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Implementing the Nagoya Protocol on ABS: A Hypothetical Case Study on Enforcing Benefit Sharing in Norway

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Abstract: In October 2010, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising From Their Utilization (NP) was adopted at the Conference of the Parties (COP-10) of the Convention on Biological Diversity (CBD). The NP establishes rules on measures to be taken by user countries in the context of access and benefit sharing (ABS). The future success of ABS as embedded in CBD and the Nagoya Protocol depends on their implementation at a national level. The binding rules of CBD and NP have in common that they need to be transformed into national legal and political contexts to establish a functional system for ABS. This article addresses measures that are needed in the international regime to secure adoption and implementation of user-country measures which are compatible with provider-country legislation. It analyses one current example of user-country legislation: the recently adopted Norwegian legislation, for the purpose of finding options for and obstacles to implementing obligations in the CBD and the NP in national law and in actual practice. One part of the ABS challenge is that obligations in the CBD and the NP apply to states, whereas the actual users of genetic resources are mostly private or public enterprises: companies, universities or other institutions. Despite showing a promising start, far from all challenges of a functional ABS system are solved.

Keywords: implementation of ABS; Nagoya Protocol; Norway; Nature Diversity Act; user-country legislation

In October 2010, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising From Their Utilization (NP) was adopted at the Conference of the Parties (COP-10) of the Convention on Biological Diversity (CBD). The NP establishes rules on measures to be taken by user countries in the context of access and benefit sharing (ABS). There is a need to discuss good practice and implementation of the Protocol. For countries parties to the CBD but not yet parties to the Protocol, it is crucial to discuss how the obligation to ensure that users of genetic resources share benefits arising from their use of such resources can be implemented in national legislation. This article draws upon the experience from one of the few user countries to have implemented such legislation and seeks to identify elements which can form a part of national legislation implementing article 15.7 of the CBD seen in conjunction with, in particular, articles 5, 6, 7, 9, 15, 16, 17, 18 and 19 of the Nagoya Protocol. We assume that all countries that are parties to the CBD, being bound by its article 15, are

committed to fulfilling their ABS obligations. This article addresses measures that are needed in the international regime to secure adoption and implementation of user-country measures which are compatible with provider-country legislation.[1] For these purposes, we will analyse one current example of user-country legislation: the recently adopted Norwegian legislation. The intention here is to analyse options for and obstacles to implementing obligations in the CBD and the NP in national law and in actual practice. One part of the ABS challenge is that obligations in the CBD and the NP apply to states, whereas the actual users of genetic resources are mostly private or public enterprises: companies, universities or other institutions. Countries need to take measures to ensure that the actual users of genetic resources meet the ABS standards.[2]

Legal certainty and functionality were important objectives during the negotiations of the Nagoya Protocol. "Legal certainty" has been explained as the ability of each user, provider, national legislator, official, judge, arbitrator or other person to know, with a relatively high degree of certainty, whether the regime applies to a particular person or action, and, if so, what the regime will require (or probably require) in each instance.[3]

This contribution takes the ABS discussion to the ground level by considering how existing national user-measures would apply to a particular transaction. These discussions take the form of a "thought-experiment" (hypothetical case study) considering particular types of legal or administrative action and how they relate to measures adopted by provider countries.

Outline of User-Country Obligations in the Nagoya Protocol

The first step of our analysis is to identify the measures that the Nagoya Protocol requires user countries to take, in light of obligations under article 15 of the CBD (Tvedt and Young, 2007). A general observation is that both article 15.7 of the CBD and the NP offer a level of flexibility for countries when implementing ABS measures in their legislation. Our objective is not to provide a complete implementation study, but to present the provisions of the NP as a background for better understanding this case study: the implementation of user-country obligations in Norway.

One core element of the NP is that user countries undertake an obligation to take measures so that "benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable with the Party providing such resources ..." (NP art. 5.1). For this purpose "each Party shall take legislative, administrative or policy measures, as appropriate" (NP Art. 5.3). These provisions share common features with CBD Art. 15.7. According to article 6.2 of the NP, user countries undertake to ensure that access to genetic resources takes place in accordance with prior informed consent. This obligation is further elaborated in NP art. 15:

1. Each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures to provide that genetic resources utilized within its jurisdiction have been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the other Party.

2. Parties shall take appropriate, effective and proportionate measures to address situations of non-compliance with measures adopted in accordance with paragraph 1 above.

3. Parties shall, as far as possible and as appropriate, cooperate in cases of alleged violation of domestic access and benefit-sharing legislation or regulatory requirements referred to in paragraph 1 above.

Similar obligations are established in relation to access to traditional knowledge associated with genetic resources in articles 7 and 16 of the NP.

The wording of articles 15 and 16 emphasizes that user countries shall ensure that users have adhered to the legislation of provider countries and that user countries shall address situations of non-compliance. This means that "access" is essential for making ABS operational. During the negotiations there were considerable divergences regarding exactly when "access to genetic resources" happens. One fairly common opinion among user countries was that a genetic resource is accessed at the point in time when the biological sample is crossing a border; by contrast, provider countries often opined that access occurs when biological material is used for the purpose of taking advantage of its genetic material, independent of when and under which conditions the biological material actually crosses a border.[4] Between these views there is a gap in practical effects for the application of ABS. To establish a functional system for implementing the NP, countries will need to agree on when "access" happens.

One mechanism which can streamline ABS is NP art. 19.1, which encourages the "development, update and use of sectoral and cross-sectoral model contractual clauses". The development of such models will contribute to a higher degree of legal functionality of the ABS system.

Important from the perspective of technical enforcement is art. 18, which provides some general rules and standards regarding implementation and enforcement of mutually agreed terms (MAT). Mutually agreed terms is one of the core legal vehicles for governing ABS transactions across borders. User countries undertake to designate checkpoints and to share information through certificates of compliance, in order to monitor utilization of genetic resources and thus support compliance with the ABS obligations (art. 17).

According to article 10:

> Parties shall consider the need for and modalities of a global multilateral benefit sharing mechanism to address the fair and equitable sharing of benefits derived from the utilization of genetic resources and traditional knowledge associated with genetic resources that occur in *transboundary situations* or for which it *is not possible to grant or obtain* prior informed consent. [emphasis added]

This provision was brought onto the table at a very late stage of the negotiations and needs to be further developed in order to become operational. It could become an important tool to ensure effective benefit sharing. However, the obligations to share benefits with the global multilateral benefit sharing mechanism should be designed so that they do not undermine the incentives to enter into mutually agreed terms with the party providing access to the genetic resource.

This overview of the core user-country rules of the NP is not exhaustive, and each of the provisions gives rise to questions when implemented in national legislation. Despite attempts during negotiations to go into detail with regard to how a functional ABS system can be constructed (see Tvedt and Rukundo, 2010), the Working Group maintained the principle of sovereignty of countries to regulate access to genetic resources under their jurisdiction. The NP does not alter the basic understanding that ABS is based on a contract between the provider country and user of genetic resources, or an administrative decision of the provider country.

