Marine Genetic Resources Beyond National Jurisdictions: Components of an Informed, Fair and Progressive Internationally Binding Legal Instrument

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Abstract:
Negotiations on an internationally binding legal instrument on marine genetic resources beyond national jurisdictions will commence in September 2018. Based on international biodiversity law, patent rights and the recent developments in the governance and circulation of genetic resources, this note suggests ten key components for an informed, fair and progressive internationally binding instrument on marine genetic resources (MGR) beyond national jurisdictions.

Starting in September 2018, negotiations on an internationally binding legal instrument on biodiversity and marine genetic resources beyond national jurisdictions will commence. This note is intended to inform country representatives, negotiators, legal and technical advisers of spring boards and road blocks to an acceptable agreement under UNGA resolution 69/292. Biodiversity beyond national borders is the last global commons, and technological developments means that it is ripe for harvesting. The principle of freedom of the seas means that there is no regulatory policing possible, which makes the need for a global governance regime that is fair, informed and progressive an urgent one.

To be informed the current treaty process must take advantage of the learning associated with the implementation of international biodiversity law in the recent past. Our notions of fairness has also come a long way and from the early misty notions of Ethical, Legal, Social Issues (ELSI) associated with genetic resources. The treaty must be progressive and make allowances for the non-linear evolution of the technology as well as the differentials in access, and rates of usage of marine genetic resources in different parts of the globe. With these aspirational principles in mind, this note discusses ten key components for an informed, fair and progressive internationally binding treaty on marine genetic resources (MGR) beyond national jurisdictions.

This note was developed as a response to the *Mare Geneticum* framework[1] discussed at Aberdeen University. The ideas expressed here can be used as building blocks of alternate proposals. This note focuses on contentious issues that if left unresolved are likely to lead to further problems down the line.

1. Common Heritage of Humanity

The key question which is related to and must be answered before the relevance of Common Heritage of Humanity (CHH) as a principle can be resolved, is the need for and scope of a binding international instrument on marine genetic resources beyond national

[1] A Broggiato et al 'Mare Geneticum: Balancing the Governance of Marine Genetic Resources in International Waters' 2017 Available here http://booksandjournals.brillonline.com/content/journals/10.1163/15718085-

jurisdiction. Whilst 'mineral resources' covered in Part XI of UNCLOS do not include marine genetic resources (MGR) and the area of the deep sea floor, it can be argued that its ecosystems, biodiversity and thus MGR are within the purview of the common heritage of humanity principle, though various parties have chosen not to pursue this legal debate.[2] There are three approaches that may be taken with respect to CHH – to decide to adopt the principle that MGR in areas beyond national jurisdictions (ABNJ) are subject to the principle of CHH; that they are not subject to the principle of CHH or to park this question for later and focus instead on agreeing the elements of a governance or access regime.

In the context of areas beyond national jurisdiction (ABNJ) a principle question is whether any application of the CHH principle to MGR connotes communal ownership or merely the joint management of global commons that are held to be CHH. The five component principles of CHH will also require interpretative consensus on how they may apply to the management, use and inevitable commercialisation of MGR. The difficulty of resolving these has meant that parties such as the EU and the US may want to shelve the central question of the application of the CHH principle[3] both as a matter of communal ownership as well as the principle undergirding a global management regime for to MGRs, until a plan to manage and govern the resources has been agreed. This approach has advantages as a negotiating gambit but risks setting in motion a path dependent and normatively incoherent governance regime.

The current regime in ABNJ means that any entity can access MGR freely and in accordance with international law, so the need for a global regime to manage the resources is an urgent one. No treaty can allow for all aspects of an emerging technological area, and for purposes of normative coherence it is important that the treaty be grounded in an approach that can be drawn on to deal with unprecedented or unpredictable legal circumstances.

Resolve: Whether the Common Heritage of Humanity principle applies to the ownership of the marine genetic resource in areas beyond national jurisdiction itself or only (or at least) to a joint management regime over global commons of which marine genetic resources are a part.

2. The Legal Status of Access

The issue of conditions of access cannot be resolved without a fuller understanding of the legal status, and consequences of the act of accessing genetic resources. Implementing measures under the Nagoya Protocol, a supplementary instrument of international law under the Convention on Biological Diversity (CBD) allows for access of genetic resources to be treated differently from utilisation of such resources. However access is not defined in either

[2] M Bourrel, T Thiele, D Currie 'The Common Heritage of Mankind as a Means to Assess And Advance Equity in Deep Sea Mining' Marine Policy 2016. Available here <http://www.lse.ac.uk/iga/assets/documents/publications/2017/common-of-heritage-of-mankind-deep-sea-mining.pdf>

