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Disclosure of Origin in IPR Applications: Options and Perspectives of Users and Providers of Genetic Resources

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1. BACKGROUND¹

In recent years, there has been growing concern among biodiverse countries about misappropriation of genetic resources (GRs) under their sovereignty. In particular, these countries are concerned about intellectual property rights (IPRs) being granted for inventions based on these resources and their subsequent commercial exploitation by foreign companies and scientists, without any benefits returning to them. This has led to calls for reform of the intellectual property system. The introduction of disclosure requirements (DRs) into patent law has been proposed as one important measure to help countries maintain sovereign control over their resources.² Proponents of this measure suggest that it will achieve this through increasing transparency within the patent system and by facilitating monitoring of the use of genetic resources. However, many remain unconvinced about the feasibility of implementing such requirements and their effectiveness in preventing misappropriation of resources.

Such requirements have already been introduced by a number of countries, and proposals are also being discussed for the introduction of international legislation on this issue. Indeed, DRs have become an important issue within international negotiations on trade and the environment, with ongoing debate within the Conference of the Parties to the Convention on Biological Diversity (CBD), World Trade Organisation (WTO) and the World Intellectual Property Organisation (WIPO).

With respect to the CBD, negotiations are underway on an international regime on access and benefit-sharing (ABS).³ Many countries consider that DRs should be an integral part of such a regime, in order to monitor the use of GRs or additionally, to enforce ABS requirements. Consequently, they have been one focus of debate within recent negotiations. The current draft text on the development of an international ABS regime includes extensive references to this measure – although the fact that these are all bracketed reflects the divergence of opinion on this issue.⁴

In the WTO, DRs are being debated as part of the Doha round of trade negotiations. These negotiations are at a crucial phase, with the pressure on to conclude them by the end of 2006 to avoid collapse of this round of talks. DRs are on the agenda in discussions over the relationship between the TRIPS Agreement and the CBD. Developing countries are pushing for amendment of the TRIPS Agreement, which they regard as necessary to ensure mutual supportiveness of these agreements. However, a number of countries do not think that there is any conflict, and are opposed to dealing with issues linked to the CBD within this forum.

DRs are also being discussed in WIPO, where reform of the Patent Cooperation Treaty has been proposed to allow for DRs in international patent applications, and they are being considered as part of the discussions over further international harmonisation of the patent system, under the draft Substantive Patent Law Treaty (SPLT). Debate on the issue of DRs within WIPO seems likely to increase in momentum with the opening of discussions on the establishment of a development agenda for this organisation.

¹ The authors are grateful to all those who participated in the research, as well as to those who provided comments and input during the preparation of this report, in particular, to Graham Dutfield, manager of the IPDEV project.

² Disclosure requirements refer to a variety of different measures within patent law. Further details of these are provided in the report: Disclosure Requirements in Patent Applications: the State of the Art of National and Regional Measures. IPDEV Workpackage 8, Interim Report. February 2006.

³ One of the objectives of the CBD (set out in Article 1 of the Convention) is for the "fair and equitable sharing of the benefits arising out of the utilisation of genetic resources". One avenue being explored to help achieve this goal is the development of an international regime on ABS within the framework of the CBD. Negotiations are ongoing, the 9th Conference of the Parties (held in Curitiba, Brazil in March 2006) requesting that work continues to elaborate and negotiate the nature, scope and elements of such a regime.

⁴ UNEP/COP/8/31 (20-31 March, 2006) Decision VIII/4, Annex.

2. INTRODUCTION TO PROJECT

PROJECT AIMS, METHODS AND DATA SOURCES

This project was aimed at evaluating the effectiveness, feasibility, and acceptance of current and proposed national mechanisms for disclosure requirements within patent applications. The project also sought to assess the prospects for harmonisation of these measures within the European Union.

The research began with a review of the existing legislation on disclosure, and a report was produced describing the state of the art of national and regional measures.⁵ This enabled the identification of countries for further analysis. The research focused on European experiences, but also examined the cases of a number of biodiverse countries. This was done to gain the perspective of those countries that are primarily the providers of genetic resources.

A questionnaire survey was undertaken during the summer of 2005. The questionnaires sought to determine experiences with the existing legislation, opinions of the potential impact of implementing DRs more widely, either within Europe or internationally, and views on alternative or additional measures aimed at facilitating fair and equitable access and benefit-sharing. The questions asked in the survey are listed in appendix I.

The questionnaires were sent to government officials, NGOs, academics, patent attorneys and industry representatives. The survey focused on the six countries within Europe in which DRs have been introduced or proposed. Questionnaires were also sent out more widely within Europe, as well as to representatives from the USA, New Zealand and a number of biodiverse, developing countries.

A total of 368 questionnaires were sent out, and these elicited 74 responses, including 16 participants representing developing countries. The distribution of responses by sector is shown in table 1. (The full list of organisations and countries represented in the survey is shown in appendix II.)

Follow-up interviews were undertaken during October – November 2005. A total of 18 interviews were conducted in Belgium, Denmark, Norway and Sweden. These were with government representatives as well as some members of industry and academia.

Table 1: Breakdown of participants in the questionnaire survey

Sector	Number of responses	
	Total:	Developing Country:
Private sector (industry)	20	0
Private sector (attorneys)	5	2
Government	10	2
Patent offices	9	2
Academic institutes / NGOs	30	10
	74	16

A two-day workshop was held at Chatham House on 9-10th February 2006, for further discussion and analysis of the research findings and to consider their policy implications. The workshop included 40 participants from throughout Europe (Belgium, Denmark, Germany, Netherlands,

⁵ Disclosure Requirements in Patent Applications: the State of the Art of National and Regional Measures. IPDEV Interim Report. (2005)

Norway, Switzerland, UK) and also further afield, including Canada, Colombia, Japan, Peru, South Africa and the USA. The organisations represented are listed in appendix III. The meeting was held under the Chatham House Rule, to facilitate frank and open discussions.⁶

The workshop was organised around a series of parallel working groups. The groups, each focussing on slightly different areas, addressed the following questions:

- What impact will DRs have on patent attorneys and patent offices?
- What should be the consequences of non-compliance with disclosure requirements?
- What link is needed between an invention and the genetic resource / traditional knowledge in order for disclosure to be triggered?
- What definitions and terminology should be used?
- What should the extent of disclosure requirements be? Should disclosure be required of: geographical origin or of source; evidence of PIC; evidence of benefit-sharing?
- Should disclosure be required for traditional knowledge?
- Should there be further harmonisation of DRs within European patent legislation?
- What additional measures could be taken to enhance the effectiveness of disclosure requirements?
- What alternative measures or areas of legislation could be developed within Europe?

3. RESULTS

3a. CURRENT LEGISLATION AND EXPERIENCES OF IMPLEMENTATION.

THE IMPLEMENTATION OF DRS IN EUROPE⁷

The implementation of national legislation on DRs by European countries was prompted by the adoption of the EU Biotechnology Directive in 1998. Under this Directive, disclosure of the geographical origin of biological material is encouraged. Recital 27 states that:

“Whereas if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents.”⁸

The inclusion of a reference to DRs in the Directive was first proposed by Denmark. It was the subject of some debate and negotiation between the European member states, and due to the reservations of a number of countries the paragraph on DRs was included in the Directive's Preamble rather than in the main text. This means that it does not create a legally enforceable obligation, and indeed, when implementing the Directive, not all countries adopted legislation on this issue. Just five countries have done so to date (Belgium, Denmark, Germany, Norway and Sweden), and one other (Switzerland) has draft legislation, currently being considered by its parliament. (See appendix IV for details of the national legislation.)

⁶ The Chatham House Rule states that "when a meeting, or part thereof, is held under the Chatham House Rule, participants are free to use the information received, but neither the identity nor the affiliation of the speaker(s), nor that of any other participant, may be revealed."

⁷ The following discussion relates mainly to Belgium, Denmark, Norway and Sweden, as interviews were undertaken here, enabling more indepth analysis. Information on the process of developing DR legislation in Germany and Switzerland was limited to that provided in the questionnaires.

⁸ Directive 98/44/EC of the European Parliament and of the Council, of 6 July 1998, on the legal protection of biotechnological inventions. Available online at: http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l_213/l_21319980730en00130021.pdf

The decision of these countries to adopt DRs was influenced by a range of factors. For example, the Danish Government was keen to implement such legislation because it had been proactive on this issue within Europe. Also significant was the fact that the national debates on disclosure were part of a wider consultation on implementing the EU Directive. The Directive was very controversial in some of the countries, mainly because it formalised the patenting of life-forms. This was the case in Norway, where the Directive met with considerable opposition,⁹ and so the introduction of DRs was, in part, a means of appeasing those opposed to it.

During the national debates, voices were raised both in support of and opposed to DRs. Those stakeholders who were more supportive of DRs tended to be those who were involved with environmental or development issues – these included NGOs, some academics and also certain government departments. Typically, they were motivated by the wish to promote the aims of the CBD, and also to support developing countries on this issue, many of whom are strong proponents of DRs.

Industry and those government departments dealing with trade and industry or economic affairs were more sceptical, concerned as to the potential impact of DRs on the biotechnology industry, and on research and development activities. There was particular concern within a number of government departments as to the impact of such legislation on smaller companies, as it is they who tend to apply for national patents rather than going through the international system. Questions were also raised as to the effectiveness of this measure in dealing with ABS issues, and furthermore, whether such issues were in fact best dealt with by the IP system. (These concerns remain for many, as is considered in more detail below.)

It was reported that during the process of these national debates there was some convergence of views and a more informed debate developed. For example, initially, many of those coming from within the patent and industry sector did not recognise any link between the IP system and ABS issues. Rather, the latter was regarded as being completely alien to IPRs, and so DRs were considered inappropriate to the patent system. While there is still debate as to whether ABS issues are best addressed through the IP system, there has been some acceptance of the links between these two areas, and a growing awareness of the need to address these issues within the IP system. On the opposite side, among the proponents of DRs there has been greater recognition of some of the problems which need to be addressed if more wide-ranging DRs are to be introduced, for example, the need for clarification of terminology and definitions (see later for further consideration of this issue). In fact a couple of participants reported that they had changed their view, no longer supporting a requirement that would be linked to patent validity, but favouring a formal requirement on the basis that this would be more feasible and widely acceptable.

However, in none of the countries was the adoption of DRs highly controversial. This was perhaps because of the recognition that these national requirements would have a limited impact because of their narrow scope – they only affect national patent applications which are a small proportion of the total applications made. Indeed, in all six countries the adoption of national DRs was regarded, to a large degree, as a means of showing political support for this issue, rather than actually having a significant impact on improving ABS. Thus, they were adopted in part in order to show support for developing countries on this issue and also as a potentially valuable first step towards the elaboration of such a requirement at the international level.

⁹ Norway had the option of implementing the Directive or not because it is in the European Economic Area rather than being a member of the EU.

The approaches adopted

The particular approaches to DRs that were adopted by these countries reflected the concerns and balance of interests within each of the countries. For this reason, and also because of differences in their legal framework, there was some variation in the legislation adopted.

In the five countries which have implemented legislation, disclosure is only required for applications involving genetic resources and not for those which have utilised TK. This was because of concerns over the difficulties of defining the concept "TK", and so it was thought that such a requirement would not be workable. In Switzerland this was regarded as less problematic, and was felt to be outweighed by the argument that disclosure of TK would be a useful measure to allow the providers of such knowledge to trace its use, and in particular, to facilitate searches for prior art. Therefore, its draft law requires disclosure for inventions based on either genetic resources or TK related to genetic resources.

Regarding the information that is to be disclosed, Belgium, Denmark, Germany and Sweden all followed the EU Directive, requiring disclosure of the geographical origin. Switzerland's draft legislation uses slightly different terminology, requiring declaration of "source" rather than origin. The term "source", as it is defined in the Swiss proposal, is a broader concept than that of origin and was employed in order to deal with those situations in which the origin was unknown. Thus, source is defined as the entity that is competent to grant access to the genetic resources, or to participate in the sharing of benefits arising from their utilisation. Applicants would be required to declare the "primary source" (in other words, the origin), which may be the country or community providing the genetic resources, or if this is unknown, to disclose the "secondary source", for example a gene bank or botanic garden.¹⁰

Norway introduced a more extensive requirement, reflecting the high degree of political support here for this measure. Disclosure is required of the providing country and also of the country of origin, if this is different. Furthermore, information on whether PIC has been sought is also required (although not evidence of the PIC itself), if this is required by the providing country or country of origin. This information must be declared with respect to the providing country, but for the country of origin the option exists to state that it is not known whether PIC is required.