Recent Developments in Norwegian Legislation

Norway's Legislative Efforts to Meet Obligations under Article 15.7 of the CBD: The Norwegian Nature Diversity Act

Section 60 of the Norwegian Nature Diversity Act, which passed the Storting (the Parliament of Norway) on 19 June 2009, implemented a general rule concerning genetic material from other countries.[5] Together with the disclosure requirements in section 8b of the Patent Act[6] and section 4(3) of the Act relating to the Plant Breeder's Right,[7] section 60 of the Nature Diversity Act constitutes the ABS user-country measures of Norway. In the following we discuss these provisions and their potential application as well as implications for interpretation and implementation of user-country obligations under the NP.

The Nature Diversity Act specifically recognizes that the main entity responsible for regulating access and benefit sharing is the provider country. This is in line with the approach in NP art. 15. Although the government considered including a specific statement of the obligation to share benefits, it concluded that the Act did not need such a clause, leaving it to the provider countries to require benefit sharing.[8] The preparatory works explicitly state that "these measures [provided in the act] do not alone fully solve the challenge of meeting the obligation of fair and equitable benefit sharing,"[9] clearly recognize that the measures require support in other legal and political tools, and call on provider countries to provide the supplementary tools needed. The preparatory works also emphasize the need for controlling the right to use the material either at the time of use or at the time of commercialization rather than at the time of access, recognizing that a "utilization approach" is the most practical and enforceable option for an international regime.

Giving Binding Effect to the Consent Given by the Provider

In order to implement ABS, section 60(1) of the Nature Diversity Act states:

> The import for utilisation in Norway of genetic material from a state that requires consent for collection or export of such material may only take place in accordance with such consent. The person that has control of the material is bound by the conditions that have been set for consent. The state may enforce the conditions by bringing legal action on behalf of the person that set them.

This paragraph imposes two important obligations upon any user of genetic material. Import of genetic material to Norway can take place only in accordance with *prior informed consent*. After the import, any possessor of the material is bound by the *prior informed consent*. Norway thus instructs its courts and authorities to directly apply the terms set by the provider country.

Although a huge step forward in ABS implementation, this approach has two weaknesses: (1) It creates a level of uncertainty for Norwegian users and decision-makers, given that access legislation will vary among countries, creating legal uncertainty as to whether and how each country's provider-side law will affect rights and obligations of users. The uncertainty is likely to increase significantly if the importer of the genetic materials subsequently transfers these to a third party. (2) There is no specific minimum requirement to ensure *fair and equitable* benefit sharing, neither in the Norwegian Act nor in the NP. The Act apparently assumes that benefit sharing in accordance with provider-country requirements will be fair and equitable.

In recognition of the resource difficulties for a provider wanting to enforce a benefit-sharing clause, the Act establishes procedural competence for Norwegian authorities to take legal action on behalf of the relevant country or institution. This rule is a major addition to the former legal situation in Norway relating to ABS (Tvedt, 2006). While it is most likely that the Office of the Attorney General would be responsible for acting on behalf of the Norwegian government (the *state*), [10] the initiative to bring a case to the attention of the Attorney General needs to come from another governmental body or institutions with specialized competence. Hence, a provider of genetic materials who wants to benefit from section 60 of the Nature Diversity Act would probably be best helped by contacting the Norwegian National Focal Point for Access and Benefit Sharing within the Ministry of the Environment.[11] It should be noted that the decision on whether to initiate a case on behalf of a provider would depend on the discretion of Norwegian authorities. According to the Public Administration Act, the authorities will probably have to provide a reasoned decision on whether to initiate a case, and the provider has the right of administrative appeal.[12]

According to chapter IX of the Nature Diversity Act, a user who fails to comply with the requirements of section 60 may be ordered to provide the information, and may, if failing to comply with the order, be subject to a coercive fine (sections 69 and 73 respectively). Wilful or negligent violation of obligations under section 60 may also be subject to penal proceedings according to section 75 of the Act. Possible penalties are fines and up to one to three years imprisonment, depending on the severity of the crime. Norwegian penal legislation opens for penalties being applied not only to persons, but also to enterprises: see sections 48 a) and 48 b) of the General Civil Penal Code.[13] Enterprises can be punished even if no individual person may be prosecuted for the action in question.

Obligation to Possess and Pass on Information

Section 60(2) of the Nature Diversity Act extends the importer's substantive obligation to subsequent utilizers of the genetic material:

> When genetic material from another country is utilised in Norway for research or commercial purposes, it shall be accompanied by information regarding the country from which the genetic material has been received (provider country). If national law in the provider country requires consent for the collection of biological material, it shall be accompanied by information to the effect that such consent has been obtained.

On the one hand, the requirement that genetic material be followed by relevant documentation could be read to indicate that the government views *genetic resources* as a physical rather than an informational resource (Schei and Tvedt, 2010). This reading of the provision is supported by the fact that parallel provisions in the Patent Act and the Act relating to the Plant Breeder's Right apply to biological material (see below). On the other hand, nothing would prevent countries from requiring documentation to follow the exchange of genetic resources in the form of information, independent of the biological material from which such resources have been derived. Such a requirement may from a practical perspective be more difficult to enforce when applied to information than when applied to biological material as such.

Section 60(3) extends the information requirement to instances where a genetic resource has been imported through a third country:

> If the provider country is a country other than the country of origin of the genetic

> material, the country of origin shall also be stated. The country of origin means the country in which the material was collected from *in situ* sources. If national law in the country of origin requires consent for the collection of genetic material, information as to whether such consent has been obtained shall be provided. If the information under this paragraph is not known, this shall be stated.

The information requirement could thus be fulfilled by stating that the country of origin and conditions for using the material are unknown. The effect of including this option in section 60 is far-reaching. Where the importer or user does not have the information, there is no specific obligation to search for such information. In such instances, it would be hard for the Norwegian authorities or the country of origin to raise claims concerning benefit sharing, as they would carry the initial burden of proving the claim. The effect of this rule is thus likely to render section 60 ineffective when the genetic material has been imported through a third country or where the origin of the genetic material is unclear.

Article 10 of the NP will be particularly important in such situations. Depending on the modalities of the future Global Multilateral Benefit-sharing Mechanism, user countries could undertake obligations to ensure that users of genetic resources contribute to the Mechanism where the origin of the genetic resource remains unknown. Thus, a patentee informing that the origin of the material is unknown might become a trigger-point for the benefit-sharing obligation with the Mechanism rather than with the actual unknown provider country. Unless accompanied by specific obligations to search for and provide information concerning the origin of the genetic resource, the Mechanism could significantly undermine the effectiveness of obligations to share benefits directly with the country of origin. One consequence could be to weaken the incentive of countries of origin to ensure effective conservation of their biological diversity (NP art. 1).

