Implications of biological information digitization: Access and benefit sharing of plant genetic resources

Stuart J. Smyth1 | Diego M. Macall1 | Peter W. B. Phillips2 | Jeremy de Beer3

1Department of Agricultural and Resource Economics, University of Saskatchewan, Saskatoon, Canada
2The Johnson-Shoyama Graduate School of Public Policy, University of Saskatchewan, Saskatoon, Canada
3Faculty of Law, Common Law Section, University of Ottawa, Ottawa, Canada

Abstract
The decoupling of biological information from its material source has changed debates about global access and benefit sharing (ABS) of genetic resources. What does the digitization of biological information imply for genetic resources of proven and potential value? What implications does digital sequence information (DSI) have for individuals and groups, who have invested time and effort in augmenting and refining valuable characteristics in genetic resources? Stakeholders discussing this issue in various international fora unanimously acknowledge there are currently more questions than answers. Online digital publicly accessible resources represent a transformative technological shift, resulting in intellectual property governance gaps. This article provides interdisciplinary perspectives on options available to governments to continue advancing the goals of ABS, when physical access to genetic resources is no longer needed because DSI is readily accessible. It envisions four governance scenarios.

KEYWORDS
digital sequence information, genetic resources, intellectual property rights, Nagoya Protocol, World Intellectual Property Organization

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Electronic copy available at: https://ssrn.com/abstract=3677616
1 | INTRODUCTION

The decoupling of biological information from its material source has changed the global access and benefit sharing (ABS) of genetic resources debate. Until recently, to make use of a genetic resource required physical access to it, or at least to its tangible DNA. The ability to "digitize" biological information opens a host of possibilities, as well as issues that will need to be addressed. What does the digitization of biological information imply for genetic resources of proven and potential value? What implications does digital sequence information (DSI) have for individuals and groups, who have invested time and effort in augmenting and refining valuable characteristics in genetic resources?

In light of such questions, this article provides interdisciplinary perspective on options available to governments and firms to continue advancing the goals of ABS, when physical access to genetic resources is no longer needed because DSI is readily accessible. By examining the challenges of DSI governance at the intersection of law, economics, political science, and public policy, this article offers new insight into the nature of the problem and potential solutions.

The ability to "digitize" biological information has coincided with the development and application of novel genome editing technologies, big data, and synthetic biology (SB). Although different in their scope and depth of application, combined, these technologies and scientific disciplines could considerably loosen the constraints to plant engineering and modification. Implications of DSI are explored through the specific sectoral lens of access to plant genetic resources for agricultural crop and plant breeding, a topic of keen interest that is currently being deliberated in various international fora. Whether private or public, plant breeding requires access to a wide pool of genetic resources (vast amounts of data) to create novel plant varieties, which themselves are genetic resources. As countries have become interdependent for their food production, international cooperation against the backdrop of emerging technologies and scientific disciplines is imperative. How DSI that at the extreme can become completely disembodied and independent of underlying genetic resources are governed, will have profound direct and indirect effects on relevant stakeholders in both the private and public sector. Stakeholders who at times have, and likely will continue to have, complimentary and competing political, economic, and social interests.

The objective of this article is to frame the DSI big data challenge within an agricultural intellectual property (IP) context, focusing on the governance challenges that decision makers will have once the relevant international institutions and agencies have been determined. The domestic legislation of only a limited number of countries is either implicitly or explicitly suited to address DSI governance challenges. For example, Brazilian Law 13.123 Chapter I Article 2 I states that in accordance with concepts and definitions pertaining to the Convention on Biological Diversity (CBD), genetic information or metabolism information originating from vegetables (plants), animals, and microbes are Brazilian genetic heritage. Article 10(4)(ii)(D) of the Patents Act, 1970 (as amended up to Patents [Amendment] Act, 2005) of India requires the disclosure of the source and geographical origin of biological material, when used in an invention. However, the policies, programs, and practices of most countries are currently built on the embodied nature of genetic resources.

The rupture of the bond between tangible and intangible resources challenges existing governance models and requires detailed exploration (Reichman, Uhlir, & Dedeurwaerdere, 2016). It raises difficult conceptual questions in the field of IP in particular. For example, under the Nagoya Protocol (NP) to the CBD, is DSI itself a genetic resource or does DSI instead constitute or arise from the utilization of genetic resources? What exactly is the resource: the physical sample or the information within it? Is DSI copyrightable data, either on its own or a database compilation? How does DSI intersect with patent or plant breeders' rights regimes, or with the protection of trade secrets or undisclosed test data? How is DSI connected to the traditional knowledge (TK) governance models of Indigenous Peoples and Local Communities? What exactly is the relationship between information, data, and knowledge? This article facilitates answers to such questions not through a specific legal doctrinal analysis, but rather by situating the questions in an interdisciplinary framework of various future scenarios for DSI governance. And it adds to our current understandings of the problem a discussion of DSI in the context of multilevel, network

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governance regimes. Who and through which international institutions and framing paradigms (economic, legal, policy, social, or a combination of these) the core questions are answered, this article suggests, will influence what the answers are.

The article is structured as follows: institutions involved in trying to harmonize terminology and meaning around the concept of DSI are presented, a description of how DSI will enhance applications of genome editing and SB follows, which leads to a discussion of the implications of digital agriculture for relations in the agri-food sector, and then how ABS of genetic resources is relevant to the DSI institutional landscape is discussed. The article concludes with four envisioned DSI governance scenarios, given current available governance capacities, and with the importance and relevance of determining who the key decision-making stakeholders may ultimately be.

2 | DEFINING DSI

The economics of genomics has precipitated the gradual coalescence of biology and data science; which has created a host of novel opportunities as well as challenges (Aubry, 2019; Marden, 2018; Peccoud, Gallegos, Murch, Buchholz, & Raman, 2018). The genome of an organism contains its genetic information (or code), which is responsible for the development and homeostasis of organelles, cells, tissues, organs, and organ systems. This information can now be uncovered and subsequently stored, edited, and transferred digitally. In just over two decades, the number of molecular biology databases has gone from fewer than 200, to nearly 1,700 (Anonymous, 2016). The genomes of multiple organisms in their entirety, or segments thereof, are now freely accessible to anyone with an internet connection. Perhaps most importantly, this information can be converted into tangible biological constituents (Boles et al., 2017).

