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Access and Benefit Sharing Legislation for Marine Bioprospecting: Lessons From Australia for the Role of Marbank in Norway

G. Kristin Rosendal
Fridtjof Nansen Institute

Anne Ingeborg Myhr
GenØk—Centre for Biosafety

Morten Walløe Tvedt
Fridtjof Nansen Institute

Marine bioprospecting offers possibilities for sustainable innovation based on marine genetic resources. How to regulate the use of such marine genetic resources entails several challenges. The rationale for the introduction of legislation on access and benefit sharing (ABS) from the use of genetic resources is elaborated using Norway as a case. Similarities and differences from other initiatives are presented with Australia as the comparative case. Several lessons are transferable to the Norwegian situation, and may also be of high relevance to other countries introducing ABS legislation. In both Norway and Australia, there is an expressed need for an ABS system that can include a model that is based on access permissions rather than mere registration. There are difficulties involved in monitoring the genetic material from access to actual commercial product, and in distinguishing between bioprospecting for scientific and commercial use, which complicates a determination of when benefit sharing should be triggered. We suggest that the idea of benefit-sharing could be supported by the principle of cost-sharing.

Keywords CBD; user-country legislation; marine bioprospecting; genetic resources

A number of countries have collections of marine organisms. Collections are found in museums, within R&D institutions and private companies. Diverse groups of facilities have accumulated an increasing variety of sample types, such as marine benthos, microalgae and bacteria, extending over a wide range of biological species. As the collection and preservation initiatives have moved into inclusion of genetic materials for both scientific and commercial purposes, the need of appropriate legislation and contracts has become evident.

In this article, we start by clarifying the rationale behind the introduction of legislation on access and benefit sharing (ABS) from use of genetic resources, using Norway and its Marbank collection as a case. Marbank has a central role in Norwegian marine bioprospecting. Norway is in the process of establishing a set of ABS regulations, an *administrative order*, in line with its Nature Diversity Act and following obligations resting in the ABS regime of the Convention on Biological Diversity (CBD) and its Nagoya Protocol. We look at the state of the administrative order and ask why it has been delayed and how the lack of ABS regulations may affect the work of Marbank. Third, we compare the role and challenges facing Marbank with those affecting similar institutions in Australia, where domestic ABS legislation is much further developed. Finally, we discuss remaining barriers to ABS.

Before starting on the main subject of this article, a quick backdrop on the general state of ABS legislation in Norway is in order. The Nature Diversity Act makes it illegal to import foreign genetic resources if access has not followed ABS regulations in the provider country. Moreover, the Norwegian

Patent Act obliges Norwegian users of foreign genetic material to disclose information about the origin and legality of access in patent applications. These obligations on Norwegian users of foreign genetic material go further than those of most other user countries.[1]

Both Norway's Nature Diversity Act (2009) and the Marine Resource Act (2008) regulate access rights to marine biological resources, including access to marine genetic resources. Because the common administrative order under these two acts is still pending, Norwegian ABS legislation is currently targeting Norwegian users abroad, not external users in Norway. As regards bioprospecting at home, both acts confer competence on the government to establish such regulations (the administrative order) requiring permits for access to Norwegian genetic resources, rules on benefit sharing and information on the use of traditional knowledge. This administrative order is still in the pipeline and until it emerges, bioprospecting remains largely unregulated in Norway.

Australia represents an interesting comparative case to Norway. Like Norway, Australia is a developed country with large marine biodiversity collections. Unlike Norway, Australia has an advanced ABS legislation system for bioprospecting within the country (Prip *et al*., 2014). In the following, we identify known challenges relating to Australia's ABS experience, in particular difficulties involved in distinguishing between the scientific and the commercial intent of bioprospectors. On this basis, we identify a need for mechanisms to ensure improved monitoring of outcomes by scientific and commercial investigations of material originating from marine repositories in Norway. The study suggests that in order to ensure continuation of marine bioprospecting, long-term funding is crucial and we discuss whether the principle of cost sharing can support benefit sharing to further ensure sustainable innovation from marine genetic resources.

This article is the product of a multidisciplinary collaboration between law, political science and biology. Methodologically, we apply a primarily legal approach to this explorative and comparative analysis, added to by discussing institutional, political and biological aspects of marine bioprospecting. Data material is drawn from legal texts, consultation responses, academic ABS studies and reports and also builds on an interview with Marbank officials.

