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PROBLEMS AND SOLUTIONS OF ACCESS TO GENETIC RESOURCES AND BENEFIT SHARING: A THEORETICAL PERSPECTIVE PART II

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Article

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Gerd Winter, Professor of Public Law, Research Unit for European Environmental Law (FEU), University of Bremen, Email: gwinter@uni-bremen.de

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1 INTRODUCTION

Article 15 of the Convention on Biological Diversity (CBD) acknowledges that states have sovereign rights over their genetic resources including to determine access to their genetic resources (GE) and request that benefits arising from the utilisation are shared with them (ABS). Concretising this framework the Nagoya Protocol (NP) of 2010 defines the scope of the ABS regime to be access for utilisation (i.e. research and development), empowers states providing GR (provider states) to require prior informed consent (PIC) and mutually agreed terms (MAT) for access to their GR , ask them to provide for legal certainty of relevant domestic regulation, require users to seek PIC of indigenous and local communities if accessing traditional knowledge associated with GR, obliges users of GR to share benefits arising from the utilisation of GR with the provider state, and asks states hosting users of GR to ensure compliance with access regulations of provider states. In terms of regulatory tasks all this means that states may regulate access if intending to make use of their sovereign right over their GR, and they must regulate utilisations performed within their jurisdiction of GR accessed in provider state countries. Of course, both issues can be – und usually is - contained in one and the same law so that one better speaks of states in their capacity as provider and/or user state.

In the first part of this article a number of problems have been discussed that have arisen from present law and practice and are still unsolved. There may be ways, and some have been considered, of how to solve those problems without fundamentally putting the ABS concept into question. However, the multitude of difficulties indicates that there may be underlying reasons that call for more basic changes of model design. This will be discussed in the following second part of this article.

2 REFLECTING ON PRINCIPLES UNDERLYING ABS CONCEPTS

Nine open problems have been identified. They are:

(1) how should utilisation be defined having in mind the interest of researchers in freedom of research and the interest of providers in participating in R&D and resulting benefits
(2) whether R&D results should be held confidential in order to allow commercial gain, or made public in order to enhance the public domain of knowledge
(3) what criteria are appropriate to draw a line between relevant and irrelevant contributions of GR in multicausal development of products
(4) how R&D on derivatives can be linked to R&D on genetic resources from which the derivates originate
(5) whether public data bases that store digital sequence information can and should be reformed to carry conditions for utilisation and benefit sharing stipulated by provider states
(6) whether and how the contractual obligation to share benefits should be improved by administrative oversight on the user side
(7) how in situations of transboundary GR the right of one provider to take all benefits can be integrated in a pool setting
(8) whether on the user side the costs and benefits of ABS are well distributed between public and private sector utilisation and commercialisation
(9) how much the transactions in the ABS system cost, and whether the costs are justifiable.

Problems (1) to (8) are concerned with equity of sharing benefits. While (7) and (8) refer to internal 'horizontal' problems on the provider (7) and user side (8), issues (1) – (6) point to the 'vertical' equity

relation between providers and users.[1] Issue (9) raises problems of formal design and costs of transactions. Issues (1) to (6) will now be dealt with in more depth because they are the crucial ones in ABS matters. They have arisen out of the quid pro quo-model implemented on the basis of the NP which is that GR are offered in exchange for the promise that benefits will be shared.

This model can be applied on the level of involved persons as well as of states. Persons may - as cultivators - rather be occupied with conserving natural resources and therefore appear as providers of GR, or they may – as scientists and inventors - focus on doing R&D and therefore appear as users of GR. Both sides are represented by their states so that it is common to speak of provider and user states if regulatory issues are addressed. Of course, one state may regulate both providers and users, especially where these two groups belong to different and possibly conflicting cultures/ regions within a state. In such cases one may rather speak of provider and user regulatory regimes. The two layers of persons and states are somewhat confused by the NP because it - so to speak diagonally - refers to provider states on the one side and users, not user states on the other. But this can in theoretical contexts be corrected if participants of discussions make clear whether a topic is raised concerning the quid pro quo on the level of persons, of regulatory regimes or of entire states. For the sake of simplification I will concentrate on the relationship between provider and user states having in mind that they represent providers or users as persons, and, as the case may be, as actors both within their own jurisdiction and within transnational relations.

In order to ensure benefit sharing the provider states have interest to fully direct the R&D process but this is bound to fail because the R&D process is unavoidably the more 'socialised' the more researchers and developers become involved, the more open access to R&D results and especially DSI is pursued, the more kinds and origins of GR are drawn into the utilisation and commercialisation activities, and the more user states delink utilisation and commercialisation from access conditions.

When considering more basic alternatives to the present ABS regime discussants often focus on the number of participant states differentiating between bilateralism and multilateralism. I believe it is more seminal to focus on who controls the valorisation chain of GR, differentiating between control by provider or by user states.

Control by provider states, or the upstream model, means that provider states oversee the downstream process up until benefit generation and sharing, while control by user states, or the downstream model, delinks the chain from provider oversight and instead obligates users and their states to ensure the sharing of benefits. The distinction partially overlaps with that between bilateralism and multilateralism because while the upstream models could be bilateral and multilateral the downstream models only make sense if being multilateral.

