energy will rise. To ensure that nature can continue to support our wellbeing, legitimate and efficient governance mechanisms are essential, to endeavour to promote the continued sustainable use of natural resources.

As shown in this article, new ICTs can contribute to closing global governance gaps, in particular by making information accessible and by reducing the democratic deficit of some global decision-making mechanisms. Although global governance mechanisms will probably remain diverse and plural with no centralised institution of solid authority, new ICTs do offer the possibility to improve consensus-building mechanisms and include all relevant stakeholders in the decision-making process. In this sense, IUCN is at the forefront of future transformations with a unique multi-stakeholder decision-making process.

Notes

1 Held, D., McGrew, A.G., Goldblatt, D. and Perraton, J. 1999. *Global Transformations: Politics, Economics, and Culture*, at 16. Stanford CA: Stanford University Press.
2 Castells, M. 1996. *The Rise of the Network Society. The Information Age: Economy, Society and Culture. Volume I*, at 32. Cambridge MA and Oxford: Blackwell.
3 *Ibid.*
4 *Ibid.*, at 30.
5 Castells, M. 2012. *Networks of Outrage and Hope. Social Movements in the Internet Age*, at 25. Cambridge: Polity Press.
6 Edwards, M. 2014. *Civil Society*, at 81. Cambridge: Polity Press.
7 *[The screen of a mobile device (as opposed to earlier television and computer screens). Ed.]* *Supra*, note 2, at 78.
8 Tapscott, D. 2008. *Wikinomics: How Mass Collaboration Changes Everything*, at 45. New York: Portfolio, Penguin Group.
9 *Ibid.*, at 58.
10 *Supra*, note 2, at 31.
11 *Ibid.*
12 *Supra*, note 8, at 63.
13 *[See https://www.theguardian.com/world/2016/apr/06/panama-papers-all-revelations-so-far-data-leak; and https://www.globalwitness.org/en-gb/press-releases/call-tax-havens-open-after-offshore-expose/?gclid=CO31jNi9hM4CFRITGwod1EAIzQ. Ed.]*
14 Mohr, N., Lalloz, E. and O'Brien, D. 2012. *Mobile Web Watch 2012*, at 16. New York: Accenture Publishing. Online at https://www.accenture.com/t20151123T001914__w__/ch-de/_acnmedia/Accenture/Conversion-Assets/DotCom/Documents/Local/de-ch/PDF/Accenture-Mobile-Web-Watch-Internet-Usage-Survey-2012.pdf.
15 *Supra*, note 8, at 75.
16 For more detailed information on the organisation's activities, see Ushahidi website: http://www.ushahidi.com/mission/.
17 *[See https://en.wikipedia.org/wiki/Web_2.0. Ed.]*
18 Kaldor, M., Moore, H. and Selchow, S. 2012. "Global Civil Society 2012: Ten years of critical reflection", at 30. *Global Civil Society Yearbook*. London: Palgrave Macmillan.
19 Deibert, R. 2012. "The Growing Dark Side of Cyberspace (…and What To Do About It)". *The Penn State Journal of Law & International Affairs* 1(2): 260–274, at 263.
20 Grant, R.W. and Keohane, R.O. 2005. "Accountability and Abuses of Power in World Politics". *American Political Science Review* 99(1): 29–43.
21 Arendt, H. 1970. *On violence*, at 45. Boston MA: Houghton Mifflin Harcourt.
22 Keohane, R.O. 2011. "Global Governance and Legitimacy". *Review of International Political Economy* 18(1): 99–109.
23 Zürn, M. 2004. "Global Governance and Legitimacy Problems." *Government and Opposition* 39(2): 260–287.
24 *Ibid.*, at 261.
25 *Supra,* note 22, at 103.
26 *Ibid.*, at 29.
27 *Ibid.*, at 26.
28 Poate, D., Gregorowski, R. and Blackshaw, U. 2011. *External Review of IUCN 2011, Final Report.* London: ITAD in association with Biodiversity International Ltd. Online at http://cmsdata.iucn.org/downloads/external_review_of_iucn_2011.pdf.
29 The Motions Process was revised after 2012, with new statutes in 2015.
30 IUCN. 2012. *Resolutions and Recommendations*. Gland: IUCN. Online at http://2012congress.iucn.org/cmsdata.iucn.org.iucn.vm.iway.ch/downloads/resolutions_and_recommendations_2012.pdf.
31 *Ibid.*
32 *Supra*, note 28, at 115. *[The other 28.1 percent of the membership is divided as follows: 6.2 percent are international NGOs, 12.3 percent are government agencies, 7.2 percent are research organisations, and the remaining 2.4 percent are characterised as "other organisations". The government agencies that are members are generally counted among the State members. Ed.]*
33 *[According to the IUCN Statutes (online at https://www.iucn.org/downloads/statutes_en.pdf), resolutions and recommendations must receive a simple majority of each of the two primary categories of members – Category A, which includes State members, government agency members and political/economic integration organizations (such as the EU); and Category B, which includes both national and international non-governmental organizations. Ed.]*

Nagoya Protocol

The Missing Link in ABS

The Relationship between Resource and Product

by Morten Walløe Tvedt[i], Vincent Eijsink[ii], Ida Helene Steen[iii], Roger Strand[iv] and G. Kristin Rosendal[v]

Recently, some have raised expectations regarding the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (NP) (2010). They have claimed that, by agreeing and ratifying the NP and enabling its entry into force in October 2014, countries have begun to bring access and benefit sharing (ABS) closer to becoming a functional measure for equitable sharing of biodiversity-related benefits and responsibilities, while making funds available for conservation and sustainable use. What is still relatively unexplored is the mechanism for linking each particular genetic resource with the product or process purportedly created utilising that resource, that eventually generates the benefits to be shared. The term "genetic resources", as used in the NP and the Convention on Biological Diversity (CBD), is the starting point for

[i] Senior research fellow, Fridtjof Nansen Institute, Oslo, Norway.
[ii] Professor, Norwegian University of Life Sciences, Ås, Norway.
[iii] Researcher, Department of Biology, Centre for Geobiology, University of Bergen, Bergen, Norway.
[iv] Professor, Centre for the Study of the Sciences and the Humanities, University of Bergen.
[v] Research professor, Fridtjof Nansen Institute.

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this discussion. The benefit-related provision of the CBD and NP both refer to utilisation of genetic resources as the most important trigger for benefit sharing.

Despite the progress made in the NP, however, there are still open questions that need to be resolved before private enterprises can be effectively and legally bound to explore and utilise natural diversity in a manner that benefits all, including sharing a part of their earnings from genetic resources with the providers of such resources.[1] These questions were left open by the CBD and NP, and thus have to be resolved at the domestic scale, *i.e.*, through national implementation and in private ABS contracts. Indeed, the NP presupposes that all countries, both user and provider, will adopt national implementing legislation or at least a national policy regulating access to genetic resources.[2] The authors argue that such national measures are essential, due to the difficulties involved in specifying triggers for benefit sharing and turning them into concrete, contractually binding language. Specifically, there is a need to clarify the relationship between each genetic resource and the product, process or service derived through its utilisation, which creates an economic benefit.

