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Finding Traditional Knowledge's Place in the Digital Sequence Information Debate

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In biodiversity, agriculture, and health, policy-makers are struggling with a difficult knot of considerations as they seek a solution to the access and benefit-sharing (ABS) issues posed by digital sequence information (DSI).

This discussion paper is intended to prompt thinking about one of the most important of those issues, how traditional knowledge (TK) and the rights of indigenous people and local communities (IPLCs) should be addressed in relation to DSI. In raising this discussion, which has not been given due attention by policy-makers to date, this paper primarily focuses on the Convention on Biological Diversity (CBD).

For over 25 years, CBD Parties have worked to develop ABS laws and regulations to facilitate the sharing and use of biodiversity for the Convention's purposes. These systems typically rely on the material transfer agreements associated with shipments of physical samples. These documents, which are usually legally binding, show compliance by users of genetic resources with their obligations to obtain prior informed consent of resource providers (including of IPLCs) and to negotiate mutually agreed terms for benefit sharing.

Particularly since the Nagoya Protocol entered into force in 2014, the legal systems for transfer of physical samples of genetic resources between countries have become better established. Yet, at the very same time, the technological realities of how genetic resources are used have been shifting. To an increasing extent, use of DNA sequences and other DSI – in lieu of and in addition to use of physical samples – generates benefits from use of biodiversity. That certainly includes valuable commercial products. But material transfer agreements don't typically cover transfer and use of DSI like sequence information. As such, the rise of DSI as a means of transferring and commercially exploiting biodiversity poses an existential threat to the CBD through its potential to undermine the Convention's third objective (fair and equitable benefit sharing).

Prelude: Unquestionable value

Only a few years ago, some questioned the assertion that DSI could undermine ABS laws. Some governments suggested that there was no proof that DSI was being used without benefit sharing, or did not accept that

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DSI could be used to evade benefit-sharing requirements. Some other governments, fortunately fewer, still assert – as if to deliberately threaten the viability of the CBD – that there should be no benefit sharing for DSI at all.

In 2020, the falsehoods of those positions have been laid bare. The American company Regeneron has received orders worth over US$400 million for its Ebola treatment, REGN-EB3, which it made using West African DSI it found in GenBank, a so-called 'open access' database that imposes no requirements on its users. If, rather than pulling a sequence from an 'open access' database and synthesizing it, the company had instead used a sample of the Ebola virus strain in physical form, it would have been obligated to sign a material transfer agreement requiring benefit sharing with Africa. For example, free or discounted doses of Regeneron's products for use in African countries. But because Regeneron downloaded from GenBank, the company avoided such obligations[1]. This case is a perfectly clear example of DSI undermining the third objective of the Convention.

If there was any question remaining, COVID-19 has laid the matter to rest. In late January 2020, Kate Broderick, a research director at Inovio, a US vaccine company, explained to the BBC that to design a COVID vaccine all Inovio needed was a SARS-CoV-2 virus sequence. Said Broderick, '*We downloaded* [the SARS-CoV-2 sequence] *and started working on it immediately. And essentially overnight, we designed the vaccine*.' Within days, the company synthesized that candidate vaccine and began clinical testing in mammals[2].

Broderick was, however, apparently being modest. According to another Inovio research director named Trevor Smith, it didn't take the company an entire night, it actually only took three hours. Said Smith to the US press a few days later, '*We have an algorithm which we designed, and we put the DNA sequence into our algorithm and came up with the vaccine in that short amount of time*.'[3]

Not to be outdone, on the same day that Broderick's BBC interview aired, US diagnostics maker IDbyDNA touted its DSI database diagnostic platform, claiming that it could now diagnose COVID-19 (as the disease caused by SARS-CoV-2 is called) by direct 'next generation' sequencing, a service the company offers to hospitals. The company's tests rely on a proprietary database of DSI of 50,000 microorganisms, including more than 3,000 pathogens.[4] On the same day, the company announced that it had received US$20 million in new venture capital investments.[5]

So, within days of being posted on the Internet, SARS-CoV-2 DSI had been converted into a physical product (candidate vaccine) and incorporated into the proprietary DSI database of a company selling sequencing and diagnostic services. And Inovio and IDbyDNA are only two examples of the dozens, and perhaps hundreds, of companies doing so.

So much for arguing that use of DSI doesn't translate into physical products and enable avoidance of material transfer agreements. The matter has been laid to rest. Those countries that still advance such arguments, for example Japan, should be understood as launching attacks on the CBD itself.

