of one commentator:

“LDCs in particular do not have local experts to evaluate the suitability of model international laws to local economic, social and cultural conditions. LDCs often lack drafting expertise and are reliant upon outside legal drafters, who may be brought in from those western legal systems to which the LDC has historical links as consultants or on contract basis for a set period. The problem is especially acute in the case of IP since there are very few people who possess both the specialised technical skills of legislative drafting, as well as expertise in IP law.”<sup>4</sup>

Thus, because the policymaking process is complex and technical, governments may seek to short circuit the process, particularly in the face of international agreed deadlines. They may therefore leave it to their own IP experts, if available, to construct legislation with minimal intra-government consultation. Or they may rely on foreign expertise. Either way the consistency of the IP legislation with development policies may not be subject to adequate scrutiny.

The ability of developing countries to co-ordinate policy across government in undertaking IP-related reforms is therefore crucial. The evidence suggests that some countries have established mechanisms to improve the co-ordination of policy making and advice, with the main participants being the key ministries most involved i.e. health, justice, science, environment, agriculture, education or culture (for copyright and related rights). However, these mechanisms are often only embryonic and their degree of effectiveness is yet to become apparent – particularly in respect of integration of IP issues with other areas of economic and development policy. In many cases, this may reflect the fact that such co-ordinating bodies are not able to draw readily on a supply of the necessary technical advice and expertise, but it will also reflect divergent interests within government.

### **Box 7.1 Participatory Policy Making in Action: South Africa**

Since the late 1990s, the South African Government has been considering reforms to the country’s copyright legislation. In the past, the publishing industry was the main interest group participating in the process of influencing government policy on copyright. However, in recent years, the educational sector has played an increasingly active role, calling for amendments to the law to address electronic copyright and to make provision for distance education, special educational programmes and the needs of disabled people (for example, the blind).

In 1998, the Department of Trade and Industry published Draft Regulations to amend the current Regulations attached to the Copyright Act. The educational sector responded by setting up a Copyright Task Team, under the auspices of the South African Vice-Chancellors’ Association (SAUVCA) and the Committee of Technikon Principals (CTP). Stakeholders were invited to present position papers on the Draft Regulations and then to submit comments on them. As the Draft Regulations were restrictive to education, the Copyright Task Team submitted a consolidated document of comments and objections from the educational sector. As a result, the Draft Regulations were suspended.

In May 2000, the Department of Trade and Industry again published proposals to amend the Copyright Act. The SAUVCA/CTP Electronic Copyright Task Team was established to address the proposed amendments, as well as other issues not included in the proposals (e.g. those mentioned above). The proposed amendments were again restrictive to education. After the said Task Team held discussions with four Government Departments, namely, Trade and Industry; Education; Communication; and Arts, Culture, Science and Technology, a number of the more contentious amendments were withdrawn.

In January 2001, both Task Teams were disbanded to create two more permanent Intellectual Property Committees to represent the educational sector, namely, the SAUVCA IP Committee and the CTP IP Committee. These Committees have since held discussions with the Department of Trade and Industry, the Publishers’ Association of South Africa, the International Publishers’ Association and the Business Software Alliance. The SAUVCA IP Committee is currently preparing a working document on “fair use” and “multiple copying for educational purposes,” for further discussion with stakeholders.

An under-emphasised aspect of IP reform in developing countries is the importance of the policymaking process itself, and the capacity for stakeholders, in government and outside, to participate in shaping policy and new laws. At one extreme, a country such as India has a broad-based, extensive system for public consultation and debate (including public workshops on controversial topics such as protection of biodiversity and traditional knowledge), as well as a high level of expertise within the academic, business and legal communities. At the other, in one sub-Saharan African developing country we reviewed, new copyright legislation was passed after just a technical drafting process with minimal public consultation or debate.

Developing countries such as Kenya, for example, which have longer traditions of IP policy making and a larger constituency of IP lawyers, academics and interested civil society organisations, are somewhere in the middle of this spectrum. During our visit, for example, we were able to meet the recently established TRIPS sub-committee responsible for considering how Kenya implements the TRIPS Agreement. This sub-committee included representatives from various government departments as well as from the private sector. In many developing countries, however, we believe there is still substantial room for improvement in terms of building a genuinely participatory process for IP policy reform. This objective should be given more emphasis by governments and donors alike.

**Developing countries and donors should work together to ensure that national IP reform processes are properly “joined-up” with related areas of development policy. Likewise, greater efforts are needed to encourage more participation by national stakeholders in IP reforms. In providing technical assistance, donors must be mindful of the need to help build the capacity of local institutions to undertake IP policy research and dialogue with stakeholders, in addition to providing international experts and legal advice.**

## IPR ADMINISTRATION AND INSTITUTIONS

### Introduction

There is very wide variation in the volumes of IPR applications and grants processed by developing countries (see Table 7.1.) and this has an important bearing on the institutional requirements for IPR administration. Applications are in part determined by whether the country is a member of the PCT or other international arrangement or of a regional organisation. But in most developing countries only a very small proportion of applications made under these agreements currently enter the “national phase” where substantive grant and registration takes place. Other factors include differences in national IP laws and regulations (which may be more or less attractive to applicants) and the IP policies of multinational corporations.

A WIPO study in 1996<sup>5</sup> surveyed 96 developing countries and found that in over two-thirds of the sample, administration of industrial property was performed by a department within a ministry of industry and trade, or a ministry of justice. In 10 countries, an independent government agency was responsible for administration of industrial property. The administration of copyright was performed by a department in a ministry of education or culture in a third of the sample and by an independent copyright agency in 15 cases. Interestingly, in another third of the countries sampled, there was no special unit identified at all within the government with responsibility for copyright administration.

But there appears to have been a significant increase in the number of developing countries that have moved to establish a single, semi-autonomous IP institution with responsibility for administration of both industrial property and copyright. Jamaica and Tanzania are two examples. There are good arguments for establishing a single, semi-autonomous IP administration office,

**Table 7.1 Volumes of Applications and Grants in Eight Developing Countries, 1996-98**

Country	1996		1997		1998	
	Appls	Grants	Appls	Grants	Appls	Grants
<b>Patents</b>						
China*	52714	2976	61382	3494	82289	4735
Guatemala	104	8	135	15	207	17
India	8292	1020	10155	N/a	10108	1711
Jamaica	79	23	70	21	60	16
Kyrgyzstan*	20305	125	25103	133	33905	91
Malawi*	39034	117	49934	49	67760	80
Sudan*	39061	97	49920	37	67719	64
Viet Nam*	22243	61	27440	111	35748	N/a
<b>Trademarks</b>						
China**	150074	121475	145944	217605	153692	98961
Guatemala	8206	5490	10588	6369	9988	4806
India	N/a	4436	43302	N/a	36271	4840
Jamaica	1537	1346	1883	2195	2005	1966
Kyrgyzstan**	2803	3297	3008	2592	3112	2760
Malawi	624	316	819	422	582	320
Sudan**	1508	1508	1482	1482	1514	1514
Viet Nam**	8440	6615	7830	5174	2838	2534

Source: WIPO website. [www.wipo.int](http://www.wipo.int)

\* Member of PCT during this period. \*\* Member of Madrid Agreement or Protocol during this period.

Note: The cost of designating countries under the PCT is negligible hence applicants routinely designate a large number of countries. So although the total numbers of patent applications in the PCT member countries shown appear very large, only a very much smaller number of these enter into the "national phase" where action is required by national offices involving the grant of a substantive patent in the country concerned.

under the supervision of a suitable government ministry. These include the separation of the policy and administrative functions; creation of a more business-oriented approach to cost-recovery and expenditure control (including capital investment strategies and market-based staff remuneration); and the potential benefits from better policy co-ordination across different areas of IP.

## Human Resources

The number of staff involved in IPR administration in developing countries varies enormously: from one untrained person in the Ministry of Trade and Industry in Eritrea to over 800 hundred staff across three different government agencies in India. To meet the minimum administrative standards required by TRIPS, the number required for a skeleton office handling very low volumes of IPR applications would be perhaps 10 professionals and a similar number of administrative/support staff. This requirement could be expected to rise over time with increased volumes of IPR applications.

## Box 7.2 Making up the Numbers: the Staffing of IP Offices in Seven Developing Countries

**India:** The Patent Office has a total staff of approximately 300 against an authorised complement of 530 (this includes 40 patent examiners out of an authorised total of 190 examiners). The Trade Marks Registry has a total of 259 staff against an authorised total of 282. And the Copyright Office has a total staff of 12, of which 9 are professional posts.

**Jamaica:** The recently established Intellectual Property Office, under the Ministry of Industry, Commerce and Technology, has a complement of 51 posts, of which only around half are currently filled.

**Kenya:** The Intellectual Property Institute has an establishment of 97 staff, 26 of which are professional posts and 71 are administrative.

**St Lucia:** The Registry of Companies and Intellectual Property, under the Attorney General's Department, has a complement of 9 posts with one post currently vacant.

**Trinidad and Tobago:** The Intellectual Property Office has a complement of 23 staff at present, with 6 posts vacant. A revised organisational structure proposes increasing the staff complement to 54 posts to handle the present workload.

**Tanzania:** The Intellectual Property Division of the Business Registrations and Licensing Agency has 20 staff (11 professional and 9 administrative).

**Vietnam:** The National Office of Industrial Property has 136 staff in total (87 professionals and 49 support staff) and there are a further 22 staff in the Copyright Office.

**Source:** Leesti, M. & Pengelly, T. (2002) *"Institutional Issues for Developing Countries in Intellectual Property Policymaking, Administration and Enforcement"*, Commission on Intellectual Property Rights Background Paper, p.27

Almost all developing countries face shortages of professional staff in their national IP administration. In LDCs and the smaller, low income developing countries, the availability of technical and legal expertise tends to be in short supply. Where legal expertise does exist, there is no IPR speciality. In the more advanced or larger developing countries there is generally a greater availability of legal expertise in IP, particularly in the trademark field.

## Information Technologies

IT systems are now a critical requirement for efficient IP administration. They enable easy access to a wide range of information on IP policy subjects as well as to the on-line patent databases and libraries of organisations like WIPO and the major patent offices. They are thus an important determinant of institutional capacity. Whilst the basic hardware requirements are fairly limited for small IP offices and the necessary software is readily available, the extent of automation and Internet-connectivity is surprisingly low.<sup>6</sup> Although some larger, higher income developing countries have fully automated systems for searching and application processing, a large number of countries still have manual, paper-based systems. This not only hinders efficient processing of applications but also greatly complicates collection of important statistical and management information.

# EXAMINATION VERSUS REGISTRATION SYSTEMS AND COOPERATIVE ARRANGEMENTS

The administration of industrial property rights involves receiving applications, formal examination (if applicable), granting or registration of the IPRs, publication, and processing of possible oppositions. As some IPRs expire after specified periods of time, further steps are required to complete renewal procedures and documentation of the decision. The level of public administration required for copyright and related rights is minimal, however, as these rights are automatically acquired and do not require renewals.

By far the most challenging aspect is the substantive examination of patent applications to ensure not only that the claimed invention is novel, inventive and industrially applicable, but also that the applicant meets the disclosure requirements. Some patent applications now run to thousands of pages of technical data, in a wide array of technology fields, and substantive examination involves both professional/technical competence and access to the international patent information computer databases. Such institutional capacity requirements are very much beyond the reach of most IPR administration agencies in the developing world (with a few exceptions). Very few developing countries are capable of doing substantive examination in a broad range of technology sectors in-house.

One way for developing countries to resolve this problem is through use of a registration system under which patents would simply be accepted and granted without substantive review. There might be a simple review to ensure that the formalities of the law were satisfied. This would strongly reduce the costs of patent offices and human resource requirements. But, lacking a filter for registration, abusive practices of patenting may flourish. Given the presumption of validity that such a patent might enjoy, the burden of proving a patent invalid falls on the public or affected competitors. This may be too heavy a burden. In addition, establishing a local examination system, even if resource-constrained, permits the creation of capacity to draft and read patent documents, and to use them as a source of information. High mobility of patent offices' personnel often ensures the transfer of such capacity to the private sector or research institutions.

## Regional or International Co-operation

Many developing countries have decided that regional and/or international co-operation in IPR administration is essential to reduce costs and increase efficiency. For patents in particular, many rely to a greater or lesser extent on the work of the EPO and the patent offices of the US and Japan, who together undertake the substantive examination for the majority of applications worldwide. In practice, there are three main options open to developing countries for regional/international co-operation.

### Patent Co-operation Treaty

The first option is membership of the PCT and Madrid systems. Membership of the PCT system allows national patent offices to minimize search, examination and publication tasks. It also allows domestic applicants to file for international patent protection in all PCT members at relatively low cost (plus residents of developing countries get a 75% reduction in all PCT fees). Membership of the Madrid system produces similar advantages in trademark administration as the PCT.<sup>7</sup>

Countries may opt to apply Chapter I (International Application and Search) of the PCT only, and not Chapter II (International Preliminary Examination) if they consider that the examination made by a foreign patent office would lead to the application of standards and criteria significantly different from those in force locally, particularly in critical areas such as pharmaceuticals and biotechnology.