The term “digital sequence information” was introduced in decisions by the CBD (CBD XIII/16) and the NP (NP 2/14). Terminology associated with genetic sequence use, transmission of this data and implications of using different terms have all been explored by the World Health Organization (WHO), the World Intellectual Property Organization (WIPO), and the World Trade Organization (WTO; WHO, WIPO and WTO, 2012). Harmonizing terminology and meaning around and about DSI would seem a logical and achievable goal upon the involvement of important organizations such as these. However, because the term DSI is used by multiple disciplines (which themselves are evolving), and that within each of these disciplines the concept underlying the term is slightly different, definitions of DSI differ across disciplines (CGRFA, 2017; Heinemann, Coray, & Thaler, 2018). For example, the WHO understands DSI to be “the order of the nucleotides in DNA and Ribonucleic acid (RNA),” whereas the Food and Agriculture Organization (FAO) of the United Nations (UN) states that “differences in terminology in scientific circles reflect differences in the material referred to, which makes it difficult to harmonize terminology” (FAO, 2020; WHO, 2018).

From a technical perspective, DSI represents basic knowledge of gene function, gene position, and protein expression, thus providing knowledge pertaining to the gene’s location, role, and structure. The legal definition of DSI is focused on the embodiment of the knowledge, meaning that the knowledge could pertain to the application of a single gene, or to the greater value of the full plant genome sequence. When DSI is defined within a policy context, the definition becomes even broader still, whereby it can include all of the research into the sequencing of the plant genome, the value of the sequenced genome and the application potential of this sequenced genome.

In this article, DSI is understood as another facet of “big data” (Stephens et al., 2015). Conceptually, the term refers to the ability to sequence all or part of hundreds or thousands of plant samples originating from various sources. This process can yield vast amounts of data; it would be very difficult operationally to track the depth and scope of information utilized from any individual source in any final product (Marden, 2018). Moreover, although the costs of producing biological information might be relatively high (but falling each year), digital technologies permit storing, distributing, and analyzing the disembodied data with low or zero marginal costs (Dedeurwaerdere, Melidini-Ghidi, & Broggiato, 2016).
3 | EMERGING TECHNOLOGIES TO EXPLOIT DSI

As new technologies and scientific disciplines capable of utilizing DSI emerge, its salience will only increase. In illustration, this section of the article explores emerging technologies in the fields of gene editing, SB, and digital agriculture. To varying degrees, these technologies and scientific disciplines are already making use of DSI.

3.1 | Genome editing technologies

Mutagenetic technologies advanced rapidly in the 2000s into what are now collectively known as genome editing. Technologies such as transcription activator-like effector nuclease and zinc-finger nucleases enable researchers to induce targeted and controlled site-specific genome changes via the development of site-directed nucleases. These plant breeding tools evolved rapidly, allowing for the discovery of clustered regularly interspaced short palindromic repeats (CRISPR; Doudna & Charpentier, 2014). Applications of the CRISPR system have expanded quickly, through the development of such specific tools as CRISPR/Cas9, CRISPR/Cas12a, or CRISPR/Cas13 (Chen et al., 2018; Gootenberg et al., 2018). Each Cas variation manipulates the nucleotide sequence of the guide RNA enabling the protein to be programmed to target any DNA sequence for cleavage.

Genome editing has numerous advantages over earlier genetic modification technologies. Most significantly, it allows for targeted single gene mutation across an entire plant genome. However, this technology has not rendered conventional genetic modification obsolete, as it cannot be applied to an organism whose genome has not been sequenced (Friedrichs et al., 2019). Notwithstanding this constraint, the CRISPR suite of breeding tools are an easier more versatile and accurate form of mutagenesis, capable of producing a desired trait into a parent, which is then reproduced in its progeny without losing any efficacy (Georges & Ray, 2017). This technology is able to substantially increase the rate of mutation within a targeted genome, making the effects on the plants more significant (Song et al., 2016), as it can be programmed to target specific segments of genetic code or edit DNA with great accuracy (Barrangou, 2015).

Importantly for this discussion, genome editing holds global potential for plant breeding in both developed and developing countries, as it allows for more targeted local and regional solutions to improve food security (Scheben & Edwards, 2017). For instance, Miao et al. (2018) made use of CRISPR/Cas9 technology to create a rice variety that yields 25–31% more than plants bred without employing the technology. This has profound implications for the potential mitigation of the effects of climate change, as well as contributing to food security. Moreover, some states have already begun delineating their regulatory approach toward this technology. Waltz (2016) reports that the first CRISPR-edited product approved in the United States was the common white button mushroom; although the developer has declared that it will not be commercialized. What was unique about this approval was that the US Department of Agriculture determined that genome editing technologies do not require regulation.

Nonetheless, for all the benefits CRISPR/Cas9 seems capable of providing, Smyth (2017) identifies that not all governments will embrace this technology. In 2016, in response to a lawsuit launched by environmental non-governmental organization, a French court referred to the Court of Justice of the European Union (CJEU) a request to interpret European Law pertaining to new plant breeding techniques, especially CRISPR/Cas9. On July 25, 2018, the CJEU ruled that genome-edited crops are subject to the European Union’s regulatory restrictions in the same way transgenic, genetically modified (GM) organisms are regulated (CJEU, 2018). Genome-edited crops developed by site-specific, targeted genetic engineering techniques will now face rigorous regulatory review before they can be introduced into the market. Most large-area GM crops, like herbicide-tolerant soybeans, canola and insect-resistant maize have failed to secure full food and feed approvals, in part because the costs, time and uncertainty of regulatory compliance make the process prohibitive (Smyth, McDonald, & Falck-Zepeda, 2014). Smaller area, niche crops derived through genome editing would probably face the same economic calculus.
3.2 | SB

Sustained biotechnology research has led to a field now known as SB. Depending on whom is consulted, it is regarded as either a new branch of biotechnology or a logical extension thereof (Kuzma, Kokotovich, & Kuzhabekova, 2016). Owing to the field being in its developing stage, and the fact that the two main fields it encompasses (biology and engineering) are vying to impose their corresponding terminology, it cannot be simply defined (Calvert, 2012). In our analysis, SB is understood as the UK Royal Society (2019, p. 1) explains: “the design and construction of novel artificial biological pathways, organisms and devices or the redesign of existing natural biological systems.” Ultimately, SB aims to produce defined parts assembled in particular ways (with standard rules for their connections) that execute predetermined (preprogrammed) functions within a living organism.

