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Bio-Based Innovation and the Global Patent System: Exploring the WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge

This opinion critically examines the 2024 WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge, a new instrument addressing the use of genetic resources (GR), and traditional knowledge associated with GR (ATK) in the global patent system. Given the Treaty's position at the intersection of intellectual property and environmental law, this article discusses its history and negotiation in the first part, including the Treaty's links to the Convention on Biological Diversity (CBD) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). It then discusses the concept of bio-based innovation and its role in the bioeconomy. Following this, the article assesses the Treaty's contents, including its context and objectives, scope, the Patent Disclosure Requirement (PDR), sanctions and remedies for non-compliance with the PDR, information systems on GR and ATK, and its relationship with other international instruments. The article highlights the extensive diplomatic negotiations that shaped the final text and considers potential amendments that could be made during the Treaty's review process. The Treaty is intended to improve the global patent system's effectiveness, transparency, and quality concerning GR and ATK and to prevent Offices from granting patents erroneously. Its provisions present new challenges and complexities for stakeholders, and its long-term success will depend on ongoing international collaboration and engagement, both within and outside the Treaty's framework, and ensuring equitable benefit-sharing from the use of GR and ATK as part of a global sustainable bioeconomy.

I. Background and historical context

The Diplomatic Conference to Conclude an International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources (Diplomatic Conference) was held from 13–24 May 2024 at WIPO Headquarters in Geneva and resulted in the new WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge¹ (GRATK Treaty). This marks a significant step forward in bridging global intellectual property (IP) and biodiversity law.

The GRATK Treaty is WIPO's first in over a decade, and the only one to address the complex interface

between patents, GR and ATK.² It emerged from over two decades of study, debate and negotiation under the aegis of the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) – a forum established by the WIPO General Assembly that has met nearly 50 times since 2001.³

The Treaty represents a concerted effort to balance the interests of biodiversity-rich developing countries, Indigenous Peoples and Local Communities (IPLC), and the biotechnology industry. Its origins lie in debates on biotechnology and intellectual property (IP) dating back to the early 1980s.⁴

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¹ WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge, 24 May 2024 (not in force), WIPO Doc GRATK/DC/7; Chidi Oguamanam, 'The New WIPO Genetic Resources and Associated Traditional Knowledge Treaty: A Symbolic and Modest Step Toward an Inclusive and Just IP System' (24 May 2024) <<https://www.oguamanam.com/publications/new-wipo-treaty>> accessed 16 September 2024; Frédéric Perron-Welch, 'Striking a Balance Between Innovation and Tradition in the Global Patent System' (2024) 19(10) JIPLP 747. As of 16 July 2024, there were 36 signatories to the Treaty <<https://www.wipo.int/export/sites/www/treaties/en/docs/pdf/gratk.pdf>> accessed 16 September 2024.

² Perron-Welch, 'Striking a Balance Between Innovation and Tradition' (n 1).

³ Chidi Oguamanam, 'Understanding African and Like-Minded Countries' Positions at WIPO-IGC' (2020) 60(2) IDEA 151, 169–223; David Laux, 'Intellectual Property Protection for Genetic Resources, Traditional Knowledge, and Folklore: Will the On-Going WIPO Efforts Result in a Formal Treaty?' (2023) 103(4) Journal of the Patent and Trademark Office Society 353, 354–64; Gert Würtenberger and Stephan Freischem, 'GRUR Taskforce IGC: The WIPO Draft International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources – Overview and Analysis' [2024] GRUR International 139.

⁴ Frédéric Perron-Welch, 'Biodiversity, Traditional Knowledge and Patents: Unpacking the WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge' [2025] Transnational Environmental Law (forthcoming).

One root is in negotiations between industrialized ‘user’ and developing ‘provider’ countries over access to genetic resources (GR) and traditional knowledge, innovations and practices related to biodiversity, which resulted in the 1992 Convention on Biological Diversity⁵ (CBD) and its rules on access and benefit-sharing (ABS).⁶ This divide is less contentious now that many countries are both users and providers of GR and ATK, but only 2/3 of WIPO Member States are party to the CBD’s specialized instrument on ABS – the 2010 Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization⁷ (Nagoya Protocol).

Another root of the GRATK Treaty is in debates over the patenting of life forms during the World Trade Organization (WTO) negotiations,⁸ a right provided for in the 1994 Agreement on Trade-Related Aspects of Intellectual Property Rights⁹ (TRIPS Agreement) and its three-step test on patentable subject matter involving novelty, inventiveness, and utility.¹⁰ As a product of nature, GR cannot be patented.¹¹ However, TRIPS ensures that wide areas of biotechnology are accessible to patent protection,¹² and the practice of patentability of micro-organisms in particular is recognized.¹³ The WTO remains engaged on this issue, and despite decades of inconclusive negotiations, with diverse viewpoints represented throughout, no conclusion is in sight.¹⁴

As the CBD addresses biotechnology, GR and patents,¹⁵ establishing a patent disclosure requirement

(PDR) was recognized by the early 1990s as a possible tool to link ABS and IP.¹⁶ Yet, it took decades of challenging negotiations across three different fora – the CBD, WTO, and WIPO – before discussions were concluded based on the work of the WIPO IGC.¹⁷ Working from a Basic Proposal with substantive provisions drawn from the 2019 IGC Chair’s Text,¹⁸ Member States vigorously debated the proposed text for two weeks before agreeing to a diplomatic compromise put forward by the President of the Diplomatic Conference in the early hours of 24 May 2024.¹⁹ Diplomatic Conference negotiations occurred on parallel tracks, with Main Committee I (MC I) addressing the substantive provisions (Preamble – Art. 10 of the Basic Proposal), while Main Committee II (MC II) looked at administrative matters and final provisions (Arts. 11–23 of the Basic Proposal).

Substantive issues were negotiated and agreed upon in line with the five Guardrail Principles (Guardrails) established by the President of MC I,²⁰ which included that: (1) the Basic Proposal establishes a disclosure requirement for patents only; (2) broader (*sui generis*) protection of traditional knowledge and traditional cultural expressions is the work of the IGC; (3) existing international law is not re-interpreted; (4) policy flexibility is needed for national implementation; and (5) emerging issues can be addressed in the Review.²¹

This often meant returning to the Basic Proposal after lengthy debates, consultations, and alternative text proposals.²² The GRATK Treaty explicitly acknowledges that States will only address certain issues in the Review (like Art. 10 of the Nagoya Protocol) and formalizes the Review with that purpose. WIPO Member States debated the length of time before Parties would conduct the review, but did not challenge the underlying rationale, also agreeing that a Diplomatic Conference convened by the Assembly could amend the Treaty to revise its scope.²³

⁵ Convention on Biological Diversity, 5 June 1992 (in force 29 December 1993), 1760 UNTS 79 (‘CBD’).

⁶ *ibid* art 1 states that the CBD’s third objective is: ‘the fair and equitable sharing of the benefits arising out of the utilization of ... [GR], including by appropriate access to ... [GR] and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.’ See Pedro Henrique D Batista, ‘The WIPO IGC Chair’s Draft on IP and Genetic Resources – Reasons for Concern’ (2024) 19(4) *JIPLP* 328, 329; Würtenberger and Freischem (n 3) 139.

⁷ Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, 29 October 2010 (in force 12 October 2014) 3008 UNTS 3 (‘Nagoya Protocol’). As of 16 September 2024, the Nagoya Protocol has 141 Parties. See <<https://absch.cbd.int/en/countries>> accessed 16 September 2024.

