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Industry Responses to Evolving Regulation of Marine Bioprospecting in Polar Regions

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10.1 Introduction

A central question in biodiversity governance is how the international community will regulate the conservation and equitable sharing of benefits from the utilization of marine genetic resources in areas beyond national jurisdiction (ABNJ). The equity question concerns how to secure benefits from global commons resources for all, not only for financially and technologically strong actors. The access and benefit-sharing (ABS) principles set out in the Convention on Biological Diversity (CBD) (CBD, 1993) and elaborated in its 2014 Nagoya Protocol are decisive rules on these equity concerns. ABS is central to the CBD Post-2020 Global Biodiversity Framework deliberations, which have been delayed due to COVID-19, but which are expected to be adopted in 2022. Along with the pandemic, ABS also put health and biodiversity relationships more prominently on the political agenda, as nature can be both a resource (genetic resources as sources of medicines) and pose threats through zoonoses, depending on how biodiversity is governed (UNEP, ILRI, 2020). Legal regulation of the utilization of genetic material from ABNJ in the polar regions is currently subject to negotiation within the framework of the United Nations Convention on the Law of the Sea (UNCLOS), based on UN General Assembly decision 72/249, 2017. The ABNJ remain among the few unregulated areas of the world in which bioprospecting is taking place, as the ABS principles of the CBD do not apply directly outside national jurisdiction. The growing focus on the value of marine genetic resources, not least for medicinal development, is likely to be affected by the evolving legal conditions for access and rights to use this material. Addressing a central theme of this volume, we examine the potential effects of the options on the negotiating table in terms of transformative biodiversity governance (TBG).

Here we investigate various aspects of the equity questions, taking stock of evolving regulatory regimes for dealing with the technological aspects of marine bioprospecting, with emphasis on the bioprospectors themselves. First, as we examine legal processes in the making, this study addresses the anticipatory dimension of transformative governance, where the options are still open and malleable. Second, as bioprospectors are central in the utilization of genetic resources, a better understanding of their role and positions is an

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important element in governing the equity issues of biodiversity conservation and use. By focusing on actors we can examine stakeholder participation, which is central to the TBG debate discussed in this volume. Third, studying the responses and behavior of corporate bioprospecting actors allows an often-neglected focus on technological development as a driver and underlying cause of biodiversity loss. Questions of how to deal with digital sequence information (DSI) and synthetic biology are at the core of international governance of genetic resources (see Box 10.1). Thus, this chapter speaks to Chapter 7 on DSI in this volume, from a more empirically oriented angle.

In multilateral environmental cooperation, issues of North–South divides and equity usually focus on technology transfer and capacity building whenever technology is addressed. Technological developments may also have direct economic and distributional ramifications for poorer countries. We examine how vested interests in biotechnology could challenge transformative change by undermining the principle of equitable sharing of benefits arising from utilization of genetic resources, the ABS regime, as this is central to transformative biodiversity governance (see Chaffin et al., 2016).

"Bioprospecting" refers to the systematic search for biochemical and genetic information in nature, in order to develop commercially valuable products for pharmaceutical, agricultural, cosmetic and other applications (Svenson, 2013). Marine organisms may be more likely than terrestrial species to contain useful natural compounds, partly because they have evolved in response to extreme environments (see e.g. Bodnar, 2016). However, less than 1 percent of marine organisms have been explored scientifically, and little is known about their rarity or vulnerability. Recent technological advances are making the marine genetic resources of the Arctic and Antarctic Oceans increasingly available and of commercial interest. Collecting biological material from these regions is still very costly and conducted predominantly by a small number of state-funded, oceangoing vessels (see Leary, 2018; Müller and Schøyen, 2021). In view of the high levels of public funding that go into infrastructure, collections in biobanks, and delivery of ready bioactive compounds – all of which is necessary to develop commercial products – this has raised questions of *cost-sharing* as well as benefit-sharing in bioprospecting (Rosendal et al., 2016). A handful of multinational corporations are behind more than 80 percent of the patent applications on this material, with BASF alone filing almost half of the patent applications on marine genetic resources since 1988 (Blasiak et al., 2018). As bioprospecting is largely conducted by private (often multinational) corporations, we must ask whether and how these bioprospectors respond to emerging measures in the ABS legislation.

There are very few studies of bioprospectors, except for some cases of terrestrial medicinal plants (Wynberg et al., 2009). Also, ABS issues regarding utilization of genetic resources in ABNJ are less explored in social scientific terms than are those lying within national territories. For ABNJ, most of the literature available is from the legal field (Arico, 2010; Drankier et al., 2012; Greiber, 2011; Jørem and Tvedt, 2014; Tvedt, 2020). ABS-related studies within the aquaculture and agriculture breeding sector have shown that both commercial and noncommercial breeders alike would prefer aquatic and plant genetic resources to be freely (affordably) accessible, although commercial breeders also need to ensure revenues (royalties) from their own innovations and breeding results through some

form of intellectual property rights (Greer and Harvey, 2004; Olesen et al., 2007; Rosendal et al., 2006; 2013). Similar dilemmas are likely to emerge among marine bioprospectors, as many will need to seek access to genetic material through biobank collections, and many will seek to patent the material. With this chapter, we aim to fill the knowledge gaps concerning the ABS strategies of marine bioprospectors in order to inform the debate on TBG.

