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PART I

Gerd Winter

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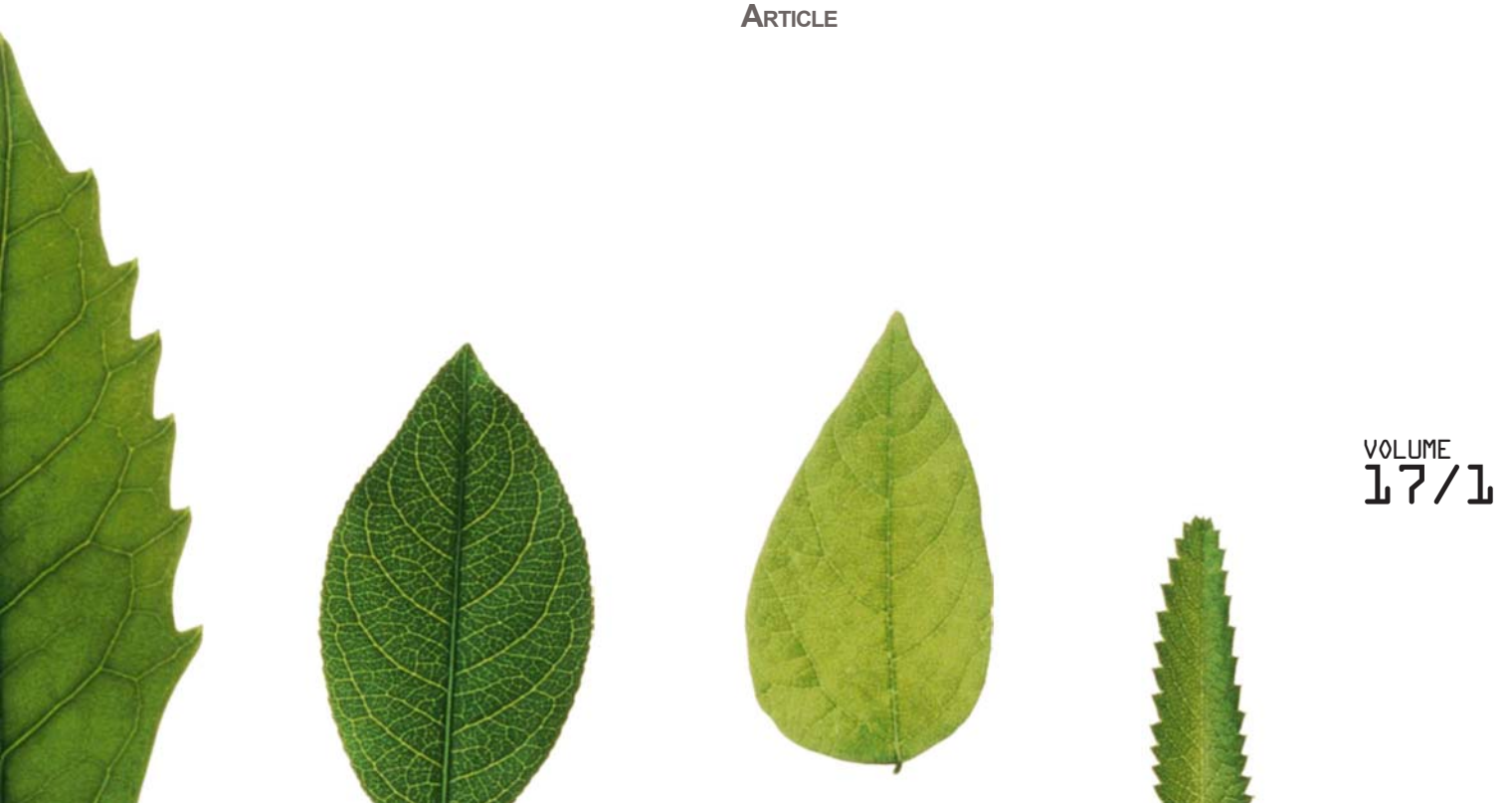

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Article

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

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1 INTRODUCTION

The regime called access to genetic resources and benefit sharing (ABS) is based on the principle of sovereign rights of states over their biological resources. The principle was acknowledged by Article 3 of the Convention on Biological Diversity (CBD) of 1992 and by its Art. 15 extended to genetic resources. In Article 2 'genetic resources' (GR) is defined as 'genetic material of actual or potential value', and 'genetic material' as 'any material of plant, animal, microbial or other origin containing functional units of heredity'. According to Art. 15 (1) and (7) the Contracting States are authorized to determine access to their genetic resources and obligated to aim at 'sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilisation of genetic resources with the Contracting Party providing such resources'.

This framework was further concretized by the Nagoya Protocol (NP) of 2010. The NP defines the scope of application 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 or GR for which such communities have the established right to grant access, obliges users of GR to share benefits arising from the utilisation of GR with the provider state and share benefits arising from the utilisation of GR and associated traditional knowledge held by indigenous and local communities with the same, and asks states hosting users of GR to ensure compliance with access regulation 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 – and 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.