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1 Hammond E 2019. 'Ebola: Company avoids benefit-sharing obligation by using sequences'. Third World Network Briefing Paper #99. May. https://twn.my/title2/briefing_papers/No99.pdf

2 BBC News 2020. 'Coronavirus: The US laboratory developing a vaccine'. 30 January. URL: https://www.bbc.com/news/av/health-51305193/

3 CBS Channel 8 (San Diego, CA) 2020. 'San Diego lab discovers COVID-19 vaccine in 3 hours'. 11 February. URL: https://www.cbs8. com/article/news/health/coronavirus/coronavirus-vaccine-san-diego/509-e18e37f6-347c-4b08-ad33-910968abb04f

4 Genetic Engineering and Biotechnology News 2020. 'IDbyDNA to Advance Platform, Now Including Novel Coronavirus, Expand Commercial Operations'. 29 January. URL: https://www.genengnews.com/news/idbydna-to-advance-platform-now-including-novel-coronavirus-expand-commercial-operations/

5 Genomeweb 2020. 'IDbyDNA Raises $20M in Series B Financing'. 29 January. URL: https://www.genomeweb.com/sequencing/idbydna-raises-20m-series-b-financing

More than money

Obviously, the economic stakes of DSI are huge. From pills to plant varieties, and a million other things, biodiversity plays a central role in the global economy, and DSI is increasingly central to biodiversity-related commercial research and product development.

But reduction of the issue to purely economic terms underplays its significance. It is also about upholding commitments to those that create and conserve diversity, and about adapting agreements that set out collective human, environmental and social goals to a changing technological reality.

Those goals include governments honouring their obligation to create a fairer global system to share benefits derived from biodiversity research, and to recognise and protect the rights of IPLCs. This is not only a lofty and important moral issue – made more poignant by the particular threat that COVID poses for many indigenous peoples – it is also a practical matter: IPLCs are generally outstanding biodiversity stewards, and empowering them is unmistakably the right thing to do, in light of both historical injustices and the increasingly apparent value of solutions that spring from human cultural diversity in confronting problems like climate change. That is, the important insights and beneficial, different ways of doing things based on the knowledge gained from long-term biodiversity-cultural relationships of IPLCs.

To date, however, in the Biodiversity Convention, where IPLCs' importance is prominently and formally recognised in treaty text, IPLCs have been on the sidelines of DSI discussions. They were not represented on the first Ad Hoc Technical Expert Group (AHTEG) on the matter and have not vigorously participated in the Convention's DSI-related processes, or for that matter, consultations held in parallel.

It should be noted, however, that at the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), farmers' organisations have been more prominently represented on DSI. Allied with NGOs and many developing country governments, farmers played an important role in stopping a draft agreement to modify the Treaty. Notably, the draft failed mainly because it did not include a solution for DSI and benefit sharing for crops.

The result at the ITPGRFA shows that the stakes involved in the DSI debate are understood by many IPLCs, even though they have so far been marginalised in the CBD DSI discussion. And it shows that when IPLCs are afforded their rightful place at the table in the DSI debate, they can be active and influential participants.

Oversimplified arguments – Traditional knowledge and DSI so far

Over the past year, usually reasonable people who have worked in ABS for many years have been overheard to remark that traditional knowledge and DSI may not be linked at all. Such a perception, it should be noted, requires a fairly narrow conceptualization of the definition of what DSI includes. (And defining DSI is a matter of immediate focus in the international discussion.)

The reasoning of such positions appears to be that DSI will ultimately be defined as DNA and RNA sequences, amino acid sequences, and may also include epigenetic information and protein structures. Since DSI will possibly have this relatively narrow definition, the stuff of DSI will be strings of letters and diagrams that generally come from biotechnological observations and interventions. Hence, the reasoning seems to be, DSI will not include the kinds of knowledge that IPLCs develop and maintain in relation to genetic resources. That is, IPLC farmers will be more far more likely to be able to tell you about the growth habit of a plant rather than what nucleotide is found at position XXXXXX of the reference build of its genome.

Ipso, the oversimplified argument goes, a benefit-sharing system for DSI does not need to include TK-related provisions. Since TK doesn't fall within the definition of DSI, there's no need to worry about it. Or so the overoptimistic line of thought runs.