⁸ Mahadev G Bhat, ‘Trade-Related Intellectual Property Rights to Biological Resources: Socioeconomic Implications for Developing Countries’ (1996) 19(3) *Ecological Economics* 205, 205–08; Jagjit Plahe and others, ‘Review of Article 27.3(b) and the Patenting of Life Forms: Hitting a BRIC Wall in the WTO?’ (2021) 26(2) *International Negotiation* 289, 295.

⁹ Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994 (in force 1 January 1995), 1869 UNTS 299.

¹⁰ *ibid* art 27.1; Andreas Neef and Susanne Reyes-Knoche in Peter-Tobias Stoll, Jan Busche and Katrin Arend (eds), *WTO – Trade-Related Aspects of Intellectual Property Rights* (Brill Nijhoff 2009) art 27.1. Würtenberger and Freischem (n 3) 141–42.

¹¹ Jill T Powlick, ‘Patents and Laboratory Medicine: What is Required to Turn an Unpatentable Natural Phenomenon or Law of Nature into a Patentable Invention?’ (2012) 58(8) *Clinical Chemistry* 1205; Alice Yuen-Ting Wong and Albert Wai-Kit Chan, ‘Myriad and Its Implications for Patent Protection of Isolated Natural Products in the United States’ (2014) 9 *Chinese Medicine* 17.

¹² Susanne Reyes-Knoche in Peter-Tobias Stoll, Jan Busche and Katrin Arend (eds), *WTO – Trade-Related Aspects of Intellectual Property Rights* (Brill Nijhoff 2009) art 27.3 lit b, 502.

¹³ *ibid* 505.

¹⁴ Alejandro Madrazo, ‘Biocolonialism: TRIPs and the Genetic No Man’s Land’ (2013) 25(4) *Georgetown International Environmental Law Review* 487; Plahe and others (n 8).

¹⁵ CBD (n 5) arts 16(3) and 16(5).

¹⁶ See eg Frédéric Hendrickx and others, ‘Access to Genetic Resources: A Legal Analysis’ in Vicente Sánchez and Calestous Juma (eds), *Biodiplomacy: Genetic Resources and International Relations* (African Centre for Technology Studies 1994) 148; The Crucible Group, *People, Plants, and Patents: The Impact of Intellectual Property on Biodiversity, Conservation, Trade, and Rural Society* (International Development Research Centre 1994) 68.

¹⁷ Paul Kuruk, ‘Preventing Misappropriation: The Disclosure Requirement’ in Paul Kuruk, *Traditional Knowledge, Genetic Resources, Customary Law and Intellectual Property* (Edward Elgar 2020) 405–12; Viviana Muñoz Tellez, *A Breakthrough in Negotiations on Intellectual Property, Protection of Genetic Resources and Traditional Knowledge in WIPO?* (South Centre 2022) 2; WIPO, *63rd Assemblies: List of Decisions – 2022* (WIPO 2022) 7–8.

¹⁸ Basic Proposal for an International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources, WIPO Doc. GRATK/DC/3 (‘Basic Proposal’); Chair’s Text of a Draft International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge associated with Genetic Resources, WIPO Doc. WIPO/GRTKF/IC/43/5, Annex (‘Chair’s Text’); Batista (n 6) 328; Würtenberger and Freischem (n 3) 144.

¹⁹ Formally, the President’s Final Proposal for a WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge, 24 May 2024 (on file with the author); Perron-Welch, ‘Striking a Balance Between Innovation and Tradition in the Global Patent System’ (n 1).

²⁰ Jodie McAlister, ‘Non-paper – Guardrail Principles’ (WIPO, 14 May 2024) <https://www.wipo.int/edocs/mdocs/tk/en/gratk_dc/gratk_dc_non_paper.pdf> accessed 16 September 2024.

²¹ *ibid*.

²² Author’s notes (on file).

²³ GRATK Treaty (n 1) art 14.

To foster consensus, negotiations were mostly held in an informal manner, including through *ad hoc* working groups, breakout groups, and – ultimately – consultations on a Proposal by the President of the Diplomatic Conference.²⁴ Although Member States and negotiating blocs sometimes reverted to longstanding IGC positions as *demandeurs* or *non-demandeurs* of a new legal instrument,²⁵ divisions were gradually overcome through the diligent efforts of the Presidents of MC I (Australia), MC II (Namibia), and the President of the Diplomatic Conference (Brazil), who guided negotiators toward agreement on a compromise between full harmonization and the exercise of national flexibilities.²⁶ A low bar to entry into force was established at 15 eligible Parties (which include WIPO Member States and the European Union; membership by regional IP organizations must be approved by the Assembly of the Parties).²⁷

This article focuses on the substantive issues addressed by the GRATK Treaty with the aim of informing IP practitioners, patent examiners, lawmakers, and academics of the practical implications of this new Treaty that aims to improve the effectiveness, transparency and quality of the patent system and prevent the erroneous grant of patents, sometimes referred to as ‘misappropriation’²⁸ or ‘biopiracy’²⁹ in the literature.

In doing so, this article seeks to address a few systematic questions and ambiguities identified on terms and definitions,³⁰ and clarify the legal relationship between the GRATK Treaty and other international instruments, particularly the Nagoya Protocol.

II. The bioeconomy and bio-based innovation

The bioeconomy is a new paradigm aiming create, develop, and revitalize economic systems through the sustainable use of renewable biological resources, which will play a central role in the radical transformation needed to bring environmental sustainability to economic activities in the

first half of the 21st century and living in harmony with nature.³¹ While the bioeconomy concept is still quite ambiguous and widely contested,³² biotechnology is recognized as a core element.³³ A 2019 definition describes the bioeconomy as ‘the set of economic activities in which biotechnology and the life sciences ... contribute[s] centrally to primary production and industry through the conversion of biomass into food, materials, chemicals and fuels.’³⁴ It is highly knowledge-intensive, as acknowledged by the European concept of a ‘Knowledge-Based Bioeconomy’.³⁵

Bio-based innovation – or the outcome of research and development based on genetic resources³⁶ – will be critical to the urgently needed transition to a sustainable bioeconomy. Life and biological sciences and technologies are the drivers and enablers of bio-based innovation.³⁷ They are now undergoing a transformative revolution resulting from the convergence of decades of developments in the biological sciences and advancements in computing, automation, and artificial intelligence (AI), fueling a new wave of innovation influencing many sectors, with profound social and economic impacts.³⁸ Now heavily data-driven, the life and biological sciences rely on inventions supporting the digitalisation of bio-based innovation and the use of bioinformatics, AI and deep learning.³⁹ Indeed, this has been identified as a constituent element of the 4th Industrial Revolution characterized by a fusing of the digital, physical, and biological worlds.⁴⁰

³¹ Andreas Pyka and Klaus Prettnner, ‘Economic Growth, Development, and Innovation: The Transformation Towards a Knowledge-Based Bioeconomy’ in Iris Lewandowski (ed), *Bioeconomy: Shaping the Transition to a Sustainable, Biobased Economy* (Springer 2018) 334; Alfredo Aguilar, Thomasz Twardowski and Roland Wohlgemuth, ‘Bioeconomy for Sustainable Development’ (2019) 14(8) *Biotechnology Journal* 1800638, 1; CBD, ‘Kunming-Montreal Global Biodiversity Framework’ UN Doc. CBD/COP/DEC/15/4, Annex, para 10: ‘The vision ... is a world of living in harmony with nature where “by 2050, biodiversity is valued, conserved, restored and wisely used, maintaining ecosystem services, sustaining a healthy planet and delivering benefits essential for all people.”’