Rationale for ABS in Norway

The three objectives of the CBD are the conservation and sustainable use of biodiversity and the equitable sharing of benefits deriving from the use of genetic resources. The ABS regime of the CBD was set up to promote all of these aims: fair and equitable benefit sharing as well as the conservation and sustainable use of biodiversity. Promoting equity and fairness is seen as an incentive to ensure conservation and sustainable use. This is because the bulk of terrestrial species diversity is found in tropical parts of the world, hence often in countries with low ability to harvest the economic and technological gains from the use of genetic resources. In practice, there may not always be a causal link between equity and conservation. Countries differ in their perceptions of whether conservation or equity constitutes the most important rationale for ABS; differences largely follow the well-known South (the typical provider of genetic resources)/North (the typical user of genetic resources) divide. With the Nagoya Protocol, the link between fairness and equity on the one hand and conservation and sustainable use on the other has become more explicit.[2]

User countries are required by the Nagoya Protocol to establish legal measures to control their actors' use of genetic resources when bioprospecting in other countries, while providers typically wish to establish ABS legislation to control external bioprospectors within their territories. Norway is both a user and a provider of genetic resources. For Norway as a user country, the obligation on its users when prospecting abroad derives from the obligations set out in the wording of the Nature Diversity Act. The regulation of access to Norwegian genetic resources, however, has its basis in the acts, but is not made operative before an administrative order specifies the system for ABS with detailed rules.

Norway and Australia are similar in that both represent arguably atypical cases. Both combine the role of user and provider to a greater extent than most developed countries. They differ, however, in that Australia has well-developed ABS legislation to control external users at home while Norway has so far been much more concerned with regulating Norwegian bioprospectors abroad.[3]

Judging from national policy documents and strategies, however, it is clear that Norway, too, has interests in regulating bioprospecting at home.

Domestic *economic interest and investments* in marine bioprospecting have increased rapidly over the last couple of decades while the same resources receive significant and increasing attention from external pharmaceutical commercial companies (Big Pharma). In Norway, rapidly growing political interest is accompanied by high levels of public funding and investments in marine bioprospecting as a source of new and sustainable value creation. In 2009, Norway's interest was highlighted in the national strategy for marine bioprospecting ("Marine bioprospecting—a source of new and viable wealth creation" 2009–2024), in which the Norwegian government states that it will regulate marine biological resources and make them more accessible to researchers, industry and international participants. This initiative provided funding for a national infrastructure and for research in the fields of natural marine products and drug discovery. At the Norwegian Research Council (NRC), marine research and bioprospecting have been given high priority since 2001 (NRC 2001, 2009, 2013). This national interest was recently confirmed by the Norwegian government's initiative to develop a national strategy for bioeconomy and to draft a master plan for marine research.

The development of Norwegian marine bioprospecting was aided by the establishment of the Research Council's FUGE research program[4] (succeeded by BIOTEK2021), spurring widespread calls for a repository bank for marine organisms and extracts of them (Dalmo and Jørgensen, 2004). It was suggested that a marine repository in Norway should facilitate collection, taxonomy, creation of databases, extraction and preservation of marine resources for research and commercial purposes.

In 2003, the national marine biobank, Marbank, was established as a project to collect biological material from Norwegian waters. This was in close cooperation with the Norwegian Ministry of Fisheries and it was initiated by UiT—Arctic University of Norway (formerly University of Tromsø), the Norwegian Polar Institute and the Institute of Marine Research. Samples collected in Marbank are from the Arctic, the Barents Sea and from the coast of Northern Norway. In 2009, Marbank was given a coordinating role for a network of marine collections in Norway, including UiT, the Institute of Marine Research, SINTEF/NTNU[5] and UNI-Research/the University of Bergen. In 2012, Marbank was transferred from UiT to the Institute of Marine Research—a large Norwegian center for marine research.

Turning to the *conservation and sustainable use* aspects of ABS, it is a common perception and criticism—mostly among user countries—that the ABS regime has not been able significantly to stimulate conservation and sustainable use of biodiversity (Morgera *et al*., 2012). This, however, is questionable argument since the lack of progress is mainly due to ABS measures not being implemented at the national level; not least user country measures. Moreover, the absence of tangible benefits for biodiversity conservation would hardly represent a valid argument against the equity dimension of the ABS regime, seeing how equity and conservation are both valid aims of the ABS regime. Furthermore, ABS was never meant to carry sole responsibility for biodiversity conservation (Oberthür and Rosendal, 2014). Interestingly, although examples of conservation and resource mobilization benefits from ABS remain scarce, we see that also developed countries such as Norway and Australia are showing a growing interest in regulating the use of genetic resources found within their territories.

In Norway, the total number of species is estimated at 55,000; only 44,000 have been identified (Norwegian Biodiversity Centre, 2015), and those in marine areas are relatively less explored than terrestrial ones. Through its CBD conservation obligations, Norway is primarily responsible for its endemic species, and therefore manages only a tiny fraction of the world's biological diversity.