But just as DSI allows biopiracy through evasion of the (material transfer) agreements that implement national legal requirements for benefit sharing for use of physical materials, DSI also facilitates the piracy of related traditional knowledge and genetic resources linked to IPLCs. That is, just as national access laws are undermined by DSI, so is IPLCs' control of their own knowledge and resources. If national governments are victims of their laws being circumvented, IPLCs are potentially victims of their control over use of their biodiversity knowledge also being circumvented.

That policy thinkers are trying to simplify the issue of DSI is understandable. It is hard to weave provisions to deal with the 21st Century realities of DSI onto the 20th Century CBD. But, in 2020 and 2021, what would be wrong and should unequivocally be relegated to the past would be for the CBD to adopt an approach to DSI that deals new injustice to IPLCs.

And if policy-makers ignore the need to address the rights of IPLCs that are intertwined with the DSI issue, particularly the misappropriation of traditional knowledge, then they will be doing precisely that – repeating the sordid past of 'new' conservation policies that are inimical to IPLC interests.

Fortunately there are solutions and, depending on the approach CBD Parties take to DSI benefit sharing, these may not be particularly difficult to adopt and implement.

PIC and DSI

If an oversimplified understanding of the impacts of DSI is one reason why the relationships between traditional knowledge and DSI have so far been under-appreciated, there is another important reason – one that few policy-makers have yet to have the stomach to publicly discuss.

That is the prior informed consent (PIC)[6] rights of IPLCs when it comes to DSI. More particularly, fears among governments and DSI users of the possible consequences of solutions that imply that PIC is needed for use of DSI of biodiversity linked to IPLCs.

If one imagines a world, which is essentially upon us, in which terabytes of DSI containing information on hundreds of thousands of species are hosted online and readily searchable by anyone with an Internet connection, and single searches might return hundreds of hits from unique DSI sampling instances, if use of a proportion, maybe a big proportion, of those hits required PIC from IPLCs, then, it is feared, the resulting bureaucratic procedures could seize up practically the whole of biological research.

Paralysis of biological research is obviously not the end state that anyone is seeking, even if ill-informed scientists mired in the depths of stove-piped disciplines (e.g. some areas of taxonomy) may sometimes malignantly accuse civil society and its allies of such a ridiculous intent.

But fear of inconvenience to biotech researchers is no excuse for DSI policies that deny a broad class of people their rights.

To be clear, there are at least two distinct general cases that apply when thinking about DSI and PIC:

One is in the case of new access to a physical genetic resource, and the other is access to DSI in databases, including DSI generated now and in the future from samples already collected. That is, the problem of databases like Genbank (arguably unethically) continuing to accumulate sequences related to traditional knowledge without even the slightest consideration of the attendant rights issues.

Indeed, the more radical fundamentalists of the so-called 'open access' database lobby would deny they have any moral or legal obligation to care about the rights of IPLCs, though the same strident defenders of no-strings-attached free distribution of DSI are careful to use disclaimers to absolve themselves of legal liabilities in disputes that emerge over rights to sequences in their databases.

6 The term 'Prior Informed Consent' is used by the CBD, though IPLCs generally prefer 'Free Prior Informed Consent' (FPIC), the term used in the UN Declaration on the Rights of Indigenous Peoples.

In the first case, where genetic resources are newly accessed from IPLCs, community rights are clear and undeniable. For physical samples of biodiversity newly accessed now and henceforth, through PIC and MAT (mutually agreed terms) rights, an indigenous community has every right to spell out the permitted uses of DSI generated from those resources, and related traditional knowledge.

Put slightly differently, IPLCs can withhold PIC for any activity involving DSI of new collections, except those uses to which IPLCs explicitly agree. Communities can, for example, prohibit sequencing of materials provided. There are many other possibilities: IPLCs might retain control of any DSI generated and require new PIC for its use, IPLCs might limit with whom DSI can be shared, and/or prohibit uploading of DSI to databases that refuse to respect their rights.

IPLCs need national legally binding ABS rules that enable them to use material transfer agreements and other ABS instruments in which such stipulations are made, so that the instruments are made enforceable through national law (contract law and ABS law). IPLCs will also need to take into consideration the degree of trust they have with counterparts in such agreements to strictly uphold their commitments.

The second case is how to deal with the enormous and growing quantity of DSI related to IPLCs that is found in databases, especially public behemoths like Genbank, but also in smaller and private databases. This includes existing DSI, DSI generated from already collected resources, and DSI generated from the plants and other biodiversity of IPLCs when it has been collected without proper PIC and MAT applicable to DSI.

