

Integrating Intellectual Property Rights and Development Policy Daniel Alexander, London

The Millennium Development Goals recognise the importance of reducing poverty and hunger, improving health and education, and ensuring environmental sustainability. Accordingly, the international community has committed itself to reducing the proportion of people in poverty by half by 2015. In 1999, an estimated 1.2 billion people survived on less than one dollar a day, and nearly 2.8 billion people lived on less than two dollars a day. About 90 percent of these people were in South or East Asia or sub-Saharan Africa. HIV/AIDS, tuberculosis, and malaria claim millions of lives in these countries every year. For more than 120 million children of primary school age, education is out of reach.

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 Intellectual Property Rights. 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.

Some argue strongly, particularly in business and government in developed countries, that Intellectual Property Rights help stimulate economic growth and reduce poverty. They say there is no reason why what works so well for developed countries could not do the same in developing countries. Others, particularly from developing countries and NGOs, argue the opposite equally vehemently. IP rights can do little to stimulate invention in developing countries, because the prerequisite human and technical capacity may be absent. Moreover, they increase the costs of essential medicines and agricultural inputs, hitting poor people and farmers particularly hard.

During the last 20 years or so, the level, scope, territorial extent, and role of IP protection have expanded at an unprecedented pace. Genetic materials have become widely patented. IP rights have been modified or created to cover new technologies, particularly biotechnology and information technology. Technologies produced in the public sector are routinely patented. The World Trade Organisation (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) has extended minimum standards for IP protection globally. There are continuing discussions in WIPO¹ 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.

The functioning of IPR systems raises genuine concerns, even in developed countries. The submission of patent applications has increased tremendously in recent years – as has the perception that many patents of "low quality" and broad scope are being issued. Companies may incur considerable costs, in time and money, determining how – or whether - to conduct research without infringing upon other companies' patent rights, or defending their own patent rights against other companies. This raises questions as to whether the substantial costs involved in patent litigation are a necessary price to pay for the incentives offered by the patent system, or whether ways can be found to reduce them. How does this proliferation of patents affect competition and research?

¹ World Trade Organisation

The concerns about the impact of IP in developed countries are important for developing countries as well. Developing countries can learn from the experience of developed countries in devising their own systems. In addition, the IP system in developed countries has had direct impacts on developing countries. Restrictions on access to materials and data on the Internet can affect everyone. IP rules and regulations may be hampering research on important diseases or new crops that affect developing countries but that is actually carried out in developed countries. Developing countries may not be sharing appropriately in the benefits from commercialisation of their knowledge or genetic resources when they are patented in developed countries.

The Commission's fundamental task was 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. We believe that IP protection of some kind is appropriate at some stage for developing countries. The system provides incentives to invent and develop new technologies that may benefit society.

But incentives work differently, depending on the supply response they evoke. They impose costs on consumers and other users of protected technologies. The balance of costs and benefits will vary according to how the rights are applied and according to the economic and social circumstances of the country where they are being applied. Standards of IP protection that may be suitable for developed countries may produce more costs than benefits when applied in developing countries, which rely in large part on knowledge generated elsewhere to satisfy their basic needs and foster development.

Although most developing countries do not have a strong technological base, they do have genetic resources and traditional knowledge that are of value to them and to the world at large. This gives rise to a further key question. Can the "modern" IP system help to protect these resources of knowledge and ensure that the benefits of their use are equitably shared? At the other end of the scale, the Internet offers enormous opportunities for access to scientific and research information needed by developing countries, whose access to traditional media may be limited by lack of resources. But forms of encryption and IP rules may, paradoxically, make this material less accessible than it is now with printed material. It also needs to be considered what sort of rights intellectual property protection confers. The conferring of IP rights is an instrument of public policy, which should be designed so that the benefit to society (for instance through the invention of a new drug or technology) outweighs the cost to society (for instance, the higher cost of a drug and the costs of administering the IP system). But the IP right is a private one, so the financial benefits and costs fall on different groups within society. The 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. 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 necessities of life for poor people.