The ABS national regimes have meanwhile taken quite differentiated forms concerning both the provider and user functions. An example for a sophisticated form for provider functions is the Brazilian regime.[1] Its characteristics are: the access regime covers not only genetic material but also genetic information; R&D on GR acquired as commodities are also categorized as access, even if conducted in a foreign country; foreign users must cooperate with domestic researchers; non-commercial research and development (R&D) must first be registered; notification and presentation of mutually agreed terms (MAT) are required if commercialisation of finished products or reproductive material is planned; domestic proxies of foreign users can be made liable for sharing benefits; special scrutiny is applied concerning access to traditional knowledge associated with genetic resources (aTK); incoming revenue is earmarked for nature conservation and/or local/indigenous communities. On the side of user compliance the EU probably has the most developed regime.[2] Its characteristics include: users of GR are subject to basic duties to ensure compliance with provider state requirements concerning access to the GR and aTK, utilisation, marketing and sharing of benefits arising from utilisation; due diligence declarations are to be submitted by users about lawful access at stages of research funding and premarketing; competent authorities have to check the lawfulness of access and utilisation; simplified

1 Law 13.123 of 20 May 2015 (Access and Benefits Sharing of Genetic Resources and Associated Traditional knowledge) <www.wipo.int/news/en/wipolex/2015/article_0014.html>.

2 The core legal act is Regulation (EU) 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union, [2014] OJ L 150/59. More specific guidance is offered by the European Commission in its Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 [...] [2021] OJ C 13/01, hereafter referred to as Commission Guidance (2021).

procedures are foreseen for acquisitions of GR from registered collections.

As a further component of implementing the NP the support for ABS transactions was established at the international level through the ABS Clearing House (ABSCH) which operates a database storing national legislation, national responsible authorities and individual access permits, such registered permits serving as internationally recognized certificate of compliance.[3]

In spite of this major progress in regime building there are a number of still unsolved problems. They will first be presented. Second, the reasons why so many problems remain unsolved shall be reflected, and in particular whether underlying principles of equitable sharing of advantages between parties have been disregarded. Third, building on such reflection and keeping additional criteria in mind a number of reformatory approaches will be sketched out and discussed.

2 PROBLEMS[4]

The following problems shall now be explained in turn: the definition of utilisation, the distinction between commercial and non-commercial utilisation, multiplicity of GR in final products, the range of derivatives, the treatment of digital sequence information, the enforcement of benefit sharing, transaction costs on both the provider and user side, the transboundary occurrence of GR, burden sharing between research institutions and industry, and traditional knowledge associated with GR.

2.1 The Definition of Utilisation: Too Narrow, Too Broad?

The material scope of ABS regimes is, among others, framed by the notion 'access to genetic resources for their utilisation' (Art. 6 NP). Although the term 'access' alludes to the physical taking or purchase of samples some legal systems extend it to include situations where an organism that was bought for consumption subsequently becomes object of R&D.[5] The EU approach is to categorise the change as R&D which is also somewhat strange because it would imply that non-accessed GR are utilized.[6]

Some more difficulties arise from the scope delineated by 'genetic resources'. Although the term is legally defined[7] there is a need to draw lines such as, for instance, with regard to GR associated to accessed GR, human microbiota, alien species, etc. But they can be found and have reasonably been laid out by the Commission Guidance (2021). A still debatable question is how the terms 'genetic resources' and 'biological resources' relate to each other but that can be solved too.[8]

An unresolved issue however is the definition of utilisation. While Art. 2(c) NP defines it as 'to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology' it is not determined what research and development means. It is widely agreed that there is no precise line between research and development, but that they may overlap, and anyway that they do not need to come together, but that, for instance, research without development – often called basic - is also utilisation.

3 Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, Nagoya, 29 October 2010, UN Doc. UNEP/CBD/COP/DEC/X/1, art. 14 [hereafter NP].

4 'Problem' is simply meant to be an issue inciting further study. See its Greek origin in 'pro' = before and 'ballein' = to throw, hence something thrown before someone.

5 See, for instance, Art. 2 VIII of the Brazilian Law 13.123 which defines 'access' to include research and development which is surprising because R&D in the NP sense means utilisation.

6 Commission Guidance (2021) (n 2) para 3.4.

7 Convention on Biological Diversity, Rio de Janeiro, 5 June 1992, 1760 UNTS 79, Art. 2 [hereafter CBD].

8 While 'genetic resources' refers to the genetic program, 'biological resources' is rather used in relation to organisms as phenotypes, such as if they are stored in a collection, traded as commodity, etc.

However, it is unclear what the actual content of research and development shall be. The Commission Guidance proposes a 'litmus test' which is whether the R&D 'creates new insight into characteristics of the genetic resource which is of (potential) benefit to the further process of product development'.[9] It is thus the 'new insight', and one regarding the genetic program that is considered as decisive.

