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Morten Walløe Tvedt and Olivier Rukundo

FRIDTJOF NANSENS INSTITUTT
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Access and Benefit Sharing
ABS Capacity Development Initiative for Africa

Functionality of an ABS Protocol[1]

Morten Walløe Tvedt[2]
Fridtjof Nansen Institute
and
Olivier Rukundo[3]

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Morten Walløe Tvedt
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Abstract

The present study is an analysis of the draft Protocol on Access and Benefit Sharing which came into being after the deliberations of the resumed Ninth Meeting of the Ad Hoc Open-ended Working Group on Access and Benefit sharing which took place in July 2010 in Montreal. The study examines a range of contentious issues where disagreement has prevailed among negotiating parties and regional groups, with a view to providing a legal analysis of the state of play of the negotiations. It is our hope that this can contribute to a better technical understanding of some of the issues at the core of the negotiations and assist in the preparations for the last round of negotiations before the adoption of the Protocol. The idea is to share our perspectives on where negotiations stand at this juncture. The aim is to offer some thoughts as to how certain provisions of the draft Protocol can be dealt with in view of ensuring that the Protocol will effectively contribute to the fulfilment of the third objective of the CBD. The provisions of the Protocol, as they currently stand, will not be conducive to the fair and equitable sharing of benefits unless the wording can be further clarified to ensure that the Protocol will be implemented into national legislation and that it will in fact have legal effect on users of genetic resources. Particular attention is given to issues related to the scope, utilisation, and relationship of the prospective Protocol with other international instruments, pathogens and elements at the nexus between access and compliance.

Key Words:

Access and benefit sharing, pathogens, utilisation of genetic resources, functionality

Orders to:

Fridtjof Nansen Institute
Postboks 326
N-1326 Lysaker, Norway.

Tel: (47) 6711 1900
Fax: (47) 6711 1910
Email: post@fni.no
Internet: www.fni.no

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1 Background

This study has been motivated by the deliberations of the resumed ABS-WG-9, which took place in Montreal, Canada, in July 2010. It has one overall objective: to contribute to the functionality of access and benefit sharing (ABS) as set out in the Convention on Biological Diversity (CBD) under its Article 15. It is based on the assumption that all contracting parties to the CBD are politically committed to ensuring the effective implementation of the third objective of the Convention.

This study has been undertaken immediately after the resumed meeting of ABS-WG-9, with a view to making it available to countries and other stakeholders in preparation for the second resumed session of the Ninth Meeting of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing. During the deliberations in Montreal it became evident that delegations had arrived at political 'red lines' on certain issues, and that additional instructions would be needed from capitals to allow delegations to engage further in these questions. The topics examined in this study are issues upon which the delegates still need to develop a common understanding and where major disagreements prevail. It has now become apparent that reaching a common understanding on certain issues such as utilisation of genetic resources might help to unlock other difficult issues in the negotiations. Solving these kinds of issues can ensure that the Protocol is operational and implementable, so that it can effectively contribute to making ABS functional. The following sections take a closer look at selected provisions of the draft Protocol to see how it can be given effect in international law and in relevant domestic frameworks.

2 How can the Protocol be made functional?

Before embarking on a detailed analysis of selected provisions of the draft Protocol, we offer a few remarks on how an ABS system can be made functional. At its core, the ABS-challenge is about creating incentives for private (or public) entities (which create benefits using 'genetic resources'), to share these benefits in a fair and equitable manner. ABS becomes an international issue when a genetic resource of one country is used in another jurisdiction or country.

The functionality of the Protocol rests on finding an adequate balance between two imperatives. On the one hand, developing countries often advocate for strong compliance mechanisms coupled with clear benefit-sharing obligations. This is essentially based on a view that provider-side law and contractual provisions are currently insufficient in dealing with misappropriation and/or misuse. On the other hand, it is not enough to require user-side measures: the Protocol must also make those measures reasonable from the perspective of the user side. The challenge is how to create an adequate balance between these two imperatives without compromising effective compliance and without introducing undue legal uncertainty for users of genetic resources.

One basic assumption seems to be that ABS is made functional by the use of contracts between the providing country and the user. The challenge is, however, twofold: 1) creating incentives for users to enter into such contracts, and 2) making such contracts enforceable in the jurisdictions where the genetic resources are being used. The legislation of the user country needs to be clear as to the situations in which users will be bound by specific ABS obligations. The response to this can be found in the CBD in its Article 15.7, particularly through a close examination of how the utilisation of genetic resources can act as the trigger-point for benefit sharing.[4] Thus several of the difficult issues in the current negotiations can be solved by enhancing clarity and certainty on the concept of utilisation as a trigger-point/end-point as regard to when benefits shall be shared.

One legal challenge in ABS is that the Protocol and the CBD itself are binding upon states, whereas benefits are created by private entities, like companies, universities etc. Thus, for the Protocol to have any effects on the private users of genetic resources, its obligations need to be implemented in the home jurisdiction of the user. The challenge in international law is that the principle of sovereignty prevents the law of one country (the providing country) from having legal effects in the jurisdiction of another country (user country), unless the user country recognises in its own legislation any such legal effects (reciprocity). If one user of genetic resources shall be expected to enter into mutually agreed terms (MAT) and share a fair and equitable portion of the benefits arising out of utilisation of genetic resources, there must be incentives for that user to do so.[5] The private company must be obliged under the laws in its home jurisdiction to share benefits or to have an agreement describing how benefits are to be shared.

3 Temporal scope

A basic area of disagreement in the current negotiations relates to the discussions around the issue of the temporal scope of the Protocol. The temporal scope is reflected in the text highlighted in grey:

ARTICLE 3

SCOPE

> This Protocol shall apply to genetic resources within the scope of the Convention on Biological Diversity and to the benefits arising from [any][the] utilization of such resources [that were acquired after the entry into force of this Protocol for a Party with Parties providing such resources] [or its derivatives].

A similar idea on the issue of temporal scope is also reflected in Article 3*bis* of the draft Protocol: '[This Protocol does not apply to: [...] e) genetic resources and traditional knowledge associated with genetic resources acquired prior to the entry into force of the Protocol'.

