

TEMPLATE FOR COMMENTS

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Title of document reviewed:	The Emergence and Growth of Digital Sequence Information in Research and Development: Implications for the Conservation and Sustainable Use of Biodiversity, and Fair and Equitable Benefit-Sharing – A Fact-Finding and Scoping Study Undertaken for the Secretariat of the Convention on Biological Diversity	
Comments on the draft fact-finding and scoping study		
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		<i>General:</i> The Peruvian Society for Environmental Law (SPDA) thanks the authors of this report for their dedication and hard work in producing this study in a very short period of time. It is understandable that within the timeline granted for the study, relevant and available literature and sources which, in some cases, pre-date the CBD, have not been necessarily reviewed nor cited.

		<p><u>General:</u> As the main general comment, SPDA believes the report would benefit greatly from more economic thinking, which is key and has been historically absent in ABS debates in general. It is quite striking that economists – except for a handful- have been routinely absent in ABS discussions and policy/legal developments. This seems a major shortcoming which SPDA would like to stress and highlight. When economics is applied to the informational dimension of genetic resources (DSI or “natural information” as the all-embracing and inclusive concept SPDA advocates for), there is are well tested set of principles and a theoretical framework which solves many of the outstanding issues and problems identified in the study.</p> <p>For the purpose of biotechnology development and all derived disciplines in the “omics” world, it is information “extracted” from genetic resources where the value in products and services development resides. Nobel prizes in economics have been awarded in the field of the economics of information theory. On the other hand, for over two decades, scholars including May, Swanson, Stone, Vogel, and others, have reflected (in more or less detail) on how these widely accepted economic principles may apply to ABS in particular.</p> <p>However, their influence has been frustratingly limited due to many reasons, explained in detail in Chapter 4, Resistance to correction, Ruiz, M. Genetic Resources as Natural Information: Implications for the CBD and the Nagoya Protocol. Earthscan from Routledge, 2016. Results of their solid contributions openly challenge the efficiency and effectiveness of current bilateral ABS schemes and frameworks. An almost “natural” departure from these frameworks and bilateralism results from applying economics to DSI. Therefore, an economics perspective in the study is critically required to ensure sound recommendations and workable policy/legal options. A few examples of this follow, below:</p>
15	4-6	<p><i>“Monetary benefits growing from the use of digital sequence information are largely speculative to date, and are potentially complex due to challenges in identifying provenance and the value of any given sequence or part.”</i></p> <p>In the context of the economics of information theory, this sentence is only accurate if seen through the limited lenses of bilateral contracts or bilateral negotiations of MAT. The flaws in bilateralism and limited economic reasoning in ABS over the years, have been highlighted repeatedly for more than two decades by the authors mentioned above, and others. In essence, under bilateralism (ABS contracts and MAT) on which the CBD is founded (a crass error in the CBD’s origin), monetary benefits from the use of digital sequence information cannot be realized because of well reported “jurisdiction shopping” by users. This phenomenon will eliminate any possibility for extracting an economic rent. A particular dimension goes unnoticed throughout the report: when more than one country provides the physical sample from which digital sequence information was obtained (widely disseminated and diffused genetic resources are a common occurrence), a price war and race to the bottom will inevitably ensue. Current levels of royalties, when made available and accessible due to confidentiality concerns in ABS contracts, are “peanuts [paid for] for biodiversity” (Drahos 2004). This is an expected and perfectly predictable result under bilateral ABS contracts and MAT.</p> <p>See, Drahos, Peter. 2004. “Intellectual Property Engineering: The Role of the Chemical, Pharmaceutical and Biotechnology Industries”. Chapter 12 in Burton Ong, ed, <i>Intellectual Property and Biological Resources</i>, Marshall Cavendish Academic.</p>

9	7-8	<p><i>“Distinctions between academic, governmental or industry research using genetic sequences have become increasingly blurred, as have those between different industrial sectors.”</i></p> <p>The issue of “distinctions” between types of research are only relevant under current bilateral, ABS contractual agreements. Under a multilateral regime, based on “bounded openness”. distinctions would be basically, irrelevant – research would be encouraged and facilitated and a simple condition of disclosure imposed on use of DSI (or natural information) and benefits shared (distributed among countries which possess the species of origin of the DSI) when and if money is generated from access and the utilization of DSI.</p>
15	11	<p><i>“Given the blurring boundaries between commercial and non-commercial user, all might gain access on the same terms.”</i></p> <p>Acknowledgement of the blurred boundaries between commercial and non-commercial research in genetic resources has been voiced for at least a couple of decades. It is not a “new” problem. Furthermore, the real problem is not that access is granted on the same terms but that it is granted, given considerable hurdles faced by researches throughout the world! Under “bounded openness” there is no need to differentiate between commercial or non-commercial research. No need for <i>ad hoc</i> non-commercial research contracts. Access should be facilitated for all types of research: and conditions only imposed if commercially successful products/services are generated through the use and value added to DSI.</p>
16	22	<p><i>“Monitoring is critical for effective benefit sharing, yet genetic sequences are far more difficult to monitor than physical genetic resources.”</i></p> <p>Monitoring whether physical samples or information may be complicated, <i>under bilateralism</i> and an “ABS contract based regime”. However, under the possibility opened by the Nagoya Protocol and its articles 10 and 11, monitoring would only be relevant and required when IP is invoked or asserted over the value added to the digital or “natural information”. Even in these cases, only a small fraction of innovations based on digital information will have a commercial or industrial success and so monitoring becomes a much more focused and targeted endeavor: in those cases where a product/service may be commercially viable. A simple disclosure rule at the moment of applying for IP would not only be more effective and efficient (in terms of monitoring) but eliminate transaction costs imposed by bilateralism and current ABS rules. This idea has been extensively described by Vogel, <i>et al.</i>, using the notion of “bounded openness” under which, quite simply, digital/natural information could flow freely (facilitated access) for the purpose of biotechnological developments and only <i>ex post</i> would interest in verifying utilization of digital information be of relevance.</p>

