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Book

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Centre for International
Governance Innovation

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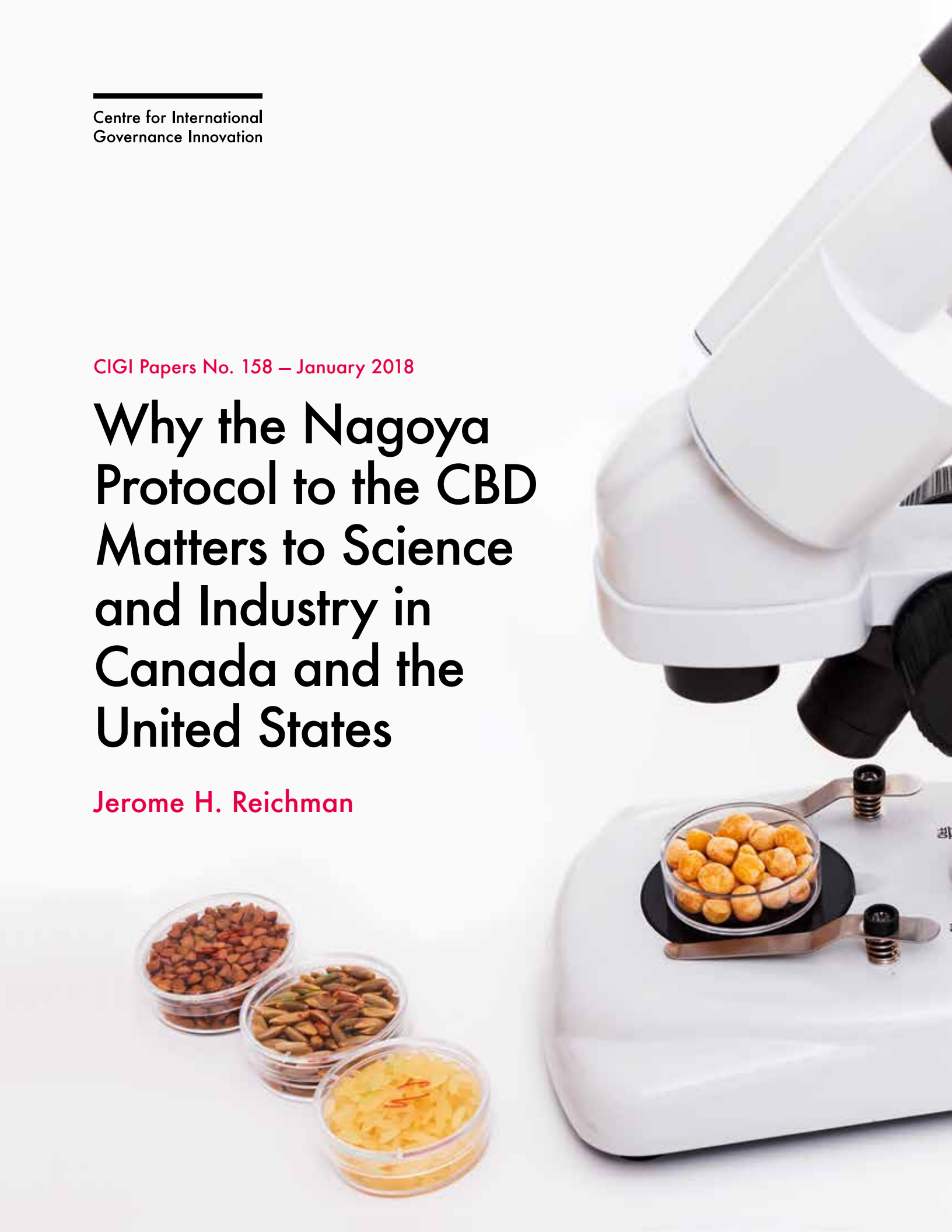

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About the Author

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Jerome is a graduate of the University of Chicago and of Yale Law School. He worked for the United Nations in Geneva in the 1970s and then taught at Ohio State and Vanderbilt universities. He has taught at Duke for the past 17 years. He is consultant to numerous intergovernmental and non-governmental organizations and a member of the board of editors for the *Journal of International Economic Law* and of the Scientific Advisory Board of *Il Diritto di Autore* (Rome).

In collaboration with Keith Maskus, Jerome published *International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime* with Cambridge University Press in 2005. Jerome's most recent books are *Governing Digitally Integrated Genetic Resources, Data and Literature: Global Intellectual Property Strategies for a Redesigned Microbial Research Commons*, co-authored with Tom Dedeurwaerdere and Paul Uhlir (Cambridge University Press, 2016) and *The World Blind Union Guide to the Marrakesh Treaty*, co-authored with Laurence Helfer, Molly Land and Ruth Okediji (Oxford University Press, 2017).

Among his most recent journal publications are "Intellectual Property in the Twenty-First Century: Will the Developing Countries Lead or Follow?" (2009); "Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options" (2009); "Rethinking the Role of Clinical Trial Data in International Intellectual Property Law: The Case for a Public Goods Approach" (2009); "Harmonization Without Consensus: Critical Reflections on Drafting a Substantive Patent Law Treaty" (2007) (co-authored with Rochelle Dreyfuss); and "The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions" (2007) (co-authored with Frederick Abbott).

About the International Law Research Program

The International Law Research Program (ILRP) at CIGI is an integrated multidisciplinary research program that provides leading academics, government and private sector legal experts, as well as students from Canada and abroad, with the opportunity to contribute to advancements in international law.

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Acronyms and Abbreviations

ABS	access and benefit sharing
ATCC	American Type Culture Collection
CBD	Convention on Biological Diversity
CGIAR	Consultative Group on International Agricultural Research
COMPARE	Collaborative Management Platform for Detection and Analysis of (Re-)emerging and Foodborne Outbreaks in Europe
FAO	Food and Agriculture Organization
GBRCN	Global Biological Resource Centre Network
IARCs	International Agricultural Research Centres
IP	intellectual property
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
IUCN	International Union for Conservation of Nature and Natural Resources
MAT	mutually agreed terms
MIRRI	Microbial Resource Research Infrastructure
PIC	prior informed consent
PIP	Pandemic Influenza Preparedness
SMTAs	standard material transfer agreements
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
WDCM	World Data Centre for Microorganisms
WFCC	World Federation for Culture Collections
WHO	World Health Organization
WTO	World Trade Organization

Executive Summary

Transnational exchanges of plant, microbial and animal genetic resources are essential for scientific and agricultural research as well as for downstream commercial applications in many important fields, including food security and medicines.

Exports of *in situ* plant cultivars and microbial specimens discovered through bioprospecting require the permission of provider governments under the Convention on Biological Diversity (CBD) of 1992, with specific regard to prior informed consent (PIC), mutually agreed terms (MAT) and access and benefit-sharing (ABS) agreements. *Ex situ* plant cultivars for both research and applications are available from seed banks governed by the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA, 2001), subject to benefit-sharing obligations imposed on commercial applications by standard material transfer agreements (SMTAs). Similarly, *ex situ* microbial specimens are made available for research and applications from public repositories governed by the World Federation for Culture Collections (WFCC) under SMTAs consistent with the CBD. In all cases, the use of traditional knowledge associated with genetic resources requires the permission of relevant Indigenous populations, including PIC, MAT and ABS.

The Nagoya Protocol to the CBD (2010), entered into force in 2014, further requires all member countries to cooperate in cross-border enforcement of the CBD's provisions. Under the protocol, end products based on or derived from genetic resources, including genomic sequence data, will become subject to seizure by national checkpoints unless they comply with the CBD. Compliance certificates will be made available for this purpose by a clearing house to be established under the protocol.

With specific regard to science policy, article 4 of the Nagoya Protocol expressly validates multilateral regimes of facilitated access to *ex situ* genetic resources for both basic and applied research, subject to built-in "take-and-pay" rules for commercial applications. The ITPGRFA was thus rendered legally consistent with the CBD by dint of the Nagoya Protocol.

