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Access and Benefit-Sharing in Canada

Glimpses from the National Experiences of Brazil, Namibia and Australia to Inform Indigenous-Sensitive Policy

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Abstract

Through a review of international obligations under the *Convention on Biological Diversity* (CBD), the *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization* (NP) and with reference to other instruments, this chapter surveys national measures related to access and benefit-sharing (ABS) in Brazil, Namibia and Australia. It identifies insights from those experiences as the basis of policy recommendations to shape the existing and evolving ABS framework in Canada. Operationalization of ABS in Canada requires the effective involvement of Indigenous peoples grounded in mutual respect. Empowerment of Indigenous governance of genetic resources (GR) and traditional knowledge (TK), integration of adequate administrative review to evaluate and monitor utilization, facilitation of fair and equitable benefit-sharing and the inclusion of a disclosure of origin requirement in the patent framework provide areas of opportunity to support the implementation of the NP and reconciliation with Indigenous peoples in Canada.

INTRODUCTION

The intersection of biotechnology and access and benefit-sharing (ABS) has wide ramifications for fairness, equity, justice, reconciliation, ethics and power relations with regard to Indigenous peoples in Canada. This chapter explores legal measures and trends on ABS both internationally and nationally and their insights toward a Canadian ABS regime. First, the chapter briefly outlines relevant international

https://doi.org/10.1017/9781108557122.010 Published online by Cambridge University Press

obligations including the *Convention on Biological Diversity* (CBD), and the *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization* (NP), alongside a highlight of related instruments. Second, it surveys legal measures from comparatively experienced jurisdictions on ABS including Brazil, Namibia and Australia to identify points of convergence and divergence in relation to the Canadian context. Finally, the chapter makes recommendations on how to integrate ABS into the Canadian legal landscape in a way that is sensitive to Indigenous peoples.

OBLIGATIONS UNDER INTERNATIONAL INSTRUMENTS

The global ABS framework is made up of interconnected mutually supportive obligations established by the CBD. Those obligations were further refined through the NP. Other relevant ABS-related instruments include the *International Treaty on Plant Genetic Resources for Food and Agriculture* (ITPGRFA), the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS) and the work of the World Intellectual Property Organization Intergovernmental Committee (WIPO-IGC) on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore on the Draft Articles on TK and related developments on the interface of intellectual property rights (IPRs) and GRs.

Convention on Biological Diversity (CBD)

The CBD is the preeminent international legal instrument on biodiversity. Its threefold objectives are: promoting conservation and sustainable use of biodiversity; ensuring fair and equitable benefit-sharing arising out of the utilization of GRs and advance through granting sovereignty to States over biodiversity and reciprocal obligations (both substantive and procedural) incidental to the obligations (CBD, Article 1, 3; Glowka et al., 1994: 15). Relating to ABS, Parties are obliged to implement legal measures which: (i) preserve and protect TK defined as 'knowledge, innovations and practices' of ILCs (CBD, Article 8(j); Glowka et al., 1994: 47–8), (ii) facilitate access to GRs for environmentally sound uses (CBD, Article 15(1–2); Glowka et al., 1994: 76) based on prior informed consent (PIC) and mutually agreed terms (MAT) (CBD, Article 15(4–5); Glowka et al., 1994: 80–1), which includes the equitable sharing of benefits derived from utilization of GRs (CBD, Article 15(7); Glowka et al., 1994: 82–3), (iii) provide for transfer of technology associated with the use of the provided GRs (CBD, Article 16(3); Glowka et al., 1994: 89–90) and (iv) allow for participation of provider countries in biotechnological research (CBD, Article 19(1)) and priority access to the research results and biotechnology products based on GRs provided (CBD, Article 19(2)).

The Nagoya Protocol on ABS (Nagoya Protocol)

The NP's objective is to implement the ABS provisions of the CBD (Nagoya Protocol, Article 1). Pursuant to Article 2 (c) and (e), the operative scope of the NP governs 'utilization of GRs' defined to include research and development (R&D) on the biochemical composition directly or through biotechnology, as well as 'derivatives' which encompasses biochemical compounds including gene expression and metabolites (Oguamanam, Chapter 11). Article 3 establishes a framework for ABS relating to utilization of GRs and associated TK (Glowka & Normand in Morgera et al., 2013: 28). Article 4(1–4) states the implementation of the NP intends to be mutually supportive of obligations established under other instruments (Glowka et al., 1994: 77–80), with deference given to specialized ABS instruments such as the ITPGRFA (Cabrera et al., 2013).

In exercising sovereignty over GRs, Parties to the NP are obliged to establish appropriate measures to ensure: (i) access to GRs is based on the PIC or approval and involvement of ILCs (NP, Article 6), (ii) access to TK, which is associated with GRs and held by ILCs, is based on PIC (NP, Article 7) and (iii) utilization of GRs and TK provides for equitable sharing of benefits with providers, in particular ILCs, based on established MAT (NP, Article 5). Article 12 provides that Parties to NP are to take into account the customary laws of ILCs, cooperate with ILCs in establishing community protocols on access to GRs and TK, develop mechanisms to inform users of ABS obligations, and not restrict the customary use of GRs and TK in and among ILCs (Morgera et al., 2014: 217–28). Pursuant to Article 13, each Party must designate a National Focal Point (NFP) as a governmental liaison, as well as at least one Competent National Authority (CNA) to provide regulatory oversight and processing of applications relating to GRs and TK (Greiber et al., 2012: 144–8). Additionally, in accordance with Articles 15–17, Parties must take measures to monitor utilization of GRs and TK to ensure that access and utilization in that jurisdiction are grounded in PIC and MAT, with appropriate compliance measures established, including checkpoints to validate the legality of access by users.