ABS is based on a somewhat unrealistic model, which assumes that access to one specific genetic resource leads to the utilisation of that specific resource in a specific way, which in turn creates specific quantifiable benefits that will be shared with its provider. This article discusses the nature and strength of the linkage between the genetic resource and whatever product, process or service is derived from or produced through utilisation of the resource. It focuses on two key questions: "What linkage between genetic resource and product is required to trigger a benefit-sharing obligation?" and "How can this linkage be evaluated, quantified and applied in a manner that creates a predictable and reasonable benefit-sharing element within the ABS regime?"

These topics have recently engendered practical concerns for the authors of this paper, while working together in the interdisciplinary research project "NorZymeD" which aims to develop new and improved hydrolytic enzymes for blue and green biorefining industries. Figure 1 shows a possible route from genetic resources to product in this project, illustrating the potential complexity of the value-creating chain and the long pathway that runs from a genetic resource to a product.

In 2013, the Norwegian government circulated a proposal for a new ABS administrative regulation in which a benefit-sharing obligation for access to and utilisation of Norwegian genetic material was described in detail. This draft regulation was not, however, sufficiently detailed to handle practical situations such as those shown in Figure 1. The present paper uses this particular research and development project as its point of departure for a broader analysis of the legal situation of ABS. Its goal is to demonstrate how to understand, develop and, eventually, quantify the link between genetic resources and the products from which benefits are expected to be shared with the country providing access to its genetic material. This is a critical issue since it defines the functional trigger of the obligation to share benefits. In addition to being crucial for ABS under the CBD, exploring this link is also of interest for implementation of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) and the World Health Organization's system for exchange of influenza viruses with pandemic potential. When a private party enters into a contract with a country or an indigenous or local community, clarification of the triggers for the benefit-sharing obligation is an essential element. Existing contractual practice or background law do not currently clarify these issues. Accordingly, the issue is of quite general importance and, as will be clear in what follows, of considerable complexity. The many bioprospecting and biotechnology cases with relevance to ABS legislation demonstrate the continuing existence of a large number of gaps in this element of the ABS system. While examining the case of NorZymeD in detail, the authors will also comment on the extent to which the aspects and implications discussed are more generally relevant.

The Simple Story: One Product Harvested from One Genetic Resource

ABS is often understood as a relatively straightforward relationship between a particular genetic resource, sometimes understood as a particular biological sample, which is used to develop a particular product. Norwegian regulatory discourse provides a striking example of this view and its implications. The Norwegian regulatory proposal of 2013 cited the story of a fungus called *Tolypocladium inflatum*, which was found in 1969, identified and used to develop the drug Cyclosporine A[3] – an immunosuppressant used to prevent the body from rejecting a transplanted organ. In this much discussed case, a Swiss researcher took soil samples on the Hardangervidda (a mountain plateau in central Southern Norway), brought them back to the laboratory in Switzerland, and developed a new blockbuster drug (Sandimmun – a commercial name for Cyclosporine A) that has created revenues of approximately US$ 1 billion/year for Sandoz and later Novartis.[4] Cyclosporine A is a natural product of *T. inflatum* and as such can be harvested directly from the fungal culture. The drug is still produced in this way and not by chemical synthesis. As late as in 2000 (and possibly still) the originally collected culture from the Hardangervidda soil sample was still being used. Thus, this example rather clearly supports the perception of one genetic resource/sample leading directly to one chemical product that can be sold as one blockbuster drug, producing identifiable benefits.

This story played a prominent role in the understanding of genetic resources in Norway and is described in detail in the draft regulation. The use of such examples, however, is ambiguous, and there may be a tension between this story's simplicity and its representativity.

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While comparable situations may arise, such as vaccine development,[5] the majority of genetic-based innovation cases unfold in a more complex manner.

Sectors and business models involving the utilisation of genetic material differ. There are a number of far more indirect, complicated and complex ways of using genetic material. As an example, one might ask how the Cyclosporine A case would be affected if Sandoz/Novartis were to market a synthetic variant of the drug, developed after years of research and large investments, based on their identification of the compound in the fungus from Hardangervidda?

The Norwegian draft regulation cites *The Economics of Ecosystems and Biodiversity* (also known as the TEEB report) to support its statement that the pharmaceutical sector has an estimated annual value of US$ 600 billion of which 25–50 percent is based on genetic resources.[6] Although the value chain may in some cases be difficult to trace, that in itself is not an argument against sharing benefits from the utilisation of genetic resources and sharing responsibilities for maintaining biodiversity.

This article explores enzyme development for advanced biorefining as an alternative model for exploring the genetic resources-product link – a model that is much more complex than the example of Cyclosporine A. In the following section, we provide a theoretical discussion of practical situations as well as the biotechnology project NorZymeD as an illustration of the difference between it and the Cyclosporine A example.

How is Value Created in and Added to a Biotechnological Product?

To those companies and institutions engaged in the science of drug development and other fields of biotechnology, bioprospecting represents both opportunity and risk. The opportunities lie in the undiscovered diversity of biological functions and chemical structures that can be utilised for new products and services. The risks are several. Promising discoveries and their successful utilisation at an industrial scale are uncertain and infrequent. Commercial success depends on (large) investments in research and development, issues of property rights, market competition, profit margins and lately also ABS schemes. In the scientific debate, one will find optimistic as well pessimistic perspectives on bioprospecting, the latter arguing that combinatorial chemistry and, in the case of enzymes, high-throughput enzyme engineering, offer equally promising or better alternatives.[7] One way to pursue this debate is to ask how value is created in and added to a biotechnological product; what steps are (or may be) taken; and what kind of capital is invested in the process (natural capital including genetic resources, infrastructure, labour power and prior knowledge). Our main example concerns development of new and/or improved hydrolytic enzymes for improved bioprocessing of lignocellulosic biomasses such as wood and by-products from the fish industry.

One line of work is the development of new candidate enzymes. This may be done in different ways and by different actors. Often academic and public institutions take the first steps – collecting, describing, systematising, screening for bioactive compounds and undertaking bio-assays to promote commercial use of the material.[8] For the purpose of clarity, we provide three utilisation paradigms below, to which we shall return several times in the course of our analysis:

A) **Optimising known enzymes into candidates**. One may begin with known enzymes (*e.g.*, those in current use) and try to change their molecular structure, with the aim of optimisation (improving their functional properties). The work, laboratory infrastructure and scientific knowledge necessary in order to imagine and identify promising changes, and to design a rational optimisation strategy, can be done without any input of new genetic resources. Publicly available information (see below) may sometimes be useful in this work. For example, it may use known typical sequence features of enzymes produced by organisms living under extreme conditions. One question is whether this known enzyme in current use is still linked to a genetic resource in a manner that would trigger benefit sharing.