Nevertheless, species and ecosystem diversity found in the country is important and in some cases unique both in the Nordic region and globally. Other marine bioprospecting initiatives have mainly been aimed at warmer and shallower waters and more that 60% of the marine materials that have been collected in marine collections are from the Pacific region (Leal *et al*., 2012). This may change as the Polar Regions are assumed to have an equally high potential for bioprospecting of marine products. Development of culture-independent techniques may expand interest in bioprospecting from invertebrates to microorganisms living under extreme conditions (Akondi and Lakshmi, 2013; Pascale *et al*., 2012).

Norway manages some of the most productive marine areas in the northern hemisphere. The cold conditions of several Norwegian marine biotypes make the biological resources from these ecosystems especially interesting for research, innovation and commercial industry with their potentially unique properties related to their adaption to extreme temperatures (Svenson, 2013). Our national policy will affect how Norway shoulders its share of the global burdens, as required by the principle of *conservation and sustainable use* of biological diversity set out in the CBD. Moreover, Norway's highly visible international profile in advocating the CBD throughout would seem to represent a strong motive for Norway to honor its obligations following from the CBD and its ABS regime.

An additional national motive is tied to the *economic value* of Norway's marine biological material. The economic potential to do research and product development on marine genetic resources might become economically important in the event of successful findings and development of commercially successful products. As the oil age comes to an end, the fisheries and marine sector, including marine bioprospecting, will become an increasingly important target for Norwegian R&D investments and source of revenue as well as an important area in the national strategy on bioeconomy. Securing public revenue from private companies' oil and gas revenues has been important and was based on forward-looking legal systems: the regulation of rights to and benefits from Norwegian genetic material can have similar future importance.

Summing up, the importance of the marine sector to Norwegian economic development is significant and increasing. The high level of public funding involved in infrastructure, technological developments and education of relevance to biotechnology and marine bioprospecting implies a responsibility to ensure that revenue from the use of genetic resources is secured for the common good of society, as the Marine Resources Act confirms: "Wild living marine resources belong to Norwegian society as a whole."[6] In addition, Norway has a responsibility to the global community to safeguard endemic biological diversity. It is clear from national strategy documents that Norway aims to develop ABS regulations aimed at bioprospecting at home.

ABS in Norway: Legal Action and Inaction

In 2013, the ministries involved (Climate and the Environment, and Coastal Affairs and Fisheries) presented a draft administrative order with the aim to secure Norwegian rights and commercial exploitation of genetic resources, benefits to society, and sustainable use of the resources. The administrative order is, however, still awaiting political action from the current ministries involved (the Ministry of Climate and the Environment and the reorganized Ministry of Trade, Industry and Fisheries). These have the competence and responsibility for drafting the administrative order and getting it approved by the Cabinet. Why is the administrative order still pending and how does this situation affect the work of Marbank?

There may be a number of reasons that explain the ministries' inertia. Clearly, there is uncertainty about means and aims.[7] First—regarding uncertain means, the authorities are still apparently in the process of trying out various models for ABS, claiming uncertainty regarding which would be best suited for the Norwegian situation. Technological progress within biotechnology has increased the speed of genome sequencing, and the emerging understanding of genetic elements and mechanisms has created new means

for genomic approaches as well as new fields, such as synthetic biology. These developments represent new challenges and may increase uncertainties concerning how ABS could be put into practice, compounding this first cause of delay.

Second—regarding uncertain aims, the recent reorganization of the ministry, where the old ministry of coastal affairs and fisheries was (sub) merged with that of trade and industrial development, may have engendered a change in priorities, with less weight on the BS in ABS and more focus on industrial and commercial interests in access. This could prompt worries that making the private biotechnology sector pay for access to genetic material could lead to more reluctance to invest in the field, thereby losing more opportunities than ABS could hopefully generate. The combined effects of these views would also be in line with the priorities of Norway's current blue–blue coalition government; the shift in government since the administrative order was first called for has clearly not made for a speedier expedition.

Third, political tardiness could also have been nurtured by the skeptical response of commercial users to the first draft. The consultation responses from commercial actors may have revealed stronger opposition to ABS than expected.

The consultations on the draft directive resulted overall in widespread support for the objective of benefit sharing, with actors realizing the need for an ABS system. There also is strong support for a model based on access permissions rather than mere registration. Still, some industry actors are critical of what they fear may become a cumbersome and expensive access model, and at the point of time of the hearing many recommend waiting for the EU to complete their ABS model in response to the Nagoya Protocol. Some are dismayed by what they consider to be a far too simplistic view in the draft of the process by which genetic resources are developed into a commercial product. Most agree that bioprospecting is by nature commercial, but some still express concern that the ABS system could complicate non-commercial research. Non-commercial actors responding to the draft would like to see a stronger harmonization with patent legislation – making the patent void unless followed by the CBD ABS principles of *prior informed consent* and *mutually agreed terms* (response from the Norwegian Biotechnology Advisory Board) or even prohibiting the patenting of genetic material acquired in Norwegian nature outright (response from the Development Fund). The most surprising response came from one of the two ministries involved in the drafting of the administrative order, i.e., Ministry of Trade, Industry and Fisheries. Officials there point out that the regime envisaged for reporting and control is hardly in harmony with the Government's goals to simplify administrative procedures.[8] This strongly supports the second of our three likely explanations of the delay in the administrative order.

