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Access and Benefit-Sharing in the Age of Digital Biology

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Abstract

This chapter explores whether and how genomic resources can be protected by the communities from, or countries in which they are accessed. Specifically, it asks whether the Nagoya Protocol on Access and Benefit-Sharing can be an effective mechanism to reassure communities about the sharing of gene sequencing data. These questions are of particular importance to Indigenous peoples and local communities, as many have troubling historical experiences with colonization and associated natural resource exploitation. Many Indigenous and local communities (ILCs) live in developing countries, which are particularly sensitive to access and benefit-sharing (ABS) issues. Different but equally serious challenges exist for Indigenous peoples in developed countries like Canada, Australia, New Zealand and elsewhere. Until outcomes of implementation of the Nagoya Protocol are captured, Indigenous peoples and Local Communities (IPLCs) remain in a quandary as to how to protect digitized genetic resources within their territories or under their jurisdiction. To advance our understanding of legal and regulatory options, this chapter integrates normative and positive perspectives on the mechanisms for access and benefit-sharing in the age of digital biology.

INTRODUCTION

It is often said that science is ahead of regulation. This truism is exemplified in the science relating to genomic sequence information, digital biology and the instantaneous global transfer of electronic information. The tsunami of genomic information being generated in research laboratories the world over has the potential to be shared with any other laboratory in real time. The challenge this creates is how to

viably ensure that value generated from the sharing of genomic information is identified and ethically allocated.

For decades, normative, legal and political discourse around access and benefit-sharing has been around 'genetic' resources. Science, however, has advanced far beyond genetics (the study of heredity) into genomics (the study of genes, their functions, and their interrelationships). While it took a full decade, from 1990 to 2000, to sequence the human genome, today genomes can be sequenced in mere days, if not hours. The cost, both fiscally and in time, to sequence the human genome is staggering. While occupying the time of an estimated 2,000 research scientists for a full decade, the entire project cost in the range of US$1 billion. By comparison, today any individual can have their genome sequenced in less than 24 hours, by one person, for less than US$1,000. With advancements in genomic knowledge growing exponentially from year to year, the task of trying to ensure that some modicum of regulation governs this field is a gargantuan one.

Such scientific advances are particularly challenging for those interested in the nature, value, use, preservation and ownership of a wide range of genetic resources – the inputs to genomics – that are embodied in populations of microbes, plants, animals and humans. These resources can be found *in situ* in organisms in all climates and cultures on land, in the sea and in the air or *ex situ* in botanical gardens, gene banks and public and private research collections. Genetic resources are inextricably intertwined with the environment (including human populations as hosts and users) and the knowledge and practices of their custodians. However, genetic resources' underlying meaning and utility are becoming disembodied from their hosts and severed from their custodians due to the advance of genomic and phenomic methods, the development of computational capacity to simulate design, growth and function, and emerging gene editing and synthetic biological techniques. Each innovation in some way works to disconnect the utility and function of organisms from their base of traditional knowledge and related biological assets.

At the same time, our understanding on Indigenous peoples' knowledge governance systems is evolving. No longer is Indigenous knowledge governance necessarily seen as 'traditional.' Indigenous peoples' knowledge-based practices are highly innovative; but focused on maintaining sustainable systems rather than creating economic artefacts (Drahos & Frankel, 2012). The cross-cultural reconciliation of Indigenous and Western approaches to biological knowledge is, however, a work-in-progress (Oguamanam, 2015)

So, the science of genomic sequence information has advanced so rapidly that the international agreement that was drafted to govern this issue was out of date by the time it came into force. The Nagoya Protocol negotiations concluded in October 2010 and the instrument came into force four years later. However, advancements have, to a large extent, arguably rendered the Nagoya Protocol essentially an ineffective governance mechanism as it does not deal with the pressing issue of digital technology transfer (*but see* Oguamanam, Chapter 11). The key question that

remains unresolved, and which we explore, is whether digitized data about innovation-related practices that involve genetic resources are 'knowledge' about or 'derivatives' of those genetic resources.[1]

In these evolving contexts, the governance task is a complex one that has been generating discussion for at least a decade. Commentaries, contributions and insights have been advanced by individual scholars, groups of scholars, intellectual think tanks, and national governments over this period of time. Each contribution enhances the vast pool of knowledge that will be needed to ensure that access and benefit-sharing (ABS) over genetic resources and their associated traditional knowledge is managed in an economically efficient and ethical manner.