When filling alternative concepts with reason the underlying idea of justice between providers and users is of importance. There are many conceptions of justice, but those most apposite for the present context are three: commutative, distributional and interactional. Commutative justice means an equivalent quid pro quo between two equal parties: the countries holding GR are conceived as owners of a commodity that can be sold in exchange for non-monetary and monetary benefits. In contrast, distributive justice starts with the observation that the two parties are unequal because staying at different stages of development, and engages in assisting the weaker side.[2] Interactional

1 For the distinction between horizontal and vertical equity see G Winter, 'Common Pools of Genetic Resources and Related Traditional and Modern Knowledge' in E C Kamau and G Winter (eds), Common Pools of Genetic Resources. Equity and Innovation in International Biodiversity Law (Routledge 2013) 3-24, 4.

2 For the meaning and Aristotelian origin of the two concepts see the instructive article of A-H Chroust and D L Osborne, 'Aristotle's Conception of Justice' (1942) 17 Notre Dame Law Review 129-143 <http://scholarship.law.nd.edu/ndlr/vol17/iss2/2> on their application in the ABS context see P-T Stoll, 'Access to Genetic Resources and Benefit Sharing – Underlying Concepts and the Idea of Justice' in E C Kamau and G Winter (eds), Genetic Resources, Traditional Knowledge and the Law. Solutions for Access and Benefit Sharing (Earthscan 2009) 3-18.

justice is based on mutual recognition of partners as being equivalent but genuinely different; it builds on fair procedures striving for consensual solutions that are acceptable for the partners.

The three concepts may also influence the basic expectations and attitudes of ABS related interactions at both the law-making and law-applying levels: In a commutative framing the parties will negotiate about the costs of conservation, the value of the genetic resources, the costs of involving provider state personnel, the value of the knowledge shared, etc., finally translating qualitative into monetarised assessments. In contrast, in a distributive framing the unequal starting points of the parties are addressed apart from or in addition to the fair pricing of GRs as commodities. Joint ventures of R&D and the sharing of R&D results will rather be seen as based on normative principles and flanked by more general technical, scientific and financial support. Finally, in an interactional framing the building of trust is paramount and (truthful) consensus indication of fair solutions. The framing is, for instance, suited to create cooperation between competent authorities of provider and user states in organising transborder transactions.

Asking how the three concepts of justice may contribute to more fundamental alternatives for ABS all of them should play a role. In short, (commutatively) fair deals should be struck, (distributionally) weaker parties should be assisted, and (interactionally) trust should be built among parties. This should apply to the relations between providers and users as well as concerning internal oppositions within the provider and the user sides. Nevertheless, justice between providers and users is not the ultimate goal of ABS. According to its Art. 1 the paramount objective of the CBD is the conservation of biodiversity, ABS being only the third. ABS must therefore be understood as being instrumental for the first by provisioning knowledge and funds. In more theoretical terms, ABS has at its immediate aim fairness between human beings, and as its more fundamental aim the adaptation of human beings to their natural life conditions. This must be kept in mind when alternatives of ABS regimes are designed.

3 ALTERNATIVE CONCEPTS

The upstream and downstream concepts will now be examined in more detail.

3.1 Variants of the Upstream Model

I suggest to distinguish between three upstream models: ABS closed shops, R&D joint ventures, and provider driven databases.

3.1.1 ABS Closed Shop

In the 'ABS closed shop' the GR are intended to generate benefits only after very few steps of R&D activities which can easily be controlled by provider states. That is, in particular, the case if:

- chemical substances are extracted from a GR and used as or built into an already envisaged specific product
- organisms are modified by only a small number of clearly traceable steps
- genetic traits coding for specific functions are extracted and transferred into an organism where they are still clearly identifiable

Such 'close to access' situation can – vertically - be organised between one provider state and one user. It could also – horizontally – include a group of like-minded provider states which would then pool biological resources they have in common, and it could invite a group of users who cooperate in specified ways. It is particularly useful for seed exchange by local providers and users,[3] but transnational pools could also be imagined.

The parties would need to delimit the allowable utilisation and commercialisation as well as the

3 See for an examples M Tapia and B Tobin, 'Guardians of the Seed: The Role of Andean Farmers in the Caring and Sharing of Agrobiodiversity' in Kamau and Winter (n 1) 79-99.

participating partners. PIC and MAT would specify what GR shall be accessed, how they shall be utilised, if DSI shall be allowed to be uploaded to data bases, whether and how results shall be commercialised, what information about R&D progress shall when be exchanged, and how benefits shall be shared. In that way closed shops would be formed. They very much resound the original idea of ABS which was modelled on simple cases of alleged biopiracy (such as the hoodia plant)[4] where the accessed biological resource was brought to the market only after few and traceable steps of R&D.

3.1.2 R&D Networks and Joint Ventures

There is an older tradition of ex situ collections to form networks that allow exchange of GR for research purposes. A major example is the International Plant Exchange Network (IPEN) which embraces 600 institutions from 100 countries.[5] Their core use restriction is that the research must be non-commercial. This reflects their goal to enhance the public knowledge about wild and domesticated plants. By that restriction states providing plants from in situ conditions are ensured not to forego shares in commercial benefits.[6] They rather contribute to the knowledge pool and benefit from having free and possibly preferential access to the same.

The picture is somewhat different with ABS concerning in situ GR. A historical look at the development of provider state ABS regimes shows that many states started with rather strict access requirements in a hope to produce monetary gains. This hope was widely frustrated. In reaction there is now more appreciation for non-monetary benefits in the public debate and even by some states. Much emphasis is now being put on the participation of provider state personnel in R&D projects. Such practices have developed informally even without regulatory requirements of provider states.[7] But many states have meanwhile introduced regulations that make access by foreign researchers to their GR conditional on the participation of domestic researchers, impose respective PIC conditions or ask for appropriate clauses in MAT and MTA.[8] The contractual rights and obligations could bring domestic researchers on equal footing with the external researchers so that the usual practices of R&D apply, such as mutual information and cooperation, joint publications, joint applications for and possession of IPRs, joint marketing of products and services, but also joint decisions about feeding information into the knowledge commons.