The WFCC has developed SMTAs to cover its activities as "trusted intermediaries." However, it should consider reorganizing itself as an international regime for facilitated exchanges of *ex situ* microbial materials, with a built-in take-and-pay rule for commercial applications. Such a redesigned Microbial Research Commons should adopt a science-friendly governance structure that improves upon the scheme implemented by the United Nations Food and Agriculture Organization's (FAO's) ITPGRFA, and it should also incorporate the World Data Centre for Microorganisms (WDCM), currently situated in China.

The Propertization of Plant, Microbial and Animal Genetic Resources

Transnational exchanges of plant, microbial and animal genetic resources, together with traditional knowledge concerning their uses by Indigenous communities, have always been essential components of human survival and economic stability.[1] As Evanson Chege Kamau succinctly framed it, "No country is self-sufficient: all depend on crops and genetic diversity within these crops from other countries and regions."[2]

Throughout the nineteenth and early twentieth centuries, bioprospectors could freely explore biodiversity-rich environments, often located in colonies governed by the economic powers of the day, in order to discover and isolate *in situ* genetic resources of potential interest to their respective

1 See e.g. Kevin McCluskey et al, "The U.S. Culture Collection Network Responding to the Requirements of the Nagoya Protocol on Access and Benefit Sharing" (2017) 8:4 mBio 1 (stating that "access to living resources has been foundational to research, health care, agriculture, and industry since the beginning of modern biology" at 2); Christine Godt, "Networks of *ex situ* collections of genetic resources" in Evanson Chege Kamau & Gerd Winter, eds, *Common Pools of Genetic Resources: Equity and Innovation in International Biodiversity Law* (London, UK: Routledge, 2013), 246 [*Common Pools of Genetic Resources*]. See also National Research Council, *A New Biology for the 21st Century* (Washington, DC: National Academies Press, 2009), emphasizing the fundamental importance of microbiology in a New Biology paradigm.

2 Evanson Chege Kamau, "The multilateral system of the International Treaty on Plant Genetic Resources for Food and Agriculture: lessons and room for further development" in *Common Pools of Genetic Resources*, *supra* note 1 at 343, n 1.

scientific, agricultural or industrial endeavours.[3] Once scientifically validated, particularly important exemplars of these *in situ* genetic resources were often deposited in *ex situ* public repositories, such as the agricultural seed banks managed by the Consultative Group on International Agricultural Research (CGIAR)[4] and — for microbial specimens — the WFCC.[5] Operating as basic components of the global scientific infrastructure, these repositories provided both public and private users with *ex situ* genetic resources, normally (but not uniformly) at the marginal cost of distribution, as befitted their status as global public goods.[6]

The once-customary view that genetic resources, together with associated traditional knowledge, constituted the "common heritage of mankind"[7] was first directly challenged in 1962, when the United Nations adopted a declaration on the sovereignty of states over natural resources.[8] By the 1990s, when the most-developed countries were demanding universal respect for patented microbes and plant breeders' rights under what eventually became the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) of 1994,[9] the developing countries struck back with "biopiracy" claims of their own. Specifically, they argued that the downstream innovations protected by intellectual property (IP) rights in the Global North were often based on genetic resources taken from the biodiversity-rich countries, along with associated traditional knowledge of Indigenous populations. From this perspective, unauthorized use of these same genetic resources and traditional knowledge, even for public research purposes, constituted an illegal encroachment on their territorial sovereignty.[10] In 1992, that thesis became firmly established in the CBD, now signed by some 190 countries.[11] The United States is also a signatory, but Congress has never ratified this treaty.[12]

The professed goal of harmonized IP rights under the TRIPS Agreement was to stimulate higher levels of investment in innovation generally. This initiative responded to opportunities generated by an increasingly integrated global marketplace, in which commercial transfers of technology could occur without territorial governments imposing

3 See generally Jerome H Reichman, Paul F Uhlir & Tom Dedeurwaerdere, *Governing Digitally Integrated Genetic Resources, Data, and Literature: Global Intellectual Property Strategies for a Redesigned Microbial Research Commons* (New York: Cambridge University Press, 2016) ch 2, s 1 ("Historical Importance of Genetic Resources as Global Public Goods").

4 CGIAR, "Crop Genebank Knowledge Base", online: <http://cropgenebank.sgrp.cgiar.org>. See e.g. Michael Halewood, "Governing the management and use of pooled microbial genetic resources: Lessons from the global crop commons" (2010) 4:1 Intl J Commons 404. See generally Reichman, Uhlir & Dedeurwaerdere, *supra* note 3 at 46–50, 112–15, 121–30 (explaining the role of the CGIAR under the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) of 2001).

5 WFCC, "About WFCC", online: <www.wfcc.info/about/>. See e.g. David Smith, Dagmar Fritze & Erko Stackebrandt, "Public Service Collections and Biological Resource Centers of Microorganisms" in Eugene Rosenberg et al, eds, *The Prokaryotes: Prokaryotic Biology and Symbionic Associations* (Berlin: Springer, 2013) 267.

6 See generally Reichman, Uhlir & Dedeurwaerdere, *supra* note 3, ch 2 at 37–82 ("Between Private and Public Goods: Emergence of the Transnational Research Commons for Plant and Microbial Genetic Resources"). One of the world's major suppliers of *ex situ* genetic resources, the American Type Culture Collection (ATCC), has operated on a commercial basis since losing US government funding in the 1960s. See ATCC, "About ATCC" [ATCC], online: <www.atcc.org/en/About/About_ATCC.aspx>.

7 See *International Undertaking on Plant Genetic Resources*, UNFAO Res 8/83, 22nd Sess (5–23 November 1983). See also Reichman, Uhlir & Dedeurwaerdere, *supra* note 3 at 50–52 ("Short-Lived Recognition of Plant Genetic Resources as the Common Heritage of Mankind").

8 See *Permanent Sovereignty Over Natural Resources*, GA Res 1803 (XVII), UNGAOR UN Doc A/RES/1803 (1962) [1962 Declaration]. For a skeptical view of claims to *ex situ* genetic resources, based on a misunderstood interpretation of the "common heritage" principle, see Jonathan Curci, *The Protection of Biodiversity and Traditional Knowledge in International Law of Intellectual Property* (Cambridge, UK: Cambridge University Press, 2010) at 9. See also Graham Dutfield, *Intellectual Property, Biogenetic Resources and Traditional Knowledge*, 2nd ed (Abingdon, UK: Earthscan, 2004) at 5–6. For the demise of the common heritage principle and its implications, for plant genetic resources in particular, see Reichman, Uhlir & Dedeurwaerdere, *supra* note 3, ch 2, ss I.B, III.A.

9 *Agreement on Trade-Related Aspects of Intellectual Property Rights*, 15 April 1994, 108 Stat 4809, 1869 UNTS 299 art 27 [*TRIPS Agreement*]; *International Convention for the Protection of New Varieties of Plants*, 2 December 1961, 33 UST 2703, 815 UNTS 89 (as subsequently amended) 1978 and 1991. See e.g. Julianna Santilli, *Agrobiodiversity and the Law: Regulating Genetic Resources, Food Security and Cultural Diversity* (Abingdon, UK: Earthscan, 2012). Plant variety protection systems covered new plant varieties that are distinct, uniform and stable for a limited period of time, initially on a copyright-like model, eventually on a patent-like model. See JH Reichman, "Legal Hybrids Between the Patent and Copyright Paradigms" (1994) 94 Colum L Rev 2432 at 2465–72.

10 See e.g. Burton Ong, "Harnessing the Biological Bounty of Nature: Mapping the Wilderness of Legal, Socio-Cultural, Geo-Political and Environmental Issues" in Burton Ong, ed, *Intellectual Property and Biological Resources: Perspectives on contemporary issues* (Singapore: Marshall Cavendish Academic, 2004) at 1, 3–4, 18. See also Sarah A Laird, ed, *Biodiversity and Traditional Knowledge: Equitable Partnerships in Practice* (London, UK: Earthscan: 2002).