The remaining clauses in section 60 of the Nature Diversity Act address the obligation to provide information when the utilization of genetic resources involves the use of traditional knowledge and where access to the genetic material is provided under the Multilateral System of ABS under Part IV of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA, 2001).

The Link to Patent Law

Norway has adopted provisions concerning disclosure of information concerning the origin of biological material, in section 8b of the Patent Act[14] and section 4(3) of the Act relating to the Plant Breeder's Right. The required disclosures under the Patent Act involve several different and complementary types of information:

> The countries from which the inventor received or collected the biological material;
>
> If prior informed consent is required in the provider country, information about the existence of such consent shall be included;
>
> The country of origin, if different from the provider country; if information concerning the country of origin is not known, this shall be stated;
>
> If prior informed consent is required in the country of origin, information about the existence of such consent shall be included;
>
> If access to the biological materials has been provided in pursuance of articles 12.2 and 12.3 of the ITPGRFA, a copy of the standard material transfer agreement shall be enclosed with the patent application.

The same obligations to provide information apply to applications for plant variety protection.

Interestingly, the focus of these obligations is on *biological* material – not *genetic resources*, as in CBD article 15.7 and the Protocol. This means that the disclosure obligations go beyond what is required for ABS purposes under the CBD. The obligations will, for example, apply also to instances in which an invention is based on a chemical or other component found in the biological material.

One condition for triggering the disclosure requirements is that "an invention concerns or uses biological material", which implies a very low threshold of dependency or similarity between the biological material and the invention. The Patent Act goes on to specify that the disclosure requirements apply also "where the inventor has altered the structure of the received material", underscoring the legislator's desire to give broad scope to the rule by including all genetically modified organisms. A second condition for triggering the disclosure obligations is that the user country is not the same as the country of origin, with the latter understood as "the country from which the material was collected from its natural environment".

The Patent Act requires the applicant to state whether prior informed consent exists if the country of origin requires such consent in its domestic legislation. However, there is no further requirement to inform about the *content* of the prior informed consent, in particular the conditions on which the consent has been given, so that the authorities would be able to control the lawfulness of the subsequent use of the biological material. Similarly, there is no obligation to inform about agreements concerning benefit sharing. When the biological material has passed through a third country, the patent applicant shall inform about the country of origin and whether prior informed consent exists in relation to this country. However, if this information is not known to the patent applicant, the applicant need only include a statement to this effect in the application.

Against this background, we can observe that the obligations contained in section 8b of the Patent Act and section 60 of the Nature Diversity Act do not create a functional regime for benefit sharing on their own. Their contribution is to provide information which could hypothetically be used in an enforcement action under section 60 of the Nature Diversity Act. It is also not always easy, from a practical-legal point of view, to prove that an invention "concerns or uses" a particular biological material. The challenge of applying and enforcing the obligation may be very difficult to overcome, particularly since enforcement, ultimately through penal sanctions, would depend on fulfilling the evidentiary standards of *in dubio pro re*—one is assumed innocent until proven guilty. In the case of a false statement, including statements that relevant information is unavailable or that there is no relevant information, the applicant is subject to penal sanctions under sections 73 and 75 of the Nature Diversity Act or section 166 of the General Civil Penal Code (in cases of non-compliance with the Patent Act and the Act relating to the Plant Breeder's Right). In the latter cases, the prosecutor must investigate whether the information is wrongful, and must provide sufficient evidence, beyond any reasonable doubt, for the information both being wrongful and that it was wrongful deliberately.[15] A patent applicant found guilty of false statements about the origin or the provider or regarding prior informed consent may face fines or imprisonment for a maximum of two years. Fines will be due to the Norwegian government. There is no follow-up procedure to ensure that benefits must be shared with the provider or the country of origin. There is thus discrepancy between the objective of benefit sharing and the procedures to be applied in cases of breaches of the law.

One significant reason why the disclosure requirements are unlikely to contribute effectively to benefit sharing is the lack of specific and automatic legal consequences from non-compliance. As noted in the Patent Act, the consequence of not meeting the disclosure obligation "is without prejudice to the processing of patent applications or the validity of rights arising from granted patents."[16] The same reservation has been included in section 4(3) of the Act relating to the Plant Breeder's Right.

A further limitation of the practical significance of the patent disclosure requirement as a functionally effective user-country measure arises from its limited application. Section 8b of the Patent Act applies only to patent applications addressed to and filed directly with the Norwegian Patent Office, and not when patents are sent via the system under the Patent Cooperation Treaty (PCT).[17] Moreover, since Norway joined the European Patent Organisation (EPO), the number of patents filed directly with the Norwegian Patent Office has declined significantly.[18] The lack of a corresponding disclosure requirement in the European Patent Convention may be a motivating factor for patentees to channel biotechnological patents through the European system rather than through the Norwegian system.

For the information gathered through the arrangement set up under the Patent Act and the Act relating to the Plant Breeder's Right to contribute to effective benefit sharing, the relevant authorities would need to ensure that information is passed on to authorities tasked with following up section 60 of the Nature Diversity Act. As no procedures or information are available on the websites of the relevant Norwegian institutions, we asked whether information concerning origin of genetic materials was available concerning patent applications and applications for plant variety rights, and whether there were procedures to make such information available to source countries or authorities responsible for following up section 60 of the Nature Diversity Act. The Ministry of the Environment, the Norwegian Industrial Property Office and the Norwegian Plant Variety Board responded that no procedures had been established to ensure availability and transfer of information. The Norwegian Contact Point to Access and Benefit Sharing had no information regarding intellectual property rights based on genetic materials originating outside Norway. The Norwegian Industrial Property Office informed us of the existence of 17 applications relevant to section 8b of the Patent Act, which has been in force since 2003. Of these, 13 had been withdrawn or rejected, and information was thus not publicly available. Of the remaining four, two had included information on country of origin, one application had been rejected, and one was still so early in the application process that no information was available. The Norwegian Plant Variety Board informed us that they had no information available concerning the origin of genetic materials related to applications for plant variety rights.

Against this background, we conclude that, although Norway has adopted legislation that has been regarded as very advanced[19] and beneficial to benefit sharing, no significant administrative efforts have been put in place to ensure effective implementation. The relevant legislation was adopted in 2003 (amendment to the Patent Act) and 2009 (the Nature Diversity Act and the amendment to the Act relating to the Plant Breeder's Right). The failure of Norwegian authorities to follow up is particularly troubling in light of the political importance of the amendment to the Patent Act[20] and the more than eight years spent in preparing the Nature Diversity Act.[21]

A Hypothetical Case Study: Enforcing Benefit Sharing in Norway

Three ABS Situations

With this hypothetical case study, we take up the following three ABS situations:

(1) The provider country and the user have agreed to mutually agreed terms (MAT) in the form of an instrument that can be applied and enforced as a 'contract';

(2) The provider country has given its prior informed consent (PIC) as an administrative decision granting a right to use genetic resources under specific conditions;

(3) The user has not complied with ABS requirements of the provider country.

