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Marine genetic resources beyond national jurisdictions: Negotiating options on intellectual property

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148

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Paper

7 March 2022

MARINE GENETIC RESOURCES BEYOND NATIONAL JURISDICTIONS: NEGOTIATING OPTIONS ON INTELLECTUAL PROPERTY

Siva Thambisetty



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RESEARCH PAPER

148

MARINE GENETIC RESOURCES BEYOND NATIONAL JURISDICTIONS: NEGOTIATING OPTIONS ON INTELLECTUAL PROPERTY

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SOUTH CENTRE

7 MARCH 2022

* Associate Professor of Law, London School of Economics and Political Science (LSE). This paper is a revised and updated version of a policy brief prepared to aid discussion during an online Workshop on Intellectual Property Arrangements in the international legally binding instrument under the United Nations Convention on the Law of the Sea on the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction (BBNJ Instrument) organised by the LSE Law School for the G77+China group of negotiators in July 2020 (LSE Law Policy Briefing Paper 48).

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ABSTRACT

Negotiations on marine biological diversity of areas beyond national jurisdiction (BBNJ) convene after a significant hiatus during which intellectual property monopolies have come under intense normative and pragmatic scrutiny. This paper historicises developments in legal arrangements over intellectual property and biodiversity to propose several negotiating options on the control, use and circulation of marine genetic resources of areas beyond national jurisdiction. The text-based options presented here operationalise an equitable approach taking into account the interests of low power groups, cross-cutting issues and the often ignored question of the ownership and use of marine genetic resources through intellectual property rights.

Les négociations sur les ressources génétiques marines des zones ne relevant pas de la juridiction nationale se réunissent après une interruption importante au cours de laquelle les monopoles de propriété intellectuelle ont fait l'objet d'un examen normatif et pragmatique intense. Ce document fait l'historique de l'évolution des dispositions juridiques relatives à la propriété intellectuelle et à la biodiversité afin de proposer plusieurs options de négociation sur le contrôle, l'utilisation et la circulation des ressources génétiques marines des zones ne relevant pas de la juridiction nationale. Les options de texte présentées ici rendent opérationnelle une approche équitable prenant en compte les intérêts des groupes à faible pouvoir, les questions transversales et la question souvent ignorée de la possession et de l'utilisation des ressources génétiques marines par le biais des droits de propriété intellectuelle.

Las negociaciones sobre los recursos genéticos marinos más allá de la jurisdicción nacional se convocan después de un importante paréntesis durante el cual los monopolios de la propiedad intelectual han sido objeto de un intenso escrutinio normativo y pragmático. Este documento analiza la evolución de los acuerdos jurídicos sobre propiedad intelectual y biodiversidad para proponer varias opciones de negociación sobre el control, la utilización y la circulación de los recursos genéticos marinos de las zonas más allá de la jurisdicción nacional. Las opciones basadas en textos que aquí se presentan hacen operativo un enfoque equitativo que tiene en cuenta los intereses de los grupos de bajo poder, las cuestiones transversales y la cuestión, a menudo ignorada, de la propiedad y el uso de los recursos genéticos marinos a través de los derechos de propiedad intelectual.

TABLE OF CONTENTS

ABSTRACT.....	<i>iii</i>
1. INTRODUCTION: NEGOTIATING THE BBNJ INSTRUMENT IN THE PANDEMIC	5
2. INTELLECTUAL PROPERTY STATUS QUO: CAPITULATION OR PROGRESS?	7
3. LEVERAGING PROGRESS ON CONSERVATION GOALS WITH BIODISCOVERY AND INNOVATION.....	9
4. TEXT-BASED OPTIONS	10
Article 10.....	10
Article 10bis	14
Article 11	14
Article 12.....	19
Article 13.....	23
Article 54	24

1. INTRODUCTION: NEGOTIATING THE BBNJ INSTRUMENT IN THE PANDEMIC

The world in March 2022 is materially different to the world in March 2020 when the Fourth Session of the Intergovernmental Conference (IGC4) on an international legally binding instrument under the UN Convention on the Law of the Sea (UNCLOS) on the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction (BBNJ) was first postponed. A defining feature of the international response to COVID-19 has been the iniquitous distribution of COVID-19 vaccines and the central role played by intellectual property (IP) monopolies in inadequate production driven scarcity. The TRIPS waiver proposal, put forward by South Africa and India in October 2020 and supported at the WTO by over 100 countries holds many lessons for any international negotiations related to IP arrangements in a post-pandemic world; it has energised debate about the normative, political and legal case for IP across the development divide. The case for the waiver is based on careful analysis of the effect that a suspension of rules made under the TRIPS agreement would have in the production of COVID-19 vaccines, and is backed by meticulous academic and policy-based research.¹ Yet vaccine scarcity is leading to what WHO Director Dr Tedros Ghebreyesus has referred to as a two-tier pandemic where high rates of vaccination in high income countries is moving them much faster out of a pandemic and into an endemic situation with COVID-19. Even as the working definition of “fully vaccinated” becomes three doses, only 10 per cent of people in low income countries have received at least one dose, while in high income countries it is 77 per cent. Meanwhile COVAX has emerged as a poorly designed and weakly implemented philanthropic measure that simply “manages” acute demand rather than establish steady supply to meet that demand.² Despite goodwill and best efforts on the part of high income State Parties, we see private owners of IP monopolies working outside of global equity considerations unless these are implemented in law or politics.

The central role played by an unbending IP regime in fuelling scarcity of vaccines³ imparts at least three lessons that negotiators in IGC4 should ideally bear in mind. First, if the BBNJ instrument leaves technology transfer and capacity building (the core issue of the TRIPS waiver) to voluntary measures, then we will likely never see transfer of valuable technologies that are protected by different kinds of IP rights – patents, trade secrets, commercially sensitive information, copyright etc. Any serious proposal to bridge the marine scientific research capacity gap must include limitations on the use of IP in furtherance of the aims of the BBNJ instrument. Secondly, intellectual property incentives that work to encourage biodiscovery and innovation may well work against the dissemination and transfer of technology. If you agree conceptually with the first part, you may also be committing to the latter unless you put mitigations to enable technology transfer in place. Thirdly, it is time to lay to rest the idea that philanthropy alone can change the status quo when it comes to capacity building and technology transfer. So long as both the design and implementation of voluntary or philanthropic measures are driven by the same power and knowledge asymmetries that are a function of the technology gap and the development divide, they tend

¹ Thambisetty, McDonagh, McMahon, Kang and Dutfield, “The TRIPS Intellectual Property Waiver Proposal: Creating the Rights Incentives in Patent Law and Politics to end the COVID-19 Pandemic”, *Cambridge Law Journal*, July 2022 (forthcoming); LSE WPS 06/2021 available from https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3851737; Signed by close to 200 global IP academics and scholars see “Academic Open Letter in Support of the TRIPS Intellectual Property Waiver Proposal”, LSE Law Policy Briefing Paper no 46 (2021) Available from https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3885568; H G Ruse-Khan and F Paddeu, *A TRIPS-Covid Waiver and Overlapping Commitments to Protect Intellectual Property Rights Under International IP and Investments Agreements*, Research Paper No. 144 (Geneva, South Centre, 27 Jan 2022). Available from <https://www.southcentre.int/wp-content/uploads/2022/01/RP-144.pdf>.