The ABS debate has a history of conflict regarding accusations of biopiracy; therefore, ABS strategies may be sensitive data for the corporations. Moreover, corporations rarely provide position papers in international negotiations. In order to disclose information and compensate for the lack of position papers to the UNCLOS negotiations, we have examined bioprospector responses to public hearings on two draft proposals for Norwegian ABS legislation. Further, in-depth, semi-structured interviews have been conducted with key actors in two corporations, to complement the analysis (see Yin, 2003). Data have also been collected from public records, secondary literature and interviews with seven key actors from ministries, R&D institutes and international scientific organizations (see footnotes for details). Most of the interview materials were collected between 2012 and 2018, but data collection on the international negotiation process has continued to spring 2021.

We have chosen Norway as a case for three reasons, in addition to easy access. First, resources from marine and polar areas are traditional core Norwegian interests. Second, Norway is investing heavily in marine research and innovation: marine bioprospecting, samples collections to marine biobanks and high-cost oceangoing vessels (about €150 million in public funding to the most recent vessel, *Kronprins Haakon*, alone) (see Müller and Schøyen, 2021). Third, Norway has a long history of advocating the access and equitable benefit-sharing regime of the CBD, further specified in its Nagoya Protocol, but ABS regulations at home are still stalling, with long and controversial debates and hearings. All this makes Norway a relevant case for examining the political scope between norms expressed internationally and concern for domestic interests (Rosendal et al., 2016).[1]

We begin by presenting an analytical framework for assessing and explaining corporate strategies and responses to evolving regulations, outlining the main conflicts of the ABS debate. Next, after explaining what marine bioprospecting entails, we turn to the international legal debate on such activities and the current governance of genetic resources in the polar regions. In Sections 10.4 and 10.5 we present findings from our embedded case study of Norwegian actors engaged in polar marine bioprospecting, based on the analytical models for assessing corporate strategies. In the concluding section we offer inputs to the debate on transforming biodiversity governance based on our analysis.

10.2 Analytical Framework on Corporate Strategies

Our examination concerns responses to the new ABS regulation as regards bioprospecting companies and industry associations – here broadly defined as actors with commercial interests. As such regulation is still evolving, we focus mainly on *political responses* that

[1] https://bit.ly/3nrd03g.

may, or may not, lead to actual *market adaptation* (Kolk and Pinkse, 2004). "Political responses" refer here to strategic company support of (proactive) or opposition to (reactive) emerging regulation. These strategies are ideal-typical opposite poles: Real-life companies engaged in a wide range of activities cannot be expected to fit perfectly with such opposing extremes. Our aim is to assess the degree of fit between expectations and observations in the content and direction of corporate strategies in relation to ABS regulations.

We focus on three "ideal type" models for explaining company responses (Skjærseth and Eikeland, 2013; 2019). The first model sees companies as reactive and "reluctant adapters" to strengthened regulations. This "reactive" model is grounded in the traditional economic view of the firm as a unitary, rational, profit-maximizing agent that develops strategies based on full information on the relative costs of various alternatives (Ambec et al., 2011; Gravelle and Rees, 1981). As new ABS regulations (in ABNJ) would charge companies for previously free access to genetic material and impose administrative and compliance costs that could erode profits, regulation is held to divert capital away from other investments, thus threatening a firm's competitiveness. We expect political responses that seek to minimize new regulatory costs by opposition to the ABS regime: saying "no" to all kinds of monetary benefit-sharing and resisting expanding its legal scope. Opposition expressed in interviews and lobby papers will be in line with this expectation.

The second model views companies as "proactive innovators." This model is based on bounded rationality and the search for new market opportunities. The "proactive" response model assumes that firms are "boundedly rational" (Simon, 1976). Profit maximization is seen as central, with strategic managerial choices influenced by the design of regulations, organizational practices and operating procedures, perceptions of risks and opportunities, and information constraints, habits or routines (Cyert and March, 1963; Delmas and Toffel 2008; Sanchez 1997).

Anchored in these assumptions, environmental regulation does not necessarily represent a threat to profits and competitiveness; on the contrary, it may contribute to innovation, improved performance and competitive advantages (Esty and Winston, 2006). According to Porter and van der Linde (1995a; 2005b), "appropriately" designed regulation may spur learning about resource inefficiencies and technological improvements, reduce uncertainty about future investment and stimulate innovations that can offset the costs of compliance. Adjusting to appropriately designed regulations, a company may support regulation and view compliance as a rational way to improve profits and attract new customers. Promoting a profile of green equity can also help companies avoid accusations of "biopiracy," and hence secure access to resources and collaboration with partners that can promote and increase such access.