Common to all three situations is that we assume that the provider country has adopted access legislation in accordance with CBD art. 15 and NP art. 6.

It may be difficult to distinguish clearly between situation (1), where the relationship between the provider and the user is based on a contract, and situation (2), where it is based on an administrative decision. The starting point is that administrative decisions involve the exercise of public authority and need a clear basis in legislation, while contracts are based on negotiation between the provider and the user, and require the agreement of both. The problem to distinguish occurs where a public authority enters into negotiations prior to establishing a benefit-sharing arrangement, and where the final arrangement has elements of both an administrative decision and a contractual relationship. Such problems are likely to occur when providers and users shall determine the modalities for benefit sharing. The law of the provider country forms the basis for determining whether there is a contract or an administrative decision in such instances. It is important that the process for implementing the NP encourages provider states to clarify whether their benefit-sharing arrangements are to be regarded as contracts or as administrative decisions.

The topic in the following is to examine how the above three situations would fare under the current legal regime in Norway. Our objective is to identify the reasonable elements that need to be included in national implementation measures in user countries in order to ensure effective benefit sharing. We will ask how a provider country could secure its interests in each of the three situations by relying on the ABS provisions of the Norwegian Nature Diversity Act and Patent Act, as described above, in the context of the Norwegian legal regime. This provides a practical legal point of view – that of an attorney of law in Norway preparing a case before the courts on behalf of a provider country. In other words: how can an attorney argue a case before a Norwegian court, and what might be the outcome of court proceedings? Before turning to how a case would proceed before the courts, we will look into some issues relating to out-of-court settlement.

Initial Awareness of a Potential Infringement

The first challenge the provider country faces is to become aware of the fact that a genetic resource originating in that country is being utilized in Norway, as Norway's ABS regime does not provide any guarantee that a relevant provider country will be so informed. Where the user has agreed to an ABS contract (situation 1) and where the provider country has issued an administrative decision concerning future use of the genetic resource (situation 2), the provider country has an independent opportunity to keep track of the use of the genetic resources. However, neither the provider country nor Norwegian officials would necessarily be aware of relevant use of a genetic resource in Norway. In general, the use of a genetic resource has no obvious external verifiable manifestations that would be controllable by either government. The provider country could detect such use only (1) where the contractual obligation or administrative decision requires reporting back to the provider country and provides a possibility of inspection, or (2) where Norwegian authorities engage in oversight activities, including reporting to the provider country. If the private user has failed to comply with provider-country requirements (situation 3), the Norwegian disclosure requirements (section 60 of the Nature Diversity Act, section 8b of the Patent Act and section 4(3) of the Act relating to the Plant Breeder's Right) are unlikely to compete with the private user's incentive *not* to disclose the origin of the material, as long as the systems of control and sanctions in Norway remain ineffective.

The above challenges could be addressed on the basis of user-country measures to be taken in accordance with articles 15 to 17 of the NP. One option for implementation could be for Norway to establish a framework under which users of genetic materials are faced with the burden of proving that

their use of the genetic materials is not subject to any benefit-sharing obligations. The NP does not provide for such a specific rule, but user countries could adopt such a rule in order to fulfil their obligations under the Protocol. It would be hard to imagine such a framework without basing it on international cooperation, in particular through information sharing. Such a system is envisaged under article 17 of the NP, which provides for "internationally recognized certificates of compliance". This would be a significant means for users to ensure recognition as ABS-compliant entities. The system of *checkpoints* as envisaged in NP article 17 could operate to provide both the user and the countries with significant opportunities to document compliance. Legislation adopted by a user country which places the burden of proof on the user of genetic resources would significantly strengthen the effectiveness of the measures envisaged in art. 17 of the NP.

Enforcement Outside the Norwegian Court System

Supposing that the provider country has overcome the challenge of identifying a user who is in violation of obligations according to a contract, an administrative decision of the provider country or the legislation of the provider country, it must next embark on the process of turning that information into enforceable rights to benefits. The provider country could take enforcement actions against a user under its own legal system, provided that it has jurisdiction over activities or assets of the user. Where the user has no assets or activities in the provider country, that country has limited avenues for forcing the user to share benefits. It could seek to enforce a favourable domestic decision through the Norwegian justice system (see section 46 of the Norwegian Act relating to the Courts of Justice, 1915). Establishing a corporate structure with different limited companies conducting collection activities in the provider country and commercial activities in the user country could limit the possibility of a provider country to force the user to share benefits.

Section 60 of the Nature Diversity Act does not state any substantive obligation to share benefits with the provider country. Current Norwegian legislation does not make benefit-sharing obligations according to foreign court decisions enforceable in Norway (see section 19-16 of the Disputes Act, 2005 no. 90). Irrespective of whether the provider country gives its consent in an administrative decision or through a contract, such instruments will not be directly enforceable in Norway.

Provider countries that make access dependent on ABS contracts would have a clear advantage, since such contractual obligations can frequently be enforced in other jurisdictions. A contract would be binding as long as it is not found to be void, and could, depending on the dispute settlement clause included in the contract, be brought to arbitration. The decision of an arbitration tribunal could be subject to subsequent enforcement in domestic legal systems.[22]

Bringing the User to a Norwegian Court

Access to Courts for Plaintiffs from another Country

In order to bring a case to court in Norway, the plaintiff must, in addition to defining a *case* or *cause of action* on which a court can decide, meet three general conditions:

(1) The plaintiff must have capacity to sue: section 2-1 of the Dispute Act (2005 no. 90) lists the entities which have the capacity to sue and be sued before a court in Norway. Foreigners and their states are not mentioned explicitly, but it must be assumed that they have the same capacity to sue before Norwegian courts as do Norwegians and Norwegian public authorities.[23] The main reservation in this

context is that disputes concerning international matters "may only be brought before the Norwegian courts if the facts of the case have a sufficiently strong connection to Norway."[24] If the use that triggers a benefit-sharing obligation takes place in Norway, and there is a sufficient legal basis in the Norwegian legal system for bringing a case, we may assume that the case has a sufficiently strong connection to Norway. The legal basis may be contractual obligations or action on the section 60 of the Nature Diversity Act, see immediately below.