[3] The European Union is for instance proposing a pragmatic approach that does not discuss this legal base. Development of an International Legally-Binding Instrument under UNCLOS on the Conservation and Sustainable Use of Marine Biological Diversity of Areas Beyond National Jurisdiction (BBNJ Process): EU and Member States Position Paper 22 Feb 2017. Available here < http://www.un.org/depts/los/biodiversity/prepcom_files/rolling_comp/EU_Written_Submission_on_Marine_Genetic_Resources.pdf>

the CBD or the Protocol. This ambiguity leads to structural problems in implementation as well as to uncertainty w.r.t access from ex situ collections of genetic resources.[4]

Access and utilisation of genetic resources under the Nagoya Protcol may not happen at the same time or the same place or by the same entity. Under the EUR implementing the Nagoya Protocol[5] for instance, benefit-sharing obligations are triggered by use, rather than access; whereas most provider countries consider their benefit-sharing to be triggered when a genetic resource or associated traditional knowledge is used, even if physical access took place before the Nagoya Protocol was implemented in the provider country. This results in the so-called temporal loophole and is a significant lacuna in the global implementation of the Nagoya Protocol.[6]

The *Mare Geneticum* framework suggests that access should not be included within the definition of utilisation, along with the assertion that there is 'no direct and immediate commercial value at the access point, so there is no need for authorisation'.[7] This is a disingenuous position for the following reasons. Legally, access is the pivotal act which ignites the value chain of that genetic resource, and also identifies that particular resource as having been acquired beyond national jurisdictions. Access is the act that leads to acquisition of a resource, to possession, and without access there cannot be utilisation, including commercialisation. Unlike territories within national jurisdictions the acquisition of MGR beyond territorial waters if left unrecorded, would be tantamount to abandonment of any principle of communal ownership. Arguably the Nagoya Protocol also has an impact here, because in order to exercise due diligence in acquisition of genetic resources access would have to be traceable in some form, at least to prove that it was not acquired in territorial waters.

Resolve: Any binding international instrument must recognise and define 'access' of marine genetic resources beyond national jurisdiction and imbue the act of access with any rights and obligations of benefit-sharing that attach under the instrument.

3.The Access Gap

There are very great differentials in the scientific and technical capacity to use or access MGR beyond national jurisdictions. The *Mare Geneticum* framework estimates that only around 29 countries (developing and developed) have had access to MGR from hydrothermal vents.[8] This disparity or 'access gap' does not necessarily cleave on the same lines as developing and developed countries. Only very few developed countries (Ireland and Norway for example) have national marine biodiscovery programs as part of blue economy growth, whereas China has made remarkable strides in biotechnology over the last two

[4] Florian Rabitz 'Biopiracy after the Nagoya Protocol: Problem Structure, Regime Design and Implementation Challenges' Journal of the Brazillian Political Science Organisation 2015 9 (2) 30-53. Available here < http://www.scielo.br/pdf/bpsr/v9n2/1981-3821:bpsr-9-2-0030.pdf>

[5] EUR 511/2014

[6] 'The Two Worlds of Nagoya: ABS Legislation in the EU and Provider Countries: Discrepancies and How to Deal with Them' Natural Justice/Public Eye Report Dec 2016

[7] *Mare Geneticum* framework n 1 above p 22

[8] *Mare Geneticum* framework n 1 above p 15

decades[9] and is one of five countries that possesses manned research submersibles able to dive under 4000 metres in 2012.[10]

In terms of being primed for the negotiating process the inability, and inability to engage in deep-sea expeditions amongst a majority of countries is likely to be accompanied by a fear of losing out on bio-scientific and commercial gains. There is much in the recent history of biotechnology that justifies this fear – including private appropriation of human genetic resources through patents, despite the UNESCO Declaration that denotes the human genome as common heritage of humanity .[11]

It is because of the reality of and likely entrenched nature of technical barriers that the legal status of access of MGR becomes paramount. If we do not imbue the act of access with legal status to which obligations are attached, it would amount to little more than a might is right[12] approach when it comes to appropriating marine genetic resources beyond national jurisdictions. A recent study has detailed how 98 % of 1600 gene sequences associated with species found in deep sea and hydrothermal vents, are owned by actors located or headquartered in only 10 countries.[13]

The *Mare Geneticum* framework also makes a distinction between the commercialisation of marine biodiversity products from shallower waters, primarily coastal states' jurisdiction and the potential of MGR in areas beyond national jurisdictions.[14]

> 'Biochemists are often effusively enthusiastic about the diversity of biomolecules produced by marine organisms compared to their terrestrial counterparts. However, to date, the realisation of this potential in relation to ABNJ has been slow compared to national jurisdictions.'[15]

It might well be true that commercialization of marine biodiversity from shallower waters has been more prolific because it is easier to access, and because scientific techniques previously required that samples be fresh for analyses. Research vessels can now allow prep work and analyses to be carried out on board, thus increasing the shelf-life of the samples' biodiscovery potential.[16] The synthetic chemistry route also enhances the ease with which genetic resources may be used to produce valuable products or derivatives. Furthermore, ongoing research[17] tells us that the Nagoya Protocol is influencing sample choice by both companies

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[9] According to some reports China has also refused to participate in monetary benefit sharing as they already perceive themselves as net-providers rather than net recipients (Aberdeen Workshop discussion, n 1 above).