² G Yamey, “Rich Countries Should Tithe Their Vaccines”, *Nature* 590 529 (25 February 2021).

to maintain status quo. In a legally binding instrument, the focus should be on enforceable legal measures and obligations to mandate behaviour that moves us all towards agreed goals.

It is difficult to imagine a more hardworking set of legal provisions in international law dealing with biodiversity than Articles 10–13 in the BBNJ draft instrument. Together these by omission and commission, establish and operationalise the property status of marine genetic resources beyond national jurisdiction, set up modalities of benefit sharing, mark a shift from an environmental to a biotechnological approach to these resources by referring to intellectual property arrangements over them and also attempt to deal with compliance of unspecified obligations. Within these broad aspects there are many different variations of what State Parties would like to see, and yet more ways of using language to achieve degrees of certainty and helpful ambiguity.

This Research Paper develops an equitable approach to the agreement that will facilitate goals widely acknowledged as desirable.⁴ The suggested text is in [this colour](#), and the struck out text is from the draft instrument as we head towards IGC4. The approach in this paper is informed by historicising the growth of intellectual property and benefit-sharing norms around genetic resources⁵ and attempts to reflect the more vocally expressed ambitions for the instrument from the G77 group of countries as represented in conference room papers and statements.

For the reader, and from their own perspective, it would be helpful during negotiations to distinguish between what was referred to during negotiations on the Convention on Biological Diversity (CBD) as bricks (must-haves) on which there is already a level of agreement, and bullets (may-haves), the aspects on which there is no consensus, or which needs further clarification. Or in BBNJ terms, mainsails (must-haves) and spinnakers (may-haves).

⁴ S Thambisetty, “Marine genetic resources beyond national jurisdiction: elements of a new international legally binding instrument”, (2018) LSE Law Policy Briefing Papers Series (32). Available from https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3219995.

⁵ S Thambisetty, “Biodiversity Beyond National Jurisdiction: (Intellectual) Property Heuristics”, in *Biodiversity Beyond National Jurisdiction: Intractable Challenges and Potential Solutions*, MH Nordquist and R Long (eds). (Brill Nijhoff, 2020) pp 131–146.

2. INTELLECTUAL PROPERTY STATUS QUO: CAPITULATION OR PROGRESS?

Before addressing the text of the articles there are three broad overarching guidelines to bear in mind that undergirds the approach here. First, spreading the content of BBNJ negotiations over four different issues requires us to pay attention to invisible cross cutting issues and interconnectivities. This can complicate the negotiation process because many of these cross-cutting issues are poorly articulated or are subject to selective usage and therefore to political leveraging. One such issue is the identity and status of marine genetic resources. Here attempts to define the ‘ocean genome’ as a single entity to enable more cohesive approaches in law and governance are to be welcomed.⁶ The definition adopted in the Ocean Genome Report ‘ensemble of genetic material present in all marine biodiversity, including both the physical genes and the information they encode’ is conceptually helpful because it keeps physical genetic resources and sequence information together in scope and suggests that the distinction of areas beyond national jurisdiction (ABNJ) and national jurisdictions are man-made and imposed rather than natural. Ideally the definition should inform mechanisms directed to use of the ocean genome, as well as those directed to preventing its further degradation. A common framework approach to the ocean genome should permeate all four packages being discussed in the BBNJ.

Secondly, intellectual property (IP) issues have become something of an outcast in many BBNJ fora whether by design or inadvertently — the complexity of the subject matter and political divisions it generates make it difficult to find consensus. Here are a few reasons why it is difficult to talk of intellectual property across the development divide. First, since the TRIPS agreement we know that intellectual property has different implications for different socio-economic levels. Generally, across the development divide countries tend to be preoccupied with either the incentive function or the allocative function. Intellectual property is a much better tool for the first and not very good at the second particularly when affordability and accessibility to technologies are of primary importance.⁷

Secondly, discussion on intellectual property is hamstrung by lack of agreement on scope of the terminology used. The term “genetic resource” in the CBD is linked to physicality and location but in its current form in the draft BBNJ instrument, the term is not just a matter of lexical interpretation but also one of scientific opinion. 28 years on from the CBD, we must reflect on how this definition and fragmented use of physical and informational sources across the packages is hampering discussion on intellectual property arrangements over the ocean genome.

Thirdly, intellectual property is inextricably linked to the question of ownership of these resources. “Commons” does not mean an absence of ownership but rather a surfeit of ownership or joint interests. Curtailing the scope of how intellectual property controls the use of genetic resources is therefore a legitimate matter of concern for this agreement and flows legally and normatively from the commons status of the marine genetic resources of the ABNJ. Fourth, international inter-governmental conversations on intellectual property often exhibit an extraordinary deference to dominant narratives on this subject despite a large body of academic and policy-based critique of the domestic and international implementation

⁶ R Blasiak, R Wynberg, K Grorud-Colvert, S Thambisetty, (lead authors) “Ocean Genome: Conservation and the Fair, Equitable and Sustainable Use of Marine Genetic Resources”, Report submitted to the HLP on a Sustainable Ocean Economy (17 April 2020). [Hereafter Ocean Genome Report] Available from <https://www.oceanpanel.org/blue-papers/ocean-genome-conservation-and-fair-equitable-and-sustainable-use-marine-genetic>; R Blasiak, R Wynberg, K Grorud-Colvert, S Thambisetty, (lead authors) “The Ocean Genome and Future Prospects for Conservation and Equity”, *Nature Sustainability* (4 May 2020). Available from <https://doi.org/10.1038/s41893-020-0522-9>.

⁷ See for instance G77 opening statement at IGC3 on “dissemination” of technologies.

of intellectual property rights. If the BBNJ instrument does not heed the last 30 years of analysis on the effects of IP across the development divide then the implementation of this agreement will always be hampered by the perceived failings of the multilateral process.

Fifth and finally, this suite of Articles (Arts. 10–13) suffers from regime complexity which has been described as the most significant feature of international cooperation in the twenty-first century⁸ and arises when substantive competences overlap across different treaties and institutional mandates. As there is no hierarchy amongst international agreements, issues become stuck. Regime complexity here can be assuaged by focussing on ABNJ, as this is the unique mandate of the BBNJ process, and by providing guidance that can be interpreted in lateral regimes and used productively in domestic implementation. Awareness of regime complexity need not be the same as being stymied by it.

⁸ K J Alter and K Raustiala, "The Rise of International Regime Complexity", (2018) *Annual Review of Law and Social Science*, vol. 14:329–349.