(2) The object of the dispute must be subject to a legal claim: under Norwegian law, only "legal claims" can be brought before a court.[25] A claim is considered to be *legal* where it meets certain standards. In particular, the claim must have a "legal basis".[26] This requirement is easily met where the claimant has a contract and can show a breach of contractual terms (situation 1). If, however, the case is based on the user's violation of a foreign administrative decision (situation 2), the existence of a valid "legal claim" is less obvious, and the result is much less certain. A benefit-sharing claim brought under such circumstances would have to depend on the existence of a legal basis in Norwegian legislation. Arguably, such a legal basis exists in the second sentence of section 60(1) of the Nature Diversity Act: "The person that has control of the material is bound by the conditions that have been set for consent."[27] The preparatory works underline that this sentence implies that the user has a legal duty "according to Norwegian law".[28]

Whether there exists a legal basis where the genetic material has been accessed in violation of the access legislation in the provider country (situation 3) is more uncertain. In such situations, it can be argued that there is no "consent" or related conditions, and thus that the second sentence of section 60(1) of the Nature Diversity Act is inapplicable. The Act refers to foreign access legislation, but it does only establish a duty to import genetic material to Norway in accordance with the legislation of the provider country; it does not give the foreign act as such validity under Norwegian jurisdiction. Thus, import of genetic material without complying with access legislation is illegal, and such illegal import can be prosecuted by Norwegian authorities under sections 69, 73 and 75 of the Act. On the one hand, it can therefore be argued that the lack of explicit consent means that providers or the provider country have no legal basis for bringing the case before a Norwegian court. Moreover, it can be argued that the fact that section 60 specifically refers to consent, whereas legislation is not mentioned, implies that the law-maker has intended to make a difference: the individually-determined consent is made binding under Norwegian law, but foreign legislation is not. Arguably, this makes sense in terms of legal certainty for the user of genetic material, as access legislation in general does not specify conditions for accessing the material. On the other hand, it can be argued that the user of genetic materials has implicitly agreed to conditions set out in provider-country legislation by importing the material or making use of it, and that such implicit agreement would suffice as a legal basis according to the second sentence of section 60(1). Moreover, it can be argued that a user of genetic materials should not be rewarded for not seeking explicit consent before importing genetic materials to Norway. While it remains unclear whether a sufficient legal basis would exist in these situations, it is our opinion that Norwegian courts would be unlikely to find in favour of the provider or the provider country, should such a case arise.

(3) The claimant must "show a genuine need to have the claim determined against the defendant":[29] This requirement implies that the person bringing the case must have a sufficiently close connection to the case. The provider and the provider country would generally fulfil this requirement. The requirement would probably prevent a Norwegian non-governmental organization (NGO) from bringing a user to court with a provider country as the intended beneficiary. Norwegian case-law mostly supports the right of access to justice for NGOs where they promote common interests. Case-law does not provide a basis for arguing that NGOs have a sufficiently strong interest in bringing cases on behalf of a provider or provider country. However, a possibility for bringing a case may exist where ABS falls

within the objectives of the NGO as set out in its constituting documents and where the legal claim concerns the duties of the user and not the rights of the provider or the provider state.

Cases Based on Section 60(1) of the Nature Diversity Act

The third sentence of section 60(1) states that: "The state may enforce the conditions by bringing legal action on behalf of the person that set them." Hence, the Norwegian government can enforce provider-country conditions through legal action on behalf of the provider country or relevant private party. A possibly limiting factor concerns the reference to "conditions". The preparatory works indicate that the form in which the "conditions" are stated is not decisive for the government's ability to bring a case. Statements in the preparatory works clearly indicate that relevant conditions may follow from administrative decisions of the provider country (situation 2).[30] Where the genetic materials have been accessed in violation of provider-country legislation, and no specific conditions have been established in a contract or an administrative decision (situation 3), it remains unclear whether the Norwegian government can bring a case to Norwegian courts on behalf of the provider or the provider country. This issue is parallel to the one discussed immediately above. One difference is the more specific reference to persons having set "conditions". However, the provision does not rule out the possibility that conditions could be set directly through legislation and that a case thus could be brought to the benefit of the country that has adopted the legislation. The preparatory works support such an interpretation as it refers to the foreign legislation, but the reference does not explicitly resolve the issue.[31] Such an interpretation would also be in line with our conclusion above.

The English translation of section 60 indicates that the provider country or relevant private party must to some extent be involved in the claim, since the action must be brought *on behalf* of them. However, the translation is somewhat misleading on this point, since the Norwegian version only requires the action to be brought "to the advantage" of the person who set the conditions. As there is no further comment on this issue in the preparatory works, we can assume that no strict requirements concerning the involvement of the provider country or relevant private parties would apply if the Norwegian government wanted to bring a case concerning benefit sharing before a Norwegian court.

The Norwegian example shows that, to enable enforcement of benefit sharing by national courts in user countries, relevant national legislation must be adapted to identify and empower persons or officials to bring cases to court. While similar issues can be expected to arise in many user countries, such legislation must be adapted to the court system of each user country. When implementing the NP, countries need to consider how to facilitate access to the courts for non-nationals, and provide guidance on how contracts or administrative decisions can be formulated in order to enhance opportunities for cross-border enforcement (see NP Art. 18).

It would be appropriate for Norwegian authorities to consult with relevant interested parties in the provider country when considering whether to bring a case. Moreover, one might expect the diplomatic or consular mission of the provider country to become involved. The decision on whether a case shall be brought to court is at the discretion of the Norwegian government, but it seems reasonable to expect Norwegian courts to reject a case where the provider or provider country has expressed objections to having the case brought to court or to the way in which the case is presented.

Norwegian Courts – Addressing Substantive Issues

In the following, we look into various issues that might arise when a Norwegian court is asked to resolve substantive issues regarding benefit sharing. We focus on cases where the conditions for benefit

sharing have been set out in contracts (situation 1) and administrative decisions (situation 2). We shall deal with these two situations in parallel.

Validity: As we assume that issues concerning the validity of contractual obligations would follow ordinary rules concerning validity of international contracts,[32] our focus here will be restricted to the validity of the provider country's administrative decision. The problem arises when the defendant claims that the decision setting out the benefit-sharing conditions is invalid. The validity of the decision must then be determined on the basis of the law of the provider country. Moreover, according to rules under international law concerning state immunity, cases concerning the validity of administrative decisions can be raised only before courts of the decision-making states.[33] Hence, a Norwegian court must reject any claim concerning the invalidity of the administrative decision in question. The question is thus whether a Norwegian court can (or would) contribute to enforcement of a foreign administrative decision in a case where the validity of the decision is contested. On the one hand, a Norwegian court can be assumed to remain reluctant to pronounce on the validity of a foreign administrative decision, and thus be likely to reject the case for lack of jurisdiction—either on the basis of state immunity[34] or applying the Norwegian version of the principle of *forum non conveniens*.[35] On the other hand, rejection of cases on such grounds would in practice make section 60 of the Nature Diversity Act entirely ineffective in cases concerning administrative decisions. Norwegian courts are thus likely to be faced with the dilemma of having to choose between rejecting the case for lack of jurisdiction and deciding the case on the basis of an assumption that the administrative decision is valid even though the Norwegian respondent challenges its validity or applicability. A third possibility could be to make a request to the appropriate authorities or courts of the provider country in order to get an authoritative statement concerning the validity of the administrative decision. However, in the absence of agreement between Norway and provider countries concerning recognition of decisions of courts or administrative authorities, which is the case for most potential provider countries, Norwegian courts are unlikely to resort to such an option. Against this background, it can be argued that there is a need to develop mechanisms for recognition of administrative decisions of provider countries as part of the implementation of the NP.

