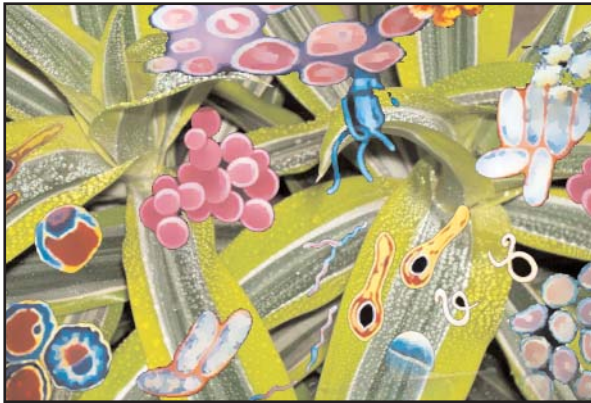




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## Patenting Genetic Resources: Striving for the Right Balance

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### Summary

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- The emotive political debate on the appropriate patent rules for inventions involving genetic resources should not overshadow the real need to ensure that providers of genetic resources receive equitable compensation for their access and use.
- Proposals to modify patent rules by requiring applicants to disclose the source of origin of genetic resources have attracted many proponents, but the case remains unproven. Other policy instruments may be more effective in ensuring equitable benefits while not being so burdensome as to stifle access and research.
- Until the fundamental debates on the role and scope of the intellectual property system are settled, it will be difficult to design patent rules that are effective in preventing misappropriation of genetic resources.

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### Introduction

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Genetic resources continue to play an essential role in today's world – in agriculture, medicine and a wide range of industrial applications. Much knowledge related to the uses of these resources is held by traditional communities, and new understanding and applications are also developed through Western scientific processes. However, the largest repository of genetic diversity and traditional knowledge is found in tropical countries, and consequently there has been a long history of bio-prospectors seeking new genetic resources for commercial applications in these countries.

It is this situation that has triggered many years of debate and policy development, which ultimately led to the conclusion of the 1992 UN Convention on Biological Diversity (CBD). The CBD seeks to facilitate access to genetic resources, while ensuring that there is equitable sharing of the benefits arising from their use. All this is set within the wider context of aiming to conserve and sustainably use biological diversity, while also ensuring respect for the knowledge of traditional and local communities. Thus, the CBD strives to reach a balance between the interests and needs of developed and developing countries, such that each gains from cooperating in such a framework.

This Briefing Paper examines one continuing debate about how far these principles should apply: i.e. how the intellectual property rights system ought to treat inventions involving genetic resources and traditional knowledge. This debate addresses issues that lie at the heart of the CBD: on what basis should access to genetic resources take place; what kind of commercialization should take place; and what terms should exist to ensure equitable benefit-sharing? Resolution of these issues has important implications for the future of biotechnology, conservation of biological diversity, protection of indigenous culture and international trade relations.

In recent years, there have been growing calls for reform of patent legislation in order to address concerns about the equity of the intellectual property system. This has arisen from the granting of a number of controversial patents for inventions in which genetic resources or traditional knowledge have been utilized, although it should be noted that many of these patent decisions were ultimately reversed. The right of the inventors to claim intellectual property rights (IPRs) over such resources has been disputed on the basis that they had been misappropriated from the country of origin or communities where the resources or traditional knowledge (TK) originated.

The link between the intellectual property system and resource misappropriation is an issue of international concern, and is the subject of ongoing discussions within various international forums. Although a range of positions exists, the debate hinges principally on the different perspectives of developed and developing countries. Developing countries are often the source of

genetic resources and TK, because of their wealth of biological and cultural diversity, while the users of these resources tend to be located in developed countries, where much of the biotechnology industry and the most valuable markets are located and hence where the vast majority of patent applications are made. Consequently, the use and patenting of genetic resources has come to be viewed as a question of the rights of developing versus developed countries, with the granting of intellectual property rights over such resources being described as the latest form of colonialism.