According to the Commission this shall exclude from scope a vast number of activities, including

- the taxonomic identification of genetic material by morphological or molecular analysis,
- the sequencing of genomes,
- use of GR as testing or reference tools,
- the processing of GR for incorporation in a product where its properties are already known (such as, for example, the processing of Aloe Vera for incorporation into cosmetics),
- the storing of GR in collections and related assessment of their health,
- the rearing and culturing of GR (such as farm animals),
- trading, transfer and exchange of GR and related knowledge, unless the material has been transformed into a 'half product',
- discovery and description of new species, as long as this is done without additional research on the genetic and/or biochemical composition of the genetic resources to discover or making use of the properties (functions) of the genes,
- the description and documentation of the distinctive nature or features of GR, unless this is combined with research on specific properties of the GR,
- phylogenetic analysis,
- large scale screening except for research on selected genetic information,
- behavioural studies on GR (e.g. to find out about their biocontrol properties) unless the genetic influence on behaviour is explored,
- vectors used to introduce foreign material into host organisms unless new knowledge about the vector is created,
- GR exploited to produce active compounds for further use,
- the use of invariant laboratory strains as a model for research,
- crossing and selection of GR for maintenance and conservation of breeds and varieties,
- known reproductive technologies,
- use of plant varieties legally protected by plant variety rights, registers or listings,
- the processing of known GR for subsequent incorporation in a product,
- formulation of a product by mixing or adding known ingredients or compounds,
- the testing of products unless the test results are used to modify the product.[10]

A note on definition theory may be appropriate here: Terms should be defined with a view on contexts and purpose rather than with regard to general dictionary wisdom. Reference to a dictionary is however how the EU Commission proceeds. It also refers to the OECD Frascati Manual which formally standardizes terms for statistics.[11]

Looking therefore at context and purpose the litmus test would be appropriate if the NP primarily aimed at promoting the progress of biological sciences. However, its objective is rather to find a compromise between the interests of provider states and users (including their states), based on the acceptance of sovereign rights of provider states. Such compromise can rather be found by creating and sharing benefits, be they non-monetary or monetary. Therefore, in that line the definition of research and development would be broader including some of those activities that are auxiliary to the core R&D process, such as the sequencing of genomes, molecular analysis, taxonomic research, introduction of (known) genes into other organisms, etc.

9 Commission Guidance (2021) (n 2) para. 2.3.3.1.

10 Compiled from Commission Guidance (2021) (n 2) para 2.3.3.2. and Annex II.

11 OECD, Frascati Manual 2015. Guidelines for collecting and reporting data on research and experimental development. The measurement of scientific, technological and innovation activities (OECD Publishing 2015) <http://dx.doi.org/10.1787/9789264239012-en>.

In conclusion the 'litmus test' proposed by the EU Commission tends to privilege user over provider interests and may drive provider states to exaggerate PIC and MAT conditions in order to draw some of the excluded items back into scope. The result would be a patchwork of different requirements that makes the tracing back of benefits overly complicated. Provider states setting strict conditions would also be exposed to jurisdiction shopping by users so that their sovereign rights run void. We are therefore confronted with the problem that strict requirements strangulate user freedoms, weak requirements frustrate provider interests, and differentiated requirements are difficult to implement.

2.2 R&D for Private Gain or for the Public Domain?

More problems arise concerning the handling of material or information resulting from the utilisation of GR. Two questions stand out: should the results be published or allowed to be kept private, and should they be commercialised or allowed for free use?

Concerning publication the CBD has various provision advocating the enhancement of public knowledge about GR and their sustainable use[12] while the NP does not address the issue directly. On the other hand the sovereign rights of provider states include that the the states are free to hinder the publication of R&D research results.

Concerning commercialisation the CBD and NP introduce the term commercial in two contexts. One is related to R&D activities: Art. 8 (b) NP asks for simplified access procedures for research with non-commercial intention. Likewise, Art. 17 (4) (i) NP lists commercial or non-commercial uses as possible content of the internationally recognized certificate of compliance (IRCC). The other context is the bringing on the market (or not) of products[13] from R&D, which is called commercialisation (or not) of products. This is referred to as a final step of handling GR (Art. 5 (1) NP, Art. 15 (7) CBD), and as an activity that shall be supervised by checkpoints (Art. 17 (1) (iv) NP.[14]

The problems of publication and commercial use are obviously interrelated. Commercialisation frequently implies to keep the result secret in order to exclude competitors, or to obtain intellectual property protection which makes the R&D result public but restricts its use. In contrast, free use is frequently based on published material or information.[15]

This interrelation leads to practical conflicts of interest. For instance, users in the public sphere normally wish to publish their results, possibly even including commercialisable ones, while the provider state may rather wish to keep them secret in order not to jeopardise subsequent commercialisation. In contrast, users in the private sphere are normally interested in holding them secret until they are brought to the market, or in restricting their further use through intellectual property protection, while provider states may be interested in making results public in order to build up domestic R&D capacity or generally participate in the global research commons.