In the following we look in more detail at the types of collections that are found in Marbank, the state of the material, how much scientific work has gone into making the material ready for screening and where the material goes when it leaves the collection. Our empirical material also includes the type of activity associated with accessing the collection (basic/academic or applied/commercial research). This makes it relevant to compare with the situation in Australia and discuss whether lessons are transferable to the Norwegian situation.

The Role and Mandate of Marbank in Bioprospecting

Marbank is hosted by the Institute of Marine Research (IMR) and shares facilities with the analytical platform Marbio and Arctic Biodiscovery Centre with the aim of creating value from Arctic biomolecules. The repositories and laboratories are located in SIVA—Innovation Centre in Tromsø. The purpose of Marbank is to collect, catalog, prepare and coordinate marine samples from different collections for scientific research, commercial opportunities and exploitation. The national strategy states as its purpose to increase the academic and commercial use of material found through marine bioprospecting by making such resources accessible (Ministry of Fisheries *et al*., 2009).

Marbank has the national responsibility for the collection and processing of marine organisms for applied scientific research and aims for a wide assortment of marine species. The material archived and stored includes whole organisms, biochemical extracts and taxonomic and genetic samples from marine microorganisms, invertebrates and vertebrates. All samples are cataloged in a national database. With funding from the Norwegian Research Council, Marbank worked closely with the former Ministry of Fisheries and has since 2012 become a permanent institution and part of the Institute of Marine Research. Under Marbank, 14,000 kg of organisms have been collected, covering 1,200 species of marine invertebrates, 110 species of microalgae and 3,000 16S rDNA characterized bacteria strains, all from 1,100 locations along the Norwegian coast and Spitsbergen islands. One of Marbank's tasks is to create and participate in an active network and build a common database for the marine organisms and samples for which access is offered. Marbank has close cooperation with the co-located platform Marbio and the Arctic Biodiscovery Centre.

Using Marbio (the analytical platform for screening and identification at UiT, the Arctic University of Norway), about 150 bioactive compounds have been characterized and 50 potential lead candidates produced. Marbio has processed 600 biological samples from 507 species, prepared a library of more than 3,000 extracts/fractions, and performed 316,000 screening events based on the Marbank material.

The Arctic Biodiscovery Centre is tasked with exploring bioactive medical products, pharmaceutical processes and products as well as interesting biological material for industrial purposes through the screening of Arctic organisms. As of 2015, the center is organized under the UiT umbrella. The Arctic Biodiscovery Centre is built on the knowledge and infrastructure established through the former MabCent-SFI project and comprises a complete pipeline from discovery of biomolecules to their use in various biotechnological applications. MabCent-SFI was established with funding from the Norwegian Research Council (43%), the UiT (32%) and commercial partners (biotechnology companies) (25%). It has been the main contributor of marine organisms and extracts for bioactive compound screening (MabCent-SFI, Summary Report, 2007–2015, p. 17; Svenson, 2013), and has delivered 20 assays (test methods for screening) and more than 300,000 screening events in the search for bioactive compounds (anti-cancer, etc.), and so far three patent applications have emerged from the research. Under the new structure the Arctic Biodiscovery Centre is not tied to former funding private partners and can collaborate with other institutions and private sector industries in both Norway and internationally.

In order to discuss the options and challenges facing Marbank and its collaborating partners and network in the task of providing genetic material to users, it is useful to compare the legal framework for these activities with those of similar institutions for marine collections in Australia. The Australian case has revealed difficulties involved in distinguishing between the scientific and the commercial intent of bioprospectors and the R&D processes (Prip *et al*., 2014).

Comparing the Australian Institute for Marine Sciences (AIMS) and the Eskitis Institute with Marbank

In Australia, large collections of genetic material (samples) can be found within academic institutions, of which a great deal has already been made ready for further examination for their active compounds. Here we describe the activities and ABS-related challenges at the Eskitis Institute at Griffiths University and AIMS, comparing these with those of Marbank and its associated network and collaborating partners and users of marine material (Marbio and the Arctic Biodiscovery Centre). We start with a brief presentation of ABS legislation in Australia, building on Prip *et al*. (2014).