³² Thomas Vogelpohl and Annette Elisabeth Töller, ‘Perspectives on the Bioeconomy as an Emerging Policy Field’ (2021) 23(2) *Journal of Environmental Policy & Planning* 143, 147.

³³ CBD (n 5) art 2: “‘Biotechnology’ means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.”

³⁴ OECD, *Innovation Ecosystems in the Bioeconomy* (OECD 2019) 9.

³⁵ Manfred Kircher and others, ‘KBBE: The Knowledge-Based Bioeconomy: Concept, Status and Future Prospects’ (2022) 2 *EFB Bioeconomy Journal* 100034, 2.

³⁶ Elisa Morgera, ‘SDG 15: Protect, Restore and Promote Sustainable Use of Terrestrial Ecosystems, Sustainably Manage Forests, Combat Desertification, and Halt and Reverse Land Degradation and Halt Biodiversity Loss’ in Jonas Ebbesson and Ellen Hey (eds), *The Cambridge Handbook of the Sustainable Development Goals and International Law* (CUP 2022) 393.

³⁷ Sven Wydra and others, *Life and Biological Sciences and Technologies as Engines for Bio-Based Innovation: Studies on Support to Research and Innovation Policy in the Area of Bio-Based Products and Services. Independent Expert Report* (European Union 2021) 81.

³⁸ Frédéric Perron-Welch, ‘Synthetic Biology and Its Potential Implications for BioTrade and Access and Benefit-Sharing’ (UNCTAD 2019); Michael Chui and others, ‘The Bio Revolution: Innovations Transforming Economies, Societies, and Our Lives’ (McKinsey Global Institute 2020).

³⁹ Wydra and others (n 37) 83. See further Haseong Kim, ‘AI, Big Data, and Robots for the Evolution of Biotechnology’ (2019) 17(4) *Genomics & Informatics* e44.

⁴⁰ Klaus Schwab, *The Fourth Industrial Revolution* (Crown Currency 2017); Cath O’Driscoll, ‘Designer Biology’ (2017) 81(3) *Chemistry & Industry* 30, 32; Víctor de Lorenzo and Markus Schmidt, ‘Biological Standards for the Knowledge-Based BioEconomy: What is at Stake’ (2018) 40(Pt A) *New Biotechnology* 170, 171.

²⁴ The so-called ‘President’s Proposal’ (on file with the author). Chidi Oguamanam, ‘WIPO Diplomatic Conference on Genetic Resources and Associated Traditional Knowledge: Slow Progress, Hopeful Outlook’ (20 May 2024) <<https://abs-canada.org/wipo-diplomatic-conference-slow-progress-hopeful-outlook/>> accessed 16 September 2024.

²⁵ Wend Wendland, ‘International Negotiations on Indigenous Knowledge to Resume at WIPO: A View of the Journey So Far and the Way Ahead’ (February 2022) <https://www.wipo.int/wipo_magazine_digital/en/2022/article_0001.html> accessed 16 September 2024.

²⁶ Oguamanam, ‘WIPO Diplomatic Conference on Genetic Resources and Associated Traditional Knowledge’ (n 24); Perron-Welch, ‘Striking a Balance Between Innovation and Tradition in the Global Patent System’ (n 1); Author’s notes (on file).

²⁷ GRATK Treaty (n 1) arts 12 and 17.

²⁸ Batista (n 6) 328; Württenberger and Freischem (n 3) 145.

²⁹ Hamdallah Zedan, ‘Patents and Biopiracy: The Search for Appropriate Policy and Legal Responses’ (2005) 12(1) *The Brown Journal of World Affairs* 189; Ikechi Mgbeoji, *Global Biopiracy: Patents, Plants and Indigenous Knowledge* (Cornell University Press 2006); Oluwatobiloba Moody, ‘Addressing Biopiracy through an Access and Benefit Sharing Regime Complex: In Search of Effective Protection for Traditional Knowledge Associated with Genetic Resources’ (2016) 16 *Asper Review of International Business and Trade Law* 231; Chidi Oguamanam and Christopher Koziol, ‘Biopiracy Flashpoints and Increasing Tensions over ABS in Canada’ in Chidi Oguamanam (ed), *Genetic Resources, Justice and Reconciliation: Canada and Global Access and Benefit Sharing* (CUP 2018).

³⁰ Württenberger and Freischem (n 3) 140.

Patents are critical to bio-based innovation as they provide an incentive to undertake the critical research and development needed to meet contemporary sustainability challenges, and they have shown a steady global growth in numbers this century.⁴¹ The GRATK Treaty will help ensure that the growth in the number of patents for bio-based innovations is accompanied by greater transparency, securing the quality of the patent system and reducing uncertainty about the validity of patents over inventions based on GR and ATK, to the benefit of all stakeholders. In doing so, it may help address some risks and opportunities facing traditional knowledge systems in the 4th Industrial Revolution and the continued evolution of the bioeconomy as a knowledge-intensive area.⁴²

III. Context and objectives

International norm-setting in the IP field is facing challenges because of greater acknowledgement of the patent system's role in the knowledge-based economy, as inventors seek protection across more commercial sectors and geographic territories, and concerns emerge over the patent system's social and economic roles, including in sensitive policy areas like ABS.⁴³

Patent treaties are aimed at areas that are impossible or impractical to address strictly under national patent law given an era's particular technical, political and economic circumstances.⁴⁴ Increasing transparency on the use of GR and ATK in the patent system certainly falls into this category due to our contemporary globalized economy and commercial dynamics in the field of modern biotechnology⁴⁵ – where many States are now both users and providers of GR and ATK – making it a logical area for international regulation.

Setting an international PDR norm in the global patent system through the GRATK Treaty required over two decades of work at the IGC, and the Treaty only addresses part of the work of that forum.⁴⁶ The main challenge lay in balancing the need for transparency with the burden on innovators given that States and stakeholders have differing views on what constitutes reasonable disclosure. Biodiversity-rich developing countries and IPLC seek stringent requirements to prevent biopiracy, while industry stakeholders argue for flexibility to minimize impacts on innovation.

Like other treaties making up the patent system, the GRATK Treaty establishes common rules which increase international legal certainty by committing States to

bring their national laws closer together by consenting to implement the same or similar legal standards to those prescribed in the treaty.⁴⁷

The main rules in the GRATK Treaty relate to the international PDR, as expressed in Arts. 3 and 5.⁴⁸ As the functioning of a PDR was understood prior to the Diplomatic Conference,⁴⁹ the crux of the negotiations on this norm focused on defining a common approach to disclosure – including on the scope, trigger and content of the PDR (Arts. 2 and 3)⁵⁰ – and delineating the limits of pre- and post-grant sanctions and remedies for non-compliance (Art. 5).⁵¹

The *non-demandeurs* were not entirely successful in promoting the most forgiving standard of harmonization where Parties may not implement post-grant patent law sanctions because negotiators did not agree to this 'ceiling'. As is the case with most new international agreements, States may need to modify existing national and regional laws to align with the Treaty's requirements.