There is a large body of scholarly work on this topic (for example, see Phillips and Onwuekwe, 2007; Oguamanam, 2010; Oguamanam, 2011; Gold and Bubela, 2012; Koutouki et al., 2012; de Beer and Dylan, 2015). Interestingly, much of the work to date has a strong normative framing, as the scholars involved are both committed to and motivated by a desire to find a more equitable regime for traditional knowledge (TK), in an effort to support the advancement of the rights of Indigenous peoples. While this work is valuable, it does tend to be more aspirational and exhortatory than analytical and descriptive. Similarly, think tanks, international organizations and many countries have grappled with ABS, its application, regulation and governance. This chapter moves beyond the normative to examine how the various governance systems fit with the new reality and offers some strategic options.

BACKGROUND

There is quite an extensive body of literature that examines the definition of rights for TK and the framing of claims to benefits from those accessing those rights. The root of this debate was the 1983 International Undertaking on Plant Genetic Resources (IUPGR), which strove 'to ensure that plant genetic resources of present or potential economic and/or social importance, particularly for agriculture, will be explored, preserved, evaluated and made available for plant breeding and other research purposes' (IUPGR, 1983). Its fundamental assumption was 'that plant genetic resources are a common heritage of mankind and consequently should be available without restriction' (ibid). Many developing nations and quite a few scholars were concerned about that blanket appropriation of the TK embodied in seeds (Sullivan, 2004). In 1996, the United Nations Environmental Program in the context of the Convention on Biological Diversity (CBD) developed a set of guidelines on appropriate roles and structures for ABS. In addition to 8(j) (*in situ* conservation) of the CBD, a number of other articles offer direction and advice, including: 16 (provisions on access to and transfer of technology), 17 (exchange of information), 18 (technical and scientific cooperation), 19 (the handling and distribution of the benefits of biotechnology) and 20 and 21 (financial resources and mechanisms). These provisions suggest benefits that could involve: monetary

compensation in the forms of fees, research support, royalties and salaries; or non-monetary benefits, such as in-kind support for institutions and communities, information, transfer of equipment, software and knowhow, training, joint R&D, capacity building and local employment.

Recently, there has been significant debate and effort invested in negotiating a range of international conventions or treaties to delimit and protect Indigenous rights to genetic resources, involving the International Labour Organization, the UN and InterAmerican Draft Declarations on Rights of Indigenous peoples, the UNDP/UNCTAD and the European, Asian and African Development Banks. In the context of plant genetic resources, in particular, there are a number of special institutions involved in delimiting rights and facilitating ABS. These include the CBD (1992), the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of the Their Utilization (2002), Agenda 21 and the Cartagena Protocol on Biosafety (2000), the IUPGR (1983) and ITPGR (2001), the CGIAR centres and related gene banks and various national programs (e.g. CIDA and SEDA). The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) is a supplementary agreement to the CBD. The Protocol entered into force in 2014. The main task of the Protocol members is to advance the policy and practice of accessing and utilizing genetic resources (GR) and associated traditional knowledge (ATK) in research and development activities. The Protocol created a clearing house mechanism to facilitate the collection and sharing of information on the national implementation of ABS, inducing legislative and other measures, permits, relevant authorities and institutions as well as codes of conduct and best practices.

The challenge facing all the systems is that the explicit link between TK and GR in modern scientific knowledge varies widely. Even without the scientific advancements we are focused on, many *ex situ* GR have become disconnected from their roots. New bibliometric and biometric tools and methods are helping to reveal some of the roots of some accessions to establish a chain of custody through ethnographic and scientific explorers' reports. The International Barcoding of Life Project (iBOL), which has barcoded and sequenced more than two million species, has discovered some challenges in the way we think about the environment we live in. Their analysis has determined that (a) taxonomists have mis-assigned about 10% of genetic material as distinct species, (b) we underestimated the number of species by at least a scalar, (c) our understanding of diffusion of species is too narrow and (d) the food chain for many species is far more complex and subtle than the macro-diets suggest. Ultimately, the concordance between species, source and utility is breaking down, which poses hitherto unknown and unforeseen challenges.