Interpretation of foreign administrative decisions: Norwegian courts may be faced with difficult interpretive issues when fulfilling their role under section 60 of the Nature Diversity Act. The starting point would be the wording of the decision, which should in general be interpreted in light of the relevant provider country legislation. These tasks are significantly facilitated through the establishment of lists of National Contact Points to Access and Benefit Sharing and of Competent National Authorities on Access and Benefit Sharing under the CBD.[36] However, there are still many countries not represented on these lists, and significant challenges related to interpreting the decisions and provider country legislation might remain despite the availability of relevant contact persons. Moreover, given the fact that Norwegian authorities are most likely to initiate cases on behalf of provider countries that lack resources to enforce the decisions themselves (least developed countries in particular), one might fear that the authorities in these countries may lack resources to respond appropriately to requests from the Norwegian authorities; moreover, the relevant decisions and legislation may reflect legal traditions significantly different from those of the Norwegian legal system. Examples could be how local custom and the interests of indigenous communities should be addressed. In many cases there might be significant uncertainty related to the interpretation of administrative decisions in light of provider-country legislation. There is thus a need to focus on capacity building of national contact points and competent national authorities, so that they may contribute as effectively as possible to clarifying the content of conditions set out in provider-country administrative decisions. Such capacity-building efforts could also focus on enabling national contact points and competent national authorities to provide

evidence concerning the validity of such decisions.

Interpretation of contracts: While the validity of ABS contracts might not give rise to issues of particular concern, it may be relevant to discuss whether the interpretation and application of such contracts would raise issues of particular concern. We may identify four main concerns in this context: (1) ABS is an unknown legal concept among judges in Norway, and there might be little understanding of the underlying rationale of the contract. (2) ABS will relate to technical questions of biotechnology, gene-technology or a related technical field. Judges are trained in law and very seldom in biology or even less in these technical fields, the understanding of which might be essential for an appropriate interpretation of the contract. (3) Until now, there has, to our knowledge, been a complete absence of jurisprudence for ABS contracts, as no court in any country has ever interpreted a contract that has been characterized as an ABS contract. The absence of jurisprudence might create a challenge for the initial cases, as it adds to the other challenges facing judges in this area. (4) As the contracts will be established on the basis of requirements in provider-country legislation, an understanding of the legislation might be essential for interpretation of the contractual obligations. Hence, similar issues to those identified above concerning interpretation of administrative decisions are likely to arise when courts interpret contracts. There might be significant uncertainty related to the interpretation of contracts in light of provider-country legislation in some cases. Against this background, it will be of importance during the implementation of article 19 of the NP to encourage more extensive and consistent use of standard contracts, frequently referred to as "standard material transfer agreements", and to encourage effective involvement of national contact points in contractual issues.

Applying law to the facts: If Norwegian courts can overcome the difficulties of interpreting administrative decisions or contracts, they will then face challenges in applying the law to the facts. Norwegian courts will in general have no particular difficulties with regard to establishing facts related to Norway, including assessing the benefits arising from the use of genetic resources in Norway. However, there might be significant problems in establishing facts that take place within other countries. Such problems might concern, *inter alia*, determining the exact function of the genetic material in question in relation to the contested use, claims by the defendant that similar genetic materials from a number of different sources have been used in developing the product in question, and disagreement between the defendant and the provider country regarding how the genetic material has been collected. Although such problems may be significant, it can be argued that similar problems would arise in any case involving transborder elements, and that problems of clarifying the facts of the case will have to be resolved on an individual basis, taking into account the framework for cooperation between the relevant authorities. The NP provides for limited guidance in this respect, but national contact points could play an important role. There is also a need for capacity building, for example in the form of an explanatory guide to the NP.

Enforcement of the decision: Ensuring effective benefit sharing based on a decision by a Norwegian court might involve some additional challenges. Such challenges depend on whether benefit sharing is to take place on the basis of contractual terms or terms set out in an administrative decision, and on the nature of the benefits to be shared—in particular, whether the benefits are economic, including monetary or not (see the annex to the NP). We may assume that issues concerning non-monetary benefits to be shared in the context of sample collection or the use of private or public land will be resolved within the provider country. Such benefits may include deposits of samples of genetic materials found, information sharing and research cooperation. Due to the close relationship between bioprospecting activities and such benefits, as well as problems associated with business secrets and confidentiality, it would not be reasonable for user-country courts to intervene to secure such benefit sharing. Hence, claims relating to such benefit sharing are likely to be rejected on the basis of *forum non*

conveniens or similar rules.[37] However, there might be exceptions: for example where it appears that the user has made more extensive searches for genetic material than those provided for in the contract and the provider country has few possibilities to ensure effective benefit sharing on the basis of the activities that have actually taken place.

In cases concerning contractual obligations, it can be noted that most ABS contracts available for review include provisions under which users transfer monetary or other economic benefits (Young, 2009). As such benefit sharing will generally depend on the benefits actually generated in user countries, it would be reasonable to expect Norwegian courts to address such benefit-sharing claims. Even where the benefits to be shared have been set out in terms of payments for access to the genetic resource and where the user has failed to meet such an obligation, it can be argued that it is appropriate for Norwegian courts to deal with the case so that benefit sharing based on the claim can be enforced.

Court actions relating to enforcement of administrative decisions give rise to some additional problems. While claims based on contracts in Norway and in many other countries can be adjusted on the basis of arguments related to the reasonableness of the terms of the contracts,[38] there is no similar legal basis for adjusting claims based on the reasonableness of the terms of *administrative decisions* of other countries. The finding of a Norwegian court that certain conditions in an administrative decision of another country cannot be applied due to their unreasonableness would be in conflict with international comity, and potentially also with the immunity of the state in question. Hence, where a Norwegian court is faced with an argument that the administrative decision cannot be enforced due to its unreasonableness, it can be argued that the court should reject the case. On the other hand, such an approach would enable defendants to prevent Norwegian courts from dealing with benefit-sharing claims based on foreign administrative decisions. Against this background, it can be argued that Norwegian courts should not be prevented from addressing cases where the reasonableness of an administrative decision is contested, since such a decision would not directly rule on the validity of the administrative decision: it would merely determine whether the Norwegian legal system could be used to enforce the administrative decision. In our view, considerable uncertainty attends how such a case would fare in Norwegian courts, and it would be good if such problems could be dealt with in the context of the implementation of the NP.