As the Basic Proposal suggested, the GRATK Treaty aims to promote and enhance the efficacy, transparency, and quality of the patent system in relation to GR and ATK, recognizing the importance of patent offices having access to appropriate information to prevent patents from being granted erroneously for inventions that are not novel or inventive.⁵²

This dual objective appeals to the interests of all potential Parties by simultaneously seeking to improve the patent system and prevent misappropriation.⁵³ The Chair's Notes indicate that the term 'efficacy' was used to indicate that a PDR that improves the transparency and quality of the patent system should be effective, practical, easily implementable, and not result in overly burdensome transaction costs at the national level.⁵⁴ Indeed, while justly aiming to prevent misappropriation, a PDR could pose practical challenges for patent applicants and overly burdensome requirements should be avoided as they could hinder compliance and innovation, working against the transparency and traceability of GR and ATK.

The Treaty's reference to 'preventing erroneous grants of patents' aims to address the concerns of biodiversity-rich countries and holders of GR and ATK over 'misappropriation' or 'biopiracy' of their resources and

⁴⁷ Miyamoto (n 43) 30.

⁴⁸ Perron-Welch, 'Striking a Balance Between Innovation and Tradition in the Global Patent System' (n 1).

⁴⁹ See eg Donna O Perdue, 'Patent Disclosure Requirements Related to Genetic Resources: The Right Tool for the Job?' (2017) 36(6) *Biotechnology Law Report* 285; Claudio Chiarolla, 'Intellectual Property from a Global Environmental Law Perspective: Lessons from Patent Disclosure Requirements for Genetic Resources and Traditional Knowledge' (2019) 8(3) *Transnational Environmental Law* 503; WIPO, *Key Questions on Patent Disclosure Requirements for Genetic Resources and Traditional Knowledge* (2nd edn, WIPO 2020).

⁵⁰ Author's notes (on file); cf Basic Proposal (n 18) art 2 '[materially/directly] based on' and GRATK Treaty (n 1) art 2, 'based on'.

⁵¹ Negotiators deleted art 6.5 of the Basic Proposal on alternative dispute resolution, and the President of the Diplomatic Conference inserted a new para 5.2^{bis}, which allows Parties to exclude cases of fraud from rectification.

⁵² GRATK Treaty (n 1) preambular paras 1-2 and art 1(a)-(b).

⁵³ Perron-Welch, 'Striking a Balance Between Innovation and Tradition in the Global Patent System' (n 1).

⁵⁴ Chair's Text (n 18) 5; Würtenberger and Freischem (n 3) 145.

⁴¹ European Commission Joint Research Centre, *Exploring the Global Landscape of Biotech Innovation: Preliminary Insights from Patent Analysis* (Publications Office of the European Union 2024).

⁴² Chidi Oguamanam, 'Transition to the Fourth Industrial Revolution: Africa's Science, Technology and Innovation Framework and Indigenous Knowledge Systems' (2022) 15(1) *African Journal of Legal Studies* 1, 2.

⁴³ Tomoko Miyamoto, 'International Treaties and Patent Law Harmonization: Today and Beyond' in Toshiko Takenaka (ed), *Research Handbook on Patent Law and Theory* (2nd edn, Edward Elgar 2019) 27.

⁴⁴ *ibid* 29.

⁴⁵ See further European Commission Joint Research Centre (n 41).

⁴⁶ Chidi Oguamanam, 'The Significance of the WIPO 2024 Diplomatic Conference on Genetic Resources and Traditional Knowledge: Ten Major Issues' (7 May 2024) <<https://abs-canada.org/the-significance-of-the-wipo-2024-diplomatic-conference-ten-major-issues/>> accessed 16 September 2024; Laux (n 3).

knowledge through the patent system, while using a more neutral and technical term.⁵⁵ This is underscored through the preamble's recognition of the potential role of the patent system in contributing to the protection of GR and ATK.⁵⁶

It is important to note in this context that the GRATK Treaty aims at providing a form of defensive protection for GR and ATK, not positive *sui generis* protection – an open topic of discussion at the IGC. Higher quality patents contribute to a more robust and reliable patent system, which is beneficial for all stakeholders in the long term because benefit-sharing depends on securing healthy financial returns for novel bio-based products.

Parties further recognize that increased legal certainty and consistency results from an international disclosure requirement on GR and ATK in patent applications, which benefits the patent system as well as 'providers' and 'users' of GR and ATK.⁵⁷ Higher quality patents contribute to a robust and reliable patent system, which benefits all stakeholders and rights holders.

As the GRATK Treaty lies at the nexus of IP law and the ABS regime complex,⁵⁸ Parties recognize the general need for mutual supportiveness with other instruments related to GR and ATK in the preamble and the text of the agreement.⁵⁹ By indirectly promoting the legal use of GR and ATK through transparency, the Treaty supports a sustainable innovation ecosystem that supports biodiversity conservation and sustainable use through the fair and equitable sharing of benefits from the utilization of GR and ATK.⁶⁰ Through compliance with national ABS law, innovators will engage in practices that do not deplete or harm the biodiversity from which GR are derived.

Underscoring the GRATK Treaty's origins at WIPO – a forum that is a staunch supporter of the patent system and where the framing of discussions caters to patent holders⁶¹ – Parties recognize and reaffirm the underlying role that the IP system plays in promoting innovation, transfer and dissemination of knowledge and economic development, to the mutual advantage of 'providers' and 'users' of GR and ATK.⁶² This links IP with ABS, recognized in the CBD and Nagoya Protocol in the context of access to and transfer of technology – including biotechnology – covered by IP rights.⁶³

Notably, this is the first WIPO Treaty to address the role of Indigenous Peoples and local communities

(IPLC). Participation by Indigenous Peoples has been an important feature of the IGC's dynamics, and since the adoption of the United Nations Declaration on the Rights of Indigenous Peoples⁶⁴ (UNDRIP), they have sought to introduce its wording and provisions into deliberations.⁶⁵

Building on the precedent set by the Nagoya Protocol,⁶⁶ Parties acknowledge the UNDRIP,⁶⁷ an international human rights instrument that includes a provision on the right of Indigenous Peoples to 'maintain, control, protect and develop their ... traditional knowledge ... as well as the manifestations of their sciences, technologies and cultures, including ... [GR], seeds, medicines, [and] knowledge of the properties of fauna and flora ... [and] the right to maintain, control, protect and develop their ... [IP] over such... traditional knowledge'.⁶⁸ It also includes a requirement for States to take effective measures to recognize and protect the exercise of these rights in conjunction with Indigenous Peoples.⁶⁹

In text that was not part of the Basic Proposal but arose from the debate on the continued participation of IPLC in implementation, Parties affirmed 'that best efforts should be made to include Indigenous Peoples and local communities, as applicable, in implementing this Treaty'.⁷⁰ At the international level, this means institutionalizing existing IGC practice on the 'effective participation' of Indigenous Peoples.⁷¹ At the domestic level, Parties may do this through the implementation of information systems,⁷² but will do so in accordance with their right to determine 'the appropriate method of implementing the provisions of this Treaty within their own legal systems and practices'.⁷³

IV. Scope of application

The scope of the GRATK Treaty can be determined from its Preamble and Art. 1 (Objectives), Art. 2 (List of Terms), Art. 3 (Disclosure Requirement), and Art. 4 (Non-Retroactivity).⁷⁴ Guided by these provisions, this

⁵⁵ Ahmed Abdel-Latif, 'Revisiting the Creation of the IGC: The Limits of Constructive Ambiguity?' in Daniel Robinson and others (eds), *Protecting Traditional Knowledge: The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore* (Routledge 2017) 24.