3. LEVERAGING PROGRESS ON CONSERVATION GOALS WITH BIODISCOVERY AND INNOVATION

The central problem in the negotiations is a lack of *quid pro quo* to heighten the intellectual property elements. On the one hand, the status quo is favourable to those who engage in MSR—so there is no political will on their part to change that. On the other hand, keeping existing arrangements on intellectual property, minus mitigating measures, is almost certain to exacerbate the technological gap between developed and developing countries even further,⁹ and goes against growing domestic and international policy critiques of such IPR regimes—so accepting status quo around intellectual property as *fait accompli* hits at the very need for this instrument. The particular way in which the negotiations have been split into four different packages, dealt with in seeming isolation from each other, have also hampered the ability of low power groups to make strategic gains on the right to participate in responsible and inclusive innovation and industry based on marine biodiversity.

98 per cent of patents citing marine genes are filed by 10 countries and scientific publication counts show the dominance of a small number of countries. Based on an analysis of available data The Ocean Genome Report observes that while most marine exploration is undertaken by a handful of high-income countries, sampling is often conducted in low- or middle-income tropical countries. It is known that the benefits of marine biodiversity can extend far beyond the successful development of a product or technology and include for instance the availability of biorepositories of local species for further investigation and highly skilled researchers, advanced equipment and an improved publication profile. All of these together can boost the capacity of a region to thrive via industries while contributing to the protection and sustainable use of biodiversity itself. For these reasons biodiversity and innovation is inextricably linked to conservation and sustainable use of the ocean genome. Therefore, it makes sense to link agreement on conservation goals to agreement on equitable and sustainable utilization of genetic resources through biodiversity and innovation during negotiations.

Consider two instances of recent negotiations where capacity building and technology transfer should have been on the table, linked in a meaningful way to intellectual property arrangements. In the case of the CBD, access to genetic resources and conservation goals were traded with a meaningful benefit-sharing system, but even here intellectual property was not really addressed. If we maintain the silos of the BBNJ negotiation package then doing nothing is optimum for those who are currently engaging in MSR under a freedom of the high seas regime—that is they already have access. In the Paris Agreement (2015), after intense negotiations “no text” on IP was adopted. Article 10 institutes a “Technology Mechanism” which adopts the language of resilience, mitigation, adaptation and cooperative action on technology development and transfer.

These two precedents give some indication of the asymmetry in international law that has always accompanied global standards in intellectual property rights, but these rights are critical to how our systems are set up to innovate and **intentionally** transfer **valuable** technologies. Therefore, although not easy, this is a discussion that needs to be had head on, strengthened by past learning on complex international negotiations. In the final count leverage may come from viewing issues under Arts. 10–13 as cross cutting and balanced by the need to agree on conservation goals.

⁹ See n 5 above.

4. TEXT-BASED OPTIONS

[Article 10

[Collection of] [and] [Access to] marine genetic resources of areas beyond national jurisdiction]

1. *In situ* and *ex situ* ~~[collection of]~~ access to marine genetic resources, including associated digital sequence information and data, within the scope of this Part shall be subject to ~~[Alt. 1. [prior] [and] [post-cruise] notification to the secretariat [, which shall include an indication of the location and date of [collection] [access], the resources to be [collected] [accessed], the purposes for which the resources will be utilized and the entity that will [collect] [access] the resources] [of [collection of] [access to] marine genetic resources of areas beyond national jurisdiction].]~~

~~Alt. 2. a [permit] [licence] issued in the manner and under the terms and conditions set forth in paragraph 2.~~

2. States Parties shall take the necessary legislative, administrative or policy measures, as appropriate, to ensure that any access as per paragraph 1 above, shall be subject *inter alia* to:

(a) *In the case of in situ, access disclosure of, and in the case of ex situ, access to* the geographical coordinates of the location in ABNJ where marine genetic resources were ~~[collected] [accessed]~~; such information must be transmitted and stored in a form that allows the MGRs and associated DSID to be identified at all relevant times.

(b) Appropriate capacity-building;

(c) The transfer of marine technology;

(d) The deposit of samples, data and related information in open source platforms, such as databases, repositories or gene banks; accompanied by identifiers and conditions of grant of the permit;

(e) Contributions as appropriate to the multilateral benefit sharing mechanism referred to in Art. 11. ~~to the special fund;~~

(f) Environmental impact assessments where relevant;

(g) limitations on the exercise of any intellectual property rights or other rights that inhibits compliance with any of the conditions specified in the permit

(h) Equitable benefit sharing that takes conservation and sustainable goals into account

(i) Other relevant terms and conditions as may be determined by the Conference of the Parties, including in relation to ~~[the collection of]~~ [access to] marine genetic resources in ecologically and biologically significant areas, vulnerable marine ecosystems and other specially protected

areas, in order to ensure the conservation and sustainable use of the resources therein.

3. States Parties shall take the necessary legislative, administrative or policy measures, as appropriate, to ensure that *ex situ* access to marine genetic resources and associated digital sequence information and data within the scope of this Part is free and open, used as per the terms of the permit granted, and that such access is facilitated for developing State Parties. ~~[, subject to articles 11 and 13].~~

~~[4. States Parties shall take the necessary legislative, administrative or policy measures, as appropriate, to ensure that access to [marine genetic resources *in silico*] [[and] [digital sequence information] [genetic sequence data]] is facilitated [, subject to articles 11 and 13].~~

[5. States Parties shall take the necessary legislative, administrative or policy measures, as appropriate, to ensure that activities with respect to marine genetic resources of areas beyond national jurisdiction that may result in the utilization of marine genetic resources found in areas both within and beyond national jurisdiction are subject to appropriate the prior notification and consultation with of the coastal States [and any other relevant State concerned], with a view to avoiding infringement of the rights and legitimate interests of those States.

~~[6. States Parties shall take the necessary legislative, administrative or policy measures, as appropriate, to ensure that marine genetic resources of areas beyond national jurisdiction utilized within their jurisdiction have been [collected] [and] [accessed] in accordance with this Part.]~~

Link to status of MGRs: The underlying significance of Article 10 is that it must align with the specific approach to the *status* of marine genetic resources in areas beyond national jurisdiction—whether these are seen as subject to a common heritage of humanity principle, or seen in light of the freedom of the high seas, and the resultant conditions under which access is realized. Herein lies the significance of “notification”, and “permits/licenses”. “Notification” could be unilateral and presumes no reason to deny permission. Although there is not much difference between permit or license, they are both granted based on acceptance of conditions, which need to be set out. A permit if correctly set up could be seen as akin to the “mutually agreed terms” under the Nagoya Protocol and can be the first step in recording obligations and monitoring compliance.

It may also be possible to keep the language of “notification” with the understanding that such notification automatically triggers obligations/conditions such as a permit would.

Outlier proposals: Auction of permits or tiered upfront/ or time delayed payments for the grant of permits (not reliant on actual sampling) that would feed into a multilateral benefit-sharing mechanism.