[10] National Institute of Genetics (2015). Access to Marine Genetic Resources and Benefits-haring from Their Academic Use, Report of MGR Workshop in Japan (edited by Hajimu Morioka), Tokyo, available from http://nig-chizai.sakura.ne.jp/abs_tft/wpcontent/uploads/2016/08/Marine-genetic-resources.pdf as cited in Carlos Correa *Access to and Benefit-Sharing of Marine Genetic Resources Beyond National Jurisdiction: Developing a New Legally Binding Instrument* South Centre Research Paper 79 (September 2017) p 6

[11] 1997 UNESCO Universal Declaration on the Human Genome and Human Rights. See Cahill LS 'Genetics, Commodification, and Social Justice in the Globalization Era' 2001 Kennedy Inst of Ethics J 11 (3) 221-38. Available here < https://www.ncbi.nlm.nih.gov/pubmed/11700680>

[12] Referred to as a first-come-first-served rule under the principle of freedom in the high sea in the National Institute of Genetics (2015) report n 10 above.

[13] Blasiak et al 'Corporate Control and Global Governance of Marine Genetic Resources' Science Advances 6th June 2018 Available here < http://advances.sciencemag.org/content/4/6/eaar5237>

[14] *Mare Geneticum* n 1 above P 13

[15] ibid p 33

[16] I am grateful to Oonagh McMeel, Seascape for this point.

[17] Research by author as part of a EU funded INMARE project < http://www.inmare-h2020.eu/>

and non-commercial researchers alike, with legal clarity a dominant concern. Crucially at the moment samples from areas beyond national jurisdictions provide greater legal clarity than from within national jurisdictions.

Resolve: Technical barriers or the access gap, in so far as they both exist should not be allowed to downplay the commercial and technical prospects of marine genetic resources accessed from areas beyond national jurisdictions. As long as some can access such marine genetic resources, the communal nature of such resources remains under threat.

4. Notification/Registration or Authorisation

Currently it is legal to access marine genetic resources due to the principle of freedom of the high seas, and there are indications that considerable research activity on the high seas is ongoing.[18] In order to maintain a rudimentary possibility of benefit-sharing, any governance regime would need to urgently put in place some form of recording or registering access.

Arts 256 and 257 of UNCLOS give all states the 'right to conduct marine scientific research'. This begs the question whether any governance regime that involves recording or registering access would diminish that right. However that right is subject to Art 138 which requires international cooperation and mutual understanding. So it seems fair to conclude that any governance regime under UNCLOS would need some form of registration of who is accessing MGR and where, at the minimum without which there would be no possibility of cooperation or mutual understanding of how marine genetic resources are being handled. Such registration could involve either 'notification' or a more consequential 'authorisation' regime.

An authorisation regime for marine genetic resources beyond national jurisdictions could invest authority in an international organisation which would administer or hand out the authorisations based on certain prior agreed conditions (such as reserved places on expeditions for scientists from poorer countries). While this is appealing the scheme would rely on front loaded understanding of the scope of the authority vested, which might prove difficult to negotiate.

In this context a governance regime that centralises notification – such as the *Mare Geneticum* framework proposal is likely to move the process along favourably. Such notification would still have to fit the remit under GA resolution 69/292 which extends only to 'conservation and sustainable use' including in the sharing of benefits. Notification will work on a voluntary basis as there will be no authority to prevent a scientific expedition. However given the need to perform environmental impact assessments and ensure sustainable use, it would be appropriate for notification processes to be used alongside scientific, environmental and conservation related undertakings. This could be done on a due diligence basis, strengthened with robust corporate social responsibility ethos around MGR from the high seas. Here it is worth noting that agreeing on the CHH principle would strengthen the basis of such social responsibility by corporations and other entities.

[18] See discussion in C Correa South Centre Report n 10 above.

Resolve: Registering scientific expeditions on the high seas either through notification or authorisation is a necessary, although not sufficient, component of the management of biodiversity beyond national jurisdictions.