## Contracting Out

The second option is to contract out patent administration to another national or international patent office, or a private organisation. For example, the EPO offers a service for search and examination for patents for some countries in Eastern Europe. A similar system for patents is offered to developing countries, although no country has yet taken advantage of this option. Developing countries are also able to seek assistance from WIPO's Patent Information Services (WPIS) for search and examination of individual patent applications.<sup>8</sup> A further variation is to utilise expertise within local universities, where this exists, for technical examination of patent applications, as is the practice in Chile, for example. Similarly, in Brazil, the Ministry of Health is obliged by law to assist the Industrial Property Institute (INPI) in the examination of pharmaceutical patents.

## Regional Organisations

The third option is membership of a regional industrial property system. There are currently four regional industrial property organisations in the developing world. In Eastern Europe and Central Asia, the Eurasian Patent Office has nine member states. In the Arab region, the Gulf Co-operation Council Patent Office includes six member countries. Within the African region, there are two regional industrial property organisations: OAPI and ARIPO which have 16 and 15 member states respectively. In addition, the six countries of the Andean Pact have developed common IP legislation (though this is still administered individually by national governments) and there are ongoing initiatives in the Caribbean and in South-East Asia. There are currently no regional industrial property administration organisations in Latin America, the Caribbean, Pacific, South Asia, or South East Asia. A majority of the LDCs (27 out of 49) are currently not members of regional IP organisations.

Whilst regional co-operation offers advantages for developing countries, it is principally focused in the area of IPR administration. This still leaves the requirement for national institutions to perform the important functions related to policymaking, participation in international rulemaking, enforcement and regulation of IPRs. Regional organisations, therefore, may complement, rather than wholly replace, an effective national IP infrastructure.

At the same time, regional/international co-operation also has some potential disadvantages for developing countries. First, membership of a regional system, depending upon its structure and the flexibility which is built in to cater for members' national interests, may make it more difficult for individual developing countries to apply IP regimes tailored to their needs (for example, with different terms and levels of protection in certain fields of technology). For example, LDC members of OAPI cannot take advantage of the extended transition period under TRIPS or the longer extension on pharmaceutical product protection granted to them in the Doha Declaration, unless the recently revised Bangui Agreement is amended to that effect. This is not the case for LDC members of the ARIPO system, who have more flexibility to fashion their own patent legislation and practice.<sup>9</sup> Second, membership of a regional or international patent system may create difficulties for a developing country to operate an effective system of oppositions for challenging the validity of patents. Finally, reliance upon regional institutions may hinder building up the (still) necessary IP related expertise and institutional capacities at the national level (for example, in policy making, enforcement and regulation).

Clearly, developing countries need to weigh the advantages and disadvantages of regional and international co-operation and choose the patent regime that is best suited to their national circumstances. At the same time, it may be helpful for the advocates of IP-related regional/international co-operation to demonstrate how some of the potential disadvantages for developing countries may be overcome or mitigated in practice. A more active and informed debate could help developing countries to understand the advantages and disadvantages of regional/international co-operation and reach the correct decision.

# COSTS AND REVENUES

## The Cost of an IP System

The establishment and operation of the IP infrastructure in developing countries involves a range of both one-time and recurrent costs. One-time costs could include acquisition of office premises; automation (hardware and software) and office equipment; consultancy services (for policy research, the drafting of new legislation, design of automation strategies, management re-organisation etc); and training of staff in the relevant agencies dealing with policy/law making, administration and enforcement. Recurrent costs could include staff salaries and benefits; charges for utilities; information technology equipment maintenance; communications services (including development of an annual report and website); travel expenses for participation in meetings of the international and regional organisations; and annual contributions to WIPO and regional organisations.

It is very difficult to draw general conclusions about the scale of these costs in developing countries, primarily because of different volumes of IPR applications required to be processed, variances in local labour and accommodation costs, and policy choices that different developing countries make in designing their IP infrastructure. For example, costs will be far higher in developing countries that operate substantive patent examination systems, compared to those using a registration system without any examination.

A 1996 study by UNCTAD reported some estimates of the institutional costs of compliance with TRIPS in developing countries.<sup>10</sup> In Chile, additional fixed costs to upgrade the IP infrastructure were estimated at \$718,000, with annual recurrent costs increasing to \$837,000. In Egypt, the fixed costs were estimated at \$800,000 with additional annual training costs of around \$1 million. Bangladesh anticipated one-time costs of only \$250,000 (drafting legislation) and \$1.1 million in annual costs for judicial work, equipment and enforcement costs, exclusive of training. The World Bank recently estimated that a comprehensive upgrade of the IPR regime in developing countries, including training, could require capital expenditure of \$1.5 to 2 million, although evidence from a 1999 survey of relevant World Bank projects suggested that these costs could be far higher.<sup>11</sup> A recent report on modernizing Jamaica's IP system estimated initial automation costs alone of around \$300,000.<sup>12</sup>

## Meeting the Costs

In most developing countries, IPR administration agencies charge various fees for services related to processing applications for IP rights and also for renewing those rights once awarded. In some larger developing countries, such fee revenues are significant and far exceed their operating expenditures. In Chile, for example, fee revenues from the administration of industrial property rights amounted to \$6 million in 1995, compared to recurrent expenditure of \$1 million in the same period. In developed countries, IP offices often earn substantial surpluses, normally contributing significant sums to national treasuries.

The research that we commissioned indicates typically more modest, though increasing, revenue streams in many developing countries.<sup>14</sup> For example, IP fees revenues for the 1999/2000 financial year were \$2.5million in India, \$629,000 in Kenya, \$230,000 in Trinidad, \$214,000 in Tanzania and \$162,000 in Jamaica. Fees from trademark administration are typically the largest single source of revenue as the granting of patents and other IPRs produces much lower revenues by comparison. This is especially true in low income developing countries.

Of course, the critical financial issue is the balance between revenues and expenditures. As the World Bank has pointed out, it seems hardly desirable that developing countries should divert resources from over-burdened health and education budgets to subsidise the administration of IPRs. Yet, this is a real risk in some smaller or low income developing countries which are likely to process very low volumes of IPRs for many years to come. From our own research on eight

developing countries, four appeared to be generating sufficient revenues from IP fees to cover administration expenditures, at least in terms of operating if not capital costs. However, Jamaica's IP office appears to be currently operating at a loss (about \$120,000 in the 1999/2000 financial year) so requiring a subsidy from Jamaica's taxpayers, whilst in three other countries we examined, insufficient data were available for us to reach a judgement.<sup>15</sup>

Most developing countries will probably need to structure their capital investment programmes for IPR in stages and ensure that the service fees are set at a level where the full range of financial costs incurred in the IP system are recovered. This points to the need for rigorous financial management and accounting systems and for fees to be reviewed on a regular basis. The evidence we reviewed suggests that these conditions are not in place in some developing countries: for example, in Uganda patent fees were last revised in 1993.

As high fees may discourage some types of applicants from obtaining IPRs, a number of countries have chosen to adopt a tiered-system of charges, where reduced fees are charged to non-profit organisations, individuals and small commercial organisations, such as those where the number of employees or level of turnover falls below specified thresholds. This seems a very sensible cost-recovery policy to adopt, as it should provide a means of developing the national IP infrastructure and delivering improved services for users, without placing additional burdens on public finances. A policy of charging higher fees to applicants from developed countries may strike some as attractive, but this would be inconsistent with the principle of national treatment required under the Paris Convention and TRIPS. But because the overwhelming majority of patent applications in most developing countries are from abroad, a comparable income may be generated with a tiered system.

Over time, streamlining IPR administration through automation and regional or international co-operation in some countries may help to generate higher volumes of patent applications and granted patents for which fees can be charged. And of course, part of the answer is clearly the provision of technical and financial assistance from donors. But such assistance is not a panacea for developing countries: it can never be guaranteed; resources are limited and other priorities may be more pressing; and it is mainly available only for one-time investment costs, rather than for financing a recurrent deficit in operating budgets.

**Developing countries should aim to recover the full costs of upgrading and maintaining their national IP infrastructure through the fees charged to users of the system. They should also consider adopting a tiered system of fees for IPR registration. The level of charges to users should be regularly reviewed to ensure that they enable full recovery of the costs of administering the system.**

## ENFORCEMENT

### Enforcement in Developing Countries

IPRs are valuable to rights holders only if they are well enforced, which implies that legal systems need to be effective. At the same time, legal systems must have the capacity to nullify invalid IP rights, such as patents that have been granted despite the existence of relevant prior art. TRIPS sets out detailed minimum requirements for enforcement of IPRs. For many developing countries, particularly low income ones, compliance with these provisions of TRIPS presents considerable institutional challenges for judicial systems, civil and criminal procedures and the enforcement authorities. In addition the strengthening of enforcement can be highly sensitive in political terms if it increases prices for poor consumers, or threatens employment in industries that are infringing or even the tax revenues derived from them.

In many developing countries, specialist areas of commercial law, such as IP, are a challenge to their judicial systems. In these circumstances, administration of IP laws in the courts is likely to be

especially difficult, as judges and lawyers require in-depth knowledge of complex technical and legal concepts. This state of affairs poses possible dangers in terms of both “under-enforcement” and “over-enforcement” of IP rights in developing countries.

Industry associations such as the Business Software Alliance and the International Intellectual Property Alliance often estimate very high levels of IPR infringement in developing countries.<sup>16</sup> Evidence of the extent of IPR infringement in developing countries is problematic, as reliable official statistics are often unavailable. However, it is generally accepted that the extent of the IPR infringement problem in most low income countries is greatest in the areas of copyright (counterfeiting of products such as computer software and music cassettes which are easy to copy) and trademark infringements, although it needs to be noted that, in terms of lost revenues, use of counterfeit products is more significant in the developed world.<sup>17</sup>

We agree that enforcement systems in developing countries need to address serious IPR infringements more effectively. This is important to protect the incentives that the system offers to IP rights holders. But it is also important that developing countries develop institutions capable of doing this in a balanced, pro-competitive way. More specifically, enforcement institutions in developing countries need to be robust enough to decide if IP rights are valid or invalid and to resist their potential abuse by restrictive business practices such as “strategic litigation.” For example, as developing countries come under pressure to provide systems whereby injunctions can be more readily and easily obtained, there is a risk that these could be abused by IP rights holders and so inhibit legitimate competition. As IP enforcement systems in developing countries are strengthened in line with TRIPS, it is essential that proper emphasis be placed on the need to protect the public interest and develop fair proceedings for both parties in disputes.

Effective enforcement of IPRs tends to rise with income levels, so institutional weaknesses in this area are likely to be greatest in the poorest countries. For example, in Tanzania and Uganda there is little evidence of cases involving IPR infringement proceeding through the judicial system, whilst in Kenya, in recent years, the customs authorities have made 50 seizures of counterfeit goods and 20 IPR-related criminal cases have been brought before the courts.<sup>18</sup> Some developing countries, such as Thailand and China, have gone further and established specialised courts to hear IPR-related cases as a means of improving their capacities for national enforcement, though such a measure is not formally required under TRIPS. A more attractive approach for developing countries is probably to establish (or strengthen) a commercial court, which may hear IPR-related cases *inter alia* and provide improved access to justice for the business sector as a whole. In any event, in most developing countries, a considerable programme of training for the judiciary and other enforcement agencies in IP subjects will be required.<sup>19</sup>

The “private” nature of IP rights suggests the importance of resolution of disputes between parties either out of court or under civil law. Indeed, as state enforcement of IPRs is a resource-intensive activity, there is a strong case for developing countries to adopt IPR legislation that emphasises enforcement through a civil rather than a criminal justice system. This would reduce the enforcement burden on the government in the case of counterfeiting on a large scale, although the state enforcement agencies would still be required to intervene. That said, we note that developing countries have come under pressure from industry which advocates enforcement regimes based on state initiatives for the prosecution of infringements. Such pressures should be resisted, and right owners assume the initiative and costs of enforcing their private rights.

**Developing countries should ensure that their IP legislation and procedures emphasise, to the maximum possible extent, enforcement of IPRs through administrative action and through the civil rather than criminal justice system. Enforcement procedures should be fair and equitable to both parties and ensure that injunctions and other measures, are not used unduly by IP rightsholders to block legitimate competition. Public funds and donor programmes should mainly be used to improve IP enforcement as part of broader strengthening of the legal and judicial systems.**

## Enforcement in Developed Countries

So far, this section has focussed exclusively on issues related to enforcement of IP rights in developing countries. This reflects the weight of the discussion of the enforcement topic in the literature we have reviewed. By contrast, it seems to us that there is very little discussion or recognition of the problems which face IP rights holders from the developing world in enforcing their rights in countries like the UK, the US or Japan, for example, where the costs of litigation may be prohibitive. This means that firms from developing countries competing in developed countries are vulnerable to strategic litigation involving IP rights. A related problem, as shown by the case of turmeric (see Box 4.2 in Chapter 4), is the granting of invalid IP rights by third countries on knowledge that exists as prior art in developing countries. Developed countries must consider how they could improve access to their justice systems for developing countries in IP-related cases.

**Developed countries should implement procedures to facilitate effective access to their intellectual property systems by inventors from developing nations. These might include, for example, fee differentials that favour poor or non-profit inventors, pro bono systems, arrangements for recovery of legal fees by prevailing parties in litigation, or inclusion of appropriate IP implementation costs in technical assistance programmes.**

## REGULATING INTELLECTUAL PROPERTY RIGHTS

Regulation of IP rights, particularly in relation to matters of special public interest (as with compulsory licensing) or in relation to controlling anti-competitive practice by rights holders should be given high priority in the design of public policy and institutional infrastructure. As well as the development of appropriate regulatory frameworks *per se*, an important part of effective regulation is the undertaking of regular, periodic reviews of all aspects of the national IP regime, to ensure that these are relevant and appropriate.