We believe policy makers need to consider the available evidence, imperfect as it may be, before further extending IP rights. Too often, the interests of the "producer" dominate in the evolution of IP policy, and those of the ultimate consumer are either not heard or heeded. In IPR discussions between developed and developed countries, a similar imbalance exists. Developing countries negotiate from a position of relative weakness. The difficulty is that they are "second comers" in a world that has been shaped by the "first comers." The question is how they can mould their IP systems to suit their own economic, social, and technological conditions, as developed countries did in the past.

Intellectual property systems may, if we are not careful, introduce distortions that are detrimental to the interests of developing countries. Developed countries should pay more attention to reconciling their commercial self-interest with the need to reduce poverty in developing countries, which is in everyone's interest. Higher IP standards should not be pressed on developing countries without a serious and objective assessment of their impact on development and poor people. We need to ensure that the global IP system evolves so that the needs of developing countries are incorporated and, most importantly, so that it contributes to the reduction of poverty in 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.

Intellectual Property and Development

Patents and copyright inherently confer both costs and benefits to individuals and companies, and to society at large. They provide an incentive for invention or creation that may benefit society, as well as the rights holder, but they also impose costs on the users of protected works.

Historically, now-developed countries used IP protection as a flexible instrument to help promote their industrialisation. Discrimination against foreigners – by refusing them the right to IP protection or by charging higher fees – was common, as was the exclusion of entire sectors, such as food or pharmaceuticals, from patentability. In some countries, the patent system was fully implemented only well into the 20th century. The East Asian countries, the most successful recent examples of development, have grown and developed their scientific and technical capabilities in the context of weak IP regimes. Now, under TRIPS and growing pressures for harmonisation, most developing nations are restricted in how they can apply the IP system. They may not discriminate among fields of technology, or by nationality, and the use of various tools of IP policy that were used historically are circumscribed under TRIPS.

The contemporary evidence suggests that, because developing countries are large net importers of technology from the developed world, the globalisation of IP protection will result in very substantial additional net transfers from developing to developed countries. The benefits to developing countries from IP protection would have to come from an offsetting dynamic stimulus to trade, the development of technology, investment, and growth.

In developed countries, strong evidence suggests that certain types of companies, particularly the pharmaceutical industry, consider Intellectual Property Rights are essential in promoting innovation. However, there is much less evidence from developing countries indicating that IPR systems are a key stimulus for innovation. Indeed, for most developing countries with weak technological capacity, the evidence on trade, foreign investment, and growth suggests IP protection will have little impact. Nor is it likely that the benefits of IP protection will outweigh the costs in the foreseeable future. For more technologically advanced developing countries, the balance is finer. Dynamic gains may be achieved through IP protection, but at costs to other industries and consumers.

The crucial issue in respect of IP is perhaps 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. 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. Technology transfer and the development of a sustainable indigenous technological capability are determined by many factors, including but by no means limited to Intellectual Property Rights. Moreover, the global economy has changed fundamentally since technology transfer was last high on the

international agenda when the International Code of Conduct on Technology Transfer was being discussed in the early 1980s.

In today's liberalised and competitive environment, companies in developing countries can no longer compete on the basis of importing "mature" technologies from developed countries and producing them behind tariff barriers. And companies are more wary of transferring technology in ways that may increase the competition they face. The problem is less about obtaining 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 without any counterbalancing strengthening of competition policies globally. Therefore, it may be unwise to focus on TRIPS as a principal means of facilitating technology transfer. A wider agenda needs to be pursued, as is currently being done in the WTO. Developed countries need to give serious consideration to their policies for encouraging technology transfer. In addition, they should promote more effective research and cooperation with and among developing countries to strengthen their scientific and technological capabilities.