Neither the CBD nor the NP nor even national implementing legislation provide guidance for such conflicts. Concrete provisions how to solve such conflicts are largely lacking. There is only a weak admonition in Art. 8 (b) NP to facilitate non-commercial research which by implication will be published. Even the core terms – publication, commercial/non-commercial – are hardly ever

12 CBD (n 7) Arts. 7, 12, 13, 15 (6), 17.

13 Corresponding to common definitions (OECD 2015 (n 11) the term product is here used to cover goods and services.

14 For a national implementation see EU Regulation 511/2014, Art. 3 (6) and 4 (3) (b) (iv). See also the preambular considerations Nos. 3 and 6.

15 See the definition proposed by DFG, Model clauses for mutually agreed terms on access to genetic resources and benefit sharing, DFG 2021, which is: '"Utilisation for non-commercial purposes" means research and development that aims at enhancing knowledge about the accessed genetic resource, including products and processes developed therefrom, and making such knowledge publicly available and usable at no more than incremental cost for dissemination'.

defined.[16] Absent guidance by international or national law the matter is largely left to the negotiations and finally PIC and MAT conditions between provider states and users, and thus to the de facto bargaining power of the two parties. The outcome may be to the disadvantage of provider states, or users, or the general public interest in open and non-commercial research contributing to the conservation of biodiversity.

2.3 Multi-contributions to the Development of Products: When Should There be a Cut-off?

R&D processes on genetic resources can embrace long chains and networks of activities and involve a multitude of different genetic resources. This is particularly evident in animal and plant breeding where multiple stages of reproduction may diminish the influence of an original contribution as compared with multiple other traits flowing into the product. In such case, it can be doubted that there is still a 'benefit arising from the utilisation of genetic resources' (emphasis added), and that fairness and equity do demand the sharing of benefits.[17] The situation is different if the original trait and its function are still noticeable in the final product. As a solution cut-off criteria might be used that draw a line between what has disappeared and what is still noticeable. This could be tried by a quantitative criterion such as, for instance, a minimum percentage of an original genome in the final product. But often a highly important property originates from a much smaller percentage, and unimportant functions may be due to larger ones. One could use a qualitative criterion instead, such as whether a trait is present in the finished product and determinant to its functional characteristics.[18] But that is hardly operational in borderline cases.

Another solution would be to draw a line at the stage of the marketing of a product. While the revenue obtained would be subject to benefit sharing R&D on the finished product would not be utilisation of the original GR and thus be out of scope. For instance, a new plant variety bred from accessed GR and marketed would be subject to benefit sharing, while the further breeding of a subsequent variety developed from the first would be considered to be cut off from the original traits.[19] But why should traits and properties that are still influential in the subsequent product be set aside only because a new variety has been generated? It may be new in terms of plant variety Protection law but ABS does not protect intellectual ingenuity. It rewards the conservation of GR, and that is not overruled by intellectual efforts.

A further problem of multi-causality is that the different products emerging from the chain of breeding will belong to all states which possess them in in-situ conditions, i.e. in 'surroundings where they have developed their distinctive properties'.[20] This can be many states which makes it difficult for the provider of some trait to trace marketing and claim benefit sharing.

16 For an exception see the comprehensive definition of commercialisation see Art. 1 (1) of the South African National Environment Management Laws Act, 2004, as amended by Act No 14 of 2013: 'commercialisation, in relation to indigenous biological resources, includes the following activities: (a) the filing of any complete intellectual property application, whether in South Africa or elsewhere; (b) obtaining or transferring any intellectual property rights or other rights; (c) commencing product development, including the conducting of market research and seeking pre-market approval for the sale of resulting products; (d) the multiplication of indigenous biological resources through cultivation, propagation, cloning or other means to develop and produce products, such as drugs, industrial enzymes, food flavours, fragrances, cosmetics, emulsifiers, oleoresins, colours ex-tracts and essential oils; (e)trading in and exporting of indigenous biological resources to develop and produce products, such as drugs, industry enzymes, food flavours, fragrances, cosmetics, emulsifiers, oleoresins, colours, extracts and essential oils; and (f) commercial exploitation;" See further von C von Kries and G Winter, 'Defining Commercial and Non-commercial Research and Development under the Nagoya Protocol and in other Contexts' 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) 60-74.

17 Cf. NP (n 3) Art. 5.

18 Similar Art. 17 of the Brazilian Act 13.321 of 20.05.2015 which states: 'In the case of a finished product, the genetic heritage or the associated traditional knowledge component must be one of the key elements of value adding to the product, in accordance with this Act'.

19 Commission Guidance (2021) (n 2) para. 8.4.

20 Cf. NP (n 3) Art. 2 paras. 4 and 12.

In conclusion, one more problem emerges, namely the need but difficulty to determine and trace the specific contribution of accessed GR in cases of multi-causality of product development.

2.4 Derivatives: How to Link with Genetic Resources?

According to Art. 2 (e) NP derivate means 'a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity'.