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### Background

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The role and purpose of the intellectual property (IP) system, in particular the patent system, is increasingly being queried and challenged by certain countries and sectors. Some feel that the system is biased towards the interests of industrialized countries and big business, while the concerns and needs of developing countries are not adequately taken into account. Attempts within the World Intellectual Property Organization (WIPO) to elaborate a 'development agenda' are aimed at addressing some of these concerns. One aspect of these concerns relates to the granting of IPRs over genetic resources and traditional knowledge. In particular, the granting of patents over certain inventions based on such resources has led to claims that these were misappropriated and to accusations of 'biopiracy'.<sup>1</sup>

There are two main reasons why this has become such an important issue over the last decade. First, provider countries wish to benefit more from the commercialization of products based on their genetic resources, and this desire is coupled with a growing recognition and articulation of national and community rights over genetic resources and TK. This has arisen largely as a result of the CBD, which recognized the sovereignty of countries over their genetic resources, and also called for the fair and equitable sharing of benefits arising from their use. In addition, the CBD highlighted the need for the respect and maintenance of the traditional knowledge of indigenous and local communities.

In conjunction with this, there has developed a widespread belief that significant economic benefits can be gained from the commercialization of genetic resources. Although many people (especially in the private sector) feel that this case has been overstated, this view has been encouraged by a few high-profile examples that have met with commercial success – for example, one of the most frequently cited cases is that of the rosy periwinkle (*Catharanthus roseus*) from which highly profitable cancer drugs were developed.<sup>2</sup> Such examples have led to the wish to capture some of these benefits among those countries that are typically the providers of such resources.

Secondly, there is a trend towards widening the scope of the types of inventions for which patents have

been granted, as well as an apparent lowering of the standard of novelty that is required in some countries.<sup>3</sup> Thus patents are increasingly being granted not only for living organisms (microbes, animals and plants), but also for products in which the degree of 'invention' is very low – for example, gene sequences or compounds that have been discovered in nature, or to which minimal changes have been made.

Both these factors have brought about a radical change in attitudes and expectations related to the access and use of resources. Thus there has been a shift away from the view that genetic resources are open access or are global goods, towards a situation in which biodiversity is increasingly being regarded as a commodity, and as something that can be, and is being, privatized.<sup>4</sup>

This trend raises ethical concerns for many, for example, over whether IPRs should be granted for living organisms, or elements of these (such as gene sequences). At the same time, it has resulted in growing concern about resource misappropriation, the IP system being seen as a tool that is enabling institutions and researchers to appropriate the resources and knowledge of rural communities and of developing countries. There is concern both that traditional property rights have not been respected – for example, the use and commercial development of TK may be culturally offensive – and also that some communities and countries may have been deprived of benefits arising from the use of their resources without their consent.

It is among developing countries that concern about these issues is greatest, mainly because they are rich in genetic resources and TK. However, the history of colonialism and continuing inequalities between countries also go some way towards explaining the strength of feeling about this issue; indeed biopiracy has been described as today's form of colonialism.<sup>5</sup>

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## What is biopiracy?

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The term 'biopiracy' is widely bandied about, but it is not always clear to what exactly it refers. For example, it has been used to describe the granting of IPRs to 'foreign' inventors when their inventions have used the genetic resources or TK of another country – sometimes regardless of the conditions under which these resources were accessed, and the nature of any agreements or contracts that were made. Thus, the very act of a 'foreign' inventor obtaining IPRs over an invention that has been developed from another country's resources is regarded as a form of biopiracy.

Biopiracy can also be defined as the theft of a biological resource – in a narrow sense, this would be the case where the laws of a country have been broken, for example, when accessing the resource or through breach of an access agreement. This term may also be applied to the patenting of spurious 'inventions' – i.e. in which there is a lack of novelty and inventive step.<sup>6</sup>

In some cases of supposed biopiracy, no laws may have been broken. For example, the company or researcher in question may have obtained the resources prior to implementation of the CBD, or from a country in which there were no Access and Benefit-Sharing (ABS) laws. Alternatively, the resource may have been accessed from an *ex-situ* resource, such as a gene-bank or botanical garden, or the TK that led to the invention may have been widely published, or the properties widely known – for example, by numerous different peoples, in a number of countries.