- Appropriate incentive policies should be considered in developed countries to promote technology transfer, for instance tax breaks for companies that license technology to developing countries.
- Effective competition policies should be established in developing countries.
- More public funds should be made available to promote indigenous scientific and technological capability in developing countries through scientific and technological cooperation. For instance, the proposed Global Research Alliance between developing and developed country research institutions should be supported.
- Commitments should be made to ensure that the benefits of publicly funded research are available to all, including developing countries.

Health

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. But the evidence suggests that the IP system hardly plays any role in stimulating research on diseases particularly prevalent in developing countries, except for those diseases where there is also a substantial market in the developed world (e.g. diabetes or heart disease). Nor is it likely that the globalisation of IP protection will lead to greater investment by the private sector for the development of treatments for diseases that primarily affect developing countries. The evidence also suggests that patent protection has an effect on the prices charged for medicines. In developed countries, generic competition causes prices to fall quite sharply, particularly if the market is large enough to support a number of generic competitors. In the absence of patents in developing countries, more people would be able to afford treatments they need. When TRIPS comes fully into force after 2005, particularly when countries such as India have to introduce patent protection, the existing competition from generic suppliers will diminish.

The IP system is one factor among several that affects poor people's access to healthcare. Other important constraints to access to medicines in developing countries are the lack of resources, and the absence of a suitable health infrastructure (including hospitals, clinics, health workers, equipment and an adequate supply of drugs) to administer medicines safely and efficaciously. Moreover, developing countries may adopt other policies, for example, taxes on medicines, which adversely affect access.

As intellectual property rights are strengthened globally, the cost of medicines in developing countries is likely to increase, unless effective steps are taken to facilitate their availability at lower cost in developing countries. There are a number of IP policies that both developed and developing countries can adopt to promote cheaper prices for medicines in developing countries which the Commission does not believe will adversely affect the incentives for research on relevant diseases. One means of obtaining medicines at lower prices, amongst others discussed in the report, is for countries to use a mechanism called "compulsory licensing." This allows countries to license the manufacture of patented medicines to other manufacturers if there are good reasons to do so (e.g. when the government considers the price of a medicine is unjustifiably high). It can also be useful as a bargaining tool in price negotiations with producers of patented medicines. For instance, the US envisaged this possibility when negotiating the price of Cipro following the anthrax attacks last year. The importance of the IP system being used to improve access to medicines and public health was emphasised in a Declaration on TRIPS and Public Health at the WTO Ministerial meeting in Doha last year.

A major issue at Doha was how countries without the capacity to manufacture medicines could procure them under the existing rules for compulsory licensing. There are a number of ways this can be achieved which are discussed in the report. A crucial issue is how this can be effected in such a way that it provides appropriate incentives for the potential suppliers of medicines and cheaper prices than the patentee is able to offer.

Apart from international measures to facilitate access to medicines, developing countries need to adopt IP rules in their legislation and practices that limit the extent of patenting and facilitate the introduction of generic competition. Doha also allowed Least Developed Countries (Least Developed Countries) to exempt pharmaceutical products from patent protection until at least 2016. But most Least Developed Countries have already provided such protection and would need to amend their legislation accordingly.

- Because the IP system does little to stimulate research on diseases that particularly affect poor people, 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.
- 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 economic 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.
- The IP system can help to establish differential pricing mechanisms, which would allow prices for drugs to be lower in developing countries, while higher prices are maintained in developed countries. If differential pricing is to work, then it is necessary to stop low priced drugs leaking back to developed countries. Developed countries should maintain and strengthen their legislative regimes to prevent imports of low priced pharmaceutical products originating from developing countries and to help maintain the price differential. However, developing countries should aim to facilitate in their legislation their ability to import patented medicines if they can get them cheaper elsewhere in the world. TRIPS allows countries to set their own rules on what are technically called "parallel imports."
- Developing countries should establish workable laws and procedures to allow them to use compulsory licensing. They should also make similar provisions for what is called "government use." Many developed countries have such laws that allow their governments to make use of patented inventions without infringing a patent under a wide range of circumstances.