In a realistic perspective it must be admitted that such cooperation on equal footing will collide with the fact that the experiences and qualifications of researchers on the two sides will often be different.[9] The model

4 E C Kamau, 'Common Pools of Traditional Knowledge and Related Genetic Resources: A Case Study of San-Hoodia' in Kamau and Winter (n 1) 40-54; R Wynberg and R Chennels, 'Green Diamonds of the South. A Review of the San-Hoodia Case' in R Wynberg, D Schroeder and R Chennels (eds), Indigenous Peoples, Consent and Benefit-sharing: Lessons from the San-Hoodia Case (Springer 2009) 89-124.

5 See www.bgci.org/our-work/policy-and-advocacy/access-and-benefit-sharing/the-international-plant-exchange-network/. C Godt, 'Networks of Ex Situ Collections of Genetic Resources' in Kamau and Winter (n 1) 246-267 (251-253).

6 Note, however, Godt's warning that providers of in situ GR may become sceptical whether the line to commercial research can reliably be drawn (ibid 261).

7 For empirical case studies of provider-user scientific cooperation see E Beck, 'Experiences in International Ecological/biological Research' in E C Kamau, G Winter and P-T Stoll (eds), Research and Development on Genetic Resources. Public Domain Approaches in Implementing the Nagoya Protocol (Routledge 2015) 165-174; H I Boga, 'Local Scientist's Experience with Bioscience Research Authorization Process in Kenya: Need for Facilitation' in Kamau, Winter and Stoll (n 7) 181-192; J Cabrera Medaglia, 'The Role of the National Biodiversity Institute in the Use of Biodiversity for Sustainable Development -forming Bioprospecting Partnerships' in Kamau and Winter (n 2) 243-268.

8 So, for example, Brazil, Ecuador, Kenya, South Africa, etc. See the related contributions in E C Kamau (ed), Global Transformations in the Use of Biodiversity for Research and Development: Post Nagoya Protocol Implementation Amid Unresolved and Arising Issues (Springer forthcoming).

9 See for a case in Panama where the local activities were negotiated to only extend to the collection, extraction and testing of the material (which was plants with antimalarial properties) M Heinrich and others, 'Access and Benefit Sharing under the Nagoya Protocol—Quo Vadis? Six Latin American Case Studies Assessing Opportunities and Risk' (2020) 11 Frontiers in Pharmacology 13 <www.frontiersin.org/articles/10.3389/fphar.2020.00765/full>. Interestingly there was a second user striving for access who did not even accept these conditions and opted out.

therefore relies on an incremental learning on the provider side and the continuous assistance by the user side. In effect, it may be more rewarding for the provider state to build up capacities than nurturing faint hopes of monetary compensation.

The model is compatible with making data and research results publicly available and usable without any condition set by PIC or MAT of provider states. The only but possibly rewarding link to them is the obligation of users to reliably and effectively collaborate with provider personnel.

Concerning the legal basis the design of an R&D cooperative would very much depend on the specific situation (what kind of GR? what kind of project? what kind of division of labour? etc.). This means that it will best be laid out in private/administrative law contracts, as possibly prefigured by national legislation, rather than needing an international agreement of the kind offered by Art. 10 NP.

3.1.3 Provider Conditioned Databases

It has been observed that provider conditions more and more lose impact with the digital utilisation of GR. Public databases commonly offer unconditioned open access hiding or disregarding possible conditions of their utilisation. In contrast, modern bioinformatics are about to explore just the opposite: to note and transfer any legal conditions together with the hitherto pure data on genomes, functions and biological conditions.

One simple possibility is to create an electronic link between databases and ABS. On the data side, any submission of nucleotide sequence data (NSD) receives an accession number (AN) provided by the International Nucleotide Sequence Database Collaboration (INSDC). On the ABS side, the Internationally Recognized Certificate of Compliance (IRCC) is marked by a Unique Identifier (UI) generated by the ABS Clearinghouse. If a user submits to INSDC the UI together with NSD is stored as part of the metadata file, and if on the other side the ABS Clearinghouse stores the AN as part of the IRCC this would allow to link NSD stored in INSDC with ABS PIC and MAT.[10]

Another link could be created through the so-called country tag. Since 1998 INSDC has required to fill in a metadata field pointing to the country of origin of the submitted NSD.[11] Such notification however does not inform about whether and with what content PIC and MAT were required and issued. Somewhat more instructive are databases that collect information about samples. Such bases have been set up more recently and are fast growing.[12] They enable that NSD submitted to INSDC nucleotide databases can be traced to the samples from which they were derived. This allows to learn about the location, time and collected organisms, but not about PIC and MAT conditions.

Those conditions could be included in databases if apart from the scientific DSI layer a 'legal layer' was created that contains information about PIC and MAT conditions.[13] Both layers would be interlinked so that any user would know about conditions attached to the NSD she accesses. Due to the huge volume of additional information storage such a system would need to be operated through blockchain technology. However, the seeming perfection of such a system is I believe at the same time its failure. It ends up in a nightmare of big data overdrive. If really implemented a huge number of the trillions of stored genes must possibly be linked to a varying and over time changing bouquet of use conditions, be it concerning publication, attribution, reporting, modes of utilisation, commercialisation, etc. Even if this was

10 See further Rohden and others, 'Combined Study on DSI in Public and Private Databases and DSI Traceability' (2019) <https://www.cbd.int/abs/DSI-peer/Study-Traceability-databases.pdf> 36; B Fedder, Marine Genetic Resources, Access and Benefit Sharing. Legal and Biological Perspectives (Routledge 2013) 122 et seq.