B) **Searching for candidates in libraries**. One may search in the large publicly available libraries of known genes and enzymes. These libraries carry information on structure and, to some degree, on biological function that is either known or postulated on the basis of structural similarity. This requires work and the scientific knowledge necessary to be able to utilise the information in the libraries. For the libraries, again a similar question is how the information on structure and biological function are linked to a genetic resource in a manner triggering benefit sharing.

C) **Prospecting for candidates**. One may perform bioprospecting in order to discover new candidates. This requires knowledge and work to devise a search strategy, and knowledge, work and infrastructure to perform the searches. For instance, in the case of NorZymeD, scientific knowledge led to a search for genetic resources at high-temperature vents in deep oceans. Searches of this sort require large investments in work, equipment and infrastructure. If new genetic resources are found, they enter the process as natural capital. For material found in the wild, the origin is more direct; however, it can become problematic to trace the link back to such material after several steps of research and development.

Paradigms A, B and C are neither mutually exclusive nor independent. Because of the risks and uncertainties involved in each, a rational strategy for enzyme development may be to combine all three. For instance, new knowledge about existing enzymes (A and B) may refine the bioprospecting strategy (C), increasing its chances of success. Conversely, characterisation of the

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structure and functions of hitherto unknown enzymes (new genetic resources) may lead to a refinement of strategies A and B. One pertinent question is whether a genetic resource has been "utilised" if its scientific characterisation contributed to an improved search strategy by which new product candidates were found in existing enzyme libraries. Furthermore, one needs to ask how the contribution of the genetic resource to the added value of a product depends on the size of the contribution of the other, co-existing and coordinated components of the overall search strategy.

The manner in which the resource is used may also vary. In the case of Cyclosporine A, the substance can be taken directly from the fungus to the final product (after a process of chemical separation). In other situations, however, there may be non-trivial research and development tasks involved along the path to a final product, and the amino acid sequence, spatial structure and/or the functional properties of the final enzyme may be quite different from the original enzyme candidate(s). Such tasks also require their own work, knowledge and infrastructure.

When dealing with enzymes, however, the situation becomes more complicated. One particularly difficult question is how much an enzyme must be modified, by truncation, fusing to another protein or, most commonly, by one or more changes in the protein sequence, before it is no longer reasonable to say that it is still the same, albeit modified, enzyme. Notably, such modifications are often essential in developing a promising lead enzyme into an industrially applicable biocatalyst, so that both the original enzyme candidate and the modifications are necessary conditions for achieving the final product.

To complicate matters further, the development of an industrial enzyme product involves a number of other non-trivial tasks that require work, knowledge and infrastructure (Figure 1). Returning to the Cyclosporine A story, other fungi were known to produce the same substance. The specific advantage of *T. inflatum* was its readiness to grow in culture.

In general, the task of industrial-scale production may be very challenging and involve a number of steps:

(1) Synthesis of the gene with codon optimisation for the expression host, meaning that the gene sequence, but not the protein sequence, will be changed considerably for the gene.
(2) Finding the most suitable expression host and optimisation of enzyme production to levels that are economically sustainable.
(3) Downstream processing of the produced enzyme, including, *e.g.*, partial purification from culture broth.
(4) Application testing and formulation of the enzyme product, either as a stand-alone enzyme or as part of an enzyme cocktail (see Figure 1).
(5) Optimising enzyme properties using protein engineering technologies; properties need to be adapted to use in one or various industrial processes that may vary in terms of *e.g.*, operational temperature and pH.
(6) Re-optimising the industrial processes in which the enzyme is going to be used (an iterative process, together with step 5).

Several of these steps are far from trivial and will include important innovations and inventive steps. Thus, the apparently "simple" challenge of producing sufficient amounts of the enzyme at a sufficiently low cost is far from trivial. If each of these steps happen in one single private company, then tracing the link from the material to the final product is easier than if the steps are made in different companies, some without a contractual obligation to the provider of the genetic material. The creation of a new product can be seen as a complex process that involves contributions of work, knowledge, means of production, infrastructure and natural capital (which includes new genetic resources). The different contributions can be described as (more or less) necessary components in a sufficient causal complex. A particular genetic resource may be needed for one particular technical solution to an obstacle in making the product; but this may be just one solution among several others that do not require the genetic resource in the same way or at all. In the case chosen here, we find this complexity. In other cases, initial steps can be funded and conducted by publicly funded institutions. The collection activity itself can make a very valuable contribution to the bioprospecting process since it then becomes easier for private actors to get access to ready-made assays that can shorten the period of search. Collections or gene banks are often funded by the public or the public contributes with infrastructure; in all such situations, ABS becomes a question of whether and how the private companies, national or foreign, shall be obliged to contribute to maintaining these early steps in the innovation process. Perhaps both for our case and in general, these challenges are related to how one defines "access". If access is understood to refer to the point at which things are collected in the wild, ABS regulation will have consequences that are quite different from those that would arise where "access" is understood to refer to the point at which a private company undertakes direct R&D activities involving genetic material (prepared genetic samples and bio-assays of the resource's composition and characteristics).

A final complexity concerns the identity of the product. Let us imagine that a new enzyme is discovered that is remarkably stable at high temperatures and salinity (which is a research goal for our NorZymeD project). Perhaps the enzymatic function of this protein is without commercial interest. However, as already alluded to above, the scientific characterisation of the protein may reveal structural features that enable it to maintain stability. Let us then imagine that a known industrial enzyme is modified so that these same stabilising structural features are now achieved in this enzyme. The modified enzyme can be used under higher temperatures and salt concentrations, and this increases the efficiency of the industrial process which allows the industrial company to increase the total value of its end product.

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So, the genetic resource was utilised, but what was its product:

- knowledge about protein stability?
- the modified (other) enzyme?
- the improved industrial process?
- the increased amount of end product?
- all of the end product? or
- all of the above?

These questions, along with the one concerning when "access" is happening, are core questions that ABS will have to resolve for the system to become a functional legal system.

Genetic Resources – the Derivative Discussion in the CBD

After having considered these examples of the complicated reality of the conversion of genetic resources to commercial products, the next issue is to explore how to deal with this reality within the framework of the legally binding treaty-language of the CBD and the NP. The question is to explore how the core definitions in international law relate to this rather differentiated situation in research and development.