A Norwegian court might also be faced with a "legal personality" question: Who is legally entitled to receive the benefits? Normally, this question will be decided when Norwegian authorities define the claim to be brought forward. The question of whether benefits are to be transferred to a government or other legal or physical persons within the provider country is not resolved in detail in the NP, as provider countries enjoy significant freedom in determining how the benefits shall be distributed among stakeholders (see in particular articles 5(2), 5(5), 8 and 9). The basis for defining the right-holder must therefore be the administrative decision or the contract, and a Norwegian court must make its decision on this basis. Any subsequent disagreement relating to the ultimate beneficiaries, such as whether and how funds are to be made available to indigenous communities, should be determined by the legal system of the provider country.

Effects of a Norwegian case for potential cases within other countries: Finally, it can be asked whether a case concerning benefit sharing brought by Norwegian authorities against a user before a Norwegian court would prevent the provider country or other interested parties from bringing the same or similar claims against the same user in the courts of the provider country or in other countries (the user's home country in particular). The answer depends on the national rules of the country in which the parallel claim is brought, and, where relevant, on treaties between this country and Norway. The Norwegian case would be brought by Norwegian authorities "to the advantage of the person that set" the benefit-sharing conditions (section 60 of the Nature Diversity Act). The problem arises if the provider

country or other interested parties are dissatisfied with the way in which Norwegian authorities and courts deal with their case. It can be argued that a provider country or other interested parties should have broad opportunities to bring parallel proceedings. In general, arguments based on *res judicata* would apply only where the case is between the same parties. Depending on the rules of the country in question, parallel proceedings might be resolved in different ways. Some legal systems might reject the new case on the basis of *res judicata*, whereas other systems might accept the whole case or selected claims. Regardless, it would not seem reasonable for a court to reject a case on the basis of *res judicata* where the claimant has a reasonable claim that Norwegian authorities and courts have not dealt appropriately with important aspects of that case.

Enforcement of a Judgment from another Country

The provider country or other interested parties might seek to avoid some of the uncertainties and challenges described above by obtaining a verdict on their benefit-sharing claim in the provider country, and subsequently seek enforcement of this verdict in Norway. While there exist various treaties on the recognition of foreign judgments,[39] such treaties are in general regional and/or subject-specific. Hence, these rules are in practice not relevant to the recognition of foreign judgments concerning benefit sharing.[40]

Whether Norwegian authorities or courts will contribute to enforcement of foreign courts' decisions on benefit sharing will thus in practice be a matter of Norwegian law. According to section 4-1(2)(f) of the Act relating to Enforcement of Claims (no. 86, 1992) and section 19-16 of the Dispute Act (no. 90, 2005), enforcement of a foreign judgment would require legal basis in a Norwegian Act. As there exists no such legal basis of relevance, a foreign judgment concerning benefit sharing cannot be enforced through the Norwegian legal system. Against this background, it would be of interest to consider developing a common instrument to encourage general recognition of foreign judgments and arbitral awards, as a coordinated effort to ensure effective implementation of article 18(3)(b) of the NP.

Some Concluding Remarks – Lessons from Norwegian User-Country Legislation Relevant for Implementation of the Nagoya Protocol

The above thought-experiment has shown that Norwegian legislation, hailed as the most advanced regime of user-country measures (Morgera and Tsioumani, 2010, pp. 156–7), is in fact far from resolving all the issues relevant and necessary for creation of an effective benefit-sharing system. This is not necessarily due to any failure on the part of the Norwegian government, which has taken serious and important steps that will at least enable and mandate greater attention to user side-issues within Norway. When it comes to implementing ABS and the NP in a functional way, however, it is clear that the legislature of one country, acting on its own, cannot resolve all the challenges relating to enforcement of ABS obligations towards users within its jurisdiction.

The Norwegian regime for ABS has introduced some suitable and potentially effective instruments to assist in the implementation of the access legislation of provider countries. While the regime is new and its effectiveness in practice thus cannot yet be determined, we have in this article indicated certain weaknesses and opportunities inherent in the regime. Especially important is the observation that the effectiveness of the Norwegian regime depends on three main factors: (1) It needs to be followed up through the establishment of effective administrative procedures. (2) It depends on coordination and cooperation with provider countries, which can be greatly enhanced through

implementation of the NP. (3) To some extent it also depends on coordination and cooperation with other user countries and their willingness to implement similar regimes. This latter point is illustrated by recent developments in the patent regime, whereby obligations in Norwegian legislation will lose effect through the possibility of filing patent applications through the PCT or EPO systems.

As demonstrated through the above analysis, the effectiveness of the ABS regime will largely depend on two types of international mechanisms: mechanisms using networks of national contact points and multilateral "clearing houses" for information sharing, including mechanisms to ensure capacity building; and agreed legal and *soft law* (NP article 20) mechanisms to ensure coordination of national legal regimes. Such mechanisms can take up the challenges identified above, but not necessarily resolve them.

The functionality of ABS and the success of the NP will depend on creating incentives that encourage users to participate. This remains a challenge also after the NP has been agreed and moves into its implementation phase. One important issue concerns the modalities to be chosen for the Global Multilateral Benefit-Sharing Mechanism (NP article 10). Such a mechanism can contribute considerably to the volume of benefit sharing—but it can also undermine the role of provider-country access legislation, thereby also undermining provider countries' perception of the fairness and equitability of the ABS regime.

The three situations studied (contracts, administrative decisions and violation of provider country legislation) raise distinct and different challenges for making an ABS regime functional. These distinctions are reflected in the text of the NP and will be central when implementing it in domestic legislation. Model contractual clauses, as prescribed in article 19, will be important to assist user countries seeking to enable the enforcement of contracts between providers and users within their judicial system. The judicial systems of user countries cannot resolve all benefit-sharing issues. Particular problems arise in relation to administrative decisions and violation of provider-country legislation. There is consequently significant need for establishing a multilateral mechanism to ensure mutual recognition of foreign judgments and arbitral awards and work to implement the rules of the NP into national functional legal system.

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[1] Terminology may create confusion in an article dealing with both the international level of ABS (the relationship of the countries as "Contracting Parties") and the private level (the relationships between the "parties to a contract"). Accordingly, countries that are Contracting Parties to the CBD and to the NP are here referred to as "countries", and participants in an individual ABS relationship are referred to as "parties to the ABS contract".

[2] The definition of "genetic resources" is one of the legal problems associated with implementing a functional ABS system; see Schei and Tvedt, 2010. "Genetic material" is found within biological material, and most biological material may be moved across national boundaries legally without *prior informed consent* or *mutually agreed terms*, save some exceptions for species that are thought to be dangerous (dangerous or poisonous animals, plant pests, narcotic substances, biological weapons, etc.) or endangered, whose international movement is sometimes prohibited. Once one has a specimen in hand, a user's activities are often not monitored, or are very difficult to monitor by external or government observers.