11 *Convention on Biological Diversity*, 5 June 1992, 1760 UNTS 79, 31 ILM 818 (entered into force 29 December 1993) [*CBD*], online: <www.cbd.int/convention/text>.

12 US Department of State, "Treaties Pending in the Senate (updated as of May 8, 2017)", online: <www.state.gov/s/l/treaty/pending/>.

protectionist trade barriers.[13] The professed aim of the CBD was to support the conservation of genetic resources by provider countries, especially the developing countries, and to reward their Indigenous populations whose traditional knowledge may have informed commercial applications of those same genetic resources.[14]

In effect, the CBD imposed territorial sovereignty on all genetic resources, as well as related traditional knowledge, and it conditioned the rights of anyone — including research scientists — to remove or otherwise use such resources on the permission of the relevant government authorities.[15] Key implementing provisions are found in articles 15 and 16. Article 15(2) establishes the authority of national governments to regulate access to genetic resources under domestic legislation.[16] Access, where granted, shall be on terms that are mutually agreed,[17] subject to PIC,[18] with fair and equitable sharing of benefits arising from research and development.[19] Traditional knowledge of Indigenous communities is expressly included within these same ABS obligations.[20]

In principle, developing-country providers of genetic resources should also obtain access to — and transfer of — technology that makes use of their genetic resources, "including technology protected by patents and other intellectual property rights, on mutually agreed terms."[21] Also included in this scheme are permissions for publications or transfers of genetic information based on relevant genetic resources and the duty to share benefits from commercial uses of *ex situ* specimen collections.[22] A multilateral benefit-sharing fund should also be established by the COP for purposes of managing both mandatory and voluntary contributions.[23]

Taken together, these provisions of the CBD established the premises for an international regime of misappropriation with respect to unauthorized uses of genetic resources — plant, microbial, animal — and all related traditional knowledge originating from the territories of nation-states adhering to the CBD.[24] Under what may be deemed the "bilateral approach," research scientists in Occitania who want to study plant or microbial genetic resources originating from Ruritania must negotiate first with the Ruritanian government (PIC); sign an agreement with the designated national authority; obtain legitimate access to the specimens; and agree to the conditions under which any commercial gains from the research results will be shared with the provider country ("on fair and equitable terms").[25]

However, as reasonable as these arrangements may sound, they are in practice onerous and often unworkable from the scientific researchers' perspective. In the first place, provider countries have been slow to enact implementing legislation, and, once enacted, these laws tend to be diverse and complicated, and often full of both legal and practical uncertainties.[26] Second, there is no consensus regarding ABS obligations applicable to genetic resources acquired before 1993, when the

13 See e.g. Keith E Maskus, *Private Rights and Public Problems: The Global Economics of Intellectual Property in the 21st Century*, 2nd ed (Washington, DC: Peterson Institute for International Economics, 2012); Peter K Yu, "The International Enclosure Movement" (2007) 82 Ind LJ 827; JH Reichman, "Universal Minimum Standards of Intellectual Property Protection Under the TRIPS Component of the WTO Agreement" (1998) 29 Intl Lawyer 345, online: <http://scholarship.law.duke.edu/faculty_scholarship/687>.

14 See e.g. Evanson C Kamau & Gerd Winter, eds, *Genetic Resources, Traditional Knowledge & the Law: Solutions for Access & Benefit Sharing* (London, UK: Earthscan, 2009); Regine Andersen, *Governing Agrobiodiversity: Plant Genetics and Developing Countries* (Farnham, UK: Ashgate, 2008); Charles McManis, ed, *Biodiversity & the Law: Intellectual Property, Biotechnology & Traditional Knowledge* (London, UK: Earthscan, 2007); Dutfield, *supra* note 8.

15 See *CBD*, *supra* note 11, arts 2, 8, 15–16, 19–20.

16 *Ibid*, art 15(2).

17 *Ibid*, art 15(4).

18 *Ibid*, art 15(5).

19 *Ibid*, art 15(7).

20 *Ibid*, art 8(j).

21 *Ibid*, art 16(3).

22 See e.g. Tomme Young et al, "Analysis of Claims of 'Unauthorized Access and Misappropriation of Genetic Resources and Associated Traditional Knowledge'" in Tomme Young, ed, *Governing ABS: Addressing the Need for Sectoral, Geographical, Legal, and International Integration in the ABS Regime* (Gland, Switzerland: International Union for the Conservation of Nature and Natural Resources [IUCN], 2009) 97 at 117. See also Reichman, Uhlir & Dedeurwaerdere, *supra* note 3 at 91–99.

23 See *CBD*, *supra* note 11, arts 20–21.

24 See e.g. Young et al, *supra* note 22 at 98–116.

25 See also Reichman, Uhlir & Dedeurwaerdere, *supra* note 3 at 91–96 (citing authorities).

26 See e.g. Margo A Bagley & Arti K Rai, *The Nagoya Protocol and Synthetic Biology: A Look at the Potential Impacts* (Washington, DC: Woodrow Wilson International Center for Scholars, 2013) at 16–17, online: <www.synbioproject.org/site/assets/files/1276/nagoya_final.pdf>. See also Darrell A Posey & Graham Dutfield, *Beyond Intellectual Property: Toward Traditional Resource Rights for Indigenous Peoples and Global Communities* (Ottawa: International Development Research Centre, 1996) at 147–53 (stressing the need for overseas collectors to fulfill conditions acceptable to local providers of biological resources before access is granted, as well as the rights of local communities to veto commercial applications and to share the benefits when they agree to commercialization).

CBD took effect.[27] This same problem resurfaced with the adoption of the Nagoya Protocol to the CBD in 2010,[28] as discussed below.[29]

Still another complicating factor is that some countries, such as Canada and the United States, are both providers and users of genetic resources covered by the CBD.[30] Moreover, even a country that does not typically provide *in situ* genetic resources or related traditional knowledge may nonetheless be the place where major providers of *ex situ* genetic resources are located, as occurs with the ATCC in the United States.[31]

Disregarding these and other technical legal issues, the *ex ante* negotiations obligatory under the CBD are ill-suited to the needs of early-stage scientific research, for the following reasons.

- They entail very high transaction costs and other technical and administrative barriers to research.
- *In situ* resources are intrinsically of uncertain value until later scientific work is done to validate them and evaluate potential applications.
- National authorities in developing countries tend to cling to their *in situ* genetic resources and thereby impose very restrictive conditions that sometimes make it difficult for their own scientists, let alone foreign researchers, to obtain *in situ* (or even *ex situ*) specimens from seed banks or culture collections.[32]

In short, under the bilateral or case-by-case approach, each party tends to overvalue or undervalue the potential worth of any given specimen, before value-adding research has been undertaken. This tendency impedes research and threatens to limit not only research outputs but also the development of medicines and agricultural or other end products in the first place, resulting in fewer benefits to share for everybody.[33]

Faced with these obstacles, scientists depend increasingly on access to *ex situ* plant and microbial genetic resources made available from agricultural seed banks and microbial culture collections around the world,[34] as well as on deposits of genomic data in publicly available repositories.[35] Once identified and validated by experts, these *ex situ* genetic resources are made freely available for public and private research under SMTAs that typically attempt to distinguish between commercial and non-commercial research.[36]

From an international legal perspective, however, a big question left on the table after 1993 was whether these time-honoured scientific research practices remained valid under the CBD. In other words, were the *ex situ* public seed banks and microbial culture collections legally operational under the CBD after 1992 — or were they persistent violators that distributed misappropriated genetic materials in violation of international law?

27 See e.g. Bagley & Rai, *supra* note 26 at 17–20; see further Thomas Greiber et al, *An Explanatory Guide to the Nagoya Protocol on Access and Benefit-sharing* (IUCN Environmental Policy and Law Paper No 83) (Gland, Switzerland & Bonn, Germany: IUCN & IUCN Environmental Law Centre, 2012) at 72–73.