"Appropriate" in this case can be assumed to imply adhering to the basic principles of ABS, while not condoning any kind of expansion in its legal scope. "Proactive response" to the ABS regime means accepting *monetary* benefit-sharing with "provider" countries, but excludes *derivatives* (see Box 10.1), excludes monitoring through *disclosure* of origin of genetic material through patent application systems and limits the *time scope* to the entry into force of the CBD's Nagoya Protocol in 2014 rather than to the CBD itself (1993) (ENB, 2018; Oberthür and Rosendal, 2014). The idea behind *disclosure* is that intellectual property

Box 10.1: The derivative debate

The CBD, Article 2, defines "genetic resources" as genetic material of actual or potential value, and "genetic material" as any material of plant, animal, microbial or other origin containing functional units of heredity. The second definition has given rise to dispute, as genetic sequences and enzymes applied in synthetic biology do not necessarily contain functional units of heredity. The real value of genetic resources lies, however, in their information. Hence developing countries argue that such derivatives of genetic resources must remain part of the ABS regime even when this material does not contain functional units of heredity. Technological developments in synthetic biology have produced large quantities of biological data, which are stored online in databanks. This digital sequence information on genetic resources is increasingly replacing the need to access biological samples of genetic resources in nature and this has major implications for the CBD architecture on ABS (see Chapter 7). If access to derivatives, necessary to foster scientific research, is not accompanied by benefit-sharing modalities, the CBD's third objective on equitable sharing may become increasingly undermined. Similarly, it may be argued that all new drugs that enter the market still originate from the natural world, and that excluding derivatives would also exclude incentives for biodiversity conservation. Industry actors, coordinating their views on DSI through the International Chamber of Commerce (ICC), would strongly oppose the expansion of the CBD and the Nagoya Protocol to cover DSI (ICC, 2017).

rights (IPR) systems are most useful for monitoring ABS, hence the proposal to include the origin of genetic resources in patent applications (Jørem and Tvedt, 2014; Morgera et al., 2013; Prip et al., 2014). Some of these elements have been included in the 2014 EU ABS regulation, which accepts the basic principles of monetary benefit-sharing and derivatives, but not disclosure and extended time scope. We will use acceptance or support as expressed in interviews and government consultations to check whether these elements are in line with expectations.

The third "social responsibility" model assumes that company managers can have mixed motivations that may include social norms of responsibility, in addition to profit maximization. This perspective builds on the tentative assumptions that managers evaluate options broadly in terms of social, economic and political aspects, and that their response to regulation is affected by social norms of responsibility. Regulation can affect such norms of responsibility for companies operating in a complex political and social environment where consumers and civil society organizations play an important role.

Norm-guided behavior has increasingly been incorporated into economic studies of responses to governmental regulation (Esty and Winston, 2006) and is discussed in the vast literature on corporate social responsibility (CSR). Companies can contribute to providing public goods, for instance through voluntary CSR principles and measures. However, since voluntary contributions are rarely deemed sufficient to provide important public goods, like conserving biodiversity, additional state regulation is normally viewed as necessary (Barth and Wolff, 2009). In the context of ABS and bioprospecting, expected responses here are full acceptance of ABS: accepting *monetary* benefit-sharing, accepting the inclusion of *derivatives*, linking monitoring to *disclosure* through IPR/patent systems

and setting the *time scope* to the entry into force of the CBD (1993). This position accepts an ABS design broadly in line with what developing countries have generally fronted in ABS negotiations. However, empirical assessment of this perspective may prove challenging, as corporate norm-guided behavior is difficult to distinguish from other motivations.

10.3 Governing Bioprospecting in the Polar Regions

10.3.1 Marine Bioprospecting

There is increasing economic interest in genetic material from marine bacteria, sponges, krill, corals and seaweeds. Marine biotechnology research includes aquaculture, novel products such as Omega 3, fatty acids from fish oil, carotenoids, pigments, flavorings and nutritional supplements (Blunt et al., 2011). The total value is difficult to assess and may be overrated (Leary, 2018), but Blasiak et al. (2018) estimate the value of global marine bioprospecting in 2025 at $6.4 billion. However, although the number of patent applications based on marine genetic resources is increasing, only 1–2 percent of preclinical candidates become commercial products (Leary, 2018). Patent applications merely indicate a demand for patent rights, not actual control, and there is yet little information regarding patents granted.

Bioprospecting the high seas is a cost-intensive, high-risk activity. Apart from possible legal constraints on bioprospecting, collectors also face economic and biological challenges. Economic: Only a few research vessels are equipped to access and collect samples in the polar regions. Some of the collected material is already known and has been analyzed, isolated and characterized, as most species studied have a large geographical distribution (Svenson, 2013). Biological: The high-cost, high-risk nature of collecting makes resampling difficult; hence the motivation to stock up as much as the vessel's freezing capacity allows, which gives rise to issues of sustainability in harvesting (Svenson, 2013).

Reflecting the high costs, marine bioprospecting and patent applications come predominantly from a few developed nations and their industries (Arnaud-Haond et al., 2011; Müller and Schøyen, 2021; Oldham and Kindness, 2020). Beside Australia, Germany, Norway, Russia, the USA and UK, China is currently preparing to join this exclusive club,[2] having established a large marine science center in Qindao, Shandong province, aiming to study the extreme marine environments of the Polar regions, and building ocean-going vessels specifically rigged for collecting marine samples.[3]

Bioprospecting takes place by directly collecting organic material from nature, and through genetic sequencing of such material that has already entered biobanks. At the time of harvesting (collecting from the wild), the material typically includes all kinds of living specimens or samples from organisms. On return to shore, the marine material is usually stored in biobanks in various forms, from living organisms through dried material to prepared laboratory samples. From these, new expressions can be made, including

[2] China was accepted as an observer in Arctic Council in 2013; Beijing sees the Arctic as part of its Belt and Road project, with interests in transport, oil and gas, and marine natural resources (Rottem and Soltvedt, 2020).