The rationale for developing countries to establish such regulatory systems and instruments in respect of IPRs is well documented.<sup>20</sup> Indeed, it is perhaps an overlooked fact that developed countries have introduced stronger IP protection in the context of competition regimes and other regulatory regimes designed to ensure that IP rights do not harm the public interest. In the US particularly, but also in other developed countries, pro-competitive regulation of IP rights and control of related restrictive business practices are key features of anti-trust legislation and these are regularly put into effect by the courts, competition authorities and by other relevant government agencies.

Seen from the institutional perspective, however, effective regulation of IP rights to standards common in the developed world is likely to present significant challenges for policymakers, administrators and enforcement agencies in developing countries. This is borne out by our own research in eight developing countries, which revealed that there is no record of any cases related to IP issues being brought through the courts under legislation relating to competition.<sup>21</sup> As one commentator recently put it:

“...in most developing countries mechanisms aiming at controlling restrictive business practices or the misuse of IP rights are weak or non-existent. Similarly, developing countries are generally unprepared or unable to neutralize the impact that price increases resulting from the establishment or reinforcement of IP rights may have on access to protected products, particularly by the low income population.”<sup>22</sup>

Only about 50 developing countries and transition economies currently have so far adopted specific competition laws. More developing countries, including LDCs like Uganda, are, however, now developing such legislation. Other developing countries may include provisions related to

regulation of IP rights within their existing IP laws. But the existence of legislation to address competition issues in a developing country does not mean that competent institutions, able to tackle complex IP-related issues effectively, will be in place.

For example, the skills and judgements required for the administration of compulsory licences, such as determining what constitutes “reasonable commercial terms” and “economic value of the authorisation” are quite sophisticated and may well go beyond the existing institutional capacities of many developing countries. This point is born out by the fact that compulsory licences have hardly ever been used by developing countries (although it can be argued that simply the threat of such licences might have proved sufficient or that national authorities are unwilling to utilise this instrument).

There is a clear dilemma here for developing countries. On the one hand, establishing an effective regulatory framework, including competition policy, is an important complementary step for introducing stronger IP protection. On the other, although larger developing nations (for example, India) are making efforts to strengthen and upgrade their institutional capacities in this area, for many nations this is likely to be just as complex and difficult a task as establishing an IPR regime. A widely held view in the developed world is that the IP system can only function as intended if complemented by an effective framework for competition policy. This raises the question of whether an IP system alone is a worthwhile goal for developing countries.

There is no easy solution to this dilemma. For LDCs, there is a good case for extending the transition period for the introduction of IPR regimes, as we discuss in Chapter 8. For other developing countries, the case for developing a competition regime does not rest solely on its relationship with IPRs. The widespread privatisation of state industries and increased concentration in many markets in the last two decades is another powerful reason for having an effective competition policy, as both developed and developing countries have learnt. We conclude therefore that a higher priority should be accorded to strengthening competition policies in developing countries.

**Developed countries and international institutions that provide assistance for the development of IPR regimes in developing countries should provide such assistance in concert with the development of appropriate competition policies and institutions.**

## TECHNICAL ASSISTANCE AND CAPACITY BUILDING

### Current Programmes

Under Article 67 of TRIPS, WTO Members from developed countries are obliged to provide technical and financial assistance to developing countries to facilitate its implementation. Most developed countries provide some sort of IP-related technical assistance to developing countries. This is done either bilaterally (mainly by national patent offices) or multilaterally. The principal international organisations involved in the provision of IP-related technical assistance to developing countries are WIPO, EPO, the World Bank, UNDP and UNCTAD. A number of non-governmental organisations are also active in undertaking research and providing technical assistance to developing countries in the area of IP.

The types of technical assistance which have been provided by donor organisations fall into the following broad categories: general and specialised training; legal advice and assistance with preparing draft laws; support for modernising IPR administration offices and collective management systems; access to patent information services (including search and examination); exchange of information among lawmakers and judges; and the promotion of local innovation and creativity. As most donors do not have agencies in the locality, short-term advisory missions and consultants are normally deployed in developing countries to plan, deliver and monitor programme activities.

Training and human resource development has been a major focus, an important example being the WIPO Worldwide Academy established in Geneva in 1998. More recently, assistance for automation of IPR administration in developing countries and regional IP organisations has also become significant. In particular, we note the WIPONet programme, being implemented by WIPO over 5 years at an estimated cost of \$20 million. The programme will provide on-line services such as Internet connectivity, hosting of national IP websites, secure electronic mail and exchange of IP data to 154 IP offices around the world. Clearly WIPONet has the potential to deliver substantial benefits, although it is too early to judge the extent of its impact.

## Assessing the Impact of Technical Assistance

Given the lack of evaluation exercises yet undertaken, it is difficult to comment authoritatively on the impact and effectiveness of technical co-operation undertaken by the various donor organisations in specific countries or regions. It is important for ensuring effectiveness and value for money, however, that donors undertake such evaluation exercises, individually and collectively, as a routine activity within the programme management cycle. In the same vein, we have been struck by the paucity of literature which identifies 'best practice' for IP-related technical assistance. This contrasts with the sectors such as environment and trade, where donors and developing countries have come together to develop a body of internationally agreed guidelines in fora such as the OECD Development Assistance Committee. A similar exercise focused on IP-related technical assistance might be very valuable.

It is clear that there have been some considerable achievements in the last 5-10 years in terms of modernising the IP infrastructure and developing the associated human resources in the developing world. Large numbers of people, from a variety of professional backgrounds, have received general and specialised training in IP subjects. This is particularly important for the educational system and the working bar that enable nations to use their own IP systems and participate effectively in international negotiations and in negotiations with suppliers of foreign technology. Equally, many developing countries have overhauled their IP legislation and have taken advantage of mechanisms for international co-operation such as the PCT and Madrid systems to make important efficiency gains and provide improved service levels. Perhaps the regions where there has been the biggest impact are Latin America and Eastern Europe, but there has also been significant development of institutional capacities in other developing countries like China, Morocco, Vietnam, Trinidad and Tobago, and India.

At the same time, many low income countries, and particularly LDCs, still face considerable challenges in developing their IP infrastructure. Taking this into account, there are some important general issues for the financing, design and delivery of technical co-operation to developing countries, and particularly the poorest countries, that need be addressed immediately.

## Financing Further Technical Assistance

More finance for the necessary institutional reforms and capacity building in developing countries needs to be provided as many developing countries struggle to implement the TRIPS Agreement over the next few years. Whilst we believe this requirement to be significant, it is not possible to suggest the precise amount. Capacity building needs for each country have to be assessed individually. As a rough order of magnitude, however, the World Bank's recent estimate, noted above, of \$1.5 to \$2 million per country for a comprehensive upgrade of the IPR regime seems to us to be a reasonable starting point. But clearly, more work needs to be done by donors and developing countries to assess and quantify the relevant needs.

A related question, of course, is from where should the additional necessary finance be secured. As we have demonstrated earlier in this report, most developing countries have very low levels of IPR creation, so technical assistance related to strengthening IP protection is unusual in that a

significant share of the resultant direct benefits can be expected to go to foreign IPR holders who are mainly from the developed countries. Moreover, in LDCs and other low income countries, extremely low levels of human and economic development mean that priority is rightly given to increasing aid expenditures on basic health and education services for poor people.

Taking the above points into account, we believe there are compelling arguments that the costs of modernising the national IP infrastructure in such countries should be met by IP rightsholders. In fact, this is what organisations such as WIPO and EPO and the patent offices of some developed countries already do, to a great extent, by generating revenues for their technical assistance programmes from fees for services provided to IP rightsholders.<sup>23</sup> Additional financing for technical assistance could be generated relatively easily and equitably in this way.<sup>24</sup>

**WIPO, the EPO and developed countries should significantly expand their programmes of IP-related technical assistance. The additional financing required could be raised through modest increases in IPR user fees, such as PCT charges, rather than from already over-stretched aid budgets. Donors could also seek to direct more technical assistance at LDCs in view of their special needs in developing an IP regime, as well as the wider institutional infrastructure they require for effective enforcement and regulation.**

## Ensuring Effective Delivery of Technical Assistance

Our sense from discussions with those involved is that there is a great deal of scope for improvement in the delivery and coordination of assistance in the IP field. Much money has been spent in various ways by many different institutions but the results do not seem commensurate with the effort. The design and delivery of IP-related technical assistance to developing countries needs to be improved. It needs to be much better integrated with the overall national development strategy of individual countries. Too often, IP-related technical assistance appears to be planned and delivered in isolation from other development programmes. For example, new IP legislation may be prepared for countries by specialist agencies like WIPO, but the institutional infrastructure to administer the new regime is not put in place because larger, mainstream development agencies have not been involved. On the other hand, World Bank-funded projects in Brazil, Indonesia and Mexico have taken a more holistic approach to upgrading the national IP architecture. In these cases, modernisation of the IP regime was one component of much broader programmes of policy reform and capacity building aimed at stimulating R&D spending and improving competitiveness.

Activities have also not always been well co-ordinated by the multiple donors involved, or by the countries that are receiving such assistance. This has resulted in duplication of efforts or, at worst, conflicting advice. In Vietnam, for example, eight different donor agencies had provided assistance in the country between 1996 and 2001.<sup>25</sup> A large part of the problem is that the main IP donors (for example, WIPO and EPO) do not have any staff based in country, and co-ordination of planning and delivery of assistance is therefore somewhat hampered. In this respect, it might therefore be useful for donors to consider experimenting, on a pilot basis, with in-country or in-region field managers to improve co-ordination of their IP-related technical assistance programmes on the ground in developing countries.

It seems to us that a crucial opportunity for improving donor co-ordination and integrating IP-related assistance programmes better within the national development strategies, is the Integrated Framework for Trade-Related Technical Assistance for LDCs (Integrated Framework). This initiative brings together multilateral and bilateral donors (including the World Bank, UNDP, UNCTAD and WTO but not WIPO or EPO) to undertake joint needs assessment and programming for trade capacity development and trade reform. As the Integrated Framework theoretically already includes support for TRIPS implementation in LDCs, this appears to be the appropriate vehicle for deepening co-ordination amongst donors on IP-related assistance. In practical terms, the first step could be for WIPO and EPO to join formally the Integrated Framework's group of core donors.

**IP-related technical assistance should be organised in relation to an individual country's specific development needs and priorities. One way to do this is to incorporate such assistance within the Integrated Framework to facilitate better integration with national development plans and donor assistance strategies.**

Finally, in order to address these new challenges, donors and developing countries need to find new ways of working together more effectively. In particular, better use should be made of the existing institutional mechanisms, at the national, regional and international levels, for understanding the IP-related capacity building needs of developing countries, for sharing information on technical assistance projects, and for undertaking collaborative sector-level reviews as a part of a continuous elaboration of best practice.

**Donors should strengthen systems for the monitoring and evaluation of their IP-related development co-operation programmes. As an important first step, a working group of donors and developing countries should be established to commission and oversee a sector-wide impact review of IP-related technical assistance to developing countries since 1995. A team of external evaluators should carry out this review.**

We return in the next chapter to the question of the appropriateness of the content of the technical assistance provided by international and national agencies.

<sup>1</sup> It should be noted that many developed countries find the coordination of IP policy difficult too, but this is not normally compounded by lack of technical expertise.

<sup>2</sup> An interesting case study in the area of plant genetic resources is Petit, M. et al (2001) *"Why Governments Can't Make Policy: The Case of Plant Genetic Resources in the International Arena"*, CIP, Lima.  
Source: <http://www.cipotato.org/market/whygov/FlyerGR1.pdf>

<sup>3</sup> From January 1996 to December 2000, 119 developing countries and regional organisations received assistance from WIPO through preparation of draft IP laws. See WIPO (2001a) *"WIPO's Legal and Technical Assistance to Developing Countries For the Implementation of the TRIPS Agreement From January 1 1996 to December 31 2000"*, WIPO, Geneva.  
Source: [http://www.wipo.org/eng/meetings/2000/ace\\_ip/pdf/wipo\\_trips\\_2000\\_1.pdf](http://www.wipo.org/eng/meetings/2000/ace_ip/pdf/wipo_trips_2000_1.pdf)

<sup>4</sup> Drahos, P. (2002) *"Developing Countries and International Intellectual Property Standard-Setting"*, Commission on Intellectual Property Rights Background Paper 8, Commission on Intellectual Property Rights, London, p 21. Source: <http://www.iprcommission.org>

<sup>5</sup> Institute for Economic Research (1996) *"Study on the Financial and Other Implications of the Implementation of the TRIPS Agreement for Developing Countries"*, WIPO, Geneva.

<sup>6</sup> According to WIPO, 154 IP offices around the world currently lack Internet connectivity, WIPO (2001b) *"Revised Draft Program and Budget 2002-2003"*, WIPO, Geneva.  
Source: [http://www.wipo.org/eng/document/govbody/budget/2002\\_03/rev/pdf/introduction.pdf](http://www.wipo.org/eng/document/govbody/budget/2002_03/rev/pdf/introduction.pdf)

<sup>7</sup> At the time of writing, membership of the Madrid system (70 countries) is considerably lower than that of the PCT (115 countries).