Thus a distinction can be drawn between biopiracy in a legal sense (where a law has actually been broken – e.g. breaching ABS legislation) and biopiracy in a 'moral' sense, the latter being highly subjective. Indeed, it is these differences in opinion as to what biopiracy is that have led to a lack of clarity on this issue and have contributed to difficulties in finding a solution.

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## Accessing genetic resources: the current situation

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In many countries, access to and use of genetic resources, particularly by foreign researchers and the private sector, have declined significantly in recent years. There are a number of reasons for this.

One factor is that advances in technology mean that researchers now have less need to access new materials, both because genetic resources can be analysed in far greater depth than before, and also because of the increasing use of synthetic materials. In addition to this, obtaining permission to access genetic resources has become very difficult in a number of countries. In response to the adoption of the CBD, some countries have introduced legislation to control access to and use of their genetic resources.<sup>7</sup> In many cases, the process of implementation has been very prolonged, and has served to impede the collection and use of resources.<sup>8</sup> In addition, some countries have drawn up very strict legislation, or it is being interpreted in such a way. Consequently, few access permits or agreements for research have been granted, and in some countries, research by foreign parties has effectively come to a halt, with no permits being granted.<sup>9</sup> Furthermore, at the local level, for example among traditional communities or other resource owners, there is a great deal of uncertainty and lack of trust of outside researchers. Therefore, many resource owners are uncertain as to whether, and how, to enter into access agreements.

For researchers, the complexity of some of the national access regimes is acting as a deterrent. Consequently, many are either choosing to work in other countries, where ABS legislation has yet to be implemented or where it is simpler, or they are deciding to work in other sectors. Thus, the industrial sector has reported a decline in interest in using genetic resources because of the associated regulatory difficulties and uncertainties.<sup>10</sup> This shift has also been driven by concern

within the private sector that in an uncertain legal context, they will be accused of biopiracy – the degree of legal uncertainty in some countries means that it is sometimes difficult to ensure that the correct procedure has been followed. Indeed, a survey of claims of resource misappropriation found that it is often those who are seeking to comply with ABS requirements who are accused of biopiracy<sup>11</sup> – thus, it is often those that are compliant who are being punished, presumably because it is easiest to find out about their research activities. This has resulted in disillusionment with the CBD within certain sectors, and a questioning of the motives and goals of some developing countries and NGOs.

Indeed, the decline in research and development activities observed in many countries runs counter to the objectives of the CBD, one of which is the sustainable use of all biological resources, including genetic resources. Such a situation is potentially detrimental to all – no benefits will be generated for source countries, while scientific advances will be hindered and no new products developed. If the goals of the CBD are to be achieved, there is a need to restore trust between the resource owners and users.

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### Possible solutions

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The scale of the problem of genetic resource misappropriation is hotly debated. While some advocates claim that the developing world has lost vast sums of money from the exploitation of its natural resources by foreign parties, well-documented cases are actually few and far between. Whatever the actual situation, it is apparent that in some quarters trust in those who wish to use genetic resources, and also in the IP system, is very low. Therefore, there is growing recognition of the need to address this situation – although the best way to do this remains disputed.

The main debate is over whether there should be reform of the patent system. Those in favour argue that the current system is fundamentally inequitable, and that it should not be possible to grant IP rights over resources that have been misappropriated. However, opponents of reform argue that issues of equity should not be addressed within the patent system. They hold that concerns related to equity and ABS lie outside its scope, since the function of the patent system is simply to promote innovation – although this is a contentious argument.