[3] Personal communication, Erlend Ek, Norwegian embassy, Beijing, October 9, 2018. www.xinhuanet.com/english/2018-02/08/c_136959522.htm. See also http://www.qnlm.ac/en/index.

taxonomic information, ready-made assays, biochemical compositions, DNA sequencing, DSI, screened genomes and synthesized enzymes (biological molecules) copying those found (Tvedt, 2020). Enzymes are a central part of polar marine bioprospecting for their function in catalyzing chemical reactions in living organisms (respiration, digestion, etc.).[4] Bacteria for antibiotics and anticancer agents form another major group (Oldham and Kindness, 2020). As shown in Box 10.1, synthetic biology and the use of DSI are increasingly affecting the ABS debate, and also invoking and intensifying the derivative debate in UNCLOS (Lai et al., 2019; Wolman, 2016).

10.3.2 Governing Bioprospecting

Three levels of law are relevant for polar bioprospecting. At the *regional level*, Antarctica is governed by the Antarctic Treaty System (ATS). The legal overlap between ATS and UNCLOS regarding Antarctica is subject to some controversy; however, neither of these regimes has regulations relating directly to marine bioprospecting. The *international level* includes the rules in UNCLOS, treaties on patent law harmonization and the general rules concerning ABS in the CBD. A general ruling in UNCLOS, Article 118, states that the parties shall cooperate in the conservation and management of living resources in the areas of the high seas. The ABS regime of the CBD is more specific about ABS conduct in bioprospecting, and might take precedence over UNCLOS through "lex specialis" (as more specific legal acts tend to take precedence over less specific ones). The ABS regime is also more inclusive, with 196 ratifying member states, as against 168 UNCLOS ratifications. The USA has not ratified either. The CBDs ABS regime demands prior informed consent (PIC) and mutually agreed terms (MAT) about where genetic material is found and under what conditions the material has been appropriated. Unlike UNCLOS, the ABS regime is not directly applicable outside of national jurisdiction, however.

In the ongoing UNCLOS negotiations (based on UN General Assembly decision 72/249, 2017), developing countries have advocated an ABS regime, whereas the developed countries' main concern has been with open access to the high seas (Blasiak et al., 2016). Developing countries favor an ABS regime along the lines of the CBD, which may involve mandatory, monetary benefit-sharing upon commercialization, the inclusion of derivatives, linking monitoring of ABS to patent systems (with mandatory disclosure of origin of genetic material in patent applications) and that the time scope for collected material is reckoned from the entry into force of the CBD (1993). Most of the developed countries, and increasingly China, are opposed to a fully fledged ABS regime along the lines of the CBD.[5] Unlike the case in the CBD, FAO, WIPO and WTO, corporations and industry associations are hardly represented in the UNCLOS preparatory committee meetings where ABS and marine bioprospecting are discussed. They are, however, active in lobbying state actors on UNCLOS agenda issues.[6] The ICC coordinates industry views on use of genetic resources within national borders, but this strategy does not address ABNJ directly (ICC, 2018). The

[4] https://www.britannica.com/science/enzyme [5] https://enb.iisd.org/vol25/enb25129e.html.
[6] Personal communication at Antarctic Conference in Tromsø, May 7, 2018, with Professor Steven Chown, Director of SCAR (Scientific Commission on Antarctic Research), of the Antarctic Treaty System.

biotechnology industry is concerned with reducing legal uncertainty, which, many argue, is hampering innovation and the development of products from marine habitats (ICC, 2018).[7]

The UNCLOS negotiating parties are split between the principle of the freedom of the high seas versus principles on ABS from use of marine genetic resources. This is predominantly a North–South conflict, exacerbated by the diverging norms embedded in internationally harmonized patent regimes (IPR[8]), and the ABS regime of the CBD with its Nagoya Protocol, respectively (Oberthür and Rosendal, 2014). In the polar regions the IPR–ABS discussion assumes new aspects as it relates to regulations of resources beyond national jurisdiction. The debate here can be seen as about striving to fill a legislative gap in the governance of genetic resources, as genetic resources in ABNJ are not directly covered by the CBD ABS regime. This concerns the access to and equitable sharing of benefits arising from the use of what may be regarded as a global commons resource, traditionally conceived of as a Common Heritage of Mankind (the CHM principle) (De Lucia, 2019). The central argument linked to the global commons nature of these resources concerns the need to maintain affordable access to the resources also for those without the financial means to conduct bioprospecting on the high seas. Such access might, for instance, be achieved through common pool collections of marine genetic samples (Jørem and Tvedt, 2014; Tvedt, 2020). The transparency necessary to realize benefit-sharing could also be achieved by notification through a clearinghouse mechanism: Prip (2021) argues that such a notification system should cover not only marine genetic resources (MGRs) collected in the sea, but also those held *ex situ*, as in gene banks, as well as DSI on MGRs. Another advantage of a common pool collection and a clearinghouse mechanism concerns sustainability in harvesting: Duplicates would be accessible to all, instead of each collector needing to collect their own sample, which might reduce the pressure on potentially rare marine specimens.