11 Rohden and others (n 10) 38-39.

12 ibid 34.

13 Such model was sketched out by the so-called WiLDSI study, see A H Scholz and others, 'Finding Compromise on ABS & DSI in the CBD: Requirements & Policy Ideas from a Scientific Perspective' (2020) <www.dsmz.de/fileadmin/user_upload/Collection-_allg/Final_WiLDSI_White_Paper_Oct7_2020.pdf>.

technically manageable,[14] such data masses would cause tremendous costs in operational manpower, submitter and user time, ambitious technology and energy consumption.[15] And the system would be highly susceptible to mistakes by submitters or operators and evasion by users. It is therefore highly probable that the many well-minded proposals cannot or will not be realised.

3.2 Variants of the Downstream Model

Downstream models are characterised by delinking the utilisation and commercialisation of GR and related information from the control by provider states. Provider states only come back in as beneficiaries of the shared benefits. Thus, access, utilisation (R&D) and commercialisation are free for anybody but whenever benefits emerge they must be shared.

Three variants of the downstream model can be distinguished: subscription, bounded openness of natural information, and a biodiversity levy.

3.2.1 Subscription of Beneficiaries

The subscription concept was recently elaborated as one of the enhancement measures proposed for the Multilateral System of the ITPGRFA.[16]

The Multilateral System (MS) embraces 65 crop varieties possessed by public institutions in the contracting states.[17] Under the MS access is enabled for the purpose of utilisation and conservation for research, breeding and training for food and agriculture, provided that such purpose does not include chemical, pharmaceutical and/or other non-food/feed industrial uses. Specimen of the varieties are exchanged between the providing institutions and recipients subject to a standard material transfer agreement (SMTA).[18] Recipients are free to utilize, cultivate and sell the GR. Monetary benefits are not to be shared (but 'encouraged') if the marketed product is available without restriction to others for further research and breeding.[19] In case of such restriction 1.1 per cent of the revenue must be paid into a common fund from which PGRFA conservation projects in developing countries and countries with economies in transition are supported.[20] The fund thus constitutes a pool that delinks the sharing of monetary benefits from the individual provider but maintains the purpose of assisting providers in general in their conservation endeavours. However, the system has by now not generated much monetary revenue.[21] But its main purpose is anyway the promotion of non-monetary

14 For the technical implications see P Oldham, 'Digital Sequence Information – Technical Aspects' <https://ec.europa.eu/environment/nature/biodiversity/international/abs/pdf/Final_Report_technical_aspects_of_DSI.pdf> 41 et seq.; Scholz and others (n 13) 31 et seq.

15 C Baraniuk, 'Bitcoin's Energy Consumption "Equals that of Switzerland"' BBC News (3 July 2019)<www.bbc.co.-uk/news/technology-48853230>; Oldham (n 14) 46.

16 FAO, 'Report of the Ad Hoc Open-ended Working Group to Enhance the Functioning of the Multilateral System at the 8th session of the Governing Body', IT/GB-8/19/8.2 Rev.1. (2019) <www.lawinsider.com/documents/3zcURENNLU>.

17 They are listed in Annex I to the ITPGRFA, see Art. 11.1 ITPGRFA. In addition, GR held in ex situ conditions in trust of the International Research Centers (IARCs) of the Consultative Group on International Agricultural Research (CGIAR) are included in the Multilateral System, based on related agreements. These GR can be those listed in Annex I and others. See Art. 15.1 ITPGRFA.

18 Cf. Art. 12.4 ITPGRFA. The SMTA is available at <www.fao.org/3/a-bc083e.pdf>.

19 Art. 13.2(d) ITPGRFA; Art. 6.7 and 6.8 with Annex 2 SMTA.

20 Art. 13.4 ITPGR.

21 The precise volume of contributions flowing into the fund are not disclosed at the ITPGR website. Of high importance are voluntary contributions of contracting parties such as the annual payment by Norway of about 100.000.- $ <www.fao.org/plant-treaty/news/news-detail/en/c/1201486/>. The dimension of available funds can be inferred from the fact that only about 5 million dollars were available for the last (2017) call for proposals of the benefit sharing fund <www.fao.org/fileadmin/user_upload/faoweb/plant-treaty/cfp4/cfp_4_2017_0_en.pdf>.

benefits, such as exchange of information, transfer of technology, and capacity building.[22]

The reformatory concept does strive for enhancing monetary flows. This shall be done by an amendment of the SMTA. The core idea is that payments shall be made for products with and without restrictions but varying the owed amount.[23]

Concerning the revenue basis two systems are distinguished. In the 'single access system' the payments are related to the specific plant or plant material obtained on the basis of the respective SMTA. In contrast, in the 'subscription system' the link to the accessed plants is generalised. The subscriber pays annually a certain percentage on sales of products derived from any plant or plant material that belongs to the Multilateral System no matter if the subscriber had obtained the relevant sample from a member of the system or not. As this implies that payments in relation to a range of plants have to be made the percentage shall be lower than in the single access system.[24]

The enhancement of monetary benefit sharing does not set aside the rights and obligations to share non-monetary benefits including information resulting from R&D on the material, transfer of technology and capacity building.[25] The advantage of the concept is thus that it enhances monetary benefit sharing without leaving the sharing of non-monetary advantages aside. The shares providers receive are however generalised in the sense that they may obtain knowledge and money from the pool but lose their power of individually directing the utilisation and commercialisation process. Another advantage is the possibility of 'horizontal' equity between providers as well as between recipients: neither providers nor users 'take it all' but share with others of their kind.