Sequencing the genomes of agriculturally important crops and plants will yield vast amounts of DSI; importantly, information about complex genetic circuits and gene regulation in plants will become available. While it will take time to make sense of this information, eventually, it will help in the design of traits that are new to evolution and beneficial to humanity (Medford & Prasad, 2014).

3.3 | Big data in agriculture

“Big data” is the term used to refer to large information sets and the digital tools used to collect, compile, and analyze them. Scientists have always dealt with data sets to undertake research; big data’s novelty resides in the high volume of information, and its accompanying constraints and opportunities. De Mauro, Greco, and Grimaldi (2016, p. 131) identify the main themes within big data and propose a formal definition for the otherwise nebulous concept: “Big Data is the Information asset characterized by such a High Volume, Velocity and Variety to require specific Technology and Analytical Methods for its transformation into value.” Big data can be used to identify the underlying dynamics of problems in complex systems that are not readily obvious or accessible except through the mining of vast amounts of data (Symons & Boschetti, 2013).

Beyond the technical specifications of big data, its applications in agriculture has already generated a host of issues, especially legal and social ones about access, governance, and ownership. Bronson and Knezevic (2016) reviewed current applications of big data in the agri-food sector and found that several tools used to collect and analyze it may have implications for power relationships in the North American food system. However, they posit that issues around big data are more complex than data ownership that exacerbates inequity between food system players. A series of companies, ranging from John Deere to a host of small entrepreneurial firms, are offering a range of sensors, mechanical innovations, algorithms and services whereby data on weather, soil, crops, and agronomic decisions can be collected and then used by farmers to make other agronomic decisions (Phillips, Relf-Eckstein, Wixted, & Jobe, 2017).

But who owns what remains contested. de Beer (2017) examines how ownership of data, which is generally not directly owned, could be governed. Open data in theory can be accessed and used or shared by anyone. In contrast, closed data are not available to anyone outside the system or organization that controls it. But data can also be shared among specific groups for specific purposes, with limited access otherwise. Some assert that open data will lead to positive outcomes for everyone. Quite often however, that simply leads to suboptimal use. Access and usage is influenced by resource availability, such as know-how, infrastructure and fiscal constraints. Data ownership pertains to a great degree on social and cultural norms. In many communities, such as indigenous communities (and in some research communities), the key rules governing data are those set and enforced endogenously (Crookshanks & Phillips, 2013).

The sequencing of plant genomes has direct implications for the applicability of gene editing and SB, while the evolution of digital agriculture will have implications for relations among actors in the agri-food sector. Given the current governance landscape (or lack thereof), big data in agriculture and plant research is likely to face barriers.
The next section of the article explores one of the main issues about DSI that will need to be addressed moving forward: the access to, and sharing of, genetic resources. The challenge that big data, genome sequencing, and online accessibility creates for ABS is the lack of traceability. Researchers are able to access online genetic resources, free of any contractual or legal obligations to identify application of valued genetic data. This lack of obligation has the potential to create situations where a genetic resource is used, generating fiscal benefits for the user, yet restricting the likelihood of any of the fiscal benefits accruing to the source of the genetic resource. The anonymous access to online genetic resources may significantly reduce the level of benefits that could ultimately be shared.

4 | ACCESS AND BENEFIT SHARING OF GENETIC RESOURCES

Biological resources can be understood as a form of capital that are governed by individual countries but are of importance to the entire world. As recently as 1993, food, fiber, and raw materials of biological origin constituted almost half of the global economy (UNEP, 1993). Given the pressures climate change and population growth are placing on food production systems, more and better use of genetic resources is needed. Emerging technologies are simply making the already complicated international debate on genetic resource governance more complex.

For Oberthür and Rosendal (2014), the international governance of genetic resources is an attempt to redistribute the benefits of biological resource utilization to create incentives for biodiversity conservation. They point out that many developing tropical countries are rich in genetic resources and associated traditional knowledge (GRAATK), but the technological capacity to exploit these resides mostly in developed countries. Naturally, this mismatch in ownership and technological capacity gave rise to a dichotomy in actor interest. Those rich in GRAATK wish to conserve them and benefit from their use, whereas those with well-developed technological capacity wish to exploit them. Countries rich in GRAATK had some of their interests embodied in the CBD signed in 1992. Article 15 of the CBD recognizes the sovereignty of countries over their natural resources, thus acknowledging every country’s right to legislate access to them. Article 15 also states that access to genetic resources is to occur on mutually agreed terms (MAT), and with prior informed consent (PIC).

Interestingly, although the term "genetic resource" is at the basis of the ABS debate, legally defining the term is difficult. Tvedt and Schei (2014) note that a legal definition of the term needs to meet two contradictory virtues: (a) it must retain a protean quality, so the term maintains relevance with emerging technologies; and (b) it must be precise enough so that there is sufficient legal certainty to know whether one is operating inside or outside the ABS system. Tvedt and Schei assert that the definition set forth in CBD (albeit a product of 1992 knowledge) is versatile enough to be relevant to emerging biotechnologies. In contrast, Deplazes-Zemp (2018) argues that genetic resources are an informational rather than tangible type of natural resource, due to their biological function and how they are currently valued and used. In her view, the CBDs definition of genetic resources (pertaining to the material), is not adequate to their actual use. Watanabe (2019) notes that DSI could trigger the NP ABS mechanism, which would result in significant oversight and paperwork (Bagley & Rai, 2014; Redford, Brooks, Macfarlane, & Adams, 2019; Sollbeger, 2018).

The challenges of applying the term "genetic resources" in practice has not escaped the attention of negotiators in international fora. Article 2 of the CBD defines genetic material as any material of plant, animal, microbial, or other origin containing functional units of heredity, while “Genetic resources” means genetic material of actual or potential value. While there is considerable legal debate about precisely what is, or is not, included in the scope of genetic resources, the lack of political consensus has prevented a universal, formal definition from being attained (CBD, 2008).

With clearly divergent political and economic interests, without a universally accepted meaning of genetic resource specifically against the backdrop of emerging transformative biological technologies, a wide array of entities are engaged in trying to govern ABS. The current global governance "regime complex" around DSI has
become even more complicated than when Raustiala and Victor (2004) dissected the governance of plant genetic resources over 15 years ago.