Access vs Collection: The use of the term “access” has been contrasted with “collection” in recent discussions (Norway – “collection” and EU – “right to collect”). It is worth dwelling on the difference in the scope of these two terms and what that might mean for equitable Treaty structure. Access is a well-established term in the use and circulation of genetic resources

and is a more encompassing and inclusive term than “collection”; and would mean for instance closer scrutiny and more reporting on MGR-related cruises. “Access” suggests a process of parleying access to the waters of areas beyond national jurisdiction (ABNJ), not simply an activity (“collection”). “Collection” on the face of it assumes right to access the waters of the ABNJ. While it has the advantage of being specific and place-bound it also brings to mind physical samples and could distance Article 10, and therefore the scope of the instrument, from digital sequence information and data.

We might also consider the difference between the two terms in terms of ease of monitoring. “Access” may or may not result in “collection” of samples, but because the process of negotiating ‘access’ begins outside the ABNJ, it lends itself better to scrutiny and imposition of conditions. “Collection” or “right to collect” references the activity that takes place once in the waters of the ABNJ so it seems to indicate that MGR-related cruises would not need to take permission, unless they had self-declared that they were also “collecting” which would be the only activity that comes under the purview of Art. 10.

Whichever term is agreed in Article 10, the material scope of the instrument, implicitly and explicitly will rest heavily on it.

Conditional Permit: The grant of a permit or license to “access” or “collect” samples would mean that the entity granted such a permit would be obligated by the conditions of such grant of notification or permit. These conditions/obligations can be stated in a simplified or standardized format referring to many aspects on which a degree of consensus already exists—such as capacity building and technology transfer and making data openly accessible (rather than freely) with/without a short embargo period.¹⁰ A conditional permit could further oblige parties to participate in and contribute to a multilateral benefit sharing mechanism as specified in Art. 11.

Access and use of terms: Access will tally with specific proposals submitted under Article 1, “Use of Terms”. Without going into these in great detail here, it is worth pointing out that ex situ access, without further qualification will imply only ex situ access to physical samples. Anything more, such as ex situ access to digital sequence information and data (DSID) will have to be explicitly accounted for.

Use of CIHM: Some State Parties see a role here for the Clearing House Mechanism (CIHM) for inventory purposes (Norway) or to further transparency (EU). These inventory or transparency measures are likely to be subject to restrictions such as those related to commercially sensitive information, trade secrets or confidential information, defined as such domestically. It is worth noting that such roles in this Article for the CIHM appear linked to a right to access or collect MGRs; and so arguably, it sits better with a ‘notification’ mechanism.

Non-public information: There is reference to different degrees of accessibility of information, using terms such as “non-public” information (Article 34) which has further implications and should be addressed collectively rather than being left to different interpretations in different articles including those dealing with the CIHM. Non-public is a very broad term and can potentially be deemed to be so (through legislation or regulatory measures), if a Party decides it is not public.

There are two models that could be adopted here and in other contexts where this term is relevant. In the first, individual entities decide what is non-public. In the second, the notification (or monitoring body in Art. 34) is given full disclosure, and then any information prejudicing (not simply “related to”) intellectual property rights may be withheld so long as it

¹⁰ See S Thambisetty n 3 above for a discussion on the pros and cons of embargo periods.

is not essential to the notification or monitoring process. The Aarhus Convention includes the important qualifier that a refusal to disclose must have some basis in national law (for example in trade secret or data exclusivity legislation), and where such disclosure may have “adverse effects” on confidentiality of commercial and industrial information, intellectual property rights, or personal data or files relating to a natural person where that person has not consented to such disclosure. This aspect is particularly critical in the case of EIA results being made public for monitoring and follow-up purposes. If there are different definitions in domestic law on what is regarded as “commercially sensitive” when disclosing to CIHM, then it is likely to result in a race to the top, where those engaging in marine scientific research decide to function under countries’ with the highest protection. To avoid this, the instrument must specify narrow circumstances under which disclosure/transparency measures can be circumvented or insist on mandatory disclosure to authorities that would have powers to scrutinize and report on sensitive information.

Compliance and the Clearing House Mechanism (CIHM): In order to make the CIHM part of a binding obligation – it needs to be clear whether it is an aid to compliance with the instrument or just about compliance with “terms of use” agreed as per any permit or license. If it is about “terms of use” and minus other obligatory/mandatory measures it is in effect a very weak compliance mechanism.

Article 51 on CIHM: This is modelled on CBD Art. 18(3), where it is ineffective and largely unremarkable. At present Art. 51 envisages different kinds of information – administrative information (Art. 51(3)(c) – record of benefits shared; Art. 51 (3) (e) – opportunities for capacity building; Monitoring mechanism/ record or information (Art. 51(3) (a) holding notices, information on TK repositories); substantive compliance (Art. 51(3) (b) which seems to suggest CIHM will also act as a “track and trace mechanism”). The range, and kinds of information the CIHM will carry seems haphazard with no clear indication of which constitutes mandatory obligations, and which are voluntary measures, or the consequences of failure to meet stipulated obligations.

Any new text should at the least make a distinction between record keeping that will aid monitoring and those that are directed to enforcement of the instrument; distinguish between publication and compliance with substantive obligations (for instance publishing pre or post cruise information is not the same as sharing access to data or genetic information; or link between publication of EIA reports and effective implementation including follow-up actions)

Enforcement structure: It would be productive to consider whether the enforcement structure would involve a solely public international law framework where domestic legislation implemented by State Parties are the primary means of enforcing compliance or whether the body administering the notification or permit process would have standing to resolve disputes with those engaging in marine scientific research and taking on obligations of equitable benefit sharing (“terms of use”). Giving such a body, standing by making it a recipient of ‘benefit-sharing’, or by introducing an ‘arbitration clause’ would work well if a multilateral benefit sharing mechanism was the primary or most prominent means of benefit-sharing under the instrument. There is precedent for this in the FAO having third party beneficiary status (without liabilities) under the International Treaty on Plant Genetic Resource for Food and Agriculture that can initiate dispute settlement under Art. 8. The governing body also as the right to request appropriate information including samples as necessary from both provider and recipient with respect to the obligations in the agreement.

**[Article 10bis
Access to traditional knowledge of indigenous peoples and
local communities associated with marine genetic resources
[collected] [accessed] in areas beyond national jurisdiction]**

[States Parties shall take legislative, administrative or policy measures, as appropriate, with the aim of ensuring that traditional knowledge associated with marine genetic resources ~~[collected]~~ [accessed] in areas beyond national jurisdiction that is held by indigenous peoples and local communities shall only be accessed with the prior and informed consent or approval and involvement of these indigenous peoples and local communities. The clearing-house mechanism may act as an intermediary to facilitate access to such traditional knowledge *where appropriate*. Access to, *and use of* such traditional knowledge shall be on mutually agreed terms.]

Establishing the right of IPLCs: As a matter of establishing the right of IPLCs this or a similarly worded provision is essential. It may be possible to streamline Art. 10 further, and to consider whether Art. 10*bis* may be replaced by a new Art. 10 (2) (i) which could state the following as conditions of grant of a permit:

“An undertaking to record the use of any traditional knowledge associated with marine genetic resources accessed in areas beyond national jurisdiction that is held by, or originates from, indigenous peoples and local communities; and access and use of such traditional knowledge only after prior informed consent, approval and involvement of these indigenous people and local communities; any such use taking place on mutually agreed terms”.