Other Relevant International Instruments

There is a range of parallel international instruments at the nexus of ABS and TK of ILCs. First, the ITPGRFA provides a framework for conservation and sustainable use of global plant genetic resources for food and agriculture, facilitating access under the multilateral system of access and benefit-sharing (MLS) based on a standard material transfer agreement (SMTA) (ITPGRFA, *Preamble*; Moore & Tymowski, 2005: 19–31). Farmers' rights, which recognize the contribution of ILCs to global crop diversity, are affirmed with deference given to national legislation in implementing protections for TK associated with a PGRFA, and the facilitation of

equitable benefit-sharing (ITPGRFA, Article 9; Moore & Tymowski, 2004: 67–78). Both non-monetary and monetary benefit-sharing is provided for under the MLS and are administered through a trust fund for farmers, especially those in developing countries (ITPGRFA, Article 11–13, 19f; SMTA 2006). Samples obtained from the MLS are governed by the ITPGRFA, as opposed to associated TK which remains governed by the domestic ABS framework if one is in place.

Second, TRIPS provides minimum international standards pertaining to IP under the World Trade Organization (WTO). Patents are particularly relevant to the ABS discussion and were a key consideration in the NP negotiations (Glowka & Normand in Morgera et al., 2013: 46). Under Article 27(1) of TRIPS, patents are applicable to inventions, both products and processes, in 'all fields of technology' provided they satisfy the criteria of being 'new,' 'involve an inventive step,' and have an 'industrial application,' and apply without discrimination to the place of invention or production, or the type of technology (Taubman et al., 2012: 98–100). Article 29 provides that applicants must provide sufficiently 'clear and complete' disclosure to allow a person skilled in the art to complete the invention, including the 'best mode' of operation and information regarding foreign corresponding applications. Where TK is used in an innovation, there is currently no explicit requirement under TRIPS to disclose the origin of the TK used in the resulting patent application.

Finally, the WIPO-IGC has been the principal forum for negotiations relating to the development of (a) binding international instrument(s) for the protection of TK, and to explore modalities to further clarify the interface of IPRs and GRs. While still under negotiation, the Draft Articles on TK favours creating a *sui generis* instrument which provides adequate recognition, respect, and protections to TK held by ILCs, promotes conservation and sustainable use of both biodiversity and TK, prevents misappropriation, and facilitates access based on fair and equitable benefit-sharing (Draft TK, Annex at 2–4). Reconciling the divergence between the current TRIPS obligations and the rights of ILCs to 'maintain, control, protect and develop' their TK, including related intellectual property, affirmed under the *United Nations Declarations on the Rights of Indigenous peoples* (UNDRIP) (UNGA Res 61/295, Article 31), the Draft TK Articles aim to provide minimum protections. Key aspects under negotiation include: (i) the establishment of key criteria to define TK (Draft TK, Article 3, Annex at 9), (ii) creation of a tiered system which recognizes ILCs as holders of TK and provides substantive protections based on the level of cultural significance, including secrecy and extent of diffusion, (iii) procedural requirements of PIC, MAT, and a right to control access (Draft TK, Article 4–5, Annex at 10–12), (iv) development of digital TK databases (Draft TK, Article 5BIS, Annex at 13) and (v) addition of a mandatory disclosure of country of origin for inventions relating to or using TK in applications for intellectual property rights (Draft TK, Article 7, Annex at 16–17).

The IGC is negotiating legal measures to clarify the intersection of IPRs relating to GRs and TK with two distinct approaches emerging. The first provides for a clear disclosure of origin requirement, and the other contains no disclosure

requirement, opting instead for a due diligence approach (WIPO IP & GRs, Article 3, ALT 3, 6).

Under the first approach, where an application for IP protection 'includes utilization of [/is directly based on] GRs and/or TK,' the applicant must: disclose the provider, the country of origin, and supplier of GRs and TK and demonstrate compliance with domestic ABS legislation or provide a declaration where the source or origin is unknown (WIPO IP & GRs, Article 3.1). The alternative takes a defensive approach which includes no new disclosure requirement unless the location of the sample is necessary for a person skilled in the art to actualize the invention (WIPO IP & GRs, Article ALT 3.1). A due diligence system is proposed whereby a review would be conducted to determine whether applicants are in compliance with domestic ABS requirements (WIPO IP & GRs, Article 6), and a database system employed facilitating communication across patent offices to prevent the granting of erroneous patents (WIPO IP & GRs, Article 6–7). Even though the IGC negotiation is a work in progress the nature of those negotiations and issues being canvassed can inform and enrich domestic policy at the nexus of ABS and IP rights. Part of IGC's mandate is to remain cognizant of the relationship between its work and related international regimes and instruments which directly include the CBD and the NP on ABS.