<sup>8</sup> According to the WIPO website "WPIS provides a conduit for channelling search requests from a wide range of users in developing countries to the Industrial Property Offices of those countries who have agreed to assist in providing these searches. The searches are free to those requesting them. For some search requests, for example, those from ARIPO, examination is also carried out. Since the start of the program in 1975, until the end of July 2001, almost 15,000 search requests have been processed free of charge from over 90 developing countries and 14 intergovernmental organizations and countries in transition. In the year 2000 1,315 search requests were received from 39 developing countries. These reports also covered special requests for novelty search and substantive examination as to the patentability of patent applications in developing countries as well as special requests for search and examination of patent applications submitted by ARIPO. In the early 1990s, the majority of requests came from users in the Asia and Pacific region; more recently users from Latin American countries are more active."

<sup>9</sup> For more discussion of the ARIPO and OAPI regional industrial property systems, see Leesti, M. & Pengelly, T. (2002) *"Institutional Issues for Developing Countries in Intellectual Property Policymaking, Administration and Enforcement"*, Commission on Intellectual Property Rights Background Paper 9, Commission on Intellectual Property Rights, London, pp.38-39.  
Source: <http://www.iprcommission.org>

- <sup>10</sup> UNCTAD (1996) *“The TRIPS Agreement and the Developing Countries”*, UNCTAD, Geneva.
- <sup>11</sup> World Bank (2002) *“Global Economic Prospects and the Developing Countries 2002”*, World Bank, Washington DC, chapter 5, “Intellectual Property: Balancing Incentives with Competitive Access”.  
Source: <http://www.worldbank.org/prospects/gep2002/full.htm>
- <sup>12</sup> Lehman, B. (2000) *“Modernizing Jamaica’s Intellectual Property System”*, International Intellectual Property Institute, Washington DC, p.62. Source: <http://www.iipi.org/activities/research.htm>
- <sup>13</sup> UNCTAD (1996).
- <sup>14</sup> Leesti, M. & Pengelly, T. (2002), p.109.
- <sup>15</sup> Leesti, M. & Pengelly, T. (2002), Section 3.5.
- <sup>16</sup> For example, it has been estimated that computer software infringement levels in Vietnam and China in 2000 were 97% and 94% respectively. Business Software Alliance (2001) *“Sixth Annual BSA Global Software Piracy Study”*, BSA. Source: <http://www.bsa.org/resources/2001-05-21.55.pdf>
- <sup>17</sup> For example, North America, Western Europe and Japan alone account for over 65% of global revenue losses from counterfeit computer software, Business Software Alliance (2001).
- <sup>18</sup> Leesti, M. & Pengelly, T. (2002), p.95.
- <sup>19</sup> In the US, for instance, courts apply a traditional four-part test of equitable jurisprudence to decide whether or not to issue a preliminary injunction, including an analysis of whether there is a reasonable likelihood that the patent, if challenged by the defendant as being invalid, will be declared valid. It assumes that there will be harm caused to the titleholder, but balances this against the harm that the alleged infringer will suffer in case the measure was wrongly granted. The effect of granting an injunction on the public interest (for instance, access to medicines) is also taken into account. Injunctions are very exceptionally granted *inaudita parte*. See Chisum, D. (2000) *“Chisum on patents. A treatise of the law of patentability, validity and infringement”*, Lexis Publishing, US.
- <sup>20</sup> For example UNCTAD (1996), and Correa, C. (1999) *“Intellectual Property Rights and the Use of Compulsory Licenses: Options for the Developing Countries”*, South Centre, Geneva.  
Source: <http://www.southcentre.org/publications/compliance/toc.htm>
- <sup>21</sup> Leesti, M. & Pengelly, T. (2002), p.32.
- <sup>22</sup> Correa, C. (1999), p.1.
- <sup>23</sup> WIPO’s total projected income of 530 million Swiss francs for 2002/3 includes fee revenues of over 455 million Swiss francs.
- <sup>24</sup> If PCT fees alone had remained at the level of the 1996-1997 biennium – rather than being substantially reduced – projected PCT fee income for the 2002-2003 biennium would have been 279 million Swiss francs higher, see WIPO (2001b).
- <sup>25</sup> Leesti, M. & Pengelly, T. (2002), p.44.



# THE INTERNATIONAL ARCHITECTURE



## INTRODUCTION

The implication of our analysis is that the interests of developing countries are best served by tailoring their intellectual property regimes to their particular economic and social circumstances. Just as developed countries currently exhibit significant variations in how they apply IPRs, and did so to an even greater extent in the past, so should developing countries be free to proceed accordingly. Indeed, it is perhaps more important for developing countries because costly errors of policy will be harder to bear. A crucial question, however, is how this objective can be accommodated within the complex international architecture of multilateral, regional and bilateral IP rules and standards which impose unprecedented limits on the freedom of countries to act as they see fit in this field. (See Box 8.1 for an overview).

This question arises not only in the context of the existing regulations but may also be asked of the future regulations currently under discussion. As we discuss in Chapter 6, the current debate about more comprehensive international harmonisation of patent systems in WIPO raises in acute form the issue of how developing countries' interests can appropriately be protected and furthered in the international system. More generally, our conclusions place a responsibility on the international community to assess whether the mechanisms in place for negotiating intellectual property standards, both multilaterally and bilaterally, take sufficient account of the interests of developing countries and poor people. We consider that the institutional framework is not optimally suited to this task and needs to display considerably greater sensitivity to these issues.

The central questions, which we address below, are as follows:

- Do the key international institutions, in particular WTO and WIPO, provide adequate advice and analysis based on an understanding of the particular needs of developing countries, and poor people?
- In their bilateral relations with developing countries, do developed countries take sufficient account of the impact of IPRs on developing countries and in particular poor people in them?
- Are developing countries themselves sufficiently aware of where their own interests lie, and do they have the capacity to secure those interests in bilateral and multilateral negotiations?

In order to answer these questions, it is necessary to gain some understanding of the international architecture for IP, how rules are formulated at that level and how the institutions help in embedding them into national law.

### Box 8.1 The International IP Architecture: Multilateral, Regional and Bilateral Rules

The architecture of the global IPR regime has become increasingly complex, and includes a diversity of multilateral agreements, international organizations, regional conventions and bilateral arrangements.

#### Multilateral treaties

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

- Standard setting treaties*, which define agreed basic standards of protection. These include the Paris Convention, the Berne Convention and the Rome Convention. Important non-WIPO treaties of this kind include the International Convention for the Protection of New Varieties of Plants (UPOV) and TRIPS.
- Global protection system treaties*, which facilitate filing or registering of IPRs in more than one country. These include the Patent Cooperation Treaty (PCT), and the Madrid Agreement Concerning the International Registration of Marks.
- Classification treaties*, which organise information concerning inventions, trademarks and industrial designs into indexed, manageable structures for ease of retrieval. One example is the Strasbourg Agreement Concerning the International Patent Classification.

Other international agreements with an IPR content include the International Treaty on Plant Genetic Resources for Food and Agriculture and the Convention on Biological Diversity.

#### Regional treaties or instruments

Examples of these kinds of agreement include the European Patent Convention, the Harare Protocol on Patent and Industrial Designs within the Framework of ARIPO, and the Andean Community Common Regime on Industrial Property.

#### Regional trade agreements

Regional trade agreements normally have sections governing IP standards. For example, the North American Free Trade Association, the proposed Free Trade Area of the Americas, the EU/ACP Cotonou Agreement.

#### 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 US and Jordan, but there are many others (see Table 8.1).

Source: UNCTAD/ICTSD (2002).<sup>1</sup>

## INTERNATIONAL STANDARD SETTING: WIPO AND WTO

There are several international institutions involved in standard setting for intellectual property. WIPO is the principal international institution responsible for organising the negotiation of IP Treaties and their administration. With the inclusion of TRIPS in the Uruguay Round, intellectual property has also come under the aegis of the WTO, the successor to GATT, and some would argue that WIPO's influence has thereby diminished. A special Council for TRIPS was created within the WTO structure to administer the TRIPS Agreement.

The secretariats of both WIPO and WTO serve organisations which are governed by members. National governments determine policy and decide the outcome of negotiations. In reality, as in any bureaucracy where governance has a dispersed structure, the secretariat and its leadership play a greater or lesser role in defining the important issues, and determining the range of possible solutions. WIPO and the WTO also respond to a range of external influences, outside the formal structure of governance, including from member states, some of which have greater influence than others, and external pressure groups including industry, industry associations and NGOs.

Governments and others perceive that the WTO is particularly important as an institution for establishing trade rules which are binding. This is because of the generality of its scope and the fact that it has the power to impose sanctions that may significantly affect national policy. This is why the developed countries chose GATT/WTO, rather than WIPO, as the appropriate mechanism for the globalisation of IP protection through TRIPS. It is also why, for instance, so much attention was focused on the Doha Declaration on TRIPS and Public Health by industry, governments and NGOs. The importance of the WTO in the context of IP rule-making is not so much due to its particular competence in international standard setting for IP (although it has a high quality intellectual property division), but because its mechanism for dispute settlement is a potent tool, which members can use to enforce the TRIPS obligations of their trading partners, backed by the threat of trade sanctions. To date, there have been 24 cases of dispute settlement cases concerning TRIPS in the WTO, the vast majority having been brought by the US and the EU.<sup>2</sup>

In contrast, WIPO has a greater depth of expertise in the field of intellectual property. But it is a very different type of organisation for two reasons. First, about 90% of its funding comes not from member governments (as in WTO or other UN agencies) but from the private sector by way of fees paid by patent applicants under the PCT - effectively from the community of patentees.<sup>3</sup> Secondly WIPO is, by its founding charter, solely concerned with the promotion of IPRs. Its objectives and functions do not include a development objective.<sup>4</sup>

As might be expected from WIPO's interpretation of its mission (see Box 8.2), the organisation is a firm advocate of stronger IP protection in developing countries. Indeed, the analyses in WIPO's various published policy documents pay little attention to the possible adverse consequences of such protection. IP rights are, in the main, presented as unequivocally beneficial. For instance, a publication on WIPO's website entitled "*Intellectual Property – Power Tool for Economic Growth*" states that ideas that:

"...patents are not relevant to developing nations, or that they are incompatible with the economic objectives of the developing nations - are pernicious myths. The reason why these notions are pernicious is because they give the impression that it is possible to simply opt {out} of the international patent system, and yet still achieve economic development. This is an error as patents are an essential component of economic strategy, regardless of whether the country is developed or in the process of economic development."<sup>5</sup>

We do not read too much into any individual statement such as this but it is, we believe, indicative of a particular perspective which prevails at WIPO. As is evident from this report, it is beyond question that there is a rather more complex link between intellectual property protection and development than such statements suggest. We recognise that WIPO has a role to play in promoting IPRs. However, we believe that it needs to do so in a much more nuanced way that is fully consistent with the economic and social goals to which the UN, and the international community are committed. A more balanced approach to the analysis of IPRs, and, in consequence WIPO programmes, would be beneficial to both the organisation and the developing world, which forms the majority of its membership.

WIPO should give more explicit recognition to the fact that IP protection has both benefits and costs, and give greater emphasis to the need for IP regimes to be appropriately tailored to the individual circumstances of developing countries. This would, we believe, certainly involve greater

### Box 8.2 The World Intellectual Property Organisation (WIPO)

WIPO began life in 1893 as BIRPI (the French acronym for the United International Bureaux for the Protection of Industrial Property). This was a body established principally to administer service the Paris and Berne Conventions on industrial property and copyright. It was only restructured and reconstituted as a UN agency as recently as 1974.

WIPO's objectives, as set out in the Convention establishing it, are to "promote the protection of intellectual property throughout the world". In the light of that objective, its first function is to "promote the development of measures designed to facilitate the efficient protection of intellectual property throughout the world and to harmonize national legislation in this field."<sup>6</sup> It is "convinced of the need to ensure that developing countries...are fully integrated into the international intellectual property system." It believes that "harmonization of national policies on the establishment of intellectual property rights should be sought, with the aim of protection at the global level."<sup>7</sup> This is the perspective in which it manages its cooperation and technical assistance activities with developing countries.

Today, the main functions of WIPO are to serve as a forum for negotiation of international IP treaties; to administer such treaties and operate the systems of global protection such as the Patent Cooperation Treaty (PCT) and the Madrid system; and to provide technical assistance and training to developing countries and countries in transition.

The PCT aims to simplify and reduce the cost of obtaining international patent protection. By filing one international patent application under the PCT, an applicant can simultaneously seek protection for an invention in over one hundred countries. Recent PCT applications are published in the PCT Gazette to facilitate public access to technical information.

WIPONET is a global digital information network, providing network infrastructure and services for improved information exchange, to enable the integration of IP information resources, processes and systems of the worldwide IP communities, particularly the IP offices of member States. WIPONET will also provide a portal for other WIPO-provided systems, such as the Intellectual Property Digital Libraries (IPDLs), and eventually to on-line filing under the PCT.

The Internet Corporation for Assigned Names and Numbers (ICANN) administers a system for resolving domain name disputes involving trademarks, and a system of best practices for domain name registration authorities, designed to avoid such conflicts.

The WIPO Worldwide Academy is an institution which provides teaching, training, advisory, and research services in intellectual property.

Source: <http://www.wipo.int>

sensitivity in providing assistance to developing countries in implementing TRIPS and appropriate other measures to ensure that IP rights operate in the public interest.