5 | DSI GOVERNANCE INSTRUMENTS AND INSTITUTIONS

Globally, as the DSI debates move forward, numerous institutions and international legal instruments have become relevant to its governance. This section of the article discusses in greater detail developments related to the CBD, the WTO, the WIPO, the FAO, the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), and the WHO.

5.1 | The CBD

The CBD was an international response to the recognition that while biological diversity is a global asset of value to present and future generations, the threat to its loss has never been greater. The CBDs three main objectives are:

- the conservation of biological diversity;
- the sustainable use of the components of biological diversity; and
- the fair and equitable sharing of the benefits arising out of the utilization of genetic resources.

Two articles within the CBD text are useful in illustrating the effects the decoupling of biological information from its material source. Article 15 recognizes the sovereign right of states over their genetic resources, as well as their right to legislate access to them. Article 8(j) calls for the respect, preservation and maintenance of knowledge, innovations and practices of indigenous and local communities. Members of the CBD recognize that most genetic resources have associated TK. Thus, internationally governing ABS is not simply a matter of PIC and MAT over genetic exchanges between states and organizations; it also involves the stewards of TK.

Given that the CBD does not detail how to establish adequate infrastructure or institutions to accommodate ABS or TK use, a supplementary agreement was developed to address this gap. The NP was tasked with accomplishing just that. While some genetic resource provider countries might assert that intangible genetic information falls within the scope of their national CBD or NP implementing legislation, neither legal instrument explicitly addresses the new technological reality (Bagley, 2015). There are a range of significant challenges to the NP. One is that it has not been ratified by all signatories to the CBD and a few key countries, such as the United States, are simply not parties to this entire scheme. Bagley points out a number of other challenges. First, the temporal scope and breadth of coverage of the NP are left undetailed; it is not clear if the NP pertains to GRAATK before the NP coming into force or not. Moreover, once the genetic information of interest has been uncovered and used for its first purpose, can that information be stored and subsequently shared or commercialized?

Concretely, the NP does not contemplate "digital biopiracy" (Yilmaz, 2017). Some assert the NP is a "masterpiece in creative ambiguity" (Oliva, 2011), as issues the signatory countries could not agree on, were left unresolved. However, de Beer (2009) suggests that it is logical for parties to accept ambiguity when negotiating difficult subjects because ambiguity can later be negotiated, albeit to the convenience of the parties involved. Given the ambiguities, what do the CBD and NP mean for international efforts in crop breeding in a world of DSI? A unique characteristic of crop breeding is how genetic resources used in the process of creating new varieties are sourced. Most sourcing is done from ex situ collections and mainly through intermediaries (CBD, 2009). This is troublesome because Davis, Smit, Kidd, Sharrock, and Allenstein (2015) conducted a world-wide survey of botanical garden staff to probe their awareness of ABS, the CBD and the NP. They found that many botanical gardens are not yet ready to implement the monitoring provisions of the NP, nor are their staff very familiar with the CBD, ABS, or...
the NP itself. Furthermore, Deplazes-Zemp et al. (2018) point out that applying the same regulations to both commercial and noncommercial research of genetic resources may actually end up harming the Global South.

Embedded within certain crops and plants are the vested economic, social and cultural interests of individuals and social groups. If these crops and plants are sequenced, these interests will now be embedded within this DSI. However, the main international legal instrument, and subsequent instruments, designed to conserve and fairly and equitably use biodiversity do not provide a clear guide on how to go about DSI.

There are three possibilities: (a) DSI is itself a genetic resource, despite its decoupling from physical, biological material, (b) DSI is a utilization of a genetic resource, the resource being the physical material and the utilization being the extraction of information about the material, or (c) DSI is neither a resource not utilization of the resource, but the application of the DSI could be indirect utilization of the resource. Which of these approaches to DSI under the NP is correct based on current international law, and which ought to be correct normatively, is far from settled.

At the CBD's COP14/NP COP-MOP3 meeting in Sharm El-Sheikh, Egypt, parties decided to:

• Establish a science and policy-based process on DSI and a new Ad Hoc Technical Expert Group (AHTEG).
• Compile views on terminology, scope, domestic measures, and ABS.
• Commission further studies on current DSI use, digital information traceability, DSI databases and what provider countries are doing in domestic legislation to address DSI.

In January 2020 a series of three studies was released in preparation for COP15/MOP4 in Beijing, China, 2020. One addresses the scientific aspects of DSI, including the concept, scope, and current use (CBD, 2020a); another addresses DSI and traceability in public and private databases (CBD, 2020b); and another addresses various domestic ABS measures arising from commercial and noncommercial use of DSI (CBD, 2020c). While the AHTEG and CBD CoP complete their valuable and diligent work, the lack of clarity on DSI and its implications persist with negative implications for many DSI stakeholders.

5.2 | WTO

A potential conflict between the NP and the WTO’s agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) has not been fully explored. Feng (2017) discusses the importance of patent applicants disclosing the geographical origins of biological resources at the base of their inventions (further discussed below). Feng posits that the misappropriation of biological resources without proper compensation can be stopped by using both legal instruments in unison. However, this suggestion does not contemplate DSI, nor does it offer answers should countries be party to TRIPS, but not the NP. Therefore, it is legitimate to question what set of rules or instruments would take precedence in the event of a dispute over DSI. The answer is of paramount importance because TRIPS is the principal legal system on which most national legislations pertaining to intellectual property rights (IPRs) are now built (Maskus, 2014). A response to the needed harmonization of IP systems of various countries, the instrument was signed and ratified by both developed and developing countries because it linked IPRs to international free trade.

For countries not party to the NP, particularly influential countries such as the United States, the WTO and TRIPS is a arguably the most significant governance forum for DSI. Kerr, Smyth, Phillips, and Phillipson (2014) explore the potential conflict between the Cartagena Protocol on Biosafety to the CBD and WTO-related agreements. In analyzing these two divergent regulatory regimes, they note that when two treaties in the same subject area conflict, the latter treaty prevails in the event of a dispute between two states that are party to both instruments. They assert that the International Law Commission responded to the potential conflict between successive treaties with Article 30 of the Vienna Convention on the Law of Treaties (UN, 1969). Kerr et al. (2014)
conclude that because the WTO is the latter treaty, it must play a role in clarifying conflicting rules because it has the legal responsibility, as well as the institutional competence to do so.