[3] A detailed analysis of the question of "legal certainty" was undertaken in 2005: IUCN Canada. 'Summary Analysis: Legal Certainty for Users of Genetic Resources under Existing Access and Benefit-sharing (ABS) Legislation and Policy,' distributed at AHWG-ABS-3 as UNEP/CBD/WGABS/3/INF10, which noted that: "The [best] ways to enhance legal certainty for users … are to balance that need against the sovereign obligations of providers need for certainty."

[4] Based on personal observations during the negotiations of the NP.

[5] An English version of the Act is available at http://www.regjeringen.no/en/doc/Laws/Acts/nature-diversity-act.html?id=570549 [accessed February 2011].

[6] An English version of the Patent Act is available at http://www.patentstyret.no/patentsact [accessed February 2011].

[7] An English version of the Act relating to the Plant Breeder's Right is available at http://www.ub.uio.no/ujur/ulovdata/lov-19930312-032-eng.pdf [accessed February 2011]. Note that this translation has not been updated with the relevant provision on disclosure.

[8] Ot.prp 52, 2008-2009, p. 312.

[9] *Ibid*., p. 311.

[10] There is currently no English-language version of the web-page of the Norwegian Office of the Attorney General, see http://www.regjeringsadvokaten.no/ [accessed February 2011].

[11] See http://www.cbd.int/doc/lists/nfp-abs.pdf [accessed February 2011].

[12] See sections 24–32 of the Act, an English version of which is available at http://www.ub.uio.no/ujur/ulovdata/lov-19670210-000-eng.pdf [accessed February 2011].

[13] The English version of the Code is available at http://www.ub.uio.no/ujur/ulovdata/lov-19020522-010-eng.pdf [accessed February 2011].

[14] Section 8b states the following: "If an invention concerns or uses biological material or traditional knowledge, the patent application shall include information on the country from which the inventor collected or received the material or the knowledge (the providing country). If it follows from the national law in the providing country that access to biological material or use of traditional knowledge shall be subject to prior consent, the application shall state whether such consent has been obtained.

If the providing country is not the same as the country of origin of the biological material or the traditional knowledge, the application shall also state the country of origin. For biological material, the country of origin means the country from which the material was collected from its natural environment and, for traditional knowledge, the country in which the knowledge was developed. If the national law in the country of origin requires that access to biological material or the use of traditional knowledge shall be subject to prior consent, the application shall state whether such consent has been obtained. If the information set out in this subsection is not known, the applicant shall state that.

For biological material, the duty to disclose information under the first and second paragraphs applies even where the inventor has altered the structure of the received material. The duty to disclose information does not apply to biological material derived from the human body. If access to biological material has been provided in pursuance of Article 12.2 and Article 12.3 of the International Treaty of 3 November 2001 on Plant Genetic Resources for Food and Agriculture, a copy of the standard material transfer agreement (MTA) stipulated in Article 12.4 of the Treaty shall be enclosed with the patent application instead of the information stipulated in the first and second paragraphs.

[15] See section 40 of the General Civil Penal Code.

[16] Patent Act § 8b, see also the EU Patent Directive which prohibits rejection of a patent application as a consequence of not complying with the obligation: (1) non-compliance "has no effect for the proceeding of the patent application"; and (2) lack of information shall not have any effect on the validity of a patent after it has been granted.

[17] In such cases, Article 27 of the PCT prevents countries from imposing different or additional requirements to the content of a patent application than those listed in that treaty: "National Requirements (1) No national law shall require compliance with requirements relating to the form or contents of the international application different from or additional to those which are provided for in this Treaty and the Regulations."

[18] The expectation was that the number of patent applications would decline from between 6,000 and 6,500 applications to between 1,300 and 1,400 applications; see St.prp. no. 35 (2006-2007) concerning Norway's ratification of the European Patent Convention (in Norwegian) at 34.

[19] Norway's Nature Diversity Act was among six acts nominated for the Future Policy Award 2010: see <http://www.worldfuturecouncil.org/3454.html#c47432> [accessed March 2011].

[20] The 2003 amendment of the Patent Act was related to the decision of 31 January 2003 to include Directive 98/44/EC on the legal protection of biotechnological inventions in the Agreement on the European Economic Area (1993). This was a highly controversial issue among political parties in Norway, and section 8b of the Patent Act represented a significant element of the political compromise.

[21] The Committee preparing the Nature Diversity Act was established in April 2001; see NOU 2004:28 section 3.

[22] For Norway, see sections 45 and 46 of the Arbitration Act (2004 no. 25).

[23] See NOU 2001:32 Bind B, 'Rett på sak' p. 655. One topic that remains unclear is which conditions relating to their ability to sue must be determined on the basis of Norwegian law.

[24] See section 4-3 of the Dispute Act (2005 no. 90).

[25] Section 1-3 of the Dispute Act (2005 no. 90).

[26] *Ibid*.

[27] See also section 59(5) of the Act, which concerns legal action in relation to intellectual property rights on genetic material obtained from public collections.

[28] See Ot.prp. no. 52 (2008-2009) at 444.

[29] Section 1-3(2) of the Dispute Act (2005 no. 90).

[30] See Ot.prp. no. 52 (2008-2009) at 444.

[31] *Ibid*.

[32] There are no specific characteristics of benefit-sharing contracts indicating that such contracts give rise to issues or problems that distinguish such contracts from other contracts. See also Young, 2009.

[33] See in particular articles 5 and 6 of the United Nations Convention on Jurisdictional Immunities of States and their Property (2004).

[34] As the case would not be raised against the provider state, but in the interest of the provider state against a private party, it can be asked whether a state immunity argument would be available to the defendant. According to article 6.2(b) of the United Nations Convention on Jurisdictional Immunities of States and their Property (2004), this depends on whether the "proceeding in effect seeks to affect the property, rights, interests or activities of that other State". On the Norwegian approach to state immunity, see Alvik, 2006.

[35] See section 4-3(1) of the Dispute Act (2005 no. 90): "Disputes in international matters may only be brought before the Norwegian courts if the facts of the case have a sufficiently strong connection to Norway." On the Norwegian rules, see Heimdal, 2008. For a discussion of the role of domestic courts in such cases, see Benvenisti and Downs, 2009.

[36] See <http://www.cbd.int/doc/lists/nfp-abs.pdf> and <http://www.cbd.int/doc/lists/nfp-abs-cna.pdf> respectively [accessed February 2011].

[37] For Norway, see section 4-3 of the Dispute Act (no. 90, 2005).

[38] For Norway, see section 36 of the Act relating to Conclusion of Agreements, etc. (31 May 1981 no. 4).

[39] For an overview of relevant treaties, see <http://www.jus.uio.no/english/services/library/treaties/11/11-04/> [accessed March 2011].

[40] The main exception is judgments originating in courts of a state party to the Lugano Convention on Jurisdiction and the Recognition and Enforcement of Judgments in Civil and Commercial Matters (2007). However, this Convention applies only in relations between some European states, and would not be relevant in most cases concerning benefit sharing.