⁵⁶ *ibid* preambular para 3.

⁵⁷ *ibid* preambular para 4 and art 3.

⁵⁸ Sylvain Aubry and others, 'Bringing Access and Benefit Sharing into the Digital Age' (2022) 4(1) *Plants, People, Planet* 5, 6; Elisa Morgera, 'Inter-State Benefit-Sharing from Access to Genetic Resources' in Elisa Morgera, *Fair and Equitable Benefit-sharing in International Law* (OUP 2024) 63.

⁵⁹ *ibid* preambular para 5 and art 7.

⁶⁰ Nagoya Protocol (n 7) art 9.

⁶¹ Abdel-Latif (n 55) 24.

⁶² *ibid* preambular para 6.

⁶³ CBD (n 5) art 16; Elisa Morgera, 'Inter-State Benefit-Sharing as Scientific and Technological Cooperation' in Elisa Morgera, *Fair and Equitable Benefit-sharing in International Law* (OUP 2024) 104.

⁶⁴ United Nations Declaration on the Rights of Indigenous Peoples, UN Doc. A/RES/61/295 ('UNDRIP').

⁶⁵ Abdel-Latif (n 55) 26-27.

⁶⁶ Konstantia Koutouki and Katharina Rogalla von Bieberstein, 'The Nagoya Protocol: Sustainable Access and Benefits-Sharing for Indigenous and Local Communities' (2012) 13(3) *Vermont Journal of Environmental Law* 513, 525.

⁶⁷ *ibid* preambular para 7.

⁶⁸ UNDRIP (n 64) art 31.1.

⁶⁹ *ibid* art 31.2.

⁷⁰ GRATK Treaty (n 1) preambular para 8.

⁷¹ *ibid* art 10.1(c). For critiques of this approach, see eg Veronica Gordon, 'Appropriation without Representation? The Limited Role of Indigenous Groups in WIPO's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore' (2014) 16(3) *Vanderbilt Journal of Entertainment and Technology Law* 629; Charles Lawson, Edwin Bikundo and Kieran Tranter, 'The Perils of Parliamentarism: The World Intellectual Property Organization and Indigenous Peoples' (2019) 39(2) *Oxford Journal of Legal Studies* 285.

⁷² *ibid* art 6.1.

⁷³ *ibid* art 9.2.

⁷⁴ Vienna Convention on the Law of Treaties, 23 May 1969 (in force 27 Jan 1980) 1155 UNTS 331; arts 31.1-31.2 hold that a treaty must be 'interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose' and that the context includes the text and preamble. In addition, art 31.4 states that 'special meaning shall be given to a term if it is established that the parties so intended.'

section of the article aims to define the Treaty's substantive, material, territorial and temporal scopes.

The Treaty's substantive scope covers patent law and the patent system, with an emphasis on ensuring that offices have the information needed to prevent patents from being granted erroneously for inventions that aren't new or inventive in regard to GR and/or ATK – implying that it is primarily concerned with utility patents for (bio)technical inventions.⁷⁵ Regarding plants in particular, in accordance with Art. 27 of the TRIPS Agreement, the term patent could cover patents 'on plants as such, on parts of the genome of plants or on plant groups and related use and process claims.'⁷⁶ The clear exclusion of plant variety protection and design patents narrows the treaty's focus and ensures that its provisions are manageable and targeted.

The GRATK Treaty defines the legal act involved (an 'application'⁷⁷), the connection to innovation ('based on'⁷⁸), and the actors (the 'applicant'⁷⁹ and the 'office'⁸⁰) in Art. 2, while Art. 3 establishes the norm on disclosure for claimed inventions in a patent application.

Given the Treaty's tight focus on patent law and the patent system, its substantive scope does not include plant variety protection, and the link to novelty and inventiveness in its aims suggests that design patents are not included either.⁸¹ As a result, it 'is largely an administrative treaty designed to enhance the transparency of the patent system.'⁸²

The Treaty's material scope is established in part by two terms drawn directly from the CBD: 'genetic material'⁸³ and 'genetic resources'.⁸⁴ This means that "recourse can be taken to the interpretations that have been established"⁸⁵ by the Conferences of the Parties (COP) to the CBD, interpretations such as its clarification that human GR are not included.⁸⁶

Although the concept of 'functional units of heredity' is now interpreted as more than just 'genes', the term GR remains linked to the embodiment of genetic information.⁸⁷ Consequently, the Treaty's scope does not cover claimed inventions based on a 'derivative'⁸⁸ that does not contain functional units of heredity,⁸⁹ nor does it address claimed inventions strictly based on 'digital sequence information on genetic resources'⁹⁰ (DSI) that did not utilize GR.⁹¹

The Treaty's scope over ATK is less clear as WIPO Member States deemed it premature to adopt a definition because of traditional knowledge negotiations on a different track under the IGC.⁹² The result is that the term ATK is left to be defined and interpreted according to national laws, regional agreements and judicial rulings, which causes some uncertainty.⁹³ This legal void introduces the possibility for inconsistencies and uncertainties but could be addressed by the IGC or Assembly.

Based on the Treaty's definitions and the deletion of Basic Proposal's provision on exceptions and limitations,⁹⁴ its geographical scope is global. While CBD terms like 'country of origin of genetic resources'⁹⁵ and 'in situ conditions'⁹⁶ speak to GR under national jurisdiction, the definition of 'source of genetic resources' includes 'any source from which the applicant has obtained the genetic resources ...'.⁹⁷ Consequently, the

⁸⁷ Würtenberger and Freischem (n 3) 146.

⁸⁸ Nagoya Protocol (n 7) art 2(e): "Derivative" means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity."

⁸⁹ GRATK Treaty (n 1) art. 8 suggests this interpretation as Parties commit to review the Treaty's scope and contents, 'addressing issues such as the possible extension of the disclosure requirement in Article 3 ... to derivatives ...'. See also Batista (n 6) 333; Würtenberger and Freischem (n 3) 146–47.

⁹⁰ CBD COP Decision 15/9 *Digital Sequence Information on Genetic Resources*, UN Doc. CBD/COP/DEC/15/9.

⁹¹ Batista (n 6) 333–34; Würtenberger and Freischem (n 3) 146 notes that: 'mere access to genetic information (as an "intangible" subject matter) will very likely not satisfy the requirement of a use of genetic material, which is by definition "tangible".' GRATK Treaty (n 1) art 8 also suggests this indirectly in through the review of the Treaty's scope and contents including 'addressing other issues arising from new and emerging technologies that are relevant for ... [its] application ...'.

⁹² Chair's Text (n 18) 7.

⁹³ Würtenberger and Freischem (n 3) 148. See eg African Regional Intellectual Property Organization (ARIPO), 'Swakopmund Protocol on The Protection Of Traditional Knowledge And Expression Of Folklore', 9 August 2010 (in force 11 May 2015, amended 6 December 2016) (ARIPO 2017) art 2: "Traditional knowledge" shall refer to any knowledge originating from a local or traditional community that is the result of intellectual activity and insight in a traditional context, including know-how, skills, innovations, practices and learning, where the knowledge is embodied in the traditional lifestyle of a community, or contained in the codified knowledge systems passed on from one generation to another. The term shall not be limited to a specific technical field, and may include agricultural, environmental or medical knowledge, and knowledge associated with genetic resources."