The recent revolutions in digital and *omics* spheres are further disconnecting utility from provenance. As we move further from genetics to genomics, automated phenotyping and digital plants, animals and microbes, we are less reliant on the underlying genetic material to undertake discovery research. This is combined with

new breeding tools that supplement traditional plant breeding with transgenic modification and now gene editing (e.g. CRISPR/Cas9) that reduce the need for access to genetic materials (Oguamanam & Jain, 2017). The end game for some is synthetic biology, where the genetic design is built directly from the component nucleic acids with no use of pre-existing organisms.

ABS MECHANISMS IN USE

Even while new genetic engineering techniques that can potentially improve the precision of DNA transformations are being developed, countries continue facing challenges implementing the legal instruments intended to manage the ownership, control and exploitation of new innovations. Even when countries have signed, ratified and elaborated a host of legal instruments (domestic, regional, international or some combination) intended to define TK and facilitate ABS, a series of barriers persist.

Crookshanks and Phillips (2012) undertook a comparative analysis of the ABS/TK landscape, offering a typology that differentiated systems based on whether they align more with the narrow commercial goals of the TRIPS agreement of the WTO or the broader socio-economic-ethical objectives of the CBD. Similarly, different countries would pursue their goals either through legal and regulatory mechanisms or via a broader range of institutions and partnerships. When this typology was applied to a range of biodiverse countries, the authors observed that many Latin American countries tended to use legal and regulatory mechanism first to pursue commercial benefits and then other non-pecuniary benefits while African and Asian nations have a more diverse set of goals and approaches.

Peru (a megadiverse country) serves as a useful illustrative example. In an effort to safeguard its biological diversity, Peru has signed and ratified the Nagoya Protocol. Peru's ABS regime is detailed in two laws and four decrees (UEBT, 2016). The two main legal instruments detailing Peruvian ABS requirements and procedures are the Rules on Access to GR and Law N° 27811. Article 7 of the Rules on Access to GR, indicates that the Peruvian state prioritizes the transfer and implementation of technologies that employ the country's GR. While Article 20 states that – when appropriate – a contract enabling access to GR, must contain, *inter alia*, provisions that contemplate the just and equitable distribution of benefits. Article 27 of Law N° 27811, indicates the minimum clauses a contract to access GR is to contain. According to clause (c), in case TK is employed, compensation will be an initial monetary or equivalent payment, and no less than five per cent of gross sales resulting from the commercialization of goods developed either directly or indirectly from having employed TK.

According to the Union for Ethical Bio Trade (UEBT), Peru has granted over 80 authorizations to access GR. From these authorizations, benefits have been limited, and for the most part have focused on the sharing of research results and

developing national capacities (non-pecuniary benefits). However, the country has not been able to overcome: (1) a weak legal and institutional framework to manage ABS in congruence with the Protocol; (2) lack of knowledge of relevant stakeholders on the access and utilization of genetic resources and 'Fair Benefit-Sharing;' (3) and limited experience in applying ABS mechanisms to access and management of genetic resources associated with TK (GEF, 2017). In an effort to address these barriers, relevant Peruvian authorities in conjunction with the Global Environment Facility (GEF) have resubmitted a project aimed at strengthening local capacity in harmonizing domestic legal instruments with the Nagoya Protocol.

ABS systems vary widely. Canada, for example, is party to the CBD but not the Nagoya Protocol. Canada does not possess a comprehensive framework that governs GR associated with Indigenous TK, but does have a robust set of IP laws. According to Aboriginal participants in the Canada-wide Focus Group on ABS organized by ABS Canada (ABS Canada Focus Group Report, Moncton, 2015; Ottawa, 2016; Saskatoon, 2017), the very idea of discussing plants and animals as 'resources' is not compatible with Aboriginal views, and any legal system or policy that starts with this premise will generate confusion and resistance. Any action in this direction is likely to be rejected by the communities those policies are meant to protect (ABS Canada, 2017). Thus, the very discourse used when discussing TK and ABS can be a barrier to implementation. ABS Canada undertook a series of focus groups and symposiums aimed at educating, training, and network-building on ABS with Indigenous peoples and other stakeholders as parties whose interests are critically engaged in ABS. The meetings have yielded mixed results, but a consistent feature has been the resurgence of historical tensions between Indigenous peoples and Canada's colonial administration. Phillips et al. (2012) surveyed Canadian First Nations about their practices for handling TK and ABS and discovered that few had structured and fully functioning systems.