The third legal level refers to private rights subject to domestic legislation, contracts and patents. Updated information on national ABS legislation can be found at the CBD Clearing House site.[9] The majority of developing countries have enacted, or are in the process of enacting, ABS legislation, whereas this is less widespread in developed, typical "user" countries. In 2014, the EU issued ABS legislation that is in support of mandatory monetary benefit-sharing and includes acceptance of derivatives and disclosure. The EU legislation timeframe is limited to 2014 (with the entry into force of the Nagoya Protocol) and does not cover utilization of genetic resources back to the establishment of the ABS regime in 1993. Iceland regulates bioprospecting in relation to microbes isolated from their geothermal areas (Leary, 2008), and Queensland, Australia has ABS for commercial bioprospecting at home (Prip et al., 2014). Sweden and Denmark have determined that for the time being they do not intend to regulate ABS of genetic resources within their own national borders; similarly, Russia has no ABS regulation. The USA, which is not party to the CBD, has ABS-like regulations for bioprospecting within its national parks. Norway and Denmark have

[7] Observation by Morten Walløe Tvedt at Brest meeting of biobank collections, May 14–15, 2018.
[8] Mainly the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the World Intellectual Property Organization.
[9] https://absch.cbd.int/en/countries.

advanced ABS regimes for regulating Norwegian and Danish bioprospecting abroad. Both countries have modified their patent acts, requiring disclosure of where genetic material is found and under what conditions the material has been appropriated (PIC and MAT obligations). Norway and Finland are in the process of developing ABS regimes for regulating bioprospecting also at home. In Norway, an administrative order on how to regulate ABS and foreign bioprospectors at home has been subjected to two separate hearings (2012 and 2017). In our case study of Norway, we pay specific attention to this decision-making process, which was still pending at the time of writing (spring 2021).

10.4 The Case of Norway: Bioprospecting Policies and Positions

The polar regions (Antarctic and Arctic) are part of Norway's identity as a polar nation. Norway is one of the seven claimant Parties to Antarctica. The Norwegian government's marine bioprospecting strategy (White Paper, 2009: 7) aims to "strengthen bioprospecting activities in the High North by giving priority to the collection of marine organisms from the northern ocean region." Of the Arctic states, Norway has the most highly developed marine biotechnology sector and has territorial waters and an exclusive economic zone (EEZ) ranging from the North Sea and Skagerrak to the polar areas surrounding Svalbard, Jan Mayen and the Barents Sea.

Norwegian (and foreign) bioprospectors receive considerable public funding through the research programs under the Research Council of Norway and public funding of oceangoing research vessels collecting biological samples, as well as access to the marine samples deposited in the public marine biobank – Marbank in Tromsø (Svendsen, 2013). Most marine bioprospecting activities involve collaboration between academia and business, of which MabCent has been the largest in Norway (Greco and Cinquegrani, 2016; MabCent Report, 2015). A recurrent complaint associated with these public–private partnerships concerns the patent processes, which are necessary for commercial actors but tend to delay the publication of research results, on which the academic actors depend (MabCent Report, 2015, Prip et al., 2014; Rosendal et al., 2016). In 2015, MabCent was replaced by the Arctic Biodiscovery Centre at the Arctic University, which is not contractually linked to any specific commercial partner.[10]

About one third of the materials and samples in Marbank have their origin in ABNJ. This makes it pertinent to examine bioprospector positions in the UNCLOS debate as well as on relevant Norwegian policies. The lack of position papers and plenary statements in UNCLOS caused us to look elsewhere to identify the specific industry interests in marine bioprospecting. We gained some indications of bioprospector positions and strategies by evaluating the hearing responses from the two consultation processes (2012 and 2017) on the Norwegian draft ABS administrative order. These hearings appear highly relevant for our purposes, for two reasons: First, it is difficult to distinguish between marine material collected from areas *within* national jurisdiction and in ABNJ. Researchers on board the vessels collecting materials will know where the samples have been collected, but the

[10] https://bit.ly/34snBnM.

sampled organisms may well occur in many locations both *within and beyond* national jurisdiction. Second, the hearings cover the same issues, relevant at international and domestic levels, concerning the regulation of accessing samples from marine biobanks and regulating access and use of genetic digital sequence information and derivatives such as enzymes. Third, the corporate actors involved have an interest in marine resources from locations both within national jurisdiction and in ABNJ.

In examining the hearing responses, we distinguish among positions according to the three corporate models described above. Both drafts aim to comply with the CBD/Nagoya Protocol objectives for ABS. The first draft of the Norwegian ABS administrative order (2012) included monetary benefit-sharing, and defined derivatives (enzymes, digital sequences) as part of genetic resources. The hearing revealed strong support for this ABS model among public actors and NGO respondents, whereas industry actors were critical of what they feared could become a cumbersome, expensive access model (Rosendal et al., 2016).[11] Seven of the eight commercially oriented actors opposed the draft ABS legislation, albeit with conditional support, as they pointed to pending ABS legislation in the EU. One of the eight commercial respondents supported the full text of the ABS draft, citing the need to secure equitable sharing of benefits from the use of genetic resources.

In 2017, a revised draft administrative order on ABS was circulated. To accommodate industry responses to the first round of hearings, the revised draft did not mention monetary compensation except as a voluntary fee for access to public biobank collections. Also, the draft excluded enzymes – in other words, derivatives.