It is complicated whether, based on assessments of the Vienna Convention on the Law of Treaties, in terms of international treaty precedence, the WTO and not the CBD would be the agreement used in incidences of dispute. The WTO and the TRIPS Agreement are firmly grounded in western, industrial economy notions and concepts of IP (Maskus, 2014), and as a practical matter, includes dispute settlement mechanisms not present in the CBD. The uncertainty regarding how DSI will be internationally governed may, therefore, be partially mitigated with the knowledge that formal disputes regarding DSI would be settled pursuant to the provisions of the TRIPS Agreement.

The TRIPS Agreement clearly articulates the boundaries of IP, which ultimately reduces the potential for formal recognition of ABS and TK. The more formal rules of IP as defined by the TRIPS Agreement, provide some clarity for DSI governance, as it moves the discussion away from the more nebulous aspects of the role, function, and importance of ABS and TK. For example, it is arguable that DSI is already protected by IP regimes promulgated by the WTO (and as discussed below, WIPO).

DSI compiled into a database with sufficiently original selection and arrangement of data is protected by copyright as an original work. In some jurisdictions, such as the European Union and Mexico, data that required a substantial investment to collect might itself be copyright protected. DSI that is undisclosed can be protected as confidential information, and even DSI that is disclosed pursuant to health or agricultural regulatory requirements can also be protected against reuse by third parties. Moreover, if a patent applicant claims DSI as part of a new, useful, and nonobvious invention, a patent will be granted; although the law in many jurisdictions does not allow for the protection of raw genetic information or essentially biological processes. The point is that the most common and effective for DSI currently comes via the IP regimes already established by the WTO and WIPO.

5.3 | WIPO

For almost two decades, the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) has had a mandate to negotiate a text-based instrument(s) for the effective protection of genetic resources, TK and folklore. Negotiations have been ongoing on a parallel basis on three instruments: a text for genetic resources, a text for TK, and a text for Traditional Cultural Expressions. Oguamanam (2018) notes that the genetic resource text is the most advanced of the instruments. The first consolidated text on genetic resources was produced in the 20th IGC in 2012. It continued to evolve in subsequent IGC meetings: 22, 23, 29, and 30.

A recent attempt to refine the genetic resource text was at the 36th IGC in June 2018, in which member states were unable to reach a consensus on “Consolidated Document on Intellectual Property and Genetic Resources Rev2” (IGC, 2018a, 2018b). That disputed draft offered a set of alternatives to Articles 2–7 (in Rev1), to accommodate the wish of some member states for there to be no mandatory disclosure requirement. Furthermore, an alternative to Article 4.3 (which contemplates ABS and PIC), stating that no obligation shall be placed on compliance with ABS and PIC was reinstated (Saez, 2018).

The group tasked with drafting the text indicated that the issues of ABS and PIC require a lot more work and deliberation. Saez (2018) noted that the particular concerns with Rev2 related to the disclosure proposals. Some countries perceive disclosure proposals as a means with which to weaken the patent system (not strengthen it) because it would allow patents to be challenged. The result might be a transfer of wealth from developed to developing countries. Beyond this “progress,” IGC 40 in 2019, saw further deliberation and update to gap analyses on TK and governance gaps (IGC, 2019).

TK has been mentioned extensively throughout this article. It is an important concept that permeates many of the agreements on ABS. However, exactly what is TK? For all that is known and accepted about TK, a universally accepted definition for this concept does not yet exist. How TK is defined is no trivial matter because in IP
protection, there is a link between subject matter definition and scope of protection (WIPO, 2018). Generally, TK is understood to be: the knowledge, know-how, skills and practices that are developed, sustained and passed on from generation to generation within a community, often forming part of its cultural or spiritual identity (WIPO, 2009).

Conflicts and challenges have emerged as interest in the use of TK has grown (Phillips, 2014). How to properly safeguard TK’s integrity in an increasingly interconnected world is a challenge. Over the past two decades, scholars have explored distinct ways in which western laws and institutions can be refined to safeguard TK (see, e.g., Ansong, 2018; CBD 2011; Dagne, 2012; Oguamanam, 2004a, 2004b; Posey & Dutfield, 1996; Weeraworawit, 2003). Proposed approaches and scopes of protection have varied, and no prevalent paradigm or widely accepted proposal has yet emerged. The difficulty stems not only from the fact that TK is difficult to define but also that indigenous groups around the world enjoy different degrees of political recognition and inclusion (Drahos, 2014; Rimmer, 2015).

Importantly for this discussion, it is not clear that TK can be decoupled from a plant’s underlying genomic information should it be transcribed into DSI. That is, if an indigenous group has reared a particular plant to express desired traits over generations, if said plant’s genome is sequenced, embedded within this DSI is the TK of the indigenous group that reared the plant. The question, therefore, for those developing DSI governance is whether and how the “information” in DSI is distinguishable from the “knowledge” in TK. At present, there does not seem to be a feasible way to legally or politically dissociate TK from the DSI of a sequenced plant.

5.4 | ITPGRFA

The ITPGRFA, administered by the FAO, has the main goal of supporting the sustainable use of plant genetic resources for food and agriculture. At its core, the multilateral system allows contracting members to access a gene pool made up of 64 major crops (world diet staples among them). The ITPGRFA recognizes that plant genetic resources for food production require special consideration to increase ease of access. However, the instrument did not become a vehicle for altering IPRs (Halewood & Nnadozie, 2008). The ITPGRFA simply specifies the rules for accessing plant genetic material and for sharing results of research and breeding on that material.

The standard material transfer agreement is the modality (contractual instrument) through which contracting parties provide facilitated access to the global gene pool. Plant samples are contributed to the global gene pool by governments, international institutions, and legal or natural persons (anyone within the jurisdiction of the contracting parties). When the ITPGRFA was negotiated, governments were unable to commit to including resources that were subject to the rights of individuals and legal entities under national law (Manzella, 2013). Application of the ITPGRFA was limited to resources governments could directly manage and control. However, not including plant resources under the direct control of governments does not mean the ITPGRFA ignores these resources. Annex I of the multilateral system serves as the basis by which more crops and plant samples can be added by anyone with a desire to contribute plant genetic resources.