In other words, the second case revolves around what to do about the rights of IPLCs in relation to the DSI of genetic resources that are closely linked to them, where DSI facilitates exploitation of their knowledge without PIC and MAT, and what to do about actors that acquire and use that DSI and traditional knowledge through databases in lieu of directly dealing with the rightful owners.

A quick bit of searching of both well-known and more obscure plants related to IPLCs shows the seriousness of this problem (See Table 1). Searches of species DSI in GenBank, and scientific citations of those species in the US National Institutes of Health PubMed database show that the medicinal and agricultural plants of IPLCs are already being sequenced and uploaded into Genbank and linked to publications, many of which document, discuss, and/or attempt to build upon traditional knowledge.

Finding a solution

If obtaining new PIC and MAT for every access of every sequence linked to IPLC traditional knowledge is technically unworkable without creating a debilitating bureaucratic overhead, what then could be a fair and equitable approach that would permit continued access to IPLC-related DSI and ensure benefit sharing with IPLCs?

Many participants in discussions about how to ensure benefit sharing for use of DSI more broadly (i.e. not just for IPLC-related DSI) have begun to consider the possibility of a multilateral approach. This approach might allow the current system of 'open access' databases to continue in a central role for scientific research, albeit with revised terms and conditions that create obligations for benefit sharing in the case of commercial use.

For developed countries this general approach appears to hold out the possibility of a resolution to the DSI debates that is less disruptive of existing systems and not administratively overly complicated, while for developing countries it also offers a system that may not be overly administratively complex and which will create benefit-sharing obligations of sufficient legal strength to be generally dependable.

Of course many details are to be worked out and a multilaterally-oriented effort could fail. And, with COVID-related delays, it may be two or more years before it could be finalised even as pressure mounts.

Table 1: Some Examples of IPLC Medicinal and Food Plant Sequences in GenBank and associated scientific publications (frequently containing traditional knowledge)

Plant	Origin	Genbank Genes	GenBank Nucleotides	GenBank Proteins	Species cites in PUBMED
Ají *Capsicum baccatum*	South America	393	2,111	36,580	82
Oca *Oxalis tuberosa*	South America	–	46	40	39
Maca *Lepidium meyeni*	South America	132	52	277	165
Cacao *Theobroma cacao*	South America, Mesoamerica	32,937	202,204	76,585	1,738
Achiote *Bixa orellana*	South America, Mesoamerica	130	1,171	387	212
Frangipangi *Plumeria rubra*	South America, Mesoamerica	–	62	105	46
Calabash tree *Crescentia cujete*	South America, Mesoamerica, Caribbean	–	21	103	56
Peyote *Lophophora williamsii*	Mesoamerica	–	21	10	44
Montezuma cypress *Taxodium mucronatum*	Mesoamerica	120	42	187	20
Guatemalan indigo *Indigofera suffruticosa*	Mesoamerica	–	25	19	46
Golden thryallis *Galphimia glauca*	Mesoamerica	–	59	50	37
Habanero (type) *Capsicum chinense*	Mesoamerica, Caribbean	134	2,076	35,686	235
Sapodilla *Manilkara zapota*	Mesoamerica, Caribbean	–	108	137	105
Areca (betel) nut *Areca catechu*	South Asia, Asia, Pacific	–	131	93	361
Tumerics *Curcuma spp.*	South Asia, Asia, Pacific	665	77,432	2,903	5,267
Ajwain *Trachyspermum ammi*	Africa, Near East, South Asia	–	84	74	185
Apple of Sodom *Calotropis procera*	Africa, Near East South Asia, Asia	133	117	339	371
Ashwaganda *Withania somnifera*	Near East, South Asia, Asia	–	74,573	306	1,208
Indian bay leaf *Cinnamomum tamala*	South Asia	–	41	21	86
Sa lae *Broussonetia kurzii*	Asia	132	10	177	2
Fingerroot *Boesenbergia rotunda*	Asia	–	63	34	87