NATIONAL LEGAL MEASURES

The following brief survey of ABS frameworks aims to illuminate available approaches. These jurisdictions were specifically selected based on their domestic drivers and experiences. Both Brazil and Australia are federal states which have significant Indigenous populations and a colonial history. Both view themselves as users and providers of genetic resources. Namibia provides an example of decentralized governance options based on empowerment of local communities. These experiences can inform Canada's options.

Brazil

Brazil signed on early to the CBD, yet it is currently not a NP Party. It adopted *Provisional Measure n. 2.186–16/2001(MP)* in 2001 as an interim approach to implementation of Article 15 of the CBD and to address fears over misappropriation of GRs (Cabrera et al., 2014: 18–23). The Genetic Heritage Management Council (*Conselho de Gestão do Patrimônio Genético* – CGEN) was tasked as the Competent National Authority (CAN). Over its tenure, CGEN has issued 41 resolutions to refine operational aspects and address challenges with the administration of the domestic ABS framework (ABS Initiative, 2014: 8–9). Early experience with ABS in Brazil illustrated that challenges posed by overly bureaucratic requirements inhibited R&D, highlighted the need for clear procedures for obtaining legal access to GRs/TK, as well as mechanisms for effective monitoring and enforcement in

cases of non-compliance (ABS Initiative, 2014: 26). In 2014, progress began on the development of a new domestic ABS framework with the introduction of *Bill 7735–2014 (Draft)*, resulting in the adoption of *Law No. 13,123* (2015) and *Decree No. 8,772* (2016) which made significant modifications to the pre-existing framework. The new framework applies to GRs found both *in-situ* and *ex-situ*, as well as to TK and derivatives (Law No. 13123, Article 1). It targets all forms of access to GRs and TK, including their remittance abroad and economic exploitation of final products or genetic material accessed under both the previous and the new systems (Decree 8,772, Article 2(I–III), Article 2(§1–3), Chapter VIII). CGEN remains the CNA, with thematic and sectoral chambers and an interdisciplinary plenary comprised of 60% public officials while the remaining 40% are from the private sector, ILCs, and academia (Law No. 13123, Article 6; Decree 8,772, Article 4–7, 8–19).

Access to GRs or TK for commercial exploration or economic exploitation of a finished product is restricted to domestic entities (Law No. 13123, Article 11(§1)). The rights of traditional farmers and ILCs to protection from misappropriation of their TK, their right to participation in national decision making relating to GRs and TK, and the free exchange of such resources and knowledge in and among ILCs are explicitly enshrined, with a database managed by CGEN established to collect forms of TK as a component of Brazilian cultural heritage (Law No. 13123, Article 8, 10). Where TK has an identifiable source, access to it requires PIC of the holder (Law No. 13123, Article 9(§1)); however, even in the case of an individual holder, TK is viewed as collective in nature (Law No. 13123, Article 10(§2)). An online registration system called the National System of Management of Genetic Heritage and Associated Traditional Knowledge (*Sistema Nacional de Gestão do Patrimônio Genético e do Conhecimento Tradicional Associado* – SisGen) is used rather than a permit scheme to simplify the process. Domestic applicants submit the required information to facilitate access to GRs and TK without the need for the prior approval of CGEN (Law No. 13123, Article 12; Decree 8,772, Article 20). Where access to a traditional or previously unknown plant varieties occurs, a deposit of reproductive material is to be made into an *in-situ* or *ex-situ* collection, with the ILC retaining ownership, and access to TK governed by the broader ABS framework (Decree 8,772, Article 18 (§3–4)). Remittance abroad of samples to foreign institutions must first receive the prior approval of CGEN based explicitly on the proposed use, and the establishment of MAT (Law No. 13123, Article 11(§2), 13(§1–2), 15; Decree 8,772, Article 27–9). Registration with CGEN is a prerequisite to the granting of intellectual property rights on the finished product or genetic material relating to GRs and TK. Documentation demonstrating legal access and utilization of GRs or TK is a mandatory requirement (Law No. 13123, Article 12(§2), 47; Decree 8,772, Article 20(§1)).

Utilization for commercial purposes requires notification of intention to CGEN, and negotiation of a benefit-sharing agreement (BSA) which includes both monetary and non-monetary benefits, within one year of notification (Law No. 13123, Article 16, 19; Decree 8,772, Article 55). Requirements for fair and equitable

benefit-sharing apply to economic exploitation of finished products or reproductive material from GRs and associated TK regardless of the place of production. Additionally, benefit-sharing obligations apply across the value chain inclusive of: the manufacturer of the end product, intermediary producers, and the transferees of IP rights or licensees of final products regardless of who obtained prior access (Law No. 13123, Article 17(§1–4)). Small businesses, cooperatives, and traditional farmers are exempted from the benefit-sharing obligation (Law No. 13123, Article 17(§5)). Where TK is accessed from ILCs, resulting contractual benefit-sharing is administered through the National Fund for Benefit-sharing (*Fundo Nacional para a Repartição de Benefícios* – FNRB) (Law No. 13123, Article 17(§6), 30–3; Decree 8,772, Article 96–102). Importantly, where the final product is produced abroad, domestically situated subsidiaries, affiliates, and intermediaries involved in the value chain are held jointly liable for the benefit-sharing requirements, with benefit-sharing calculations based on the best available information (Law No. 13123, Article 17(§7–8)).