28 *2010 Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the 1992 Convention on Biological Diversity*, 29 October 2010 (Montreal: Secretariat of the Convention on Biological Diversity, 2011) (entered into force 12 October 2014) [Nagoya Protocol], online: <www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf>. See also *Report of the Sixth Meeting of the Conference of the Parties to the Convention on Biological Diversity*, The Hague, 7–19 April 2002, UN Doc UNEP/CBD/COP/6/20 (27 May 2002) at Annex 2, online: <www.cbd.int/doc/meetings/cop/cop-06/official/cop-06-20-en.pdf>; *Bonn Guidelines on Access to Genetic Resources and Equitable Sharing of the Benefits Arising out of their Utilization* (Montreal: Secretariat of the Convention on Biological Diversity, 2002), online: <www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf>.

29 See below notes 59–82 and accompanying text.

30 See e.g. Chidi Oguamanam, "Genetic Resources & Access and Benefit Sharing: Policies, Prospects and Opportunities for Canada after Nagoya" (2011) 22:2 J Envtl L & Prac 87 at 108–11; see also ATCC, *supra* note 6.

31 See ATCC, *supra* note 6. See further Reichman, Uhlir & Dedeurwaerdere, *supra* note 3, ch 4 ("The Existing Microbial Research Commons Confronts Proprietary Obstacles").

32 Cf Reichman, Uhlir & Dedeurwaerdere, *supra* note 3, at 100–106 ("The Threat to Public Scientific Research on Plant and Microbial Genetic Resources").

33 See *ibid* at 106–10 ("Major Weaknesses of the 'Bilateral Approach'"), 250–56.

34 See *ibid* at 111–18; see also Sarah A Laird & Rachel P Wynberg (with contributions from Arash Iranzadeh & Anna Sliva Kooser), "The Emergence and Growth of Digital Sequence Information in Research and Development: Implications for the Conservation and Sustainable Use of Biodiversity, and Fair and Equitable Benefit Sharing" (9 November 2017) Secretariat of the Convention on Biological Diversity Fact-Finding and Scoping Study, online: <www.researchgate.net/publication/321005788_The_Emergence_and_Growth_of_Digital_Sequence_Information_in_Research_and_Development_Implications_for_the_conservation_and_sustainable_use_of_biodiversity_and_fair_and_equitable_benefit_sharing>.

35 See Reichman, Uhlir & Dedeurwaerdere, *supra* note 3, ch 8 ("Fully Exploiting Data-Intensive Research Opportunities in the Networked Environment").

36 *Ibid*, ch 4 at 170–98 (citing authorities). But see *ibid*, ch 4 at 199–209 ("Contractual Restrictions on Access to and Use of Upstream Microbial Genetic Resources in Both Developed and Developing Countries"), 210–30 ("The Research Community Pushes Back").

The Legal Status of *Ex Situ* Plant and Microbial Transactions after the Nagoya Protocol (2010)

The primary value of public seed banks and microbial culture collections is to serve as inputs to basic research, with unknown outcomes, including eventual commercial applications.[37] Nevertheless, it was clear from the outset that public scientific repositories would have to comply with the CBD,[38] given that the CBD itself failed to acknowledge the importance of exempting basic scientific infrastructure. The task of conforming the operations of these *ex situ* collections to the ABS obligations of the CBD was, however, greatly complicated by the failure of the CBD to specify how its multilateral regime of misappropriation was to be enforced in practice.

The immediate result of this tension and uncertainty was a crisis for the agricultural and microbiological research communities with regard to access to both *ex situ* plant and microbial genetic resources. The very legality of the public seed banks, indispensable for agricultural science, and of the culture collections, indispensable for microbiology, was called into question, while the CGIAR was reportedly on the verge of collapse.[39]

In the late 1990s, the FAO responded to this emergency by sponsoring an international treaty to rescue and legitimatize the CGIAR's public seed banks for plant cultivars. A primary objective was to legally establish the seed banks as an international entity operating under the auspices of a multilateral treaty of facilitated access that would authorize them to continue exchanging *ex situ* plant cultivars for research and breeding purposes. This project gave rise to the ITPGRFA of 2001,[40] which for the sake of convenience we may call the "crop commons."[41]

The ITPGRFA, which is administered by the FAO, promotes the conservation of plant genetic resources for food and agriculture and the equitable sharing of benefits from the use thereof for sustainable agriculture and food security.[42] In so doing, the treaty also established a built-in benefit-sharing regime for users of *ex situ* plant cultivars accessed from the CGIAR's seed banks.[43] Under this regime, would-be commercial users were subject to a liability rule, that is, a take-and-pay rule, embodied in the treaty and enforced by SMTAs. Commercial plant breeders who wished to take cultivars from the crop commons were required in principle to pay a small royalty on sales of downstream applications to the benefit-sharing fund of the multilateral system, but they were not obliged to negotiate directly with provider governments.[44]

Moreover, the ITPGRFA forbids users to take IP rights on *ex situ* plant cultivars in the form

37 See e.g. David Smith, "Culture Collections" (2012) 79 Advances in Applied Microbiology 73 at 75–76; Cletus Kurtzman, "The Agricultural Research Service Culture Collection: Germplasm Accessions and Research Programs" in Paul F Uhlir, ed, *Designing the Microbial Research Commons: Proceedings of an International Symposium* (Washington, DC: National Academies Press, 2011) 55; Derek Byerlee & HJ Dubin, "Crop Improvement in the CGIAR as a Global Success Story of Open Access and International Collaboration" (2010) 4:1 Intl J Commons 452 at 456–57.

38 See e.g. WFCC, "Information Document on Access to ex-situ Microbial Genetic Resources within the Framework of the Convention on Biological Diversity" (1996) (background document submitted to the UNEP/PBD/COP/3/Inf.19), online: <www.wfcc.info/index.php/wfcc_library/genetic_res/>; see also EC, *Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union (text with EEA relevance)*, [2014] OJ, L 150/59 [EU Regulation 511/2014].

39 Reichman, Uhlir & Dedeurwaerdere, *supra* note 3, ch 3 at 111–17 ("Destabilizing the Exchange of Plant and Microbial Genetic Resources as Global Public Goods").

40 *International Treaty on Plant Genetic Resources for Food and Agriculture*, 3 November 2001, 2400 UNTS 303 (entered into force 29 June 2004) [*ITPGRFA*].

41 See e.g. Laurence R Helfer, "Comment II: Using Intellectual Property Rights to Preserve the Global Genetic Commons: The International Treaty on Plant Genetic Resources for Food and Agriculture" in Keith E Maskus & Jerome H Reichman, eds, *International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime* (Cambridge, UK: Cambridge University Press, 2005) 217 at 217–19.

42 *ITPGRFA*, *supra* note 40, arts 5–6. For specific crops covered so far, see Annex I.

43 *ITPGRFA*, *supra* note 40, arts 10–15. The treaty also envisioned that *in situ* plant genetic resources residing in the public domain of provider countries would also be placed under the multilateral regime, but these provisions have so far not been implemented. See *ibid*, arts 4, 7. For further details about ITPGRFA see Reichman, Uhlir & Dedeurwaerdere, *supra* note 3 at 119–130. For the SMTAs, see *ibid*, ch 3 at 125–29.

44 *ITPGRFA*, *supra* note 40, arts 10–15. See further Daniele Manzella, "The design and mechanics of the multilateral system of access and benefit sharing" in Michael Halewood, Isabel López Noriega & Selim Louafi, eds, *Crop Genetic Resources as a Global Commons: Challenges in International Law and Governance* (Abingdon, UK: Earthscan, 2013), 150 at 156 [*Crop Genetic Resources*]; Santilli, *supra* note 9 at 143.

received from the multilateral system.[45] Users can, however, protect downstream applications of plant cultivars received from the system, subject to the payment of a small royalty to the benefit-sharing fund from sales of end products. The Governing Body (composed of member governments) was established to manage this international regime, and the FAO itself volunteered to enforce its SMTAs and related decisions when needed.[46]

However, the strengths of the ITPGRFA were partly offset by a number of weaknesses.[47] For example, the take-and-pay rule could be waived if the commercial users agreed to allow a broad research exemption for further uses of any new plant varieties subsequently developed and protected either by patents or plant breeders' rights.[48] But why should commercial users of genetic resources be allowed to waive benefit-sharing royalties when the whole purpose of a multilateral regime was to support research and applications? One would have expected a multilateral regime to provide *both* a research exemption for science *and* a reasonable royalty under the take-and-pay regime to support the costs of the multilateral system, if nothing else.