The "Genetic Resources" Definition

The idea of the CBD, as supplemented by the NP, is to establish legal regulation targeting the biological material which serves as inputs to the kinds of innovative processes described above. The CBD establishes "genetic resources" as a legal and political term in the following wording: "'Genetic resources' means genetic material of actual or potential value…. 'Genetic material' means any material of plant, animal, microbial or other origin containing functional units of heredity".

The idea of this definition is to confirm a legal basis for countries to regulate aspects of property rights and rights to access genetic resources.[9] The challenge is how this definition can relate to the actual world of biotechnology. The term which triggers benefit sharing is "utilization of genetic resources". Thus, the trigger for when biotechnology is obliged to share benefits consists of two elements.

The first element is that "genetic material" may have any biological origin, "plant, animal, microbial or other", and is, as has been noted elsewhere, "a subset of biological resources".[10] This means that all the three examples from above, A, B and C, are included by this element in the definition as long as the origin of the samples is biological, even after the information has been transferred into another form, *e.g.*, a synthetic gene.

The definition of "genetic resources" further depends on two criteria: firstly, "functional units of heredity", and, secondly, the "value" of such functional units of heredity. The meaning of these expressions is not elaborated in the CBD, although their definition and practical application are essential to establishing a legal framework that regulates the actual utilisation of genetic resources (both for the users and for the countries receiving benefits) in a manner conducive to the needs of conservation and sustainable use of biological diversity.

"Functional" is used here in a biological sense, and relates basically to genes, which, when the CBD was drafted (1992), were generally considered the only functional units of DNA in organisms. "Functional" has several connotations in the English language, two of which are relevant here: "relating to, or having a function" and "working or operating" (*Compact Oxford English Dictionary*). Both these understandings are valid for the definition covering the situations described above in paradigms A–C. The main idea of this term is to establish a distinction between use of biological resources for drawing benefits from the hereditary material and the pure bulk biological properties of the organic material (*e.g.*, using a gene found in seaweed *versus* eating the seaweed). "Functional" could refer both to the genetic structure *per se*, and to the information encapsulated in the DNA sequence, which can be screened and transferred into another form and become functional.[11] Vogel *et al.* claim the aspects of "genetic resources as natural information" to be more important than the value as biological material.[12] A consequential argument supports this interpretation: if genetic information were not covered by the definition, development of new techniques would quickly outdate the CBD. In conclusion, there are convincing arguments for the term "genetic material" to also cover cases where genetic information is transferred into new modes of appearance and states. Summing up, from the practical perspective in biotechnology, paradigms A–C above are all covered by the definition and thus potentially trigger a benefit-sharing obligation.

Returning to the CBD/NP definition, "genetic resources" are defined as genetic material of "actual or potential value". When utilisation of biological material aims at capturing the value of the genetic material, then this criterion in the definition is met. In biotechnology, typically the value is mostly connected to the use of the genetic structure and information, so this element of the definition would not make any of the examples discussed above fall outside the scope of the obligations. ABS rests on a fundamental separation between, on one hand, sales of biological resources for bulk purposes (for example, when coffee is sold to a retailer), and, on the other, the utilisation of the genetic material in, *e.g.*, plant breeding or the development of a new industrial enzyme. The exact economic value of a certain gene or part of a DNA molecule is difficult to assess before it has undergone research and has been utilised. The use of a gene may take many forms and may include several value-creating steps, as discussed above and illustrated in Figure 1.[13]

Thus, the CBD definition of "genetic resources" does not delimit the scope of benefit-sharing obligations in respect of any of the activities in the examples above. We may also conclude that the way that the CBD defines "genetic resources" does not create the legal certainty needed by businesses that seek to determine whether or not benefit-sharing obligations apply.

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"Utilization of Genetic Resources"

One might have hoped that the NP would bring about more clarity and guidance to the question of which activities should trigger benefit sharing. In the negotiations leading to the Protocol, these issues were indeed discussed. The discussions focused on two questions: whether "derivatives" are included in the definition of genetic resources; and, to a lesser extent, on what is meant by "utilization of genetic resources". Instead of adopting concrete guidance clarifying this question, the NP adopted only new, broad and unspecific language, building on the definition of genetic resources in the CBD. Article 2 of the NP "defines" the "utilization of genetic resources":

> *(c) "Utilization of genetic resources" means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention;*
>
> *(d) "Biotechnology" as defined in Article 2 of the Convention means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.*

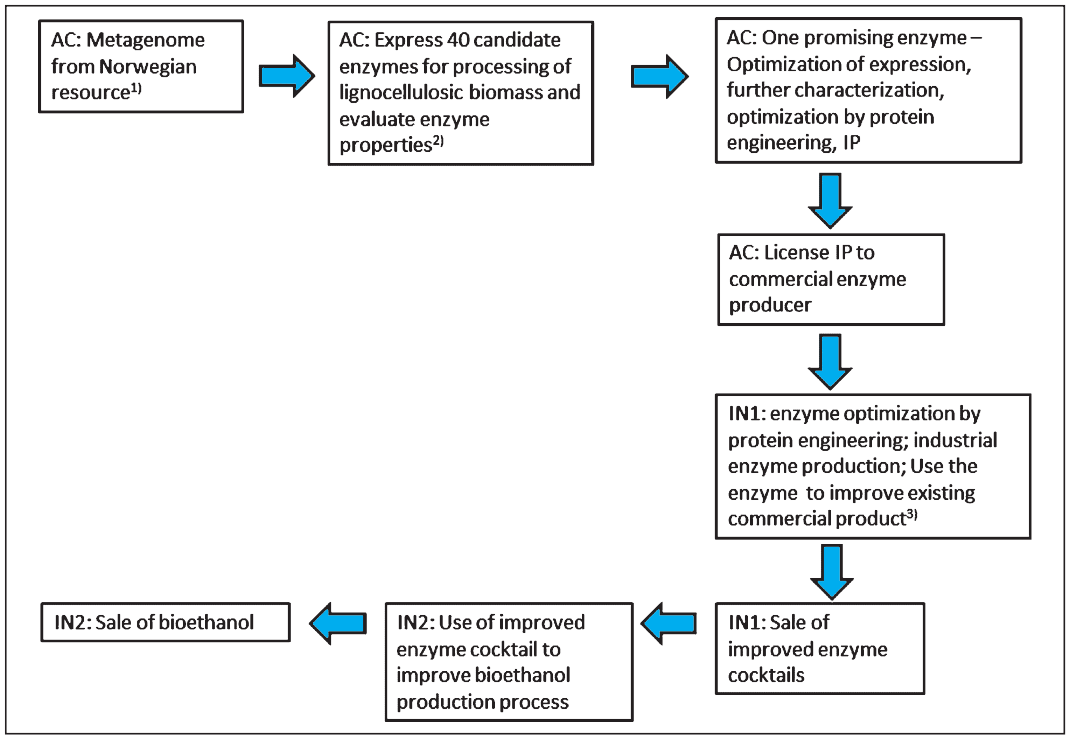
From this definition, the NP appears to broadly include activities that might trigger benefit-sharing obligations at the national level, although the wording does not clarify what triggers the benefit-sharing obligation.