Challenges to implementation: Based on experience with the Nagoya Protocol a number of challenges to implementation may arise including—the problem of delineating traditional knowledge related to sovereign territories and areas beyond national jurisdiction (ABNJ), the potential need to record relevant traditional knowledge and the financial, administrative and other burdens of doing so, the possibility that traditional knowledge related to ABNJ can be recorded in scientific or other publications and so may still end up being used without needing contact with the IPLCs.

TK sourced from elsewhere: The wording should take account of use of TK that is sourced for instance from research publications, which do not technically “use” the functional element of the information but maybe said to be merely “reporting”. Hence the suggested addition in blue.

**[Article 11
[Fair and equitable] sharing of benefits]**

[1. States Parties, including their nationals, that have ~~[collected]~~ accessed *or* utilized marine genetic resources of areas beyond national jurisdiction shall ~~[may]~~ share *monetary and non-monetary* benefits arising therefrom in a fair and equitable manner with other States Parties, with consideration for the special requirements of developing States Parties, in particular least developed countries, landlocked developing

countries, geographically disadvantaged States, small island developing States, coastal African States and developing middle-income countries and in accordance with this Part.

~~[2. Benefits [shall] [may] include [monetary and] non-monetary benefits.]~~

[2] In order to share the benefits arising from the access or utilization of marine genetic resources and any associated traditional knowledge fairly and equitably, State Parties shall ensure that their nationals, entities and juridical persons under their responsibility contribute fairly to a multilateral benefit sharing mechanism; guidelines for monetary [and non-monetary] contributions as set out in *Annex x* will, inter alia ensure contributions from

(a) Those accruing benefits, including commercial from the access, storage, and utilization of marine genetic resources, including associated digital sequence information and data of areas beyond national jurisdiction.

(b) Those accessing and using associated traditional knowledge to gain value from marine genetic resources and

[3] The rate of fair and equitable payments of monetary benefits shall be determined by the Conference of the Parties and set out in *annex x*.

[4] Contributions made to the multilateral benefit sharing mechanism shall be used equitably to

(a) To contribute to the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction;

(b) To promote scientific research and facilitate ~~[the collection of]~~ [access to] marine genetic resources of areas beyond national jurisdiction;]

(c) To build capacity to ~~[collect]~~ access and utilize marine genetic resources of areas beyond national jurisdiction ~~[, including through common funding or pool funding for research cruises and collaboration in sample collection and data access where adjacent coastal States [shall] [may] be invited to participate, taking into account the varying economic circumstances of States that wish to participate];]~~

~~— (d) To create and strengthen the capacity of States Parties to conserve and use sustainably marine biological diversity of areas beyond national jurisdiction, with a focus on small island developing States;]~~

(e) To support the transfer of marine technology; and to facilitate access to affordable technologies

~~— (f) To assist developing States Parties in attending the meetings of the Conference of the Parties.~~

~~(g) For the operational costs of establishing and maintaining the multilateral benefit sharing mechanism~~

~~{3. Benefits arising from [the collection of] [access to] [the utilization of] marine genetic resources of areas beyond national jurisdiction [shall] [may] be shared at different stages, in accordance with the following provisions:~~

~~— [(a) Monetary benefits [shall] [may] be shared against an embargo period for [marine genetic resources *in silico*] [digital sequence information] [genetic sequence data] or upon the commercialization of products that are based on marine genetic resources of areas beyond national jurisdiction [in the form of milestone payments]. The rate of payments of monetary benefits shall be determined by the Conference of the Parties. [Payments shall be made to the special fund];]~~

~~— [(b) Non-monetary benefits [, such as access to samples and sample collections, sharing of information, such as pre-cruise or pre-research information, post-cruise or post-research notification, transfer of technology and capacity-building,] [shall] [may] be shared upon [the collection of] [access to] [the utilization of] marine genetic resources of areas beyond national jurisdiction. Samples, data and related information [shall] [may] be made available in open access [through the clearing-house mechanism [upon [collection] [access] [after [...] years]]]. [[Marine genetic resources *in silico*] [Digital sequence information] [Genetic sequence data] related to marine genetic resources of areas beyond national jurisdiction [shall] [may] be published and used taking into account current international practice in the field.]]]~~

5. Contributions made under para 2 above does not preclude capacity building and technology transfer obligations mandated by other parts of this Agreement.

6. States Parties shall take the necessary legislative, administrative or policy measures, as appropriate, with the aim of ensuring that benefits arising from ~~[the collection of]~~ access to or the utilization of marine genetic resources of areas beyond national jurisdiction by natural or juridical persons under their jurisdiction are shared in accordance with this Part.

Annex x (To consider)

- Kinds of permits and conditions associated with them
- Compliance measures to be enforced by State Parties (treaty compliance + terms of use compliance)
- Proportion of benefits to be shared if monetary
- Non-monetary benefit sharing measures including non-exclusive licensing measures, guidelines on affordable technologies, and conditions of access to sequence information and data, use of compulsory licensing
- Guidelines on how any monetary contributions will be used/dispersed.

The proposal here with respect to Article 11 aims to entrench fair and equitable benefit sharing as a principle of public international law while also establishing a modality for such

benefit sharing. Such recognition will bring substantive linkages to other systems and rights such as UN Sustainable Development Goals, and human rights and provide some leverage in dealing with the worst impacts of regime complexes. Recognition of equitable benefit sharing as a principle of law¹¹ will also likely strengthen lateral ABS regimes, and bring unprecedented or under-accounted for situations into the purview of this instrument.

Access and utilisation: Here it is suggested that benefit sharing be established in relation to both access and utilisation. A key point to note is that if only “access” is used, then MGRs accessed prior to the instrument coming into force will not fall under the purview of any new Agreement. If both “access” and “utilization” are used, then it would be possible to add a qualification to the effect that MGRs accessed prior to entry into force, but used or utilised after entry into force should be subject to obligations of benefit-sharing. This would have to be reflected in Article 8.3 of the draft instrument.¹²

Separating access and utilisation: In such a case ideally upfront payments/ commitments would need to be established at the time of access that takes into account speculative gains further down the R&D pipeline.

Multilateral benefit-sharing mechanism: There are several good reasons to think that a multilateral benefit sharing mechanism is the optimal way forward for this instrument to actualise benefit-sharing. First, there is no bilateral architecture in the instrument, (unlike in the CBD) so conventional mutually agreed terms (MATs) or terms of use, through contracts or permits agreed with specific State Parties cannot be applied here.

Secondly, the use of DSID, through the research and development pipeline poses a challenge as benefit sharing requires obligations to be pinned down to particular individuals or entities, which becomes problematic when the physical resource itself is no longer central to effective benefit sharing.¹³ A multilateral benefit sharing mechanism with standardised norms of sharing, that is not necessarily linked to access, may provide a streamlined way to share monetary and non-monetary benefits. Thirdly, in order to prevent location-shopping or choice of least burdensome benefit-sharing regimes, (particularly given Art. 12.3 of the draft instrument), it is important that benefit sharing regimes here match or exceed those under the Nagoya Protocol. This would prevent a race to the bottom.