Furthermore, the ITPGRFA expressly disavowed any tracking requirements for plant cultivars (unlike the public microbial culture collections).[49] Still another notable defect is that the Governing Body consists entirely of government appointees, with little voice and no voting rights for the relevant scientific and Indigenous communities.[50]

Notwithstanding these and other flaws in the design of the ITPGRFA, administrators of the crop commons have been remarkably successful in managing and further developing the multilateral regime for facilitated access to plant genetic resources. A major turning point occurred in 2006 when agreements between the Governing Body and the CGIAR's international agricultural research centres (IARCs)[51] reaffirmed the status of *ex situ* collections held by the centres as "global public goods" and formally placed their seed banks under the auspices of the treaty.[52] Thus shielded politically, the seed banks have been distributing about 600 plant cultivars per day to researchers and commercial breeders in both developed and developing countries under SMTAs approved by the Governing Body.[53]

There has also been an increase of materials sent to the centres by developing countries after a decade of decline, and some important agricultural research institutes not affiliated with the CGIAR have also joined the system.[54] Voluntary contributions to the benefit-sharing fund have also flowed in, enabling the Secretariat to fund numerous training courses and research publications.[55] About 3,500 new plant varieties have been evaluated for resilience to stresses.[56] A global information system on plant genetic resources is also being constructed, and is expected to become a major resource for agricultural research data available on an open-access basis.[57]

Notwithstanding these accomplishments under the treaty, or perhaps because of its very success, there was a perceived need to solidify its legal foundations with respect to two underlying concerns. First, given that the CBD, as drafted in 1992, had contemplated only a state-to-state bilateral regime of ABS, was the establishment of a multilateral regime for facilitated access to plant genetic resources legally consistent with the CBD? Moreover, if the ITPGRFA and the CBD could be rendered legally compatible in theory, the bigger concern was their compatibility in practice. More to the point, how were pending proposals concerning

45 *ITPGRFA*, *supra* note 40, art 12.3(b)(e).

46 *Ibid*, arts 10–15; Reichman, Uhlir & Dedeurwaerdere, *supra* note 3 at 119–130 (citing authorities); 496–504 for analysis of the Governing Body.

47 Compare Reichman, Uhlir & Dedeurwaerdere, *supra* note 3 at 131–35 ("Demonstrable Achievements") with 135–42 ("Major Weaknesses").

48 See FAO Conference, Commission on Genetic Resources for Food and Agriculture, "Standard Material Transfer Agreement" (2006), at para 6(8) [FAO Conference], online: <www.fao.org/3/a-bc083e.pdf>.

49 *ITPGRFA*, *supra* note 40, art 13(3). However, a general notification of use must be sent to the Governing Body.

50 See further Reichman, Uhlir & Dedeurwaerdere, *supra* note 3 at 496–99 ("A Two-Headed Governance Construct").

51 Eight CGIAR-affiliated IARCs, with a total of nearly 700,000 *ex situ* accessions, were parties to this agreement. See Isabel López Noriega, Peterson Wambugu & Alejandro Mejías, "Assessment of progress to make the multilateral system functional: incentives and challenges at the country level" in *Crop Genetic Resources*, *supra* note 44, 199 at 205.

52 For details, see Reichman, Uhlir & Dedeurwaerdere, *supra* note 3 at 121–30 (citing authorities).

53 Interview of Shakheel Bhatti, former director general of the ITPGRFA (10 October 2016).

54 *Ibid*; López Noriega, Wambugu & Mejías, *supra* note 51 at 205–6.

55 Communications provided by the Secretariat of the ITPGRFA to Duke University School of Law (2016) (on file with the author).

56 *Ibid*.

57 *Ibid*.

global enforcement of the CBD's misappropriation regime at the national level to be reconciled with the very scientific and industrial uses of plant genetic resources that the crop commons aimed to promote? These and other related questions were specifically addressed in the Nagoya Protocol to the CBD of 2010, which entered into force in 2014.[58]

General Enforcement Measures under the Nagoya Protocol

Articles 3, 12 and 16 of the Nagoya Protocol expressly apply compliance measures to both the genetic resources within the scope of the CBD and the associated traditional knowledge.[59] Besides derivatives (broadly construed) and stand-alone biochemical components of genetic resources, ABS obligations under the CBD arguably cover related data, know-how and other relevant information pertaining to research on genetic resources "up to their commercialization."[60] This conclusion follows in part because the legislative history appears to include "sequencing genes and genomes" within the definition of "utilization of genetic resources" in article 2(c).[61]

Given this broad subject matter coverage, a primary objective of the Nagoya Protocol was to oblige signatory states to adopt compliance measures that would make the CBD's ABS requirements enforceable at the local level, ideally in courts or through other administrative processes.[62] In this context, access to traditional knowledge associated with genetic resources was given explicit consideration, including detailed compliance obligations to be implemented in domestic legislation.[63] Transboundary cooperation with respect to compliance is expressly required.[64]

The Nagoya Protocol does not prescribe any uniform compliance text that member states must adopt in this regard.[65] However, the protocol does encourage member states to develop model contractual clauses for mutually agreed terms.[66] It also requires states to establish national checkpoints and focal points for purposes of compliance, and to share relevant information via a platform — the ABS Clearing-House — to be established under the protocol.[67] Also envisioned are internationally recognizable certificates of compliance to facilitate legitimate cross-border transactions and to impede transgressors.[68]

Implicit in all these obligations is the risk that non-compliant goods may be treated as contraband and seized by national border agents. In other words, here the developing countries promoting the Nagoya Protocol have applied lessons drawn from articles 41–61 of the TRIPS Agreement of 1994, which first introduced strong enforcement measures into international IP law.[69] To be sure, under the TRIPS Agreement, members of the World Trade Organization (WTO) must establish border controls and other measures to block or seize counterfeit knowledge goods.[70] The Nagoya Protocol, instead, imposes duties of transborder cooperation to enforce ABS obligations on all member states,[71] along with the previously mentioned national checkpoints and focal points.[72] Taken together, these and other compliance measures could lead to a globalized enforcement regime under the CBD that would resemble that of TRIPS in many respects.

58 See *Nagoya Protocol*, *supra* note 28.

59 *Ibid*, arts 1–3, 16. For broad definitions of "utilization of genetic resources," "biotechnology" and "derivatives," all covered by the CBD, see especially article 2.

60 See e.g. Gurdial Singh Nijar, *The Nagoya Protocol on Access and Benefit Sharing of Genetic Resources: Analysis and Implementation Options for Developing Countries* (Research Paper No 36) (Geneva: South Centre, 2011) at 35.

61 See UNEP, *Report of the Meeting of the Group of Legal and Technical Experts on Concepts, Terms, Working Definitions, and Sectoral Approaches*, UN Doc UNEP/CBD/WG-ABS/7/2 (2008). See also Laird & Wynberg, *supra* note 34.

62 See *Nagoya Protocol*, *supra* note 28, arts 6–7, 12–16.

63 See *ibid*, arts 7, 12, 16. According to Gurdial Singh Nijar, "nothing in the Protocol allows for access to publicly available TK [traditional knowledge] or TK that is diffused and has no identifiable holders (and that is consequently held by the State) without PIC and MAT." See Nijar, *supra* note 60 at 36.

64 See *Nagoya Protocol*, *supra* note 28, art 11.

65 *Ibid*, arts 15–16.

66 *Ibid*, art 19.

67 *Ibid*, arts 6, 13, 15–16, 17(2).

68 *Ibid*, arts 6–7, 17(3).