Furthermore, opponents hold that patent reform is not an efficient or effective means of preventing resource misappropriation, which would be best addressed at the point of access to genetic resources instead of the point of use – for example, through the wider implementation of clear and effective ABS legislation. This would have the advantage that all resource use would fall within its scope, not just those uses which result in patent applications. Indeed, given that patenting of genetic resources accounts for a very small proportion of the

total use of genetic resources, it has been suggested that too much attention has been focused on the patent system. Certainly, the development of clear and effective ABS legislation, and its wider implementation, should be a priority. However, the two options are not mutually exclusive and could be pursued in parallel.

A variety of proposals have been put forward for improving the IP system – either through reform of the patent system itself, or by taking a wider approach. The proposal that has attracted the most attention has been for the introduction of disclosure requirements (DRs) into patent legislation for inventions concerning genetic resources or TK. Such a step has been taken by a number of countries with respect to their national patent legislation and is also at the centre of much debate within international forums, as will be considered in more detail below.

Alternative options for improving equity within the IP system include the use of some of the existing provisions within patent law, such as the use of *ordre public* provisions or the doctrine of ‘unclean hands’. There is also the possibility of applying patent law much more strictly – thus, of raising the bar for the novelty requirement and of improving searches for prior art.<sup>12</sup> This could go a long way towards restoring trust in the IP system through helping to prevent the granting of ‘bad’ patents in the first place. Solutions could also be sought in other areas of law, for example, that related to unfair competition and ABS. Other possible means of improving equity could be through the use of collective approaches to risk and burden-sharing, or international legal cooperation to facilitate the enforcement of ABS legislation. These options will be described in more detail below.

### ***Disclosure requirements and their limitations***

DRs have been proposed as a means to help ensure that patents are not granted to inventions based on resources that have been improperly accessed or utilized. These measures refer to a requirement placed on patent applicants to disclose certain information about the genetic resources or TK that they have used in their invention. Thus, they may be required to disclose the source or providing country of these resources, evidence that prior informed consent (PIC) had been obtained, or evidence of fair and equitable ABS.

Two discrete aims have been proposed for such legislation. The proposed design of the legislation and, in particular, the consequences of non-compliance, is determined by which of these is sought. One option is that DRs could be used as a measure to prevent the granting of patents to inventions in which there has been inequitable conduct – for example, through making patent validity dependent on compliance with a requirement for evidence of PIC. Alternatively, DRs could simply be used as a transparency measure – for example, disclosure of geographic origin could facilitate the monitoring of genetic resource use by the providing

countries, and any breaches of good practice could be pursued through other legal means.

There is ongoing debate as to which approach is better. The arguments are based in part on the feasibility and effectiveness of each approach, but also, more fundamentally, on what the role of the IP system should be in preventing resource misappropriation, an issue touched on earlier – i.e. whether the IP system should enable sanctions to be applied for breach of ABS regulations, or whether these should be sought through other means.

DRs have already been introduced by a number of countries and regions, including the Andean Community, India, Brazil, the EU and certain of its member states. However, such legislation has been of limited effectiveness, in large part because it applies only to patent applications that are made nationally. International or European patents, applied for through the Patent Co-operation Treaty (PCT) or European Patent Office, are not affected by any of the existing measures. There are two means to address this. One is to make such national legislation applicable to both national and international patent applications (an approach being considered by Switzerland). The other is to introduce an international requirement, through amending either the TRIPS agreement (on Trade-Related Aspects of Intellectual Property Rights) or the PCT. This is currently being debated within the World Trade Organization (WTO), WIPO and the CBD.

As highlighted above, these issues are of particular concern for many developing countries. Consequently, they are behind many of the proposals that have been made within these various forums. While this is a reflection of their genuine concerns, it should also be noted that politics has an important role to play in these negotiations – thus, reform of patent legislation is viewed by some as an important bargaining chip within WTO negotiations, while progress on these issues within the CBD has been linked to the need to reach agreement within the WTO.