Disclosure of PIC was apparently considered in Sweden and Denmark, as well as in Switzerland's draft legislation. However, this was not adopted because of concerns over the feasibility of such a measure, given the patchy nature of national access legislation in many source countries. In addition, it was argued in Switzerland that disclosure of PIC is not necessary since disclosure of the source is sufficient to achieve the objectives of this measure – for Switzerland, these include enhancing transparency, assisting in prior art searches and improving trust in the patent system.

None of the countries introduced a DR for evidence of fair and equitable ABS. This was either simply not considered (the case in Belgium and Denmark) or it was not thought to be feasible (in Norway and Switzerland). The problems of feasibility that were highlighted were the subjective nature of determining what is "fair and equitable", and also the fact that patent applicants would not be able to provide evidence of benefit-sharing because the commercial benefits would not yet be known.

The other area in which the national legislation on DRs varies is in relation to the consequences of non-disclosure. During the debates on this issue, some proponents of disclosure argued for

¹⁰ Addor, F. (2005) Switzerland's proposals regarding the declaration of the source of genetic resources and traditional knowledge in patent applications and Switzerland's views on the declaration of evidence of prior informed consent and benefit sharing in patent applications. ICTSD/CIEL/IDDRI/IUCN/QUNO Dialogue on *Disclosure Requirements: Incorporating the CBD Principles in the TRIPS Agreement On the Road to Hong Kong*. WTO Public Symposium, Geneva, Switzerland. 21 April 2005.

strict DRs, i.e. affecting the validity of patents. Such strict requirements were not adopted by any of the countries, largely due to concerns that this could create legal uncertainty, a critical issue for industry. In addition, concerns were expressed that substantive requirements would be in conflict with TRIPS (although this is debatable¹¹). It was for this reason that Norway and Denmark took the route of criminal sanctions. In both these countries, non-compliance would not affect the handling of a patent application nor the validity of a granted patent. However, penalties could be imposed under their penal codes, since these include an obligation to provide correct information to a public authority. This would allow for the imposition of a fine or a prison sentence.

In Sweden there was also concern over the compatibility of a mandatory requirement with TRIPS. However, the approach taken in Norway and Denmark was not an option here because the Swedish civil code does not enable prosecution in the case of a false declaration being made within a patent application. Therefore, Sweden decided to introduce a voluntary requirement, with no sanctions for non-compliance.

In Belgium, a novel approach to disclosure had initially been considered, it being proposed that non-compliance with a DR would be contrary to the concept of *ordre public* and morality, on the basis that in such a case the invention would have been developed in breach of the CBD. However, this was not adopted, apparently because the legislation never made it through parliament due to changes in government. Instead, Belgium introduced a simple formal requirement. Under this legislation, non-compliance could, in theory, result in a patent application not being processed, although this would seem an unlikely event given that the patent office does not check compliance.¹² If a patent has been granted, then criminal sanctions could be sought through the courts for wrongful disclosure, and this could result in a fine or payment of damages. Switzerland has proposed a similar measure. Under its draft law, failure to comply would result in rejection of the patent application, while wrongful declaration could be prosecuted *ex officio*, and the applicant would be liable to a fine of up to 100,000 Swiss Francs. In such cases, the draft law also allows for the judge to order publication of the ruling – the intention behind this being that this would function as an incentive for compliance.

IMPACT OF DR LEGISLATION

Europe

In the five countries where DRs have been implemented, these measures have had limited impact. This is in part because they have not been in place very long. Denmark was the first to introduce DRs, amending its legislation in 2000. In Norway and Sweden DRs were introduced in 2004, and in Belgium and Germany this took place in 2005.

Another reason for the limited impact of these requirements is that they only refer to national patent applications. Consequently, a very small number of patent applications are affected by this legislation. The Norwegian office estimated that about 20% of all patent applications that they receive are national. Similarly, the Swedish office estimated that national applications accounted for 25% of all biotechnology related applications (of which there are about 300 a year), although most of these go on to be filed through the EPO and are discontinued at the national level.

¹¹ Sarnoff, J. (2004) 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. In this paper it is argued that there is no conflict between mandatory DRs and the TRIPS agreement.

¹² The Belgian patent office is not a searching authority, and so has no research facilities. Belgian patents, valid for 6 years, can be granted without a search on the prior art. For patents of 20 years, prior art search is outsourced to the European Patent Office. There is no examination of patentability.

Indeed, to overcome this problem, the draft Swiss legislation would also apply to international applications.

Only the Norwegian patent office had data on the number of applications in which disclosure had been made. They had received three such applications, but only one of these is still active – one having been withdrawn and a second shelved.¹³

None of the other patent offices kept records of applications where disclosure had been made, but they all estimated that there had been few, if any. In Denmark, no applications in which disclosure had been made could be recalled, and it was thought likely that there had not been any. In the 6 months since implementation of Belgium's disclosure requirement (from May to October 2005) a quick survey of patent applications found that there had been just six national applications concerning pharmaceuticals, although it was unknown whether these used biological matter.

This pattern is mirrored in the responses from the private sector, in which only two companies (out of 20 respondents) reported having been asked to comply with a disclosure requirement. This is perhaps a reflection of the fact that nearly all the respondents from the private sector were from large companies, and they tend to make patent applications through the international or European systems rather than applying for national patents.

Thus, it would seem that these requirements have had barely any impact on patent applicants. However, in Norway it was reported that the implementation of DR legislation did create some uncertainty among patent applicants as to when disclosure would be triggered. The patent office received a number of enquiries about this, as well as some queries about the national ABS legislation of other countries.

The impact of DRs on the work of patent offices has also been minimal. The offices of Belgium, Denmark, Norway and Sweden all reported that the introduction of DRs had not impacted significantly on their work. This is not surprising, given the small number of applications and the fact that none of them check on whether disclosure should have been made, nor whether the information provided is correct. One additional task reported was that being undertaken by the Belgian patent office during October 2005 to adapt the patent application form. This was being amended to include a question on whether an invention has been developed from biological matter. In none of the other countries had this been done, and so there is no specific question for applicants to answer or forms to fill out.

Developing countries – Brazil, Colombia, Costa Rica, Peru.¹⁴

Experiences of implementing legislation on DRs in Brazil, Colombia, Costa Rica and Peru were reported on in the survey questionnaires. With the exception of Costa Rica, all these countries had experienced severe problems of implementation.

In 2001, Brazil introduced a Provisional Measure requiring patent applicants to disclose the origin of any genetic material or associated traditional knowledge used in an invention (Article 31, Provisional Measure No. 2.186-16 of August 23, 2001). However, this requirement has not taken effect. This is because of legal uncertainty over how it should be enforced, since the rules to implement this measure have not been developed.

DRs were not thought to pose a problem for the functioning of Brazil's patent office, since the office does not have a large backlog of patents and it is currently planning to increase the

¹³ Information on the third application is not yet publicly available, since it was made within the last 18 months (as of May 2006).

¹⁴ The national legislation of these countries is outlined in Appendix IV.

number of patent examiners. Furthermore, biotechnology patents represent a small percentage of the applications. More significantly, it was noted that any checks on compliance would probably be undertaken by a separate institute, that responsible for ABS, and so any problems of monitoring and enforcement would fall on this institute.

Difficulties with implementing the legislation were also reported from Colombia. As a member of the Andean Community, disclosure in Colombia is required as outlined under Community Decision 486 (Common Intellectual Property Regime, December 2000). This requires that applications for patents disclose the access contract and evidence of PIC for genetic resources or TK. The legal framework regarding access to genetic resources is outlined in Decision 391 (Common Regime on Access to Genetic Resources, July 1996). However, because of difficulties in implementing this Decision, the access system is very complex and unclear, and to date there has only been one access agreement granted. The complexities of the system also resulted in one case in which an applicant for a Colombian patent did not comply with the requirement to file an access agreement. Such an agreement had apparently not been obtained by the applicant because of the difficulties of doing so, although this was subsequently rectified through a provisional permit being granted, allowing processing of the patent.

In Peru, another member of the Andean Community, implementation of the Community Decisions has also proven problematic. Here, the rules to implement the disclosure requirement have not been implemented, and consequently, this measure has yet to be utilised within Peru.

In Costa Rica, there have also been no cases of disclosure. However, this is not because of implementation problems, but rather, because of the narrow applicability of the disclosure requirement.¹⁵ Patent applications involving biodiversity or TK need to be accompanied by a certificate of origin, but this only applies if the resources or knowledge are from Costa Rica and not if they originate from any other territory.

The legislation of all the developing countries considered here only applies to genetic resources from within their own territory – that of the Andean community only refers to GRs from its member states, and the Brazilian legislation to GRs from its national territory. Therefore, even when effectively implemented, these measures will be limited in their scope. This raises questions as to the effectiveness of such legislation as a measure to facilitate ABS, as discussed in further detail below.

WHAT CAN BE LEARNT FROM EXPERIENCES OF IMPLEMENTING DRS?

The previous sections highlighted that existing national DRs have had little impact, either on patent applicants or on the work of patent offices. While this means that experiences of this legislation are limited, there are some lessons that can be learnt.

One important issue, noted within Europe, was the lack of information on patent applications in which disclosure had been made. One objective that has been identified for DRs is to enhance the transparency of the patent system. However, the existing legislation has done little to achieve this. The European patent offices do not monitor applications in which disclosure has been made. Furthermore, although the patents are made available online, there is no means to search for those in which disclosure has been made. This would make it difficult for a third party, for example the provider of a resource, to search for any relevant applications. If DRs are to be effective as a transparency measure, then a system needs to be established to monitor these applications and to make this information easily accessible.

¹⁵ Here, the ABS legislation is apparently functioning effectively, and some 25 access agreements have been granted (as of January 2006), about half of which were for commercial use of genetic resources.

Another lesson that can be drawn from these experiences, and in particular those from the developing countries, is that such legislation needs to be carefully designed if it is to be effective. While it is relatively easy to amend patent legislation to require disclosure, it is quite another matter to ensure that it is usable, either for patent applicants or patent officials. For example, patent officials in Brazil, uncertain as to how to enforce the DR legislation, have called for further rules to clarify this. In Colombia, the problems of utilisation lie with patent applicants, because of the difficulties of complying with the country's access legislation. This latter example illustrates a potential problem with proposals in which disclosure of an access agreement or other form of PIC is required. A concern of many, and in particular those from industry, is that such requirements could prove impossible to comply with since many countries do not have such legislation, or alternatively their institutional arrangements are so complex that it is difficult to ensure that the correct procedure has been followed.

The final point to highlight is the narrow scope of these measures. This undermines their effectiveness as a tool to prevent resource misappropriation or to facilitate ABS because they could easily be circumvented. As explained above, they are of limited scope because they only apply to national patent applications – a problem that would be resolved if an international DR were introduced, and this is one of the arguments used to justify such proposals. In the case of the developing countries, their legislation is even more narrowly applicable, since disclosure is only required for applications that utilise national or regional genetic resources. For example, disclosure would not be required for patent applications in Costa Rica if Brazilian genetic resources had been used, or vice versa. Costa Rica took this approach in order to avoid the question of how to deal with resources that come from countries in which no access legislation has been implemented. This problem remains, but it could perhaps be better addressed by including a clause stating that disclosure of PIC is only needed where this is a requirement in the country of origin – as implemented by Norway.

It was acknowledged by many that the legislation of the developing countries could have been better designed, and that the shortcomings were largely due to the limited experience of designing such legislation among policy makers. This would suggest that these national measures have been of some value in building expertise. Indeed, one important reason given by both the European and developing countries for introducing these national measures was that they would provide useful models for the design of such legislation, and so provide valuable experience for the implementation of an international requirement.

An additional reason given for implementing these measures was to build political support for this measure – an objective both of the developing countries and some of these European countries. Thus, it was suggested that this would demonstrate that there exists the political will within these countries to progress on this issue. Within Europe, an additional motivation for introducing this legislation was to show support for developing countries. According to some, this latter motivation was not simply out of a desire to implement the goals of the CBD, but also the hope of gaining concessions from developing countries in international negotiations, in particular within the WTO.