3.1 What would be the practical consequences of this temporal scope

As a first step, the analysis will aim at examining the implications of including a temporal scope dimension into the Protocol. This suggested wording establishes legal consequences connected to the point of time when the Protocol enters into force.

The wording 'for a Party with Parties' is ambiguous. It could be interpreted as meaning that the rules of the Protocol apply only when *both* the providing country and the user country have become members. Such a rule would create a serious problem for providing countries. The entry into force for each provider country is dependent on two things – (i) the entry into force of the Protocol and (ii) the date of ratification by that individual country. That would leave genetic resources worldwide unregulated (subject to the CBD in general) from today until 90 days after the 50th country has ratified/acceded to the Protocol (Article 28.1). Additionally, for each ratifying country, the Protocol enters into force a further 90 days after the ratification by that country.[6] For 50 countries to ratify, experience with other Conventions has shown that it normally takes at least 22 months after signing.[7]

Such an individual temporal scope for each providing country would create difficulty in ascertaining whether or not the Protocol applies to access to its genetic material.

This would also put time pressure on providing countries to ratify the Protocol, as they probably would want their genetic material to be covered by it. In addition, this could create a disincentive for user countries to ratify, as this would effectively leave them outside the coverage of the Protocol until their ratification plus 90 days.

It bears noting that the CBD is a legally binding international treaty. As such, the benefit-sharing obligations enshrined under the CBD have been substantive international law since its entry into force in 1993. The draft Protocol creates legal uncertainty as it raises some unanswered questions: Which rules should apply to genetic resources acquired between the entry into force of the Convention and the entry into force of the Protocol? And which rules should apply to genetic resources that were acquired prior to the Convention, but not 'in accordance with the Convention'? The current draft Protocol does not suggest any solutions to these temporal aspects.

As noted above, the CBD has been binding international law for the last 18 years. To suggest a temporal scope which would exclude all acts or situations of access which occurred during these past two decades prior to the entry into force of the Protocol would be akin to placing a stamp of approval and acceptance on some illegal access that took place during these years without corresponding benefit-sharing. This temporal scope would actually create strong incentives to acquire genetic resources before the actual entry into force of the Protocol, as it would not be possible to take any measures under the Protocol against any such access, regardless of the fact that such acts would have been undertaken in compliance or not with the legal situation at that time.

3.2 A closer look at the rationale for including a temporal scope

The rationale in introducing such language was to ensure that the Protocol would be applied in a non-retroactive manner. This is indeed a valid concern, as non-retroactivity is a legal principle that often arises in international and national law.

Retroactivity essentially means that new legal consequences and obligations prescribed by a new legal instrument are connected to an action or situation that took place before the entry into force of the said instrument.

The issue of retroactivity in ABS has two dimensions: one is the application of the Protocol as part of international law; the second concerns the rules in domestic legislation regarding obligations upon private users of genetic resources. Whether the rules of the Protocol are legal or not, is an issue for international law. The implementation of any obligations upon the private user under the user country legislation is something else: here the constitution and domestic legislation of that country apply. Retroactivity in international law says something about what the content of a new obligation could be; retroactivity in national law protects private parties against their own state.

3.2.1 Retroactivity in domestic law

To understand the concept of retroactivity in domestic law, there is a need to create nuances, as there are different types of actions and situations that can be envisaged. Some actions took place in the past and have ended; some actions took place in the past, but may still have consequences for the future; and yet some situations started out in the past and are

still ongoing/continuing activities. Each nation would have different types of protection for its citizens in each of these situations.

Applying this in the ABS context would suggest that requiring the sharing of benefits that were created in the past would be a classic example of a retroactive law. This has also not been proposed by anyone in the negotiations. Nonetheless, new situations can be regulated by new rules. That implies that new uses of genetic resources after the entry into force of the national law regardless of the time of their acquisition can be regulated by the act of implementing the rules of the Protocol. Ongoing situations can also be regulated by new rules. That implies that new legal consequences for ongoing use of genetic resources acquired prior to the entry into force of the Protocol can be attached with new legal consequences applicable also after that point of time in domestic legislation.

3.2.2 Retroactivity in international law

To assess whether a rule in the Protocol has retroactive effects that are not legal is a question of international law. The Vienna Convention on the Law of Treaties (Vienna Convention) provides a clear interpretation of the concept of retroactivity. Article 28 of the *Vienna Convention* states the general principle: a treaty shall not be applied retroactively 'unless a different intention appears from the treaty or is otherwise established'– i.e., countries may choose to give a treaty such effect. Article 28 further provides that 'absent a contrary intention, a treaty cannot apply to acts or facts which took place, or situations which ceased to exist, before the date of its entry into force.' This article covers not only any 'act', but also any 'fact' or 'situation which ceased to exist'. It follows logically that Article 28 also necessarily implies that, absent a contrary intention, treaty obligations *do* apply to any 'situation' which has not ceased to exist – that is, to any situation that arose in the past, but continues to exist under the new treaty.

The principle of non-retroactive application of treaties has been referred to by Panels and Appellate body to solve some pertinent issues regarding the effect of the entry into force of the WTO agreement. In those cases, the retroactivity was accepted.[8]

3.2.3 Does the draft Protocol suggest any elements of retroactivity?

As stated above, the CBD has been a binding convention since 1993, so states have been obliged to impose benefit-sharing measures for almost 18 years now. The question regarding retroactivity for the Protocol is whether it introduces new rules or provides clarification of existing obligations. This assessment needs to be done for each draft article in comparison with the CBD.

4 Exemptions from the scope of the Protocol

Another core area of divergence in the negotiations pertains to the geographical scope and limitations as to which types of genetic resources should be excluded from the Protocol. The list of exemptions in the current draft Protocol reads as follows:

> [This Protocol does not apply to:
>
> a) human genetic resources;
>
> b) resources beyond national jurisdictions;
>
> c) genetic resources under the Multilateral System of the International Treaty on Plant Genetic Resources for Food and Agriculture, both current and as may be amended by the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture;
>
> d) genetic resources when utilized solely as a commodity;
>
> e) genetic resources and traditional knowledge associated with genetic resources acquired prior to the entry into force of the Protocol;
>
> f) human pathogens;
>
> g) Antarctic Treaty.]
>
> [This Protocol does not apply to genetic resources beyond the limits of national jurisdiction or to those located in the Antarctic Treaty Area, which is the area south of latitude 60 South.]