Although the working group elaborating the subscriber model has produced a very differentiated draft leaving only a seemingly manageable number of controversies bracketed[26] the willingness of ITPGRFA parties to agree seems to have lost momentum.

Nevertheless, the concept may serve as an inspiration for pooling GR other than plants for food and agriculture, such as plants for pharmaceutical purposes, plants and fragrances for cosmetic purposes, extremophile microorganisms for industrial processes, cattle, pigs or poultry for livestock husbandry, fish for aquaculture, etc.

While the described system is based on biological resources in the material sense, it can also be connected with pooling the corresponding DSI layer. In terms of the models suggested in the WiLDSI study the corresponding option would be the Membership Fee Model, although some qualification is appropriate. The DSI resulting from R&D on the GR pool would need to be stored in a database that is separated from the general free access base. Access to the separated base would require the payment of user fees which would be calculated according criteria corresponding to those applied for the material pool.[27] The revenue from those fees can be used for supporting biodiversity protection in the provider states participating in the subscription model.

3.2.2 Bounded Openness of Access and Benefit Sharing

The subscription model even if connected with DSI pools is still tied to GR as material. In contrast the 'bounded openness' model is more fundamentally based on information. The model was designed by

22 Art. 13.2 (a)-(c) ITPGRFA. See further E Tsioumani, 'Exploring Fair and Equitable Benefit-Sharing from the Lab to the Land (Part I): Agricultural Research and Development in the Context of Conservation and the Sustainable Use of Agricultural Biodiversity' (BENELEX Working Paper N. 4, 2018) chapter 3.2. <www.academia.edu/9383163)Tsioumani>.

23 FAO, ITPGR, 8th Session of the Governing Body, IT/GB-8/19/1.2 Rev.1 <www.fao.org/3/na890en/na890en.pdf>. The draft sets the rates at 1.1 – 2 per cent for products with restrictions and 0.1 to 0.5 per cent for products without restrictions. Cf Articles 6.7 and 6.8 and Annex II of the draft SMTA.

24 The range shall be 0.01 to 0.1 per cent, without still unelaborated differences between products with and without restrictions. See Article 6.11 and Annex III of the draft SMTA (n 23).

25 Art. 6.9 SMTA.

26 See FAO, ITPGR, 8th Session of the Governing Body (n 23).

27 Scholz and others (n 13) 20-22. See in particular p. 22 where the authors point to the difficulties of determining the basis of membership fees.

John Henry Vogel and Manuel Ruiz-Muller. It has the following characteristics:[28]

Access to GR is understood to mean access to 'natural information' as such or as imbedded in material. Access may be in situ or ex situ. Utilisation of GR is understood as adding value to 'natural information'. 'Natural information' (or more exactly biotic natural information) is defined as 'an expression generated and extracted from matter that is living or was once alive, where 'expression' refers to any distinction, non-uniformity or difference that was unintentional'. Natural information shall flow freely through the entire chain from for R&D to commercial success. Commercial success occurs if significant monetary benefits arise from an intellectual property right that is based on value added to natural information. Benefits accruing from natural information utilized in goods and services which are not protected by IPR and lie in the public domain are not subject to the bounded openness sharing system. Non-monetary benefits are not subject to the bounded openness system. They will be shared according to provider state regulation, PIC and MAT. Whether natural information was utilised or not must be disclosed in the application for intellectual property. Monetary benefits derived from access and utilisation of natural information are subject to the payment of royalties. Royalties are to be paid into a Global Fund. The amount of royalties are determined according to criteria approved by the COP of the Bounded Openness System. Such criteria may be characteristics of products, utilisations and IPRs. The holder of an IPR classifies his/her good or service according to the criteria established by the COP for determining which royalty is applicable for the value added to the natural information. The holder of an IPR derived from added value to natural information duly notifies the ABS Clearing House of the commercialisation and the classification of the good or service; the Clearing House also monitors patents and commercialised products. The countries of origin of the natural information[29] receive a percentage of the monetary benefits proportional to the relative holdings of the natural information. A technical mechanism is established that identifies the countries of origin of the species from which the natural information could have been extracted, including the geography of the habitats, deploying the technology available at the time of commercial success to calculate the said distribution. Should the royalties accrued not cover the costs for determination of distribution, or should the natural information be ubiquitous, the royalties are dedicated to the infrastructure of the system.