As a means to this end, we also believe that WIPO would benefit from drawing a wider group of constituencies with an interest in the IP system into its policy-making process, such as consumer organisations. WIPO has always been responsive to the needs of the industrial sectors which make intensive use of IP. We are less persuaded that it is as responsive to the interests of consumers or users of IP-protected products. It is of crucial importance in this respect that WIPO is not perceived as being receptive primarily to those organisations which have an interest in stronger IP protection.<sup>8</sup>

Quite recently, WIPO set up two advisory bodies: a Policy Advisory Commission (PAC) and an Industry Advisory Commission (IAC). We welcome the establishment of these groups whose role is to provide expert advice to WIPO. We also welcome the recognition, noted below, of the need for a wider range of views to be represented in policy making. But we think that the membership of these bodies should reflect more systematically those diverse interests in society that have an interest in IP, both as producers of it or users. Thus representatives from industry, scientists, consumer groups and other civil society organisations, as well as IP experts and government representatives would enable WIPO to play a more effective role in facilitating dialogue with its broad constituency of stakeholders. This greater involvement with a wider representation of users and interest groups could usefully be complemented by closer co-operation with other relevant international organisations, such as the WHO (particularly for implementing the Doha Declaration), FAO, UNCTAD and the World Bank.<sup>9</sup>

**WIPO should act to integrate development objectives into its approach to the promotion of IP protection in developing countries. It should give explicit recognition to both the benefits and costs of IP protection and the corresponding need to adjust domestic regimes in developing countries to ensure that the costs do not outweigh the benefits. It is for WIPO to determine what substantive steps are necessary to achieve this aim but it should as a minimum ensure that its advisory committees include representatives from a wide range of constituencies and, in addition, seek closer cooperation with other relevant international organisations.**

If WIPO adopts the approach we suggest, a question arises as to whether its current articles will permit it to do so legitimately. The objectives laid down for many international organisations are broad and multi-faceted, and allow for considerable flexibility in interpretation if member states wish to change the activities of the organisation in response to changing circumstances. Unlike many of these organisations, WIPO has a very specific mandate in its constitution - to promote the protection of intellectual property throughout the world, including the harmonisation of national legislation. We are not sure that this mandate can be interpreted to allow WIPO to adjust its approach in developing countries to reflect the economic need to balance the benefits and costs of IP protection.

**Unless they are clearly able to integrate the required balance into their operations by means of appropriate reinterpretation of their articles, WIPO member states should revise the WIPO articles to allow them to do so.**

## THE TRIPS AGREEMENT

There has been much debate about whether the subject matter of the TRIPS agreement belongs in WTO. Some commentators have taken the view that the WTO is essentially a free trade organisation and the global enforcement of IP standards, among nations at very different levels of social and economic development, should not fall within its terms of reference. They argue that intellectual property is not a matter concerned with trade, and further, that as TRIPS will principally benefit the developed countries, the credibility of the WTO as an instrument to promote free trade in the interests of all countries is weakened. A leading exponent of this view is Jagdish Bhagwati:

"TRIPS does not involve mutual gain; rather, it positions the WTO primarily as a collector of intellectual property-related rents on behalf of multinational corporations (MNCs). This is a bad image for the WTO and in the view of many, especially the non-governmental organizations, reflects the "capture" of the WTO by the MNCs."<sup>10</sup>

Others counter this argument by stating that IP protection has always been integral to trade and commercial diplomacy. On this view, TRIPS was produced as a result of bargaining between sovereign states as part of a larger package of trade-offs in which there were supposed to be gains for all. Whilst not all developing countries participated in the TRIPS negotiations, they were free to do so and leading developing countries, most notably India and Brazil, did participate actively.

It appears to us that, despite the history of the Uruguay Round negotiations and the asymmetries in negotiating capacity and power between the developed and developing countries, TRIPS is likely to remain an integral part of the WTO framework. While we have reservations about the extension of TRIPS standards to all developing countries, we recognise that it is most unlikely that any WTO members would be keen to renegotiate the agreement. Many members fear that in seeking particular amendments they would be obliged to compromise elsewhere in ways that may not bring a net benefit to them. The TRIPS Agreement, like others in the WTO, is subject to periodic review and genuine proposals for improving TRIPS provisions to benefit developing countries must be given proper consideration. But beyond these general points, we wish to draw two other specific conclusions from the evidence and our consultations about TRIPS.

## Assisting Developing Countries to Implement TRIPS

First, it is of prime importance that WTO members complete their work in clarifying the flexibilities within TRIPS regarding public health and that developing countries are enabled to utilise these and other flexibilities in the Agreement. Much new IP legislation has been introduced in developing countries since 1995 and some commentators<sup>11</sup> have expressed concern that the flexibilities available under TRIPS have not been fully utilised to reflect local needs. Our investigations of the current or draft IP laws of about around 70 developing countries and LDCs found, for example, that only around a quarter of these countries specifically excluded plants and animals from patent protection, less than half provided for international exhaustion of patent rights and less than a fifth specifically provided a so-called "Bolar" exception to patent rights.<sup>12</sup> Of course, there may be good reasons why a developing country might not wish to make use of these flexibilities, having made an informed decision not to do so. Their freedom to manoeuvre may also be constrained by other commitments, such as bilateral agreements.

But it might also be because those in charge of the legislative process are unaware of the options available, or the full implications of these options. As we note in Chapter 7, developing countries receive technical assistance in the IP field from a wide range of national and international institutions, such as the EPO, the USPTO, and the IP authorities of developed countries. But WIPO, as the international institution responsible for the promotion of IP, has a pivotal role in the setting of standards in this area, through its model laws and the nature of the technical assistance it provides. Our comments on this subject are therefore appropriately directed at WIPO, but they apply as well to all the other bodies involved in advising developing countries on IP matters.

We found that while some, particularly in developing country IP offices, highly value WIPO's technical assistance, substantial concerns have been raised by a number of individuals and organisations, about whether the assistance provided by WIPO has always been appropriately tailored to the circumstances of the developing country concerned.<sup>13</sup> Hitherto, the confidential nature of the consultations between WIPO officials and a developing country, together with the absence of a formal WIPO policy statement on the nature of its technical assistance made it difficult to assess whether there was substance to in these concerns. In addition, WIPO did not publicise its model IP laws and annotations which would have indicated the extent to which it was providing

advice consistent with all the flexibilities under TRIPS. There is also evidence that, in cases where WIPO's assistance has been acknowledged, the result has not incorporated all TRIPS flexibilities. For instance, the revised Bangui Agreement for the OAPI countries, where WIPO's assistance is acknowledged, has been criticised in various quarters for going further than TRIPS. It obliges LDC members (the majority of OAPI members) who ratify it to apply TRIPS in advance of need; it restricts the issuance of compulsory licences to a greater extent than required by TRIPS; it does not explicitly allow parallel imports; it incorporates the elements of UPOV 1991 in the agreement and it provides for a copyright term of 70 years after the death of the author.

However, very recently WIPO has introduced a page on its website which describes the legislative assistance it provides in relation to TRIPS and the Doha Declaration. This serves to allay some of these concerns. In addition to making available the model IP laws it uses, WIPO also notes that:

"WIPO's advice takes into account all the flexibilities that are open to members under the TRIPS Agreement including those confirmed in the Doha Ministerial Declaration on the TRIPS Agreement and Public Health ("the Doha Ministerial Declaration"). WIPO's advice takes into account the unique situation of each country, given that Member States have different legal systems and different political and cultural structures. WIPO follows up its written legal advice with an interactive process between the Organization and major stakeholders in the Member State concerned. To strengthen the TRIPS implementation process during the last four years, WIPO has promoted the interaction among stakeholders at the national level to include, for example, officials of Law Reform Commissions, Chambers of Commerce and Federation of Industries, Research and Development institutions, Parliamentarians, high-level officials of Ministries of Trade, Agriculture, Health, Science and Technology, Culture, Justice, Environment, among others."<sup>14</sup>

We welcome this statement of WIPO's commitment to provide advice to developing countries which takes account of the flexibilities in TRIPS, and the particular circumstances of each country. In addition we attach importance, as we note in the previous chapter, to a wide-ranging consultative process in the development and evolution of each country's IP legislation. Such consultation is essential if IP laws are to be devised in line with development objectives in agriculture, health and industry. Nevertheless, we think that this is the beginning of the process required to make WIPO truly responsive to the specific needs of developing countries. For example, WIPO's current model law on patents requires further work in our view if it is to provide the best guidance on how developing countries can utilise the flexibilities in TRIPS.<sup>15</sup> Other organisational and procedural changes may also be necessary to embed these new policies operationally. Other providers of IP technical assistance need also to consider their policies in the same light.

**WIPO should take action to make effective its stated policy of being more responsive to the need to adapt its IP advice to the specific circumstances of the particular developing country it is assisting. We also recommend that it, and the government concerned, involve a wider range of stakeholders in the preparation of IP laws both within government and outside, and both potential producers and users of IP. Other providers of technical assistance to developing countries should take equivalent steps.**

## Timetable for Implementing TRIPS

Our second conclusion regarding TRIPS is that, consistent with the overall analysis of this report, we are not persuaded by the arguments that developing countries at very different stages of development should be required to adopt a specific date (January 2000 for developing countries, January 2006 for LDCs) when they will provide the TRIPS standards of protection within their domestic IP regimes, regardless of their progress in creating a viable technological base. On the contrary, we believe there are strong arguments for greater flexibility in setting an optimum time to strengthen IP protection, taking into account the nation's level of economic, social and technological development.

In TRIPS there are provisions made for the extension of the transitional period for LDCs by the TRIPS Council, although the logic of our argument applies to a wider range of low income developing countries.<sup>16</sup> We think that TRIPS would be improved by utilising these provisions to take greater account of the special needs of LDCs. These countries need longer to devise appropriate IP regimes and to establish the necessary administrative and institutional infrastructure, as well as the required regulatory frameworks, including complementary legislation such as competition law. The challenges are formidable and developing countries will incur significant costs if they rush to establish an IP regime that is inappropriate to their level of development. And, quite obviously, the governments of many LDCs, particularly in sub-Saharan Africa are facing much more immediate demands in critically important areas such as health, education and food security.

We do not think that granting LDCs the option of a longer transition period for TRIPS will materially damage the interests of developed nations. The Doha Declaration began this process by agreeing on the extension of the transition period for LDCs to provide patent protection to pharmaceuticals to at least 2016. It seems logical that the extension of that transition period should now be broadened to cover the implementation of TRIPS as a whole. It could be readily implemented by the TRIPS Council in complete conformity with the existing provisions of Article 66.1 of the Agreement. Furthermore, we think the TRIPS Council should also consider introducing criteria to decide the basis on which LDCs should enforce TRIPS obligations after 2016. These criteria could include indicators of economic development and scientific and technological capability, related to the criterion specified in the Article of “the need for flexibility to create a viable technological base.”<sup>17</sup>

**LDCs should be granted an extended transition period for implementation of TRIPS until at least 2016. The TRIPS Council should consider introducing criteria based on indicators of economic and technological development for deciding the basis of further extensions after this deadline. LDCs that have already adopted TRIPS standards of IP protection should be free to amend their legislation if they so desire within this extended transition period.**

## IP IN BILATERAL AND REGIONAL AGREEMENTS

Developed countries, the US and the EU in particular, have sought to encourage developing countries to comply with international IP treaties, or to adopt higher standards of IP protection. In the past, trade concessions have been withheld and trade sanctions implemented against certain developing countries whose IP regimes have not met the expectations of their trading partners in the developed world.<sup>18</sup> More recently, there has been a trend for developed countries to seek commitments on IP standards from an increasing number of developing countries in bilateral or regional trade and investment agreements that go beyond TRIPS.<sup>19</sup> Table 8.1 below, provides some examples.<sup>20</sup>

We accept that to a degree, developed countries have a legitimate interest in the IP standards of their trading partners. In our judgement, regional and bilateral agreements are much less preferable to the setting of multilateral standards, where the negotiating capabilities of developed and developing countries although remaining asymmetrical, are counterbalanced by numerical advantage and the ability to build alliances. Moreover, there is a risk that regional/bilateral agreements could undermine the multilateral system by limiting more generally the use by developing countries of the flexibilities and exceptions in TRIPS. In particular the Most Favoured Nation Principle means that terms agreed bilaterally or regionally must be offered to all other WTO members on the same basis.

It is unrealistic to think that IP standard setting will disappear altogether from bilateral and regional commercial diplomacy. The imperative, then, is for developed countries to ensure that their policy objectives for IP standards in regional/bilateral trade agreements are demonstrably consistent with their broader objectives for promoting international development and poverty

reduction. To that end we would encourage developed countries, rather like developing countries (see Chapter 7), to incorporate a wider range of stakeholders, within government and without, in their policymaking on IP. IP policy too must integrate development considerations and that should be done as much by developed countries as by developing. Developing countries should not have to accept IP rights imposed by the developed world, outside their existing commitments to international agreements. Negotiators for developed countries need to take account of the costs to developing countries of higher IP standards, as well as the benefits to their own industries.