4.1 Long list of exemptions: Problems of evidence and legal certainty

The CBD itself, including its definition of 'genetic resources', takes a comprehensive perspective in its unqualified reference to 'biological origin'. The establishment of a list of sectoral-based exemptions, geographical exemptions or temporal limitations indicates a shift from the comprehensive perspective of the CBD. Exemptions create a need for assessing whether one genetic resource is inside or outside the ABS regime, which is not an exercise that is foreseen by the Convention. This introduces a level of legal uncertainty.

The manner in which the exemptions are worded also adds to legal uncertainty. To make a functional system, each exemption or exclusion needs to be clear in and out of itself. A functional system requires the inclusion of clear procedures or criteria upon which users can rely on to prove that they are indeed operating legally outside the ABS system. To become more certain they need to be expressed more clearly and in detail. Unclear language often leads to difficult issues concerning evidence. If such clarity is not provided by the Protocol, it might eventually lead to the creation of 'loopholes' in the system.

Additionally, a general list of exemptions would create a shift towards placing the burden of proof on the provider country to demonstrate that the acquired resources do fall within the scope of applicability of the Protocol. The onus would thus be removed from the user to prove that he has acquired resources outside of the system. Such a shift in ABS would introduce a major difficulty in terms of functionality, as it is less difficult to prove that the resources have been legally acquired outside the system than it is to establish that those resources that have been taken fall within the scope of the system. One potential measure to avoid such difficulty could perhaps be to include a general obligation upon the users of genetic resources to prove that they are operating legally outside the system.

4.2 A look at some of the suggested exemptions

The suggested exemptions are of rather different character, since some refer to geographical origin, others to biological species, and yet others hinge on the temporal utilisation of genetic resources and traditional knowledge.

4.2.1 Human genetic resources

The first suggested exemption refers to human genetic material. The topic 'human genetic resources' has not been a prominent issue in the ABS deliberations.[9] Although, formally speaking, humans form a part of the animal kingdom in biology, it is a political issue whether access to and benefit sharing from commercial and other utilisation of human genetic resources shall be excluded from the Protocol. It is worth noting that a human gene is patentable subject-matter in most patent systems of the world. It is suggested that the rationale for this exemption needs to be further clarified.

4.2.2 Geographical origin

There are suggestions for two geographical exemptions: beyond national jurisdiction, and south of 60 degrees (a reference to the Antarctic area).[10] The way the draft Protocol is worded suggests that these genetic resources should be excluded from the scope of the Protocol. However, that would introduce a level of legal uncertainty into it, as users could claim that they are validly using genetic resources acquired within these areas, and thus operating legally outside the scope of the Protocol. Another option could be not to exclude these resources from the Protocol, but to specify that a user would be deemed to meet the requirements of the Protocol, if he can validly prove that he is using resources found in these areas.

4.2.3 The International Treaty on Plant Genetic Resources (ITPGRFA)

Excluding plant genetic resources covered by the Multilateral System when used for food and agricultural purposes resolves the relationship between the only sectoral ABS system and the Protocol. However, specifying an exception for the ITFGRFA might create several uncertainties.

One major practical uncertainty is that not all parties to the CBD are parties to the ITPGRFA. A general exemption of a large number of plant genetic resources, on the sole basis that they fall under the ambit of another treaty, could potentially create loopholes. If the Protocol specifies that the entire list of plant genetic resources (or of Annex I crops) fall outside the scope of the Protocol, that might leave many genetic resources of non-parties to the ITPGRF entirely outside the coverage of either instrument. Countries not party to the IT might have an interest in the Protocol being applied to these specific resources so that they are not left unregulated.

4.4.4 Utilisation of genetic resources as commodity

The rationale behind this exception is clear enough: ABS shall not apply to the sales of biological resources as such across boarders, e.g. the Protocol is not intended to regulate the sales of, say, bananas for consumption as food. The problem essentially pertains to how this point is formulated (including the lack of a precise legal meaning of 'commodity') in that it does not provide legal clarity into the system. There are no external verifiable factors that can be used as evidence before a court of law. This challenge can however be solved more smoothly through the definition of 'utilisation of genetic resources', as discussed in greater detail in section 7 below. To add further clarity, it might be fruitful to define clear uses as commodities that would fall outside the scope of ABS. This would also add clarity to the more detailed and specific /nuanced understanding of utilisation of genetic, by indicating what falls outside this concept of law. The potential impact of this clause demonstrates the strong package-interlinkage among many of the most difficult issues under negotiation in the Protocol.

5 Pathogens – emergency situations

5.1 Pathogens in CBD rationale and regulation

A core of the deliberations in Montreal pertained to the issue of pathogens. In Article 3 of the draft Protocol, it is suggested that '[This Protocol does not apply to: [...] f) human pathogens'. In Article 6.2, a special regulation of pathogens is suggested:

> In the development and implementation of their national legislation on access and benefit-sharing, Parties shall:
>
> (b) [Pay due regard to **emergency situations** including serious threats to public health, food security or biological diversity, according to national legislation.][Provide **immediate access** to [**pathogens**][genetic resources] falling also under the scope of relevant international organizations and conventions, such as the World Health Organization, the International Plant Protection Convention, or the World Animal Health Organization, and which are of particular public concern for the health of humans, animals or plants, in ways and for uses provided for in existing and future rules, procedures or practices on the sharing of pathogens and related benefits established under those international organizations and conventions[, taking into consideration [the legal, structural and/or administrative obstacles to the optimal implementation of] the World Trade Organization paragraph 6 system]];[11]

A first observation is that there are two different situations reflected in the draft Protocol: either to completely exclude all *human pathogens* or to establish a special system for access to pathogens where their utilisation raises 'particularly public concern for the health of humans, animals or plants'. This is another exclusion whose impact will increase uncertainty unless the meaning of the term 'pathogens' is defined or explained in the Protocol. The development of a clearly agreed definition or understanding of this concept is crucial for anyone seeking to understand the implications of the draft.