It is clear that not any chemical compound but only one that originates from GR qualifies as derivative. However, there is uncertainty as to whether R&D on a derivative is utilisation and thus in scope of related obligations. Art. 2 (d) and (c) NP can be read to mean that R&D must be part of utilisation of GR. In that line Regulation (EU) 511/2014 does not address R&D on derivatives as an independent activity. The Commission Guidance (2021) specifies this postulating a 'continuity' of R&D on the derivative with R&D on the genetic resource.[21] Such 'combined access' excludes from scope the acquisition of a derivative for research on the same derivative without reach to the genetic origin. However, Art. 2 NP could as well be understood to just require a link between R&D on the biochemical compound and existing knowledge about its genetic origin. Imagine a chemical compound deriving from a GR is found to have high pharmaceutical value: should that be out of scope if the user has not combined her chemical research with research on the genetic resource? This would appear to me to discriminate against provider state interests and disregard that such derivative utilisation has been exemplary cases of biopiracy in the run-up of international and national ABS law-making.

2.5 Digital Sequence Information: Volatile or Enclosed?

It has become common practice to sequence the genome of an organism and upload the resulting data to databases. Most of these are publicly accessible so that anyone can download the information, do their own research, synthesise genes and develop their own products. Such information is called digital sequence information (DSI). Rohden et al, drawing on proposal of a CBD Ad Hoc Technical Expert Group (AHTEG) suggest to subdivide DSI to contain nucleic sequence data (NSD) and subsidiary information (SI). NSD refers to the nucleic acid sequence reads and the associated data plus information on the sequence assembly, its annotation and genetic mapping, while SI is information on, inter alia, gene expression, ecological and abiotic relationships, functions, morphology and phenotype, taxonomy and modalities of use.[22]

Some provider states have included information on genetic resources in their definition of genetic (or biological) resources.[23] This is, for instance, the case in South Africa where 'genetic resources' is defined to include '(a) any genetic material; (b) the genetic potential, characteristics of information of any species'.[24] Concerning the ABS-regime for bioprospection this requires that a permit must be obtained for R&D not only on genetic material but also on information about it.

Such claims could be understood to stipulate a new kind of intellectual property right, one, so to speak, in 'wild' information as opposed to 'invented' information as required by patent law. However, such exclusive right would hardly be supported neither by Art. 15 CBD nor Art. 5 NP which after all speak of material, not information as object of sovereign

21 Commission Guidance (2021) (n 2) para. 2.3.4.

22 F 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>.

23 For an overview see M Bagley and others, 'Fact-finding Study on how Domestic Measures Address Benefit-Sharing Arising from Commercial and Non-commercial Use of Digital Sequence Information on Genetic Resources and Address the Use of Digital Sequence Information on Genetic Resources and Address the Use of Digital Sequence Information on Genetic Resources for Research and Development' (2020) 31 et seq <www.cbd.int/doc/c/428d/017b/1b0c60b47af50c81a1a34d52/dsi-ahteg-2020-01-05-en.pdf>.

24 Art. 1 ((1) Act No. 10 of 2004: National Environmental Management: Biodiversity Act, 2004, as amended by Act No. 14 of 2013: National Environment Management Laws Act, 2013.

rights.[25] While based on their sovereignty provider states may well introduce new IPRs, but for a transborder reach involving acceptance and enforcement by other states an international treaty would have to be established like the Paris Convention for the Protection of Industrial Property.[26]

This, however, does not exclude that a less sophisticated version of property is conceived. It should first of all be clear about the notion of information. Information is opposed to material. It is the result of cognition and explanation of material. Material although 'being out there' is of no relevance if not perceived through information. Therefore, property in material is unavoidably property in a described and explained object, or in short, it is property in 'informed' material. Property rights therefore intricately extend to information insofar information describes propertied material.

If no exclusive right can be established relative rights can. They can be specified by provider state legislation and PIC/MAT. Such framing may shape rights and obligations concerning reporting, publication, applications, commercialisation, etc.[27] The undisputed right of regulating access to GR as material can thus serve as leverage for determining how the GR including related information shall be used. Users are bound by related administrative acts containing PIC and contracts containing MAT. User states are obliged to ensure compliance with PIC and MAT conditions at least concerning research and development.[28]

The crucial question of course is to what extent such conditions are made known and respected if DSI is stored in open access databases and accessed by users of the same. In order to answer that question a look at the database landscape is needed.[29] The core public structure for research on NSD is the International Nucleotide Sequence Database Collaboration (INSDC). It coordinates the three largest databases: Genbank, operated by the US National Center for Biotechnology Information (NCB), European Nucleotide Archive (ENA), operated by EMBL-European Bioinformatics Institute (EBI) under the auspices of European Molecular Biology Laboratory (EMBL), and DNA Data Bank of Japan (DDBJ) which is operated by the National Genetics Research Institute in Japan. Most of the costs of the databases – which are substantial - are born by the US federal government, 20 European states and the Japanese state, respectively. INSDC with its focus on nucleic data is surrounded by approximately 1600 biological databases that store scientific information on biological resources beyond NSD and SI, but interact with INSDC. Billions of sequences are stored at the INSDC bases, with trillions