In response to these changes in the ABS design, the commercial respondents welcomed the 2017 draft administrative order. In general, their responses moved from what we expected in the first to the second model, apparently due mainly to the announced adjustment on excluding enzymes. In 2012, nearly all commercial respondents had referred to forthcoming EU legislation on ABS as a reason for stalling, but EU legislation was not mentioned by them in the 2017 hearings. This is hardly surprising, as the EU's ABS legislation in 2014 came out in support of mandatory monetary benefit-sharing and acceptance of derivatives and disclosure (setting the timeframe to the Nagoya Protocol [2014], and not the CBD [1993], though).[12] The 2017 hearing received twenty-nine responses, including nine from actors with commercial interests in marine bioprospecting, such as ArcticZymes (part of the MabCent consortium).

As monetary benefit-sharing was dropped to accommodate industry interests, the issue of access-fees (or "cost-sharing" [Rosendal et al., 2016]) in biobanks became relevant. The 2017 draft proposed that public (but not private) biobank collections should allow free access, and here the university museums and Marbank were critical. Marbank argued that the revised draft order might dissuade private collectors from sharing and depositing their material with Marbank, while having free access to Marbank's material and being free to patent innovations based on this material.[13] In Marbank's view, the public collectors that provide marine genetic

[11] This is based on the authors' reading of all the consultation responses to the 2012 draft administrative order.

[12] EU No. 511/2014. See also SEPA, 2018: 10: "The Regulation also applies to derivatives which were acquired at the same time as the genetic resource. Derivatives are defined as naturally occurring biochemical compositions that result from the genetic expression or metabolism of biological or genetic resources, although they do not contain functional units of genetic material. Examples of these are enzymes, proteins and essential oils."

[13] Interview / personal communication with Kjersti Lie Gabrielsen, Director of Marbank, May 8, 2018.

material would be left with no rights, whereas the commercial users of the material would have no obligations. In practice, access to Marbank has usually taken place through academia–industry consortia, but corporate actors are currently not allowed access, in anticipation of the new legislation.[14] Similar criticism came from noncommercial actors, who argued that the revised draft was no longer in compliance with the CBD's ABS obligations, and warned that monopolization might follow from the lack of restraints on patenting.[15] Critics pointed at the flaw in the 2017 draft: Unlike ABS regulations in the EU, it does not include enzymes and derivatives and may hence undermine the CBD's ABS regime and be poorly equipped to deal with synthetic biology activities.[16] As noted, enzymes constitute about one third of marine bioprospecting. This may partly explain why ArcticZymes reacted positively to the revised draft order.

According to the Norwegian Ministry of Trade, Industry, and Fisheries, which is responsible for the ABS administrative order, however, enzymes will not be excluded from the (still pending) ABS legislation.[17] The reason is that excluding enzymes would not be compatible with EU legislation, let alone the CBD (see note 12, on enzymes [as derivatives] being part of the EU definition of genetic resources).

10.5 Variation in Corporate Strategies

We have examined the ABS positions of two bioprospecting corporations in further detail (see Table 10.1). Novozymes is a multinational corporation, headquartered in Denmark, and among the world's largest producers of industrial enzymes. ArcticZymes, based in Tromsø, Norway, is a smaller company that is part of a multinational pharmaceutical corporation, Biotec Pharmacon (thus also part of MabCent); now known as ArcticZymes Technologies.

10.5.1 Novozymes

Novozymes (part of NovoNordic until 2000) is actively engaged in the ABS issue, with the explicit policy of adhering to the ABS principles of the CBD. Going further than the EU's ABS legislation, Novozymes holds that ABS starts with the entry into force of the CBD in 1993. Further, the corporation is set on avoiding accusations of biopiracy. According to its explicit policy:

> Novozymes endorses the globally recognized principles in the CBD and ABS. As a part of our obligation towards the CBD, we only take samples in agreement with all relevant laws and regulations in the countries we operate in. In addition, we have stringent internal procedures including a database system for traceability of genetic resources to ensure that we live up to our commitments.[18]

[14] Interview / personal communication with Kjersti Lie Gabrielsen, Director of Marbank, May 8, 2018.
[15] This view was central in the hearing letters from the Research Council of Norway, the National Ethical Research Committees, the Norwegian Institute of Marine Research, the Ministry of Agriculture and the Norwegian Coastal Administration.
[16] This is based on the authors' reading of all the consultation responses to the 2017 draft administrative order.
[17] Personal communication with NN, of the Ministry of Trade and Fisheries and responsible for the second draft administrative order, August 29, 2018, at the FNI Genetic Resources Seminar, Lysaker, Norway. At the time of writing, the administrative order is still pending.
[18] www.novozymes.com/en/about-us/positions-policies.

The strong ABS policy is often linked to Novozymes' and NovoNordic's first CEO, Steen Riisgaard – due partly to his background from the NGO sector, which included Friends of the Earth and WWF, Denmark, and due partly to his many official statements on how enzymes technology can contribute to a more environmentally friendly world.[19]

Still, the ABS regime seems to have had more of a hampering effect on Novozymes' bioprospecting than boosting it. As a direct result of the CBD principles on ABS, most of its bioprospecting collaboration with university partners in developing countries stopped in the mid 1990s. According to our interviewees at Novozymes, this is because ABS legislation is sometimes inappropriately designed, leaving too much legal uncertainty regarding documentation of PIC and MAT about where genetic material is found and under what conditions the material has been appropriated.[20] And indeed, when Brazil changed its ABS legislation (2015–2017) to a simpler system, Novozymes reengaged in cooperation.[21] The Brazilian example indicates that it is possible to design "appropriate" ABS legislation that provides bioprospectors with enough legal certainty to trust in collaboration.