5. Binaries of Commercial/Non-Commercial and Academic/non-Academic

The adversarial nature of the Nagoya Protocol negotiations has appeared to weaponise the distinction between commercial and non-commercial often equating these with non-academic and academic respectively.[19] Yet, traditional notions of academic and non-academic have been considerably blurred during the early years of biotechnology, and the prospect of patenting academic research has changed traditional academic norms of sharing.[20] Most universities, where academics might be expected to work have technology transfer offices who will insist on patents being sought for research results across the board, even prioritising patents over possible publications.[21] This is facilitated by the kinds of patent claims possible. Bio-informatically derived information, inventions detailing only speculative uses, and low inventive step thresholds all mean that even raw sequence data associated with informed guesses as to use, would qualify as a invention eligible for a patent.[22]

Star scientists are also known to move between commercial and academic entities, taking their research and expertise with them. [23] The idea of public funding means little in the case of countries which have national biodiscovery programmes when these also fund public/private collaborations with intended commercial objectives, even while building sample collections from expeditions on publicly funded research cruises.

Similarly it cannot be said that publications are the exclusive preserve of academics either, commercial entities also publish to signal knowledge assets they possess in order to remain attractive for investment. We also see property pre-empting investments from private corporations which have invested in populating and maintaining public respositories or libraries of genetic information in order to spoil competitors challenges or to move the level of innovation forward.[24]In such cases the giving away of information in the short term, while it might seem perverse, is actually in the best longer-term interests of the corporations involved.

This blurring of the lines matters because it is important not to ascribe any prior intention or motives to 'purely academic' research or 'non-commercial research'. Instead of relying on outdated labels as short cuts, it is important to ascribe motives only based on the stated intention and practice of the scientists involved. This view expressed in the *Mare Geneticum* framework is potentially misleading:

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[19] Through for instance the protocol's recommendation to promote non-commercial research in Art 8.

[20] See for instance Haas, M., & Park, S 'To Share or Not to Share? Professional Norms, Reference Groups, and Information Withholding Among Life Scientists' 2010 Organization Science, 21 (4), 873-891.

[21] See discussion in Eisenberg and Heller 'Can Patents Deter Innovation? The Anticommons in Biomedical Innovation' Science 280 (5364) May 1 1998 pp. 698-701

[22] See for instance the rules on 'uses' of patents derived from European Jurisprudence in UK Supreme Court decision HGS v Eli Lilly [2011] UKSC 51. Also see 'Global Status and Trends in Intellectual Property Claims: Genomics, Proteomics and Biotechnology' UNEP/CBD/WG-ABS/3/INF/411 January 2005 and S Thambisetty 'Learning Needs of the Patent System and Emerging Technologies: A Focus on Synthetic Biology (2014) IPQ 13

[23] S Thambisetty 'Patents as Credence Goods' 2007 Oxford J of Legal Stud 27(4) 707-740

[24] R Merges 'A New Dynamism in the Public Domain' 2004 (71) Uni of Chi LR 183-203

> 'In situ access to MGR is generally done without commercial intent. Indeed, most deep-sea and high-seas expeditions are publicly funded, rendering MGR sampling cruises in ABNJ non-commercial in character, or at least with intentions that are not solely or primarily commercial.'[25]

In the specific context of access to genetic resources on the high seas, we must not make the assumption that academic researchers will not patent their newly acquired genetic resources or information, or that they are more or solely interested in publications rather than patents.

The irrelevance of the stated binaries is particularly damaging when it is also layered with the view that patents on their own should not be taken to indicate commercial intent. As suggested by the *Mare Geneticum* framework

> 'at present, there are a number of patents and pending applications based on MGR in ABNJ… This can be interpreted as evidence for commercial interest. However, the existence of such patents does not necessarily indicate the eventual development of marketable products. Moreover, there is increasing evidence of academia seeking patents to protect their intellectual property (IP), even without true commercial intent.'[26]

There is a crucial distinction between commercial intent and commercial prospect – which the *Mare Geneticum* framework perhaps loses sight of. While no one ought to take a patent as a definite commercial prospect, everyone knows it is a good signal of probable value.[27] Although only a tiny proportion of patents end up being commercialised, patents provide an exclusivity that is essential for any commercial intent. So while a patent is not a guarantee of a commercial prospect it is difficult to have commercial intent without one. Patents also have technical and commercial information spill-overs. Beyond the very invention that it describes, a patent adds commercial worth to corporate entities and academic departments alike. It signals the star quality of scientists associated with patents – all of which can translate into commercial value

Conversely it should also be noted that the lack of a patent does not indicate only non-commercial motives. Many SMEs may choose not to patent as they risk exposure of their discoveries to bigger market players without having the resources to litigate.[28] In addition the prohibitive costs of patenting means not all will opt for one. This should lead to a note of caution that any analyses of patents as an indication of commercial activity could be misleading.

Resolve: Labels such as academics/non-commercial, and commercial/non-academic, must not be used to signal good faith advantages – the fact is that all research entities are a complex mix of self and public interest in different proportion, expressed through a range of measures such as publications and patents. Instead focus on and reward the nature of the research, ability and explicit intentions to participate in open-science initiatives and academic norms of sharing.