25 See further on the ongoing doctrinal debate C Lawson, F Humphries and M Rourke, 'The Future of Information under the CBD, Nagoya Protocol, Plant Treaty, and PIP Framework' (2019) 22 J World Intellect Prop 103–119 <https://doi.org/10.1111/jwip.12118>; T Spranger, 'Expert Opinion on the Applicability of the Convention on Biological Diversity and the Nagoya Protocol to Digital Sequence Information' Submitted on behalf of the German Federal Ministry of Education and Research (BMFT 2019) <https://www.bmbf.de/files/Legal_opinion_DSI_-Prof_Spranger_EN_BF.PDF>; Chr Lyal, 'Digital Sequence Information on Genetic Resources and the Convention on Biological Diversity' 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). For a doctrinal discussion on the usefulness of the distinction between exclusive and relative intellectual property rights see Chr Godt, '"Data Property": Entitlements Between "Ownership", Factual Control and Access to Commons' in B Akkermans and A Berlee (eds), "Sjef-sache". Essays in Honour of Prof. Mr. Dr. J.H.M. (Sjef) van Erp on the Occasion of His Retirement (Eleven International Publishing forthcoming).

26 Accessible via <https://wipolex.wipo.int/en/treaties/textdetails/12633>.

27 See for an overview of practices Bagley and others (n 23) p. 31 et seq. As an alternative construction the African Group of Negotiators on Biodiversity to the CBD Ad Hoc Group on Digital Sequence Information has suggested that sequencing activities should be regarded as utilisation of GR, which – I believe - implies that DSI would be a result of R&D and as such contribute to the further generation of benefits. Available at <www.cbd.int/abs/DSI-views/2019/AfricanGroup-DSI.pdf>. For further elaboration of this classification see K Sollberger, 'Digital Sequence Information and the Nagoya Protocol. Legal Expert Brief on Behalf of the Swiss Federal Office for the Environment (FOEN)' 7 April 2018 <https://www.bafu.admin.ch/bafu/de/home/themen/biotechnologie/biotechnologie—rechtliche-grundlagen/rechtsgutachten.html>.

28 Concerning subsequent applications and commercialisation this is not (or not clearly) the case See above chapter.

29 See Rohden and others (n 22) 17 et seq.

of DNA bases. The sequences can comprise bases ranging from a few to millions each. Millions of sequences are submitted per year. Researchers submitting data to INSDC are responsible to pursue intellectual property rights (IPRs) they may own on a piece of information, and are liable for any damage that may arise from uses of their data that violate third parties' IPRs. All data are freely accessible without registration. 10-15 million users per year are estimated to visit the INSDC webpages.[30] Users accessing data may make any use of them, including for publication (although credit to author and database are to be given), research, development, and commercialisation. It is their responsibility to pay tribute to any IPRs rights that may exist. The institutions maintaining the databases disclaim any liability for violation of the same.

As for ABS relevant information INSDC practices do not provide means for tracing data uses back to provider state PIC and MAT. PIC and MAT in most countries are issued in paper form or pdf files which can technically not be linked to INSDC entries. The only indication of origin INSDC offers is that data submitted shall inform about the country of origin of the pertinent organism. But that is only implemented in a small percentage of cases and does not anyway allow the tracing back to possible PIC and MAT conditions on utilisation and commercialisation.[31] The powerful trend towards digitalisation of genetic information and its culture of open access is therefore a major problem for the principle of sovereign rights of provider states.

2.6 The Benefit Sharing Monitoring Gap: Unjustifiable but Realistic?

While utilisation of GR has attracted much legal attention the sharing of benefits is still regulatory terra incognita. Regulatory progress in the EU, for instance, has been concerned with what kinds of utilisation are within or beyond scope but not as much with ensuring benefit sharing (BS). Still, Art. 5 (3) NP, somewhat concretising Art. 8 (7) CBD, mandates Contracting Parties, including user states, to take measures, 'as appropriate' to ensure that benefits are shared. This obligation of course allows states to establish straightforward governmental monitoring and enforcement of BS. But the NP itself is less demanding. The user state shall 'designate check points' that 'should be relevant' 'to the collection of relevant information at, inter alia, any stage of [...] pre-commercialisation and commercialisation' (Art. 17 (1) (a) (iv) NP), it 'shall, as far as possible and as appropriate, cooperate in cases of alleged violation of domestic [...] benefit-sharing legislation' (Art. 15 (3) NP).

The concept chosen instead is a contractual model. It bases the implementation of benefit sharing on mutually agreed terms (MAT) between provider states and individual users. If disputes arise from MAT such as if a user refuses to share benefits the provider state can only enforce contractual obligations seeking recourse at user state courts, or at its own courts risking non-recognition of decisions in user states.[32]

The EU in its user state function could have gone beyond what the NP sets as a minimum standard but did not do so, or only did so with some slight hint. It reserves its most powerful instrument of monitoring, namely due diligence declarations, to the stages of receival of research funding and of final development of a product (Art. 7 (1 and (2) Regulation (EU) 511/2014. It is only with some doctrinal creativity that one can conclude from Art. 9 (1) and (2) Regulation (EU) 511/2014 that administrative bodies have powers or even duties to supervise subsequent commercialisation and benefit sharing.[33]

Provider states thus depend on their own capacities and powers to monitor pre-commercialisation, commercialisation and the sharing of benefits. But states often lack the skilled human and financial resources needed, and they do not have legal powers of investigation and prosecution in user states.