The core of BO – open R&D and commercialisation plus compulsory benefit sharing – is I believe very much to the point. There are nevertheless concerns of which I will mention four.[30]

- The term 'natural information' which is core for the concept is not clearly defined. The authors' definition – 'expression generated and extracted from living matter' - refers to real things rather than information, because information cannot be 'extracted' but is rather derived from observation and explanation. Therefore 'natural information' should be defined as information not 'out

28 Summarized from J H Vogel, 'Foreword' in M Ruiz Muller, Genetic Resources as Natural Information. Implications for the Convention on Biological Diversity and Nagoya Protocol (Routledge 2015) xii – xxv; M Ruiz Muller, J H Vogel and K Angerer, Proposal: Legal Elements for the 'Global Multilateral Benefit-Sharing Mechanism ...', Version 1.0, Creative Commons License (CC)2018 https://www.uni-giessen.de/fbz/fb11/institute/histor/mitarbeiter/mitarb_dwnl/GMBSMV.1.0RuizVogelAngererPDFENGLISH.pdf and a personal mail exchange between M. Ruiz Muller and myself of 31.08.2020.See also N Pauchard, Gouverner les ressources génétiques. Les stratégies des acteurs face aux droits de propriété et aux règles sur l'accès et le partage des avantages (Editions Alphil-Presses Universitaires Suisses 2020), 413-462, who recently joined the BO advocats, as does Chr Lyal, 'Digital Sequence Information on Genetic Resources and the Convention on Biological Diversity' in Kamau (n 8) ch. 5.

29 A more recent qualification is that only natural information in terrestrial species is covered while another allocation scheme will be developed for GR in areas beyond national jurisdiction (personal communication from Manuel Ruiz Muller).

30 Objections that are of less importance and possibly refutable are the following: It is unclear how (as the definition says) information can be 'extracted' from matter, where the line between natural information as such and added value by utilisation shall be drawn (e.g. is the discovery of a gene function natural information or added R&D?), and whether the value of the final product/service includes the value of both the natural information and the utilisation, or either.

of' but 'about' living matter. Even then, however, it remains unclear what 'living matter' means. The term appears to be infinitely wide. The concept is thus still due to concretise what kind of living matter shall be referred to.

- The BO concept demands royalty payments only from users whose product or service is protected by IPR. If the product or service is in the public domain this is considered as benefit for all. However, many users, if not the majority, generate market success through other means than IPR, such as by trade secrets, competitive pricing. early bird marketing, peculiar design and formulations, advertisement campaigns, etc. Should their revenue not also be subject to royalty payment?
- BO aims at creating an international body called 'technical mechanism' that shall be in charge of an overwhelming burden of tasks. It shall check the contribution of natural information to any IPR protected product or service, including the application of cut-off criteria, calculate and collect the royalty payments, monitor the species to which the information is related, identify the countries where and in what density the relevant GR occur, determine and allocate funds accordingly, register IPRs based on natural information (or collaborate with the ABSCH if that conducts the register), check any offences against the system and impose appropriate sanctions. As thousands of individual cases must be handled a huge bureaucracy will have to be established to perform all these functions. Hardly any executive body of that kind has ever been instituted on the level of international law, and there is no reason to believe that ABS is ground enough for such pioneering endeavour.
- More fundamentally, however, I have doubts about the rationale on which the obligation to pay is based. BO is founded on the economics of information, which works with categories such as property in information, competition of right holders (risking price dumping through jurisdiction shopping), the formation of oligopolies that build market power for right holders, and the possibility of patenting plus sharing IPR triggered revenue.[31] The reason for making users share benefits is thus ownership in the information, constituted as bargaining power and enhanced by cooperation (or cartel) of right holders when BO shall be established by international treaty. In pure terms of homo oeconomicus provider as well as user states will agree on a BO concept, provider states because a collective approach is more efficient than an individual one where jurisdiction shopping may frustrate revenue expectations, and user states, because in a cartel situation they are forced to give in and pay. But economic man is not how the real world operates. In this world a substantive idea attractive for both providers and users is needed. It is provided by the ecologics rather than economics of information. In an ecological sense rights of information are not meant to just generate revenue but rather to do that for a purpose, which is the conservation of biodiversity. With that orientation both providers and users may be more willing to subscribe to the pool concept rather than if they were called to maximise their individual interests. I will come back to this when discussing the bio-levy.

3.2.3 The Biodiversity Levy (or bio-levy)

While BO still maintains a link between benefit sharing and accessed GR – even though loosened because the link is established ex post of the access and in a generalised way – the concept of biodiversity levy abandons any such link. This allows to extend the view on ABS to the comprehensive and fast developing world of bioeconomy. According to a Commission paper of 2012:[32]

31 See for details J H Vogel and others, 'The Economics of Information, Studiously Ignored in the Nagoya Protocol on Access to Genetic Resources and Benefit Sharing' (2011) 7/1 Law, Environment and Development Journal 52 – 64 <www.lead-journal.org/content/11052.pdf>.

32 European Commission, 'Innovating for Sustainable Growth. A Bioeconomy for Europe' (Publication Office of the Union 2012) 16.

> The bioeconomy encompasses the production of renewable biological resources and their conversion into food, feed, bio-based products and bioenergy. It includes agriculture, forestry, fisheries, food and pulp and paper production, as well as parts of chemical, biotechnological and energy industries. Its sectors have a strong innovation potential due to their use of a wide range of sciences (life sciences, agronomy, ecology, food science and social sciences), enabling and industrial technologies (biotechnology, nanotechnology, information and communication technologies (ICT), and engineering), and local and tacit knowledge.
>
> Based on available data from a wide range of sources it is estimated that the European bioeconomy has an annual turnover of about € 2 trillion and employs more than 22 million people and approximately 9 per cent of the total EU workforce [...].

The concept of a biodiversity levy rests on the observation that it will be very difficult if not impossible to identify the specific contributions to the bioeconomy by ABS regulated GR, this neither in the upstream model which presupposes the impossible monitoring of R&D downstream from a specific provider state to the commercialisation stage, nor in the downstream model which involves the tracing upstream from commercialisation to at least one host state in a world where multicausality is growing and may have become the new normality.