It is difficult to determine what impact the introduction of this legislation has had on debates over disclosure, and in particular, whether it has enabled any progress to be made at the international level. Some felt that the European approach was too weak to satisfy many developing countries, implying that it would have had a limited impact on negotiations. At the national level, it was reported that more informed debates have developed within Europe, which suggests that implementation of these measures has resulted in a better understanding of the issue within these countries. However, whether there is greater consensus is debatable, as is considered further below.

3b. CURRENT VIEWS ON DRS AMONG STAKEHOLDERS

OVERVIEW OF STAKEHOLDERS' OPINIONS

Participants in this research represented a wide range of viewpoints, from those opposed to any form of disclosure requirement to those advocating strict measures. Although opinions cannot be divided neatly by sector, some general patterns did emerge.

The various stakeholders concerned with this issue include those from government, industry, research institutes, NGOs and indigenous and local communities. The latter were not represented in this survey, but there were a number of participants who had been working with communities on these issues.

From within government, participants came from a number of departments and ministries with diverse responsibilities and priorities, and so their responses were correspondingly varied. Those concerned with international affairs, the environment and development issues tended to support DRs. The most common reason given for this position was that DRs would improve the transparency of the IP system, and so facilitate monitoring of resource use. In addition, the wish to support the goals of the CBD was frequently cited, as was the desire to show support for developing countries. The political value of this measure was widely acknowledged, in particular, in negotiations with the WTO.

Those departments concerned with industry and economic affairs were more sceptical, highlighting the potential negative impact of these requirements on research and development activities. Patent offices, which fall under the responsibility of these ministries, also tended to be less in favour of DRs, concerned as to their impact on the functioning of the patent system.

Representatives of the private sector were, without exception opposed to DRs, at least if these were mandatory. They included industry representatives, mainly from pharmaceutical firms but also the seed industry, and patent attorneys. The survey responses received from this sector were among the most detailed, reflecting the high level of concern about this issue. Most industry respondents were from large companies. Of the smaller companies approached, there seemed to be less awareness of this issue. Many of the small companies contacted did not respond, and of the few that did, a common response was that they did not know about this issue and that their company did not have IPR expertise because they used outside patent lawyers.

A number of the private sector respondents from within Europe felt that their views had not been fully taken into account in developing the European position on this issue. It was suggested that this issue was being used politically as a negotiating tool, for example, in negotiations over geographical indications within the WTO. There was concern that an international DR was being promoted within Europe for this reason, and not because of any evidence that it would help to achieve ABS objectives and without a full consideration of its potential impact on research and development activities.

The responses from the research and NGO sector included wide-ranging views, from those opposed to DRs to those advocating an international, mandatory requirement. A particular concern within the academic community was that research should not be overly restricted, or hindered. Several respondents felt that concerns about access rights and benefit-sharing have resulted in too great a shift away from an environment in which knowledge and expertise can be freely shared, and that this is to the detriment of research and scientific understanding. Calls were made to re-focus on the objectives for which these measures are supposed to have been developed, which include not only equitable benefit sharing but also facilitating the sustainable utilisation of resources.

The need for compromise was also highlighted. It was suggested that “hardliners”, opposed to any form of DR, risk undermining the credibility of the patent system, and that without trust, the

functioning of the IP system and research activities would both be hindered. On the opposite side, it was thought that proponents of disclosure need to recognise that DRs could serve to discourage research and development activities, particularly within industry, which would reduce the opportunities for benefit-sharing.

The developing country respondents came from a wide range of backgrounds and countries. Therefore, not surprisingly, there was no single "developing country view". However, developing country respondents did tend to be more supportive of DR proposals, and emphasised the concerns of indigenous and local communities. Another issue that was highlighted was the lack of trust in the IP system within many developing countries, which is seen as serving the interests of developed countries and of the private sector. Therefore, DRs were regarded as one measure that could help to increase the legitimacy of the IP system.

Having highlighted the differences in views between the various stakeholders, it should be noted that there was also some common ground. One area of agreement was that DRs will not be able to stop all cases of resource misappropriation, even though, at times, DRs seem to have been advocated as the solution to this entire problem. Even if effective legislation can be developed, DRs will only apply to a relatively small proportion of the uses of genetic resources – that for which patents are applied for. Therefore, this measure can only make a small contribution towards facilitating fair and equitable ABS. Other measures are also crucial, for example, clear and workable national ABS legislation, which was regarded as a priority by all sectors. The need for capacity building in many developing countries was also highlighted by many respondents. This was seen as crucial both at the national level – to develop and implement legislation and to build expertise and institutional strengths – and also at the community level, for example, to provide training in negotiation and legal skills.

Another point on which there was general agreement is that both the existing and proposed legislation on DRs still requires further elaboration of terminology and definitions. This lack of clarity creates legal uncertainty for patent applicants, particularly if disclosure is linked to patent validity. As is considered further below, such a situation could be detrimental to all – acting as a deterrent to research and development, and hindering the generation of benefits.

The various perspectives are considered in more detail in the following sections. These are organised according to the questions presented in the questionnaire survey, but opinions expressed during the interviews and workshop have also been incorporated.

RESPONSES TO THE SURVEY QUESTIONS

What advantages or disadvantages can you identify, or do you foresee, in implementing disclosure requirements?

ADVANTAGES:

Among the proponents of DRs, the main argument used to support the introduction of this measure was that it would facilitate fair and equitable ABS, one of the objectives of the CBD. It was held that this would be achieved through improving the transparency of the patent system. Thus, information on the geographic origin of a genetic resource, or of PIC, would facilitate the monitoring of resource use, particularly by the source countries. It was also suggested that the introduction of DRs could act as an incentive for countries to introduce ABS legislation. Relatively few countries have enacted such legislation, and this is a major hindrance to ensuring fair and equitable access and benefit sharing.

A further potential benefit highlighted for this measure was that it could help to increase awareness of CBD issues. This was still felt to be low, particularly in some parts of the research community. The need for greater awareness of environmental conservation and ABS issues

within the “IPR world” was also highlighted, although it was felt that there had been some positive changes in recent years – in fact, partly as a result of the debate over this issue.

An additional argument used in favour of a DR was that such a measure could enhance the patent system through helping to improve the quality of granted patents. Thus, disclosure of origin would facilitate the examination of inventorship, prior art and patentability. This was felt to be particularly relevant when TK had been used in an invention, as it would help to direct searches for prior art.

Such an outcome would also help to increase the legitimacy of the IP system. Within many developing countries, the IP system is regarded with a high degree of suspicion, and is seen as operating largely in the interests of western business concerns. Through improving the quality of patents, and also through giving greater recognition to developing country concerns, DRs were felt by many to be of value in enhancing the reputation of the IP system.

This could also help to enhance confidence between the providers and end users of genetic material, and so create an environment more conducive to the establishment of access and research agreements. Thus, such legislation would increase trust among the owners of genetic resources or TK, who would then be more willing to allow utilisation of these resources. It could also encourage relaxation of access regimes, for example, systems could be established whereby nationals of those countries with such requirements are given better access to resources. In fact, this was one of the few possible advantages identified by private sector respondents, although they did regard this outcome as somewhat tentative.

Finally, an additional benefit of DRs that was mentioned was that this measure could be useful for improving understanding of how genetic resources are being used and commercialised. This would depend on there being a system for compiling or registering the information, which does not currently exist.

DISADVANTAGES:

A number of possible disadvantages of DRs were identified by respondents. Not surprisingly most of these came from those respondents who are not in favour of DRs, but there was also recognition of some of the potential problems among their advocates.

One of the main concerns was the feasibility of such measures, with a significant number of respondents doubting whether it would in fact be possible to comply with them. This point was made both for requirements to disclose geographical origin and for disclosure of evidence of PIC. In the former case, it was highlighted that it is often difficult to determine the origin of a resource, for example, in cases in which a resource comes from an *ex situ* collection (e.g. a botanic garden or the compound library of a pharmaceutical company), and was collected many years ago. The need for clarification as to whether disclosure would refer to resources collected prior to implementation of the CBD was seen as a priority for any new legislation. Disclosure of PIC was felt by many to be even more problematic given that many countries do not have ABS legislation in place, and in some cases, the procedure to obtain access is complex and unclear – as was highlighted in the case of Colombia earlier in this report.

A further problem relates to the link between a resource and an invention that would trigger disclosure since current and proposed legislation only vaguely defines this. It was highlighted that the complexity of many research processes and the length of research chains mean that it would often be difficult to know when disclosure was required, or to determine the information for

the original resource.¹⁶ The existing legislation refers to the link between an invention and genetic resource in the following ways:

- concerns or makes use of biological material (Denmark);
- a process or product obtained using samples of components of the genetic heritage (Brazil);
- obtained or developed from genetic resources (Andean Community);
- innovations involving components of biodiversity (Costa Rica);
- to which the inventor or the applicant has had access, if the invention is directly based on the resource (Switzerland – draft legislation).

Respondents commented that it is unclear how such terminology relates to real research processes and products. For example, would disclosure be required for the use of a product if it was several generations away from the original genetic resource, or for a synthetic compound derived from lead compounds discovered in nature?

The lack of clarity over terminology and definitions in legislation was of particular concern to industry, who felt that it would create great legal uncertainty. This would particularly be the case if DRs were linked to patent validity, for example, it was suggested that such legislation could be exploited by competitors to challenge patents in order to gain free access to the invention. Therefore, there was concern that such legislation would be detrimental to those companies or researchers who were trying to operate legally and ethically. This could serve to discourage compliance, and so, have the opposite effect of the desired objective of increasing transparency.

It could also be a significant burden to companies – both because of the difficulties of complying and also because there could be delays in the processing of patent applications. A couple of respondents suggested that the public research community would be particularly disadvantaged, since they would face all the potential costs of such a system, but few advantages, as they do not usually pursue their activities for commercial purposes.

As well as being detrimental to patent applicants, it was suggested that such legal uncertainty would be a disadvantage to the source countries of genetic resources. Firstly, it would make challenges to patents very difficult to uphold in a court, or at best, would make the outcome of any legal case unpredictable. Therefore, this would be a risky strategy for those wishing to go down this route. Secondly, it would act as a deterrent to research and development activities. Ultimately, this would mean that fewer benefits would be generated from the utilisation of genetic resources. A number of respondents suggested that there had already been a shift away from the use of genetic resources, both within the industry and research sectors, because of the complexities of the ABS system in many countries and concerns about possible legal disputes.

These concerns were most strongly expressed by those from within the private sector, but were also noted by academics and those from within government. Government representatives were particularly concerned that national or regional requirements could place domestic interests at a competitive disadvantage, and hinder research and development within these jurisdictions. They were also concerned at the potential impact on the patent system, and prioritised the need for a smoothly running and efficient system.

This was one reason why more extensive requirements were not supported by many in government, and in particular, those from some patent offices. It was suggested that proposals for disclosure of PIC could place too great a workload on patent examiners because this would

¹⁶ The potential difficulties with the various terms and definitions have been clearly outlined in a number of position documents produced by members of industry, and so these are not repeated here. These documents have been produced by Chartered Institute of Patent Agents (CIPA), European Chemical Industry Council (CEFIC), European Federation of Pharmaceutical Industries and Associations (EFPIA), International Chamber of Commerce (ICC), International Seed Federation (ISF), SwedenBIO.

require them to examine “problems outside of the patent system”, and which they were not qualified to assess – for example, the access legislation of another country. It was also argued that such a requirement would not improve the patent system in any way (or no more so than disclosure of geographic origin could), for example, through helping in searches for prior art. More fundamentally, it was held that this was an area that should be dealt with outside the patent system. This latter view was held by a number of lawyers, who argued that it is wrong in principle to try to deal with ABS issues within the IPR system, since these are foreign to patent law. It was commented that patents should be a tool to encourage innovation, rather than an enforcement tool, and as such, patent law is inappropriate to police ABS – as one respondent stated “patents are certificates of inventive behaviour, and not certificates of good behaviour”.

The purported benefits of DRs for the ABS system were also called into question. It was highlighted that patents represent a very small proportion of the use of genetic resources, and that there are many circumstances in which patents are not sought. For example, in certain sectors, such as those of cosmetics, natural remedies and plant breeding, patents are only used to a limited extent. Consequently, the suggestion that DRs could help to monitor the commercial use of genetic resources and prevent resource misappropriation was disputed.