In conclusion, concerning benefit sharing an imbalance to the disadvantage of provider states was built into the NP without this being predetermined by Art. 15 CBD. User states so far refuse to go further.

30 ibid 25.

31 ibid 38-39.

32 Cf NP (n 3) Art. 18 (2).

33 See for a more detailed argumentation G Winter, 'The ABS Compliance Regime of the European Union' in E C Kamau (forthcoming) (n 25).

2.7 Transboundary Genetic Resources: Take All Benefits or Share?

Genetic resources often spread over national borders. This raises questions of justice between provider states which may be termed the horizontal relation of justice in distinction from the 'vertical' between providers and users.[34] Why should one provider state be entitled to take all of the non-monetary and monetary benefits although other states have also contributed to the preservation of the GR? Would it not lower the benefits of all provider states taken together if they compete for ABS accesses and are tempted to offer conditions that are most favourable for users but least favourable for providers?

Creating pools of GR would a way to cope with the issue. They could be set up on the basis of Art. 11 NP which encourages cooperation of parties where the same genetic resources are found in situ. An early attempt was that of the Andean Community which however has achieved not much more than serving as a tool to harmonize national legal regimes concerning ABS.[35] Pools for East Africa have been considered but not yet instituted.[36] The problem that one provider state takes it all has therefore prevailed.

2.8 Transboundary R&D Conditions: Take All Benefits or Share? Public Funding for Private Gain?

Problems of 'horizontal' equity also appear on the user side. Two of them shall be mentioned: one-sided sharing of benefits, and one-sided bearing of utilisation costs.

One-sided sharing of benefits occurs because in the normal case single users alone reap the benefits of utilisation of accessed GR although drawing on knowledge produced by many other researchers and developers. The frame of reference of this problem is the tension between intellectual property rights and the public knowledge domain. There is an overall trend towards the latter which should be kept in mind when new options are elaborated.

One-sided bearing of costs occurs because most of the costs of access are born by public research institutions while the biotech industry benefits at low cost from research results funded from public monies and published for public access. It is also to their advantage that the basic duties and administrative oversight does not extend to the marketing of products and the sharing of benefits. Therefore, hardly any considerable revenue from sales of products or licensing of patents has flown from industry to provider states. In short, research is sent to the front while industry holds itself in the background. It could be argued that the division of labour between public research and industry corresponds to normal practices of modern states where research is deemed to be publicly funded infrastructure that can freely be used for subsequent commercial activities. But the ABS idea may throw a different light on the issue. ABS rests on the general conviction that biodiversity must be conserved for the benefit of mankind, including industry, and that the willingness of host states to protect can be incentivised by benefit sharing, or more simply, through money flowing from industrialised uses to developing providers. Such flow is weak if the commercial stages come later and are anyway hard to supervise. Therefore, industry should acknowledge its interest in and accept its responsibility for preserving biodiversity, maybe by financial engagement already at earlier stages of R&D.

2.9 Transaction Burdens and Costs: Necessary or Inefficient?

While the problems described so far are substantial in kind, raising questions of equity between differing partners, problems of how transactions are organised must also be kept in mind. I have already discussed some issues insofar as they have substantial impact (such as, for instance, monitoring commercialisation). Additional issues would include legal certainty,

34 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) 3-25, at 3-4. See further Part 2 of the article.

35 M Ribadeneira Sarmiento, 'Research on Genetic Resources in Latin America and the Caribbean (LAC). Perspectives for Facilitated Access' in Kamau, Winter and Stoll (n 16) 131-150.

36 E C Kamau, 'Exploring Bases for Building Common Pools in Eastern Africa' in Kamau and Winter (n 34) 373-398.

transparency, effectiveness, and proportionality which all are stipulated by Arts. 6, 12 – 18 NP.

Legal certainty and transparency of transactions are of outstanding concern for all involved partners, and especially for researchers who have hitherto had free access to GR apart from certain manageable requirements of provider states concerning research oversight, environmental protection and international trade. ABS has exposed them to often complicated and lengthy procedures. Any new concept will have to come up with more practicable solutions.

Effectiveness and proportionality raise questions of costs efficiency of designs. The new ABS requirements have imposed a heavy administrative burden on R&D activities. On the provider side a state operating an ABS regime and striving for proper enforcement must not only supervise accesses in its domestic sphere but follow the utilisation of its accessed genetic resources both internally and abroad, from first research activities throughout to the final marketing of products and the obtaining of intellectual property rights. Financial returns of any significant size have hardly ever been reported.[37] Although monetary compensations have been envisaged since the entering into force of the CBD in 1993, they have rather consisted of upfront payments or voluntary donations.[38] In any case, the transaction costs will often have been higher than the returns. Benefits deriving from cooperation in research and development if they emerged seem to have been more rewarding than monetary benefits. By the way, R&D cooperation also involves monetary gains for the partner on the provider state side.