ABS Legislation in Australia: Contracts and Access

Regulating ABS at the federal level in Australia is the *Environment Protection and Biodiversity Conservation Act 1999*, *section 301*, Part 8A "Access to biological resources in Commonwealth areas." Those seeking access to biological resources of native species for research and development must apply for a permit from the responsible Commonwealth Minister. The permit demands prior informed consent in accordance with article 15.5 of the CBD.

Permits are available for potentially commercial/commercial and non-commercial purposes. All permit applications must demonstrate that the applied access is ecologically sustainable and consistent with the conservation of Australia's biodiversity on the basis of the precautionary principle. If access is sought for a commercial purpose there is permit fee of 50 AUD. Access for non-commercial purposes such as taxonomy is free. A fine may be imposed for accessing material without a permit or for breaching the conditions stipulated in a permit. The Competent Authority for ABS has developed model contracts to assist in the development of benefit-sharing agreements. Access for non-commercial purposes does not require such an agreement, but applicants must provide a *statutory declaration* stating that the applicant will not conduct, or allow others to conduct, commercial research without agreeing to appropriate benefit sharing arrangements. As the statuary declaration system works well, and is more general in its application than ABS, it is a good example of the use of established legal institutional structures to make ABS functional (Prip *et al*., 2014).

At the state level, Queensland enacted the Biodiscovery Act in 2004. This was the first piece of ABS legislation in Australia. The Queensland Government wished to create legal clarity and regulate biodiscovery activities in accordance with the CBD. The government recognized that great benefits for the state could be reaped from biodiscovery and thus wished to develop a legal framework to capture the benefits. This view built largely on past experience of bioprospecting collaboration—the extensive Natural Product Discovery Partnership established in the late nineties between the Queensland-based Griffith University and the pharmaceutical company Astra Zeneca (Prip *et al*., 2014). The Biodiscovery Act differs from the Commonwealth ABS regulations by not having two types of permits for, respectively, non-commercial and commercial/potentially commercial biodiscovery. Interestingly, the industry acted as advocates for the Queensland legislation, emphasizing the need for a level playing field and legal certainty (Prip *et al*., 2014).

These views and experiences certainly seem relevant to decisions pertaining to access to Norwegian collections of genetic resources. With clear similarities to the Norwegian case, large collections of genetic material (samples) can be found within academic institutions, much of which has already been readied for further examination for their active compounds. The most prominent cases are Eskitis and AIMS, and in the following we compare challenges facing them with those of Marbank and its network, Marbio and the Arctic Biodiscovery Centre.

Eskitis: What They Provide to Users and the Ensuing Commercialization Process

The Eskitis Institute for Cell and Molecular Therapies is part of the Griffith University in Brisbane. It is a drug discovery research center searching for and developing new drug and cell-based therapies. Eskitis research is supported by the Nature Bank, which has a library of over 200,000 optimized natural product fractions derived from a diverse collection of over 45,000 samples of plants and marine invertebrates. Nature Bank fractions can be accessed for screening on assay systems, with follow-up isolation chemistry at Eskitis. The Nature Bank provides the service of processing natural products of biota or crude extracts into fractions to create assay-ready screening sets. Samples are thus ready for analysis of whether novel bioactive compounds could hit a particular target or bind to a specific protein. Moreover, Eskitis houses the Queensland Compound Library (QCL). This is an automated library of nearly 400,000 pure compounds from samples. QCL provides automated retrieval of the requested samples and supervise the formatting

into the preferred micro plate format. When screening hits are identified, contact is enabled between chemists and biologists in Australia and abroad for potential collaboration.

Compared to Marbank, Eskitis has arguably advanced further in the actual delivery of ready assays. However, the activities of Marbio and the Arctic Biodiversity Centre are more like those of Eskitis in this vein and it is clearly the ambition of Marbank and cooperating partners to provide similar services to users. Hence, so far, the parallel holds.

Samples for the Eskitis Nature Bank have been collected in Australia, Indonesia, China, and Papa New Guinea. Samples are sent to i.a. the UK, US, Canada, China and Denmark in collaboration with Eskitis scientists. By comparison, Marbank samples originate mostly (but not solely) from Northern-Norwegian waters, hence making ABS less complicated.