Where monetary benefits are employed, a fixed minimum rate of 1% of annual net revenue is applied, with the Ministry of the Environment able to reduce that percentage to ensure competitiveness (Law No. 13123, Article 20–1; Decree 8,772, Article 48–9). Breaches of the benefit-sharing arrangements attract broad consequences. These include significant discriminatory fines that apply separately to individuals or legal entities (Law No. 13123, Article 27(§5); Decree 8,772, Article 78–91), and seizure of instruments, materials, samples, and products derived from GRs and TK (Law No. 13123, Article 27). Fines triple or double if the sample is an endangered species (Decree 8,772, Article 79), and can be as high as R$ 10,000,000 (Reais) for corporate misappropriation of GRs or TK through the granting of IPR domestically or internationally (Brazil, Decree 8,772, Article 80).

Brazil illustrates the evolving understanding of ABS at the domestic level in parallel with the development of the NP. It is grounded in the unique domestic drivers, circumstances, and priorities of the country as a pioneering megadiverse jurisdiction. Early concerns were raised by the scientific community over the first ABS framework with regard to the complexity of maintaining compliance within the framework, the high transaction costs, and the slow speed of administration (ABS Initiative 2014: 26). Iterative refinements made by CEGN allowed the system to progress and function, but the lack of clarity on core operational aspects – in particular, a defined scope, access procedures, administration of benefit-sharing, and compliance mechanisms – continued to undermine operationalization. The passage and entry into force of the NP further influenced domestic developments, with Brazil positioning itself confidently as both a user and provider of GRs. The new 2015 ABS framework responded to concerns identified by the research and industry stakeholders stripping away the administrative complexities, making clear requirements for access, and emphasizing key checkpoints to ensure compliance. With longstanding experience and a newly-developed ABS framework, Brazil has

attempted to adopt a measured approach balancing the interest of ILCs and those of industry and researchers in preparation for ratification of the NP.

Namibia

Beginning in 1999 Namibia initiated policies governing access to GRs and TK under the Ministry of Environment and Trade and the Ministry of Agriculture, Water and Forestry. Prioritizing the creation of a dedicated ABS instrument in the 2001 National Biodiversity Strategy and Action Plan (NBSAP), Namibia held consultations through national and regional workshops resulting in the *Draft ABS Bill* in 2006 (Namibia, 2010; Shikongo 2011; Schroder 2014). An Interim Bio-Prospecting Committee (IBPC) was created in 2007 to facilitate equitable access to GRs/TK while a national legislative framework was underway (Suleman 2017: 15). Following the signing of the Nagoya Protocol, Namibia began a process of redrafting the 2006 *Draft ABS Bill* to align with the Protocol, which it acceded to in 2014. In 2017, the *Access to Biological and Genetic Resources and Associated Traditional Knowledge Act* was introduced to the Namibian National Council for consideration.

Pursuant to the Act, 'Access' encompasses both direct or indirect acquisition of marine or terrestrial GRs found *in-situ* or *ex-situ*, derivatives, or synthetic products, as well as associated TK for research on the biological, genetic or biochemical composition, technological development, or bioprospecting which is aimed at commercial or biotechnical applications (GRTK Act 2017, Article 1). The Act pre-empts applications of synthetic biology to R&D in GRs and TK which is one of the grey areas of the NP (Bagely, 2016; Oguamanam, Chapter 11; Smyth, Phillips & De Beer, Chapter 10). 'Commercialization' is broadly defined as a collection of activities relating to GR, including: (a) filing for IPRs anywhere, (b) obtaining or transferring intellectual property rights, (c) commercial trials and product development including market research or premarket approval, (d) multiplication of GR through cultivation, propagation, and cloning or any other means to produce products, (e) any other process aimed at realizing commercial value from GR and/or TK and (f) transfer of research results based on GR or TK (GRTK Act 2017, Article 1).

The Directorate of Biological and Genetic Resources and Associated Traditional Knowledge governs access and utilization of GR and TK, ensures fair and equitable sharing of benefits, promotes capacity building and technology transfer, and monitors compliance (GRTK Act 2017, Article 5(4), (6)). Such monitoring includes the application of scientific indicators to determine if utilization of GR has transitioned from the discovery phase into the preliminary or advanced phases of commercialization to impose appropriate conditions (GRTK Act 2017, Article 6(q)). Rights relating to GR found in the land and associated TK vest in ILCs regardless of the source. TK is recognized as being collectively held by ILCs who are natural users of such knowledge (GRTK Act 2017, Article 5(1–3)). Access, utilization, or export of GR and/or TK requires a permit to be procured subject to PIC of and MAT with

rights holders including equitable benefit-sharing provisions (GRTK Act 2017, Article 8–11). Right holders can refuse access (GRTK Act 2017, Article 9(4)). Equitable benefit-sharing is grounded in the collective and inalienable rights of ILCs to protect and utilize TK under customary law. Benefit-sharing can include monetary options such as royalties, or licensing of products and process, and non-monetary options such as technology transfer, joint IP rights, and capacity building (GRTK Act 2017, Article 10, 12–13).