69 See *TRIPS Agreement*, *supra* note 9, arts 41–61.

70 See *ibid*, arts 51–60.

71 See *Nagoya Protocol*, *supra* note 28, arts 11, 14–18.

72 See *ibid*, art 13.

As matters stand, non-compliant goods emanating even from the few states not subscribing to the CBD — notably the United States — will be subject to any and all of the compliance measures to be implemented under the Nagoya Protocol. By the same token, products emanating from the United States can presumably benefit from certificates to be recognized by the ABS Clearing-House, which should facilitate transit across national checkpoints so long as compliance with ABS obligations is properly documented.[73]

Measures Favouring Scientific Research

Unlike the CBD as initially drafted in 1992, the Nagoya Protocol expressly recognizes the importance of scientific research as a supplier of both monetary and non-monetary benefits to the developing country members of the CBD.[74] The protocol then drives this point home by expressly validating the multilateral regime of facilitated access to plant genetic resources that the ITPGRFA established in 2001.[75] To the same end, the protocol bestows anticipatory recognition on other multilateral regimes of facilitated access to *ex situ* genetic resources that may similarly promote scientific research in the future, if they simultaneously ensure that benefits from downstream commercial applications will be shared with the relevant providers.[76]

To enforce this proviso as an outer limit on scientific research, article 8(a) of the protocol requires providers of *ex situ* genetic resources for non-commercial research purposes to insert a "change of intent" clause in every relevant SMTA.[77] Such a clause would impose benefit-sharing obligations on scientists whose research uses did in fact lead to downstream commercial applications. Scientific researchers must accordingly oblige end-users to respect these benefit-sharing commitments as part of any commercial value chain resulting from relevant SMTAs.

For genetic resources emanating from established multilateral regimes, such as the FAO's ITPGRFA or the WHO's PIP Framework, a built-in take-and-pay rule (that is, a liability rule) would presumably satisfy the Nagoya Protocol.[78] SMTAs issued by the CGIAR's seed banks, for example, can contractually impose benefit-sharing obligations on new commercial uses of plant cultivars obtained before the adoption of the CBD in 1993.[79] Similarly, when the country of origin remains uncertain or controversial, SMTAs can obligate end-users who commercialize plant cultivars from the crop commons to fulfil their ABS obligations by paying a share of gross revenues into a benefit-sharing fund established under the ITPGRFA for this purpose.[80]

The Nagoya Protocol would similarly establish the Global Multilateral Benefit-Sharing Mechanism for the payment of ABS obligations by end-users whenever the true provider country of the resources in question cannot be identified.[81] Even then, however, serious questions may arise about the coverage of related traditional knowledge

73 See *ibid*, arts 11, 14–18.

74 See *ibid*, arts 5(4), 8(a), 9 (promoting research). See also Evanson Chege Kamau, Bevis Fedder & Gerd Winter, *The Nagoya Protocol on Access to Genetic Resources and Benefit Sharing: What Is New and What Are the Implications for Provider and User Countries and the Scientific Community?* (2011) 6:3 L, Environment & Development J 246 at 256 (envisioning future work on issues of scientific research), online: <www.lead-journal.org/content/10246.pdf>.

75 See *Nagoya Protocol*, *supra* note 28, arts 4(1), 4(4). The preamble to the Nagoya Protocol also expressly acknowledges the fundamental role of the ITPGRFA "for achieving food security worldwide and for sustainable development of agriculture…and climate change," and for the multilateral system of access and benefit-sharing to be established under the treaty.

76 *Ibid*, arts 4(2), 4(4). The preamble also expressly acknowledges the importance of the World Health Organization's (WHO's) efforts to ensure "access to human pathogens for public health preparedness and response purposes." These efforts culminated in the WHO's Pandemic Influenza Preparedness (PIP) Framework Agreement (2011). See WHO, *Pandemic influenza preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits*, World Health Assembly, Res WHA645 (24 May 2011), online: <www.who.int/influenza/resources/pip_framework/en/>. For basic concepts of the PIP Framework and its lessons for analogous pooling arrangements in the future, see Reichman, Uhlir & Dedeurwaerdere, *supra* note 3 at 233–49.

77 *Nagoya Protocol*, *supra* note 28, art 8(a). See further Kamau, Fedder & Winter, *supra* note 74 at 258–59.

78 See above notes 42–46 and accompanying text. For a detailed analysis of the take-and-pay regime (technically a "liability rule" and not an "exclusive property right") as embodied in the ITPGRFA, see Reichman, Uhlir & Dedeurwaerdere, *supra* note 3 at 118–42 (analyzing both strengths and weaknesses of the regime).

79 SMTAs can thus cure the legal ambiguity concerning the applicability of the CBD to pre-1993 *ex situ* genetic resources and related traditional knowledge. See e.g. Nijar, *supra* note 60 at 34, concerning "Temporal scope."

80 See ITPGRFA, *supra* note 40, arts 13, 16(d)(ii). For the relevant SMTA, see FAO Conference, *supra* note 48, arts 2, 6, 7 & 8. See generally Michael Halewood, "International Efforts to Pool and Conserve Crop Genetic Resources in Times of Radical Legal Change" in Mario Cimoli et al, eds, *Intellectual Property Rights: Legal and Economic Challenges for Development* (Oxford: Oxford University Press, 2014) 288. See generally Reichman, Uhlir & Dedeurwaerdere, *supra* note 3 at 125–30 ("Notification, Benefit-Sharing and the SMTA" under ITPGRFA).

81 See e.g. *Nagoya Protocol*, *supra* note 28, art 10 ("Global Multilateral Benefit-Sharing Mechanism").

under these provisions or related SMTAs, in the absence of any multilateral agreements regulating traditional knowledge already known beyond the sphere of any given Indigenous community.[82]

Resolving these and other ABS issues, then, becomes considerably more complicated when providers of *ex situ* genetic resources do not operate within the legal constraints imposed by any international instrument consistent with article 4 of the Nagoya Protocol.[83] This topic is discussed in the next section.

The Implications for Science Policy

If the Nagoya Protocol has firmly established the legitimacy of the crop commons in public international law, it has simultaneously raised new and potentially disruptive questions concerning the operations of the pre-existing microbial research commons under the aegis of the WFCC.[84] So far, the typical response of the culture collections has been to cast themselves as "trusted intermediaries" whose operations position them midway between providers of non-monetary research benefits and those that incur benefit-sharing obligations under the protocol.[85] To this end, SMTAs authorize the use of *ex situ* microbial specimens for most research purposes, while imposing contractual obligations to share benefits with provider countries under viral licences that cover commercial applications of research results.[86]

In this same vein, the European Union's Regulation on Access to and Use of Genetic Resources, adopted in 2014 (Regulation 511/2014),[87] seeks to ensure that *ex situ* culture collections operating under national laws will effectively comply with the ABS obligations of the Nagoya Protocol.[88] This carefully drafted regulation covers all the compliance obligations of the CBD and the Nagoya Protocol. It obliges all users to exercise due diligence in ascertaining that the genetic resources and associated traditional knowledge they rely on were accessed in accordance with applicable legal requirements and to ensure that any resulting commercial benefits are shared with providers as required.[89] With specific regard to *ex situ* resources, Regulation 511/2014 seeks to establish a "register of collections," whose operations are to be certified as consistent with international legal obligations and with the duty of due diligence imposed under the regulation itself.[90]

EU member states must verify that each collection submitted for inclusion in the register of trusted intermediaries meets the monitoring and record-keeping obligations it otherwise mandates.[91] All such information bearing on due diligence will be shared with the ABS Clearing-House being established under article 14(1) of the Nagoya Protocol and with national authorities operating under the protocol.[92]

From a broader perspective, the preamble to Regulation 511/2014 expressly recognizes that the "collection of genetic resources in the wild is mostly undertaken for non-commercial purposes by academic, university and non-commercial researchers or collectors."[93] With that in mind, the commendable objective

82 See above note 63 and accompanying text.

83 See *Nagoya Protocol*, *supra* note 28, art 4; see also above notes 74–76 and accompanying text.

84 See above notes 3–6 and accompanying text.

85 See *Nagoya Protocol*, *supra* note 28, arts 4–5, 8, 15–16; see above notes 74–77 and accompanying text.

86 See e.g. Reichman, Uhlir & Dedeurwaerdere, *supra* note 3 at 214–19 ("The Core MTA of the European Union Culture Collections' Organization"); see also *ibid* at 528–38 ("The Global Biological Resource Centers Network [GBRCN] Demonstration Project"); *ibid* at 541–43 ("The Next Step: The Microbial Resource Infrastructure (MIRRI) as a European Stepping Stone to the GBRCN"). See generally David Smith & Philippe Desmeth, *Access and Benefit Sharing: A Main Preoccupation of the World Federation for Culture Collections (WFCC)* (2007), online: <https://assets.publishing.service.gov.uk/media/57a08be9e5274a27b2000e55/CBD-2007-Smith-Desmeth.pdf>.