It was also felt by a number of respondents that DRs would not be effective in policing the use of genetic resources nor in facilitating benefit-sharing. Any workable system for disclosure would have to rely to a certain degree on good faith, because of the need to allow for the various situations in which disclosure could not be made (for example, for resources collected prior to the CBD, or where no ABS legislation was in place in the source country). This flexibility could therefore be exploited by unscrupulous applicants. Furthermore, if DRs affected the validity of a patent, the loss of patent rights would probably result in no benefits accruing to the source of the genetic resources or TK in question.

It was noted that DRs are unlikely to result in significant benefits returning to the providers of genetic resources or TK, and that expectations of “green-gold” will probably be unfulfilled. It could also be difficult to establish ownership of resources, and thus, to whom benefits should be returned. For example, many genetic resources are found in more than one country, and TK may be shared by a number of communities or peoples. In fact, any benefits could be outweighed by the costs of implementing such a system, for example, because of the need to introduce new legislation, establish monitoring institutions, train staff, etc. This would be particularly acute in developing countries. Many of these countries lack the expertise and institutional capacity to implement the necessary legislation. Furthermore, there is often insufficient capacity to monitor patent applications and resource use, this requiring a high degree of co-ordination between authorities as well as new institutional arrangements. Indeed, a number of respondents expressed concern that DRs could lead to a complex, bureaucratic and inefficient system. Thus, there was considerable doubt as to whether this measure would bring any net benefits.

What measures, if any, do you think should be taken at the European or international level in relation to disclosure requirements?

Among the respondents from within Europe, there was no appetite for greater harmonisation at the European level. However, it was thought that it would be preferable to address this issue at the European rather than national level, as the latter approach would result in increased divergence between countries. Such a situation could create legal loopholes and greater uncertainty. A couple of respondents did support the introduction of an EU-wide mandatory requirement, but they viewed this as a useful first step towards the development of an international system rather than an end in itself.

In the discussions during the workshop, when asked if any possible benefits of European harmonisation could be foreseen, it was suggested that this could enable better evaluation of the

consequences of imposing such a measure. In addition, it was thought by some that a European-wide DR could improve trade relations between Europe and other countries, namely those which are the *demandeurs* on this issue. However, it was also commented that this would probably only be the case if a mandatory requirement were introduced – a suggestion that met with strong opposition from those from within the private sector. Due to their doubts about the feasibility of such a measure, they believed that this would in fact place European business at a competitive disadvantage.

Further harmonisation at the European level could be achieved either through passing a new directive, or by amending the European Patent Convention (EPC). If harmonisation was to be followed, it was felt that the latter approach would make more sense since this would mean that European patents would also be affected rather than just national patents. However, this step was not being advocated by any of the participants – the private sector was opposed to additional European legislation on this issue, while the proponents of DRs felt that there was not much to be gained from further harmonisation at this level, but that this issue should be pursued at the international level.

Similarly, within the developing countries, an international solution was regarded as the best way forward on this issue, since it was felt that an international measure would be most effective in preventing resource misappropriation.

Among the proponents of an international DR, there was general support for the approach outlined in the EU proposal, under which disclosure of the country of origin would be required.¹⁷ Many felt that disclosure of origin would be sufficient to promote ABS, arguing that such information would allow source countries to check whether their access legislation had been complied with and if PIC had been obtained. However, some felt that a more extensive requirement, with disclosure of evidence of PIC, would be necessary for this measure to be effective in encouraging compliance with ABS legislation. In a few cases, evidence of benefit-sharing was called for. However, most felt that this would not be feasible because of the subjective nature of determining whether benefit-sharing is fair and equitable, and also the difficulties in many cases of establishing who should receive these benefits.

The question was also raised as to whether disclosure of the country of origin or of provider country would be better. The former would be more difficult to comply with in many cases, but it was noted that this could be useful in controlling the use of intermediaries to access resources.

The question of whether disclosure should be required for inventions concerning TK, rather than just those based on genetic resources, was not considered in detail. Most respondents supported this in theory, but recognised that it would be difficult to implement in practice because of the lack of an internationally recognised definition for TK. Therefore, it was generally felt that this was not currently workable.

Opinions varied widely as to whether there should be sanctions for non-compliance, and if so, what form these should take. Options for sanctions against non-compliance include:

- Patent invalidity;
- Unenforceability of a patent;
- Transfer of rights of a patent;
- Imposition of benefit sharing arrangements;
- Criminal sanctions (e.g. as in Norway, Denmark and Switzerland's draft legislation);
- Halting patent processing;

¹⁷ WIPO/GRTKF/IC/8/11 (17 May 2005) Disclosure of Origin or Source of Genetic Resources and Associated Traditional Knowledge in Patent Applications. Document submitted by the European Community and its Member States. Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. Eighth Session, Geneva, June 6 to 10, 2005.

- No sanctions.

Participants from within the private sector generally felt that there should not be any sanctions because of the potential difficulties of complying with these requirements, but many other respondents thought that some sort of sanctions were needed if this measure is to be effective as a tool to encourage compliance with ABS legislation. However, it was also noted that the fear of adverse publicity could be an effective spur to compliance, just as much as any direct legal consequences.

There was strong opposition from many to a requirement that was linked with patent validity, because it was felt that this could create too much legal uncertainty, and could hinder the utilisation of genetic resources and generation of benefits (as highlighted earlier). This was a particular concern of the private sector, but the feasibility of such a strict requirement was also questioned more widely. The transfer of patent rights and imposition of benefit-sharing both met with more support and it was felt that these options should be explored in greater detail.

If an international DR were to be introduced, then clarification of the terminology and the development of workable definitions were highlighted as crucial – particularly by the private sector. However the difficulties of reaching international consensus on DRs were also highlighted, particularly if disclosure was a substantive requirement, since the compatibility of this approach with international law is contentious.

Do you think any other measures should be taken at the European or international level, either as an alternative to, or in addition to, disclosure requirements in order to facilitate fair and equitable access and benefit-sharing?

It was widely recognised among the respondents that DRs alone will not be able to solve the problem of resource misappropriation – there was the feeling that they had come to be regarded as a panacea by some. It was highlighted that, in order to improve ABS, a range of measures needs to be implemented. DRs could be one such measure but opinions varied as to the significance of their role in this.

In order to improve the effectiveness of DRs, a notification system for applications in which disclosure had been made was widely considered a priority. This was not only regarded as a measure that should be introduced in the case of an international DR being implemented, but a step that should be taken immediately. It was felt that this would enhance the effectiveness of existing measures, through improving transparency, and also enabling monitoring of their impact – something that is not currently taking place. Such a system could be established under the CBD's CHM. Its role could be limited to informing countries that their resources had been used, or it could also take on a more ambitious role, facilitating exchange agreements between the providers and users of resources. Either way, this would require the identification of competent agencies in source countries, and a significant increase in institutional capacity.

The implementation of national ABS legislation was generally regarded as the most important step that could be taken to enhance ABS. Relatively few countries have implemented such legislation to date¹⁸ and it was felt by many that improving this situation should be a priority. The private sector in particular highlighted the importance of “robust but user-friendly” ABS legislation, as well as the need to identify national focal points so that it is clear who should be contacted to obtain access and user rights. It was felt that focusing on this area would be far more effective in promoting ABS than the wider implementation of DRs, because this would cover all material being transferred and not just that for which patent applications are made. It

¹⁸ Normand, V. (2004) National implementation. Paper presented at the International Expert Workshop on Access to Genetic Resources and Benefit Sharing. 24-27 Oct. 2004, Cuernavaca, Mexico. Available online at: <http://www.canmexworkshop.com/papers.cfm>

would also improve predictability for the users of resources, for example, through clarifying the appropriate legislation and the systems through which approval for access should be obtained.

Some participants suggested that a two-tiered system could be established for access legislation, with a non-restrictive licensing policy for non-commercial research and a restrictive policy for commercial users of resources. A suggestion was also made for establishing a system for registering *bona fide* research organisations within source countries. Foreign parties who wished to access resources within this country would then have to collaborate with one of these organisations.

To facilitate enforcement of ABS regulations, the need for some kind of international legal framework was highlighted, to address the problem of how legal redress can be sought in foreign jurisdictions, and to overcome some of the inequities in power and access to legal measures. An alternative proposal was for the amendment of the national laws of user countries to regulate the activities of their citizens, for example, to ensure their compliance with international and source country ABS and TK protection measures.

A system of certificates of origin or of legal provenance was regarded as a valuable measure by many, particularly among developing country respondents. If an international certificate was developed, this could make a DR for evidence of legal access (i.e. PIC) more workable since it would provide a standard system of proof, overcoming the problem of variable national legislation. It was highlighted that, as with DRs, the lack of ABS legislation in many countries is problematic for such a measure, and also that the points at which a certificate would be required would need to be clarified. However, it was generally considered that there should be further exploration of this measure.

In the absence of ABS legislation, the need for good commercial practices was highlighted, including the use of MTAs. Codes of conduct for both industry and researchers were regarded as a useful step, and the need for industry to deal with 'black sheep' was highlighted, for example, through excluding them from trade associations. The code of conduct being developed for the use of micro-organisms (MOSAICC) was mentioned as a possible model, as well as those developed by industry, for example, the guidelines produced for members of the Biotechnology Industry Organization (BIO). The need for further awareness raising and education about CBD obligations among small firms and some sectors of the research community was also highlighted.

The establishment of a fund to compensate countries of origin when a resource comes from more than one country was proposed by a number of participants. An international industry fund for ABS development in provider countries was one suggestion, and the system being developed under FAO's ITPGRFA was regarded as a potentially useful model for this. It was also highlighted that benefits could be shared in other ways, for example, through companies providing training and building capacity in source countries.

With respect to all these possible measures, the need for capacity building measures was emphasized – both within government and civil society. To ensure the effective implementation of ABS procedures and legislation, capacity building is needed within patent offices, customs and immigration, ABS institutions and more widely within many government institutions. Within civil society, it was suggested that public understanding of the IPR system should be improved, in particular among indigenous and traditional communities, and that expertise among such communities to negotiate ABS agreements needed to be developed. This was an area which it was felt should be a priority for European countries, and that this could be one of the most valuable means of enabling progress on ABS within developing countries.

The need to deal with the particular issues and problems faced by local and indigenous peoples was emphasized by a number of respondents. It was highlighted that the rights of communities

to their traditional territories, practices and knowledge need to be guaranteed to ensure that they are able to act as custodians of genetic resources and TK. The need for further work on the issue of PIC was also noted, for example, to consider the mechanisms available for enforcement and also to develop effective mechanisms for the restitution of the rights of communities. Training of communities in negotiating skills and legal education, to help them to establish fair access agreements, was also prioritised.

Finally, it was commented that there is a need to follow through on the technology transfer commitments made in both the CBD and TRIPS, and that this should be part of a bigger, broader understanding of benefit sharing, which can help to provide support for maintaining biodiversity and viable rural livelihoods.

4. CONCLUSIONS

The aims of this project were to assess the effectiveness, feasibility, and acceptance of newly proposed and established national legislation on DRs, and also, to assess the prospects of harmonisation of these measures within the European Union.

Effectiveness

Assessing effectiveness depends on what the objectives of DRs are. There is no consensus on this – even among the participants in this research, a wide range of objectives were identified. These included: supporting the CBD's objectives, including the facilitation of access to genetic resources; enhancing fair and equitable benefit-sharing; improving transparency of the patent system; preventing misappropriation of genetic resources; enhancing the patent system through facilitating searches for prior art; improving the equity of the patent system; protecting rights over genetic resources or TK; enabling tracking of resource use; promoting confidence in the patent system.

It is very difficult to determine whether DRs have actually had an influence in these areas, either negative or positive. The fact that there have been so few patent applications in which disclosure has been made suggests that these measures have had little direct impact on these goals – indeed, with just three known applications in which disclosure was made within Europe, and only one from the developing countries surveyed, this measure will have had very little impact on any of the proposed objectives of this measure.