The bio-levy would delink benefit sharing both from a specific provider state and even from the states of origin in general.[33] In that case the system may be able to collect considerable funds for the conservation of biodiversity that are channelled to those states that undertake active measures to protect biodiversity or desist from development damaging biodiversity. This focus on additional conservation undertakings distinguishes the bio-levy from BO which rewards the presence of certain GR, not engagements (and their actual or opportunity costs) in their conservation. As for the objects subject to the bio-levy living plants, animals and microorganisms would be embraced, but not human life because human life is a good owned by the living individual person. It is open to further discussion if the biological resources in their entirety or only in the form of genetic resources would be covered. In the former case any use, including the cultivation of plants and husbandry of animals, would trigger the levy. In the latter case the levy would be confined to the utilisation of the genetic potentiality of the genetic program, and more concretely to the nucleotide sequences and their life conditions and functions.[34] Concerning the relevant use of those sources one might demarcate it by drawing on the concept of 'benefits arising from utilisation and subsequent applications and commercialisation of genetic resources' as defined in Art. 5 NP.

The reference to the genetic program would allow to engage the nucleotide databases as sources for the levy. Alternatively, if any use of biological resources in their entirety are taken as trigger the many 'downstream' biological databases could be integrated.

Another question is whether any GR or only those covered by the CBD shall be included. Considering that the idea of bio-levy emerges from the CBD principle of sovereign rights over natural resources

33 For steps in that direction concerning genetic resources for food and agriculture see S Louafi and M Schloen 'Practices of Exchanging and Utilizing Genetic Resources for Food and Agriculture and the Access and Benefit-sharing Regime' in Kamau and Winter (n 1) 193-223 (219-222).

34 Following a list proposed by 2018 Ad Hoc Technical Expert Group (AHTEG) list and its structuring by Rohden and others (n 10) 10 -11 nucleotide sequences could be defined as nucleic acid sequences and sequence assemblies while the life conditions and functions would refer to gene expression, metabolites, ecological and abiotic relationships, functions, morphology and phenotype, taxonomy and modalities of use. While the AHTEG proposed items are defined in terms of information I rather refer to the material substrate emphasizing that not the information but the material is the source of life and therefore a possible ground for a levy (see further below).

the system may indeed be confined to the biological resources existing under in situ or ex situ conditions.[35] The bio-levy would be raised on revenue products/services that arise from the material or/and information level of genetic resources, including when the DNA sequence of a gene coding for an interesting function is entirely taken from a database, without traceability of its geographic origin, and when the sequence is synthesised and inserted into an organism.

There must of course be a convincing reason why the bioeconomy should be obliged to pay. That reason could be the need to conserve biodiversity as the ultimate source for the bio-economy. Or, more fundamentally, it could be âéüó, life itself, the innate power of organisms to 're-source' (from the Latin resurgere – to rise again). Life as appearing in its diversity is thus a distinct source for research, development, production, trade and consumption. The exploration and exploitation of this 'natural' power more and more replaces earlier economic phases that rely on non-renewable dead material which is incrementally being exhausted and dissipated.

Voluntary contributions by states and private parties to the ITPGR benefit sharing fund and subscription payments within the WHO Pandemic Influenza Preparedness (PIP) Framework[36] show that the idea of paying for biodiversity use may not be beyond realistic expectations. A model case in the ITPGRFA context could be Norway which committed to a payment of 0.1 percent of seed sales in Norway.[37]

The bio-levy could be conceived as deriving a part from the value that diverse life adds to the development of products and services, just as the income and the value added taxes can be understood to derive monies from value added by labour. Alternatively, it could be conceived as a compensation for the utilisation of diverse life as a public good. It could also be conceived as the advantage offered to the provider states in exchange for their waiving of sovereign rights over their biological resources. Finally, it could be understood as a collection of funds in view of the negative side-effects the bioeconomy often causes on its very basis, the variety of life.

Once the levy is theoretically justified its destination must be considered. This could be any purpose if the levy was considered as a new tax (such as the income tax). There are however at least four reasons in favour of earmarking the levy revenue for the conservation of biodiversity. First, the bioeconomy does exploit natural resources and should collect money to preserve them. For instance, the increasing industrialised cultivation of biomass as a raw source for the bioindustry is a serious threat to biodiversity. Secondly, the genetic engineering of organisms may have disturbing side-effects on ecosystems. Thirdly, any progressive breeding and artificial modification is at times well advised to go back to the natural ancestors in order to refresh or enhance the genetic basis. Fourthly, innovations in the bioeconomy relies on the availability of a diverse gene pool.

Introducing the bio-levy would require a new international treaty which could be based on Art. 10 NP if the preconditions of that article are interpreted broadly,[38] or on a separate Protocol concluded in the framework of the CBD. As to the operational basis for the bio-levy reference could be made to the Global Environmental Facility (GEF). In consequence, the bio-levy would increase the influx of money that GEF spends for the conservation of biodiversity.

35 According to Art. 2 CBD '"In-situ conditions" means conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties'. while '"Ex-situ conservation" means the conservation of components of biological diversity outside their natural habitats'.

36 M Wilke, 'The WHO Pandemic Influenza Preparedness (PIP) Framework as a Public Health Resources Pool' in Kamau and Winter (n 1) 315-342.

37 C Lawson, F Humphries and M Rourke, 'The Future of Information under the CBD, Nagoya Protocol, Plant Treaty and PIP Framework' (2019) 22(3-4) J World Intellect Prop 103, 115-116 <https://online-library.wiley.com/doi/abs/10.1111/jwip.12118>.