A special Environmental Investment Fund was created to receive funds by way of grants, loans, or benefit-sharing contributions to strengthen conservation and sustainable use of biodiversity through the financing of projects led by ILCs relating to GRs or TK (GRTK Act 2017, Article 7). Illegal access to GRs or TK, failure to comply with the terms of access, or unpermitted GRs export are punishable by a fine, and/or a term of imprisonment (GRTK Act 2017, Article 14(1)). Lesser offences such as making false declarations for a permit, or obstruction of an investigation, are punishable by a lesser fine, and/or a shorter term of imprisonment (GRTK Act 2017, Article 14(5)). Where the act occurs as a result of the negligence of directors, members of the board or senior leadership of an organization, all individuals involved are subject to a fine, and/or a term of imprisonment. Namibia further asserts principal jurisdiction to hear cases and apply a judicial remedy regardless of where the offending individual or organization is situated (GRTK Act 2017, Article 21). Courts may also impose a declaration of forfeiture relating to any property, samples, equipment, or documents used in the commission of an offence.

Under Section 3 of the 1996 *Nature Conservation Amendments Act*, people living on communal land, especially ILCs, can apply to the relevant Minister for approval to establish conservancies. The *Promulgation of Forest Act* (2001) (*PMFA*) established the Forestry Council, which is charged with consolidating the framework for management and use of forest resources. The *PMFA* provides for measures relating to community management and use of forest-based biodiversity. Pursuant to Sections 15 and 31 of the *PMFA*, traditional authorities are authorized to designate communal land as a 'Community Forest' and they have statutory rights to establish management plans, appoint a management body, and provide for access via permit and equitable distribution of benefits from forest resources. Through the 2007 interim ABS measure, Namibia laid the administrative groundwork for the empowerment of ILCs through a decentralized approach to ABS and thus positions itself for the eventual ratification of the NP.

Australia

Australia is a federation of six states and two territories each with relative levels of sovereignty under the national government (Prip et al., 2014: 8). It passed the *Environment Protection and Biodiversity Conservation Act* (EPBC Act) in 1999 and the *Environment Protection and Biodiversity Conservation Regulations* (EPBC

Regulations) in 2000 to govern 'Commonwealth areas,' including Commonwealth land, the Australian Territorial Seas, and the Exclusive Economic Zone (EEZ) (EPBC, 1999, Section 525). In 2002, a nationally consistent approach to ABS was endorsed by the Natural Resource Management Ministerial Council (comprising Federal, State and Territory ministers for land and water) (Natural Resource Management Ministerial Council, 2002), with the EPBC Regulations amended in 2005 to include a new Part 8A (EPBC Amendment Regulations 2005). Section 301 of the EPBC Act enables the creation of regulations governing access and utilization of biological resources, including administration of access permits and facilitation of benefit-sharing. Section 528 of the EPBC, defines biological resources to include GRs, organisms or parts thereof, or any biotic component of an ecosystem with perceived or actual value.

Under the EPBC Regulations, access to biological resources is defined to include the taking of native species or any component thereof for R&D. Users are deemed to access a resource where there is a 'reasonable prospect' the resource will be subject to research (EPBC Regulations, Section 8A.03(1)). In sections 8A.07–8A.08, (h–j), 8A.10, 8A.12 of the EPBC regulations, commercial applicants are required to enter into a benefit-sharing agreement with each relevant provider, based on PIC, to obtain a permit for access to GRs or TK. Commercial applicants for access to GRs must obtain written permission from each Access Provider to (a) enter the area, (b) take samples of biological resources and (c) to remove these samples (EPBC Regulations, Section 8A.12(1)). PIC is required for access to GRs on the territories of ILCs in compliance with the *Native Title Act* 1993 (Native Title Act 1993, 24EB), with access to TK treated ostensibly as commercial in nature requiring a declaration of the knowledge obtained, MAT, and a benefit-sharing agreement (EPBC Regulations, Section 8A.08(h–j); Hawke, 2009: para 17.12–14). A model benefit-sharing agreement was developed by Australia in 2012 and includes: (i) a 2 year renewable term, (ii) benefit-sharing strata based on investment thresholds, (iii) a grant of IP rights relating to research with restrictions on transfers of IPRs without a benefit-sharing agreement, (iv) varied consequences for default including termination, reassignment of remuneration rights of third parties for samples back to the Commonwealth, (v) reporting and recordkeeping requirements and (vi) mandatory dispute settlement provisions (Australia, Model BSA 2012, Section, 3.2.1, 3.2.4, 5.1; Schedule 3–4, Section 6.1, 7.1–2, 11–12, 15–17). Nonetheless, the disclosure requirements during the patent process are inadequate to sufficiently protect against misappropriation under the Australian IP system (Australia, Patents Act 1990, Section 40, 43AA).

According to section 8A.15 of the EPBC regulations, authority over GRs of the Commonwealth is centralized at the National Ministry of Environment under the Department of Sustainability, Environment, Water, Population and Communities (SEWPC), which reviews all access permits. A decentralized approach to administration, processing, and monitoring is adopted with specialized governmental divisions and regional organizations empowered to administer access to GRs within

their region or protected area. Organizations such as the Great Barrier Reef Marine Park Authority (GBRMPA), (*Great Barrier Reef Marine Park Act* 1975, Section 6–7; *Great Barrier Reef Marine Park Regulations* 1983, Section 2A.7–2A.8), and the Australian Government Antarctic Division (AGAD) (EPBC Act, Section 197(p)), facilitate access, leveraging specialized technical expertise about the biological resource under their management. In practice, the access provider is often the Genetic Resource Management Section in the Department of Environment on behalf of the Commonwealth.