- How the issue of facilitating compulsory licensing for developing countries with inadequate manufacturing capacity is to be resolved is currently being debated in the TRIPS Council. It raises a number of quite detailed legal and practical matters. 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 solution will have little practical reality. Nor will the option of compulsory licensing be effective as a negotiating tool with companies. Whatever the solution adopted, it should be capable of quick and easy implementation to ensure that the real needs of poor people in developing countries are given priority. And it should establish conditions that provide potential suppliers with the necessary economic incentive to export medicines that are needed by these countries.
- TRIPS allows considerable flexibility in how countries may design their patent systems. Since most developing countries do not have a significant research capability, they have little to gain by providing extensive patent protection as a means of encouraging research, but they stand to lose as a result of the impact of patents on prices. Therefore developing countries should aim for strict standards of patentability to avoid granting patents that may have limited value in relation to their health objectives. Such systems should aim to promote competition, and provide safeguards in the event of abuses of the patent system.
- For instance, most developing countries should exclude diagnostic, therapeutic and surgical methods from patentability, including new uses of known products, as permitted under TRIPS.
- Developing countries should also make provisions in their law that will facilitate the entry of generic competitors as soon as the patent has expired on a particular drug. One of these provisions (the "Bolar exception") allows generic companies to develop their versions of patented drugs during the term of the patent without infringing it. Another one would be to make it easier and cheaper for generic companies to get regulatory approval for drugs similar to registered drugs, while providing for the protection of test data (e.g. clinical trials data companies require to get approval from regulators such as the FDA² in the US) against unfair commercial use.
- Those Least Developed Countries which already provide pharmaceutical protection should consider carefully how to amend their legislation to take advantage of the Doha Declaration. The TRIPS Council should review the transitional arrangements for Least Developed Countries, including those applying to join the WTO, in all fields of technology.

Copyright, Software and the Internet

There are examples of developing countries, which have benefited from copyright protection. The Indian software and film industry are good examples. But other examples are hard to identify. Many developing countries have had copyright protection for a long time but it has not proved sufficient to stimulate the growth of copyright-protected industries. Because most developing countries, particularly smaller ones, are overwhelmingly importers of copyrighted materials, and the main beneficiaries are therefore foreign rights holders, the operation of the copyright system as a whole may impose more costs than benefits for them. There are flexibilities in copyright which exist in international treaties (such as the Berne Convention) to allow copying particularly for personal and education use. These are known variously as "fair use" or "fair dealing" provisions. These have generally not proved adequate to meet the needs of developing countries, particularly in the field of education.

² Food and Drug Administration (US)

Developing countries need to put in place effective systems for enforcing rights. However, in many cases (e.g. software) the absolute scale of estimated losses from illicit copying is higher in developed countries. And weak levels of enforcement have undoubtedly had a major impact in some areas on the diffusion of knowledge and knowledge-based products in the developing world. Indeed, many poor people in developing countries have only been able to access certain works through use of unauthorised copies available at a fraction of the price of the original. An inevitable impact of stronger protection and enforcement, as required by TRIPS, will therefore be to reduce access to knowledge-related products in developing countries, with potentially damaging consequences for poor people. For instance, the cost of software is a major problem for developing countries, and the reason for the high level of illicit copying. Copyright can also be a barrier to the further development of software which is specifically adapted to local needs and requirements.

Access to the Internet in developing countries is limited, although growing rapidly in most countries. But the Internet provides an unrivalled means of low cost access to knowledge and information required by developing countries, when their access to books and journals is severely restricted by lack of resources. But the application of copyright rules to the Internet is problematic. And historic "fair use" rights may be restricted by forms of technological protection, such as encryption, which restrict access even more stringently than copyright. In the USA, recent legislation (the Digital Millennium Copyright Act - DMCA) forbids the circumvention of such technological protection, even when the purpose of circumvention does not contravene copyright laws. The EU has introduced a special form of protection of databases (the "Database Directive"), which rewards investment in the creation of databases, and which may restrict access to data by scientists or others, including in developing countries. The 1996 WIPO Copyright Treaty contains elements which may restrict the access of developing countries to information.