Preceding ABS legislation, the Griffith University had mixed experiences with bioprospecting collaboration. In 1993, Griffith entered into a National Product Discovery partnership with Astra Pharmaceuticals (later AstraZeneca, AZ), one of the world's leading pharmaceutical companies. AstraZeneca invested more than 100 million AUD in the collaboration, but it has also received significant public spending. Since the end of the deal in 2007, the Queensland State and Federal Government have financed the building of the laboratory—the QCL—that contains and "manages" the samples, integrating tube and plate storage with sample processing. The downside of the AZ deal was that the University could not collaborate with other researchers, decide on research goals or get ownership to research results (Prip *et al*., 2014). AZ had exclusive rights to the samples, which led to certain criticism of the partnership from the Australian media because multinational companies were allegedly "locking up" Australia's resources (Laird *et al*., 2008). According to key actors, Griffith University is very unlikely to enter into an exclusive agreement with just one company again (Prip *et al*., 2014).

The parallel to Norway and the Arctic Biodiscovery Centre is striking in that it caters to a number of PhD, postdocs and scientists. The need of scientists to get published to advance their academic prospects is reportedly difficult to do in combination with the need for patenting of their commercial partners, as patenting usually implies long phases of secrecy prior to the patent application (MabCent-SFI Summary report, p. 53).

The Griffith University/Astra Zeneca partnership has still not led to the commercialization of any product. However, given the often-lengthy time it takes to develop drugs from natural products, commercial products may still be developed down the line. Scientists at Griffiths questioned whether Astra Zeneca would have invested more than 100 million AUD without having obtaining any leads to new commercially interesting products (Prip *et al*., 2014). This illustrates a core practical challenge of ABS: if a particular genetic resource leads to the discovery or invention of an interesting product, what is the relevant correlation between the genetic resource and the particular commercially viable product? Often in bioprospecting there is no one-to-one correlation between a genetic resource and a product (Tvedt *et al*., forthcoming). This means that a specific sample does not necessarily lead to a specific product. The distance between the biological sample and product creates problems for establishing a benefit link from the sample to the product in the market. Adding to this problem is the lack of functional user legislation which could create incentivizing carrots or discouraging sticks, increasing willingness to comply with ABS in the countries where multinational pharmaceutical companies are operating.

Similar challenges face Marbank in their interactions with external (foreign) users of marine material. In most cases of access to the collection there is a combination of Norwegian and international (mostly private) players. Due to the lack of an ABS regime for the Norwegian marine samples, it has been an explicit Marbank objective to ensure that Norwegian researchers are involved in order to secure the value of the collection for Norwegian society. Material from Marbank is ready for commercial utilization and Marbank would like to see the legal issues regarding access described accordingly. When developing a functional contract for the use of Marbank, that contract would have had more support if the administrative regulation had been in place.

This lack is seen as a bottleneck in their work.[9] In addition, Marbank sees it as highly relevant to obtain information about and monitor how the material is being used, that is whether it has been useful, published and/or patented. This type of information is valuable with a view both to avoiding double work and to reduce the consumption of finite samples—the knowledge makes it possible to avoid others having to do the same work all over again if the result from the first round was unpromising. In Marbank's view, it would add to the value of the material for other users.[10] Moreover, such information may be of high value for the further refinement of the product or for comparing bio-activity with products of similar characteristics derived from other organisms.

Against this background, we could envisage a system in which ABS is not only tied to benefit sharing linked to the end product, but also involves sale/payment of valuable "leads" (ready assays). This is an interesting notion as it points to the element of (sub-national, domestic) cost sharing in addition to the usual argument of (international) benefit sharing. Including cost sharing in the system would raise the visibility of the high levels of public funding that go into infrastructure, collection and delivery of ready bioactive compounds to users, all of which are necessary for users to develop commercial products. This particular item has not been clarified in the draft administrative order. A drawback of such a system might be high transaction costs.

AIMS and the Challenges of Monitoring Genetic Material

Another major academic intermediary in biodiscovery is the AIMS. This federally funded research institute was established in 1979 in response to environmental concerns for the health of the Great Barrier Reef. Over the years, there have been a great number of bioprospecting expeditions in Australia involving AIMS. Part of the funding comes from the US National Cancer Institute (NCI), as part of the NCI's large anti-cancer program. Industrial interest is higher for marine than for terrestrial biological resources and AIMS is involved in a large number of activities in the sea around Australia. It has a huge collection with taxonomically identified samples, all providing screening results of material for active compounds and identification of fractions as well as geographical identification. Like the Eskitis Institute, AIMS also sends samples with ready assays to partners. AIMS always applies for non-commercial, scientific permits, but is prepared to apply for other types of permit if the research is leading toward commercialization (Prip *et al*., 2014). This has happened only once, which is puzzling in light of the strong Australian ABS legislation.