Resources found outside of 'Commonwealth areas' are subject to the jurisdiction of the relevant State or Territory, with some having developed specialized ABS frameworks. Queensland established the *Biodiscovery Act 2004* which provides a permit scheme for biodiscovery research or commercialization of native biodiversity (*Biodiscovery Act* 2004, Section 3, Schedule Section 5). Applicants wishing to conduct biodiscovery activities on land publicly owned or managed must apply to receive 'collection authority' and include a benefit-sharing agreement and a biodiscovery plan (*Biodiscovery Act* 2004, Section 3, 10–14, 17). Biodiscovery on lands of ILCs, or utilizing TK is omitted from the Act, but supplemented by the Queensland Biotechnology Code of Ethics which provides for negotiation of fair and equitable benefit-sharing where TK of ILCs is utilized (Queensland Biotechnology Code of Ethics, 2014: para 10: Prip et al., 13–14). The Northern Territory of Australia passed the *Biological Resources Act 2006* (NT) to facilitate and regulate bioprospecting activities, implement a framework of benefit-sharing for biological resources, and recognize the 'special knowledge' held by ILCs relating to these resources (Northern Territory of Australia, Biological Resources Act 2006, Section 3). Included under the framework are freehold land, Crown land, Territorial waters, Aboriginal land, Aboriginal community living area, and areas subject to 'Native Title' (Biological Resources Act, Section 6.1). Bioprospecting requires approval by the Territory, including establishing PIC and MAT through a benefit-sharing agreement with each provider (Biological Resources Act, Section 27). Where ILCs are the provider, the CNA must be satisfied that PIC and MAT are established, including a statement detailing the TK obtained and the specific benefits agreed (Biological Resources Act, Section 28–9(1)(h–i), 29(2)).

Empowered under the domestic framework, the Aboriginal and Torres Strait Islander people working with various organizations have developed and published protocols for ABS. One example covers research with Ninti One and highlights that Aboriginal and Torres Strait Islander people may wish to share various aspects of TK under clear terms including: PIC, participation in all stages of R&D, culturally sensitive and transparent partnership, and employment of Aboriginal and Torres Strait Islander people (Ninti One, Engagement Protocol 2012, Section 1–3). Benefit-sharing is established on a per project bases, based on MAT and must respect the IPRs of the community (Ninti One, Engagement Protocol 2012, Section 4–5). Aboriginal and Torres Strait Islander peoples employed in the project are required

to be paid fairly with a set payment schedule adopted for transparency (Ninti One, Engagement Protocol 2012, Section 4.3; Ninti One, Schedule of Rates of Pay 2013). Where TK is accessed in research, specific terms and a knowledge management and protection strategy must be established (Ninti One Engagement Protocol, Section 5.5). Oxfam Australia has also developed a Cultural Protocol with the Aboriginal and Torres Strait Islander peoples aimed at the protection of their cultural and IPRs. Enshrined in the Cultural Protocol are principles of respect, Indigenous control of cultural heritage, PIC, maintenance of the integrity and confidentiality of sacred information and practices, attribution, legal recognition, and equitable sharing of benefits based on MAT (Oxfam Australia, Aboriginal and Torres Strait Islander Cultural Protocols 2013: 1–6). Despite this experience and fairly robust legislative progress, Australia has yet to ratify the NP. The Australian experience illustrates the complexity of establishing an ABS regime within a federal system of a colonial state with a significant population of Indigenous peoples and the need to protect their cultural heritage.

RECOMMENDATIONS FOR INDIGENOUS-SENSITIVE ABS IN CANADA

Experiences from jurisdictions with ABS regimes can assist in establishing a robust ABS framework in Canada. The recommendations offered are drawn from legal approaches adopted in the profiled jurisdictions and contextualized to the Canadian legal landscape to illustrate practical modalities and possible ways forward. These recommendations emphasize the importance of respectful engagement with Indigenous peoples, and are meant to ensure the protection, preservation, and sustainable use of GRs and associated TK in Canada.

Establish an Interim Body

There are sub-national ABS-like schemes governing research activities in the Yukon (Scientists and Explorers Act, 2002), Nunavut, and the Northwest Territories (NWT) (Oguamanam & Koziol, Chapter 7; Scientists Act, 1988; Dylan, Chapter 5). There are national systems regulating collection in national parks and conservation areas (Parks Canada, Research and Collection Permit System), and import, export, or interprovincial transportation of listed endangered species (*Wild Animal and Plant Protection and Regulation of International and Interprovincial Trade Act*, 1992; Wild Animal and Plant Trade Regulations, 1996). However, significant gaps remain regarding an ABS regime (Dylan, Chapter 5; Oguamanam & Koziol, Chapter 7), the adequacy of PIC, the fairness of existing benefit-sharing arrangements, and ability to monitor compliance with both foreign and domestic access terms to effectively prevent misappropriation. Interim approaches were employed in both Brazil and Namibia to provide immediate institutional oversight to prevent

misappropriation while final ABS legislation was being developed. In passing *Provisional Measure n. 2.186–16/2001*, Brazil was pragmatic in recognizing that a long-term ABS solution would require more time and experience. Nonetheless, the empowerment of the CEGN to refine operational modalities in response to identified challenges allowed for the framework to evolve rather than crumble leading to the development of broader legislation and regulations in 2015 and 2016 respectively.