Digitizing plant genetic and genomic information can exponentially facilitate the sharing of information and the improvement of crop and breeding programs around the world. The DSI of important crops, in whole or in part, is already in the public domain (Appels et al., 2018), meaning it is not under the direct control of anyone. It is unclear how the ITPGRFA might apply to DSI, or whether the ITPGRFA could be updated to operationally contribute to DSI management. In their national laws, countries such as Brazil and India define information about the components of genetic resources as the subject matter of ABS (independent of physical material). However, Article 12.3(b) of the ITPGRFA states that the tracking of material is not required under this multilateral system. Given the ease with which DSI could potentially flow to researchers all over the world, and the potential benefits DSI is projected to generate, it is an open question whether governments would actively impede these exchanges for narrow national interests.

Electronic copy available at: https://ssrn.com/abstract=3677616
5.5 | WHO

Under the pandemic influenza preparedness (PIP) framework the WHO has also had a keen interest in DSI (the WHO refers to it as “genetic sequence data”). The PIP framework’s objectives are to: (a) share “influenza viruses with human pandemic potential” (IVPPs) and to (b) share the benefits derived from the sharing of those IVPPs with all countries in need. The WHO notes that by solely employing DSI, many laboratories are now able to synthesize vaccine viruses and influenza virus proteins or antibodies (WHO, 2014a, 2014b).

Owing to DSI being discussed through the lens of access to plant genetic resources for agricultural crop and plant breeding, viruses or any other living organisms are beyond the scope of this article. Interest in the WHO’s work in the DSI space in this article, is limited to the organization’s work towards establishing a clear understanding and definition of DSI. The WHO recognizes that there are different perspectives on whether DSI falls within the PIP’s definition of “biological materials.” Moreover, the WHO acknowledges the difficulty in trying to track DSI because of the various ways in which DSI may be disseminated (WHO, 2014b). In essence, the WHO’s work has run into the same seemingly intractable complexities that other institutions run up against when working in the DSI space.

6 | ASSESSING THE CONTEMPORARY DEBATE ON DSI

The CBD, ITPGRFA, and the WHO are all individually discussing DSI implications among their members (CBD, 2019; ITPGRFA, 2019; WHO, 2019). All institutions have commissioned scoping studies to review the implications of using DSI, and the ABS implications of its exchange (CBD, 2016; Heinemann et al., 2018; Laird & Wynberg, 2018; WHO PIP Advisory Group, 2016). All studies coincide that DSI has no agreed universal definition, there are multiple stakeholders with competing interests involved in this debate, the route forward on this issue is unclear and that tracking DSI is becoming increasingly difficult.

6.1 | Multilevel/network governance

Key instruments and relevant institutions that are either currently discussing DSI or have the capacity to contribute to its debate, can be grouped under four broad spheres in accordance to their main objective: Business/Economic, Environmental, Intellectual Property, and Societal (Figure 1). Solid blue lines depict direct dependencies, whereas the black dotted lines depict a common objective or lesser relation. “Floating” intuitions that have almost no relation with other institutions but have interest and capacity to contribute to the DSI–ABS governance debate, have been situated as well, such as the Organisation for Economic Cooperation and Development. Overall, one can visibly see the potential for governance congestion.

Political complexity poses further challenges to any proposed international DSI governance mechanism. In Western democracies, diffused decision-making and policy implementation is the modern political reality in respect to most important issues. Hooghe and Marks (2003) note that scholars in different disciplines have described this phenomenon as “multi-level,” “networked,” “multilateral,” “global,” or “polycentric” governance. Moreover, design of these multilevel governance systems is seldom deliberate and most often, accidental or even uncontrollable. Internationally, “multi-level governance has come to be seen as a much broader trend, one which includes the upward diffusion of power to regional and international organizations as well as the downward diffusion of power to various sub-national governments” (Harmes, 2006, pp. 725–726). This process of diffusion is not just vertical or jurisdictional. Negotiations are becoming nonhierarchical between institutions (Peters & Pierre, 2001), as non-governmental actors have taken up crucial roles in new systems of governance (Rosenau & Czempiel, 1992).
The challenges of multilevel governance have been discussed in the context of plant genetic resources generally (Raustiala & Victor, 2004), and more recently in the context of specific agricultural products like biofuels (de Beer, 2011). But the phenomenon of multilevel governance has not yet been discussed thoroughly in respect of DSI. Work to this point has mainly addressed international institutions separately. However, the rising density of international institutions makes it increasingly difficult to isolate the implications of decisions reached in any one forum. In the international arena, decisions reached in one forum, for example, do not automatically extend to, or clearly undermine, agreements developed in other forums (Raustiala & Victor, 2004).

As novel biological technologies diminish their reliance on genetic material and move toward the intangible (information), already limited policy analysis tools are likely to have difficulty in explaining this developing field’s implications. Any proposed way forward will have to be accommodated into an already complex and overlapping ensemble of established legal norms, frameworks, directives, and policies (both domestic and international).

6.2 Advancing DSI governance

Key aspects of international DSI governance need to be agreed upon by governments. Each aspect is the embodied interest of a distinct mix of private and public sectors, who in turn are comprised of groups with distinct values and divergent political and economic interests. Moreover, governments and actors have divergent institutional and
human capital capacities, and thus are unlikely to perceive DSI in the same fashion. Therefore, we should not expect decisions on DSI governance in the international arena to be a function of globally averaged values and divergent political and economic interests. History of first-generation biotechnology shows that countries are likely to undertake their own analyses and arrive at their own conclusions regarding novel biological technologies (Falck-Zepeda, Smyth, & Ludlow, 2016). The results of these analyses are likely to be ranked and “fitted” to current biotechnological regulatory regimes and become a component (subset) of a bigger decision process. Thus, contemplating the vast array of distinct values and divergent political and economic interests is important when proposing a way forward on this issue, but it is highly unlikely that any operational international governance framework will be capable of addressing all of them.

Nevertheless, “analysis-paralysis” is not a recommended course of action. Although the simplest option is to promulgate the status quo, this may be increasingly detrimental to some (such as owners of GRAATK) and could lead to the overall underutilization of genetic resources. That is because in the absence of a clear and transparent way forward, firms may be reluctant to invest in DSI-dependent technologies leading to a suboptimal outcome regarding this issue. As DSI is already eroding existing ABS mechanisms and norms (Welch, Bagley, Kuiken, & Louafi, 2017), at the very least, an exploration of potential options on how to tackle this issue is warranted.