- Publishers, including those on-line, 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.
- 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. They 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.
- 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. In order that software can be adapted to local needs, developing countries should ensure that their national copyright laws permit the reverse engineering of computer software programmes, in ways that are consistent with relevant international treaties which they have signed.
- Internet users in 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. Countries should also not follow the lead of the US and the EU by implementing legislation on the lines of the DMCA or the Database Directive.

Patent Reform

The heterogeneous nature of developing countries, especially in their technical and scientific capacities, means that they need to choose an IP system which they feel best meets their development objectives, and economic and social circumstances. 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, or which could lead to resources being diverted to litigation and disputes about patents of doubtful validity. Such systems would need to have adequate safeguards to ensure a competitive environment, and to minimise costs for consumers. This is especially important in those areas of technology such as pharmaceuticals and agriculture where the cost of providing strong patent protection is likely to be greatest.

For the vast majority of developing countries, especially those with low incomes which rely principally on imported goods and technology, the best system might be one which applies strict standards of patentability and results in fewer patents meeting the criteria for patentability. This may be preferable to a more extensive system of protection, of benefit principally to foreign patent holders. A second tier of protection based on a form of patents known as utility models which offer protection based on lower thresholds of patentability, may be more appropriate than the full patent system to the economic circumstances of many developing countries.

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 following developed countries in encouraging more patenting by research institutions and universities. Developing countries need to consider the issues raised in developed countries about the incentives and disincentives this offers in the application of technologies invented in these institutions, and about how it might affect research priorities.

The patent rules applying in developed countries are also important since much research relevant to developing countries may be carried out in developed countries, or in collaborative efforts with developed country researchers. Of particular concern are patents on tools essential for research, for example particular gene sequences in the field of biotechnology. An increase in patenting of such research tools in developed countries might hinder research relevant to developing countries. Developing countries also need to avoid, as far as possible, the same problems arising in their patent systems.

Developing countries already face formidable obstacles in implementing patent systems. There is strong pressure to harmonise the international patent system in order to overcome the problems faced, mainly in developed countries, in coping with the pressure of rapidly growing patent applications. Because the system is essentially national or regional, there is much apparent duplication of procedures, such as search and examination, which harmonisation could eliminate. The danger for developing countries is that harmonisation would be around developed country standards of protection, which may not be suitable for them. For developing countries the concern must be to ensure that they do not accept in these discussions new international rules further limiting their freedom to design appropriate patent policies, unless it can be shown it is in their interests to do so.

· Developing countries should, within the constraints of international and bilateral obligations, provide a pro-competitive patent system that limits the scope of subject matter

that can be patented; applies strict standards of patentability; facilitates competition; includes extensive safeguards against abuses of patent rights; and encourages local innovation.

- Developing countries which provide patent protection for biotechnological inventions [PT1] should ensure that patenting guidelines are such that the use of patented inventions by other researchers is limited as little as possible. For instance, if patents over genes are allowed, the guidelines should provide that the patent only covers uses set out in the patent, not other uses of the same invention which others may uncover. This will facilitate further research in the area of the patent.

- Policy makers in developing countries should consider the establishment of utility model protection for stimulating and rewarding such innovations, rather than diluting patentability standards. This should help to provide incentives for the incremental type of innovations that predominate in many developing countries.

- Whilst there is a role for IP in developing countries' public research institutions to promote the transfer and application of technologies, it is important that:

- o Generating alternative sources of funding is not seen as the principal goal, which is rather to promote technology transfer.

- o 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.

- o Patenting and licensing should only be undertaken where it is judged necessary to encourage private sector development and the application of technologies.

- o 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.

- o Getting the balance right requires the development of expertise in IP in public sector institutions which traditionally have had none, without losing sight of the objectives of public policy for research.