6. Patents and MGR Beyond National Jurisdictions

[25] *Mare Geneticum* framework n 1 above p 17
[26] *Mare Geneticum* framework n 1 above p 13.
[27] M Lemley and C Shapiro 'Probabilistic Patents' 19(2) J of Econ Perspectives 75-98 (2005)
[28] Encouraging more SMEs to patent is one of the stated aims of the push to establish the Unitary Patent court in Europe <https://www.epo.org/news-issues/news/2018/20180416b.html>

There are many aspects of patents on genetic resources that contribute to a perception that patents must not be addressed in the ABNJ context but left to a more specialised agency such as the World Intellectual Property Organisation (WIPO). Before touching on why that would not be advisable it is worth untangling some common misconceptions.

Most of the world has signed up to the TRIPS agreement, under which they are obligated to implement national patent laws at a high level of harmonisation. The major patent offices- US, EPO and Japan engage in widespread 'technical assistance' to developing country patent offices on examination procedures.[29] Additional political pressure beyond that related to the possibility of trade sanctions means that there is a remarkable degree of harmonisation and convergence of patent laws globally.[30] Most jurisdictions therefore allow patents on genetic material and data.

The isolation test of patentability used almost universally means that genetic material may be patented simply by being accessed, characterised and otherwise made available in a form that does not exist in nature. This low novelty threshold makes genetic material open to patents widely.[31] Given the possibility of patents being granted, and the pressure on both academic and commercial researchers to patent, we must assume that any researcher sampling in situ from the high seas is also likely to patent aspects of the results of the sampling cruises.

Another misconception that is particularly pernicious is that open-access genetic material acts as a sort of buffer against appropriation through patenting. If information is presented as prior art (in the sense of already available) to a patent examiner, such that an invention is no longer seen as novel or inventive, it cannot be patented. This might include genetic material or resources in the public domain. However in reality given the amount of genetic data available online and in repositories it will come down to the quality of the examination process.[32] So genetic material in the public domain can end up giving private entities an enormous competitive and commercial advantage and end up being patented anyway. Relevance of gene banks to novelty depends on the level of effort needed to locate a target sequence. Location within a gene bank in the absence of a known probe is in fact regarded as a biochemical process, similar to the isolation of a component from nature.[33]

Hence when genetic material in the form of raw data is put up in publicly accessible databases there is a very real danger that much of this will end up in private corporate control. There are indications that commercial entities are already patenting marine genetic

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[29] P Drahos 'Trust Me: Patent Offices in Developing Countries' American Journal of Law and Medicine 2008 (34) 151-174.

[30] For a general discussion see J Duffy 'Harmony and Diversity in Global Patent Law' 'Harmony and Diversity in Global Patent Law' (2002). Faculty Publications. Paper 849. http://scholarship.law.wm.edu/facpubs/849

[31] It is worth clarifying the impact of the US decision in AMP v Myriad 569 U.S. 576 here. The US Supreme Court in that case disallowed patents on genomic DNA, but allowed patents on cDNA which is exceptionally easy to derive from genomic DNA. *Myriad* therefore is an important decision with symbolic weight but does not pose insurmountable problems for businesses. See discussion in the following and related papers: S Thambisetty 'Alice and Something More: The Drift Towards European Patent Jurisprudence' 2016 J Law and Bioscience 691-696. An Australian High Court reached a similar decision in *D'Arch v Myriad Genetics Inc* [2015] HCA 35

[32] See O Jefferson et al. 'Public Disclosure of Biological Sequences in Global Patent Practice' 2015 World Patent Information https://doi.org/10.1016/j.wpi.2015.08.005

[33] P Cole 'Patentability of Genes: A European Union Perspective' Cold Spring Harb Perspect Med 2015 May 5(5). Rule 29(2) of the EPC Implementing Regulations, which states that elements of the human body that are isolated or technically produced, including a sequence or partial sequence of a gene, can constitute inventions.

resources in substantial numbers[34] and some of these may come from publicly available databases. Perversely because MGR from beyond national jurisdictions are from areas where the Nagoya Protocol does not or cannot apply, legal rights to such MGR are likely to be far more certain than MGR from within national borders. So companies with low thresholds for legal uncertainty and wanting to work only with genetic resources with clear and certain provenance would in fact be incentivised to acquire MGR from ABNJ.

If a large number of patents are granted over MGR from ABNJ, this will amount to the fragmentation of rights over resources and the private appropriation of what must be treated as global commons. Scientific innovations developed from these patented genetic material will almost certainly be inaccessible to poorer populations. For this reason privately owned patents on genetic material and information is not compatible with the idea of good governance of MGR from ABNJ in the best interests of all mankind.