An initial approach to international DSI governance is to situate this technological development within axes whose dependent variables are relevant to first-generation biotechnology, as this would allow us to build off what is already known (Figure 2). Conceptually, DSI can be situated within the ambit of existing legal norms and instruments whose limitations and domains have, to the extent possible, already been articulated. This will enable all relevant stakeholders to identify which aspects of DSI are governable given existing legal norms and which aspects require new, innovative policy solutions.

Axis 1 in Figure 2 depicts current plant breeding technologies and disciplines that sustained life science research has yielded. For most, if not all, of these technologies and disciplines, governance instruments have been adequately refined both to protect IP and foster ABS, using a mix of contracts, domestic laws and policies, and international treaties and agreements (Axis 3). Depending on the balance of IP and ABS, these instruments have worked at the local to global level (Axis 2). When combined, the axes of the conceptual model produce a three-dimensional space in which the governance mechanisms of biologically based technologies reside. The closer to the origin of this three-dimensional space a technology is situated (conventional breeding, using commercial contracts and located in individual communities, such as towns), the more effective existing governance mechanisms are in both protecting IP and fostering ABS. Conceptually, this is depicted with dotted lines. Individually, the salience of each axis is evident. By combining these axes, we show where, and what, innovative governance mechanisms are needed.

The governance of genetic modification began in the late 1980s and over the proceeding 30 years, a governance capacity was developed for these technologies. While regulation of GM technologies exists at the domestic level, there is scant governance capacity beyond this jurisdiction (green dotted line). The potential to govern DSI exists beyond the frontier of GM governance. The distance between these two governance frontiers at all three axes, identifies the governance gap that exists along each of the three axes. From a technological perspective, genome editing and SB are a significant advance as identified along Axis 1. On Axis 2, the gap illustrates that these technologies are being regulated at domestic levels, but there is a gap due to the lack of continental or international governance agreements (blue dotted line). Similarly, along Axis 3, there are no international agreements in place that provide any governance capacity, capability, or guidance for DSI.

7 | POTENTIAL SCENARIOS

International governance of DSI is spread over various agreements and institutions, resulting in international governance gaps. The private ordering of knowledge and changing physical structures as the world moves from physical property sharing to online public DSI knowledge sharing, poses challenges for knowledge mobilization.
Much, if not all, of the international governance network in existence, is designed to deal with the sharing of resources, applicability of TK and appropriate access and benefits sharing. Online digital publicly accessible resources represent a transformative technological shift, resulting in governance gaps. If physical access no longer matters, what benefits can be, or should be, expected to be shared?

The governance of ABS as it relates to DSI, is not a material governance conundrum, but an informational governance challenge. Online digital repositories of genomic sequence information, for example, are an intangible public or common pool good that lack international governance. Given the current governance environment and the contemporary discussions on the subject, should nothing truly revolutionary occur, we anticipate that there are four options for moving forward.

First, given the lack of governance capacity in this space, an existing international institution could “move into” this space and claim governance. The practical feasibility of this may be limited, given that WIPO has invested efforts for close to 20 years to reach a definition for a genetic resource, without success. For an international institution to “move into” this space, would require a substantial investment in terms of time and resources, with a less than optimal likelihood of success. This is not to suggest that the premise of doing so is unwise, rather such a move would require considerable deliberation, with a clear vision of the process required to move forward. Institutions that require consensus, may be most restricted in their ability to move successfully into this governance gap, allowing those that govern by judgment (such as the WTO’s Dispute Settlement Mechanism) or by majority opinion to be better situated for such a move.

Second, this governance gap could be viewed as a “greenfield” space, whereby an entirely new organization, institution, or convention is discussed, negotiated, agreed to and ratified. Again, citing WIPOs near two decades of effort to satisfactorily define genetic resource, suggests this approach may be problematic. The Doha Round of
WTO trade negotiations, which began in 2001 and continue today, exemplify the risk of consensus-based organizations getting bogged down in indecision and conflict. Given the sensitivities of ABS and the connectivity to TK, we are hard pressed to see this approach providing a rapid resolution to the DSI governance gap.

Third, collaboration through existing mechanisms could be employed to reach consensus more rapidly than searching for a greenfield solution. The international governance architecture has grown increasingly complex over recent decades and one approach to resolving the consensus requirement of a new agreement would be for existing organizations to agree upon a new governance mechanism, whereby all signatories to the principal organizations involved would be signatories to the new mechanism. For example, a country joining the WTO agrees to comply with the Sanitary and Phytosanitary, Technical Barriers to Trade Agreement, and TRIPS Agreements, and the commitments are mutually reinforcing. The amount of effort invested by the FAO, WIPO, and the CBD in the space already, suggests these three may be best positioned to collaboratively address the governance gap.

Fourth and perhaps the simplest or most desirable/realistic option, is to let the status quo exist. This is a complex topic, where the path forward is far from clear, even more so following the 2018 CJEU ruling on genome editing mutagenesis technology. This option allows a developer, either public or private, to engage in a one-off research contract with the owners of genetic resources. This should not be treated as an expectation of DSI utilization, given the public good, open access nature of DSI.

As innovations transition the world away from TK and physical resource access to DSI, gaps in the existing governance network are created by the disembodiment of property and knowledge. The potential for benefit sharing is eroded by not moving forward. However, moving forward requires compromise and the acceptance of new protocols. As knowledge is increasingly digitized in the plant world, physical access continually becomes less of an issue, creating a governance quandary for ABS. Realistically, a global solution to this governance gap is unlikely in the short-term (the next decade) and the speed at which science moves, may mitigate this as an issue as innovative means of benefits sharing are identified. Improved food security may be the benefit that is widely shared.

8 | CONCLUSION

The international governance landscape is populated by a wide variety of institutions that have varying definitions of IP, knowledge and benefit sharing, all of which have significant implications for the DSI debate. The pace and complexity of international negotiations to resolve existing items of diverging opinions is frustrating to many parties, organizations and private companies, to say nothing of the virtual nonexistent capacity to rapidly deal with emerging technologies. This international governance uncertainty regarding the recognition of IPRs within the agricultural sector as it pertains to plant breeding, is viewed as an investment barrier by firms, into new research and development projects involving the application of DSI, potentially limiting the commercialization of new crop varieties and ultimately, improvements to global food security.