- It is important that, in developing initiatives aimed at facilitating access to essential research tools, that 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.

- Developing countries need to identify a strategy for dealing with the risk that further harmonisation of patent laws internationally will lead to standards that do not take account of their interests. Such a strategy might seek a global standard reflecting the recommendations of this report. It could seek continued flexibility in the standards. Or it could be done by rejection of the process if it appears that the outcome will not be in the interests of developing countries.

Institutional Capacity

For most developing countries, the implementation of TRIPS, and the adaptation to new and rapidly evolving areas of IP (for example in biotechnology and software) requires changes to IP legislation. Many developing countries face particular difficulties in developing a co-ordinated IP policy. Formulation of IP policy in a developing country should be based on a sound appreciation of how the IP system might be used to promote development objectives, and widespread consultation and dialogue with those in the economic sectors most likely to

be affected. However many developing countries have weak institutional capacity, and in particular lack experienced and skilled personnel.

Developing countries need to consider the institutional options for implementing IP regimes in the face of shortages of skilled personnel, and how IT systems can be most effectively used for administration as well as searches. A critical issue is whether to use a registration or search and examination system for patents. The former, which involves just a basic check of the patent application, minimises requirements for skilled personnel in the patent office but makes it difficult to implement a patent system of the kind described in this report. Because of human resource problems, implementing the latter system, which involves a detailed check of the validity of the patent application and its adherence to patentability criteria, is more challenging. There are a number of strategies, including using international and regional approaches to facilitate search and examination, and contracting out to other government departments or universities with appropriate expertise, which developing countries may consider to resolve this dilemma.

The establishment and operation of an IP system is costly, and developing countries should not divert resources from already over-extended health and education budgets to subsidise the administration of a system for Intellectual Property Rights. Since the main beneficiaries of IP rights in most developing countries are foreign companies, it seems appropriate that the costs of IP administration should be principally borne by them through an appropriate fee structure.

Intellectual Property Rights are valuable to rights holders only if they are well enforced, which implies that legal systems need to be effective. And legal systems must also have the capacity to reject IP rights which are invalid. However, state enforcement of Intellectual Property Rights and enforcement through the criminal justice system are expensive, and in many countries judicial systems are under severe pressure, particularly in the area of commercial law. The "private" nature of IP rights supports the option of dispute resolution either out of court or under civil law in order to reduce the enforcement burden.

IP rights holders from developing countries also face difficulties in enforcing their rights in developed countries because of the prohibitive costs of taking action in the courts.

Under TRIPS, developed countries are obliged to provide technical and financial assistance to developing countries to facilitate its implementation. Most developed countries provide some sort of intellectual-property related technical assistance to developing countries. But the quality and quantity of this assistance needs to be assessed and evaluated. The results of much technical assistance do not seem commensurate with the effort and resources put into it. Assistance from different providers may be insufficiently coordinated, and insufficiently integrated with other forms of development assistance.

- Developing countries and donors should work together to ensure that national IP reform processes are properly "joined-up" with related areas of development policy. Greater efforts are needed to encourage more participation by national stakeholders in IP reforms. In providing technical assistance, donors should 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.

- 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.

- In order to minimise costs, developing countries should ensure that their IP legislation and procedures emphasise, to the maximum possible extent, enforcement of Intellectual Property Rights 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 right holders 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.
- 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.
- Developed countries and international institutions which 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.
- WIPO, EPO³ 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 charges for the PCT⁴ (the international system for filing patent applications) rather than from already over-stretched aid budgets. Donors could also seek to direct more technical assistance at Least Developed Countries 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.
- 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 for Trade-Related Assistance which aims to facilitate better integration of national development plans and donor assistance strategies.
- 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.