⁹⁴ Basic Proposal (n 18) art 4; foreshadowing this removal, Batista (n 6) 333 noted that it was challenging to understand 'to what extent an exception or limitation could be justified if the patent applicant only has to declare the origin or the source... [especially] in view of Article 3.3 ...'.

⁹⁵ GRATK Treaty (n 1) art 2: "'Country of origin of genetic resources" means the country which possesses those genetic resources in *in situ* conditions."

⁹⁶ GRATK Treaty (n 1) art 2: "'In situ conditions" means conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties."

⁹⁷ GRATK Treaty (n 1) art 2.

⁷⁵ GRATK Treaty (n 1) preambular paras 1–2 and arts 1(a)–(b).

⁷⁶ Würtenberger and Freischem (n 3) 145.

⁷⁷ GRATK Treaty (n 1) art 2: "Application" means an application for granting of a patent."

⁷⁸ GRATK Treaty (n 1) art 2: "Based on" means that the ... [GR and/or ATK] must have been necessary for the claimed invention, and that the claimed invention must depend on the specific properties of the ... [GR and/or on the ATK]."

⁷⁹ *ibid*: "Applicant" means the person whom the records of the Office show, pursuant to the applicable law, as the person who is applying for the granting of a patent, or as another person who is filing or prosecuting the application."

⁸⁰ *ibid*: "Office" means the authority of a Contracting Party entrusting with the granting of patents.' This could be a national or international office. See *ibid*: "Contracting Party" means any State or intergovernmental organization party to this Treaty.' In keeping with GRATK Treaty (n 1) art 12, the Assembly can admit intergovernmental offices as Parties.

⁸¹ This interpretation may change, as the GRATK Treaty (n 1) art 8 indicates that Parties commit to review the scope and contents of the Treaty 'addressing issues such as the extension of the disclosure requirement in Article 3 to other areas of intellectual property ...'. WIPO Member States will negotiate a Design Law Treaty which touches on GR and ATK at a Diplomatic Conference in November 2024, see Basic Proposal for the Design Law Treaty, WIPO Doc. DLT/DC/3.

⁸² Oguamanam, 'The New WIPO Genetic Resources and Associated Traditional Knowledge Treaty' (n 1).

⁸³ GRATK Treaty (n 1) art 2; CBD (n 5) art 2: "Genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity."

⁸⁴ GRATK Treaty (n 1) art 2; CBD (n 5) art 2: "Genetic resources" means genetic material of actual or potential value."

⁸⁵ Würtenberger and Freischem (n 3) 146.

⁸⁶ CBD COP Decision II/11 *Access to Genetic Resources*, UN Doc. UNEP/CBD/COP/DEC/II/11 para 2; GRATK Treaty (n 1) art 2, footnote 1.

scope of the Treaty also covers GR obtained from areas beyond national jurisdiction and ATK on such GR.⁹⁸ This means that all GR are included in the scope regardless of their origin.

States delimited the temporal scope of the GRATK Treaty through a non-retroactivity clause. A Party cannot apply the Treaty's obligations to patent applications filed before the Treaty's entry into force for that Party, except when there are existing national disclosure laws applying to such applications.⁹⁹

This provision ensures that the international PDR only applies to patent applications filed after the entry into force of the Treaty for each Party (i.e., the date of the entry into force for the first 15 Parties¹⁰⁰ or the date on which it enters into force for each subsequent Party), while safeguarding disclosure requirements in Parties that already have them as part of their legal systems.

WIPO compiled a table of 35 laws from its global database requiring different forms of disclosure in advance of the Diplomatic Conference.¹⁰¹

V. Patent disclosure requirement

As Member States expressed at the Diplomatic Conference, Art. 3 aims at regulating the pre-grant, patent prosecution phase. Article 3.1 establishes the PDR for GR, while Art. 3.2 establishes the PDR for ATK. The chapeau to each contains the trigger for the PDR ('Where the claimed invention in a patent application is based on ...'), hinging on a definition of 'based on' that establishes a two-part 'but-for' test varying slightly in application depending on the subject matter of the disclosure. It is a nuanced approach, leaving room for varied interpretations.

For GR, the trigger requires that they be necessary to the claimed invention, and that the claimed invention 'depends on their specific properties' – narrowing its application to only those GR that are essential to the claimed invention.¹⁰² The trigger for ATK requires it to be necessary for the claimed invention and that the claimed invention 'depends on' ATK.¹⁰³ Some of the ambiguity over the trigger in the Basic Proposal was addressed by streamlining the language in the definition and in the trigger, but it has been noted that there is no definitive interpretation or understanding of the term 'based on'.¹⁰⁴ Parties therefore have some flexibility to clarify the precise causal link between a claimed invention and GR and/or ATK that triggers the obligation to disclose.¹⁰⁵

Article 3.1 establishes the content of disclosure for GR once an applicant meets the trigger conditions. It requires Parties to ensure that a patent applicant discloses either the country of origin of the GR or, if this is unknown or does not apply, the source of the GR.¹⁰⁶ If there is more than one country of origin, only the country providing the GR needs to be disclosed by the applicant.¹⁰⁷ Referring to the source could be most appropriate in situations where: (1) GR do not occur in *in situ* conditions (e.g. certain living modified organisms); (2) GR are obtained from areas beyond national jurisdiction (e.g. the high seas, Antarctica); (3) GR are obtained from common pools (e.g. the Multilateral System (MLS) of the International Treaty on Plant Genetic Resources for Food and Agriculture¹⁰⁸).

A broad reading is supported by the Chair's Notes on Art. 2, which indicate that the word 'source' is used in its common meaning (from which something originates or can be obtained) and that the definition provides a non-exhaustive list – including IPLC, research centres, gene banks, the MLS, and all other *ex situ* collections or depositories of GR.¹⁰⁹

Article 3.2 defines the content of disclosure for ATK when an applicant meets the trigger conditions. It mandates Parties to require a patent applicant to 'disclose the ... [IPLC] from which they obtained the ATK, or the source of the ATK if they do not know the ... [IPLC] or this does not apply.'¹¹⁰ In the latter case, the definition of 'source' is also very broad and includes 'any source' from which the applicant obtained the ATK, including 'scientific literature, publicly accessible databases, patent applications and patent publications.'¹¹¹

Article 3.3 states that in cases where no information is known to the applicant on the origin or source of GR and/or ATK Parties must require them to make a declaration indicating this lack of information which also affirms that the declaration's content is true and correct to their best knowledge.¹¹² States agreed on this language to ensure some protection against misleading or knowingly false declarations. It responds to one well founded criticism of the Basic Proposal's Art. 3.3, namely that it was a 'mere declaration'¹¹³ founded on subjective factors that did not impose a duty of undertaking *best efforts* to obtain the information or provide other qualified criteria to show actual ignorance, making it difficult for States to prove intentional non-compliance.¹¹⁴

⁹⁸ For new rules on marine GR from areas beyond national jurisdiction, see Agreement under the United Nations Convention on the Law of the Sea on the Conservation and Sustainable Use of Marine Biological Diversity of Areas beyond National Jurisdiction, 19 June 2023 (not in force) UN Doc. A/CONF.232/2023/4 arts 9-16.

⁹⁹ GRATK Treaty (n 1) art 4.