Fourthly, in case of transboundary situations, where the MGRs may be shared by more than one sovereign territory and ABNJ, as well as cases where traditional knowledge is

¹¹ See E Morgera, “Under the Radar: The Role of Fair and Equitable Benefit Sharing in Protecting and Realizing Human Rights Connected to Natural Resources”, BENELEX Working paper N 10. Available from https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2887803; and E Morgera “The Need for and International Legal Concept of Fair and Equitable-Benefit Sharing”, Available from https://pure.strath.ac.uk/ws/portalfiles/portal/55353399/Morgera_EJIL2016_need_for_an_international_legal_concept_of_fair_and_equitable_benefit_sharing.pdf.

¹² During IGC3 negotiations, it was suggested that such retroactive application of the instrument might go against Art 28 of the Vienna Convention, however it is open to the State Parties to agree to apply the obligations of the instrument to MGRs accessed prior to entry into force, but used after. (Art 28: “Unless a different intention appears from the treaty or is otherwise established, its provisions do not bind a party in relation to any act or fact which took place or any situation which ceased to exist before the date of the entry into force of the treaty with respect to that party.”)

¹³ As per the CBD report on the implementation of domestic measures related to the use of DSI a small number of countries (16, and one subnational jurisdiction) have domestic measures in place, and a further 18 are considering implementing such DSI-related measures. To avoid divergences in implementation it would be preferable for the BBNJ instrument to establish clear norms that would streamline rather than complicate the task of sharing benefits derived from the use of DSID. M Bagley, E Karger, M Ruiz Muller, F PerronWelch, and S Thambisetty, “Fact-finding Study on How Domestic Measures Address Benefit-sharing Arising from Commercial and Non-commercial Use of Digital Sequence Information on Genetic Resources and Address the Use of Digital Sequence Information on Genetic Resources for Research and Development” Available from <https://www.cbd.int/doc/c/428d/017b/1b0c60b47af50c81a1a34d52/dsi-ahteg-2020-01-05-en.pdf>.

implicated, a multilateral benefit sharing mechanism may provide a solution. And finally, a multilateral benefit sharing mechanism comes closest to actualising the implications of a common heritage principle by emphasising the collective element in the status of MGRs as valuable resources. The Ocean Genome Report also recommends a multilateral approach to benefit sharing in the interests of coherent governance of the oceans.

The implementation of such a mechanism will require domestic legislation to enforce compliance by individuals and entities, and would require compliance to be checked at specific points—such as through intellectual property offices, or before market entry or at other points of regulatory approval. Article 11 should ideally set up the basis and principle of equitable benefit sharing to take account of utilisation of the resources through the entire research pipeline—hence the emphasis on monetary and non-monetary benefits (Art. 11.2). As a part of the negotiations, it may be possible to separate the need for a multilateral mechanism first and discuss elements of a mechanism and enforcement later. Once the principle of multilateral benefit sharing is agreed, Annex x can be used to set up the guidelines by which grants from the fund created may be equitably used (including Art. 11.4.f of the draft instrument); or this could form the basis of a subsequent Protocol (although this could lead to further delay.)

Article 12bis African Group Proposal for a Multilateral Benefit Sharing Mechanism:

This proposal can provide a starting point to build consensus. It proposes a mechanism comprising 5 elected members from those nominated by COP of which at least three are developing countries. This body would make recommendations, relating to benefit sharing including those addressing Article 51. Drawbacks of this framing potentially include the separate need for establishing the principle of equitable benefit sharing in the instrument; and the further and substantial task of building consensus on the best modality of benefit sharing will remain.

Clearing House Mechanism: Some State Parties such as EU, Australia and Norway are using CIHM in Art. 11 to allow for information prior to and deposit of data after cruises, and implementation of an embargo period up to 3 years. This suggests perhaps that the CIHM in Art. 11 is being used as a proxy benefit-sharing mechanism.

(It is worth noting here that Norway's proposal that such data include data on biochemicals, could further equitable outcomes by giving a route to take account of "utilisation" of marine genetic resources).

Embargo: References to embargo periods range from unspecified duration (Philippines, Caribbean Community, US), to "up to three years" (Norway). The original proposal for an embargo derives from an EU centric paper *Mare Geneticum* which also proposed the OPEN notification system. An embargo that grants exclusive rights to data to scientists who are principally engaged in the collection of that data, will have a multiplier effect in terms of who gets to own the information, intellectual property and any products subsequently developed from that data and ensure a period where there is no competition from other research groups. This period of exclusivity will catalyse subsequent ownership and is in effect a new property-like right and must be treated with the same caution that intellectual property rights are so as to not exacerbate research and development capacity gaps between those who are able to undertake cruises and those who cannot. It also competes directly with open-access aspirations. Ways to mitigate the impact of embargoes include a) not counting the start of the embargo period from time of removal of last of the equipment but rather from the start of the cruise, or collection/access of samples b) to consider no more than 6 months to 2 years c) differentiate between meta data, contextual data and other easily available data from immediately valuable data, such as data on biochemicals.

Annex x : Ideally annex x will define who, how and when contributions will be made to the multilateral benefit sharing mechanism. The obvious entities are those granted a permit to access marine genetic resources of the ABNJ, in which case contributions to the multilateral benefit sharing mechanism will be tied to access, and utilisation of whatever has been accessed; and State Parties that host entities that engage in MSR.

Databases, or meta-repositories that benefit from the storage of such information could also be included here, as a way of dissociating benefit-sharing from access. Many State Parties have emphasised for instance the “universal resource” nature of sequence data and information. If this is to materialise as a benefit for all Parties then it is difficult to see how it can be done without some obligations imposed on databases and repositories via the jurisdiction where such databases are situated.

Benefits could also take the form of access to affordable technologies, nonexclusive licensing¹⁴ of critical products of technologies and some forms of mandatory capacity building which can be detailed in the Annex.

Strategy: There is scope here to develop a set of guidelines that will form the basis of Annex x, or licensing guidelines, and also domestic measures that State Parties put into place like the Bonn Guidelines on Access and Benefit Sharing that was developed on the outskirts of the CBD negotiations and eventually adopted by the CBD COP in 2002. This will require considerable detailed work but once developed could quickly build up agenda-setting advantages.

[Article 12 Intellectual property rights]

1. States Parties shall cooperate to ensure that intellectual property rights are supportive of and do not run counter to the objectives of this Agreement, *in particular with respect to the rights and obligations set out in Art 10, 11, 12 and 13 of this Agreement and Art 241 of the Convention.* ~~[, and that no action is taken in the context of intellectual property rights that would undermine benefit-sharing and the traceability of marine genetic resources of areas beyond national jurisdiction].~~

2. *The access, utilisation and commercial exploitation of marine genetic resources under this Agreement, where protected by intellectual property rights shall be subject to reasonable limitations that further the objectives of this Agreement [including equitable benefit sharing, capacity building and technology transfer.]*

~~[2. [Marine genetic resources [collected] [accessed] [utilized] in accordance with this Agreement shall not be subject to patents except where such resources are modified by human intervention resulting in a product capable of industrial application.] [Unless otherwise stated in a patent application or other official filing or recognized public registry, the origin of marine genetic resources utilized in patented applications~~

¹⁴ As an example, we might look to the OECD “Guidelines for the Licensing of Genetic Inventions”, 2006. Available from <https://www.oecd.org/sti/emerging-tech/36198812.pdf>.