In an attempt to add more specificity to the definition, Article 2 of the NP also defines "derivatives":

> *(e) 'Derivative' means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity.*

Again, this definition helps in defining the breadth of genetic resources and their utilisation, showing *e.g.*, that expressed enzymes may be included, but nowhere does the Protocol link specific benefit-sharing obligations to this definition. Notably, the definition is linked to "biochemical compound" and draws the attention away from the informational aspects of genetic material.

Figure 1. One possible scenario for developing industrial enzymes for processing of lignocellulosic biomass from genetic resources (using the Norwegian NorZymeD project, a typical enzyme discovery project, as a model)



Key: AC = academia; IN1 and IN2 represent different industries.

Notes

1) Genetic resources may vary from genuinely unique resources such as microbial DNA gathered from deep-sea thermal vents, which are only accessible to certain countries using advanced infrastructure for harvesting these resources, to much more generally accessible microbial DNA harvested from biogas reactors or the gastro-intestinal tracts of a variety of animals or humans.

2) This step represents a major investment of resources, and is absolutely required in order to identify valuable elements in an otherwise very "wide" and not too interesting range of genetic resources.

3) It is possible to envision many scenarios, from the simple (the new enzyme is a product in its own right) to the highly complex. Enzymatic conversion of lignocellulose requires complex enzyme cocktails that have taken hundreds of years of soft labour power to develop and that may be improved by including the new enzyme or using the new enzyme to replace one of the existing enzyme components.

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A major complication is caused by defining the term "derivative" as "naturally occurring biochemical compound". This language leaves an open and crucial question, namely what is meant by "naturally occurring"? For example, is a protein using a recombinant expression of a synthetic gene based on the genetic information from a specific organism a naturally occurring compound? How much input from man, such as mutations in the natural protein sequence, is required before a compound is no longer "naturally occurring"?

Lack of Guidance on the Link between the Genetic Resource and the Product

In the discussion of the link between one genetic resource and a final product or service in the market, and the consequences of this link for benefit-sharing obligations, the wording of the NP does not provide any clarity, although such clarity has always been very much needed in order for the obligations to become enforceable and clear. These terms work well at the international law level, however, since they allocate discretion and obligations to countries in setting up their ABS systems. For national law and ABS contracts, a higher level of specificity is needed.[14]

Neither the CBD nor the NP is binding as such on businesses because obligations of international conventions bind States and not legal or physical persons. Therefore, these definitions must be transformed into concrete obligations at the level of persons, communities and entities if they are to become enforceable on their actual users. A search in the CBD database shows that nearly all existing national access laws use terminology indicating that they apply either "genetic resources", "genetic material" or the even broader concept of "biological resources", mostly repeating the broad and sweeping definitions from the CBD and the NP. In this way, national law is still too uncertain for businesses to know in a precise and exact manner when they are subject to the benefit-sharing obligations.

The Norwegian Proposition – and Challenges for General Rules

We shall turn now to our concrete example of Norway, where the Government is currently trying to incorporate the NP into a national access and benefit-sharing regulation. By use of this example, we will be able to analyse in greater detail the practical difficulties in providing legal certainty and clarity for users.

In 2009, the Norwegian Parliament (*Stortinget*) passed a comprehensive Nature Diversity Act regulating not only access to Norwegian genetic material, but also benefit sharing, where it involves Norway and Norwegians both as providers, and as users of genetic material from other countries.[15] The Act leaves the detailed questions concerning access to and benefit sharing from the utilisation of Norwegian genetic resources to be addressed in an administrative order. To this end, a draft administrative order was circulated by the Norwegian government in 2013, seeking to establish rules for ABS in a manner which could provide legal certainty both for the user and for Norway, when it is the country providing the resources. Such rules would apply to any potential user of Norwegian genetic resources, including Norwegian academic researchers, and the NorZymeD project discussed above.

The draft administrative order seeks to implement the Act of 2009 in a detailed and specific manner. Its two main mechanisms require (1) that everyone who wants to access genetic material must have prior permit; and (2) within six months after the permit is granted, there must be a private law agreement between the company as a user and a governmental or other legitimate representative of the provider regulating the details for how the use and benefit sharing will be organised.[16]

Draft Article 14 of the Norwegian proposition specifies the sharing of benefits, and tries to explain the link between the genetic material and the product. The following is our unofficial translation:

> *The issuing authorities shall be notified, as soon as the holder of a permit under § 8 has brought a product on the market based on Norwegian genetic material mentioned in the permit or derivatives thereof, or on information derived from that Norwegian genetic material.*[17]
>
> *The same applies if a method is initiated or developed to exploit the genetic material in order to obtain benefits. In such cases, the holder of the permit shall inform relevant stakeholders, such as landowners and indigenous and local communities, in accordance with an agreement with the issuing authorities about ongoing utilization.*[18]
>
> *Regardless of the number of permits granted according to § 8 that have contributed to a final product, the following percentages of the total gross income, for each fiscal year, from the exploitation of the genetic material, which includes sales of product, or invention of procedure* etc., *shall revert to the State:*[19]
>
> - *Up to 9,999,999 million NOK 0 percent*
> - *10,000,000 through 24,999,999 million NOK 1 percent*
> - *25,000,000 through 49,999,999 NOK 2 percent*
> - *50,000,000 through 99,999,999 NOK 3 percent*
> - *100,000,000 and more 4 percent.*
>
> *In cases where Norwegian genetic material has been or is insignificant for exploitation [of the product], the payment obligation ... is suspended.*[20]

The benefit-sharing requirements apply equally to Norwegian and foreign users of Norwegian genetic material. Norwegian users, however, conduct their activity under Norwegian jurisdiction, whereas foreign users would bring the genetic material out of Norway. In practical terms, compliance with the obligations and enforcement upon Norwegian citizens will be easier to implement and monitor than for foreign competitors using Norwegian genetic material. In our particular "NorZymeD" project, the metagenomes identified in the project will at some point be made publicly available. This raises the difficult and undecided question of

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whether other users of this then publicly available genetic information will trigger benefit-sharing obligations.