One way of defining pathogen is as follows:

> *An agent of disease. A disease producer. The term pathogen most commonly is used to refer to infectious organisms. These include bacteria (such as staph), viruses (such as HIV), and fungi (such as yeast). Less commonly, pathogen refers to a noninfectious agent of disease such as a chemical.*[12]

The two suggestions relating to pathogens – of exempting all human pathogens, and of creating a system of 'immediate and expeditious access' to a broader range of pathogens (also those being hostile to plants and animals) – are overlapping, but not identical.

It bears first noting that the term 'pathogen' may also be used to mean 'a noninfectious agent of disease such as a chemical.' A point that has often been considered in ABS discussions is whether 'biochemicals' should be included within the term 'genetic resources'. Thus, it may be necessary to consider whether the exclusion of pathogens from the Protocol would also mean that some or all biochemicals would be excluded.

The use of pathogens in an emergency situation often leads to one specific medicine or vaccine being developed for that particular pathogen, which would almost always be patented. In fact, countries members to the World Trade Organization are obliged, pursuant to Article 27 of the TRIPS Agreement, to grant patents to micro-organisms, which would in many jurisdictions imply that DNA or RNA as well as the pathogen as such are eligible for patent protection. The TRIPS Agreement does not provide for any exemptions for patentability for medicines or vaccines. A country which grants 'immediate access', according to the draft Protocol, would be bound to grant a patent to the same organism or its DNA/ RNA, including to the company that received the pathogen by this means.

If a medicine or a vaccine is patented, everyone has to pay the monopoly price required by the company. This includes the country which provided the pathogen to the pharmaceutical company based on the emergency situation. There is no legal basis for an emergency-price for such vaccines or medicines. Compulsory licensing (as prescribed in TRIPS Agreement Article 31)[13] could perhaps have been a relevant measure. Compulsory licenses authorise, in certain cases, the use of the patented invention to a third party either by a competent court or by a Patent Office (depending on the law of the country). As provided under the Paris Convention on the Protection of Industrial Property (Article 5)[14] and the TRIPS Agreement (Article 31)[15], the regime of compulsory licensing provides a system that might prevent the abuses linked to the exclusive rights conferred by a patent. Compulsory licensing is, however, not a speedy process, as it must be granted by a court subject to strict criteria. The TRIPS Agreement also requires that compensation be paid to the patent holder. Therefore, compulsory licensing is not an adequate measure to grant speedy access to medicines or vaccines in an emergency situation.

The WTO, cognizant of these challenges, adopted paragraph 6 of the Doha Declaration.[16] This mechanism was designed as an expeditious solution to the problems faced by countries with little or no pharmaceutical manufacturing capacity in using compulsory licensing under the TRIPS as a means of getting access to needed drugs. To date, this mechanism has been used by only one country, and its overall implementation remains very low.

One could argue that access to pathogen, whether for emergency situations or not, is in essence a typical ABS situation. There is a direct connection between the pathogen and the particular invention, such as medicine or vaccine, derived thereof. This leaves the pathogen-medicine situation as a typical easily proven ABS situation. The wording of the CBD defines genetic material as '... any material of plant, animal, microbial or other origin containing functional units of heredity.' There is nothing in this wording that could suggest that pathogens fall outside the scope of the CBD or ABS.

Pathogens mutate and will thus appear in new forms in the future. Therefore, they will continuously represent an interesting and valuable genetic resource for the pharmaceutical sector, and thus also a potentially valuable resource for provider countries through benefit sharing. A country

providing a pathogen will often be affected by the disease caused by that particular pathogen. Hence, that providing country may have the most compelling need to access to the products derived from the pathogens that it has provided.

5.2 WHO and on-going work on pathogens[17]

The draft Protocol refers to the '...World Health Organization, the International Plant Protection Convention, or the World Animal Health Organization' as organisations with a specific interest in this topic. In particular the World Health Organisation (WHO) has established an International Health Regulations (IHR) from 2005.[18] To date, however, there have been no clear duties for countries to exchange virus samples, and opinion differs as to the extent to which duties can be inferred from the IHR in this respect.[19]

The WHO, through its Global Influenza Surveillance Network (GISN), is currently engaging in targeted work relating to the spread of influenza viruses. The GISN has operated in basically the same way for the past 50 years, with samples of new influenza viruses being analysed annually by WHO-collaborating laboratories before a WHO committee determines which strains are most likely to affect humans in the coming months. Manufacturers then start making vaccines against these strains. Most of the 250–300 million doses of vaccine made each year are used to vaccinate people in developed countries, even though the new influenza viruses often originate in developing countries.[20]

Many other types of work are being undertaken by bodies in the WHO involving the exchange of pathogens.[21] In May 2009, the World Health Assembly (WHA) requested the Director-General to facilitate a transparent process to finalise the remaining parts of the Influenza Framework, including the elaboration of a standard material transfer agreement for access to these specific resources.[22] In May 2010, an open-ended working group was convened to examine access to influenza viruses.[23]

The draft Protocol could include flexibility if the WHO arrives at a system to which its member countries could subscribe. One suggestion here is that the WHO and the ABS Protocol could collaborate on the development and approval of a 'Joint Standard Material Transfer Agreement' which could meet the requirements of both rapid access and a fair and equitable benefit-sharing arrangement. Whether the WHO is better suited for negotiating a standard PIC/MAT system for pathogens remains an open question, however. It is after all in the interest of all the countries in the world of having a well-functioning system for sharing of pathogens as well as the vaccines or medicines developed from them.

6 Non-commercial research

There are three suggestions in the draft Protocol (Articles 5 (2) (a *bis*) and 5 (2)(c *bis*) and Article 6(a)) addressing the issue of special access requirements for particular purposes, as follows:

> 5 (a *bis)* Parties shall avoid application of discriminatory rules in processing access permits except where such rules aim at advancing local, non-commercial biodiversity and ecosystem research and education;

The meaning of this article is unclear.