Given this picture of the numerous incentives for patents on genetic resources, and the limited number of entities who have the capacity to prospect on the high seas, it would be highly irresponsible for the BBNJ process not to address the question of intellectual property rights. It is true that fora such as the WIPO are more specialised but due to a phenomenon called 'regime shifting' in the international intellectual property system, the terms in which patents and other intellectual property rights are referenced in the BBNJ forum can have robust impact on how this issue is taken up at the WIPO.[35] Unless patents on MGR from areas beyond national jurisdictions are identified as such, we run the risk of dissipating the significance of biodiversity beyond national territories.

Resolve: Recognise that the acquisition of privately owned patents is possible and is potentially incompatible with the fair, equitable and sustainable use of marine genetic resources from areas beyond national jurisdiction. Maintain the significance of biodiversity beyond national jurisdiction by allowing genetic resources to be identified as originating from beyond national jurisdictions.

7. Track and Trace: Scientific and Legal Imperative

Track and trace attached to a notification or authorisation is necessary to enable scientific accountability as well as to actualise any forthcoming benefit-sharing. Without such track and trace there would be no way to link any future actions related to the MGR to conservation, sustainable use or benefit-sharing.

The *Mare Geneticum* Framework proposes a monitoring system termed Obligatory Prior Electronic Notification (OPEN) [36] which has two significant drawbacks. First, while the OPEN system includes the elements of a scientific or technical track and trace, it does not resolve the position of ex situ and in silico genetic resources. Given that genetic resources are defined as resources with actual and *potential* value, and referencing the discussions on digital sequence information under the Nagoya Protocol,[37] track and trace must extend to in silico derivatives or versions of the genetic resources. To not do so runs the risk of making

[34] R Blasiak et al n 13 above
[35] L Helfer 'Regime Shifting in the International Intellectual Property System' Perspectives on Politics 7(1) 39-44
[36] *Mare Geneticum* framework n 1 above p 8
[37] See ongoing work of the Ad Hoc Technical Group (AHTEG) on Digital Sequence Information on Genetic Resources serving the needs of the Nagoya Protocol under the CBD. https://www.cbd.int/abs/dsi-gr/ahteg.shtml

this treaty obsolete even before it begins. Similarly, there is no good reason not to extend OPEN to ex situ collections. In fact at least within the European Union and in many other countries, due diligence requirements mean that collections ought obtain and keep information about the provenance of material and data they hold. In that sense track and trace for MGR beyond national jurisdiction enable, support and is likely necessitated, by the implementation of the Nagoya Protocol.

Secondly any notification or authorisation system should interact with the patent system. In the *Mare Geneticum* Framework, OPEN does not include legal arrangements such as patents within the scope of track and trace. In order for any track and trace system to amount to effective monitoring it must address the link between scientific and legal arrangements. Intellectual property rights are akin to legal track and trace.

Although a few countries have done so in domestic legislations, [38] the Nagoya Protocol does not institute a declaration of origin for all genetic resources in patent applications. This has led to at least two unintended and significant consequences. First it has resulted in a regulatory system where thin compliance is the norm. In order to make any sort of monetary benefit sharing possible, unless the genetic resource can be identified in the patent there is no way to either keep track or implement benefit-sharing. This has led to the possibility of contractual evasion or avoidance with no real way to oversee benefit-sharing in individual transactions or contracts.

There is also a potential decoupling of access and benefit-sharing contracts – which suggests that the difficult issue of change in intent, patents and benefit-sharing is postponed further down the value chain. Those who can abide with the legal uncertainty this involves will choose to do so, but those who cannot (such as commercial entities) will prefer to work solely with genetic resources with certainty of provenance. This has the potential to change lines of research, making some lines untenable while making others much more likely to be taken up not because they represent the best scientific prospect, but because they represent the most legally certain prospect. Both of these problems can be side-stepped in the BBNJ process by hooking the question of provenance to the patent system. This will level the playing field in terms of certainty and bolster the structural weakness related to ambiguity and functionality of using bilateral contracts to enforce normative objectives of international law.[39]

Such a declaration on provenance is not an onerous process, and can potentially be absorbed in the bibliographic information routinely submitted as part of the patent examination process. Given the logical need it fulfils, and the ease with which it can potentially be instituted the only reason not to implement this measure is to deny any possibility of monetary benefits being shared.[40]

Resolve: Any track and trace method must be both technical and legal. Declaration of provenance of marine genetic resources (in situ, ex situ and in silico) from areas beyond national jurisdiction is essential to ensure monetary benefit-sharing. If the BBNJ process does

[38] Not all of these are in prejudice to the processing of patent applications or right granted. http://www.wipo.int/export/sites/www/tk/en/documents/pdf/genetic_resources_disclosure.pdf

[39] T R Young and M W Tvedt *Drafting Successful Access and Benefit-Sharing Contracts* (Brill/Nijhoff 2017) p468

[40] Here it is worth highlighting that Norwegian patent law one of the few countries that require a declaration of Origin (DOO) for patents applications on genetic resources in s 8(b) refers to biological material rather than MGR with respect to disclosure of origin. This will include a chemical derived from biological material.

not explicit refer to patent rights it will not be able to ensure fair and sustainable use of a global commons.