The limited impact of these measures is in part due to the narrow scope of this legislation, which applies only to national patent applications. The fact that many of these DRs are voluntary, or are effectively so (given that there is no checking or monitoring of the applications), also limits their role, for example, in monitoring resource use or preventing resource misappropriation. In addition, the fact that no notification system has been established means that little progress has been made in enhancing the transparency of the patent system.

However, these measures may have had a more subtle influence. The national consultations on disclosure have apparently raised awareness of the CBD and ABS issues among researchers and industry, and this process may have helped to promote fair and equitable ABS. Implementation of these measures may also have been of value in helping to build expertise among policy makers. As highlighted above, some lessons have been learnt in the developing countries as to how such legislation could be designed.

Feasibility

Questions have been raised as to the feasibility of DRs both with respect to the ability of patent applicants to comply and of patent offices to check compliance, particularly with requirements to meet the PIC legislation of other countries. None of these national experiences can shed much light on this because of the narrow scope of these measures and the fact that compliance is not

checked. Therefore, to date, they have not been much of a burden, either for applicants or patent offices.

Within Europe, no problems of feasibility were reported. Among the developing countries, difficulties of complying with the legislation were encountered in Colombia, while in Brazil, lack of clarity of the legislation has meant that the patent office has not yet utilised this measure. These limited experiences underline the need for well thought-out legislation. This would be crucial if an international, mandatory requirement were introduced.

Another aspect of feasibility is the cost of implementing such legislation and of establishing systems to monitor and enforce compliance. This could be considerable, particularly in developing countries where expertise and institutional capacity is often limited. The transaction costs of this measure need further analysis to assess whether these might in fact outweigh any possible benefits.

Acceptance

It was reported during the survey that a more informed debate has developed within Europe since this measure was first proposed, and it seems that there has been a narrowing of the gap between the proponents and detractors of this measure. For example, the proponents of DRs recognise some of the potential problems with this measure, and conversely, its opponents acknowledge the need to address ABS issues.

However, this gap has not disappeared, and there remain fundamental differences in the perspectives of the various stakeholders, with no consensus on many areas. Among the sceptics, concerns remain as to the feasibility of this measure, for example, how the link between a resource and invention could be meaningfully defined, whether resources could be tracked through research processes and commercial exchanges, and whether there would be too high a level of legal uncertainty created, which could ultimately undermine the objective of facilitating ABS.

If this measure is to gain wider acceptance, particularly among potential patent applicants (i.e. the industry and research sectors), the question of whether workable definitions can be developed needs to be explored.

Assessing the Prospects of Harmonisation

The second question examined in this research project was the issue of harmonisation within Europe. The general consensus was that there was little to be gained from this. Rather, it was felt that this issue should be dealt with at the international level, if at all. This would create a level playing field for both the users and providers of genetic resources, and would be more effective in tracking resource use.

WAYS FORWARD

Although a more informed debate on disclosure requirements has developed in recent years, it would seem that these discussions have not moved forward significantly. One hindrance has been the fact that there has been little practical experience of implementing such legislation and so arguments continue to be based on theoretical scenarios. In spite of this limited experience, this study has been able to identify a number of key areas which warrant further exploration. These areas, listed below, provide a means of making progress on this issue.

- **Clarification of terms and definitions:** Clarification of the terms and definitions used in DR legislation was recognised by all as a priority, to allow a better assessment of the feasibility of complying with such requirements and a clear definition of their scope.

Policy makers need to work with those involved in research to develop workable definitions, and in particular, to explore how to define the link between a resource and invention that would trigger disclosure. Clearer definition of the link between a genetic resource and end product would enable clarification of the range and duration of obligations that may be associated with such resources.

Those involved in research and industry also need to determine whether a workable system could be established for tracking genetic resources. This would enable assessment of the feasibility of complying with DRs. Furthermore, regardless of whether DRs were introduced, such a system could be of value in monitoring the use of GRs and improving transparency within the sector.

- **Determining the objectives of DRs:** A wide range of objectives have been proposed for DRs. Clarification of these is required, as this would help in determining how such legislation could best be designed in order to achieve these ends.

A crucial question is whether DRs should simply be a transparency measure, aimed at facilitating enforcement of ABS legislation in other areas of legislation, or alternatively, a means to enforce ABS compliance and prevent the granting of "bad patents". In other words, what role should the patent system play in facilitating ABS?

The proponents of this measure need to clarify its objectives. This should include an assessment of what objectives could realistically be attained through introducing DRs, and a consideration of whether there are any alternative, and more efficient, means of achieving these goals.

- **Exploration of other options within the patent system:** The debate on DR legislation has often been very narrow, for example, discussion of possible sanctions for non-compliance with this measure has focused on imposing fines or making a patent invalid. Alternatives, such as enforced benefit sharing or the transfer of patent rights, have received less attention. However, these options could hold greater potential for enhancing ABS, and they met with wider support from the participants in this research.

Discussions of how to enhance the patent system and ensure that it promotes equity have also been overly narrow, with most attention being given to DRs. However, the effectiveness of this measure remains unproven, and other measures could be just as valuable, if not more so, in achieving these goals. Therefore, other options within the patent system also need to be explored. For example, the provisions on *ordre public* and morality or the doctrine of unclean hands could perhaps be utilised to prevent the enforcement of patents if these are based on illegally obtained resources.¹⁹

Those within the IP world need to explore other means of improving the patent system, to enhance the quality of patents and to ensure that it promotes, rather than undermines, equity. This would be an important step in enhancing the reputation of the IP system and restoring trust.

- **Exploration of alternatives to DRs outside the IP system:** The limitations of DRs as a means to enhance ABS were widely recognised, by both the advocates and dissenters of

¹⁹ It should be noted that the doctrine of unclean hands has only been applied to patents within the USA, and its use is controversial. In the USA, it has been used to prevent the enforcement of rights to a patent when the patent applicant withheld the fact that the invention was based on misappropriated information. (Sarnoff, J. (2004) 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 (PIIPA), June 23, 2004.)

this measure. DRs can only deal with a small part of the problem of resource misappropriation, and so a range of other measures is also needed.

The implementation of workable national ABS legislation is probably the most effective way of preventing resource misappropriation and facilitating ABS. Therefore, policy makers and national governments need to prioritise this. In particular, higher priority needs to be given to implementing effective national legislation in many developing countries, where it was suggested that the slow progress at this level reflects a “divorce of the positions at the national and international level”. A key role for Europe in this area is capacity building, and greater effort is needed to provide training and build expertise.

Other measures could also play an important role, for example, certificates of origin and systems to track genetic resources. One priority area should be developing an international system to facilitate legal enforcement of ABS regulations. These measures need further exploration, with input from all stakeholders – including the providers of resources (whether these are local communities or national governments) and end-users (who may be academics, public research institutes or private companies).

An important step for the users of resources is to monitor and control activities within their own sector. For example, codes of conduct and the establishment of model contracts need to be more widely implemented as they would help to build awareness and expertise of ABS issues, and would also improve trust among the providers of resources.

This study highlighted the fact that there remain fundamental differences between the various stakeholders on this issue. However, it was also apparent that the complexities and potential problems of DRs are widely recognised by both the supporters and dissenters of this mechanism. Such a balanced view needs to be communicated to the policy makers, as there exists a feeling that they have tended to give precedence to political issues over practical matters.

Although opinions varied widely as to the need for, and benefits of, DRs, it was acknowledged that this issue seems unlikely to go away because of its high profile within international negotiations. Therefore, all parties need to continue to engage in the debate. Furthermore, this debate needs to be based on practical questions such as costs, definitions and terminology, and the capacity of institutions and personnel. Only in this way will a solution be found which is workable and effective.

APPENDIX I: Questions asked in the questionnaire survey

QUESTIONS ASKED OF ACADEMICS / NGOS IN EUROPE:

1. Are you or your institute working on the issue of disclosure requirements for genetic resources and / or traditional knowledge in patent applications, or on related areas. Please give details (e.g. areas of research or other activities; publications).
2. Have you been, or are you currently, involved in debates within your country regarding the introduction of disclosure requirements into patent legislation? Please give details of your involvement and any impressions of the national debate. (e.g. what position you advocated, who else was involved in the debate, main areas of controversy, quality of consultation...)
3. Have you been, or are you currently, involved in debates at the EU or international level relating to disclosure requirements? Please give details of your involvement and any impressions of the debate.
4. What advantages can you identify, or do you foresee, in implementing disclosure requirements within your country? (e.g. improving transparency of the patent system; supporting mechanisms to facilitate fair and equitable access and benefit sharing in relation to genetic resources; *et al.*). Please expand.
5. What disadvantages can you identify, or do you foresee, in implementing disclosure requirements within your country? (e.g. practicality and feasibility of implementation; *et al.*) If so, what measures do you think could be taken to alleviate these problems?
6. What measures, if any, do you think should be taken at the European level in relation to disclosure requirements?
7. What measures, if any, do you think should be taken at the international level in relation to disclosure requirements?
8. Do you think any other measures should be taken at the European or international level, either as an alternative to, or in addition to, disclosure requirements in order to facilitate fair and equitable access and benefit-sharing? Please give details.

QUESTIONS ASKED OF ACADEMICS / NGOS IN DEVELOPING COUNTRIES:

1. Are you or your institute working on the issue of disclosure requirements for genetic resources and / or traditional knowledge in patent applications, or on related areas. Please give details (e.g. areas of research or other activities; publications).
2. Have you been, or are you currently, involved in debates within your country regarding the introduction of disclosure requirements into patent legislation? Please give details of your involvement and any impressions of the national debate. (e.g. what position you advocated, who else was involved in the debate, main areas of controversy, quality of consultation...)
3. What advantages can you identify, or do you foresee, in implementing disclosure requirements within your country? (e.g. improving transparency of the patent system; supporting mechanisms to facilitate fair and equitable access and benefit sharing in relation to genetic resources; *et al.*). Please expand.
4. What disadvantages can you identify, or do you foresee, in implementing disclosure requirements within your country? (e.g. practicality and feasibility of implementation; *et al.*) If so, what measures do you think could be taken to alleviate these problems?
5. Do you think any other measures should be taken within your country, either as an alternative to, or in addition to, disclosure requirements in order to facilitate fair and equitable access and benefit-sharing? Please expand.
6. What advantages can you identify, or do you foresee, in implementing disclosure requirements within those countries which are primarily the users of genetic resources? (e.g. as implemented, or proposed, in a number of European countries) Please expand.

7. What disadvantages can you identify, or do you foresee, in implementing disclosure requirements within those countries which are primarily the users of genetic resources? (e.g. as implemented, or proposed, in a number of European countries) Please expand.
8. Do you think any other measures should be taken within user countries, either as an alternative to, or in addition to, disclosure requirements in order to facilitate fair and equitable access and benefit-sharing? Please expand.
9. Have you been, or are you currently, involved in debates at the international level relating to disclosure requirements? Please give details of your involvement and any impressions of the debate. (e.g. what position you advocated, who else was involved in the debate, main areas of controversy, quality of consultation...)
10. Do you think any other measures should be taken at the international level, either as an alternative to, or in addition to, disclosure requirements in order to facilitate fair and equitable access and benefit-sharing? Please expand.

QUESTIONS ASKED OF GOVERNMENT REPRESENTATIVES IN EUROPE:

1. What are your department's / ministry's main activities and interests relating to the issue of disclosure requirements for genetic resources and/or traditional knowledge in patent applications?
2. How has your department / ministry, or its representatives, been involved in debates within your country regarding the introduction of disclosure requirements into the national patent legislation? Please give details of your involvement and any impressions of the national debate (e.g. position advocated by your department, areas of controversy...). Please also indicate which other government departments or stakeholders were involved.
3. What advantages can you identify, or do you foresee, in implementing disclosure requirements within your country? (e.g. improving transparency of the patent system; supporting mechanisms to facilitate fair and equitable access and benefit sharing in relation to genetic resources; *et al.*). Please give details.
4. What disadvantages can you identify, or do you foresee, in implementing disclosure requirements within your country? (e.g. practicality and feasibility of implementation; *et al.*) If so, what measures do you think could be taken to alleviate these problems?
5. Are there discussions currently ongoing within your country on disclosure requirements or related issues? (e.g. development of access and benefit-sharing legislation concerning national or foreign resources; *et al.*) Please give details. (e.g. areas of discussion, parties involved...).
6. Is your department / ministry involved in these discussions within your country? If so, please give details of your involvement and positions taken.
7. Has your department / ministry, or its representatives, been involved in debates at the EU or international level relating to disclosure requirements? Please give details of your involvement and positions taken.
8. What measures, if any, do you think should be taken at the European level in relation to disclosure requirements?
9. What measures, if any, do you think should be taken at the international level in relation to disclosure requirements?
10. Do you think any other measures should be taken at the European or international level, either as an alternative to, or in addition to, disclosure requirements in order to facilitate fair and equitable access and benefit-sharing? Please expand.