At present, Novozymes may be largely self-sufficient in genetic resources through its own collections, but the company acknowledges that marine genetic resources from the deep sea may be interesting and necessary in the future. Novozymes already has roughly 50,000 bacteria and fungi in its collection, which dates back over sixty years; however, as put by Peter Falholt, head of R&D at Novozymes, "I'm a little bit skeptical of synthetic biology [as being able to provide sufficient genetic material for bioprospecting], because you cannot beat four billion years of evolution" (quoted in Peplow, 2015). Their patent filings on polar, marine material date back to 1986 and 1992 for *candida Antarctica* (an enzyme, lipase), with applications ranging from food and fuels to detergents and medicine (Oldham and Kindness, 2020). Novozymes ranks as number one by a considerable margin for first patent filings involving Antarctic organisms (Oldham and Kindness, 2020): Novozymes tops the list with 300 filings, with BASF coming second with 113 filings. However, Oldham points out that in patent filing registrations, Novozymes is more likely to appear prominently because it is far more likely (than any of its competitors) to state the origin of the material in its patent applications: This is in line with the corporation's formal policy and guidelines to abide by the CBD's ABS regime. Further, BASF may appear less prominently because it is less explicit in stating the origin of its material, so the sources will not be registered in the patent filings.[22] This shows how ABS compliance could also expose a corporation to criticism, as Novozymes "appears" to have more patent filings involving marine organisms.

Novozymes does not participate directly in UNCLOS but coordinates its positions with the ICC. Although Novozymes might seem to fit into our third model given its strong language on ABS, there is agreement within the ICC group to lobby against applying ABS to genetic digital sequence information (ICC, 2017; 2019). The ICC is explicit in strongly opposing any expansion of the scope of the ABS regime to apply to digital sequence

[19] https://en.wikipedia.org/wiki/Steen_Riisgaard.
[20] Interview with representative from Novozymes, Copenhagen, October 2018.
[21] www.cbd.int/abs/ABNJ-views/2019/Brazil-DSI.pdf (on the new ABS legislation in Brazil).
[22] Personal communication with Dr. Paul Oldham of Lancaster University, UK. May 11, 2020.

information and genetic resources in ABNJ (ICC, 2017: 1). That places Novozymes closer to our second model on appropriate design, as they argue against closing the legal gap, hence against increasing the scope of ABS.

10.5.2 ArcticZymes / Biotec Pharmacon

ArcticZymes describe itself as follows: "we use access to the marine Arctic to identify novel cold-adapted enzymes for use in molecular research, in vitro diagnostics, and manufacturing."[23] It has a history of collaboration with Norwegian universities through the MabCent project, as part of holding company Biotec Pharmacon. The academic collaboration has allowed free and open access to Marbank's collections and to Marbio's ready-made assays. Access to Marbank is now a thing of the past, due to legal uncertainty linked to the fate of the Marbank material in the draft Norwegian ABS order. However, losing access to Marbank is not seen as a problem for ArcticZymes as it can find what it needs in international biobank collections and databases, where digital genetic sequences may be purchased online.[24]

Biotec Pharmacon ranks as the largest holder of patent filings on Arctic marine materials[25] and, according to MedNous (2019), "Biotec Pharmacon's inventive step was to scour the marine environment for solutions that were not already on the market and patent them." Several patented products based on cold-water enzymes are presented on ArcticZymes' online website.[26] These include proteinase, which is an unspecific endopeptidase (an enzyme) originating from an Arctic marine microbial source,[27] and glycosylase, which belongs to a family of enzymes involved in DNA repair and stemming from Atlantic cod.[28] Compared to Novozymes, ArcticZymes is a small firm that attracts scant public attention and might hence be less worried about possible accusations of biopiracy. When enzymes were excluded from the Norwegian ABS draft legislation, the company came out in favor of the ABS proposal. If enzymes were to be redefined as subject to the ABS legislation, ArcticZymes could be expected to oppose it. Hence, it is hard to judge whether it fits into our first or second model (Table 10.1).

10.6 Discussion

The hearing responses to the two draft ABS administrative orders reveal how the Norwegian authorities have found it hard to adjust domestic legislation to the global ABS regime of the CBD, for which they were strong advocators at the time. The government's response has been to change the wording of the ABS administrative order from including enzymes (2012), to excluding enzymes (2017), and then possibly to include enzymes in the regulatory scope once more. The Norwegian ABS regulation is still pending, nearly

[23] https://arcticzymes.com/company/about-us/.
[24] Interview with representative from ArcticZymes, Tromsø, September 2018. Corroborated in Hearing from ArcticZymes, Tromsø, October 3, 2017.
[25] Oldham and Kindness (2020).
[26] https://arcticzymes.com/products/enzymes/. See also ArcticZymers Technologies. 2020. Q4 Report 2020. Tromsø, Norway.
[27] https://bit.ly/3HojXKv. [28] https://bit.ly/3KdVedG.