Similarly, Namibia created the interim IBPC to enable ABS development (Nghitila, 2010: 12–14). The IBPC reviewed applications and established private benefit-sharing contracts with bio-prospectors, including The Body Shop for marula oil (Nghitila, 2010: 10). Founded in 2000, the Eudafano Women's Co-Operative (EWC), a collective of over 5,000 women who harvest marula nuts at the household level, provide refined marula products for The Body Shop among others, and has, through the Southern African Natural Products Trade Association, partnered with Aldivia S.A. to jointly own *Maruline* – a patented isolated natural marula compound. PhytoTrade membership supports compliance with fair trade pricing, and fair and equitable benefit-sharing for TK (Schreckenberg, 2003: 22–24; Suthersanen 2014).

Both CEGN and the IBPC continue to play a vital role in the ongoing evolution of ABS in each respective jurisdiction and illustrate how interim measures empower long-term legal and institutional development. The development of a comprehensive ABS system in Canada presently seems elusive. This is a challenge given the increasing vulnerability of the Arctic and Sub-Arctic region and their progressive unravelling (under the weight of climate change) as an unprecedented domain of GRs (Dylan, Chapter 5; Oguamanam & Koziol, Chapter 7). Canada may borrow from Australia and Namibia by considering an interim approach to ABS to prevent misappropriation and contribute to charting informed technical capacity at all levels.

Harmonized National Framework with Decentralized Administration

As a federation, Canada must establish an ABS framework which respects the Constitutional separation of powers. Australia established a comprehensive ABS system which governs Commonwealth territory and a significant portion of marine and terrestrial ecosystems and passed a harmonized framework with the respective states and territories (Australia 2002; Australia 2005; EPBC 1999, Section 525). While divergence remains at the state level in Australia, common substantive pillars allow for a nationally harmonized approach to the extent possible to succeed in a Federal system (see Chapter 7). A decentralized governance approach is utilized, with regional or specialized institutions empowered to process permit applications based on their technical expertise regarding the biodiversity under the purview of the organization involved (Australia EPBC Act, Section 197(p); Great Barrier Reef Marine Park Act, 1975). Indigenous communities such as the Aboriginal and Torres Strait Islander people constitute a third tier within the Australian ABS regime. They are empowered to grant access to their GRs and TK through the establishment of

PIC and MAT with oversight provided by the CNA to ensure equity (EPBC Regulation, Section 8A.08(h–j)). Should Australia accede to the NP, Indigenous communities could be further entrenching their capacity as localized CNA based on self-assessment of needs (Oguamanam & Hunka, Chapter 3) and their increased experience and strength of governance.

Namibia, as well, provides for localized governance of GRs and TK by ILCs through conservancies under a national framework. A harmonized national approach with decentralized administration allows for the utilization of localized or region-specific technical knowledge in the negotiation of MAT. Empowerment of ILCs to govern access gives deference to the community, allows for a denial of access due to cultural concerns, and reinforces self-governance. Broader consideration should be given to localized governance allowing, for example, Indigenous peoples to constitute their own focal points and CNA on access to their traditional GRs and TK in accordance with their culturally rooted protocols and practices (ABS Canada 2015, 2016, 2017).

Deferential Permit Types

The determination of a single versus multi-permit approach has important implications on the ABS efficiency. Australia has a two-permit system with a less onerous track for research activities, and a more onerous review for commercially-focused bioprospecting (EPBC Regulations, Section 8A.03(1)). All access to TK is practically treated as commercial in nature requiring the establishment of PIC and MAT with ILCs (EPBC Regulations, Section 8A.08(h–j)). Benefit-sharing based on investment strata and 2-year review cycles provide responsiveness to changes in intent (Model BSA, Section, 3.2.1, 3.2.4, 5.1; Schedule 3–4, Section 6.1, 7.1–2, 11–12, 15–17). In contrast, Brazil has a single registration system, aiming to reduce administrative hurdles to bioprospecting (Law No. 13123, Article 12; Decree 8,772, Article 20). The focus is on encouraging biodiscovery rather than providing an overly cumbersome institutional review in the early stages of research. Through restricting the conduct of biodiscovery activities to nationals and extending liability across the value chain, the registration system found in Brazil intends to foster both research and compliance. Given Canada's robust and unravelling biodiversity, a simplified access procedure for strictly non-commercial research conducted by nationals would be beneficial to incentivize biodiscovery (as in the example of the James Bay Cree and the antidiabetic health research team provided by Oguamanam & Koziol, Chapter 7). In the Canadian context, participation in any simplified procedure would still need to pass an Indigenous confidence threshold as most researchers are non-Indigenous (Bannister, Chapter 12; Oguamanam, Chapter 11). Access to TK, commercial access to GRs, or research access by foreigners should require the establishment of PIC and MAT along with robust iterative oversight to monitor compliance and transformations from non-commercial to commercial applications or utilizations.