QUESTIONS ASKED OF GOVERNMENT REPRESENTATIVES IN DEVELOPING COUNTRIES:

11. What are your department's / ministry's main activities and interests relating to the issue of disclosure requirements for genetic resources and/or traditional knowledge in patent applications?
12. How has your department / ministry, or its representatives, been involved in debates within your country regarding the introduction of disclosure requirements into the national patent legislation? Please give details of your involvement and any impressions of the national debate. (e.g. position advocated by your department, areas of controversy...) Please also indicate which other government departments or stakeholders were involved.
13. What advantages can you identify, or do you foresee, in implementing disclosure requirements within your country? (e.g. improving transparency of the patent system; supporting mechanisms to facilitate fair and equitable access and benefit sharing in relation to genetic resources; *et al.*). Please expand.
14. What disadvantages can you identify, or do you foresee, in implementing disclosure requirements within your country? (e.g. practicality and feasibility of implementation; *et al.*) If so, what measures do you think could be taken to alleviate these problems?
15. Have there been any cases of your national disclosure requirements alerting authorities to the absence of PIC or of benefit-sharing arrangements? Please give details.
16. Do you think any other measures should be taken within your country, either as an alternative to, or in addition to, disclosure requirements in order to facilitate fair and equitable access and benefit-sharing? Please expand.
17. What advantages can you identify, or do you foresee, in implementing disclosure requirements within those countries which are primarily the users of genetic resources? (e.g. as implemented, or proposed, in a number of European countries) Please expand.
18. What disadvantages can you identify, or do you foresee, in implementing disclosure requirements within those countries which are primarily the users of genetic resources? (e.g. as implemented, or proposed, in a number of European countries) Please expand.
19. Do you think any other measures should be taken within user countries, either as an alternative to, or in addition to, disclosure requirements in order to facilitate fair and equitable access and benefit-sharing? Please expand.
20. Have the disclosure requirements already implemented by user countries (e.g. some European countries) alerted you to the use of your country's genetic resources / traditional knowledge in an invention? Please give details.
21. If an enquiry was made to your country (e.g. by a European patent office) regarding the existence, or validity, of an access agreement for the use of your country's genetic resources in an invention, do you think that this could be dealt with effectively? Is the national ABS legislation sufficient, and are there institutions/processes in place, to deal with this?
22. Has your department / ministry, or its representatives, been involved in debates at the international level relating to disclosure requirements? Please give details of your involvement and positions taken.

QUESTIONS ASKED OF PATENT OFFICES IN EUROPE:

1. How many applications have been made for which disclosure of origin is required since these requirements were introduced? (If possible, please provide data for each calendar year.)
2. Have there been any cases of patent applicants failing to comply with disclosure requirements?
3. If so, what were the consequences in these specific cases? (e.g. amendments to the application, refusal of the patent, imposition of civil or criminal penalties...) Was the source country notified?
4. What advantages can you identify, or do you foresee, in implementing disclosure requirements within your country? (e.g. improving transparency of the patent system;

supporting mechanisms to facilitate fair and equitable access and benefit sharing in relation to genetic resources; *et al.*). Please expand.

5. What disadvantages can you identify, or do you foresee, in implementing disclosure requirements within your country? (e.g. impact on the workload of patent offices, feasibility of checking compliance...) If so, what measures do you think could be taken to alleviate these problems?
6. If your office has records of those patent applications concerning genetic/biological material, are these readily accessible to the source countries of these resources, or to other interested parties?
7. Has your office ever received enquiries from source countries as to what patent applications have been made, or are pending, which are based on their genetic/biological material? Please give details.
8. Have there been any cases of disclosure requirements alerting authorities to the absence of PIC or of benefit-sharing arrangements in the source countries? Please give details.
9. Are there discussions currently ongoing within your country on disclosure requirements or related issues? (e.g. development of access and benefit-sharing legislation concerning national or foreign resources; *et al.*) Please give details.
10. Is your office involved in these discussions within your country? If so, please give details of your involvement and any impressions of the national debate. (e.g. what position you advocated, who else was involved in the debate, main areas of controversy...)
11. Is your office involved in debates at the international level relating to disclosure requirements? Please give details of your involvement and any impressions of the debate.
12. What measures, if any, do you think should be taken at the European level in relation to disclosure requirements?
13. What measures, if any, do you think should be taken at the international level in relation to disclosure requirements?

QUESTIONS ASKED OF PATENT OFFICES IN DEVELOPING COUNTRIES:

1. How many applications have been made for which disclosure of origin is required since these requirements were introduced into your national legislation? (If possible, please provide data for each calendar year.)
2. Have there been any cases of patent applicants failing to comply with your national disclosure requirements? If so, what were the consequences in these specific cases?
3. Have there been any cases of your national disclosure requirements alerting authorities to the absence of PIC or of benefit-sharing arrangements? Please give details.
4. What advantages can you identify, or do you foresee, in implementing disclosure requirements within your country? (e.g. improving transparency of the patent system; supporting mechanisms to facilitate fair and equitable access and benefit sharing in relation to genetic resources; *et al.*). Please expand.
5. What disadvantages can you identify, or do you foresee, in implementing disclosure requirements within your country? (e.g. impact on the workload of patent offices, feasibility of checking compliance; *et al.*) If so, what measures do you think could be taken to alleviate these problems?
6. Do you think any other measures should be taken within your country, either as an alternative to, or in addition to, disclosure requirements in order to facilitate fair and equitable access and benefit-sharing? Please expand.
7. What advantages can you identify, or do you foresee, in implementing disclosure requirements within those countries which are primarily the users of genetic resources? (e.g. as implemented, or proposed, in a number of European countries) Please expand.
8. What disadvantages can you identify, or do you foresee, in implementing disclosure requirements within those countries which are primarily the users of genetic resources? (e.g. as implemented, or proposed, in a number of European countries) Please expand.

9. Do you think any other measures should be taken within user countries, either as an alternative to, or in addition to, disclosure requirements in order to facilitate fair and equitable access and benefit-sharing? Please expand.
10. Have the disclosure requirements already implemented by user countries (e.g. some European countries) alerted you to the use of your country's genetic resources / traditional knowledge in an invention? Please give details.
11. If an enquiry was made to your country (e.g. by a European patent office) regarding the existence, or validity, of an access agreement for the use of your country's genetic resources in an invention, do you think that this could be dealt with effectively? Is the national ABS legislation sufficient, and are there institutions/processes in place, to deal with this?
12. Has your department / ministry been involved in debates at the international level relating to disclosure requirements? Please give details of your involvement and positions taken.
13. What measures, if any, do you think should be taken at the international level in relation to disclosure requirements?
14. Do you think any other measures should be taken at the international level, either as an alternative to, or in addition to, disclosure requirements in order to facilitate fair and equitable access and benefit-sharing? Please expand.

QUESTIONS ASKED OF THE PRIVATE SECTOR

- 1) What industrial sector(s) do you operate in? Choose one or more of the following as appropriate:
 - ◇ Pharmaceuticals
 - ◇ Botanical/herbal medicines
 - ◇ Seeds
 - ◇ Horticulture
 - ◇ Crop protection
 - ◇ Industrial biotechnology
 - ◇ Cosmetics/toiletries
- 2) Has your company been, or is it currently, involved in debates within your country regarding the introduction of disclosure requirements into patent legislation? Please give details of your involvement and any impressions of the debate. (e.g. what position you advocated, who else was involved in the debate, quality of consultation, main areas of controversy...)
- 3) Has your company been, or is it currently, involved in debates at the EU or international level relating to disclosure requirements? Please give details of your involvement and any impressions of the debate.
- 4) What advantages can you identify, or do you foresee, in the case that patent applications required the submission of disclosure of geographical origin or evidence of prior informed consent? (e.g. improving transparency of the patent system; supporting mechanisms to facilitate fair and equitable access and benefit sharing in relation to genetic resources; *et al.*) Please expand.
- 5) What disadvantages can you identify, or do you foresee, in the case that patent applications required the submission of disclosure of geographical origin or evidence of prior informed consent? (e.g. practicality and feasibility of implementation; *et al.*) If so, what measures do you think could be taken to alleviate these problems?
- 6) What measures, if any, do you think should be taken at the European level in relation to disclosure requirements?
- 7) What measures, if any, do think should be taken at the international level in relation to disclosure requirements?
- 8) Do you think any other measures should be taken at the European or international level, either as an alternative to, or in addition to, disclosure requirements in order to facilitate fair and equitable access and benefit-sharing? Please expand.

- 9) Do you keep records indicating the geographical source of material acquired and of related information such as published articles, orally-transmitted traditional knowledge etc.?
- 10) If the patent system required you to disclose the geographical origin of biological/genetic material and/or related traditional knowledge used in an invention, how easy or difficult would it be to comply? Please give details.
- 11) If the patent system required you to disclose evidence of prior informed consent (PIC) from the source country for use of their biological/genetic material and/or related traditional knowledge, how easy or difficult would it be to comply? Please give details.
- 12) If the patent system required you to disclose evidence of prior informed consent (PIC) from the holders of traditional knowledge being used in an invention, how easy or difficult would it be to comply? Please give details.
- 13) Has your company ever filed a patent application in which it was required to disclose either the geographical origin, or evidence of PIC? If so, in which country was this?

APPENDIX II: Participants in the questionnaire survey

ORGANISATION	COUNTRY	SECTOR
Centro de Estudios Interdisciplinarios de Derecho Industrial y Economico (CEIDIE)	Argentina	Research / NGO
Federal Public Service Health, Food Chain Security and Environment	Belgium	Government
Belgian intellectual property office, Ministry of economic affairs	Belgium	Government
Flanders Interuniversity Institute for Biotechnology	Belgium	Research / NGO
Croplife International	Belgium	Private sector
European Federation of Pharmaceutical Industries and Associations (EFPIA)	Belgium	Private sector
Centre for Intellectual Property Rights, UC Leuven	Belgium	Research / NGO
Centro de Estudios de Desarrollo en Propiedad Intelectual (CEDPI)	Bolivia	Research / NGO
National Institute of Industrial Property (INPI)	Brazil	Government
Legal attorney	Brazil	Private sector
Bioresources Development & Conservation Programme	Cameroon	Research / NGO
Nanjing Institute of Environmental Science	China	Research / NGO
Ministry of Environment	Colombia	Government
Superintendence of Industry and Commerce	Colombia	Government
National University of Colombia	Colombia	Research / NGO
Legal consultant	Costa Rica	Private sector
Danish Patent and Trademark Office	Denmark	Government
Novozymes A/S	Denmark	Private sector
Groupe Limagrain Holding	France	Private sector
CNRS / Université Paris	France	Research / NGO
Institut du développement durable et des relations internationales (IDDR)	France	Research / NGO
Federal Ministry of Justice	Germany	Government
European Patent Office	Germany	Government
Oeko-Institut	Germany	Research / NGO
Max Planck Institute for Intellectual Property, Competition and Tax Law	Germany	Research / NGO
Trinity College	Ireland	Research / NGO
Kenya Industrial Property Institute	Kenya	Government
International Plant Genetic Resources Institute (IPGRI)	Kenya	Research / NGO
Netherlands Biotechnology Industry Association (Niaba)	Netherlands	Private sector
Centre for Intellectual Property Law (CIER), Utrecht Universit	Netherlands	Research / NGO
Ministry of Economic Development	New Zealand	Government
Norwegian Patent Office	Norway	Government
Ministry of the Environment	Norway	Government
Ministry of Justice and the Police	Norway	Government
Ministry of Foreign Affairs	Norway	Government
Norwegian Bioindustry Association	Norway	Private sector
Genesis Foundation	Norway	Research / NGO
Peruvian Society for Environmental Law (SPDA)	Peru	Research / NGO
Council for Scientific and Industrial Research	South Africa	Private Sector
Biowatch SA	South Africa	Research / NGO
South African National Biodiversity Institute	South Africa	Research / NGO