¹⁰⁰ *ibid* art 17.

¹⁰¹ WIPO, 'Disclosure Requirements Table Related to Genetic Resources and/or Traditional Knowledge' <https://www.wipo.int/export/sites/www/tk/en/docs/genetic_resources_disclosure.pdf> accessed 16 September 2024; Perron-Welch, 'Striking a Balance Between Innovation and Tradition in the Global Patent System' (n 1).

¹⁰² GRATK Treaty (n 1) art 2; Würtenberger and Freischem (n 3) 148.

¹⁰³ GRATK Treaty (n 1) art 2; *ibid*.

¹⁰⁴ *ibid* 147-48.

¹⁰⁵ *ibid* 147.

¹⁰⁶ GRATK Treaty (n 1) art 2: "Source of genetic resources" refers to any source from which the applicant has obtained the genetic resources, such as a research center, gene bank, Indigenous Peoples and local communities, the Multilateral System of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), or any other *ex situ* collection or depository of genetic resources.' *ibid* 148; Perron-Welch, 'Striking a Balance Between Innovation and Tradition in the Global Patent System' (n 1).

¹⁰⁷ GRATK Treaty (n 1) art 3 footnote 2.

¹⁰⁸ International Treaty on Plant Genetic Resources for Food and Agriculture, 3 November 2001 (in force 29 June 2004) 2400 UNTS 303.

¹⁰⁹ Chair's Text (n 18) 7; GRATK Treaty (n 1) art 2.

¹¹⁰ GRATK Treaty (n 1) arts 3.2(a)-(b); Perron-Welch, 'Striking a Balance Between Innovation and Tradition in the Global Patent System' (n 1); Würtenberger and Freischem (n 3) 148.

¹¹¹ GRATK Treaty (n 1) art 2.

¹¹² *ibid* art 3.3.

¹¹³ Batista (n 6) 333.

¹¹⁴ *ibid* 331.

By referring to ‘best knowledge’, the Treaty demarks a clearer line between ‘knowledge’ and ‘ignorance’, but it does not fully establish the scope of a patent applicant’s duty to investigate where the required information is not obvious or readily accessible.¹¹⁵ The level of due diligence needed will ultimately vary depending on national law and may be linked to the entry into force of the CBD or the Nagoya Protocol for that Party.¹¹⁶

The rest of Art. 3 concerns assistance and rectification, verification, and public disclosure.¹¹⁷ First Parties must provide guidance to patent applicants on how to meet the PDR and an opportunity for applicants ‘to rectify a failure to include the minimum information referred to in Arts. 3.1 and 3.2 or correct any disclosures that are erroneous or incorrect.’¹¹⁸ Parties cannot ‘place an obligation on Offices to verify the authenticity of the disclosure,’¹¹⁹ as they broadly do not have the competencies required. Lastly, the Parties shall make the disclosed information accessible in accordance with patent procedures, while also ensuring the protection of confidential information.¹²⁰ Given the generality of this provision, the question of the limits to official disclosure where there is a confidentiality interest on the part of the applicant will have to be addressed at the national level.¹²¹

Streamlining the disclosure process to make it minimally burdensome while ensuring transparency will enhance compliance without inhibiting innovation. Patent offices can help applicants navigate the requirements effectively by providing clear, standardized guidelines and support, such as training programs and advisory services.

VI. Sanctions and remedies for non-compliance

Article 5, which deals with sanctions and remedies for non-compliance with the PDR, was one of the most difficult provisions to negotiate. There was debate over the appropriateness and effectiveness of proposed sanctions and remedies, with some negotiators asserting that non-patent law sanctions are too lenient to deter non-compliance, while others indicated that patent law sanctions might be too strict and would stifle innovation.

The GRATK Treaty aims to strike a fine balance between the interests of potential Parties.¹²² It does not go as far as called for by some *non-demandeurs* (i.e. an absolute ban or ‘ceiling’¹²³ on patent law sanctions post-grant), but the Treaty does limit pre-grant and post-grant

patent law remedies to cases of fraud.¹²⁴ The Basic Proposal provision on alternate dispute resolution was removed.¹²⁵

Article 5.1 requires Parties to adopt sanctions and remedies for non-compliance with the disclosure requirement in Art. 3.¹²⁶ It is phrased broadly, meaning that each Party is left to determine which legal, administrative, and/or policy measures are ‘appropriate, effective and proportionate’ in the circumstances.¹²⁷ Both pre-grant and post-grant sanctions and remedies were considered to fall within the scope of this provision, but their compatibility with commitments made under existing IP treaties must be carefully considered.¹²⁸

Introducing flexible yet effective compliance measures can balance the need for monitoring and enforcement with the practicalities of innovation. In this light, the Treaty states that each Party must provide ‘an opportunity to rectify a failure to disclose the information required in Art. 3 before implementing sanctions or directing remedies.’¹²⁹ A deadline to correct errors in disclosure could be established for this purpose during patent prosecution.¹³⁰ Emphasizing rectification before imposing sanctions aims to balance enforcement with practical considerations like the overriding desire for transparency.

However, to increase the ‘incentive for patent applicants to (correctly) disclose the required information in the patent application or during patent prosecution,’¹³¹ cases involving fraudulent conduct or intent as defined by national law may be excluded from rectification.¹³²

Addressing the post-grant phase, the Treaty prevents Parties from revoking, invalidating or rendering unenforceable conferred patent rights ‘solely on the basis of an applicant’s failure to disclose the information specified in Art. 3.’¹³³ This language allows interference in granted rights in cases where there is a failure both to disclose and to comply with national ABS rules.

The broad prohibition on interference also does not apply when deception is involved.¹³⁴ The Treaty allows Parties to ‘provide for post-grant sanctions or remedies where there has been fraudulent intent in regard to the... [PDR] in accordance with its national law.’¹³⁵ As noted by one author, this is not a low threshold, as ‘the burden of proving intent would rest with the State (or an interested third party) and ... cases in which the patent applicant acted only without due diligence by declaring information incorrectly (or simply not declaring it) would not be covered.’¹³⁶ Demandeur countries aimed to address this

¹¹⁵ Würtenberger and Freischem (n 3) 148.

¹¹⁶ *ibid* 149.

¹¹⁷ *ibid*.

¹¹⁸ GRATK Treaty (n 1) art 3.4.

¹¹⁹ *ibid* art 3.5.

¹²⁰ *ibid* art 3.6.

¹²¹ Würtenberger and Freischem (n 3) 149; GRATK Treaty (n 1) art 9.

¹²² Perron-Welch, ‘Striking a Balance Between Innovation and Tradition in the Global Patent System’ (n 1).

¹²³ Margo A Bagley, ‘Of Disclosure “Straws” and IP System “Camels”: Patents, Innovation, and the Disclosure of Origin Requirement’ in Daniel F Robinson, Ahmed Abdel-Latif and Pedro Roffe (eds), *Protecting Traditional Knowledge: The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore* (Routledge 2017).

¹²⁴ Perron-Welch, ‘Striking a Balance Between Innovation and Tradition in the Global Patent System’ (n 1).

¹²⁵ Basic Proposal (n 18) art 6.5.

¹²⁶ Batista (n 6) 332.

¹²⁷ GRATK Treaty (n 1) art 5.1; *ibid*.

¹²⁸ Würtenberger and Freischem (n 3) 150.

¹²⁹ GRATK Treaty (n 1) art 5.2.