> 5((c *bis)* Provide a simplified procedure for access to genetic resources for non-commercial use in research and in accordance with national law:)

This wording suggests a 'simplified access procedure'; however, the Protocol does not clarify what would constitute a 'normal access procedure'. Without knowing this, it may make it difficult to reach consensus about whether it is possible/advisable to require an even simpler process for non-commercial researchers seeking to obtain access.

> Article 6
>
> [CONSIDERATIONS RELEVANT TO [non-commercial] RESEARCH AND EMERGENCY SITUATIONS
>
> In the development and implementation of their national legislation on access and benefit-sharing, Parties shall:
>
> (a) Create conditions [, including simplified measures on access for non-commercial research purpose,] to [facilitate,] promote and encourage [non-commercial] biodiversity-related research, considering its importance for the conservation of biological diversity and the sustainable use of its components, taking into account Article 12(b) of the CBD…))

The rationale behind simplified access for research purposes is based upon the idea of not obstructing academic research with burdensome access procedures. The draft is based on the perception that there is a clear division between commercially and non-commercially motivated research – whereas it is well known that non-commercial research can often lead to discoveries of substances and knowledge with commercial potential. Furthermore, the intent and ambitions of the original researcher may change from publication to patenting and licensing; or a private company may use the research publication and specimens as a starting point for commercialisation. This means that it is not often easy to draw clear boundaries between commercial and non-commercial research.

The tendency among those who advocate for the special needs of the non-commercial research sector is to often put emphasis on simplified access for non-commercial use, without considering the need to couple such simplified access with enforceable benefit-sharing obligations. That approach does not always capture the inherent complexity of the question, particularly since the line between commercial and non-commercial research is not always clear, with the latter often leading to the development of commercially viable and interesting products.

The difficult technical issue is how to establish simplified access regulations for non-commercial research purposes, while taking into account situations where such research would subsequently lead to the creation of economic or other types of commercial benefits. This is a problem not easily solved at the *point of time of access*. Again a clear understanding of the concept of utilisation might provide a solution. A researcher, who knows exactly what actions or types of utilisation are governed by non-commercial research provisions, can then easily take appropriate measures to ensure that he is compliant. This has the potential of introducing a higher degree of legal certainty. If such is not the case, the researcher might just as well get genetic material without any ABS requirements and do whatever he wants under the veil that the material was legally obtained for non-commercial research purposes.

If user-country measures could be designed so as to ensure fair and equitable sharing of the economic benefits arising out of non-commercial research, and ensuring that the rights and interests of the provider are protected, such measures might then constitute good justification for accepting easy access to genetic resources for academic purposes.

7 Utilisation – a key to ABS functionality

It is argued in this paper that many of the technical difficult issues in the negotiations can be potentially solved if there were a clear understanding of the concept of 'utilisation'.

7.1 Utilisation as the trigger-point for benefit sharing obligations

The concept of utilisation as contained in Articles 1 and 15.7 of the CBD can easily be seen to be the basis for a functional ABS system.[24] However, this concept did not receive much attention until halfway through the first decade after 2000, even though parties to the CBD are obliged to 'take legislative, administrative or policy measures as appropriate, [...] with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization'.

Basically, this wording suggests that the point of utilisation of genetic resources could be an important trigger-point, indicating the time at which a benefit-sharing obligation becomes actionable. If it is used and interpreted in this way, the utilisation concept could contribute to increasing legal certainty in ABS situations, both under the Protocol and under Article 15.7.[25] Moreover, it could play a major role in the development of an enforceable ABS system.[26] To have this impact, the Protocol must be clearer regarding when the user will be legally obliged to share benefits – especially, it should clarify the types of activity that constitute 'utilisation' of genetic resources, and thus trigger the benefit-sharing obligation.[27]

In the deliberations in Montreal, a small group proposed language on 'utilisation of genetic resources', which reads as follows:

> *Utilisation of genetic resources* includes/means the conduct of research and development, on the genetic and biochemical makeup/composition of genetic material/biological resources, including through the application of biotechnology as defined in Article 2 of the CBD, as well as subsequent application and commercialization.

This language captures core aspects of the rapidly evolving techniques used on genetic resources that lead to the creation of benefits. It also recognises that the uses of genetic resources will vary with the advances in knowledge and technology.

The utilisation approach could provide legal certainty to the extent that it provides concrete indicators that enable a clear test for determining whether a particular activity is governed by the ABS Protocol (and/or Article 15), and when it triggers the obligation to share benefits. Enforcement of a legal obligation is most effective when the specific prerequisites of that obligation can be empirically or externally determined. In the context of ABS, that would necessitate defining or concretely describing

the activities and end-points that constitute utilisation of genetic resources.

In addition to this wording in the operative text of the draft Protocol, it is suggested to include an annex listing types of utilisation to be included. This list is quite short and is worded as follows:

- Annex II

- LIST OF TYPICAL USES OF GENETIC RESOURCES

This list may include, but is not limited to:

(a) Modification;
(b) Biosynthesis;
(c) Breeding and selection;
(d) Propagation and cultivation;
(e) Conservation;
(f) Characterization and evaluation; or
(g) Any biotechnological application involving genetic resources in activities of research not aiming at commercialization, research and development aiming at commercialization, and commercialization.

This list is generally based on a list generated by the Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches (GLTE), which came up with a detailed list of activities that constitute typical uses of genetic resources.[28] The list proposed in Annex II to the Protocol uses the same categories of utilisation that were identified by this Group as relevant ways of characterising the utilisation of genetic resources. Although the list in draft Annex II was not meant to be exhaustive, it could provide a useful basis upon which to base a functional description of utilisation, which could be given effect in national laws. So as not to lose the dynamic character of the definition, such a list should, when and where appropriate, be revised and updated by the COP when acting as the Meeting of the Protocol. To have such a review system in place, the Protocol probably needs to set out the procedures for such a revision.

For the benefit-sharing obligation to become legally binding upon users, and thus provide incentives for getting an access contract, the obligation to share benefits should be developed so as to ensure that it will be binding under the jurisdiction of the home country. There exists no single formula for ensuring this, however, some provisions can be included in the Protocol that might help.