Regardless of these political machinations, there are also some practical considerations to bear in mind regarding the feasibility and effectiveness of these measures. With respect to feasibility, the lack of clarity regarding much of the proposed legislation raises doubts as to the ability of patent applicants to comply; for example, whether it is possible to clearly define the link between a resource and invention that will trigger the requirement. Furthermore, the very nature of genetic resources may not only make it difficult to determine the country of origin, but raises problems as to which countries or peoples have the right to claim a share of any benefits. For example, the distribution of genetic resources does not follow political boundaries, either naturally or because they have been traded around the world over the centuries. Furthermore, many resources are to be found in *ex-situ* collections (botanic gardens, crop centres, museums and gene banks). The same is true

of some TK – much knowledge is shared by a number of communities or peoples, and this may extend across a number of countries; some TK is also publicly available in academic literature. In addition, many countries have yet to implement ABS requirements, making it difficult to show evidence of PIC or ABS. In some cases, the complexity of the ABS regimes makes compliance difficult – indeed there have been cases in which researchers have been granted access and use rights by one government authority, only for this to be subsequently disputed by another.

For these various reasons, many potential patent applicants (such as the biotechnology industry) are concerned about the feasibility of these requirements, and fear that it will result in great legal uncertainty – opening the door to legal disputes and the loss of patent rights, even where no laws have been breached. As to effectiveness, the link between these requirements and their supposed objective of preventing resource misappropriation or of enhancing ABS is disputed. If DRs result in the loss of patent rights, this would serve the role of preventing the granting of ‘bad’ patents. However, it would also mean that there was no potential for the return of benefits to the source country, at least from the commercial exploitation of the patent. Alternatively, if lesser sanctions were used, or if there were none at all, this might not be sufficient to act as a deterrent for resource misappropriation. Furthermore, if DRs are to function as a transparency measure, this is dependent on the ability of countries to know when an application has been made using their resources. No monitoring of such applications is currently undertaken, and furthermore, in many countries where such legislation is already in place, compliance is not checked or verified by patent officials.

Thus, many within both industry and academia conclude that because the legislation must be sufficiently flexible to ensure that it is feasible, there will inevitably be many routes available for unscrupulous parties to avoid compliance. Consequently, they suggest that other options may be more effective.

### ***Other options within patent law***

Other options for improving the equity of the IP system are through the use of some existing legal principles within patent law. One proposal is for wider use of the doctrine of ‘unclean hands’; for example, this could apply if it is not disclosed that an invention was based on genetic resources or TK that were obtained in contravention of foreign law.<sup>13</sup> This doctrine has been used in the USA to prevent the enforcement of rights to a patent, when the patent applicant withheld the fact that the invention was based on misappropriated information.<sup>14</sup> It could also be used in combination with DR legislation – for example, the latter could operate as a transparency measure, facilitating the monitoring of patent applicants’ compliance with foreign law requirements – such as those for PIC and compliance with

ABS legislation. However, it should be noted that the doctrine of 'unclean hands' has only been applied to patents within the USA, and elsewhere its use is controversial, particularly in Europe.

Greater use of the rules on inventions that are contrary to *ordre public* and morality could also be made to reject certain patent applications.<sup>15</sup> Such provisions, as outlined in Article 27.2 of the TRIPS Agreement, are exceptions to the criteria for patentability, and refer to the exploitation of an invention. These concepts tend to be interpreted narrowly, so as not to undermine the main obligations, and most treaties and national laws have not included consideration of the way in which an invention, or any related genetic resources or TK, have been appropriated in this context. However, a wider interpretation may be possible. For example, New Zealand's legislation makes a link with ABS requirements. Here, if an invention is derived from or uses indigenous flora, fauna or traditional knowledge, and the applicant declines to provide details of any ABS arrangement that may have been entered into, there can be an objection to the application. This is possible if it is deemed that use of the invention would be contrary to *ordre public* and morality – for example, because it would be offensive to Maori people.<sup>16</sup>

### ***Improving equity through other mechanisms***

The use of competition law has been proposed as one means to prevent misappropriation of genetic resources and TK. This area of law is broad in scope and has also proved to be flexible, suggesting that it could be a valuable tool in this respect.<sup>17</sup> Indeed, within the USA, competition law has already been expanded to include a variety of 'dishonest practices' within business, including that of resource misappropriation. Here, a patent application could be prohibited under trade secrecy laws. This is outlined in the Restatement of the Law, 3rd on Unfair Competition (1995)<sup>18</sup> which 'prohibits applications for patents when access to genetic resources or traditional knowledge was obtained in another country without appropriate authority, even though the other country may not have appropriate national legislation regarding conditions for access and benefit-sharing'.<sup>19</sup> In other words, the unfair use of genetic resources or TK is considered unfair competition.

