Chapter 6

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.[1] 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.[2]

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.[3] 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."[4] 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."[5]

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."[6]

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[8] 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.[9] 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,[10] 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.[11] 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)."[12] 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,[13] 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.[14] 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." [15]

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.[16] The final text of the resulting EC Directive[17] made some provision for excluding certain groups of inventions[18] 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.[19] 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.[20] 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.[21] 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.[22] 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.[23] 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.[24]

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".[25] 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.[26] 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.[27] 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.[28] Brazil and other countries[29] 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.[30] 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.[31] 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).[32] Such a requirement, which appears to be allowable under TRIPS, differs from the current requirement to describe how to put the invention into practice.[33] 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.[34] 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.[35]

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.[36] 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.[37]

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[38] 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.[39] And in May 2002, China announced that research institutes were to be encouraged to file patents relating to government-sponsored research.[40] 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.[41]

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.[42] 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.[43] 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.[44] 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.[45] 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**.[46] 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.[47] 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.[48]

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.[49] 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.[50]

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.[51]

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.[52]

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." [53]

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." [54]

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."[55] 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.[56] 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.[57] The NIH have also introduced new guidelines that are designed to mitigate problems in biomedical research.[58] 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.[59]

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.[60]

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 HDGNR10 (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.[61] 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,[62] 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.[63] 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[64] to find and map 300,000 common SNPs.[65] 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,[66] 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.[67] 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.[68] 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.[69] Proposals have been made for further initiatives to facilitate the acceleration of biotechnology research in agriculture.[70]

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

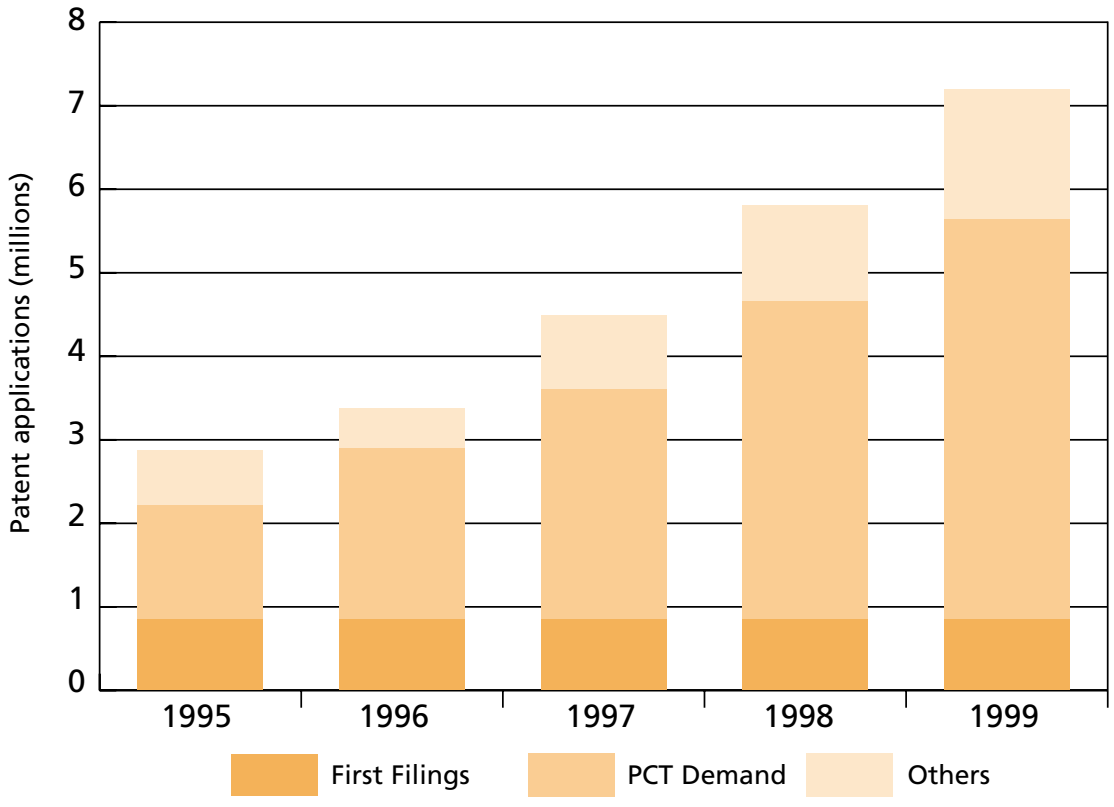
Background

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,[71] 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[72] and indications from some of the leading nations, that any treaty will be based essentially on a first-to-file system[73] 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.[74] 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.