7.2 Making ‘genetic resources’ a functional legal term

The main concept in CBD Article 15 as to ‘genetic resources’ is inherently difficult to determine objectively at the time of access,[29] since this will depend upon the ‘intention’ of the exporter or those accessing biological material.[30] If the user intends to take an action that will constitute the utilisation of a genetic resource, then the material used will be a ‘genetic

resource'. Taking the biological material for any other purpose will fall outside the definition and thus outside of the Protocol. This concept could also be applied in a way that would solve the challenge mentioned above, regarding the proposal to distinguish ABS transactions from trade in commodities.[31]

Arguably, once utilised, the actual (and some of the potential) value of the genetic material will be realised, or at least made manifest. A detailed list of activities and outcomes that constitute utilisation would provide *externally verifiable* points of time and incidents/actions that trigger benefit-sharing obligations. That would obviate the need to determine the user's or collector's intention at the point of access. At the time of access, the 'utilisation value' of a specific genetic resource is uncertain, whereas after its utilisation this value becomes manifest. A clear understanding of utilisation would also lead to more readily discernable and verifiable triggers for benefit-sharing obligations.

A clearer understanding of the utilisation of genetic resources will also contribute to solution of the current challenges of defining derivatives and specifying when their use is governed by ABS. This 'derivative challenge' generally appears to arise out of the focus on access. Typically, at the point of access, no one really knows what might result from the user's efforts. The term 'derivative' is currently used in many different ways and is attributed several varying definitions. It need not be defined at all, however, if the Protocol can include an agreed understanding of the concept of utilisation of genetic resources. If it does, then the definition of utilisation could potentially cover all the main elements that are usually thought to be included in the concept of derivatives.

Agreement on a definition of utilisation could also make it easier to define and integrate specific activities and criteria governing non-commercial academic research into the Protocol (see section 6 above). If utilisation is applied as a trigger-point for benefit-sharing obligations, it could be specified that typical non-commercial academic activities shall not trigger any monetary benefit-sharing obligation, unless/until the actual utilisation of genetic resources results in monetary benefits. Thus, a clear definition and enforceable understanding of utilisation of genetic resources could make it easier to specify different access procedures for non-commercial research.

7.3 Mutually agreed terms: Linking access to utilisation

A definition of 'utilisation' alone would not resolve the challenges related to making ABS functional. It will also be essential to link utilisation back to access and access legislation in the providing country. The general obligations linked to utilisation needs to be considered met/complied with in the cases where the user of genetic resources can provide documentation that he has followed the access requirements of a provider country.

CBD Article 15 prescribes *mutually agreed terms* in two different contexts: the first one follows from 15.4 and describes the MAT at the point of time of access; whereas the latter follows from the second sentence in Article 15.7 referring to the MAT for benefit-sharing. Despite them being

references to the same contractual mechanism, they refer to different situations or points of time. The MAT in 15.4 will be agreed upon prior to access, whereas the MAT referred to in 15.7 refers to the terms and conditions governing the sharing of benefits when benefits are arising and are due to be shared. If a MAT (15.4) is agreed upon at the time of access, the utilisation obligations can be considered fulfilled. In the case where no MAT was obtained at the point of time of access, the user will need to go back to the providing country to get a MAT (15.7) resolving how benefit sharing shall be shared.

7.4 Proving compliance

Not all genetic resources will be governed under a functional ABS system. Therefore, a user needs to be given the chance of proving that a given genetic resources has been acquired legally outside the system (subject either to exception from ABS or to the discretion of a providing country leaving its genetic resources ungoverned or open for the free access of all). The user country would need to establish procedures for verifying that a user has obtained the relevant genetic resources legally and outside the ABS system.[32]

8 Compliance

The Protocol needs to solve the difficult political as well as technical legal question of cross-border utilisation, benefit-sharing and enforcement of PIC and MAT under another jurisdiction. User measures could greatly assist in the enforcement of cross-border disputes related to the utilisation of genetic resources.

Compliance with ABS happens on two levels. Countries need to comply with the obligations in Article 15 of the CBD and the Protocol; and private parties actually creating benefits from the utilisation of genetic resources need to comply with the provider country's legislation and the requirements set by user countries.

Compliance mechanisms largely fall into one of two main categories: substantive measures and procedural issues, both need clarification under the jurisdiction of the user country to provide legal certainty and enforceability.[33] Enforcing ABS is a fundamental challenge. One major reason is that the laws of the providing country are not automatically applicable under the jurisdiction of the user country's jurisdiction. Therefore, draft Articles 12 and 14, dealing with enforcement, are of crucial interest.

One measure that has been on the table for quite some time and that has been suggested by some as a way of making ABS functional, is the proposal for 'disclosure requirements in patent applications'. Several studies have concluded that a stand-alone disclosure requirement in patent application could not alone solve the benefit-sharing challenge, however, in the eyes of many it can be a useful supplementary tool as regards compliance.[34] Article 13 and 13*bis* of the draft Protocol address, *inter alia*, the issue of a disclosure requirement. Deliberations on these articles have mainly focused on the nature of the requirements, whether they should be mandatory or voluntary, but not on functionality as part of enforcing an ABS system.

One question is where to deal with a disclosure requirement. In 1998 it was proposed in the Standing Committee on Law of the Patents in the WIPO, but was never added to the agenda. In 2001, the WIPO General Assembly established the Intergovernmental Commission on Genetic Resources, Traditional Knowledge and Folklore (IGC) to consider this and other related matters. As of today, no concrete proposal on this issue is on the table in the IGC. The proposals relating to a patent disclosure requirement have been suggested in the WTO and WIPO, such as the PCT, where they have encountered a lack of political consensus. This suggests that the CBD may be the most appropriate place to discuss and implement a substantive disclosure requirement, whether or not it is limited to patent applications. (In fact, as some CBD member states have already shown in their national legislation, such a disclosure could be formulated in a more comprehensive manner.)

9 Relationship with other international instruments

9.1 Restating a general principle

The first paragraph in draft Article 3*bis* includes a well-known formulation from other international agreements. Together these two elements include a balance between the Protocol and other legally binding parts of international law.