University of Cape Town	South Africa	Research / NGO
Swedish Patent and Registration Office	Sweden	Government
Swedish Environmental Protection Agency	Sweden	Government
Swedish Association of the Pharmaceutical Industry, LIF	Sweden	Private sector
Swedish Biodiversity Centre	Sweden	Research / NGO
Swiss Federal Institute of Intellectual Property	Switzerland	Government
WIPO	Switzerland	Government
Swiss Biotech Association (SBA)	Switzerland	Private sector
Interpharma	Switzerland	Private sector
Economiesuisse	Switzerland	Private sector
SGCI Chemie Pharma Schweiz (Swiss Society of Chemical Industries)	Switzerland	Private sector
Patent attorney	Switzerland	Private sector
Center for International Environmental Law (CIEL)	Switzerland	Research / NGO
South Centre	Switzerland	Research / NGO
Swiss Ethic Committee on Non-Human Gene Technology	Switzerland	Research / NGO
Berne Declaration	Switzerland	Research / NGO
GlaxoSmithKline	UK	Private sector
Astra Zeneca	UK	Private sector
Trade Marks Patents and Designs Federation (TMPDF)	UK	Private sector
PhytoTrade Africa	UK	Private sector
Phytopharm plc	UK	Private sector
Patent attorney	UK	Private sector
Patent attorney	UK	Private sector
SOAS	UK	Research / NGO
Lancaster University	UK	Research / NGO
IIED	UK	Research / NGO
University of Sheffield	UK	Research / NGO
Research consultant	UK	Research / NGO
Patent attorney	USA	Private sector
Eli Lilly and Company	USA	Private sector
Pioneer Hi-Bred International Inc/DuPont	USA	Private sector

APPENDIX III: Organisations represented at the workshop 'Disclosure Requirements in IPR Applications', Chatham House, 9-10th February 2006

ORGANISATION	COUNTRY	SECTOR
European Federation of Pharmaceutical Industries and Associations (EFPIA)	Belgium	Private sector
European Commission (DG Trade)	Belgium	Government
University of Liège	Belgium	Research / NGO
Institut du développement durable et des relations internationales (IDDRI)	Canada	Research / NGO
National University of Colombia	Colombia	Research / NGO
Novozymes	Denmark	Private sector
Oeko Institut	Germany	Research / NGO
European Patent Office (EPO)	Germany	Government
Max Planck Institute for Intellectual Property, Competition and Tax Law	Germany	Research / NGO
United Nations University, Institute of Advanced Studies (UNU-IAS)	Japan	Research / NGO
International Plant Genetic Resources Institute (IPGRI)	Kenya	Research / NGO
Centre for Intellectual Property Law (CIER), Utrecht Universit	Netherlands	Research / NGO
Norwegian Patent Office	Norway	Government
Fritjof Nansens Institutt	Norway	Research / NGO
Intellectual Property Board of Appeals of the Peruvian National Institute for the Defense of Competition and Protection of Intellectual Property (INDECOPI)	Peru	Government
South African National Biodiversity Institute	South Africa	Research / NGO
Economiesuisse	Switzerland	Private sector
Berne Declaration	Switzerland	Research / NGO
Beckerpatent	Switzerland	Private sector
Swiss Federal Institute of Intellectual Property	Switzerland	Government
Sheffield Institute of Biotechnological Law and Ethics	UK	Research / NGO
UK Patent office	UK	Government
Phytotrade Africa	UK	Private sector
GlaxoSmithKline	UK	Private sector
Quaker United Nations Office	UK	Research / NGO
Queen Mary Intellectual Property Research Institute	UK	Research / NGO
AstraZeneca	UK	Private sector
Dupont	USA	Private sector
American University Washington College of Law	USA	Research / NGO
Eli Lilly	USA	Private sector

Appendix IV: National and regional legislation

REGIONAL LEGISLATION

Andean Community²⁰ (Bolivia, Colombia, Ecuador, Peru, Venezuela)

The issue of disclosure of origin has been addressed in two Andean Community Decisions – Decision 391 on access and benefit-sharing, and Decision 486 on intellectual property rights. Under this legislation, patent applicants are required to disclose the access contract, PIC of indigenous and local communities, and evidence that material was accessed in accordance with national, Andean Community and international law.²¹

Community Decision 391²² (“Common Regime on Access to Genetic Resources”, signed 2nd July 1996) requires consent for the actual and potential use of a resource, covering both genetic resources and any derivatives of genetic resources. It provides for an access contract between the State, represented by the Competent National Authority, and the applicant requesting access. Under Article 35, this is subject to the requirement that:

“When access is requested to genetic resources or their by-products with an intangible component, the access contract shall incorporate, as an integral part of that contract, an annex stipulating the fair and equitable distribution of profits from use of that component.”

This requirement for an access contract is reinforced by a disclosure requirement set out in Decision 486, on the common intellectual property regime.

Decision 391 also states that IPRs for genetic resources that were obtained without compliance with the decision shall not be recognised by member states.²³ Thus, the second “Complementary Provision” provides that:

“The Member Countries shall not acknowledge rights, including intellectual property rights, over genetic resources, by-products or synthesized products and associated intangible components, that were obtained or developed through an access activity that does not comply with the provisions of this decision. Furthermore, the Member Country affected may request nullification and bring such actions as are appropriate in countries that have conferred rights or granted protective title documents.”

Decision 486 (“Common Intellectual Property Regime”) took effect in December 2000.²⁴ Article 3 states that:

“The Member Countries shall ensure that the protection granted to intellectual property elements shall be accorded while safeguarding and respecting their biological and genetic heritage, together with the traditional knowledge of their indigenous, African American, or local communities. As a result, the granting of patents on inventions that have been developed on the basis of material obtained from that heritage or that knowledge shall be subordinated to the acquisition of that material in accordance with international, Andean Community, and national law.”

Article 26 states that:

²⁰ <http://www.comunidadandina.org/>

²¹ WIPO/GRTKF/IC/1/11 (1 May 2001) (submitted by Member States of the Andean Community) contains as Annexes III and IV unofficial translations of Decision 391 and Decision 486; Relevant articles of the Community Decision are also outlined in UNEP/CBD/WG-ABS/2/3 (20 Oct. 2003) Annex;

²² Decision 391, Chapter III, Article 32. Available at: <http://www.comunidadandina.org/>

²³ UNEP/CBD/WG-ABS/2/INF/2 (29 Sept. 2003) n.109

²⁴ Full text available at: <http://www.comunidadandina.org/>

'Applications for patents shall be filed with the competent national office and shall contain: ...

(h) a copy of the contract for access, if the products or processes for which a patent application is being filed were obtained or developed from genetic resources or by-products originating in one of the Member Countries;

(i) if applicable, a copy of the document that certifies the license or authorization to use the traditional knowledge of indigenous, African American, or local communities in the Member Countries where the products or processes whose protection is being requested was obtained or developed on the basis of the knowledge originating in any one of the Member Countries, pursuant to the provisions of Decision 391 and its effective amendments and regulations;'

Article 75 provides that:

"The competent national authority may, either *ex officio* or at the request of a party, and at any time, declare a patent null and void, where:

...

(g) when pertinent, the products or processes in respect of which the patent is being filed have been obtained and developed on the basis of genetic resources or their by-products originating in one of the Member Countries, if the applicant failed to submit a copy of the contract for access to that genetic material;

(h) when pertinent, the products or processes whose protection is being requested have been obtained or developed on the basis of traditional knowledge belonging to Indigenous, African American, or local communities in the Member Countries, if the applicant has failed to submit a copy of the document certifying the existence of a license or authorization for use of that knowledge originating in any one of the member Countries."

The Andean Pact is a legally binding instrument, and Community decisions are binding on the member countries as of the date of their approval by the Commission. Therefore, with the adoption of Decision 391 in 1996, it was automatically integrated into national legislation. Although this did not require the development of any new national law, "technical ambiguities, social protest, political concerns, and institutional limitations, among other factors, forced Bolivia, Ecuador, Peru, and recently Colombia to develop national policies to facilitate the implementation of Decision 391 into their national context".²⁵

NATIONAL LEGISLATION

Belgium

In May 2005, an amendment to Belgium's patent law was introduced. Article 5 of the new law (No. 2005/11224. *Loi modifiant la loi du 28 mars 1984 sur les brevets d'invention, en ce qui concerne la brevetabilité des inventions biotechnologiques, Belgisch Staatsblad/Moniteur Belge* 13/05/2005, 22852)²⁶ modifies Article 5 of the country's patent law. Under this new legislation, disclosure is required of the geographic origin of biological matter of plant or animal origin from which inventions have been developed, where this is known. This is a formal requirement, non-compliance with which could result in the patent application not being processed. This amendment was introduced in order to implement Recital 27 of the European Union Directive on the Legal Protection of Biotechnological Inventions.

²⁵Carrizosa, Santiago, Stephen B. Brush, Brian D. Wright, and Patrick E. Mc Guire (eds) 2004. Accessing Biodiversity and Sharing the Benefits: Lessons from Implementation of the Convention on Biological Diversity. IUCN, Gland, Switzerland and Cambridge, UK, Chapter 1, p. 9. Quoted in UNEP/CBD/WG-ABS/3/2 (10 Nov. 2004) para.75

²⁶ The text of this law is available online at: http://www.just.fgov.be/index_fr.htm

Belgium had previously sought to introduce an amendment which linked compliance with the CBD to requirements that exploitation of an invention not be contrary to *ordre public* and morality. In 2000, a draft proposal to modify article 4(4) of the 1984 Belgian Patent Act (Patents, Law, (*Brevets, Loi*) BE_031, 28/3/84) (*Loi sur les brevets d'invention*) was prepared stipulating "that the exploitation of an invention is contrary to *ordre public* and morality when the invention is developed on the basis of biological material that was collected or exported in breach of articles 3²⁷, 8(j)²⁸, 15²⁹ and 16³⁰ of the CBD". On this basis, "a patent application should contain, not only a formal request, a description, one or more claims, drawings and an abstract, but also the geographical origin of the plant or animal material on the basis of which the invention was developed".

This was an unusual approach, and its legal basis was questioned since there had been no precedent for construing the *ordre public* and morality concepts so broadly.³¹ However, this amendment was not adopted.

Brazil

A disclosure requirement is a condition of patentability in Brazil. Article 31 of Brazil's Provisional Measure No. 2.186-16 stipulates that:³²

"The grant of industrial property rights by the competent bodies for a process or product obtained using samples of components of the genetic heritage is contingent on the observance of this Provisional Measure, the applicant being obliged to specify the origin of the genetic material and the associated traditional knowledge, as the case may be."

This Provisional Measure regulates the access to genetic resources, protection and access to associated traditional knowledge, sharing of benefits and access to and transfer of technology for its conservation and use.³³ Article 16 states that whenever there is a prospect of subsequent commercial use, *in situ* access to samples of components of genetic heritage and associated TK may only be granted after a Contract for Use of the Genetic Heritage and Benefit-Sharing has been signed.³⁴

Colombia

As a member of the Andean Community, Colombia is a signatory to Community Decisions, under which patent applicants are required to disclose the access contract and evidence of PIC for genetic resources or TK (see section on the Andean Community for details).

²⁷ Article 3: States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction.

²⁸ Article 8(j): Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices;

²⁹ Article 15 refers to access to genetic resources

³⁰ Article 16 refers to access to and transfer of technology

³¹ Duffield, G. (2003) *ibid.* p.34 & n.74; Van Overwalle, G. (2002) Belgium goes its own way on biodiversity and patents. *European Intellectual Property Review* 5: 233-236

³² Full text available at: <http://www.wipo.int/tk/en/documents/word/brazil-provisional-measure.doc> See also documents: WIPO/GRTKF/IC/5/INF/2 (4 April 2003) – outlines Article 31 of Brazilian Provisional Measure No 2.186-16 of August 23, 2001; WIPO/GRTKF/IC/5/9 (March 31, 2003) Section IV; UNEP/CBD/WG-ABS/2/3 (20 Oct. 2003) Annex, para.30

³³ IP/C/W/228 (24 Nov. 2000), para.23

³⁴ Brazilian Provisional Measure No. 2.186-16, of August 23, 2001, Chapter V, Article 16. This law is discussed in: WIPO/GRTKF/IC/5/9 (31 March 2003) para.11

Costa Rica

The 1998 Biodiversity Law of Costa Rica (Law No 7,788) requires a certificate of origin to accompany applications for intellectual property rights pursuant to articles 77-85.³⁵ This requirement refers only to biodiversity or TK accessed from within Costa Rica. Under this law (Article 13) the National Commission on Biodiversity Management (CONAGEBIO) was created with responsibility for policies on access to biodiversity and related traditional knowledge. A supporting Technical Office has responsibility for applications for access to the biodiversity and traditional knowledge, and provides certificates of origin to certify the legality of access.