Australian ABS legislation has mandatory permits for all bioprospecting and mandatory benefit-sharing agreements for bioprospecting with a commercial intent. This "change of intent" was captured in the *statutory declaration* in Australian Commonwealth ABS legislation. The declaration is a legal instrument that could make the user liable under Australian criminal law, although it holds a more limited prospect for following and tracking genetic material if it is transferred to third parties. Despite these strong legal means, until now there has only been one case of commercial bioprospecting in Australia involving benefit sharing (Laird *et al*., 2008). The case involves a large study of sponges with anti-cancer compounds and is based on collaboration between AIMS and the US National Cancer Institute. The use of the already long-standing and existing statutory declaration in Australian Commonwealth legislation shows how they use and apply already existing legal tools in their enforcement of ABS. This might increase the efficiency of the legislation.

One possible explanation for the lack of ABS may be the difficulty in distinguishing between bioprospecting for scientific and commercial use and thereby determining when benefit sharing should be triggered. Related to this, companies tend to argue that commercial results from biodiscovery are still so far away, there are simply no grounds for expecting benefit sharing anytime soon (Grajal, 1999; Morgera *et al*., 2012; Prip *et al*., 2014). The difficulties involved in *monitoring* the genetic material from access to actual commercial product add to this problem.

Here a paradox becomes apparent, as Australian scientists usually wait for patents to be granted before they consider publishing results from the widespread university/industry collaboration (Prip *et al*., 2014). This is necessary because publishing must be postponed in order not to block the patent criterion of novelty (the search for prior art). Patenting is, however, a strong indication of commercial interest. As both the commercialization and the patent process are claimed to be very long and costly, this implies that there is often a *delay in the sharing of scientific results* through publishing. That would be a drawback for innovation. An alternative interpretation is that there are a lot more commercial activities and results with a potential for benefit sharing taking place at a quicker pace than the meager ABS results would indicate. The strong link between commercial interest and patenting has given rise to a widespread view in Australia that linking ABS and IPR legislation through *disclosure* of the source of biological resources in patent applications could be an appropriate legal measure to track ABS compliance (Prip *et al*., 2014).

As we have already contended, similar problems related to *patenting and sharing of scientific results* are reported within MabCent-SFI (MabCent-SFI, 2015). The MabCent-SFI summary report (p. 53) concludes,

> "As a consortium, all research operations were performed on behalf of the commercial partners, and initiation of i.e. national/international collaboration outside the consortium was not directly possible. Thus, a more open structure with less secrecy and IPR considerations would obviously facilitate the collaboration issue in a better way."

As the Arctic Biodiscovery Centre and the Marbank network and collaborators are not tied to specific commercial partners at the outset, this particular problem would be less likely to arise in the future.

Challenges with Monitoring of the Genetic Material

Monitoring is a crucial issue identified by both AIMS and Eskitis as well as relating to the Norwegian draft administrative order for ABS. In Norway, the difficulties related to how to correlate a particular genetic resource to the discovery or invention of an interesting product now seem to be delaying the administrative order on an ABS system.

A small literature survey using Science-Direct and Google Scholar found that fewer than 10% of academic papers published between 1991 and 2013 said anything about whether the origin of their material was a marine bank. Discussions concerning sustainability and regulation were also rarely included in the retrieved scientific papers, underlining the urgency of implementing the ABS legislation. When it comes to purpose, almost 33% of the papers describe the intention of the study as applied research. This illustrates the potential difficulties involved in distinguishing between bioprospecting for scientific and commercial use and determining whether benefit sharing should be triggered. ABS legislation may, therefore, need to be followed by monitoring provisions that cover the entire bioprospecting chain (Bhatia and Chugh, 2015). On the other hand, it is widely acknowledged among scientists and industry players alike, both in Australia and in Norway, that bioprospecting is usually of a commercial nature (Prip *et al*., 2014).[11]

While Norway lags behind Australia with a view to ABS legislation at home, the interesting thing is that Norway has a much stronger monitoring instrument available through its revised Patent Act—at least to the extent that patent applications are submitted at home. Norway is one of very few user countries to have amended patent legislation in line with *disclosure* of origin of genetic material. The case of Marbank is similar to the Australian case also in that within Marbank there is a broad recognition that samples accessed from their collection will usually be of commercial value. Hence, in the Norwegian case one would avoid uncertainties regarding the type of permit (commercial/non-commercial) on which to base eventual contracts. This contested area of ABS governance involves balancing access to genetic resources

with intellectual property rights (IPR). The CBD ABS regime seeks to balance IPR in the sense that both systems aim to tie economic conditions on legal use of the material (Pavoni, 2012; Rosendal, 2011; Swanson, 1995).