This area of law has also been proposed as being of value for the establishment of an international instrument for the protection of TK. Thus, it has been suggested that Article 10*bis* of the Paris Convention for the Protection of Industrial Property, within which unfair competition is defined, could be used as a model to create such an instrument. This would entail establishing a legal standard, based on this article, against the misappropriation and unfair use of TK. Further work and consideration of what constitutes 'misappropriation' would be necessary in order for such a law to be effective.<sup>20</sup>

Another area where progress could be made is through international legal cooperation – for example,

reciprocal agreements on enforcement of judgments could be made. Currently, if a country's ABS legislation is breached, there are no means of seeking legal redress in other jurisdictions unless a specific agreement is in place between those countries. Similarly, it is very difficult for a government, or other interested party, to challenge a patent granted in another jurisdiction if they consider that the invention was developed in breach of their own ABS regulations.<sup>21</sup> Attempts to establish such an international instrument have not so far proved successful. The Hague Conference proposed a draft Convention on Jurisdiction and Foreign Judgments in Civil and Commercial Matters, but after the initial failure of negotiations, its mandate was dramatically reduced. The resulting Convention on Choice of Court Agreements, adopted in 2005, will have very little effect on IP matters.<sup>22</sup> Efforts have also been made to develop an international instrument specifically relating to IP enforcement and jurisdiction, but these remain in draft form – and in fact may not cover patents.<sup>23</sup>

Thus the existing state of international law in relation to the enforcement of foreign judgments does not seem to offer much hope for finding a solution, at least in the short term. Therefore, it may be worth turning to alternatives for improving equity, such as collective approaches to risk and burden-sharing. For example, an international collective fund could be established, perhaps contributed to by industry and governments, to provide compensation to those from whom genetic resources have been misappropriated. One possible model for this could be the fund that is to be established under the Food and Agriculture Organization's International Treaty on Plant Genetic Resources for Food & Agriculture (ITPGRFA). Under this Treaty, a standard Material Transfer Agreement (MTA) has been developed as part of a Multilateral System for ABS, applicable to a list of major food crops and forage plants. This MTA includes a requirement that a share of any benefits arising from the commercialization of one of these plants must be paid into an international fund (Article 13.2(d)). The beneficiaries of this fund are envisaged as being farmers, and primarily those in developing countries, who are using plant genetic resources sustainably.

An alternative approach might be to create some kind of liability regime. These are used in other sectors; for example, there is a strict liability regime for ship owners,<sup>24</sup> and a compensatory liability scheme has been proposed as an element of an international regime for ABS and also for TK protection.<sup>25</sup> This would entail requiring compulsory insurance or other financial preparedness for all those using genetic resources in case misappropriation is discovered.

### ***Improving the patent system***

It has been argued that additional tools are not in fact needed in order to improve equity within the IP system, but rather that patent requirements should be more stringently applied and checked. The US patent system in particular has been accused of having lowered the bar

considerably with respect to the degree of innovation required by an inventor. Indeed, many of the controversial patents often cited as cases of biopiracy have been a result of inadequate prior art searches or of undemanding inventive step thresholds. For example, a European patent for the fungicidal effects of neem oil was revoked by the European Patent Office (EPO) on the grounds of lack of novelty and inventive step. Similarly, a US patent for a cultivar of the Enola bean, which is very similar to a number of Mexican varieties, is being challenged on the basis of lack of novelty.<sup>26</sup>

Possible tools to prevent such cases include the establishment of databases and registers of TK, to facilitate searches for prior art, although some local and indigenous communities are opposed to recording their knowledge in such databases.<sup>27</sup> More fundamentally, a critical look is needed at the types of products for which patents are being granted. More demanding standards for the novelty requirement could help to prevent 'bad' patents being granted, and so address many of the concerns of developing countries.