Article 80 of the Biodiversity Law states that:

“Both the National Seed Office and the Registers of Intellectual and Industrial Property are obliged to consult with the Technical Office of the Commission [responsible for managing biodiversity] before granting protection of intellectual property to innovations involving components of biodiversity. They must always provide the certificate of origin issued by the Technical Office of the Commission and the prior informed consent. Justified opposition from the Technical Office will prohibit registration of a patent or protection of the innovation.”

The rules and requirements for accessing biodiversity were further elaborated in Decree no. 31514-MINAE (Rules on Access to Biodiversity), which came into force in 2003.³⁶

Denmark

In 2000, a disclosure of origin clause was enacted in Denmark's IPR legislation, requiring patent applicants to declare the geographical origin of the material, if known. Lack of information on this does not affect the patent application, but could imply a violation of the obligation in the Danish Penal Code (para. 163) to provide correct information to a public authority.

Act 412, 31/5 2000 amended the Danish Patent Act (consolidated Patent Act 926 22/9 2000).³⁷ Based on the Act, the ministerial regulations on patents (Reg.374 19/6/1998) were amended (reg.1086 11/12/2000) by supplementing paragraph 3 with the following provision (unofficial translation):

“If an invention concerns or makes use of biological material of vegetable or animal origin, the patent application shall include information on the geographical origin of the material, if known. If the applicant does not know the geographic origin of the material, this shall be indicated in the application. Lack of information on the geographical origin of the material or on the ignorance hereon does not affect the assessment of the patent application or the validity of the rights resulting from the granted patent.”³⁸

Denmark has decided not to have any access and benefit sharing regulations with regard to its own genetic resources, for example a certification of origin system.³⁹

Germany

A voluntary requirement to disclose geographical origin of biological material has been introduced into Germany's patent law. This came into force on 28th February 2005.⁴⁰ The

³⁵ UNEP/CBD/WG-ABS/2/INF/2 (29 Sept. 2003) n. 108

³⁶ Available at: <http://www.grain.org/brl/?docid=604&lawid=1872>

³⁷ Text of this act is given in UNEP/CBD/WG-ABS/2/3 (20 Oct. 2003) Annex, para.23

³⁸ UNEP/CBD/WG-ABS/2/INF/1 (30 Sept. 2003) pp.82-3

³⁹ Dutfield, (2003) *ibid.* p.36

amended text is based on Recital 27 of the EU biotechnology directive. Thus, Article 34a of Germany's patent law (of 16th December 1980) reads:

"If an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should include information on the geographical origin of such material, if known. This is without prejudice to the processing of patent applications or the validity of rights arising from granted patents."

Norway

The amended Norwegian Patent Act was adopted by Parliament in December 2003, and it came into force on 1st February 2004. The new paragraph 8 (b) reads (unofficial translation):⁴¹

"If an invention concerns or uses biological material, the inventor shall disclose in the patent application the country providing such material. If national legislation in the providing country requires prior informed consent before providing such material, the application shall include information on whether such consent has been sought.

"In cases where the providing country is different from the country of origin of the biological material, the country of origin shall also be disclosed. Country of origin is defined as the country from where the material is accessed in *in situ* conditions. In cases where national legislation in the country of origin requires prior informed consent before providing such material, the application shall include information on whether such consent has been sought. If the applicant does not know the country of origin or whether prior informed consent is required, the applicant shall state this fact in the application.

"These obligations are applicable even if the inventor has changed the structure of the material. They do not concern human material.

"Violations of the requirement to disclose information is punishable under paragraph 166 of the Penal Code. The requirement to disclose information does not affect the handling of a patent application or the validity of a patent."

Penalties for non-compliance under paragraph 166 of the General Civil Penal Code could be imposition of a fine or up to 2 years in prison. The General Civil Penal Code §166 reads as follows⁴²:

"Any person shall be liable to fines or imprisonment for a term not exceeding two years who gives false testimony in court or before a notary public or in any statement presented to the court by him as a party to or legal representative in a case, or who orally or in writing gives false testimony to any public authority in a case in which he is obliged to give such testimony, or where the testimony is intended to serve as proof.

"The same penalty shall apply to any person who causes or is accessory to causing testimony known to him to be false to be given by another person in any of the above-mentioned cases."

⁴⁰ Information on this amendment is available, in German, in the official bulletin "Blatt für PMZ" 2005, issue 3 at: <http://www.heymanns.com/servlet/PB/menu/1119800/index.html>; and on page 148 of the law "Gesetz zur Umsetzung der Richtlinie über den rechtlichen Schutz biotechnologischer Erfindungen", available at: <http://217.160.60.235/BGBL/bgbl1f/bgbl105s0146.pdf>

⁴¹ UNEP/CBD/WG-ABS/2/3 (20 Oct. 2003) Annex, para.16.

⁴² Quoted in UNEP/CBD/WG-ABS/3/5 (10 Dec. 2004) para.57

Peru

As a member of the Andean Community, Peru is a signatory to Community Decisions, under which patent applicants are required to disclose the access contract and evidence of PIC for genetic resources or TK (see section on the Andean Community for details).

Peruvian Law No. 27811 (“A Law introducing a Protection Regime for the Collective Knowledge of Indigenous Peoples derived from Biological Resources”, published 10th August 2002)⁴³ seeks to promote the fair and equitable distribution of benefits derived from the use of indigenous knowledge and to guarantee that such use was made with the prior informed consent of indigenous people. It is also aimed at avoiding the patentability of inventions based on indigenous knowledge that had not been taken into account in considering the inventive steps and innovation. Article 4(c) provides for

“relevant authorities to review patents and other intellectual property rights registered outside Peru, on the basis of national genetic resources or collective knowledge of indigenous community, in order to either claim their nullity or benefits arising from their utilization.”⁴⁴

The law links ABS requirements to the patent system, through license agreements, stating that:⁴⁵

“Where a patent is applied for in respect of goods or processes produced or developed on the basis of collective knowledge, the applicant shall be obliged to submit a copy of the license contract as a prior requirement for the grant of the rights concerned, except where the collective knowledge concerned is in the public domain. Failure to comply with this obligation shall be a cause of refusal or invalidation, as the case may be, of the patent concerned.”

The Peruvian legislation on “Protecting Access to Peruvian Biological Diversity and the Collective Knowledge of Indigenous Peoples” (Law 28216) entered into force on May 1st 2004. This legislation creates the National Commission for the Protection of Access to Peruvian Biological Diversity and to the Collective Knowledge of the Indigenous Peoples (in brief, the National Anti-Biopiracy Commission). The commission, chaired and coordinated by INDECOPI, is tasked with developing actions to identify, prevent and avoid acts of biopiracy with the aim of protecting the interests of the Peruvian State. Its functions will include creating a register of Peru’s biological resources and traditional knowledge and conducting research on patent applications granted outside Peru, which are related to Peruvian biological resources or traditional knowledge of Peruvian indigenous peoples. In addition, the commission will review patents using Peruvian biological resources that have been granted locally and internationally, and, when appropriate, undertake necessary actions to have these patents revoked.⁴⁶

Sweden

Sweden has implemented a new Rule 5(a) of the Patents Regulations (SFS 2004:162) (under the Patents Act) which came into effect on 1/5/04. This was developed in response to EC Directive 98/44, and mainly reiterates paragraph 27 of the Directive’s Preamble. It contains provisions on the disclosure of the geographical origin of biological material as follows (unofficial translation):⁴⁷

⁴³ Text available at: <http://www.wipo.int/tk/en/documents/word/peruvian-law-27811.doc>

⁴⁴ UNEP/CBD/WG-ABS/3/2 (10 Nov. 2004) para.92

⁴⁵ WIPO/GRTKF/IC/5/9 (31 March 2003) para.21

⁴⁶ IP/C/W/441 (28 Feb. 2005)

⁴⁷ UNEP/CBD/WG-ABS/2/3 (20 Oct. 2003) para.91 & Annex paras.19-20

“5(a) If an invention concerns biological material of plant or animal origin, or if it uses such material, the patent application shall include information on the geographical origin of such material, if known. If the origin is unknown, this shall be said. Lack of information on the geographical origin or on the knowledge of the applicant regarding the origin is without prejudice to the processing of the patent application or the validity of rights arising from a granted patent.”

The proposed information requirements “would apply to patent applications for any inventions based on biological material of plant or animal origin or using such material, regardless of the technology involved. The requirements would apply equally to patent applications by domestic and foreign nationals” and “regardless of where the biological material was obtained.” There would be “no consequences for the patent applicant or patent holder of any failure to meet the requirements of disclosure of the geographical origin of the biological material.” As to publication, “the information on geographical origin would be available to anyone when the patent was granted (or when 18 months had passed from the filing date or from the date from which priority was claimed).”⁴⁸

There are no consequences of non-compliance with this requirement, either within patent law or elsewhere. A correspondent from the Swedish Ministry of Justice noted that it would not be possible to introduce sanctions within the realm of patent law under current international law (i.e. the TRIPS agreement and the Patent Law Treaty).

Switzerland

The Federal Department of Justice and Police undertook a public consultation on revising the Swiss patent law between July and October 2004. A report was submitted to the Swiss Federal Council, on the basis of which the Council decided to submit the draft law to Parliament. The draft law was submitted on 23rd November 2005. Parliament will consider this during 2006, and if approved, the law could enter into force in 2007.⁴⁹

The draft law contains provisions requiring the disclosure of the source of genetic resources and traditional knowledge. This would apply to both national and international patent applications.

The proposed provisions are as follows:⁵⁰

Article 49a (new)

“Patent applications for inventions which concern genetic resources or traditional knowledge must contain a declaration of the source:

- a) of a genetic resource, to which the inventor or the applicant has had access, if the invention is directly based on this resource; in case this source is unknown to the inventor or the applicant, this must be declared accordingly;
- b) of traditional knowledge of indigenous or local communities related to genetic resources, to which the inventor or applicant has had access, if the invention is directly based on this knowledge; in case this source is unknown to the inventor or the applicant, this must be declared accordingly.”

⁴⁸ UNEP/CBD/WG-ABS/2/INF/4 (23 Oct. 2003) paras.55 & 67

⁴⁹ pers.comm., Swiss Federal Institute of Intellectual Property (20 Dec. 2005)

⁵⁰ An English translation of the draft provisions of the patent law are available at: <http://www.ige.ch/E/jurinfo/documents/j10017e.pdf>

Original documents are available:

- in German - <http://www.ige.ch/D/jurinfo/documents/j10013d.pdf> (draft provisions);
<http://www.ige.ch/D/jurinfo/documents/j10014d.pdf> (explanatory report);
- in French: <http://www.ige.ch/F/jurinfo/documents/j10013f.pdf> (draft provisions);
<http://www.ige.ch/F/jurinfo/documents/j10014f.pdf> (explanatory report).

Article 81a

“1. Whoever wilfully makes a wrongful declaration as referred to in Article 49a shall be liable to a fine of up to 100,000 Swiss Francs.

2. The judge may order the publication of the ruling.”

Article 138

“The applicant shall be required to carry out within a period of 30 months as from the filing date or the priority date, with respect to the Federal Institute of Intellectual Property, the following acts:

...

b) declare the source (Article 49a);”

Thus, under Article 81a, if the patent applicant intentionally declares the wrong source of genetic resources or traditional knowledge, the applicant is liable to a fine. Wrongful declaration of the source is an offence to be prosecuted *ex officio*. However, if the patent application does not declare the source, under Articles 59, para.2, and 59a, para.3b, of the patent law, the applicant is granted a period of time to correct this. Failure to do so will lead to the rejection of the patent application.