**Table 8.1. Examples of Bilateral Agreements Requiring TRIPS-plus Standards<sup>20</sup>**

Agreement	Date	Examples of TRIPS-plus provisions
US-Jordan Free Trade Agreement	2000	Each party must give effect to selected provisions of the WIPO Copyright Treaty and WIPO Performances and Phonograms Treaty and the UPOV (1991) Convention. Parties may not exclude plants and animals from patent protection and must provide patent term extension to compensate for unreasonable regulatory approval delay.
US-Cambodia Agreement on Trade Relations and IPRs	1996	Each party must accede to the UPOV Convention, must extend term of copyright protection in certain cases to 75 yrs from publication or 100 yrs from making (TRIPS requires only a minimum of 50 years in both cases), and Parties may not allow others to rely upon data submitted for pharmaceutical regulatory purposes for a reasonable period which shall generally be not less than 5 years.
US-Vietnam Agreement on Trade Relations	2000	Parties may not exclude from patent protection inventions that encompass more than one variety of animal or plant.

To the extent that development objectives have been given a higher priority in the policy framework of developed countries (as seemed to be demonstrated at Doha and Monterrey), then it would be unwise to let IP policy be influenced principally by domestic industrial and commercial interest groups in developed countries, whose view of what is appropriate for developing countries is very much coloured by their perception of their own interest. Governments from developed countries need to form their own view, in the light of all the evidence, as to how the interests of development in developing countries and their own commercial interests can best be reconciled. Ultimately, this should not be a zero sum game. In our view, most developed countries take insufficient account of development objectives when formulating their policies on IP internationally. More specifically, we believe that developed countries should discontinue the practice of using regional/bilateral agreements as a means of creating TRIPS-plus IP regimes in developing countries as a matter of course.<sup>21</sup> Developing countries should be free to choose, within the confines of TRIPS, where to pitch their IP regimes.

Though developing countries have the right to opt for accelerated compliance with or the adoption of standards beyond TRIPS, if they think it is in their interests to do so, developed countries should review their policies in regional/bilateral commercial diplomacy with developing countries so as to ensure that they do not impose on developing countries standards or timetables beyond TRIPS.

## PARTICIPATION BY DEVELOPING COUNTRIES

Active participation by developing countries is essential to ensure the legitimacy of standard setting and its appropriateness and relevance to nations at very different levels of development. The achievement of the Doha declaration, in part, reflected the fact that developing countries were able to present carefully developed, specific proposals that could be accommodated in WTO rulemaking. One clear implication of this, and a theme which emerged from much of our fieldwork, is that developing countries need the capacity to participate much more effectively in international IP negotiations, and on a regular rather than an exceptional basis.

To participate effectively, developing countries require a combination of four factors. These are permanent representation in Geneva; appropriately staffed expert delegations able to attend meetings and negotiations; adequate technical support for policy analysis; and functional mechanisms for policy co-ordination and discussion in capitals. In Chapter 7, we dealt with the issue of the need for more “joined-up” policymaking in developing countries, and the crucial requirement to develop expertise in policymaking in IP in their national institutions. We deal here with the other two issues.

### Permanent Representation in Geneva

Permanent representation in Geneva is important for ensuring good information flows back to capitals; participation in informal consultations and negotiations; alliance building with like-minded countries; eligibility for chairing meetings; and to enable better access to the services and assistance available from the secretariats. A recent study commissioned by the Commonwealth Secretariat<sup>22</sup> found that there are 36 developing countries, either WTO members or in the process of accession, who do not have any permanent representation in Geneva because they cannot afford the high costs of setting up and running a mission.<sup>23</sup> Our own analysis shows that 20 of the 45 LDCs who are members of either WIPO or WTO, or are in the process of WTO accession, are currently without permanent representation in Geneva. Where developing countries do have permanent representation, they are on average only half the size of those of developed countries.<sup>24</sup> There is a duality amongst developing countries in their capacity to participate. Some 30-35 developing countries, including Brazil, Egypt, India and some LDCs like Bangladesh, are effective and active participants at WTO and WIPO and accordingly exert an influence on the rule-making processes in these organisations. The rest of the developing countries, including many of the LDCs, are currently little more than spectators in WTO and WIPO, if they are present at all.

### Expert Delegations

Developing countries should ideally send expert delegations from their capitals to attend international negotiations and meetings on different IP subjects. For most developing countries, a fundamental constraint is the lack of financial resources for travel costs, notwithstanding the schemes for financial assistance available from WIPO.<sup>25</sup> Even when delegations from the capitals do attend, their expertise may be limited to IPR administration as opposed to knowledge of IP as a tool of development policy. It would be helpful, we believe, if more developing countries were able to include expertise in economics, health, environment and agriculture in their delegations at relevant IP meetings and negotiations.

We believe that this is an important issue, which may have undesirable consequences and needs to be addressed. Some donors are supporting important, project-based initiatives.<sup>26</sup> And a number of developing countries are making important progress (for example, Botswana opened a mission in Geneva in 2001 and now regularly attends TRIPS Council meetings). But more needs to be done before we are likely to see any major improvement for a significant number of developing countries.

We offer two recommendations below aimed at significantly increasing participation by developing countries in international IP standard setting. The first recommendation is aimed at ensuring that the poorer developing countries, particularly LDCs, have the opportunity of sending representatives from capitals to the important meetings in WIPO and the WTO TRIPS Council. We propose that this could be achieved, with relative ease and without excessive cost, by an expansion of the existing subsidy scheme operated by WIPO for certain meetings. The new scheme should be mainly targeted at LDCs, as they are the least well represented in Geneva and face the most severe financial constraints in sending delegations to international IP negotiations and meetings. But it should also be open to all low income developing countries.

**WIPO should expand its existing schemes for financing representatives from developing countries so that developing countries can be effectively represented at all important WIPO and WTO meetings which affect their interests. It would be for WIPO and its member states to consider how this might most effectively be done and financed from WIPO's own budgetary resources.**

The second recommendation we make aims at ways to improve the quality of participation by developing countries whose representatives may lack expertise and experience in international IP standard setting and in the examination of the relationship between IP and national interests, and who may be unfamiliar with some of the technical subjects being discussed in WIPO and the TRIPS Council. To address this issue, we propose that two full time posts for IP Advisers (one for industrial property, the other for copyright, traditional knowledge and other IP subjects) are established at UNCTAD in Geneva. After careful consideration, we conclude that UNCTAD is best placed to fulfil this role because it has a broad mandate to undertake technical assistance and research not just on IP but across the spectrum of trade and development issues. Importantly, it also appears to us that UNCTAD has the confidence of the developing countries that are likely to be the main clients for such a service. Indeed, there is a clear precedent for this measure as UNCTAD recently established a similar post to developing countries on the WTO Trade in Services negotiations, with funding from DFID.

**UNCTAD should establish two new posts for Intellectual Property Advisers to provide advice to developing countries in international IP negotiations. DFID should consider the initial funding of these posts as a follow-up to its current TRIPS-related project funding to UNCTAD.**

We emphasize that these measures are in no way intended to substitute for the strengthening of IP-related administrative and analytical capacities within national institutions in developing countries. In fact, it is our intention that these recommendations should support those made in Chapter 7.

## THE ROLE OF CIVIL SOCIETY

We have been struck by the recent extent and influence of NGOs' activity in IP. We believe that NGOs have made, and can continue to make in the future, a positive contribution to the promotion of the concerns of developing countries. Campaigns to raise awareness by development and health NGOs were important factors in the supporting developing countries in the negotiations of the Ministerial Declaration at Doha. In the fields of agriculture, genetic resources and traditional knowledge, certain NGO groups play an important role in highlighting and analysing issues of concern to developing countries.

Of course, there is a very wide diversity within the NGO community in terms of the interests they represent, the balance of activities between advocacy and research, and how vocal they are in representing their interests. Legitimate questions have been asked about whom exactly NGOs represent and to whom they are accountable. On occasion, we believe that a more reflective approach to some of the issues is called for. But the fact is that NGOs have helped to raise the profile of IP issues, and that some have access to more expertise in this field than many officials in developing countries. The crucial issues are to ensure that the role played by NGOs is constructive in relation to a proper appreciation of the interests of developing country interests, and that they are accorded an appropriate role in relation to international dialogue on these issues.

There is also concern about the perceived problem of certain NGOs acting as “proxy representatives” for the governments of developing country governments in international dialogue. But others point out that developing countries are, or should be, selective in seeking assistance from NGOs. Whatever forms such support may take, it is important that developing countries are enabled and assisted to identify and put forward their own interests. We think that developing countries will be best served by having a diversity of resources on which they can draw to assist them in making IP policy and participating in negotiations.

NGOs are certainly one source of such assistance, but the role they currently fulfil reflects the fact that they are to some extent filling a gap. We consider, as noted above, that it is imperative that other sources of such assistance, particularly the concerned international institutions, such as WHO or FAO, recognise how they might make their policy advice and technical assistance more attuned to the needs of developing countries in the IP area. But at the same time, a more constructive role for NGOs, along with other civil society groups, might be achieved by giving them greater opportunities to participate in proceedings.

**WTO and WIPO should increase the opportunities for civil society organisations to play their legitimate roles as constructively as possible. For instance, this could be done by inviting NGOs and other concerned civil society groups to sit on, or observe, appropriate advisory committees and by organising regular public dialogues on current topics in which NGOs could participate.**

## DEEPENING UNDERSTANDING ABOUT IP AND DEVELOPMENT

International rules on IP are developing very rapidly. As we note in Chapter 5, a year or so after TRIPS was agreed, WIPO completed two new international treaties concerning copyright and the Internet. The Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore is dealing with these complex issues at WIPO. And, more recently, WIPO members have started to focus on the future of the patent system at the international level. As the rules evolve, it is important that their actual and potential impact be properly understood if policymaking is to be more firmly based on evidence, and less on preconceptions of the value or otherwise of these rules to developing countries.

This challenge has two aspects. First, as we have noted, there is a need for more evidence on the effect of introducing stronger IP protection in developing countries, particularly those with low incomes, which lack a viable technological base. Secondly, the range of emerging issues where the relationship between IP protection and development needs to be analysed and understood is very broad. For instance, a sample list of just some of subjects on the future agenda over the coming five to ten years might include:

- The consequences of full implementation of TRIPS on the developing world, including the provisions relating to enforcement.
- The implications of the movement towards harmonisation and integration of patent systems at the international level.

- Impacts of patents and other IPRs in new or rapidly advancing fields of technology, such as biotechnology and software.
- The impact on access to information crucial for development on the Internet, including technological protection by publishers and other content providers, and of anti-circumvention legislation. In addition, there will be issues of how to respond when nations attempt to take legal jurisdiction over foreign servers in order to affect the way these servers distribute information over the Internet.
- Alternative models of IPR protection suitable for developing countries.
- How best to build capacity for IP policymaking, administration and enforcement in developing countries – and how donors can provide support more effectively.

Currently, research work on IP is sponsored and undertaken by a variety of public and private sector organisations – universities, NGOs, industry associations, IP institutes, and development agencies. WIPO does commission studies on particular topics (for example, it has completed a very useful programme of case studies in the field of traditional knowledge) and occasional research papers, but we are surprised that it does not support a more substantial and extensive research programme directed at the emerging issues in its field. The WIPO Worldwide Academy currently focuses principally on training, but research is a part of its mandate. We see value in WIPO building up the research work of the Academy as a means of better informing itself, and its members, about the impact of IP on developing countries at different stages of development. As we have already noted, too little research work is focused on low income developing countries; even less is undertaken by developing country organisations themselves as part of national level programmes.

We believe that the system will only improve from a development perspective if we can develop a deeper understanding of the relationships between IP and development. It is important, therefore, for the community of research sponsors and practitioners around the world to meet this challenge. More research and collation of country case studies are certainly needed on subjects such as those we have listed above. But this is by no means a definitive list. Beyond these questions of resources and research priorities, however, we believe there would also be benefits from greater collaboration and co-ordination in this field between research sponsors and practitioners in developed and developing countries.

We have in mind an international network and partnership initiative which would bring together development agencies, developing country governments, IP researchers and NGOs. The aims would be to identify priorities and promote co-ordination of research programmes; improve knowledge sharing amongst partners; and facilitate wider dissemination of findings through sponsorship of publications, conferences and Internet-based resources. A steering committee could oversee the initiative's operations and working groups could be formed on particular subjects. The initiative would probably require a small secretariat to be most effective, but ideally it would be housed within one of the partner organisations.

**Research sponsors, including WIPO, should provide funds to support additional research on the relationships between IP and development in the subject areas we have identified in our report. The establishment of an international network and an initiative for partnership amongst research sponsors, developing country governments, development agencies and academic organisations in the IP field could help by identifying and co-ordinating research priorities, sharing knowledge and facilitating wider dissemination of findings. In the first instance we recommend that DFID, in collaboration with others, take forward the definition of such an initiative.**

<sup>1</sup> UNCTAD/ICTSD (2001), *“Intellectual Property Rights and Development”*, UNCTAD, Geneva, pp.57-62.

Source: <http://www.ictsd.org/unctad-ictsd/outputs/policypaper.htm>

<sup>2</sup> See Box O.1 in Overview on TRIPS.

<sup>3</sup> WIPO (2001) *“Revised Draft Program and Budget 2002-2003”*, WIPO, Geneva.

Source: [http://www.wipo.org/eng/document/govbody/budget/2002\\_03/rev/pdf/introduction.pdf](http://www.wipo.org/eng/document/govbody/budget/2002_03/rev/pdf/introduction.pdf)

<sup>4</sup> Convention Establishing the World Intellectual Property Organization, as amended in 1979, Articles 3 and 4.