Realities in each country will vary widely depending on the realities of specific Indigenous peoples or local communities and their cultures. While some countries may have an ABS system in place, this alone does not guarantee compliance or that benefits will manifest themselves. Other countries are in the process of developing ABS systems, but maintaining sustained interest in such a complex and at times seemingly abstract issue, might prove difficult. The digitization of genetic information, which is often associated with traditional knowledge, is likely to complicate, if not overwhelm, the already lagging institutions in charge of managing ABS and TK.

NEW ETHICAL AND/OR MORAL ISSUES CREATED

Most of the work to date on ABS and TK has a strong normative framing, as the scholars involved are both committed to and motivated by a desire to find a more equitable regime for TK, in an effort to support the advancement of the rights of

Indigenous peoples. Dutfield (2004) offers the clearest and most succinct set of reasons to protect TK and organize ABS:

- to fulfil moral obligations towards Indigenous and local communities;
- to comply with legal requirements embodied in international treaties and emerging norms (e.g. the CBD) and
- for more utilitarian goals such as local, national and global economic and welfare benefits and for improved sustainable management of biodiversity and conservation.

Each of these reasons is based on an underlying moral principle: intrinsic value based in moral absolutism; procedural compliance based in legal positivism and economic liberty based in the theory of utility.

It is important to note up front that while this work is necessary and extremely valuable, it does tend to be more aspirational and exhortatory than analytical and operational. This poses a significant challenge to those tasked with managing and adjudicating systems related to ABS over genetic resources and associated TK, as the prescriptive perspective has not offered much in the way of confirmed and validated models, methods and metrics that can be relied upon to deal with claims and disputes about TK and related ABS. With the digitization of biology, this gap between aspirations and actions may prove to inhibit partnerships and further isolate Indigenous peoples from the bioscience enterprise.

Moral Obligations and Definitions

Many of those engaged in the study and governance of TK accept that there is an intrinsic value in Indigenous community structures and their embodied TK. This is an absolute moral bedrock of the field and not open to external verification. Nevertheless, it is hard to translate that into action because the causal story (Stone, 1989) is fuzzy. The policy issues around TK remain loosely framed, as there is no universally accepted definition that offers hard boundaries for what it is and how one might work with it. Phillips and Onwuekwe (2007) note that neither the CBD, the source of the international agenda related to TK and ABS, nor the Rio Declaration or Agenda 21 define the term, even though they use it in various forms. Article 8(j) of the CBD goes the furthest, identifying a range of definitions, rights and obligations related to 'traditional knowledge, innovations and practices.' Article 8(j) asserts that the parties concur that this involves 'knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity' (CBD, 1992: 8). As with any definition, the devil is in the details. The provision, in and of itself, does not define 'indigenous and local communities,' 'traditional lifestyles' or 'conservation and sustainable use.'

Dutfield (2001) contends that TK exists notwithstanding its definitional dilemma. He adopts Martha Johnson's definition of traditional ecological knowledge, as a

starting point: '[a] body of knowledge built by a group of people through generations living in close contact with nature. It includes a system of classification, a set of empirical observations about the local environment, and a system of self-management that governs resource use.' Having said that, TK remains problematic as it exhibits an array of dichotomies: it can be both explicit and implicit; it can be local or global; and it can, as a proprietary matter, be individual or collective (Jensen et al., 2007). This array of attributes means the functional space encompassed by the term is wide and variable, and is ultimately highly fluid as new technologies work to disembody knowledge claims from specific organisms found in or gathered from specific regions and peoples even as they render more sophisticated uses to which such organisms and their derivatives are applied.

Arguably, a literal reading of the Nagoya Protocol makes it hard to suggest that digitized biological data is a 'derivative' (expressly defined by Article 2(e) as 'a naturally occurring biochemical compound').[2] A better argument might be that the lines between knowledge, information, and data are blurry or non-existent in the worldview of many Indigenous peoples. Of course, the implications of each argument may not be the same.