87 EU Regulation 511/2014, *supra* note 38..

88 See e.g. Reichman, Uhlir & Dedeurwaerdere, *supra* note 3 at 219–225.

89 EU Regulation 511/2014, *supra* note 38, Preamble & arts 3–5, 21.

90 See *ibid*, arts 4–5.

91 See *ibid*, art 5(3). See also Kate Davis, Eliana Fontes & Luciane Marinoni, "*Ex situ* collections and the Nagoya Protocol: A briefing on the exchange of specimens between European and Brazilian *ex situ* collections, and the state of the art of relevant ABS practices" (Background paper prepared for the International Workshop on the role to be played by biological collections under the Nagoya Protocol, 6th EU/Brazil Sectoral Dialogue Support Facility, Brazil, 18–20 June 2013), online: <http://sectordialogues.org/sites/default/files/acoes/documentos/background_paper.pdf>.

92 See EU Regulation 511/2014, *supra* note 38, arts 6–7. See generally Reichman, Uhlir & Dedeurwaerdere, *supra* note 3 at 221–25.

93 EU Regulation 511/2014, *supra* note 38, Preamble, s 27.

of the regulation is to repress biopiracy.[94] Nonetheless, the legal foundations of the regulation remain open to question.

Under a strict reading of the Nagoya Protocol, for example, there are arguably only two recognized legal routes for accessing genetic resources under the CBD, namely, the bilateral approach for case-by-case acquisitions of *in situ* materials,[95] and the multilateral regime for facilitated access to *ex situ* genetic resources now validated by article 4 of the protocol.[96] Given this premise, one may ask whether the public microbial culture collections, in and of themselves, can fashion a *sui generis* legal status as trusted intermediaries for accessing and exchanging *ex situ* microbial genetic resources. Their own SMTAs, however carefully constructed, would not seem to provide the kind of basic international legal instrument envisioned by article 4 of the Nagoya Protocol.[97]

The European Union's Regulation 511/2014 could, of course, provide a basic international instrument for its own member states as required under article 4 of the protocol.[98] But does Regulation 511/2014 suffice to create the kind of multilateral regime envisioned by article 4(4)? Neither the Nagoya Protocol nor the CBD expressly recognizes the status of "trusted intermediaries," falling somewhere in between case-by-case negotiations under the bilateral approach or the take-and-pay rules embodied in the ITPGRFA, which do fulfill the ABS obligations of the CBD. In other words, is there room under article 4 of the Nagoya Protocol for the kind of contractually constructed access regime envisioned by Regulation 511/2014, based on the concept of due diligence by "trusted intermediaries"? Or does such a concept fall outside of the safe harbour established by that same article? And even if Regulation 511/2014 can somehow be reconciled with the Nagoya Protocol's safe harbour, what about all of the WFCC's important microbial culture collections operating outside of the territorial jurisdiction of that same instrument?[99]

A safer and better approach would seem to require the WFCC to reorganize itself as an international entity that governs a multilateral regime of facilitated access to *ex situ* microbial genetic resources and related traditional knowledge. In so doing, it need not copy the rather clumsy governance model adopted for the ITPGRFA, whose defects have elicited a growing literature.[100] On the contrary, there are now a number of organizational models for pooling scientific inputs and outputs that are far more flexible and more science-friendly than the top-down administrative structures supporting the crop commons.[101]

Envisioning a Multilateral Regime of Facilitated Access to *Ex Situ* Microbial Genetic Resources

Once the WFCC's microbial culture collections folded themselves into a multilateral format with built-in benefit-sharing arrangements, their public culture collections — like the CGIAR's seed banks[102] — would immediately acquire a recognized, preferential status under article 4 of the Nagoya Protocol.[103] As a result, national courts and administrators enforcing ABS obligations under the Nagoya Protocol to the CBD should recognize and validate SMTAs emanating from the corresponding

94 *Ibid*, ss 3, 6, 9, 10.

95 See above notes 15–25 and accompanying text.

96 See *Nagoya Protocol*, *supra* note 28, art 4(4) (legitimizing "specialized international access and benefit-sharing instrument[s]...consistent with... the objectives of the Convention and this Protocol" that may arise in the future). See further Godt, *supra* note 1 at 258.

97 See above notes 75–76 and accompanying text.

98 See above notes 75–83 and accompanying text.

99 For the geographical scope of the WFCC's microbial culture collections, see generally Reichman, Uhlir & Dedeurwaerdere, *supra* note 3, ch 4 ("The Existing Microbial Research Commons Confronts Proprietary Obstacles") at 167–99 (citing authorities).

100 See e.g. *ibid* at 130–42 ("Strengths and Weaknesses of the ITPGRFA").

101 See generally *ibid*, ch 9 ("Institutional Models for a Transnational Research Commons"); see also *ibid*, ch 10 at 579–650 (describing a proposed new governance model for a redesigned microbial research commons).

102 *ITPGRFA*, *supra* note 40. See also above notes 43–46 and accompanying text.

103 See *Nagoya Protocol*, *supra* note 28, art 4(1).

multilateral regime as both enforceable and sufficient to comply with these obligations.[104]

The formation of a multilateral regime would further provide the public microbial culture collections with a governance structure to address ongoing problems for which both science and industry need timely answers.[105] For example, under the European Union's Regulation 511/2014,[106] questions have resurfaced about the temporal scope of liability under the CBD, with particular regard to new uses of genetic resources and traditional knowledge that were acquired before the Nagoya Protocol to the CBD took effect in 2014. Provider countries in their domestic laws generally insist that new uses of older genetic resources do require ABS agreements, while the European Union's regulation exempts such uses on weak legal grounds.[107]

The European Union's Regulation 511/2014 on genetic resources in public collections also limits recognition of any "associated" traditional knowledge that could trigger benefit-sharing obligations to express commitments specified in any contractual agreements between the parties that deal with these obligations.[108] This approach attempts to prevent provider governments from claiming that other related traditional knowledge beyond that specified in any given SMTA between public collections and users was actually and wrongfully misappropriated. By the same token, the regulation does not require due diligence with regard to uses of genetic resources and traditional knowledge in the case of products developed outside the territorial boundaries of the European Union and then imported into that territory.[109] All of these positions are open to question under the Nagoya Protocol.[110]

Looking beyond the European Union's Regulation 511/2014, the criteria for legitimate access to traditional knowledge have generally been tightened under the Nagoya Protocol. For example, where local communities have obtained the right to grant access to traditional knowledge, would-be users must obtain PIC and otherwise comply with the communities' own ABS conditions.[111] Signatories to the treaty should inform users of traditional knowledge about their obligations under the CBD,[112] and local communities should be encouraged to codify these MAT and ABS obligations in protocols and model contractual clauses available to the public.[113]

While these and other provisions of the Nagoya Protocol could seriously complicate microbiological research, WFCC culture collections adhering to a memorandum of understanding that established a multilateral regime of facilitated access to *ex situ* microbial genetic resources could directly address them through a suitably devised governing body.[114] The governing body would, in turn, presumably have the capacity to deal with such issues by agreement of the member governments duly appointed to that body for such purposes.[115] The governing body of such a "microbial research commons" could thus resolve these and other issues for purposes of enabling facilitated exchanges of *ex situ* materials held by the member collections, even though the Conference of the Parties to the CBD had not yet fully resolved relevant uncertainties in pre-existing international law.[116] In the long run, empirical evidence arising from decisions along these lines by the governing bodies of both the crop commons and a microbial research commons could support better-informed decisions by the Conference of the Parties to the CBD itself.