Source: <http://www.wipo.int/clea/docs/en/wo/wo029en.htm>

<sup>5</sup> At WIPO website. Source: [http://www.wipo.int/about-wipo/en/dgo/abstract\\_ip\\_pub.htm](http://www.wipo.int/about-wipo/en/dgo/abstract_ip_pub.htm)

<sup>6</sup> See Article 4 of Convention.

<sup>7</sup> Quotations from World Intellectual Property Declaration, WIPO (2000).

Source: <http://www.wipo.int/about-wipo/en/>

<sup>8</sup> For instance, international NGO Observers at the WIPO Assemblies are mainly industry groups. See WIPO Document No. A/36/INF/3 (October 3, 2001).

Source: [http://www.wipo.int/news/en/index.html?wipo\\_content\\_frame=/news/en/conferences.html](http://www.wipo.int/news/en/index.html?wipo_content_frame=/news/en/conferences.html)

<sup>9</sup> This is also the view of WHO and the EU, who issued a joint statement following a meeting in Brussels on 6 June 2002 saying: “WHO will also seek to co-operate closely, where appropriate, with WTO and WIPO on technical assistance to developing countries implementing the TRIPS Agreement along the lines of the Doha Declaration”. Source: <http://www.who.int/inf/en/pr-2002-45.html>

<sup>10</sup> Bhagwati, J. (2000) *“What It Will Take to Get Developing Countries into a New Round of Multilateral Trade Negotiations”*, Columbia University, New York, p.21.

Source: <http://www.dfait-maeci.gc.ca/eet/02-e.pdf>

<sup>11</sup> For example, Correa, C. (2000) *“Intellectual Property Rights, the WTO and Developing Countries: the TRIPS Agreement and Policy Options”*, Zed Books, New York & Third World Network, Penang.

<sup>12</sup> See Thorpe, P. (2002) *“The Implementation of the TRIPS Agreement by Developing Countries”*, Commission on Intellectual Property Rights Background Paper 7, Commission on Intellectual Property Rights, London.

Source: <http://www.iprcommission.org>

<sup>13</sup> Conference organised by MSF, CPTech, HAI and Oxfam, *“Implementation of the Doha Declaration on the TRIPS Agreement and Public Health: Technical Assistance – How to get it right”*, 28 March 2002, Geneva.

Source: <http://www.haiweb.org/campaign/access/ReportPostDoha.pdf>

<sup>14</sup> Source: <http://www.wipo.int/cfdiplaw/en/trips/index.htm>

<sup>15</sup> The updated model law, whilst certainly an improvement on the previous version we saw, still does not specifically address in either the text or the accompanying commentary certain key issues. These include the patentability of computer programmes, or biological material such as genes or other material pre-existing in nature. We would suggest, for example, that the law should highlight, at least in the accompanying commentary, the different positions taken also on other issues such as farmer’s rights, rights in respect of the progeny of patented material and other exceptions to patent rights such as for educational uses. The various grounds on which some countries provide for compulsory licences could also be discussed, subject of course to any necessary qualification regarding possible incompatibility with international agreements. Other issues that could also be more openly addressed would include the possible interpretations of novelty, inventive step and industrial applicability (see chapter 6) and the disclosure of the origin of biological material (chapter 4).

<sup>16</sup> Article 66.1 of TRIPS.

<sup>17</sup> See Lall, S. & Albaladejo, M. (2001) *“Indicators of the Relative Importance of IPRs in Developing Countries”*, UNCTAD/ICTSD, Geneva. Source: <http://www.ictsd.org/unctad-ictsd/docs/Lall2001.pdf>.

This report sets out various measures of scientific and technical capacity in developing countries.

<sup>18</sup> Drahos, P. (2001) *“Developing Countries and International Intellectual Property Standard-Setting”*, Commission on Intellectual Property Rights Background Paper 8, Commission on Intellectual Property Rights, London. Source: <http://www.iprcommission.org>

<sup>19</sup> The Trade Act of 2002 (fast-track authority), HR3009, states: “The principal negotiating objectives of the United States regarding trade-related intellectual property are:

(A) to further promote adequate and effective protection of intellectual property rights, including through

(i) (I) ensuring accelerated and full implementation of the Agreement on Trade-Related Aspects of Intellectual Property Rights referred to in section 101(d)(15) of the Uruguay Round Agreements Act (19 U.S.C. 11 3511(d)(15)), particularly with respect to meeting enforcement obligations under that agreement; and

(ii) ensuring that the provisions of any multilateral or bilateral trade agreement governing intellectual property rights that is entered into by the United States reflect a standard of protection similar to that found in United States law;

- (ii) providing strong protection for new and emerging technologies and new methods of transmitting and distributing products embodying intellectual property;
  - (iii) preventing or eliminating discrimination with respect to matters affecting the availability, acquisition, scope, maintenance, use, and enforcement of intellectual property rights;
  - (iv) ensuring that standards of protection and enforcement keep pace with technological developments, and in particular ensuring that rightholders have the legal and technological means to control the use of their works through the Internet and other global communication media, and to prevent the unauthorized use of their works; and
  - (v) providing strong enforcement of intellectual property rights, including through accessible, expeditious, and effective civil administrative, and criminal enforcement mechanisms;
- (B) to secure fair, equitable, and non-discriminatory market access opportunities for United States persons that rely upon intellectual property protection; and
- (C) to respect the Declaration on the TRIPS Agreement and Public Health, adopted by the World Trade Organization at the Fourth Ministerial Conference at Doha, Qatar on November 14, 2001.

Source: <http://waysandmeans.house.gov/>

- <sup>20</sup> Agreement Between The United States Of America And The Kingdom Of Cambodia On Trade Relations And Intellectual Property Rights Protection (Source: [http://199.88.185.106/tcc/data/commerce\\_html/tcc\\_documents/cambodiatrade.html](http://199.88.185.106/tcc/data/commerce_html/tcc_documents/cambodiatrade.html)); US-Jordan Free Trade Agreement (Source: <http://www.ustr.gov/regions/eu-med/middleeast/textagr.pdf>); US-Vietnam Agreement on Trade Relations (Source: <http://www.ustr.gov/regions/asia-pacific/text.pdf>).
- <sup>21</sup> This is the current policy of the US Trade Representative, as reflected in the 2002 Trade Act.
- <sup>22</sup> Weekes, J. et al (2001) *"A Study on Assistance and Representation of the Developing Countries without WTO Permanent Representation in Geneva"*, Commonwealth Secretariat, London.
- <sup>23</sup> The Commonwealth Secretariat study estimated the total cost of setting up and running a 3 to 4 person mission in Geneva to be approximately \$340,000 per year.
- <sup>24</sup> Michalopoulos, C. (2001) *"Developing countries in the WTO"*, Palgrave, London.
- <sup>25</sup> The Assemblies of the Unions established under the PCT and the Madrid Agreement, two WIPO-administered treaties, have agreed to finance the travel and subsistence expenses of one government official from each Member State to their meetings in ordinary or extraordinary session. In addition, following a decision by the Assemblies of WIPO Member States in 1999, WIPO sponsors the participation of 26 government officials from different developing countries and transition countries (five each from Africa, Asia, Latin America and the Caribbean, the Arab countries, certain countries in Asia and Europe plus one from China) in meetings of a selected number of committees (dealing with patents, trademarks, copyright and traditional knowledge). See Leesti, M. & Pengelly, T. (2002) *"Institutional Issues for Developing Countries in Intellectual Property Policymaking, Administration and Enforcement"*, Commission on Intellectual Property Rights Background Paper 9, Commission on Intellectual Property Rights, London, footnote 17. Source: <http://www.iprcommission.org>
- <sup>26</sup> For example, UNCTAD, in collaboration with the International Centre for Trade and Sustainable Development, is currently implementing a project to provide developing countries with a handbook on implementation of TRIPS and on the upcoming reviews of the Agreement. The project is financed by the UK Department for International Development.



# ACRONYMS

AIDS	Acquired Immunodeficiency Syndrome
ARIPO	African Regional Industrial Property Organisation
ARV	Anti-Retroviral
CBD	Convention on Biological Diversity
CGIAR	Consultative Group on International Agricultural Research
CMH	Commission on Macroeconomics and Health (WHO)
DFID	Department for International Development (UK)
DMCA	Digital Millennium Copyright Act
EPO	European Patent Office
EU	European Union
FAO	Food and Agriculture Organisation (UN)
FDA	Food and Drugs Administration (US)
GATT	General Agreement on Tariffs and Trade
GI	Geographical Indications
GM	Genetically Modified
GSK	GlaxoSmithKline Plc
HIV	Human Immunodeficiency Virus
ICTSD	International Centre for Trade and Sustainable Development
IFAD	International Fund for Agricultural Development
IP	Intellectual Property
IPC	International Patent Classification
IPGRI	International Plant Genetic Resources Institute
IPRs	Intellectual Property Rights
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
IUPGR	International Undertaking on Plant Genetic Resources
LDC	Least Developed Country
MRC	Medical Research Council (UK)
MSF	Médecins sans Frontières
NGO	Non-Governmental Organisation
NIH	National Institutes of Health (US)
OAPI	Organisation Africaine de la Propriété Intellectuelle
OAU	Organisation of African Unity
OECD	Organisation for Economic Cooperation and Development
PBR	Plant Breeders' Rights
PCT	Patent Cooperation Treaty
PIC	Prior Informed Consent
PVP	Plant Variety Protection
R&D	Research and Development
SME	Small and Medium-sized Enterprise
STD	Sexually Transmitted Disease
TB	Tuberculosis
TK	Traditional Knowledge
TKDL	Traditional Knowledge Digital Library
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Programme
UNESCO	United Nations Educational, Scientific and Cultural Organisation
UNIDO	United Nations Industrial Development Organisation
UPOV	International Union for the Protection of New Varieties of Plants
USDA	United States Department of Agriculture
USPTO	United States Patent and Trademark Office
WHO	World Health Organisation
WIPO	World Intellectual Property Organisation
WTO	World Trade Organisation



# GLOSSARY

**Biopiracy:** There is no accepted definition of “biopiracy.” The Action Group on Erosion, Technology and Concentration (ETC Group) defines it as “the appropriation of the knowledge and genetic resources of farming and indigenous communities by individuals or institutions seeking exclusive monopoly control (usually patents or plant breeders' rights) over these resources and knowledge.”

**Bolar Exception:** An exception to patent rights allowing a third party to undertake, without the authorisation of the patentee, acts in respect of a patented product necessary for the purpose of obtaining regulatory approval for a product.

**Compulsory Licence:** A licence to exploit a patented invention granted by the state upon request to a third party for instance in order to remedy an abuse of rights by the patentee.

**Copyright:** (See Box 1.1) Exclusive rights of the creators of original literary, scientific and artistic works, which are created, without formalities, with the creation of the work, and last (as a general rule) for the life of the creator plus 50 years (70 years in the US and EU). It prevents unauthorised reproduction, public performance, recording, broadcasting, translation, or adaptation, and allows the collection of royalties for authorised use.

**Cross Licensing:** Mutual exchange of licences between patent holders.

**Database Protection:** (See Box 1.1 and Box 5.2) A *sui generis* protection system, preventing unauthorised use of data compilations, even if non-original.

**Differential or Tiered Pricing:** Practice of setting different prices for different markets, typically higher prices in richer markets and lower prices in poorer markets.

**Disclosure of Origin:** (See Box 4.4) Requirement on patent applicants to disclose in patent applications the geographical origin of biological material on which the invention is based.

**Doha Declaration (on TRIPS and Public Health):** (See Box 2.1) Declaration, agreed at the Doha WTO Ministerial Meeting in 2001, which states that to the TRIPS agreement should be interpreted and implemented in a way that supports public health. and clarifies some flexibilities allowed by the Agreement for that purpose.

**Examination (Substantive Examination):** A full examination of the patent application, undertaken by a patent examiner, to determine whether the application complies with all the legal requirements for patentability set out in the legislation. The examination takes into account any documents found during the search.

**Exhaustion of Rights:** Principle whereby the rightholders' IP rights in respect of a product are considered exhausted (i.e. he no longer can exercise any rights) when that product has been put on the market by the IP holder, or by an authorised party.

**Fair Use or Fair Dealing:** (See Box 5.1) An exception to copyright allowing third parties to use the copyrighted material in certain circumstances. National copyright laws in most countries incorporate exceptions for copying for personal use, research, education, archival copying, library use and news reporting, based on principles of 'fair dealing', or 'fair use' (US).

**Farmers' Rights:** (See Box 3.2) 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.

**Generic Medicine or Drug:** A generic drug is the chemical equivalent of a patented drug.

**Genomics:** The scientific discipline of mapping, sequencing, and analyzing genomes.

**Geographical Indication (GI):** (See Box 1.1) Name that identifies the specific geographical origin of a product when , certain qualities, reputation or other characteristics of the products can be associated with that origin.. For example, food products sometimes have qualities that derive from their place of production and local environmental factors. The GI prevents unauthorized parties from using a protected GI for products not from that region or from misleading the public as to the true origin of the product.

**Hybrid Varieties:** Varieties marketed through seeds derived as the offspring of two different varieties of plant.

**Intellectual Property Rights (IPRs):** (See Box 1.1) Rights awarded by society to individuals or organisations over inventions, literary and artistic works, and symbols, names, images, and designs used in commerce. They give the titleholder the right to prevent others from making unauthorised use of their property for a limited period.