Exploring the Substantive Triggers for Benefit Sharing

In the Norwegian draft administrative order, the following are the key phrases with respect to the triggers for benefit sharing: "has brought a product on the market on the basis of the genetic material or derivatives" or "initiated or developed a method to exploit the genetic material". With these words, the Act describes the circumstances that will trigger the benefit-sharing obligation. The wording, however, is not easily applied to value chains in biotechnology processes that are more complex than those in the Cyclosporine A case (Figure 1). Based on this wording, each product along the value chain could potentially trigger benefit sharing. This renders the interpretation of the order a largely political choice. If the obligation is to be included for each intermediate product in Figure 1, a large revenue will potentially be collected. Further downstream in the process, the link between the genetic resources and the product/benefits created may become less clear. As such, it is potentially more controversial, especially since the gross sales can be expected to be higher. Where in a more complex development chain can a user be said to have brought a product to a market? One interpretation could be that every step in a value chain when an interim product is transferred from one academic institution to another or onwards to the first or second commercial partner, can be regarded as a product. Technically, when one company or academic institution transfers something to another one in exchange for money, it will be regarded as a product sold in a market.

The situations with more complex value chains prompt a challenging question: How can any of these transactions be "the product", when other steps in a value chain are not considered as products for the purpose of triggering benefit-sharing obligations? The wording describing a product "on the basis of the genetic material or derivatives" does not clarify the relationship between the material and the product further than that there is a legal assumption that the product or process must stand in a relationship to the material in some way. Some steps in the value chain are virtually unlimited. The question of whether some or all of these transactions trigger benefit sharing is a key one. It would be relevant to discuss whether any or all of paradigms A–C trigger benefit-sharing obligations, *e.g.*, where a molecule is found in nature; where the molecule is found in an *ex-situ* collection; and/or where the molecule is inspired by a natural one but where the actual one used is made artificially.

The formulation "on the basis of the genetic material or derivatives" in the draft does, however, cleverly capture the informational aspects of the genetic resource. The draft administrative order does not indicate that the obligation is limited to some of these steps, but rather that every sale/transfer qualifies as a product and requires benefit sharing.

Bearing in mind Figure 1, it is easy to see that a requirement of benefit sharing at each and every step, regardless of the importance, can become quite unreasonable (if not completely meaningless). Ideally, the draft administrative order could have solved this challenge by introducing a metric for the contribution of the genetic material or its derivative into the added value. It did not. Rather, it introduces a binary distinction between "significant" and "insignificant". For the latter, without further definition or explanation: the obligation is suspended. Without any guidance on how to assess the significance, importance or necessity of a genetic resource in an innovation process, this solution merely pushes aside the real issue, which is to make a substantive decision on the genetic resources-product linkage and the consequent ABS requirement.

One possible, pragmatic solution might be to introduce a concept of cut-off points in the value chain. For example, one could introduce a maximum number of transfers until the product's origin is no longer clear, at which point the right to receive benefit sharing will become exhausted. A rationale for such a cut-off point is that the larger its distance from the genetic resource, the more important comparatively other inputs in innovation will be. One counter argument against a cut-off point would be that the larger turnover will probably occur later in the value chain. This could be an argument against any cut-off point or rule of exhaustion. On the other hand, letting each transfer trigger benefit sharing could end up in creating an exorbitant total sum of aggregated obligations through the value chain. One (admittedly complicated) model for how to resolve this problem could be found in value-added tax (VAT) calculations. In Norway, anyone liable to pay VAT can deduct the VAT he paid for the goods and services consumed in his part in the value-creation process. Such a proposal could easily be perceived as a tax on biotechnology and will probably be met with political opposition. Also it will only be possible for the Norwegian government to collect such a tax from Norwegian companies or activities by foreign companies in Norway. This type of solution can be argued to have negative effects and thus be met with strong counter-arguments.

Surprisingly, neither the preparatory work nor the draft regulation set out to resolve these core and rather complex questions.

Which Entity is Obliged to Share Benefits?

It is not completely clear in practice which entity would be obliged to share benefits. In biotechnology situations, the first user – which has a contract with the provider/government – is usually not the entity within the development chain that creates large revenues. In fact, that entity is often an academic institution, researcher or small bioprospecting company. Although creating the highest value, users later in the value chain are usually not bound by the initial contract.

The need to comply with the law imposes an additional technical-legal challenge – the principle of legality. For the government to impose an obligation on

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its citizens, the wording of its act must be sufficiently clear in stating the entities subject to the obligation. Uncertainty in the draft administrative regulation on this point raises doubts whether that regulation has complied with this principle.

The draft administrative order contains references both to a public permit and a private law contract. Contract law is different from public administrative law. In contracts, it is normally the legal person being party to the contract that is also obliged to fulfil the obligations according to the contract. A contract has potential to regulate the future path of research and development by imposing obligations on the contracting parties to transfer the obligation onwards to their successors; however, only the original parties to such a contract are bound by its obligations. When basing the benefit-sharing obligation on a private law agreement, only the parties to that contract are bound. To bind any succeeding party, they must either go back to the initial contractual partner, in this case the government (or other legitimate representative of the provider), or the first user must enter into an agreement with the second user to substitute him into the contract. The draft administrative order defers this question to be resolved in each contract. This just pushes the challenges forward in time rather than resolving them in the draft regulation.

The Level of Benefit Sharing Required

The next question concerns the assessment of the level of benefit sharing, a related question being what is meant by "gross income". The answers to these questions provide the basis for calculating the value that is due for sharing. The contract between the government or other legitimate representative of the provider and the user of genetic resources must specify the principles of accounting that can be used for calculating the gross sales. If left to a general rule of accounting, then it will become difficult to identify which general costs of the company are connected to the product triggering ABS. To provide legal certainty to the users of genetic resources, this is a topic which must be clarified.

The draft administrative order is based on increasing percentages for higher gross income on the products. This recognises that a company has relatively higher costs for lower volumes of sales. This will raise challenges as the development costs can be deducted over many years leaving the gross income apparently higher during the first years of the life cycle of the product. Again, we observe that no technical answer to these questions can be developed without simultaneously taking a stand on the underlying normative, political issue of determining the right level of benefit-sharing obligations and its dependence on the strength of the linkage between the genetic resource and the product.

Can Mutually Agreed Terms Resolve the Challenges?

Having observed these weak points and challenges in the draft administrative order, it seems clear that several of them can be resolved in the contract and permit that the competent authority designated by the government will enter into with interested users. This section will look into the possibilities of how to design clauses that will capture these ideas. The legal tool in the CBD and NP to solve this challenge is the concept of Mutually Agreed Terms (MAT). Using a contract as a supplement to the permit is also foreseen in the Nature Diversity Act and the draft administrative regulation. Using contracts as a tool to make ABS functional is a wise strategy as a supplement to the permit system.

A number of challenges can be foreseen in making well functioning contracts for ABS. One core challenge is that a contract requires that both parties accept the terms and conditions. In a permit system, the government representative can set one-sided terms and criteria, while a contract requires the acceptance of both parties. A contract has potential to create a tailor-made system for granting access. The most important limitation to a contract, as is also recognised in the draft regulation, is that it is only valid and binding between the two parties. The draft regulation specifies that the one holding the permit is obliged by the draft regulation to pass on the obligations in the permit and the contract to any later users of the genetic material. Thus, the first contract party would infringe the contract if not ensuring that the obligations follow the material. However, the benefit-sharing obligations as such can only be enforced upon a later user who has a contractual obligation to share benefits.

