

The Interface with Existing Intellectual Property Systems: Limits and Opportunities for Existing Intellectual Property Rights

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Purpose

This paper explores the interface between the intellectual property (IP) system and objectives of the Convention on Biological Diversity (CBD) in relation to access and benefit-sharing (ABS). The paper considers relevant aspects of the CBD and the World Trade Organisation Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) with a view to determining what flexibility exists under TRIPS to take national measures in support of ABS objectives, including prior informed consent (PIC), mutually agreed terms and benefit-sharing. Suggestions are also made about the role of IP in an international regime for ABS. The paper focuses on what role IP should have in ABS, rather than debating whether it should have a role at all.

In considering the flexibility provided by TRIPS, and what role IP should play in relation to ABS, particular attention is given to the various proposals in favour of disclosure of origin or source of genetic resources and associated traditional knowledge (TK), and evidence of PIC or benefit-sharing, in applications for patents and plant variety rights (PVRs).

The perspective offered in this paper is one of an IP policy-maker, not a CBD expert, confronted with public interest challenges from the CBD to the IP system. The challenge is not unwelcome, as it provides an opportunity to recall the fundamental rationale for the IP system – public interest – and that IP protection is not an end in itself.

Background

There has been much debate about the role or impact of IP rights (IPRs) in relation to the objectives of the CBD, even before the CBD was concluded. The woolly references to IP, for example, in Article 16 of the CBD, recognising on one hand that IPRs should be protected in the context of obligations concerning technology transfer, and on the other seeking co-operation to ensure that IPRs are “supportive of and do not run counter to” CBD objectives, provide little clarity about the IP connection and at best reflect a compromise position.

The areas of interface between the CBD and TRIPS, including the impact of the IP system on ABS, technology transfer, protection of TK and the conservation and sustainable use of biological diversity, have been considered in many contexts (including the CBD, WIPO and the TRIPS Council). Much has been written about whether the respective obligations under IP treaties and the CBD are mutually supportive or are in conflict with each other. This paper proceeds on the assumption that there is no actual legal conflict between TRIPS and the CBD, on the basis that it is possible to consistently implement the obligations under both treaties in some way. There is, however, considerable overlap in subject matter, and provisions of TRIPS in relation to patents and PVRs may limit the “possibilities” when it comes to implementation

¹ This paper reflects the personal views of the author, not the Ministry of Economic Development.

of CBD obligations in respect of ABS (and other areas of interface, not considered in this paper).

The IP system has a role, therefore, in relation to ABS and this should be clarified (including in an international regime for ABS) to provide certainty for policy makers and to avoid disputes. Whether this supportive role can be effectively played using the flexibilities available in TRIPS or would require changes to IP standards is a further question and is considered below.

The Role of IP in ABS

In determining the nature of the role of IP in ABS, it is necessary to consider more closely the ABS provisions of the CBD and examine some of the problems that have been identified and the alleged short-comings of the IP system. This section defines the problem to be solved, finds that IP is only incidental to it, but concludes that IP still has a role to play in the monitoring of ABS objectives.

The IP/ABS issues centre on the extent to which the IP system is supportive of or runs counter to the principles contained in the CBD concerning the authority of governments to grant access to genetic resources, subject to PIC and mutually agreed terms, with fair and equitable benefit-sharing (including in relation to TK). A number of commentators have suggested that the IP system thwarts ABS objectives. This is said to occur when patents or PVRs are granted for inventions or plant varieties involving genetic resources or associated TK in situations where PIC has not been obtained and agreement has not been reached concerning benefit-sharing.

In determining whether IP should respond to problems about PIC and benefit-sharing, it is useful to consider the relationship between IP and these concepts. Article 15 of the CBD requires PIC in relation to access, not PIC to the acquisition of IPRs. Article 15 does, however, require that access be on the basis of mutually agreed terms. Whether or not IP rights could be sought and how they could be exploited are conditions that could form part of the mutually agreed terms. In situations where PIC has not been obtained, the connection to IP is at best indirect, as there is likely to have been no agreement regarding IPRs.

In relation to benefit-sharing, IPRs are one possible form of benefit that could be shared, and this could be addressed in national ABS regulations or recorded in an ABS agreement. It should be recalled, however, that in many cases the genetic materials obtained will not lead to a patentable invention or PVR, and that successful commercialisation of any claimed inventions is not certain. In the wider scheme of things then, IP may play a fairly small part in the potential benefits that could flow from access.