**Landrace:** A crop cultivar or animal breed that evolved with and has been genetically improved by traditional agriculturalists, but has not been influenced by modern breeding practices.

**Open Source:** Software products in which the source code is made publicly available.

**Parallel Imports:** The import of a patented product from another country once it has been put on the latter's market by the titleholder, or other authorised party. For instance, in the EU it is legal to buy a product from a wholesaler in Portugal to retail in the UK, although the product is patented in both countries. The legal status of parallel imports is a matter for national decision, and is related to the issue of the *Exhaustion of Rights*.

**Patent:** (See Box 1.1) An exclusive right awarded to an inventor to prevent others from making, selling, distributing, importing or using their invention, without licence or authorisation, for a fixed period of time. In return, society requires that the patentee discloses the invention in the public. There are usually three requirements for patentability: novelty (new characteristics which are not *prior art*), inventive step or non-obviousness (knowledge not obvious to one skilled in the field), and industrial applicability or utility (US).

**Plant Variety Protection (PVP):** See Plant Breeders' Rights.

**Plant Breeders' Rights (PBRs):** (See Box 1.1) Rights granted to breeders of new, distinct, uniform and stable plant varieties. They normally offer protection for at least twenty years. Most countries have exceptions for farmers to save and replant seeds on their holdings, and for further research and breeding.

**Prior Art:** Publications or other public disclosures made before the filing (or priority) date of a patent application and against which the novelty and inventiveness of the invention in the patent application is judged.

**Prior Informed Consent (PIC):** The consent given by a party to an activity after being fully informed of all material facts relating to that activity. The CBD requires that access to genetic resources shall be subject to the Prior Informed Consent of the Country providing the resources.

**Registration:** A formal procedure for obtaining an IP right typically requiring an application and examination of that application. Certain IP rights such as copyright are available automatically without the need for registration. Patent applications in some countries may simply be registered after a basic check.

**Research Tools:** The full range of resources, methods and techniques that are used in research.

**Reverse Engineering:** Process of evaluating something to understand how it works in order to duplicate or enhance it. Particularly relevant in the copyright field where reverse engineering of software may be necessary to ensure interoperability with other programs. Also relevant, for example, to semiconductors and the production of generic medicines.

**Search:** A search of the *prior art* by a patent examiner, which brings to the patent applicant's attention documents which are thought by the patent examiner to establish whether the invention in the patent application is novel and inventive. Primary search material is the disclosures in other patent applications, but all forms of prior art in principle should be covered.

**Sui Generis:** Latin expression meaning "of its own kind". A *sui generis* system of protection for example for traditional knowledge would be a system of protection separate from the existing IP system.

**Technological Protection:** Technological protection refers to ways of introducing by technological means defences against copying or unauthorised use. The most common examples are forms of encryption in the digital media, and introducing characteristics into plants that make harvested seeds less productive, or possibly sterile.

**Trade Secret:** (See Box 1.1) Commercially valuable information about production methods, business plans, clientele, etc. They are protected as long as they remain secret by laws which prevent acquisition by commercially unfair means and unauthorised disclosure.

**Trademark:** (See Box 1.1) Exclusive rights to use distinctive signs, such as symbols, colours, letters, shapes or names to identify the producer of a product, and protect its associated reputation. The period of protection varies, but a trademark can be renewed indefinitely.

**Traditional Knowledge (TK):** Whilst there is no generally acceptable definition, TK includes for example tradition-based creations, innovations, literary, artistic or scientific works, performances and designs. Such knowledge is often transmitted from generation to generation and is often associated with a particular people or territory.

**Utility models:** (See Box 1.1) A utility model is a registered right which confers on its proprietor exclusive protection for an invention, in a similar manner to a patent. Many developed countries, and several developing ones, have some form of utility model system in addition to their patent system, but the precise forms of these systems vary widely. In general, as with a patent, to be protected by a utility model, an invention must be new, involve an inventive step, and lend itself to industrial application. The level of inventiveness required, however, is generally lower than that for a patent. In addition utility models may be granted without prior *examination* to establish that these conditions have been met.



# ACKNOWLEDGEMENTS

The Commission would like to thank all the very many people with whom we consulted during the course of our investigations, and who offered their valuable insights, expertise and time. We have carefully considered all their views in the preparation of this report. We are grateful to all the people we met on our visits to China, India, Brazil, Kenya, South Africa, Geneva, Brussels, Washington and London, and we also greatly appreciate the input of all those who attended our international conference in February 2002. We are particularly grateful to the authors of the Commission on Intellectual Property Rights background papers and those who participated in our expert workshops.

## List of Organisations Consulted

**BRAZIL:** A2R Environmental Fund, ABAPI, ABES, ABRASEM, Action Aid Brazil, Bioamazonia, Brazilian National Library, CREA, Daniel & Cia, Dannerman, Siemens & Ipenema Moreira, EMPRAPA, Extracta, FAPESP, FINEP, FIOCRUZ, Forum ONG Aids, GlaxoSmithKline, Grupo dela Vidda, IBAMA, IBPI, INPI, Instituto Socio Ambiental, Interfarma, Ministry of Agriculture, Ministry of Culture, Ministry of Development, Industry and Commerce, Ministry of Environment, Ministry of Foreign Affairs, Ministry of Health, Ministry of Science and Technology, Monsen, Leonardos & Cia, SBACEM, SOCIMPRO, Sun Microsystems.

**BRUSSELS, BELGIUM:** Association Internationale de la Mutualité (AIM), EFPIA (European Federation of Pharmaceutical Industries and Associations), European Commission – DG Development, European Commission – DG Trade.

**CHINA:** Beijing High Court, China Bureau of Copyright, Chinese Academy of Science, Double Crane Pharmaceuticals, Fudan University, Legend Computers, Microsoft, Ministry of Science and Technology, Office for the Protection of New Plant Varieties, Shanghai Pudong Intellectual Property Centre, Shanghai Video and Audio Software Co. Ltd, SIBS, Monsanto, SIPO, Tong Ren Tang, Tsinghua University, UK Embassy Beijing, United Gene Institute, US Consulate General Beijing, Yong You Software Company.

**GENEVA, SWITZERLAND:** Australian Permanent Mission, Canadian Permanent Mission, Center for International Environmental Law (CIEL), Ghanaian Permanent Mission, IFPMA, Indian Permanent Mission, Malaysian Permanent Mission, Peruvian Permanent Mission, Quaker United Nations Office, Third World Network, UK Permanent Mission, UNCTAD, WHO, WIPO, WTO, WWF.

**INDIA:** Abbott, Anand & Anand, BDH Biotech Ltd, Centre for Biochemical Technology, CIPLA Ltd, Corporate Law Group, Department of Indian Systems of Medicines & Homeopathy, Department of Industrial Policy and Promotion, Department of Science and Technology, GlaxoSmithKline plc, ICI India Ltd, ICRIER, IDMA, IPA, Kumaran & Sagar, National Botanical Research Institute, National Innovation Foundation, National Institute of Science Communication, National Working Group on Patent Laws, Nicholas Piramal India Ltd, Novartis Ltd, OPPI, Pfizer Ltd, Ranbaxy Laboratories Ltd, Subramaniam, Nateraj & Associates, Themis Medicare Ltd, Unichem.

**KENYA:** African Centre for Technology Studies (ACTS), African Regional Industrial Property Organisation (ARIPO), African Seed Trade Association (AFSTA), Coffee Research Foundation, Cosmos Pharmaceuticals Limited, GlaxoSmithKline (GSK), Institute of Economic Affairs (IEA), Kenya Agricultural Research Institute (KARI), Kenya Industrial Property Office (KIPO), Kenya Plant Health Inspectorate Service (KEPHIS), Kenyan Coalition for Access to Essential Medicines (KCAEM), Kenyan National Farmers Union (KNFU), Ministry of Agriculture, Ministry of Health - Chief Pharmacist, Ministry of Tourism and Trade, Registrar's General Office, Seed Trade Association of Kenya (STAK), Tea Research Foundation.

**LONDON, UK (Commission on Intellectual Property Rights International Conference and Workshops):** ActionAid, Actions Jeunesse, African Centre for Technology Studies, AIPPI, Amersham PLC, Amsterdam Center for International Law, Animal Diseases Research Institute, Aslib-IMI, Assinsel, Association of University Teachers, AstraZeneca, Australian National University, Authors' Licensing and Collecting Society Ltd, Berne Declaration, Biogenetics Inc, BioIndustry Association, Bowdoin College, Brazilian Embassy to the UK, British Computer Society, British Computer Society, British Copyright Council, British Music Rights, British Phonographic Industry, Buko Pharma-Kampagne,

Burns, Doane, Swecker and Mathis, LLP, CAB International, Cafod, Cambridge Economic Policy Associates Ltd, Caribbean Regional Negotiating Machinery, Centre for International Development at Harvard University, Centre for International Programmes and Links, CGIAR–ISNAR, Chartered Institute of Patent Agents, CIPLA Ltd, CISAC, Commonwealth Secretariat, Confederation of British Industry, Conserve Africa International, Consumer Project on Technology, Consumers International, DEFRA, DOH, DFID, Dow Jones Newswires, Drug Study Group, Duke University School of Law, ECHO International Health Services, Economic Commission for Africa, EPSRC, Essential Drugs Project, e-TALC, European Medicines Evaluation Agency, European Patent Office, Falco-Archer, Inc, FCO, Florida State University College of Law, Foga, Daley & Co, Food Right, Forum for Biotechnology and Food Security, Foundation for International Environmental Law and Development (Field), Free Software Foundation European, French Embassy Economic Service, GENE CAMPAIGN, Genetic Engineering Alliance, Genewatch UK, German Patent and Trade Mark Office, GlaxoSmithKline, Global Alliance for TB Drug Development, Herbert Smith, HM Treasury, Honeybee Network, House of Lords, IFPI, Indian Institute of Management, Indian National Botanical Research Institute, Indigenous Peoples Biodiversity Network, Information Waystations and Staging Posts, Institute for Agriculture and Trade Policy, Institute for Global Health, Institute of Arable Crops Research, Institute of Development Studies, International Association for the Protection of Intellectual Property (AIPPI), International Centre for Trade and International Chamber of Commerce, International Federation of Pharmaceutical Manufacturers' Associations, International Federation of Red Cross and Red Crescent Societies, International Indian Treaty Council, International Policy Network, International Union for the Protection of New Varieties of Plants (UPOV), International Vaccine Institute, IPPPH - Global Forum for Health Research, ITDG, John Innes Centre, Kent Law School, Kenya Mission to WTO, Kenya Plant Health Inspectorate Service, Kenyan Plant Breeders Rights Office, Ketchua-Aymara Association for Sustainable Livelihoods, Lakhanpal Productions, Library Association, Light Years IP, Limbe Botanic Garden, Linklaters and Alliance, Liverpool University, Max Planck Institute for Foreign and International Patent, Copyright and Competition Law, McDermot, Will and Emery, Médecins Sans Frontières, Merck & Co Inc, Microsoft Corporation, Monsanto, National Centre for Genetic Engineering and Biotechnology (Thailand), Natural Resources Institute, Natural Resources International Limited, Nigerian Coalition for Access to Essential Medicines, Nigerian Federal Medical Centre, NM Rothschild & Sons Limited, No Patents on Life Coalition, Non Profit Library, Congo DR, OECD, Open University, Oxfam, Oxford IP Research Centre, PATH, Pfizer Inc, Portuguese Institute of Industrial Property, Prospect, Quaker United Nations Office, Queen Mary Intellectual Property Research Institute, Research & Information System for Developing Countries, Reuters, Rothamsted International, Rouse and Co. International Ltd, Royal Botanic Gardens Kew, Royal Courts of Justice, SCF, SciDev.Net, Science Centre for Social Research Berlin, Sheffield University, Sociedad Peruana de Derecho Ambiental, South Centre, SSL International plc, Stanford University, Steptoe and Johnson, Stop AIDS Campaign, Sustainable Development, Swiss Federal Institute of Intellectual Property, The Association of the British Pharmaceutical Industry, The British Council, The British Society of Plant Breeders, The Burnhams Group, The Economist, The Journal Server Trust, The Lancet, The Patent Office, The Rockefeller Foundation, The Royal Society, The World Bank, Third World Network, Trade Marks Patents and Designs Federation, UNAIDS, UNCTAD, UNDP, Unique Solutions, United Nations Association, University College London School of Public Policy, University of the West of England, UNU/INTECH, US National Science Foundation, USTR, VSO, Wellcome Trust, Catalyst Biomedica, Willoughby & Partners, World Health Organization, World Intellectual Property Organisation, World Markets Research Centre, World Press Centre, Zambian Mission in Geneva, Zikonda and Associates.

**MUNICH, GERMANY:** European Patent Office

**WASHINGTON DC, USA:** AEI, BIO, CPTech, Dept Health and Human Services, House Judiciary Committee, IIPA, IPI, Merck, National Institute of Health, PGFM, PhRMA, Senate Judiciary Committee, State Department, USTR, Venable, World Bank.

Published by

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February 2003 (3rd edition)

The full text of the report and the executive summary can be downloaded from the Commission on Intellectual Property Rights website: <http://www.iprcommission.org>

For a hard copy of the report or further information please contact the Commission Secretariat at the above address.

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Designed and Printed by

Dsprint/redesign  
7 Jute Lane  
Brimmsdown  
Enfield EN3 7JL