58	1-2	<p><i>“Identification is the first step in monitoring and establishing an effective benefit sharing system (Garrity et al, 2009).”</i></p> <p>Identification is a “first step” only in the case where a bilateral, contractual system is in place. Under the conceptual framework and possible global multilateral regime based on “bounded openness”, identification is not a required first step, as it will only become relevant and necessary when and if a product/service which has a commercial success is developed. This narrows down the need to identify a resource/information substantially as only a limited set of products/services will reach the market and generate monetary benefits. There is no need to worry about provenance and origin, nor overregulate to ensure providers interests.</p>
17	15	<p><i>“It behooves ABS policy makers to stay abreast of the profound developments shaping research today.”</i></p> <p>The current interest in synthetic biology, DSI, and related “informational” technologies and disciplines may be new for many, but have been an area of concern and interest for a group of stakeholders almost since the approval of the CBD. These developments have been sharpening research for at least the last 30 years or so. Therefore, the phenomenon is not new, nor is the concern new nor emerging. Literature on these topics is plentiful and accessible. What is required at present is an ABS system which can positively respond and rapidly adapt to technological advances in ways current ABS regimes cannot. Current ABS regimes have proven to be dysfunctional and, especially, unfair and inequitable particularly for providers. A system based on the robust and conceptually solid notion of “bounded openness”, can readily achieve fairness and equity in benefit sharing, and satisfy the interests of both users and providers.</p> <p>See, Vogel, Joseph Henry, Klaus Angerer, Manuel Ruiz Muller and Omar Oduardo-Sierra. 2018. “Bounded Openness as the Global Multilateral Benefit-Sharing Mechanism for the Nagoya Protocol” Joseph Henry Vogel, Klaus Angerer, Manuel Ruiz Muller and Omar Oduardo-Sierra. Pages in Charles R. McManis and Burton Ong (eds) <i>Routledge Handbook on Biodiversity and the Law</i>. London: Routledge, 377-394.</p>

18	12-15	<p><i>“In addition, the Conference of the Parties requested the Executive Secretary of the CBD to commission a fact-finding and scoping study, the subject of this report, to clarify terminology and concepts and to assess the extent and the terms and conditions of the use of digital sequence information on genetic resources in the context of the CBD and the Nagoya Protocol (paragraph 3(b)).”</i></p> <p>The Notification SCBD/SPS/DC/VN/KG/jh/86500 reads “Digital Sequence Information on Genetic Resources” and <i>not</i> “Digital Sequence Information” on its own. This has important implications and is not a minor issue. SPDA prepared a detailed analysis of the notion of “Digital Sequence Information on Genetic Resources” which highlights the scaffolding of errors which this notion entails.</p> <p>See, “Unpacking ‘Digital Sequence Information on Genetic Resources’: Scaffolding of Errors to Preserve a Category Mistake” Simultaneous submission of English original and Spanish translation in response to Decision XIII/16 “Digital Sequence Information on Genetic Resources” according to its Paragraph 1 Peruvian Society of Environmental Law / Sociedad Peruana de Derecho Ambiental July 30, 2017. Available at https://www.cbd.int/abs/DSI-views/SPDA-DSI-EN.pdf</p>
53	21-24	<p><i>“As a result of the uncertainties associated with monetary benefits from bi-lateral agreements, many have suggested the establishment of a global fund to address benefit sharing from public databases (e.g. Bagley, 2015 and 2017). Experience from funds established under the ITPGRFA and the WHO PIP Framework may provide relevant lessons in this regard.”</i></p> <p>In terms of attribution of this specific idea of an international fund, many others, many years back, advocated for the development of an international funding mechanism to address benefit sharing in general. Cyrille de Klemm and Francoise Burhenne Guilmin in the late 1980’s and early 1990’s come to mind. Vogel, Ruiz, and others have also suggested this since the 1990’s. Furthermore, the International Fund created in the context of the FAO International Undertaking can also be cited as a key milestone in terms of an international mechanism to distribute benefits, in this case for conservation of PGRFA in particular.</p>
59	1	<p><i>“Identification of the provenance of digital sequence information.”</i></p> <p>Under a bilateral, contractual approach, identification of the provenance of DSI is, indeed, almost impossible to determine due to widespread diffusion of species/information. However, under a multilateral regime based on “bounded openness” provenance is determined mostly <i>ex post</i>, if and only if DSI results in a commercially successful product/service, using the currently available and potent arsenal of tools, technologies and disciplines (e.g. GIS, GPS, bioinformatics, distribution models, barcoding experiences, etc.). iBOL and the WCMC are two institutions which have advanced -to some extent- in generating knowledge related to distribution of species. There is no need for an <i>ex ante</i> determination of provenance of the DSI – unless available.</p>
		<p><u>General:</u> For non-monetary benefits, current permitting systems in place in most countries would suffice to ensure the providers actually participate in their realization. The concept of “bounded openness” is applicable to monetary benefits which, given a point in time along the R&D process, may be significant and of interest.</p>

Please submit your comments to secretariat@cbd.int or by fax at +1 514 288 6588.