ARTICLE 3 *BIS*

> [1. The provisions of this Protocol shall not affect the rights and obligations of any Contracting Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biodiversity.
>
> This paragraph is not intended to subordinate the Protocol to other international instruments.]

According to Article 30 of the Vienna Convention, in the event of incompatibility between two successive agreements relating to the same subject matter, the requirements of the later agreement shall prevail. The Vienna Convention further stipulates that where the more recent treaty includes only some of the parties to the earlier treaty, this later treaty is to prevail only with respect to those who are party to both agreements. Draft Article 3 *bis* 1 seems to go in the opposite direction, as it somehow appears to suggest that the earlier instruments would prevail over the Protocol. Some further clarification might be needed to ensure that this draft article is implementable. It was also suggested in the negotiations that the last sentence in this article be removed from the draft Protocol. This would take out its balance, as leaving only the first paragraph could potentially have the effect of subordinating the Protocol to previous legal instruments.

9.2 Linking the Protocol to two moving targets

- ARTICLE 3 *BIS*

> 3. This Protocol and other international instruments relevant to this Protocol shall be implemented in a mutually supportive manner, [[without prejudice to][bearing in mind] ongoing work or practices under relevant international organizations and conventions.]

Article 3*bis*, paragraph 3 draws on a concept familiar in international law – that each country should implement the international instruments to which it has agreed 'in a mutually supportive manner'. The suggested text, however, fails to clarify which instruments, work and practices the protocol shall mutually support. In particular, the text takes a major step away from legal certainty and from recognised international legal practice when it moves from referring to binding instruments in international law, and focuses on 'ongoing work or practices'

In international law, 'ongoing work' has no status as a source of law according to the Statues of the ICJ Art. 38. Often, in fact, where something in an international forum is described as 'ongoing', this terminology

indicates a continuing lack of consensus on the matter. To link the implementation of the ABS Protocol to such non-binding unwritten, unrecognised and sometimes even unpublished elements would ultimately increase the legal uncertainty of the ABS system. Such a provision would essentially link implementation of the Protocol to one or more moving targets, in the form of the ever evolving 'ongoing work and practices' of various international bodies and instruments.

The reference to 'practices' has no corresponding equivalent in general public international law. 'General practice recognised as law' is one of the sources of international law according to Article 38 of the Statues of the ICJ, thereby recognising *customary international law* as a general source of law. Customary international law develops through the cumulative and accepted practices of states in accordance with what is deemed or perceived to be a legal obligation (*opinio juris*). This is more specific and much narrower than the broad and unspecified term 'practices'. The unqualified, non-specific reference to practices would mean subordinating the Protocol to an undefined body of practice. It would also introduce a considerable degree of legal uncertainty and unpredictability into the Protocol.

10 Concluding remarks

A functional ABS system holds great potential for both the providers and users of genetic resources and could contribute to the conservation of biological diversity. If all the exceptions, which are currently still in brackets, become part of the Protocol, then its area of application will be very limited indeed. This would reduce whatever potential the draft Protocol might have for enabling the establishment of a functional ABS system.

If users of genetic resources are to be expected to enter into PIC and MAT and share equitably the benefits arising from their utilisation of genetic resources, then the ABS Protocol must create some incentives or other motivations for them to do so. Such incentives could be achieved by 'sticks or carrots' – that is, ABS could either establish sanctions to be applied if benefits are not shared, or through positive consequences for users who meet their benefit-sharing obligations. As it now stands, the draft Protocol contains few elements that clearly serve to create incentives for private or public users to enter into ABS contracts and share benefits that may be created thereof.

Notes

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http://www.fni.no/projects/abs_capacity_development_africa.html

[2] Morten Walløe Tvedt, Senior research fellow, Fridtjof Nansen Institute. Tvedt has published extensively in the area of biological resources law and intellectual property in recent years (see www.fni.no for a complete list of publications). The most important monograph regarding genetic resources he co-authored with Tomme R. Young, *Beyond Access: Exploring Implementation of the Fair and Equitable Sharing Commitment in the CBD*. IUCN Environmental Policy and Law Paper No. 67/1 (available in English, Spanish and French, www.fni.no/ publ/biodiversity.html). Tvedt is currently working on a monograph on patent law and the *sui generis* option in the plant sector for developing countries. He may be contacted at: mwt@fni.no or by post to Fridtjof Nansen Institute, P.O.Box 326, 1326 Lysaker, Norway.

[3] Olivier Rukundo, Legal Research Fellow, Centre for International Sustainable Development Law (CISDL). He has worked with the CISDL for the past five years as a legal scholar and researcher with its biodiversity and international trade programmes. Rukundo also acts as legal consultant for the ABS Capacity Development Initiative for Africa.

[4] Sections 4.2 and 4.3 in M.W. Tvedt and T.R. Young 2007, *Beyond Access: Exploring Implementation of the Fair and Equitable Sharing Commitment in the CBD*. Gland: IUCN.

[5] Incentives could basically be achieved either by 'sticks' or 'carrots': ABS could either establish sanctions if benefits are not shared, or it could establish positive consequences for those meeting the obligation. Tvedt and Young 2007, section 2.7.4.

[6] Draft Protocol Article 28.2 reads as follows: 'This Protocol shall enter into force for a State or regional economic integration organization that ratifies, accepts or approves this Protocol or accedes thereto after its entry into force pursuant to paragraph 1, on the ninetieth day after the date on which that State or regional economic integration organization deposits its instrument of ratification, acceptance, approval or accession.'

[7] The CBD entered into force on 29 December 1993, after having been signed in May 1992, which means 18 months from signing to entry into force.

[8] In EC-hormone the Appellate Body examined whether the Sanitary and Phytosanitary Measures (SPS Agreement) should apply to European Communities directives that were enacted before the entry into force of the WTO Agreement on 1 January 1995. The Appellate Body concluded that the SPS agreement should apply to these measures as such measures continued to exist after that date and that the SPS Agreement does not indicate any intention to limits its application to measures enacted after the entry into force of the WTO Agreement. In Canada – Patent Term, the Appellate Body stated that Article 70.1 of the TRIPS Agreement excludes obligations in respect of 'acts which occurred' before the date of the application of the TRIPS Agreement but does not exclude rights and obligations in respect of continuing situations.