Administration of Benefit-Sharing through a National Fund

Creation of a fund to facilitate collection and dissemination of monetary benefit-sharing to support conservation and sustainable use of biodiversity, or to support dispersal of benefits broadly to ILCs in the case of transboundary, trans-jurisdictional, or trans-community GRs and TK provides flexible modalities to support systemic equity. Brazil utilizes the National Fund for Benefit-sharing (FNRB) to administer benefit-sharing. Namibia uses the Environmental Investment Fund to receive benefit-sharing contributions among other income streams for use in supporting projects relating to the conservation and sustainable use of GRs and TK which are directed by ILCs. Both of these approaches mimic the ITPGRA's multilateral system discussed above. Utilization of a specialized fund in each jurisdiction illustrates the importance of integrating flexible mechanisms to support administration, oversight, and governance of benefit-sharing. Broadening potential benefit-sharing income streams outside of simply a percentage of IPR royalty to include grants, loans, and voluntary payments, as seen in Namibia, enhances the potential scope and scale of conservation and sustainable use programs. Use of a similar approach could provide Canada a practical modality to address transboundary or broadly held TK and GRs (Oguamanam & Jain, 2017) as well as facilitating dissemination of benefit-sharing across Indigenous nations.

Recognition and Protection of the Collective Rights of ILCs Over TK

Rights over TK, as enshrined in Article 31 of UNDRIP, require adequate domestic protections, with rights often recognized to be both individual and collective in nature. Brazil classifies TK as collective in nature, with PIC required where there is an identifiable holder, and benefit-sharing flowing both individually and collectively through the FNRB – the domestic benefit-sharing fund. The CNA leverages a TK database to chronicle forms and holders of TK to preserve the characteristics, and protect rights of ILCs (Law No. 13123, Article 8, 10). Namibia explicitly recognizes the collective and inalienable rights of ILCs relating to TK, provides protections under both the ABS and IP systems, and outlines a range of both monetary and non-monetary benefit-sharing options (GRTK Act 2017, Article 5(1–3), 10, 12–13).

A broad group of jurisdictions can also be identified which have integrated disclosure measures as a safeguard against misappropriation including, regionally, the Andean Community and the African Union; and, nationally, in Belgium, Bolivia, Brazil, China, Costa Rica, Cuba, Denmark, Ecuador, Egypt, the EU, Germany, India, Italy, Kyrgyzstan, Norway, Panama, Peru, Philippines, Romania, Samoa, South Africa, Sweden, Switzerland, Vanuatu and Vietnam (Henninger, in Werth & Reyes-Knoche, eds, 2010: 293–8; WIPO, Table 2016). Disclosure of the country of origin of the biological material, and increasingly TK, used in a patent at the time of applications is becoming more widely used (UNCTAD, 2014: 49–51).

Although a contentious subject, this requirement, as indicated above, features in the WIPO-IGC Draft Articles on TK and is provided as an option in the Consolidated Document on GR and IP. Unfortunately, Canada has consistently opposed these disclosure obligations in international negotiations. Innovators in Canada would gain enhanced legal certainty from the establishment of checkpoints in line with evolving international practice integrating disclosure of origin in patent applications and requiring proof of compliance with country of origin ABS legislation (Hodges & Langford, Chapter 2; Oguamanam, Chapter 14). Although there is no consensus among Indigenous peoples on the subject, development of a TK database under the care and control of Indigenous peoples of Canada could further strengthen their interests in ABS and equitable control of their TK, GRs and cultural heritage.

CONCLUSION

In its highly limited practice, the Canadian approach to ABS is lagging behind international norms, creating an environment of legal uncertainty, and providing inadequate protections for the rights of Indigenous peoples of Canada (Oguamanam & Koziol, Chapter 7; Oguamanam & Phillips, 2015). Jurisdictions such as Brazil, Namibia and Australia provide useful approaches to inform ABS practices in Canada. Establishment of an interim body to evaluate access applications, review access terms, and prevent misappropriation is a worthy prerequisite. Harmonizing the ABS framework across Canada while balancing jurisdictional powers – Federal, Provincial, Territorial and Indigenous – will be a time consuming but important long-term initiative. Under this emerging framework, differentiated permit types and ongoing review to monitor changes in intent from research to commercialization are important.

Utilization of a specialized benefit-sharing fund provides a flexible mechanism to support conservation and sustainable use by Indigenous nations broadly and dissemination of benefit-sharing for transboundary or widely held TK. Finally, recognition and protection of rights of ILCs as they relate to TK, including refinement of patent disclosure standards, and development of Indigenous controlled TK databases, is vital to prevent erosion or misappropriation of GRs and associated TK. Active progress should be made on acceding to the NP in Canada to bring the domestic approach in line with international norms, including procedural mechanisms for the establishment of PIC and MAT, integration of a formal disclosure of origin requirement in patent applications relating to GRs or TK, and a supplemental due diligence requirement on users. Integration of ABS in Canada provides an area of opportunity to overcome previous missteps in Crown-Indigenous relations, establish a framework which practically balances innovation with equity, and provides functional modalities for the sustainable development of Indigenous peoples of Canada (Oguamanam, Chapter 14). Urgent action is needed, and the experiences distilled from other jurisdictions provide useful insights into the modalities for phased implementation of ABS in Canada prior to its formal accession to the NP.

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