38 See on the related possibilities E Morgera, W Tsioumani and M Buck, Unraveling the Nagoya Protocol: A Commentary on the Nagoya Protocol on Access and Benefit-sharing to the Convention on Biological Diversity (Brill 2015) 197-208 <www.jstor.org/stable/10.1163/j.ctt1w76vvq.17>.

4 CONCLUSION

The current ABS system is loaded with impasses that taken together trigger thoughts about fundamental alternatives. The present account of the pertinent discussion leads to a setting that allows for a plurality of different systems, some of which are however mutually exclusive.

The systems can be ordered along a line from upstream to downstream of the chain of valorisation of genetic resources. Such ordering is suggested to be more seminal than the usual distinction between bilateral and multilateral systems which looks at the number of parties rather than the characteristic content of the regime. Models at the upstream end are characterised by provider state control of the chain down to benefit sharing while models at the downstream end delink benefit sharing from provider state control although providing them with shared benefits in a generalised way.

When selecting suitable models and possibly arranging combinations the following strategy can be recommended:

(1) 'Closed shop' should be retained as one option. This means that most of the current ABS regimes and application practices can persist. They should however be designed to concentrate on the extraction of biochemical derivatives (such as in the Hoodia case) and, if involving breeding or genetic engineering, only include a few steps of biotechnical modification, excluding sequences to be uploaded to public databases. This would facilitate PIC and MAT negotiations but require that the allowed utilisation and commercialisation activities are strictly limited.

(2) Provider states could also opt for 'R&D joint ventures'. Such formations can also be based on the current ABS regimes but would focus practices on joint R&D, with a strong element of serious capacity building where developing countries are involved. When negotiating PIC and MAT developing provider states would insist on favourable conditions concerning R&D cooperation, reporting, access to R&D results, joint publications, etc. But they would desist from controlling the R&D process insofar as it may generate commercialisable products and obtain commercial benefits through IPRs or from sales of products and services. In that regard they would rather strive to cooperate in commercialisation, or develop their own products and services.

(3) The progress in bioinformatics appears to make the ideal possible: that databases can be used to not only store nucleotide data and subsidiary information but also any PIC and MAT conditions. There is a vivid discussion on what models may be developed in that regard. However, if the system shall not only display conditions for entire sequences but flag that information with any individual gene accessed and possibly isolated for specific uses, and if the system shall (as appears necessary in the interest of providers) report about the actual progress in R&D results up to the marketing of products the data volume is just too huge to be mastered. It would require heavy investment in database infrastructure, high commitment to comply by users, elaborate skills to curate and update date, oversight and sanctioning powers by states providing and hosting users and databases, and, not the least, high energy input especially when it comes to using blockchain technology. I believe, the model 'provider state driven databases' can therefore not be recommended.

(4) Formations of 'subscription of beneficiaries' could be created for a defined (and incrementally enlarged) number of plant, animal or microbial species, possibly differentiating product sectors. Such pooling of GR could include many subscribing provider and user states. The pool would allow for free R&D of participants. Revenue would be created through schematic payments of user states the sources of which – taxes or user

contributions – is left to their discretion. The system would necessitate the conclusion of a separate multilateral treaty for each pool, or of a framework treaty on which pool-specific protocols could be based.

(5) 'Bounded openness' takes a further step of delinking benefit sharing from access conditions. It establishes a system of benefit sharing ex post, focussing on revenue obtained and disregarding how the GR and the information describing it was acquired. Such information, termed (biotic) natural information, shall be constituted as property of the provider states. This allows them to form an oligopoly and/or bargaining power that demands the sharing of benefits from R&D by which value is added to the natural information. Royalty payments are due for revenue generated from IPR protected products and services. The money shall be redistributed to provider countries according to the geography and density of the species from which the information is taken. The system is still unclear about its scope, and especially the notion of natural information. It also involves the creation of an international body that must be endowed with many different tasks and powers. Related correction assumed, the concept would need the conclusion of a multilateral treaty as a basis, possibly in the form of a Protocol founded on Art. 10 NP.

(6) 'Bio-levy' would be an alternative to both the subscription and bounded openness models. It could solve the problem that the latter two still imply the tracing of products back to contributions of genetic resources. For 'bio-levy' only requires that a product shall be based on inputs of life. What 'life' as the trigger of the levy shall mean, would depend on the grounds legitimating it. It could be life as a general natural power, it could be the use of any 'wild' biological resources, and – even more narrowly - it could be the utilisation of the genetic potential of 'wild' genetic resources covered by the CBD. Bioinformatics would need to be employed, but in a sense of assistance rather than selfish overdrive. The funds collected in the system can be spent applying genuine criteria of the importance of biodiversity elements and undertakings to their conservation/restoration. GEF could be considered as the operational basis. If such system was introduced closed shops and R&D joint ventures could coexist with it. The system would need to be based on a multilateral treaty, using Art. 10 NP if its source of revenue is the utilisation of GR. If the source is 'wild' biological resources, a separate Protocol bases on the CBD would be better suited.

It is obvious that although it is in my opinion the most reasonable solution of the models aimed at monetary BS it will certainly meet fierce resistance by the most powerful users who abhor any new taxing proposal. But there is more at stake than financial costs: the conservation and further evolution of biodiversity as the essence of the 'grandeur of life'.[39]

39 Ch Darwin, Origin of species (2nd edn, H M Caldwell 1860) 474.

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