Legal and Institutional Approaches

Much of the legal scholarship and most of the international negotiations, while grounded on the notion of an intrinsic moral value vested in Indigenous peoples and their unique TK related to plants, animals and microbes, smacks of legal positivism. Procedural norms and practices, irrespective of the intrinsic moral value, are proposed as the right and just way to proceed. For the most part, this style of scholarship has generated a range of valid and informative arguments in favour of extending and affirming collective rights to TK and options for managing an ABS regime. While much of this is focused on the formal intellectual property rights (IPRs) system – embodied in national patent and plant breeders' laws and in international treaties such as the WIPO and the TRIPS Agreement of the WTO – a complementary approach has been to examine the institutions and mechanisms that give effect to policies that relate to TK and ABS (e.g. CGIAR material transfers agreement system).

Against this institutional backdrop, scholars have attempted to refine how TK might be managed internationally and what rights, if any, claims of TK might have on benefit-sharing. At one extreme, Craig (2007) examines the international law and policy relating to human rights to determine if it could provide the basis for a *sui generis* system for protecting the knowledge of Indigenous people (Hodges & Langford, Chapter 2). She asserts that it is becoming increasingly clear that this type of system accords closely with a growing body of international law and policy specifically relating to the aspirations of Indigenous peoples for self-determination (Perron-Welch & Oguamanam, Chapter 6). Much work remains to be done to

understand the interplay of human, environmental and specific Indigenous rights; the often-strained relationship between environmental and Indigenous rights raises fundamental moral and procedural issues that could come to play in any dispute.

At the other extreme, Mgbeoji (2007) argues that misappropriation of Indigenous peoples' knowledge is rooted in the long-standing and ongoing 'colonial assault' on Indigenous and TK systems. He sees the emergence of Indigenous knowledge systems, including jurisprudence, as legitimate parts of modern international law, but he acknowledges that in the final analysis effective protection requires significant work at the domestic level. He asserts one will first need to explore the juridical resources already recognized by Indigenous peoples in their daily production, use, sharing and propagation of knowledge (Chartrand et al., Chapter 8). Somewhere in the middle, Castle and Gold (2007) used a set of legal and philosophical arguments to assess claims for compensatory benefits, concluding that 'justifications for benefit sharing cannot be derived from claims to property rights in traditional knowledge, if not because natural property rights are themselves problematic, then because property is normally considered free unless there is a normative justification for restricting access, particularly in the case of knowledge assets.' In essence, legal assignments of rights are purposeful rather than simply a default setting.

Dutfield (2004) bridges to a more positive approach, asserting that the moral and legal obligations embodied in our legal structure intertwine in an array of regimes and instruments, including customary law, IPR vehicles (such as patents, trade secrets, copyrights and plant variety rights), contracts law (including provisions related to trade secrets, licenses and material transfer agreements) and concepts in civil and common law related to unfair competition, privacy, breach of confidence and passing off.

In the context of digital biology that is differentially undertaken by scientists operating in formal institutions in advanced industrial economies, the complexity of modern legal structures occupies a prime position. Finding a place for TK and ABS in the context of digital biology will be complicated.

Economic Utility

Economists wade into the normative discussion of TK and ABS by using models of economic liberty and individual choice to model and estimate the impacts of various choice sets. Welfare economics offer valuable insights into the scale of any benefits related to TK. They also provide perspectives on the effects of unaided distribution and directed programs of benefit-sharing. Most of the economic argumentation and analysis related to TK and ABS has focused on two primary issues. First, many economists are vitally concerned with innovation. They are most interested in the impact of incentives and institutional factors on the rate of investment in R&D and subsequent improvements in our productive capacity. In that sense, economists tend to focus on strategies aimed at optimizing (in terms of efficiency

and effectiveness) the use of knowledge from all available sources and not explicitly about protecting and preserving special types of property. Second, a number of economists, either directly or by inference, have attempted to measure the economic value of TK, which is an important input into policy debate, specific commercial ventures and adjudicating disputes. While philosophers and lawyers assert that their concern is for moral and legal justice, they are not indifferent to the prospect of assisting Indigenous communities to gain a greater share of the economic value of their TK. The monetary value is in many ways a competing moral perspective.

Ultimately, the diversity of life on earth is based on the protein-generating capacity of plants – the main question is what value one assigns to the TK that underpins that system. Richards (2008) argues it is very difficult to accurately estimate the economic value of TK because: (i) it is often an essential component in developing other products; (ii) most TK-derived products never enter modern markets and (iii) most TK has cultural or spiritual value that cannot be quantified in monetary terms.