In paradigms A–C, the previous user, the collection/biobank, and the bioprospector alike, must pass on any benefit-sharing obligation that is to be enforceable on any second user of the material or genetic information. When or if the draft order enters into force, this will be relevant for the NorZymeD project. Each transfer between the partners in the value chain would have to include a transfer of the contract, imposing its initial obligations onto the next user. Perhaps this could be avoided if all the partners to a consortium could be parties to the original contract. From an efficiency perspective, establishing the consortium member institutions as parties to the contract would increase the number of companies and institutions that are bound directly to the original benefit-sharing obligation. This would make it easier for the government to get benefits shared back.

By increasing the number of participants in the application and the contract, the government gets more companies and academic institutions from which to solicit benefit sharing. Depending on how the subject matter and rest of the contract is formulated, perhaps the contract could be framed in a manner to avoid a situation where benefits are required to be shared for each transaction. Most research and innovation consortiums, however, are not considered to be independent legal persons. Rather, such a consortium may be variously owned (possibly by a host institute or university), and it may cease to exist when the project ends. Therefore, each of the institutions in a consortium could be required to undertake independent contractual obligations. The

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specifics of these issues are not spelled out in detail in the draft regulation and will need to be clarified. We may sum up by stating that there are a number of critical questions that must be resolved and dealt with for this mechanism to become the functional tool anticipated by the CBD and NP.

Conclusion

Solving the dilemmas of ABS regulations is not an easy task. Countries and companies will struggle with them for years to come in order to make ABS a workable model for payment for ecosystem services and/or integrating the value of nature into company accounting. ABS has not yet been shown to provide a lot of economic benefits to conservation and sustainable use of biodiversity in developing countries. There are many reasons for this, one of which is the lack of implementation of user-country legislation to create an incentive or obligation on businesses to share benefits. The long-lasting negotiations leading to the NP somewhat guided the attention of countries towards the international level and away from implementing functional systems in their national laws and policies. Almost no effort was spent on thinking strategically about how contracts should be written that would make ABS work in real life. It is easy to see now that countries would have been better off following two tracks simultaneously, *i.e.*, by developing national laws and domestic experiences at the same time as sitting at the negotiating table.

Now that the NP finally has entered into force, there is a need for implementation efforts to create the specificity, predictability and legal certainty that the general, sweeping formulae of the CBD and NP are unable to provide. This is important for all stakeholders. Governments will not be able to collect benefits until an operational system is in place, in both user countries and providing countries. On the innovation side, legal uncertainty may have a dampening effect on exploration of genetic resources for product development.

This article has shown large differences between the model bioprospecting case of Cyclosporine A, which the Norwegian ministries used as a guideline for developing an administrative order, and the more complex ways in which bioprospecting research and development take place in the real world. The significance of these differences is revealed by the two key questions set out in the introduction: "What is the linkage required to trigger a benefit-sharing obligation?" and "How is the linkage to be evaluated, quantified and applied, in order to create a predictable and reasonable benefit-sharing regime?"

When the Norwegian ministry chose Cyclosporine A as a model case, the significance of these two questions was not acknowledged. Indeed, in that simple case, the link is obvious and trivial (at least in the simplest rendering of the story). National regulation or private contracts that do not address these two questions will continue to push the main issue forward, but fail to create the needed legal certainty.

One could imagine various roads ahead in order to resolve the main issue. The easiest solution would perhaps be to admit that no valid and reliable metric for the link between genetic resources and product can be expected, and resort to a standardised up-front lump sum payment connected to the issuing of the permit. Unless the lump sums are very high, this might eliminate the risk of the dampening effect on innovation, while countries may miss out on the opportunity for large incomes in the rare cases where genetic resources create blockbuster drugs and other commercial successes. The Norwegian draft administrative order appears to try almost the opposite – that is, to assume a close link (and, strangely enough, a closer link in cases of larger revenue) unless it is "judged insignificant", without specifying how to judge and who judges. This will fail to create legal certainty.

Benefit sharing is based on the idea that the receipt of benefits from the utilisation of genetic resources will motivate that beneficiary (provider) to maintain biodiversity as a resource in the long term. ABS seeks to counterbalance intellectual property rights, through which products based on genetic resources become the subject of private exclusive rights. ABS aims at protecting the balance by obliging users to share with the countries conserving biological diversity – introducing an equity perspective into these otherwise commercial transactions, especially where a poor country needs resources for biodiversity conservation. Where the public budgets have funded infrastructure, education, collection and development of high-value bioactive products, and industry comes in at a later stage, the equity element of ABS becomes highly relevant. When governments invest in infrastructure for biotechnology, securing a fair and equitable share of benefits created from the use of genetic resources becomes a tool for re-establishing the equity in the situation.

More research could create a stronger knowledge base for the needed political and legal decisions. We have found some academic studies on the economic relationships between bioprospecting and innovation;[21] however, the current knowledge base is not strong enough to support firm conclusions. In informal conversations, both scientific and industrial stakeholders have expressed the view that a four-percent benefit share on the last product or service in the value chain would be intolerably high, given the normal margins in the market. However, more systematic knowledge is clearly needed.

Knowledge alone will not solve the issue; there are normative choices involved that are also partly political. If we return to paradigms A, B and C, we may for instance discuss the reasonableness of imposing ABS on the use of genetic resources that are identified in publicly available libraries. One could argue that such resources are no longer so tightly connected to the geographical territory of a State as to reasonably invoke a national benefit-sharing requirement. On the other hand, large collections of genetic material (samples) can be found within public institutions and a great deal of this material has already

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been made ready for further examination of their active compounds through public funding (infrastructure, collecting, systematising, identifying active compounds *etc.*).[22] Drawing a general conclusion that holding genetic resources in a collection cuts off the benefit-sharing obligation would be the task of a democratic process rather than a private contract arrangement.

Private contracts – mutually agreed terms – on the other hand, would be the right venue for the resolution of several practical difficulties and dilemmas. The case of NorZymeD illustrates the model where university and academic entities are conducting the research in nature or libraries and working with larger or smaller companies in setting up their innovation chain. This particular case exemplifies that if academic institutions are excluded from ABS regulations initially, it becomes inherently difficult to grasp the benefits from the commercial partners since only the first user is bound by the contract. The only two ways to bind a commercial partner to a contract are by involving them in the original agreement from the start or by later accepting certain terms and conditions. It is difficult to foresee how a commercial company would agree to an open negotiation after having invested in research and development, and it is unlikely that a company would freely agree to new obligations, unless there were certain requirements motivating them to do so.