International Architecture

The principal international institutions responsible for the evolution of international IP policy are WIPO and the WTO. WIPO is the principal international institution responsible for organising the negotiation of IP Treaties and their administration. WTO has a much wider mandate than WIPO, but is important in the development of IP policy, because WTO rules, particularly the dispute settlement mechanism, give it a greater enforcement capacity. WIPO's mission, as stated in its articles, is to promote IP protection globally, and the harmonisation of national legislation. It is not required by its articles to consider both the benefits and the costs of IP protection in developing countries, or the complex links between IP protection and development.

The flexibilities available to developing countries under TRIPS (for example, in setting patentability rules, or grounds for compulsory licensing) have not always been fully utilised by developing countries. This may be because of an informed decision not to do so but those countries may also be constrained by other commitments, such as bilateral agreements, or

³ European Patent Office

⁴ Patent Cooperation Treaty

because those in charge of the legislative process are not sufficiently aware of the options available, or the full implications of them. Many developing countries are heavily dependent on model laws and technical assistance provided by WIPO, although other regional and national IP offices in developed countries also play a significant role in providing advice. Although some value WIPO's advice highly, concerns have been expressed about whether its advice to developing countries fully takes account of the flexibilities in TRIPS, and considers the most appropriate use of these in relation to a country's particular economic and social circumstances.

Developing countries are required to adopt TRIPS standards of protection by an arbitrary date, 2006 if they are Least Developed Countries. The challenge of achieving this is formidable and will incur significant costs if an IP regime is established that is inappropriate to their level of development. There are strong arguments for the desirability of developing countries determining for themselves the optimum time to strengthen IP protection. There are provisions in TRIPS for the extension of the transition period for Least Developed Countries, and the Doha Declaration initiated this process by extending exemptions from patent protection for pharmaceuticals to 2016.

Developed countries to a degree have a legitimate interest in the IP standards of their trading partners. But regional and bilateral agreements that encourage developing countries to adopt higher standards of IP protection, beyond TRIPS, can undermine the multilateral system by limiting use by developing countries of flexibilities and exceptions permitted in TRIPS and other treaties. And those higher standards may not be appropriate to the stage of development of the country concerned.

Active participation by developing countries in discussions of the future of the IP system is essential to ensure both the legitimacy of standard setting and its appropriateness and relevance to nations at very different levels of development. Effective participation by developing countries depends on the expertise and experience of their representatives, who may not be familiar with some of the technical subjects being discussed in WIPO and the WTO TRIPS Council. Developing countries also get advice on IP matters from a wide variety of sources, which has some advantages in terms of diversity, but the advice will also often reflect the perspective of those giving it, rather than necessarily the best interests of the country concerned.

NGOs have made a generally positive contribution to voicing concerns about the impact of IP on developing countries. For example, public awareness campaigns by development and health NGOs were important factors in supporting developing countries in negotiating the Declaration on TRIPS and Public Health at Doha. In the area of agriculture and genetic resources, NGOs have also played a prominent role. Some have asked exactly whom NGOs represent and to whom they are accountable. This is a legitimate concern, and it is therefore crucial to ensure that their role is constructive in relation to a proper appreciation of the interests of developing countries. At the same time, they can play an important role in international dialogue on these issues.

International rules on IP are developing very quickly. 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. However, relatively little research has so far been undertaken to understand the impact.

· 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 such as the WHO, FAO⁵, UNCTAD⁶ and the World Bank.

- Unless they are clearly able to integrate development objectives 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.

- 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. It, and the government concerned, should 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.

- Least Developed Countries 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. Least Developed Countries 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.

- Although 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.

- 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.

- UNCTAD should establish two new posts for Intellectual Property Advisers to provide advice to developing countries in international IP negotiations. We suggest that DFID⁷ should consider the initial funding of these posts as a follow-up to its current TRIPS-related project funding to UNCTAD.

- 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.

- 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

⁵ Food and Agriculture Organisation (UN)

⁶ United Nations Conference on Trade and Development

⁷ Department for International Development (UK)

findings. In the first instance we recommend that DFID, in collaboration with others, take forward the definition of such an initiative.