Concluding Remarks

The Norwegian government remains hesitant with regard to the future design of ABS to regulate bioprospecting at home. For Marbank, in performing its tasks, this legal vacuum represents a prominent challenge. The skepticism of politicians toward ABS basically concerns whether industry can and should be expected to pay for access to genetic material. If the government concludes that no such payment can or should be expected, the logical consequence is that Marbank and its associated network cannot be expected to work economically independently from further public funding to secure the costly and necessary infrastructure for bioprospecting. Protocols used in bioprospecting are both time and cost intensive and require in Norwegian conditions technology adapted for polar and deep-sea searches, as well as advanced laboratory platforms. Public funding is also essential to ensure initiation of the early phases of research into the marine material. This exposes Marbank to an insecure funding situation in the future. Since collections like Marbank's are an expensive venture, long-term funding is a core need.

A second conclusion to be drawn from the deliberations in this study is that the idea of benefit sharing could be supported by, and expanded with, the principle of cost sharing. This could involve selling ready assays or leads to industrial partners. We have seen that industry is not foreign to the idea of ABS legislation that secures a level playing field and legal certainty. Legal certainty would also support the political aim of creating incentives for further innovation and R&D based on marine bioprospecting in Norway. If the revenue is to be channeled back into Norwegian R&D, the multinational pharmaceutical companies need to be somehow included as contributors. The alternative is a situation in which the large multinational players remain free riders in a system that provides ready assays for biotechnological development and where genetic material can be sent out of the country free of charge. Although some benefit sharing is currently taking place, such as research collaborations, the cost of the infrastructure remains a public responsibility. The result is that public funding is required through all the phases of the value creation chain of, for instance, medicinal products, from education, collection, infrastructure and providing ready assays—and then in addition to paying royalties to the large pharmaceutical corporations for acquiring vaccines and medicines. This remains a strong argument in favor of cost sharing even if benefit sharing is still a tough political issue to tackle.[12]

About the Authors

G. Kristin Rosendal is Research Director and Professor at the Fridtjof Nansen Institute, Norway. She holds a PhD in political science and has published extensively in on issues relating to international regimes on environment and trade, with a focus on access and benefit sharing and intellectual property rights to genetic resources (see www.fni.no for complete list of publications). With Sebastian Oberthür she is the editor of *Global Governance of Genetic Resources: Access and Benefit Sharing after the Nagoya Protocol*, London/New York, Routledge, 2014; e-mail: *kristin-rosendal@fni.no.*

Anne Ingeborg Myhr is Director at GenØk—Centre for Biosafety, Norway. She holds a PhD from the Institute of Medical Biology at the University of Tromsø. Her main experience is within risk assessment and risk management of GMOs as well as on ethical, social and legal aspects (ELSA) related to genetic engineering. During the past years new research has been extended to include environmental, health and social impacts by emerging biotechnologies including synthetic biology and nanobiotechnology.

Morten Walløe Tvedt is senior researcher at the Fridtjof Nansen Institute. Tvedt has published extensively in the area of biological resources law and intellectual property (see www.fni.no for a complete list of publications). Most important is a monograph co-authored with Tomme R. Young: Beyond Access: Exploring Implementation of the Fair and Equitable Sharing Commitment in the CBD, *IUCN Environmental Policy and Law Paper* No. 67/1.

Notes

1. Despite this, there are still challenges involved in making these obligations fully functional (see Tvedt and Fauchald, 2011).
2. Nagoya Protocol Article 1: Objective. The objective of this Protocol is the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components.
3. An increasing number of provider (developing) countries are enacting access legislation. However, since compatible legislation in user countries to support compliance with access regulations is still largely lacking, there is some way to go before the regime can work effectively (Tvedt, 2014; Tvedt and Young, 2007). ABS legislation in developing countries is often criticized for being cumbersome with a view to access and futile with a view to benefit sharing (Grajal, 1999; Morgera *et al*., 2012). Australia's ABS legislation, in contrast, has not been subject to either objection; it seems to be regarded as successful in terms of handling access issues, although verdicts are varied regarding its provision of benefits to Australia from utilization of genetic resources (Burton, 2013).
4. FUGE alone contributed 1.6 billion NOK from 2002 to 2012 (Kunnskapsdepartementet, 2011).
5. The Norwegian University of Science and Technology.
6. Lov 2008-06-06 nr 37: available in English https://lovdata.no/dokument/NL/lov/2008-06-06-37/KAPITTEL_5#§27.
7. Kjersti Lie Gabrielsen, Director at Marbank, emphasized the two first reasons in interview 22 June 2015.
8. This is based on the author's reading of all the consultation responses, including from the 11 industrial actors, to the draft administrative order (March 2013).
9. Interview with Kjersti Lie Gabrielsen, Director Marbank, 22 June 2015.
10. These views are also spelled out in the consultation response from Marbank and the Institute of Marine Research to the draft administrative order, letter of 5 April 2013.
11. Based also on the author' reading through the hearing notes from the 11 industrial actors responding to the Norwegian draft administrative order (March 2013).
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