This analysis suggests that the IP system is not the source of the problem when patents or PVRs are granted (over genetic resources or associated TK) in situations where PIC and benefit-sharing does not occur. The problem is that, in some cases, users of genetic resources do not obtain PIC or negotiate ABS agreements, and may breach conditions of ABS contracts and national laws or regulations. Only in some circumstances does IP form part of mutually agreed terms and benefit-sharing arrangements.

The solution to this problem clearly requires the establishment of systems to facilitate and encourage compliance, and effective enforcement. First and foremost, ABS systems must be established so that processes are available to users of genetic resources to obtain PIC, and these systems do not yet exist in many countries. ABS systems may rely on a range of sanctions for non-compliance including administrative penalties, contract law to enforce ABS agreements, equitable doctrines, tort and criminal provisions.

It is likely, however, that even when these systems and incentives are in place, applications may be made for IPRs in circumstances where national ABS laws or ABS agreements do not allow for this. ABS systems may also have difficulty tracking compliance with PIC and other criteria, especially where ABS arrangements have not been entered into. This is where the IP system can play a supporting role in the monitoring of ABS conditions, even where IP is not a mutually agreed term. So while IP is not technically the problem, it can form part of the solution and assist with monitoring and enforcement efforts.

The IP system can support CBD objectives, including ABS, in two ways: in the application of existing criteria concerning the granting of patents or PVRs (using the flexibilities available under TRIPS), and by the application of expanded disclosure requirements concerning the origin or source of genetic resources and associated TK. These approaches are not necessarily mutually exclusive.

Existing Features of the IP system that can Support ABS: Looking for Flexibility

There are a number of existing features of the patent system prescribed in TRIPS which could be flexibly applied in domestic legislation in a way that may support ABS objectives (including where TK is concerned). These measures would reduce the likelihood that patents will be granted where genetic resources or TK are concerned.² Some of the flexibilities listed here relate more to TK than ABS objectives but are considered on the basis that the terms of reference for the elaboration of an international regime on ABS includes TK within its scope. The degree of support to ABS of the “flexibilities” approach is, however, limited to those States that choose to adopt it.

Potential flexibilities in support of ABS (including TK) include:

- Incorporating into domestic patent law all the exclusions to patentability allowed under Article 27 of TRIPS. This could involve excluding plants and animals from patentability (but not micro-organisms), and adopting an expansive interpretation of the exclusions in Article 27.2. This Article enables Members to exclude patentability inventions when it is necessary to protect public order and morality, including the protection of human, animal or plant life and to avoid serious damage to the environment. This might include the prevention of the patenting of inventions based on genetic resources and associated TK where, for example, the commercial exploitation of such an invention is contrary to the values or belief system of indigenous people. This may in effect correlate with failure to provide PIC.
- Application of the criteria for patentability in Article 27.1 – novelty, inventive step and usefulness – to lifeform inventions, in a way that avoids the granting of overly

² There are further examples of flexibility, which may support other CBD objectives (and concerns about the patenting of lifeforms generally), that are not considered in this paper.

broad patents. This could be achieved by, for example, including as prior art for the purpose of determining novelty or inventive step, any information made available to the public in any form, anywhere in the world. IPR granting authorities could also expand their sources of TK as prior art, provide training to examiners on how to recognise TK and co-operate with IP authorities in other countries to take advantage of expertise concerning TK as prior art.

- Require additional information about the source or origin of genetic resources or associated TK to satisfy existing requirements in Article 29 of TRIPS. This Article requires applicants to “disclose the invention” by providing sufficient information so that a person “skilled in the art” could carry it out. This option is elaborated on in the next section, which considers expanded disclosure proposals.
- Adopting a sui generis system for the protection of plant varieties not modelled on the UPOV Convention. Article 27.3(b) of TRIPS requires that members provide for the protection of plant varieties either by patents or an effective sui generis system. National plant variety laws could require disclosure of origin of the plant materials used and evidence of PIC of the country, farmer or TK holder that provided such materials and associated knowledge. Mandatory disclosure may not be consistent with the UPOV Convention, which does not permit requirements other than the standard DUS3 criteria to be imposed.