Plant	Origin	Genbank Genes	GenBank Nucleotides	GenBank Proteins	Species cites in PUBMED
Chinese quinine *Dichroa febrifuga*	Asia	132	54	187	94
Durian *Duric zibethinus*	Asia	44,924	69,375	63,328	85
Vietnamese balm *Elsholtzia ciliata*	Asia	–	51	16	21
Black cohosh *Actaea racemosa*	North America (Native American)	126	2,252	112	262
Bloodroot *Sanguinaria canadensis*	North America (Native American)	–	5,731	46	137
Iboga *Tabernanthe iboga*	Africa	–	20	14	64
Baobab *Adansonia digitata*	Africa	–	168	12	193
Umckaloabo *Pelargonium sidoides*	Africa	–	74	72	111
Argania *Argania spinosa*	Africa	–	102	14	74
Arum lily *Zantedeschia aethiopica*	Africa	131	85,440	490	74
Monkey orange *Strychnos spinosa*	Africa	–	63	35	39
Fonio *Digitaria exilis*	Africa	133	88	170	42
Coffee (Arabica) *Coffea arabica*	Africa	56,903	262,956	68,621	1,095
Watermelon *Citrullus lanatus*	Africa	185	13,785	1,323	861
Monanthotaxis *Monanthotaxis spp.*	Africa	–	529	312	26
Quinoa *Chenopodium quinoa*	South America	58,937	79,300	63,785	569
Yagé *Banisteriopsis caapi*	South America	128	8	164	113
Brugmansia *Brugmansia spp.*	South America	–	149	90	128
Cinchona *Cinchona spp.*	South America	–	246	97	690

* PubMed comprises more than 30 million citations for biomedical literature from MEDLINE, life science journals, and online books. Citations may include links to full-text content from PubMed Central and publisher web sites. https://pubmed.ncbi.nim.nih.gov

But in the context of a possible multilateral mechanism for benefit sharing from the commercial use of DSI, establishing a prominent, reliable, and secured mechanism for benefit sharing with IPLCs is of paramount importance. This sharing should represent a large and fixed proportion of the total benefit sharing for DSI, in keeping with the value of IPLC-related biodiversity to industries including pharmaceuticals and agriculture. Substantive indigenous peoples' control over the allocation of such benefits is also a mandatory element. In the 2020s, the establishment of a mechanism to benefit indigenous peoples that does not count their substantial participation in its allocation is a possibility that should not be considered. In regard to structure, the United Nations Permanent Forum on Indigenous Issues (UNPFII) offers some precedents and ideas for how governments and IPLCs could share responsibility for oversight and administration of DSI-related benefit sharing. Indeed, the UNPFII itself could play a role.

The purposes to which such funding is placed – beyond that it be for IPLCs – are of course a matter to ultimately be resolved through broad-based discussions. One possibility in keeping with the source of the funding (commercial use of DSI) and the priorities of IPLCs could be to assist indigenous peoples' development of their own biocultural / biodiversity information systems, structures that reflect their culture and understanding, and that track taxonomy and biodiversity's uses as it is conceptualized and understood by native cultures.

The benefit sharing would thereby not only support IPLCs to document biocultural relationships and develop traditional knowledge, but also support the use of that knowledge for local innovation, and the development of lPLCs' own information and legal systems for the governance of their knowledge and resources.

Conclusion

While a solution to benefit sharing for DSI cannot undo historical injustices to IPLCs, new international approaches and agreements in biodiversity certainly should not repeat past mistakes. As surely as national interests are threatened by the unregulated transfer and use of DSI undermining national laws on access to biological diversity, the same phenomena also threaten the rights of IPLCs over their knowledge and resources. What this means is that a prominent and secure place for IPLCs must be found in the access and benefit-sharing solution that is developed for DSI.

The tough negotiating road ahead has been delayed by the COVID pandemic. This pause in the pace of negotiations offers the opportunity to reflect on how the CBD's goals might best be supported by a benefit-sharing solution for DSI. For generations, scientific and commercial developments in agriculture, health, and other sectors have benefitted from the knowledge and insights of IPLCs, and the genetic resources that they have protected, cared for, and developed. But the process has not been a fair one, and DSI enables further alienation of IPLCs from their resources and knowledge.

As bioinformatics, the '-omics' disciplines, and artificial intelligence come to dominate development of products based on biodiversity, it stands to reason – and is just – to preserve, fortify, and further develop the alternative biodiversity knowledge systems of indigenous peoples. Working in concert with IPLCs to dedicate DSI benefit sharing to the support of local knowledge, development of local biocultural information systems, and systems to govern them of the IPLCs themselves, benefit sharing from DSI can promote local innovation consistent with the cultures and values of IPLCs, and maintain biocultural diversity that ultimately benefits all of humanity.

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