On the user side costs arise when R&D organisations acquaint themselves with the ABS system, create IT tools checking genetic resources for ABS relevance, apply for and negotiate PIC, MAT and Material Transfer Agreements (MTAs), where required (such as in the EU) prepare due diligence declarations and store relevant information for years, and possibly employ provider state personnel for joint research projects.

In addition, administrative costs arise for the elaboration and dissemination of ABS information tools, negotiation of rules harmonising EU wide harmonisation activities, and checks of utilisation and benefit sharing.[39]

As most of the R&D results generate non-monetary benefits it is impossible to weigh them up with the transaction costs. In any case the more differentiated the ABS regimes are organised in order to ensure the sharing of monetary benefits the more financial costs will arise. Most illustrative is the blockchain model for tracing benefits to accessed GR: it may at the end eat up all – or even more of – the revenue they generate. The problem is thus how to find a system that is fair at minimal transaction costs.

2.10 Parenthesis on Traditional Knowledge Associated with Genetic Resources

In the preceding parts I almost completely disregarded traditional knowledge associated with genetic resources (aTK). This is not due to any assumed unimportance of it. On the contrary by Art. 8 (j) CBD and Arts. 7, 12 and 16 NP aTK has been laid out as a good that must be preserved, supported and compensated if accessed and utilized. Many national ABS systems have also dedicated differentiated provisions on access to the utilisation of aTK. Discussions about reforming the ABS regime have hardly ever lacked mention of aTK.

37 N Pauchard, 'Access and Benefit-Sharing under the Convention on Biological Diversity: What Can Some Numbers Tell Us about the Effectiveness of the Regulatory Regime?' (2017) 6 Resources 11 <www.mdpi.com/2079-9276/6/1/11/htm>.

38 See for upfront payments J Cabrera Medaglia, 'The Role of the National Biodiversity Institute in the Use of Biodiversity for Sustainable Development - Forming Bioprospecting Partnerships' in E C Kamau and G Winter (eds), Genetic Resources, Traditional Knowledge and the Law (Earthscan 2009) pp 243-268; for cases of voluntary payments which were made nolens volens upon moral or political pressure see 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) 402-410.

39 On experiences made with ABS practices see the survey by Milieu Analysis of implications of compliance with the EU ABS Regulation for research organisations and private sector companies, May 2020, 19 <https://ec.europa.eu/environment/nature/biodiversity/international/abs/pdf/ABS%20Regulation_Report%20on%20Compliance%20Implications%20for%20public%20and%20private%20sectors.pdf>.

Nevertheless, however, such mention is characterised by a certain sanctimoniousness accompanied by wide ignorance of what is really going on. The regulatory scrutiny somewhat stands in contrast to that lack of empirical knowledge and practical ingenuity.

Any reformatory reflection would need to first broaden the knowledge base. Indepth studies are needed on kinds of aTK, its dissemination across local communities within and across states, its hosting by individuals and communities, practices of access, kinds of utilisation, and commercialisation.[40] It could be that there are only disappointingly rare cases of access and utilisation of the kind the CBD, NP and general perceptions expect. This may especially be true in cases of deep cultural gap between genuine traditional healing and modern medicine.[41] It may further be that much of claimed traditional knowledge is already known from anthropological research of the past. On the other hand, it may be revealed that traditional knowledge is more dynamic than assumed developing at its own pace of practical experience.[42] This could be an attractive object of access and utilisation.

In conclusion the knowledge about ABS concerning aTK is not a sufficient basis for already designing options for reform. I will therefore desist from further venturing into that matter.

3 CONCLUSION

Summing up the following yet unsolved problems have been identified:

- 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
- 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
- what criteria are appropriate to draw a line between relevant and irrelevant contributions of GR in multicausal development of products
- how R&D on derivatives can be linked to R&D on genetic resources from which the derivates originate
- whether public databases that store digital sequence information can and should be reformed to carry conditions for utilisation and benefit sharing stipulated by provider states
- whether and how the contractual obligation to share benefits should be improved by administrative oversight on the user side
- how in situations of transboundary GR the right of one provider to take all benefits can be integrated in a pool setting
- whether on the user side the costs and benefits of ABS are well distributed between public and private sector utilisation and commercialisation
- how much the transactions in the ABS system cost, and whether the costs are justifiable.

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 second part of this article.[43]

40 See examples of that kind of study J K Githae, 'Potential of TK for Conventional Therapy – Prospects and Limits' in Kamau and Winter (n 38) 77-100; J Kleba, 'A Socio-legal Inquiry into the Protection of Disseminated Traditional Knowledge – Learning from Brazilian Cases' in Kamau and Winter (n 38) 119-142; E C Kamau, 'Protecting TK Amid Disseminated Knowledge – A New Task for ABS Regimes? A Kenyan Legal View' in Kamau and Winter (n 38) 143-172.

41 See further Githae ibid.

42 Kamau (n 40).

43 The second part will be published in Volume 17/2 and is available as advance publication at http://www.lead-journal.org/content/a1706.pdf'.

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