Disclosure Proposals

It has been suggested that the IP system could assist with monitoring and possibly enforcement of ABS objectives by requiring the origin or source of genetic resources and associated TK to be disclosed in applications for IPRs. Disclosure of this nature would also serve an IP purpose, by providing additional information that facilitates the determination of prior art. This would lead to better decisions about patentability and would, therefore, enhance the credibility of the IP system. It could also improve the determination of inventorship, and facilitate the working of an invention.

Some proposals go further and require disclosure of the legal context in which the genetic resources or TK was accessed. Some suggest that evidence of PIC and benefit-sharing should be disclosed, in addition to source or origin. Disclosure of this information has no connection to patent principles but could be seen as a supportive measure.

The proposals that are currently being considered by the TRIPS Council and WIPO, and the actual disclosure requirements adopted in countries such as Costa Rica, Brazil, India, Norway and the European Union, contain a number of variants. They may be *voluntary* or *mandatory* (having legal consequences in the case of no compliance), include a *formality* (generally procedural) or *substantive* requirement (having an impact on criteria for patentability), or a combination of these. Formality and substantive requirements can overlap in practice, including in relation to existing disclosure requirements where failure to comply with formalities can in some cases lead to a patent not being granted.⁴ Although substantive and

³ Distinct, Uniform and Stable (Article 5(1), 1991 UPOV Convention)

⁴ For example, failure to provide evidence that the inventor was entitled to access genetic material used to produce the invention could be a formality objection as would failure to pay renewal fees. See also WIPO/GRTKF/IC/5/10, para 31-35.

formal requirements can have legal consequences, not all consequences will be patent-related - in the sense that an application is narrowed or rejected or a patent invalidated or revoked. For example, administrative and criminal penalties may apply where incorrect information is provided.

The proposals that also include disclosure of PIC and evidence of benefit-sharing also vary. In some cases, provision of this information would be in the interests of transparency or good faith, in which case the information would be provided to provider countries or submitted to a centralised repository to assist with ABS compliance. In others, the information disclosed or evidence submitted would have a bearing on whether an IPR was granted. In this case patent granting authorities would be called upon to assess the adequacy of the information provided or might rely on the face value of any certificate of origin provided.

Impacts and Effectiveness

While disclosure may seem like a good idea in theory, there are a number of specific issues that need to be considered to determine how effective it might be to implement in practice, and its impact on IP policy objectives. These include:

- The trigger for disclosure: how direct should the relationship between the genetic resource or associated TK and the claimed invention be? This issue is not clearly addressed in many of the disclosure proposals. The trigger could be closely connected to patent principles, so as to require disclosure where it is necessary to carry out an invention, TK is prior art known to an applicant and relevant to an assessment of novelty, or where a TK holder may be a potential co-inventor. Alternatively, disclosure may be triggered where genetic resources are used in the course of research (being essential or only incidental to it).⁵ A key issue is whether derivatives would trigger an obligation to disclose. In deciding the nature of the trigger it would also be necessary to consider difficult questions such as the respective values of naturally-occurring genetic resources, TK and research and development in innovation.
- ABS systems and competent authorities must first exist for the IP system to be able to support them via disclosure: such systems and authorities do not yet exist in many countries. It is difficult to monitor or collect information about PIC, for example, if systems for obtaining it are not accessible.
- The relationship between national ABS systems in provider countries and IP offices in the country considering an IP application: if disclosure were to go beyond considering information of source as part of assessing existing patent criteria, to evidence of PIC and benefit-sharing being substantive criteria, serious questions would arise concerning the resources and technical expertise of IP examining authorities to make assessments about acts of access, adequacy of PIC and contractual obligations originating under ABS laws in other jurisdictions. Choice of law issues also arise in this context.
- Necessary documentation, such as declarations, copies of contracts or permits, would need to be determined: the establishment of a certification of origin system would address a number of the concerns that have been raised about verification of documentation.

⁵ WIPO/GRTKF/IC/5/10, para 98.

- The impact on innovation of increased regulation and compliance costs: disclosure requirements should be implemented in such a way as to preserve as far as possible the predictability and transparency of the IP system. Concerns about the cost of determining origin or source where it may have its origins in several places would need to be addressed, for example, in the exact nature of the documentation required, and perhaps by only requiring information readily or reasonably available to an applicant.⁶ Increased regulation may act as a disincentive to invest in biotechnology, with flow-on effects for the benefits available to be shared with providers of genetic resources and associated TK.