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## Conclusion

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Regardless of the view taken as to the extent of biopiracy, and how to define it, it is evident that there is a lack of trust in the IP system within certain sectors. Such a situation has the potential to undermine the functioning of this system, and more specifically the patent system, which depends on a degree of trust in order to function effectively. Furthermore, unless these concerns are addressed, it is likely that research and

development activities based on the utilization of genetic resources and TK will become increasingly difficult.

It remains unclear how best to improve equity within the IP system. Disclosure requirements are the favoured option for many, but there remain serious doubts as to their effectiveness, and the legislative options for these need further elaboration. Therefore, other legal options, as outlined here, should continue to be explored. One solution that is universally accepted as requiring action is that of implementing sound ABS legislation. However, means to enforce such legislation outside its area of jurisdiction also need to be developed to make such measures more effective.

Cries of 'biopiracy' are often met with exasperation by those from industry. Although some cases are indeed ill-founded, these should perhaps be seen more as a reflection of a deep-seated concern with the IP system and the way in which it has been developing. Recent trends do raise some fundamental questions about the proper balance of rights and obligations. In particular, the combination of a broadening in scope of patents, lowering of novelty requirements and advances in technology raises the issue of what kind of products should be patentable. These questions also link to the definition of biopiracy, and thus the issue of which types of activity are acceptable and which are not and so should be sanctioned. There also remains the question, noted earlier, of the role of the patent system. Should it be a tool to ensure equitable practice or does this lie outside its scope? If answers to these more fundamental questions are found, then perhaps it will be easier to find an effective means of improving equity within the patent system.

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## Endnotes

<sup>1</sup> It should be noted that the issue of resource misappropriation is not limited to patents – there are also concerns over the claiming of plant breeders' rights over crop resources, as well as the commercialization and trade of some resources used as foods or herbal remedies, where trade secrets may be used rather than IPRs.

<sup>2</sup> G. Dutfield, *Thinking Aloud on Disclosure of Origin*, QUNO Occasional Paper 18, October 2005.

<sup>3</sup> G. Dutfield, 'Sharing the benefits of biodiversity: is there a role for the patent system?', *Journal of World Intellectual Property* (2002), 5(6): 899–931; S. Safrin, 'Hyperownership in a time of biotechnological promise: the international conflict to control the building blocks of life', *The American Journal of International Law* (2004), 98: 641–85.

<sup>4</sup> Safrin, 'Hyperownership'.

<sup>5</sup> See for example J. Merson, 'Bio-Prospecting or Bio-Piracy: Intellectual Property Rights and Biodiversity in a Colonial and Postcolonial Context', *Osiris* (2000), 15: 282–96; G. Martin and S. Vermeulen, 'Intellectual property, indigenous knowledge, and biodiversity', *Capitalism Nature Socialism* (2005), 16(3): 27–48.

<sup>6</sup> G. Dutfield, *Report on Disclosure of Origin in Patent Applications. Report for the European Commission, DG-Trade*, Queen Mary Intellectual Property Research Institute, University of London, 2004.

<sup>7</sup> It is estimated that fewer than 30 countries have done so to date.

<sup>8</sup> L.M. Davalos, R.R. Sears, G. Raygorodetsky, B.L. Simmons, H. Cross, T. Grant, T. Barnes, L. Putzel and A.L. Porzecanski, 'Regulating access to genetic resources under the Convention on Biological Diversity: an analysis of selected case studies', *Biodiversity and Conservation* (2003), 12(7): 1511–24.