In conclusion, ABS must work on clarifying the missing link between the genetic resources and the product or process in the market. The challenge is to make this a regulation designed to cover the Cyclosporine A case, applicable to NorZymeD project, as well as other research and business models.

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FNI's online library includes a range of materials on ABS, and is available at www.fni.no.

Notes

1 Tvedt, M.W. 2014. "Beyond Nagoya: Towards a Legally Functional System of Access and Benefit-sharing". In: Oberthür, S. and Rosendal, G.K. (Eds) *Global Governance of Genetic Resources: Access and Benefit Sharing after the Nagoya Protocol*. London/New York: Routledge.

2 *Ibid.*

3 *Forslag til forskrift om uttak og utnytting av genetisk materiale (bioprospekteringsforskriften)*, at 2. Oslo: Royal Fisheries and Coastal Affairs Department/Royal Ministry for Environmental Protection.

4 Svarstad, H., Bugge, H.C. and Dhillion, S. 2000. "From Norway to Novartis: Cyclosporin from Tolypocladium inflatum in an open access bioprospecting regime". *Biodiversity and Conservation* 9: 1521–41.

5 From the bacterium or virus against which one wants to make a vaccine, the developer can take ribonucleic acid, deoxyribonucleic acid (DNA), proteins, or parts thereof and for use more or less directly in the vaccine. A Norwegian example of this is the vaccine against Pancreas Disease (PD), see Tvedt, M.W. 2013. "Disentangling Rights to Genetic Resources Illustrated by Aquaculture and Forest Sectors". *Law, Environment and Development Journal (LEAD)* 9(2): 138–139, at http://www.lead-journal.org/content/13127.pdf.

6 European Communities. 2008. *The Economics of Ecosystems and Biodiversity*. Wesseling: Welzel and Hardt.

7 Firn, R. 2001. "Bioprospecting – why is it so unrewarding?" *Biodiversity and Conservation* 12: 207–16; and Arrieta, J.M., Arnaud-Haond, S. and Duarte, C.M. 2010. "What lies underneath: Conserving the oceans' genetic resources". *Proceedings of the National Academy of Sciences of the United States of America* 107(43): 18318–18324.

8 Prip, C., Rosendal, G.K., Andresen, S. and Tvedt, M.W. 2014. *The Australian ABS Framework: A Model Case for Bioprospecting?* FNI Report 1/2014. Lysaker: Fridtjof Nansen Institute (FNI); and Rosendal, G.K., Myhr, A.I. and Tvedt, M.W. [Forthcoming]. "The Role of ABS legislation in marine bioprospecting: Lessons from Australia for the role of Marbank in Norway".

9 The term "genetic resources" has been explored elsewhere, see Schei, P.J. and Tvedt, M.W. 2010. *"Genetic Resources" in the CBD: The Wording, the Past, the Present and the Future*. FNI Report, no. 4/2010. Lysaker: FNI; Tvedt, M.W. and Schei, P.J. 2014. "The Term 'Genetic Resources': Flexible and Dynamic while Providing Legal Certainty?" In: Oberthür and Rosendal, *supra*, note 1; and *supra*, note 5.

10 Ad Hoc Open-ended Working Group on Access and Benefit-sharing. "Report of the Meeting of the Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches", at 6. CBD, Paris, 2–8 April 2009 (UNEP/CBD/WG-ABS/7/2).

11 Tvedt and Schei, *supra*, note 9. Tvedt and Young identified a broad concept of genetic resources, including: "(i) the micro/physical component (extracting, multiplying and studying genetic or biochemical material); (ii) the information (synthesis or other development, or processes to do so); and (iii) intangible and tangible being used together (*i.e.*, where a molecule/sequence cannot be synthesized or multiplied, but must be continuously collected from wild sources)" (see Tvedt, M.W. and Young, T.R. 2007. *Beyond Access: Exploring Implementation of the Fair and Equitable Sharing Commitment in the CBD*, at 65. IUCN Environmental Policy and Law Paper, no. 67/2. Gland: IUCN).

12 Vogel, J.H., Álvarez-Berríos, N., Quiñones-Vilches, N., Medina-Muñiz, J.L., Pérez-Montes, D., Arocho-Montes, A.I., Val-Merniz, N., Fuentes-Ramírez, R., Marrero-Girona, G., Valcárcel Mercado, E. and Santiago-Ríos, J. 2011. "The Economics of Information, Studiously Ignored in the Nagoya Protocol on Access to Genetic Resources and Benefit Sharing". *Law, Environment and Development Journal* 7(1): 54–65, at 55; and also Kamau, E.C., Fedder, B. and Winter, G. 2010. "The Nagoya Protocol on Access to Genetic Resources and Benefit Sharing: What Is New and What Are the Implications for Provider and User Countries and the Scientific Community?" *Law, Environment and Development Journal* 6(3): 248–262.

13 Ad Hoc Open-ended Working Group on Access and Benefit-sharing. "The Role of Commons/Open Source Licences in the International Regime on Access to Genetic Resources and Benefit-sharing", at 28. CBD, Eighth meeting, Montreal, 9–15 November 2009, Item 3 of the provisional agenda (UNEP/CBD/WG-ABS/8/INF/3, 30 July 2009).

14 *Supra*, note 5.

15 *Naturmangfoldloven*/Nature Diversity Act, Norway, LOV-2009-06-19-100.

16 *Forskriftsutkastet* [Draft Administrative Order], Article 14, sections 4, 6 and 9.

17 *Ibid.*, para. 1: *Så snart innehaveren av en tillatelse etter § 8 har brakt et produkt i omsetning på grunnlag av det genetiske materialet eller derivater av norsk genetisk materiale eller utledet informasjon som tillatelsen gjelder for, skal tildelingsmyndigheten varsles.*

18 *Ibid.*, para. 2: *Det samme gjelder dersom det er satt i gang eller utviklet en framgangsmåte for å utnytte det genetiske materialet med sikte på å oppnå fordeler. I slike tilfeller skal innehaver av tillatelsen etter nærmere overenskomst med tildelingsmyndigheten gi løpende informasjon om utnyttingen til relevante aktører slik som grunneierne, urfolk og lokalbefolkning.*

19 *Ibid.*, para. 3: *Følgende andel av samlet bruttoinntekt fra utnytting av det genetiske materialet herunder salg av produkt, oppfinnelse av fremgangsmåte mv. for det enkelte regnskapsår skal tilfalle staten, uavhengig av antall tillatelser etter § 8 som inngår i produktet.*

20 *Ibid.*, para. 4: *Betalingsforpliktelsen etter tredje ledd gjelder ikke i tilfeller der norsk genetisk materiale er eller har vært uvesentlig for utnyttingen.*

21 Firn, *supra*, note 7.

22 Prip *et al.*, *supra*, note 8; and Rosendal *et al.*, *supra*, note 8.

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