~~shall be presumed to be of areas beyond national jurisdiction.}]~~

3. States Parties shall take the necessary legislative, administrative or policy measures, as appropriate, to ensure that:

(a) Users of ~~and~~ applicants for patents on inventions that utilize or have utilized] marine genetic resources of areas beyond national jurisdiction disclose the origin of the marine genetic resources that they utilize ~~using appropriate patent classification nomenclature~~;

~~(b) Intellectual property rights applications related to the utilization of marine genetic resources of areas beyond national jurisdiction that do not comply with this Part are not approved.]~~

(b) indigenous and traditional knowledge of IPLCs used to access the value of marine genetic resource in ABNJ are not misappropriated in contravention of this Agreement.

Limitations and exceptions approach to IP: A limitations and exceptions (L&E) approach to intellectual property law acknowledges that due to particular economic, social or technological conditions the balance between intellectual property rights holders and those who need to access and use the technology, may need to be recalibrated. International treaties acknowledge this to some extent by providing general conditions for the application of such limitations, leaving it to state parties to decide if a particular limitation can be legitimately applied, and its exact scope. Limiting intellectual property rights rather than precluding them, allows for the moderation of the scope of these rights and can be presented as a strategic compromise.

There are a few different ways in which a L&E approach to the exploitation of intellectual property rights could work in the instrument. It could be automatic (such as “fair use” terms in copyright law), or be a means to control post grant price, access (through licensing terms), or availability (through measures that demand local working of patented inventions for example.) They may apply in a time-limited way—for instance granting least developed or small island developing countries a longer period to take advantage over others taking into account their special circumstances. In all such cases, limiting the exercise of intellectual property rights would be about levelling up the capacity of all countries to take part in and/or benefit from marine scientific research.

It is important to note that the common heritage of mankind principle will not prevent taking patents out on the constituent parts of this heritage (marine genetic resources), so arguably a L&E approach is a better way to actualise the common interests of humankind.

Whether such limitations would be compatible with TRIPS is a critical question, but on balance such measures could be seen as furthering the objectives of Articles 7 and 8 and possibly Art. 66.2 of TRIPS, consistent with socio-economic differences and technological development amongst countries. Limitations would be a way of factoring in disagreements on the normative basis of MGRs in BBNJ and give effect to Art. 241 UNCLOS.¹⁵

¹⁵ See n5 above.

Greater detail/guidelines on what sorts of things could amount to “reasonable limitations” on intellectual property rights could be set out by COP or State Parties through domestic measures although both of these approaches have drawbacks.

Relevant precedents for L&E approach: Art. 142 of the EU Partnership Agreement with Cariforum on the transfer of technology is helpful here as a reference point of the acknowledgement that IPR can be used in bad faith or generate information asymmetries that need moderation (emphasis added). As this is in the context of technology transfer, as an analogy it also heightens the cross cutting nature of IP across the MGR and CBTT chapters.

Art. 142 Transfer of Technology

1. The EC Party and the Signatory CARIFORUM States agree to exchange views and information on their practices and policies affecting transfer of technology, both within their respective regions and with third countries. This shall in particular include measures to facilitate information flows, business partnerships, licensing and subcontracting. Particular attention shall be paid to the conditions necessary to create an adequate enabling environment for technology transfer in host countries, including issues such as development of human capital and legal framework.

2. The EC Party and the Signatory CARIFORUM States shall take measures, as appropriate, to prevent or control licensing practices or conditions pertaining to intellectual property rights which may adversely affect the international transfer of technology and that constitute an abuse of intellectual property rights by rights holder or an abuse of obvious information asymmetries in the negotiation of licenses.

Current Art. 12.2/ Status Quo: This article repeats the status quo that is reflected in the TRIPs Agreement, it indicates business as usual as it restates criteria of patentability. It is worth noting for instance that it is relatively easy for natural products, single-celled organisms or genetic material from ABNJ in isolated form and associated digital sequence information to fulfil conditions like industrial application, novelty and inventive step. Reiterating these standards here does not enhance equitable outcomes for most developing and least developed countries. Status quo should not be regarded as a neutral position given the well-documented technology gap in marine scientific research. “Business as usual” will further entrench the divide.

Presumption that MGRs originate from ABNJ unless stated otherwise: The presumption in the second half of 12.2 could have unintended consequences—for instance if the multilateral mechanism in Art. 11 is ineffective or is implemented poorly then such a provision could become a race to the bottom in the search for the least burdensome or poorly enforced benefit sharing obligations. It could also be a way of escaping the (currently unimplemented) transboundary aspects of Art. 10 of the Nagoya Protocol.

Declaration of origin in patent applications: Declaration of origin is not an end in itself, but a way to get to an agreed outcome. This outcome could range from a rhetoric device to acknowledge ABNJ patrimony, leverage to share monetary benefits, or be in itself a non-monetary benefit due to the disclosure of technical information in the patent application. In substantive terms, combining ‘declaration of origin’ with an L&E approach to patents has the optimal potential to further the objectives of this instrument.

While a number of IP offices are currently being used as check points under the Nagoya Protocol, a fewer number take digital sequence information and data related to genetic resources into account.¹⁶ We will need new tools to fully enable IP offices to enforce a declaration of origin requirement and for IP offices to work as checkpoints. This outcome will be helped greatly by a shift in compliance from inventors responding to clear legal direction

¹⁶ CBD report on DSI domestic measures, n 13 above.

to declare origin. Use of such IP offices as checkpoints could have a multiplier effect even in patent offices that do not insist on such declarations due to the way families of patent applications are linked.¹⁷

While the direction of travel seems to be one of increasing need to disclose origin in patent applications, it needs strengthening domestically as well as through international norms such as that seen in 11.3.a above.

Patent classification number: Internationally, it may also be possible to suggest a new patent classification category for MGRs belonging to ABNJ. This is a system for examiners in patent offices or others to categorise, classify, code published patent applications according to the technical features of their content. They enable data to be retrieved easily¹⁸ as “prior art” and modifications are made frequently, as technology develops, or unprecedented innovative sectors come up. The international patent classification system is agreed internationally and currently contains 129 classes, 639 sub classes, 7,314 main groups and 61,397 subgroups. State parties could propose a new subgroup classification referring to MGRs from ABNJ. It will not be difficult to implement and will require patent offices to monitor that patent applicants are making use of the correct code when MGR from ABNJ is part of the application. Ideally this would be additional to any substantive legal agreement reached in IGC4, if not it could also work as a standalone requirement. This proposal has the advantage of being embedded in the patent system and would be non-discriminatory of patent applicants.¹⁹

Debates on track and trace have objected to disclosure of origin on two principal accounts—on grounds of burden, on grounds that “source” (in the Swiss sense)²⁰ is better than “origin”, and on the basis that it is difficult to calibrate the degree of originating material in a patent application that will justify or necessitate a declaration of ABNJ source (for instance if an invention’s sequence information relies on 5 per cent ABNJ originating information, but where such percentage does not tell us how critical it is to the result/product or inventive outcome). The patent classification number takes care of the first and third objection with relative ease. The patent classification number will record relevant technology, inventions and as a technical fix is easy to implement. With respect to whether source or origin is more suitable in the context of ABNJ, source makes sense when genetic resources can originate in more than one sovereign territory – it indicates where the GR was actually sourced from. ABNJ does not present similar problems unless one can also show that the same GR was also available in territorial waters. In all three cases patent classification numbers referring to ABNJ as origin provides a technical fix, and it does so without muddying waters of “to what end”.