8. Embargoes and Exclusivity

It has been suggested that any researcher who accesses MGR beyond national jurisdictions must be entitled to a period of embargo over the results of that sampling exercise. The *Mare Geneticum* framework suggests that this period of embargo granted to anyone who uses the OPEN notification system could also be extended by the payment of an exclusivity fee.[41] During this period there would be no obligation to publish information on what was sampled, allowing the researchers to work on either publications or patents without fear of being gazumped. It protects the investment of time, effort and money which could be seen as desirable to incentivise researchers.

A note of caution and explanation is warranted here. If research expeditions are resource and technology intensive, then the very fact that the samples were acquired and are in the possession of the research crew provides an invaluable lead mover advantage that would be very difficult to overcome. An embargo of any sort on the results of sampling cruises will entrench the lead mover advantage, enabling extraction of value both through publications and patents without fear of competition. In this context any proposed embargo will function like a right of exclusivity, much like an intellectual property right.

There is often a chain-reaction dynamic associated with property – property begets property. Introducing new property or property-like rights in an hitherto un-propertised environment often leads to demands for second generation property rights that do not have anything to do with efficiency calculations. The lead movers can have an underestimated role in triggering this increased propertisation. [42] We also know from observing patents that the first to possess a technological prospect is not always the best to disseminate or commercialise it. In this context it would be difficult to ensure that embargoes are used to develop a technical or commercial prospect and not to simply to prevent others from using it.

There may have to be an examination of the subject matter of the embargo, to ensure technical quality, characterisation of what is claimed to have been accessed, and to prevent duplication. Any notification or authorisation system or authority would also need to administer such an examination process. The ability to extend the embargo through payment of an exclusivity fee,[43] without examining the case for it is likely to have anti-competitive effects, particularly in a governance mechanism where embargoes are competing with open-access intent.

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[41] *Mare Geneticum* Framework n 1 above

[42] Group behaviour, breach of a co-operative norm and the fear of exclusion, all help explain why property rights evolve in a chain reaction without cost benefit analysis being done along the way. S Safrin 'Chain Reaction: How Property Begets Property' 2007 (82) Notre Dame Law Rev 1917

[43] When looking to set exclusivity fees – if you set the fee low and tie it to higher fees further down the line, then you force the holder of the exclusivity make a cost benefit analysis and release information from embargoes that are no longer necessary/relevant. If fees are set too low, it would make sense to just pay irrespective of whether you think you need an embargo or not. There is a parallel here with patent renewal fees. See S Scotchmer 'On the Optimality of the Patent Renewal System' The RAND J of Economics Vol 30(2) 181-196.

Resolve: Embargoes and exclusivity models should only be used if absolutely necessary because of the danger of entrenching lead movers. In the case of marine prospecting on the high seas these are the most technologically proficient developed countries and wealthy corporations. Existing technical barriers to entry mean that there should be no need for such embargoes.

9. The Malleable Nature of benefit sharing

Despite it's recurrent nature and its use in medical and genetic research, international law, and political philosophy benefit-sharing as a legal concept has never been satisfactorily defined.[44] It's aspirational nature means it has to be given meaning, content and context in every new situation. As Prof Morgera puts it

> 'Benefit-sharing is employed in international law to connote a treaty objective, an international obligation, a right a safeguard or a mechanism. But, there is no instance in which it has been unequivocally understood, fully developed or become satisfactorily operational (footnotes omitted)...'On the other hand, fragmented, but growing empirical evidence indicates that in practice benefit-sharing rarely achieves its stated objectives, and may actually end up working against its purposes. On the ground, benefit-sharing has been seen as a 'disingenuous win-win rhetoric' that leads to loss of control and access over resources by the vulnerable through 'narrative framings of the global public good' and 'dominating knowledge approaches.'[45]

Broadly, and based on our experience of the ambiguity of the Nagoya Protocol, further references to non-monetary and monetary benefit-sharing in a new BBNJ treaty process should use international biodiversity law as a point of departure rather than reference. The problem with non-monetary benefit-sharing is that it can remain largely a box-ticking exercise. Since non-monetary benefits are almost always qualitatively defined, it cannot be measured, or monitored against benchmarks. Therefore it is easy to claim benefit-sharing will and can be done; and also that benefit-sharing has been done. While it will not guarantee it, monetary benefit-sharing is virtually impossible without a formal link between any internationally binding treaty and the patent system. Conversely it would be good to acknowledge that one of the main reasons not to make such a link effective is to escape the burden of having to share monetary benefits. Perhaps the time to acknowledge this head-on has arrived.