[9] The topic is mentioned in COP 2 Decision II/11: 'Reaffirms that human genetic resources are not included within the framework of the Convention'.

[10] See also FNI Report 3/2010 'International Agreements and Processes Affecting an International Regime on Access and Benefit Sharing under the Convention on Biological Diversity Implications for its Scope and Possibilities of a Sectoral Approach', sections 3 and 4.

[11] Emphasis added here.

[12] From ICC (2009): 'Pathogens and the International Regime on Access and Benefit-Sharing', Document No. 450/1051 – 11 September 2009: http://www.iccwbo.org/policy/ip/index.html?id=2480, footnote 1; original source: http://www.medterms.com/scritp/main/art.asp?articlekey=6383 .

[13] TRIPS Agreement Article 31 Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(a) authorization of such use shall be considered on its individual merits;

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-

commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;
(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;
(d) such use shall be non-exclusive;
(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;
(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;
(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;
(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;
(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;
(l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:
(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;
(ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and
(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

[14] Full text of the Convention at:
http://www.wipo.int/treaties/en/ip/paris/trtdocs_wo020.html

[15] Full text of the Agreement at:
http://www.wto.org/english/tratop_e/trips_e/trips_e.htm

[16] Decision of the General Council of 30 August 2003, see
http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm

[17] This section is based on FNI Report 3/2010 section 5, written by O.K. Fauchald and T. Winge.

[18] International Health Regulations (IHR) 2005:
http://whqlibdoc.who.int/publications/2008/9789241580410_eng.pdf, in particular Article 6 (requiring countries to report certain disease outbreaks and

public health events to the WHO) and 7 (share information concerning the events).

[19] For a look at the different rationalities, see FNI Report 3/2010, with further references. This is linked to a public health emergency of international concern (PHEIC) and the World Health Assembly (WHA) resolution 59.2, paragraph 4[4], see http://apps.who.int/gb/ebwha/pdf_files/WHA59-REC1/e/Resolutions-en.pdf. See also Fidler 2008.

[20] Laurie Garrett and David P. Fidler (2007): 'Sharing H5N1 viruses to stop a global influenza pandemic', *PLoS Medicine,* 4 (11): 330

[21] Resolution WHA60.28:
http://apps.who.int/gb/ebwha/pdf_files/WHA60/A60_R28-en.pdf

[22] WHO (2009): 'Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits – Outcome of the process to finalize remaining elements under the pandemic influenza preparedness framework for the sharing of influenza viruses and access to vaccines and other benefits', report from the Secretariat. Executive Board, 126th Session, Provisional agenda item 4.2, EB126/4, 10 December 2009

[23] Third World Network (2010): 'WHO: Virus-benefit sharing working group set up, pandemic flu response to be reviewed', TWN Info Service on Health Issues, 27 January 2010:
http://www.twnside.org.sg/title2/health.info/2010/health20100103.htm

[24] The reasons for developing the concept of utilisation of genetic resources further are expanded on by Tvedt and Young 2007, pp. 58–60 and 65–68; and in Young and Tvedt 2009, 'Balancing building blocks of a functional ABS System', section 4.1.2. The topic has also been touched on in several submissions to the Ad Hoc Working Group.

[25] See Young and Tvedt, 2009*,* sections 1.2 and 2, for a more comprehensive discussion of legal certainties in ABS.

[26] For a discussion of enforcement of ABS, see Young and Tvedt 2009*,* sections 6 and 7.

[27] For a detailed analysis of trigger-points and ABS, see Tvedt and Young 2007, chapter 4.

[28] UNEP/CBD/WG-ABS/7/2'Report of the meeting of the group of legal and technical experts on concepts, terms, working definitions and sectoral approaches'.

[29] The difficulties of defining and enforcing the concept of 'genetic resources' is described elsewhere; see Schei and Tvedt 2010, 'Genetic Resources' in the CBD: The Wording, the Past, the Present and the Future; Tvedt and Young 2007, section 4.1 and 4.2 and Young and Tvedt 2009, section 4.1. Cabrera Medaglia, J. and C. López Silva. 2007. Addressing the Problems of Access: Protecting Sources, While Giving Users Certainty. IUCN Environmental Policy and Law Paper No. 67, The ABS Series, Book 1. See also the 'Report of the meeting of the group of legal and technical experts on concepts, terms, working definitions and sectoral approaches', 2–8 April 2009,UNEP/CBD/WG-ABS/7/2.

[30] The central definition problem ('genetic resources') is perceived very differently at each of the key moments of ABS – at access; at utilisation of genetic resources; and at the point that benefits arise from that utilisation. At the point of access, the difference between 'genetic resources' (governed by the ABS regime) and 'biological resources' (outside the ABS regime) appears to rely on the intention of the person obtaining and/or removing the resource. To make this deter-

mination one must either accept the word of that person, or possess the supernatural ability to predict and prove the intended future use of the material.

[31] Therefore, this would eliminate the need for the wording in Article 3(d) in the Draft Protocol.

[32] Tvedt and Young 2007, section 4.4.

[33] For a study of a hypothetical ABS case enforced in one user country, see Young and Tvedt 2009, section 6.3.

[34] A.L. Hoare and R.G. Tarasofsky 2007, 'Asking and telling: can "disclosure of origin' requirements in patent applications make a difference?', *Journal of World Intellectual Property*, 10 (2): 149–69; M.W. Tvedt, 2006, 'Elements for legislation in user countries to meet the fair and equitable benefit-sharing commitment', *Journal of World Intellectual Property,* 9 (2), pp. 189-212.

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FRIDTJOF NANSENS INSTITUTT
FRIDTJOF NANSEN INSTITUTE

Fridtjof Nansens vei 17, P.O. Box 326, NO-1326 Lysaker, Norway

Phone: (47) 67 11 19 00 – Fax: (47) 67 11 19 10 – E-mail: post@fni.no

Website: www.fni.no