Nevertheless, a number of groups and individuals have made attempts to estimate the gross value. The World Bank reports that agriculture comprises 31% of the GDP of low-income economies and the combined annual market of plant life forms (in pharmaceuticals, crop production, botanicals and natural care) was estimated at up to US$800 billion in 2007 (Mgbeoji, 2007; Wynberg and Laird, 2007). A 1992 UNCTAD-ICTSD Project on IPRs and sustainable development put the value of plant-based medicines in the pharmaceutical industry at US$61 billion annually, or about 10% of the annual value of production (Richards, 2008). Farnsworth (1988) asserts the link to TK was obvious in that they found 119 plant-based compounds used in medicine worldwide, 74% which had the same or related uses as the medicinal plants from which they were derived. The World Health Organization (WHO) also estimated that the global market for traditional therapies, including but going beyond medicinal compounds, at more than US$70 billion annually. As just one illustration of the scale of the issue, the Indian Government has estimated that worldwide more than 2,000 patents are issued annually based on traditional Indian medicines. More recently, a UNDP study reported that developing countries are losing as much as $300 million a year in unpaid royalties from farmers' seeds and over $5 billion a year in unpaid royalties for medicinal plants (based on a 2% royalty for material and knowledge transfers) (Shiva, 2001). As explored by Oguamanam and Koziol in Chapter 7 of this volume, it is possible for Indigenous peoples to lay down the preliminary building blocks for that kind of evaluation (no matter how elusive) in the Canadian context.

If one uses a simple model to calculate the net present value of even the most conservative transfers of TK embodied in medicinal plants and recently accessed landraces (at a discount rate of 5%, for example), the base value of these accessions is in the range of US$65 billion. Some advocates use these kinds of numbers to justify compensation claims for misappropriated value. The contrary view is that few,

if any, of the transfers of TK were exploited to their fullest economic potential without further invention and adaptation, and that most of the economic value being assigned to TK is actually more appropriately assigned to the subsequent investments in making this genetic material function in a new setting or new use. Posey (1999) also notes that economists at one level miss the core issue, in that they hesitate to assign any estimates to the intrinsic cultural or spiritual value of TK and related GR (Oguamanam, 2010). It is clear that money talks.

POLICY ISSUES AND IMPLICATIONS

In light of the reality (or at least our hypothesis) that the Nagoya Protocol will be able to offer little in the way that is practically useful to the management of digital (or synthetic) biology knowledge let alone the governance of this vital 21st century issue, the root of the issue would seem to be, how can (or will) international research development and collaborations take place in a world of digital biology? While any multitude of questions, implications and concerns can be raised in regard to this issue, it would seem that there are three basic, or fundamental considerations that can provide structure for moving forward.[3]

First, clearer distinction and definition of what is 'knowledge' is crucial. As has been the case for nearly the past decade, the identification of a gene's function is no longer patentable, as patent offices have determined that this is equivalent to discovery and is not an innovation by definition. In the context of digital biology, is the sequencing of a plant's genome knowledge or is it simply a set of data that requires analysis, assessment and the application of additional scientific techniques, prior to the generation of knowledge? As is identified above, the ability to sequence plant genomes at ever faster rates, is state-of-the-art within genomics research. The result will be vast resources of genomic data. Determining if these pools of data are knowledge will provide clarity to those involved at the public and private research levels as to what specifications may be applied to these resources at this point in the research spectrum. As a normative default, it is conceivable that both the physical GR and related knowledge should be equally subject to ABS given that generations of human conservation and curatorial efforts have been invested in their development and survival (Oguamanam, Chapter 11).

Second, should these pools of genomic data (if they are indeed determined to be knowledge) be classified as 'traditional knowledge?' The above observations establish that TK exists when there is application. Conceivably, the sequencing of a plant species that has never been used for food, medicine or any other cultural application, would suggest that this is not subject to TK protocols. While it may raise concerns about the potential for biopiracy, that is a separate argument from what is examined in the context of this chapter. The discipline of bioinformatics involves using mathematical algorithms to search through genomic databases to identify unique genes in a particular plant species. Once a unique gene is identified, digital

biology applications could be applied to develop an innovative product that is based upon, but not identical to, that which exists in the genomic database. The relationship between TK and digital biology needs to be governed by some parameters. Although some analysts and Indigenous peoples may not be so inclined,[4] it cannot remain a wide open and broadly interpreted issue, but a middle ground is possible. Defining the scope and scale of what is, and what is not, TK as it pertains to digital biology will greatly aid all researchers. It is possible that this knowledge may not need to be classified as TK to be subject to ABS. The ABS mechanisms could be made to work if a chain of custody could be constructed.