We have framed the governance gap and the challenges this is creating at an international level for DSI technologies. However, the governance challenge is going to remain opaque and unresolved until an international institution is able to step forward, and provide the time and fiscal resource investment requirements needed to resolve the uncertainty. In addition, said institution will need to secure a global consensus that validates its work within this space. The outcome would differ greatly depending on the institution that becomes the ultimate decision maker for DSI. Should the leader be a more consensus style organization such as the CBD or one of its subagreements, uncertainty would remain high due to the length of time required to reach consensus that would provide the much-needed clarity. Should a more economic oriented organization assume the mantle, such as the WIPO and aggressive mandate for resolution be adopted, uncertainty may be significantly and rapidly reduced. Clear identification of an international governance leader would be an important first step.

To some degree, innovations in plant breeding have had lower degrees of ownership priorities as the resulting benefit was an improved crop variety that could be grown locally, increasing profitability or food security, or both.
The advent of DSI and online digital genomic information databases, essentially changes the entire context of IP within the agricultural sector. It is now theoretically possible for a public or private researcher to search an online genomic database with a preset algorithm that looks for a specific gene or sequence of genes. This genetic uniqueness could then be replicated in a crop variety half a world away, in a crop that would not be capable of developing the genetic trait on its own. The decoupling of physical access to a genetic resource also offers the potential to decouple the improved food security or profitability of a new crop variety being commercially released.

Ultimately, much of the DSI debate as it pertains to IP, ABS, and TK, boils down to the international governance of big data. More and more specific varieties of each crop type are being sequenced, this genomic information is publicly accessible online and researchers with the computational abilities are able to search these genomic repositories for gene uniqueness. In this instance, the pace of scientific capability far, far outpaces the ability to govern. The nature of the ABS and TK debates have dramatically shifted, the opportunity for significant scientific improvement in crop varieties is unparalleled and the pace of governance has never been slower. Combined, the result is confusion about the application and scope of IP within agricultural research and uncertainty about whether to invest in new research given the significant degree of uncertainty. The solution lies in an international institution stepping forward, with a bold vision and strong mandate, capable of resolution.

ENDNOTES
1 Available at http://www.planalto.gov.br/ccivil_03/_Ato2015-2018/2015/Lei/L13123.htm.
2 Available at https://wipolex.wipo.int/en/legislation/details/13104.
3 Other terms for DSI include, inter alia, “genetic sequence data,” “genetic sequence information,” “genetic information,” “and dematerialized genetic resources,” and “in silicoutilization.”
4 And by extension, any legal documents enacted to accomplish any of the CBD’s documents.
5 Which Feng (2017) considers vital to combat the misappropriation without proper compensation of biological resources.

ORCID
Stuart J. Smyth http://orcid.org/0000-0003-0837-8617
Diego M. Macall http://orcid.org/0000-0002-9436-8740
Peter W. B. Phillips http://orcid.org/0000-0002-9152-5886
Jeremy de Beer http://orcid.org/0000-0001-9753-3708

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AUTHOR BIOGRAPHIES

Stuart J. Smyth is an associate professor in the Department of Agricultural and Resource Economics at the University of Saskatchewan, where he holds the Agri-Food Innovation and Sustainability Enhancement Chair. His research focuses on sustainability, agriculture, innovation, and food. Dr. Smyth publishes a weekly blog on these topics at: www.SAIFood.ca. Recent publications include authored books with William Kerr and Peter Phillips, GM Agriculture and Food Security: Fears and Facts, published by CABI (2019) and Biotechnology Regulation and Trade, published by Springer (2017).

Diego M. Macall is a research assistant in the Department of Agricultural and Resource Economics at the University of Saskatchewan. His research focuses on agricultural innovation, natural resources, and development.

Peter W. B. Phillips is distinguished professor of Public Policy and founding director of the Johnson-Shoyama Center for the Study of Science and Innovation Policy at the University of Saskatchewan. He has taught about and written extensively on the role of intellectual property rights in agriculture, including related to traditional knowledge and farmers’ privilege. He also has served as a government advisor on IPRs and as an expert witness in two litigations about property rights in the Canadian agrifood industry.

Jeremy de Beer is an award-winning professor at the University of Ottawa’s Faculty of Law, where he creates and shapes ideas—about technology innovation, intellectual property, and global trade and development. He is also a faculty member of the Centre for Law, Technology and Society, a senior fellow at the Centre for International Governance Innovation, and a senior research associate at the University of Cape Town’s IP Unit. An interdisciplinary scholar, Dr. de Beer has published more than 50 peer-reviewed chapters and articles across the disciplines of law, business, political science, and public policy.

Electronic copy available at: https://ssrn.com/abstract=3677616
How to cite this article: Smyth SJ, Macall DM, Phillips PWB, de Beer J. Implications of biological information digitization: Access and benefit sharing of plant genetic resources. J World Intellect Prop. 2020;1–21. https://doi.org/10.1111/jwip.12151

APPENDIX A

TABLE A1 List of acronyms for Figure 1

| Business/economic sphere abbreviations | Environmental sphere abbreviations | Societal sphere abbreviations |
|---------------------------------------|-----------------------------------|------------------------------|
| IPPC: International Plant Protection Convention | BONN: Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization | CGIAR: Consultative Group for International Agricultural Research |
| ISO: International Organization for Standardization | CBD: Convention on Biological Diversity | CODEX: Codex Alimentarius |
| OECD: Organisation for Economic Co-operation and Development | CPB: Cartagena Protocol on Biosafety to the Convention on Biological Diversity | DivSeek: Community driven effort to unlock crop diversity |
| OIE: World Organization for Animal Health | NP: Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) to the Convention on Biological Diversity | FAO: Food and Agriculture Organization of the United Nations |
| SPS: Sanitary and Phytosanitary Agreement | | GCDT: Global Crop Diversity Trust |
| TBT: Technical Barriers to Trade Agreement | | ILO: International Labour Organization |
| TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights | | UN: United Nations |
| WTO: World Trade Organization | | UNDRIP: United Nations Declaration on the Rights of Indigenous Peoples |
| | | UNESCO: United Nations Educational, Scientific and Cultural Organization |
| | | UPOV: International Union for the Protection of New Varieties of Plants |
| | | WHO: World Health Organization |
| | | WIPO: World Intellectual Property Organization |