<sup>9</sup> S. Carrizosa, S.B. Brush, B.D. Wright and P.E. McGuire (eds), *Assessing Biodiversity and Sharing the Benefits: Lessons from Implementing the Convention on Biological Diversity*, IUCN Environmental Policy and Law Paper No. 54, IUCN, Gland, Switzerland and Cambridge, UK, 2004.

<sup>10</sup> UNEP/CBD/WG-ABS/4/INF/5 (22 December 2005).

<sup>11</sup> UNEP/CBD/WG-ABS/4/INF/6 (22 December 2005).

<sup>12</sup> Prior art is the existing body of knowledge against which an invention is judged in order to determine whether an invention is novel and non-obvious, and therefore patentable.

<sup>13</sup> F. Abbott, 'Preservation and use of genetic resource assets and the international patent system. A study for the Ministry of Foreign Affairs of Norway', Draft of 31 March 2005, Rev. 1.2, Hong Kong Ministerial Revision; N.P. de Carvalho, 'Requiring disclosure of the origin of genetic resources and PIC in patent applications without infringing the TRIPS agreement: the problem and the solution', *Washington University Journal of Law and Policy* (2000), 2: 371–401; UNEP/CBD/WG-ABS/4/INF/2 (22 December 2005).

<sup>14</sup> J. Sarnoff, 'Compatibility with Existing International Intellectual Property Agreements of Requirements for Patent Applicants to Disclose Origins of Genetic Resources and Traditional Knowledge and Evidence of Legal Access and Benefit Sharing', Memorandum to Public Interest Intellectual Property Advisors, Inc. (PIIPA), 23 June 2004, para 2.1.3.

<sup>15</sup> C.J. Visser, 'Making Intellectual Property Laws Work for Traditional Knowledge', in J.M. Finger and P. Schuler (eds), *Poor People's Knowledge: Promoting Intellectual Property in Developing Countries*, World Bank and Oxford University Press, 2004, pp. 207–40.

<sup>16</sup> WIPO/GRTKF/IC/5/10 (2 May 2003), para 64.

<sup>17</sup> S. Bhatti, 'New Forms of *Sui Generis* Protection Relevant for the International Regime (GR and/or TK)', paper presented at the International Expert Workshop on Access to Genetic Resources and Benefit Sharing, 24–27 October 2004, Cuernavaca, Mexico.

<sup>18</sup> <http://www.ali.org/ali/Uncomp.htm>, chapter 4.

<sup>19</sup> J.D. Sarnoff and C.M. Correa, *Analysis of Options for Implementing Disclosure of Origin Requirements in Intellectual Property Applications*, UNCTAD (2005), UNCTAD/DITC/TED/2005/14, para 14.

<sup>20</sup> WIPO/GRTKF/IC/9/12 (20 April 2006), paras 29–30; Bhatti (2004), 'New Forms of *Sui Generis*'.

<sup>21</sup> Dutfield, *Thinking Aloud* (note 2 above).

<sup>22</sup> [http://www.hcch.net/index\\_en.php?act=home.splash](http://www.hcch.net/index_en.php?act=home.splash).

<sup>23</sup> J. Drexler and A. Kur, *Intellectual Property and Private International Law. Heading for the Future*, Hart Publishing, 2005; R.C. Dreyfuss and J.C. Ginsburg, 'Draft Convention on Jurisdiction and Recognition of Judgments in Intellectual Property Matters', *Chicago-Kent Law Review* (2002), 77(3): 1065–1154.

<sup>24</sup> 1992 Civil Liability Convention.

<sup>25</sup> G. Dutfield, *Protecting Traditional Knowledge and Folklore. A review of progress in diplomacy and policy formulation*, ICTSD & UNCTAD, 2003; UNEP/CBD/WG-ABS/3/INF/6 (11 January 2005).

<sup>26</sup> Dutfield, *Thinking Aloud*.

<sup>27</sup> S.K. Verma, 'Protecting Traditional Knowledge. Is a *Sui Generis* System an Answer?', *The Journal of World Intellectual Property* (2004), 7(6):765–805.

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