In order to push for such a solution, language in Art. 12 will need to reflect/suggest/recommend that other institutional bodies (under the Strasbourg Agreement) undertake exploratory work necessary. Art. 12. 3(a) does this to some extent but could also be strengthened.

¹⁷ See discussion in C Chiarolla, “Intellectual Property from a Global Environmental Law Perspective: Lessons from Patent Disclosure Requirements for Genetic Resources and Traditional Knowledge”, *Transnational Environmental Law*, 8:3 (2019), pp. 503–521.

¹⁸ Established by the Strasbourg Agreement <https://www.wipo.int/classifications/ipc/en/preface.html>.

¹⁹ See Chiarolla n 17 above.

²⁰ When origin and source are used together, the former may refer to in situ origins, whereas “source may refer to immediate source such as a collection. However, in some legal systems “source” may cover both – the country of origin, if applicable and known to the user/applicant, and if not, any other applicable and known source. For a detailed explanation of this concept of “source” see the Submission by Switzerland in Response to Document WIPO/GRTKF/IC/30/9 “The Declaration of the Source of Genetic Resources and Traditional Knowledge in the Swiss Patent Act and Related Swiss Regulations on Genetic Resources”. Available from http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_31/wipo_grtkf_ic_31_8.pdf.

[Article 13 Monitoring]

1. The Conference of the Parties shall adopt rules governing the appropriate conditions for grant of a permit under Article 10, guidelines [in annex x] for contributions to the multilateral benefit sharing mechanism under Article 11, priorities for the use of such contributions and a mandatory code of conduct for the dissemination of non-monetary benefits arising from the access, utilization and commercialization of marine genetic resources of areas beyond national jurisdiction.

2. The grant of, and monitoring of the performance of the conditions of permits granted as per this Part, and oversight of the multilateral benefit sharing mechanism—utilization of marine genetic resources of areas beyond national jurisdiction shall be carried out by a through the [clearing-house mechanism] [Scientific and Technical Body], aided by a clearing house mechanism. [obligatory prior electronic notification system managed by the secretariat and mandated existing international institutions set forth in Part [...]]] The Scientific and Technical Body may deny or revoke permits for non-compliance with conditions specified in past or current permits, [and any other actions that contravene this Agreement.]

3. In order to support the work of the Scientific and Technical Body, States Parties shall take the necessary legislative, administrative or policy measures, as appropriate, to ensure that:

(a) An identifier as per Article 10 (2) (a), is assigned to marine genetic resources [collected] [accessed] *in situ* and *ex situ* including associated digital sequence information and data. In the case of marine genetic resources accessed *ex situ* [and *in silico*] [[and] [as digital sequence information] [as genetic sequence data]]. The identifier must be appropriately linked to the conditions in the permit under which access was approved. Such identifier and information on permits shall be recorded when databases, repositories and gene banks submit the list mentioned in article 51 (3) (b) to the clearing-house mechanism;

(b) Databases, repositories and gene banks within their jurisdiction are required to maintain such identifiers and ensure that information related to the conditions attached to the permit are made available at all times when *ex situ* access as per Article 10 is facilitated. [notify the [clearing-house mechanism] [Scientific and Technical Body]] [send a notification through the obligatory prior electronic notification system managed by the secretariat and mandated existing international institutions set forth in Part [...]] when marine genetic resources of areas beyond national jurisdiction, including derivatives, are accessed;]

(c) Proponents of marine scientific research in areas beyond national jurisdiction **must** submit periodic status reports ~~[to the clearing-house mechanism]~~ [to the Scientific and Technical Body] ~~[through the obligatory prior electronic notification system managed by the secretariat and mandated existing international institutions set forth in Part [...]]~~, as well as research findings, including data collected and all associated documentation.

4. States Parties shall make available to the clearing-house mechanism information on the legislative, administrative and policy measures that have been adopted in accordance with this Part.

5. **The Scientific and Technical Body** ~~States Parties~~ shall submit reports to the Conference of the Parties about **the access, utilization and commercialisation** of marine genetic resources of areas beyond national jurisdiction. The Conference shall review such reports and make recommendations.

Clearing house mechanism: Through Articles 10 to 13 there are many different roles being put forward for a CIHM – ranging from an information repository (for information deemed not to be commercially sensitive, or confidential), to holding inventories, increasing transparency around collections of samples, and even as a benefit sharing mechanism to facilitate deposit of sequence information and data.

To move forward it is important to understand how a CIHM supports compliance, but this can possibly only happen once the substantive obligations are in place. Broadly, with respect to the substantive obligations in this Part, a CIHM works best in the context of a unilateral notification system for self-declared/ voluntary information. For any other kind of mechanism – such as conditional permits or licenses, a technical body with the legal mandate to grant, deny or revoke permits and ensure that conditions agreed to in permits are undertaken or recorded as undertaken, as well as some standing to raise and resolve disputes seems necessary. A CIHM would then support the functioning of such a body.

PART IX SETTLEMENT OF DISPUTES

Article 54 Obligation to settle disputes by peaceful means

States Parties have the obligation to settle their disputes by negotiation, inquiry, mediation, conciliation, arbitration, judicial settlement, resort to regional agencies or arrangements, or other peaceful means of their own choice.

There is little point in agreeing ambitious proposals without adding teeth to the instrument, and conversely, modest gains layered with good enforcement mechanisms can add up to substantive gains.

Two tiers of compliance and enforcement: Measures that State Parties will need to put in place in order to comply with the Agreement; and secondly measures to enforce “terms of access and use” of MGRs (entities/individuals/institutions). For the latter a hybrid measure where central institutions are strengthened to monitor compliance would work better given the need to devise “comprehensive global regime” (UNRes 69/292)

Giving the international body or authority that administers permits/ or collections status as a third party beneficiary under the instrument with powers of dispute settlement and enforcement would be one way to do this.

Need for measures to enforce compliance can include power to revoke permits or having some form institutional record of good and bad compliance across all aspects of the instrument. Alternatively, terms of access and use will pivot on domestic/legislative measures taken by state parties, which in the case of CBD has proven to be a weak tool, with high levels of administrative burdens for users and states due to divergences in interpretation and implementation.

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