Table 10.1 *Positions on ABS: ArcticZymes and Novozymes*

COMPANIES/ ORGANIZATIONS	SUPPORT OR OPPOSITION TO ABS	ARGUMENTS BASED ON MODEL 1	ARGUMENTS BASED ON MODEL 2	ARGUMENTS BASED ON MODEL 3
ARCTICZYMES	Conditional support	Oppose benefit-sharing on material from open publications and databases.	Accept monetary benefit-sharing, but not if derivatives (incl. enzymes) are defined as genetic resources.	
NOVOZYMES	Support		Accept monetary benefit-sharing. As part of ICC: do not wish to close the legal geographical and technological gaps.	Bases corporate strategy on strong language on ABS. In favor of EU ABS legislation on derivatives and goes further than EU by accepting CBD (1993) as timeline for ABS.

a decade after its conception and despite the intensity with which Norway advocated the ABS regime of the CBD. This would seem to be a classic example of how policies may change when internationally agreed policy obligations are to be translated into domestic policies, if these policies prove to entail explicit costs to specific subnational target groups. Similarly, Norway is no longer a strong advocate of ABS principles in the current process on the Post-2020 Global Biodiversity Framework.

Corporate actors were far less skeptical of the second draft administrative order, which excluded enzymes from the definition of genetic resources. The increased acceptance was due mainly to this (potentially short-lived) adjustment on excluding enzymes. The change in responses suggests an effect of adjusting the regulatory design, which is in line with our Model 2 expectations.

Model 3 responses would be closer to transformative biodiversity governance but are difficult to assess. On the rhetorical level, Novozymes' history and links to the NGO sector have made a deep impact on its policy to support ABS. Moreover, its history, not least its visibility as a large corporation, has made Novozymes cautious, as well as vulnerable to being associated with accusations of biopiracy. In effect, Novozymes has backed away from bioprospecting collaboration with countries with (arguably) unclear ABS legislation that is claimed to engender legal uncertainty. When Brazil simplified its ABS legislation, Novozymes resumed collaboration – indicating that deeds followed words, but also showing how the company's responses may be more in line with Model 2. Further, a possible problem for bioprospectors in complying with the ABS principle of disclosure is that this may expose the corporation to criticism: This is exemplified by Novozymes' reporting of origin of material in patent applications, possibly to a much larger extent than BASF reporting. Moreover, as part of the ICC collaboration in UNCLOS, Novozymes is apprehensive about any expansion of the ABS scope ("don't close the legal gap").

The takeaway message is that policymakers have legal and political room to maneuver in adjusting ABS to get bioprospecting corporations on board. The political feasibility room here might not fully correspond to the aims of transformative biodiversity governance, however.

Finally: How do corporate actors plan and strategize regarding their own access to marine biological material from ABNJ? Access may be affected if only a handful of multinational corporations come to monopolize the bulk of collected material through patent applications. Granted patents have been few, but if the majority of patent applications succeed, that would clearly undermine ABS efforts while also severely restricting access for other bioprospectors. This aspect indicates an interesting potential for common ground between ABS principles and corporate interests, which might increase the political feasibility room.

10.7 Conclusions

Future transformative biodiversity governance should heed two regulatory "gaps" in current legislation: one primarily of a *technological* nature, the second *geographical*. Developments in new biotechnologies may widen the technology gap in ABS regulations: This gap is likely

to remain open to corporate actors unless states decide to define derivatives (DSI, synthetic enzymes, etc.) as part of genetic resources. As noted, ABS legislation in the EU has included derivatives (enzymes and DSI) in its definition of genetic resources. Will industry become more inclined to accept the EU design for ABS as appropriate? And will the EU's approach to ABS have a bearing on how the UNCLOS debate deals with derivatives? (Bio)technological developments make it difficult to monitor bioprospecting, as bioprospectors can now access, sample and develop a large range of digital genetic sequences from online databanks.

With the evolving technological potential, technology has direct and significant implications for the global governance of biodiversity and genetic resources, as the ABS regime is more readily undermined by genetic resources expressed as digital sequence information. This challenge to the equity principles of the ABS regime indicates how vested interests in biotechnology might obstruct central elements in TBG.

Second, while the UNCLOS debate continues, uncertainty remains as to whether the regulatory geographical gap is likely to remain open to bioprospectors. One way of closing this gap would be to subject marine genetic resources from ABNJ to ABS regulation as global commons resources by making it mandatory to share duplicates of collected samples in common pool biobanks. This proposal features centrally on the UNCLOS agenda, along with the proposed clearinghouse mechanism. Sharing duplicates openly would, in addition, reduce pressure on rare marine species – an important point for transforming biodiversity governance.

Our study has revealed important elements and differences between formal and informal stakeholder participation and inclusion, the latter being central to the TBG debate dealt with in this volume. There are indications that multinational corporations may exert strong influence on legislative processes and policymaking, albeit being formally absent from decision-making forums, internationally and nationally. Turning to the domestic level in Norway, despite the small number of industry actors engaged in the ABS hearing processes there, they had a deep impact on the output of the first hearing and may have influenced the stalling of the regulation. On the international arena, the ABS regime clearly represents a normative victory for developing countries, who continue to advocate ABS principles in international forums also outside the CBD. However, it remains to be seen whether the ABS norms will succeed in steering UNCLOS' governance of common, marine resources in a more equitable direction. The most inclusive suggestions currently on the UNCLOS negotiation table would seem to involve a combination of establishing common pool collections for marine genetic resources and a clearinghouse mechanism.

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