Third, what is the relationship between TK and national, sub-national and community-based governance structures? It would be expected that what is believed to be TK by one community, while an inherent and inalienable right, might not be respected or supported as TK by a national, provincial, or municipal government, let alone non-Indigenous actors in the private sector. This would cause big problems: operationally, it presumes that TK protection requires some kind of validation by a government external to the Indigenous community itself. That attitude is symptomatic of the asymmetrical power relations that have historically subjected TK to validation by entities that have no authority in Indigenous cultural circles (Oguamanam, 2018). At the same time, unfortunately, this is the practical reality from the perspective of some (hopefully not most), non-Indigenous stakeholders. Those non-Indigenous stakeholders may not feel bound by, and in practice may not be forced (i.e. by judicial orders, police powers, or other state actions) to comply with Indigenous legal traditions. That is simply the sad fact of the matter. On the bright side, these governance challenges are not only a matter of policy coordination; they also implicate fundamental constitutional and human rights, raising the stakes for all concerned (de Beer and Dylan, 2015; Nichols, Chapter 4). This issue of 'who decides' is vital, particularly at the local community level as the potential to involve legal injunctions to bring research collaborations to a stand-still, is a substantial issue of concern.

The core of digital biology advancement ultimately must address, if not resolve, these three issues and translate them into the legal and institutional structures that operate both within and beyond nation states. These issues are interwoven into international institutional research collaborations (i.e. CGIAR), philanthropic research efforts (i.e. Gates Foundation) and private sector investments into agriculture R&D that will have important future impacts on crop production and food security. The review of the existing landscape assessed by Crookshanks and Phillips (2012) suggests that no single model has emerged nor is any model showing particular efficacy – instead of being a problem, one might see the diversity of models as an opportunity for trialling and experimenting with new and better approaches.

The lack of consensus regarding a model or functioning framework is having a market effect. Given this general lack of clarity, private firms may be hesitant to fully engage in public-private partnership agreements regarding innovative agricultural

research, in some instances. Simply put, the absence of a defined path, could cause some firms to step back and evaluate their participation in some development projects. A slight nudge towards a decline in R&D agriculture investments could lead to fewer new crop varieties being commercialized, with opportunity costs for example in the fight against climate change or for food security. Clarity in this contentious issue is vital, given the spill over impacts of technology innovation designed to improve food security in those countries that most desperately need it.

CONCLUSION

We have identified gaps between normative and positivist research on ABS that spans across disciplines of economics, law, political science and others. This research gap is among the factors contributing to the inadequacies of institutional governance mechanisms for the era of digital biology. The topic of ABS and digital biology had been on the table during Nagoya negotiations, but was deprioritized given the desire to achieve at least some deal before talks collapsed. As such, the underlying issues are still simmering even though there is some possibility to work within the extant Nagoya and other adjunct frameworks as demonstrated in the contributions to this volume (Oguamanam, Chapters 11, 14). Yet as we move further into the twenty-first century, rapid technological developments will continue to make physical materials transfers less relevant for scientific research collaborations. Digital data are supplanting biological samples as the mode of conveyance of GR and associate TK. Industry and Indigenous community partners must, therefore, urgently address issues of data ownership, sovereignty, and stewardship.

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NOTES

1 The problem has caught the attention of the Convention on Biological Diversity which in 2016 set up an Ad Hoc Technical Exert Working Group on Digital Sequence Information on Genetic Resources. See further discussion of that initiative by Chidi Oguamanam in Chapter 14.
2 However, as explained by Oguamanam in Chapter 14, members of the CBD Expert Working Group on Digital Sequence Information are split in their interpretation and understating of this matter.
3 See also Oguamanam's preferred solutions in Chapter 1 of this volume; these are anchored in the International Plant Treaty multilateral model of ABS and the Nagoya protocol approach to transboundary genetic resources.
4 From the outcome of the ABS Canada Focus Groups and the contribution from Oguamanam & Koziol in Chapter 7 of this volume, it is abundantly clear that this relationship invokes suspicion in Indigenous circles. It is seen as a site for power relations that would result in the use of technologies to foster biopiracy and the ongoing exploitation of Indigenous TK.