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[1] 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

[2] 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

[3] 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

[4] Letter to Robert Hooke, 5 February 1676

[5] Merges and Nelson (1990), p.916

[6] See Glossary for definition.

[7] National Science Foundation (2002) Chapter 5. Source: http://www.nsf.gov/sbe/srs/seind02/c5/c5h.htm

[8] 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.

[9] 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

[10] See TRIPS Article 27(1). Source: http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm

[11] 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).

[12] TRIPS Article 27(1).

[13] 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/gdechtml/en/g583.htm

[14] As allowed under TRIPS Articles 27(3)(b) and (a) respectively

[15] 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

[16] 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.

[17] 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

[18] Articles 5 and 6 of the EU Biotechnology Directive (EU Directive 98/44) restricts patenting relating to human and animal genetic material.

[19] 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

[20] Barton J. (2001) "Non-Obviousness" (work in progress).
Source: http://emlab.berkeley.edu/users/bhhall/ipconf/Barton901.pdf

[21] 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

[22] EPO Opposition Decision revoking EP0630405 (ICOS Corporation) 20 June 2001 (Unreported).

[23] The UK Patent Office Manual of Patent Practice Section 14.143.
Source: http://www.patent.gov.uk/patent/reference/mpp/s14_16.pdf

[24] Biogen Inc v Medeva plc House of Lords [1997] RPC 1

[25] Nuffield Council on Bioethics (2002) pp.73-74.

[26] 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.

[27] 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.

[28] 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.

[29] Egypt draft law as notified to the WTO in document IP/C/W/278
Source: http://docsonline.wto.org/DDFDocuments/t/IP/C/W278.doc; Jamaica's draft law as notified in IP/N/1/JAM/I/1
Source: http://docsonline.wto.org/DDFDocuments/t/IP/N/1JAMI1.doc

[30] 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

[31] Source: http://www.iavi.org/press/63/p20010824a.asp

[32] Correa, C. (forthcoming) *"Protection and promotion of traditional medicine"* South Centre, Geneva.

[33] 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.

[34] WIPO currently identify 49 countries providing such protection.
Source: http://www.wipo.int/sme/en/ip_business/utility_models/where.htm

[35] 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.

[36] See Chapter 1.

[37] 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

[38] 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

[39] 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

[40] "Chinese Institutes 'can keep intellectual property'", Jia Hepeng, 21 May 2000. Source: http://www.scidev.net

[41] Information provided by WIPO, derived from 2001 application statistics.

[42] Dasgupta, P. and David, P. (1994) "Towards a New Economics of Science", Research Policy, vol. 23, pp.487-521

[43] Association of University Technology Managers (2002) *"AUTM Annual Survey FY 2000: Summary",* AUTM, Northbrook IL. Source: http://www.autm.net/surveys/2000/summarynoe.pdf

[44] 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

[45] National Science Foundation (2002), Appendix Table 4.04. Source: http://www.nsf.gov/sbe/srs/seind02/append/c4/at04-04.xls

[46] Association of University Technology Managers (2002), p.10

[47] 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

[48] Colyvas, J. et al (2002)

[49] Annual Report 2000, University of California, Office of Technology Transfer. Source: http://www.ucop.edu/ott/ttimport.html

[50] National Science Foundation (2002), Chapter 5, Text Table 5-25. Source: http://www.nsf.gov/sbe/srs/seind02/c5/c5h.htm

[51] 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.

[52] 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

[53] 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 I",* MIT Press, Cambridge MA, p.3. Source: http://haas.berkeley.edu/~shapiro/thicket.pdf

[54] Testimony on 28 February, 2002. Source: http://www.ftc.gov/opp/intellect/barrrobert.doc

[55] National Institutes of Health (1998) *"Report of Working Group on Research Tools",* NIH, Washington DC. Source: http://www.nih.gov/news/researchtools/

[56] 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

[57] 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

[58] National Institutes of Health (1998); NIH Guidelines for Implementation, 1999 (Source: http://ott.od.nih.gov/NewPages/RTguide_final.html#guide).

[59] Walsh. J. et al (2000) p.31

[60] 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

[61] 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

[62] 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

[63] 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

[64] The SNP Consortium Ltd. Source: http://snp.cshl.org/

[65] 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.

[66] The International Genetics Consortium. Source: http://www.intgen.org/

[67] 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

[68] Center for the Application of Molecular Biology to International Agriculture (CAMBIA). Source: http://www.cambia.org/

[69] International Service for the Acquisition of Agri-biotech Application (ISAAA). Source: http://www.isaaa.org/

[70] 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

[71] WIPO Conference on the International Patent System, Geneva, 25-27 March 2002. Source: http://patentagenda.wipo.int/meetings/2002/program/index.html

[72] 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

[73] 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.

[74] 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