A redesigned microbial research commons should, moreover, strive to avoid some of the weaknesses of the crop commons that lurked beneath its otherwise ambitious and idealistic framework principles.[117] For example, the SMTAs implementing a multilateral microbial research commons should contain a built-

104 *Ibid*, arts 4(2)–4(4); *ITPGRFA*, *supra* note 40. See also above notes 42–50 and accompanying text (ABS under the ITPGRFA).

105 For a survey of different governance models, see *supra* note 101.

106 See *supra* notes 67–99 and accompanying text.

107 See e.g. Barbara Lassen et al, *The two worlds of Nagoya – ABS legislation in the EU and provider countries: discrepancies and how to deal with them* (Zurich & Cape Town: Public Eye & Natural Justice, 2016) at 7–12. See also Kamau, Fedder & Winter, *supra* note 74 at 255.

108 See Lassen et al, *supra* note 107 at 13–14.

109 *Ibid* at 15–16.

110 *Ibid*.

111 See Kamau, Fedder & Winter, *supra* note 74 at 252, citing *Nagoya Protocol*, *supra* note 28, arts 5.2, 5.5, 6.2(f), 7.

112 *Nagoya Protocol*, *supra* note 28, art 12.2.

113 *Ibid*, arts 12.1, 12.3. See further Kamau, Fedder & Winter, *supra* note 74 at 252 (also stressing the need for capacity building under the Nagoya Protocol, article 22).

114 Reichman, Uhlir & Dedeurwaerdere, *supra* note 3, ch 9 at 494–543.

115 *Ibid* at 526–41 (discussing the GBRCN Demonstration Project, for an empirical test of such a regime).

116 See e.g. Kamau, Fedder & Winter, *supra* note 74 at 256 (emphasizing uncertainties regarding basic research under articles 5.2 and 6.3. of the Nagoya Protocol still to be worked out by the drafters of model ABS agreements).

117 See above notes 47–50 and accompanying text.

in research exemption, together with mandatory take-and-pay benefit-sharing obligations applicable in all cases. In other words, users should be free to undertake any research, whether scientific or applied, coupled with an absolute duty to pay a compensatory royalty on any downstream commercial applications to help support the costs of the commons and to fund scientific research on microbial genetic resources, especially in provider countries.[118] A small user's access fee could also be charged for similar purposes. Needless to say, the tracking system for scientific uses of microbes — a long-standing feature of microbiological research[119] — should be retained and further perfected, in order to avoid problems arising from the lack of any tracking mechanisms for plant cultivars obtained from the crop commons.[120] The World Data Centre for Microorganisms (WDCM) should also be fully integrated into the proposed multilateral regime.[121]

Above all, the organizers of a redesigned microbial research commons should not imitate the rigid governance structure of the crop commons[122] but instead devise and adopt a more science-driven governance apparatus, in which scientists as delegates would have a legally protected voice and voting role, alongside government officials.[123] To this end, the strengths and weaknesses of a number of existing science commons initiatives launched in the past few years should be empirically evaluated,[124] in order to design an innovative, more science-friendly governance structure that breaks with the tendency of existing models to imitate the bureaucratic administrative models of many intergovernmental organizations.[125]

In sum, a pressing need for the WFCC to reorganize its existing microbial research commons in order to comply effectively and efficiently with the ABS obligations of the Nagoya Protocol to the CBD also creates an opportunity to devise a new, more enlightened governance regime that could become a model on which future science commons could build.[126] Moreover, a multilateral regime of public microbial culture collections, once properly installed, could strive to support and link up with other relevant commons initiatives, such as the COMPARE Project on infectious diseases underway in the European Union[127] and WHO's PIP Framework,[128] in a comprehensive knowledge commons supported by the superb digital framework already embodied in the WDCM.[129]

A multilateral regime of public microbial culture collections, if properly organized into a true knowledge commons, could thus yield scientific payoffs well beyond the needed compliance with the Nagoya Protocol to the CBD. By providing scientifically validated genetic resources, traditional knowledge and related data for research and applications in compliance with international law from a central portal, it could become a crucial component of the global scientific infrastructure. In turn, that infrastructure should generate more and better research inputs and outputs across scientific disciplines. In other words, a properly redesigned microbial research commons should help to forge a pathway to enable scientists everywhere to overcome the legal and institutional barriers that might otherwise stand in the way of the New Biology paradigm put forward by the US National Academies in 2009.[130] That paradigm, indeed, was a primary inspiration for undertaking the entire project on which this paper is based.

118 For detailed proposals to this effect, see Reichman, Uhlir & Dedeurwaerdere, *supra* note 3, ch 5, at 260–90 ("Designing a Third Option: *Ex Ante* 'Take and Pay' Rules for Stimulating Research and Applications"). For related governance considerations, see *ibid*, ch 10, at 598–636 ("Implementing the Multilateral Regime for Facilitated Access to *Ex Situ* Microbial Genetic Resources").

119 *Ibid* at 173–74 (unique strain identifiers in WFCC standard practice).

120 See above notes 47–50 and accompanying text.

121 See Reichman, Uhlir & Dedeurwaerdere, *supra* note 3, 426–29, 624–28 (discussing WDCM).

122 *Ibid* at 495–504 ("The Global Crop Commons: A Treaty-Based Intergovernmental Entity").

123 *Ibid*, ch 10, at 579–98 ("Organizational and Structural Considerations").

124 *Ibid*, ch 9, at 494–544 ("Selected Empirically Relevant Governance Approaches").

125 *Ibid* at 544–67 ("In Search of a Politically Acceptable and Scientifically Productive Operational Framework").

126 See e.g. Brett M Frischmann, Michael J Madison & Katherine J Strandburg, eds, *Governing Knowledge Commons* (Oxford: Oxford University Press, 2014); Elinor Ostrom, *Governing the Commons: The Evolution of Institutions for Collective Action* (Cambridge, UK: Cambridge University Press, 1990).

127 See Collaborative Management Platform for Detection and Analysis of (Re-)emerging and Foodborne Outbreaks in Europe (COMPARE), News item, "Pilot project on Machine Learning and Antimicrobial Resistance" (25 September 2017), online: <www.compare-europe.eu/news/2017/09/pilot-project-on-machine-learning-and-antimicrobial-resistance?id=45fed1d2-3bfb-4ab7-ad6e-3a17e512baa4>.

128 See PIP Framework, *supra* note 76 and accompanying text.

129 See the text accompanying note 121.

130 See National Research Council, *supra* note 1. See further Reichman, Uhlir & Dedeurwaerdere, *supra* note 3 at 19–36.

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Our research programs focus on governance of the global economy, global security and politics, and international law in collaboration with a range of strategic partners and support from the Government of Canada, the Government of Ontario, as well as founder Jim Balsillie.

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Au Centre pour l'innovation dans la gouvernance internationale (CIGI), nous formons un groupe de réflexion indépendant et non partisan qui formule des points de vue objectifs dont la portée est notamment mondiale. Nos recherches, nos avis et l'opinion publique ont des effets réels sur le monde d'aujourd'hui en apportant autant de la clarté qu'une réflexion novatrice dans l'élaboration des politiques à l'échelle internationale. En raison des travaux accomplis en collaboration et en partenariat avec des pairs et des spécialistes interdisciplinaires des plus compétents, nous sommes devenus une référence grâce à l'influence de nos recherches et à la fiabilité de nos analyses.

Nos programmes de recherche ont trait à la gouvernance dans les domaines suivants : l'économie mondiale, la sécurité et les politiques mondiales, et le droit international, et nous les exécutons avec la collaboration de nombreux partenaires stratégiques et le soutien des gouvernements du Canada et de l'Ontario ainsi que du fondateur du CIGI, Jim Balsillie.

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