These issues, along with the nature of the obligation to disclose and consequences of the failure to comply, would need to be determined in order to provide certainty to users of the IP system and if disclosure is to be an effective means to support ABS objectives.

Conclusions

The overlapping nature of CBD objectives concerning ABS and genetic resources and associated TK as the subject matter of IPRs under TRIPS suggests a role for the IP system in support of ABS objectives. While a close reading of each agreement does not suggest that a direct conflict exists, in the interests of certainty for ABS policy makers and to avoid disputes concerning implementation, the relationship of IP to ABS should be clarified in the context of an international regime.

While IP is not the major source of the problem when it comes to failure to comply with ABS rules regarding PIC, agreed terms and benefit-sharing, it can form part of the solution, in support of or in addition to ABS systems and other areas of law, including contract, tort and equitable principles. The IP system can assist in two ways: the first is in relation to existing criteria for patentability and the second relates to extended disclosure requirements.

Parties to TRIPS should, therefore, be encouraged to take advantage of the flexibilities available under TRIPS, including in relation to the definition of invention and criteria for and exclusions to patentability, to provide policy space to implement ABS policies. States would be encouraged not to take disputes in relation to flexible interpretations of TRIPS provisions to enable ABS implementation. The moratorium on non-violation disputes under TRIPS should continue to encourage flexible interpretations. Changes to existing standards, for example those related to prior art, might be considered if the flexibilities approach proved unsuccessful.

The IP system could also require mandatory disclosure of the source of genetic resources and associated TK in applications for patents and PVRs, and collect information about whether PIC and benefit-sharing has occurred. Disclosure of the source of genetic resources and associated TK would not be a new substantive requirement for patentability, but it could be used to make assessments about existing substantive patent criteria.⁷ An amendment to TRIPS, possibly to Article 29 concerning disclosure, would make it clear that disclosure of this information is permissible and required. Arguably, disclosure of source could be justified as a

⁶ Correa, C.M. , 2003. *Establishing a Disclosure of Origin Obligation in the TRIPS Agreement*, Quaker United Nations Office Occasional Paper 12, August 2003, p 6.

⁷ Correa, C.M. , 2003, p 9-10

III. Specific Issues for consideration in the elaboration of the IR:
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formality under the present provisions, but not for PIC or benefit-sharing. The legal basis of the disclosure requirement in relation to disclosure of genetic resources and TK would, therefore, be in IP principles, but it could also be connected to ABS law.

The information about whether PIC or benefit-sharing had occurred could be collected, but not assessed, by IPR granting authorities. It could be provided, along with information about source of genetic resources and associated TK in applications, to a competent authority in the provider country (if such authorities are established under an international regime). Alternatively, it might be provided to a central repository managed by WIPO or the CBD that is accessible to providers of genetic resources and associated TK. In this way the IP system would assist with the monitoring of ABS rules in general and ABS agreements where they specifically include IP as an agreed term. The legal basis for disclosure in the case of PIC and benefit-sharing would not be patent principles or IP policy, but be directed towards meeting ABS policy objectives. The IP system would not, however, go as far as to provide sanctions if ABS conditions were not met, as this would stretch the IP system too far beyond its underlying principles, function and purpose.

This paper believes that disclosure of this sort is appropriate and a good idea in theory. It is dependent, however, on ABS systems being established, and a number of practical details (identified above) would be critical to its success. It is also dependent on progress being made on these issues in the TRIPS Council, and such progress has not been rapid to date. There is certainly greater room for appreciation of how IP can serve the public interest in CBD objectives in IP fora.

There is a risk, however, that providing such clarity on the relationship between CBD objectives and provisions in TRIPS may prove redundant given the increasing prevalence of free trade agreements and bilateral and regional agreements concerning IP. These agreements often remove the flexibilities available under TRIPS and impose TRIPS-plus standards. The incidence of these arrangements is, therefore, another issue to take into account in determining the role of IP in an international regime for ABS. This factor does not mean that pursuing clarity on the IP/ABS interface is fruitless, but rather suggests that time is of the essence.