The *Mare geneticum* framework falls in the same trap by trying to focus on non-monetary benefits. Non-monetary benefits are often couched in terms of global goods – progress of science, making knowledge available etc. However like technology transfer,[46] such amorphous benefits can only be used if there is a requisite level of technical skill in local or regional communities. Often when this is not there, benefits in the form of global public

[44] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2652775/

[45] Elisa Morgera 'An International Legal Concept of Fair and Equitable Benefit-Sharing' University of Edinburgh School of Law Research Paper Series No 2015/20 at p 3

[46] There have been calls for a new international model to make technology transfer in the context of the TRIPS agreement, Art 66.2 effective. See for instance M Shugurov 'TRIPS Agreement, International Technology Transfer and least Developed Countries' Journal of Advocacy, Research and Education 2015 (2) Is. 1 74-85

goods such as scientific progress remain platitudinous. If benefit-sharing has to be truly equitable, it has to be in the form of scrutinizable and usable benefits.

In terms of benefit-sharing, as local communities are hard to identify, the treaty process provides an opportunity to establish a new concept of regional stewardship. Countries that are often bases for marine expeditions in the developing world can act as stewards for the regional development of technical and scientific capabilities. In terms of non-monetary benefits the establishment of linked technical universities to be housed in the Southern hemisphere, funded by contribution funds and capable of improving capacity for marine prospecting would be meaningful.

Resolve: International biodiversity law has shown benefits-sharing to be largely unworkable and should function as a point of departure rather than reference for conceptions of benefit-sharing for marine genetic resources in areas beyond national jurisdiction. Declaration of Provenance in patent applications is a necessary condition for any monetary benefits to be shared. Non-monetary benefits must be supported by tangible, measurable aspects and overseen by newly established regional stewardships.

10. Status and Content of Open-Access

The *Mare Geneticum* framework relies heavily on open-access obligations as a form of benefit-sharing. 'Any OPEN will contain open access conditions and benefit sharing obligation associated with the collected material whether these are monetary or not.' [47] There are at least three concerns here. First what would be the relationship between this obligation to make everything available open-access and the embargo and period of exclusivity? Does the open-access requirement only kick in after the embargo? If yes, we can expect that in that embargo period much of the valuable information will be published, in a pending patent application or otherwise amount to commercially sensitive information that cannot be shared. A full open-access model that competes with an embargo would therefore be less effective.

Secondly open-access can often be detrimental to the free availability of information because it does not prevent others from capturing openly available information in private databases or patents. The only way to prevent this would be to adopt a non-exclusive licensing model where the genetic resource is already under some property arrangement such as a patent and it is then made available for all to use, non-exclusively. This sort of arrangement is sometimes referred to as open-patenting. [48]

An alternative would be to ensure that any information or material made available through open-access obligations, could only be used if what was produced using the open-access material was also made available on an open-access basis. In other words the open-access genetic resource and information had a viral element to it that ensured that any subsequent use would also result in further open-access derivatives or products.

In case of a mixing of open-access and commercial genetic resources, it would be equitable for the commercial information to also become openly available rather than the reverse. This

[47] *Mare Geneticum* n 1 above p 18

[48] Biobrick Foundations experience here could be very useful. See M Maggiolino 'Standardised Terms and Conditions for Open Patenting' 2003 (4) Minnssota J of Law, Science and Technology 785-816

would be much more difficult to police, but could be done with robust track and trace methods. Any track and trace would then need to be prescriptive about the point at which an 'application' or 'product' from the MGR being traced by OPEN, can or cannot be privatised or commercialised.

Talk of open-access often misses another crucial element of transparency, and that is to consider the status of commercially sensitive information. Both commercial and academic entities are often reluctant to make available contractual information or licensing terms, choosing instead to cover them under the umbrella term of commercially sensitive information. This has become the bane of the Nagoya Protocol, because without being able to examine commercial contracts it is virtually impossible to tell if deep compliance in letter and spirit is in fact taking place. This is a particularly difficult barrier to overcome in the case of monetary benefits. In order to build up good practice it is important that such information be made available in a transparent manner. Any open-access initiative should include not just genetic resources but also commercial and transactional information around that genetic resource, if benefits-sharing is to be monitored and made effective.

Resolve: There are many perils in the open-access model. The relationship with embargoes, patents and commercially sensitive information must be resolved. Open-access unless well defined will remain insubstantial, difficult to police and liable to private acquisitions.