¹³⁰ Batista (n 6) 332.

¹³¹ *ibid*.

¹³² GRATK Treaty (n 1) art 5.2^{bis}.

¹³³ *ibid* art 5.3.

¹³⁴ Würtenberger and Freischem (n 3) 150.

¹³⁵ GRATK Treaty (n 1) art 5.4.

¹³⁶ Batista (n 6) 332.

partially by including ‘best knowledge’ language in Art. 3.3 (see above).

VII. Information systems

Article 6 on information systems (including databases) is a result of many years of debate and work on prior art databases for use by patent examiners in the defensive protection of GR and ATK.¹³⁷ Despite differences of opinion expressed at the IGC, databases are commonly seen as valuable support tools for patent examination and can complement the PDR.¹³⁸

As a supportive measure adding overall value to the Treaty,¹³⁹ Art. 6.1 enables Parties to establish information systems of GR and ATK in consultation, where applicable, with IPLC and other stakeholders, and considering their national circumstances.¹⁴⁰ Where Parties establish information systems, they should be made available to patent offices for search and examination of patent applications, with necessary safeguards developed in consultation with IPLC and other stakeholders.¹⁴¹ Access may be made subject to authorization by the Parties creating the systems where appropriate.¹⁴²

Establishing robust information systems is important for defensive protection of GR and ATK but challenging. These systems must be accessible, dependable, and secure to be effective. IPLC involvement in their development and management is critical for inclusivity and respect for ATK holders. Investing in the development of robust, secure, and user-friendly systems can support the Treaty’s goals, while providing training and capacity-building can enable IPLC to effectively contribute and benefit from these systems.

In a future-oriented provision, the Treaty empowers the Assembly of the Parties to establish one or more technical working groups to address any matters relating to the information systems, including access with appropriate safeguards.¹⁴³ This very modest provision was adopted rather than the text of the Basic Proposal ‘as a number of Member States felt strongly that Art. 7.3 of the Basic Proposal would seriously prejudice the work of the Assembly of the Parties.’¹⁴⁴

The significant step down in ambition when comparing Art. 7.3 of the Basic Proposal with Art. 6.3 of the Treaty reflects a lack of international agreement on the need for and pace of harmonization in this area.¹⁴⁵ While some commentators believed that a centralized WIPO portal was an area where consensus could be found,¹⁴⁶ the contents of Art. 7.3(d) of the Basic Proposal were deleted entirely.

VIII. Relationship with other international instruments

Aligning the Treaty with existing international agreements is critical to avoid conflicts and redundancies. This requires careful coordination and cooperation by and between the Parties to achieve the Treaty’s objectives without undermining other agreements. Article 7 on its relationship with other international instruments indicates that Parties must implement the Treaty in a mutually supportive manner with relevant international agreements.¹⁴⁷ As importing text from the Nagoya Protocol was contentious, negotiators included one agreed statement and one footnote to clarify the meaning of Art. 7.

The Agreed Statement¹⁴⁸ – also found in the Basic Proposal¹⁴⁹ – addresses the next steps in relation to the Patent Cooperation Treaty¹⁵⁰ (PCT), namely an amendment of the Regulations and/or Administrative Instructions. Presently, the PCT doesn’t require the disclosure of origin of GR or ATK in patent applications.¹⁵¹ Instead, it prohibits PCT Members from mandating compliance with formal requirements different from or additional to those provided for in the PCT and Regulations.¹⁵² While the PCT makes an exception for substantive patentability criteria, the PDR is designed as a formality requirement and non-compliance will normally not involve patent law at the national level, but will involve civil or criminal law penalties for fraud and misrepresentation.¹⁵³

The operation of the PCT system is improved through a continual processes of modification and updates to the PCT Regulations, Administrative Instructions, and Guidelines.¹⁵⁴ Thus, the Agreed Statement indicates that the Parties ‘request the Assembly of the International Patent Cooperation Union [PCT Union] to consider the need for amendments to the Regulations under the PCT and/or the Administrative Instructions thereunder with a view towards providing an opportunity for applicants

¹³⁷ Württenberger and Freischem (n 3) 150. See eg Graham Dutfield, *Intellectual Property, Biogenetic Resources and Traditional Knowledge* (Taylor & Francis 2004) 114-15; Jonathan Curci, ‘The Defensive Protection of Traditional Knowledge in International Patent Law’ in Jonathan Curci, *The Protection of Biodiversity and Traditional Knowledge in International Law of Intellectual Property* (CUP 2009) 225-33; Reto M Hilty, Pedro Henrique D Batista and Suelen Carls, ‘Traditional Knowledge, Databases and Prior Art: Options for an Effective Defensive Use of TK Against Undue Patent Granting’ in Irini Stamatoudi (ed), *Research Handbook on Intellectual Property and Cultural Heritage* (Edward Elgar 2022) 141-47.

¹³⁸ Daniel F Robinson and Claudio Chiarolla, ‘The Role of Databases, Contracts and Codes of Conduct’ in Daniel Robinson and others (eds), *Protecting Traditional Knowledge: The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore* (Routledge 2017) 118.

¹³⁹ Perron-Welch, ‘Striking a Balance Between Innovation and Tradition in the Global Patent System’ (n 1).

¹⁴⁰ GRATK Treaty (n 1) art 6.1.

¹⁴¹ *ibid* art 6.2.

¹⁴² *ibid*.

¹⁴³ *ibid* art 6.3.

¹⁴⁴ Perron-Welch, ‘Striking a Balance Between Innovation and Tradition in the Global Patent System’ (n 1).

¹⁴⁵ Basic Proposal (n 18) art 7.3 provides a lengthy list of potential technical working groups (eg interoperability standards and structures, guidelines on safeguards, principles and modalities on information-sharing, a centralized WIPO Portal) but negotiators deleted most. See Perron-Welch, ‘Striking a Balance Between Innovation and Tradition in the Global Patent System’ (n 1).

¹⁴⁶ Laux (n 3) 374.

¹⁴⁷ GRATK Treaty (n 1) art 7; Perron-Welch, ‘Striking a Balance Between Innovation and Tradition in the Global Patent System’ (n 1).

¹⁴⁸ GRATK Treaty (n 1) art 7 footnote 4.

¹⁴⁹ Basic Proposal (n 18) art 8 footnote 2.

¹⁵⁰ Patent Cooperation Treaty, 19 June 1970 (in force 24 January 1978) 1160 UNTS 231.

¹⁵¹ Batista (n 6) 334.

¹⁵² *ibid*.

¹⁵³ *ibid*.

¹⁵⁴ Miyamoto (n 43) 35.

who file an international application under the PCT designating a PCT Contracting State which, under its applicable national law, requires the disclosure of ... [GR and ATK], to comply with any formality requirements related to such disclosure requirement either upon filing of the international application, with effect for all such Contracting States, or subsequently, upon entry into the national phase before an Office of any such Contracting State.¹⁵⁵ It is uncertain ‘whether and when the PCT Contracting States will accept this request ... [which] further increases the risk to the effectiveness of the instrument ...’.¹⁵⁶ Thus, parallel work between the WIPO Secretariat and PCT Union prior to entry into force would be advisable to minimize risk.¹⁵⁷

As things stand, even if they become Party to the GRATK Treaty, PCT Contracting States ‘will not be able to require disclosure of origin in cases of patent applications made through the PCT system.’¹⁵⁸ Footnote 5 reinforces this by clarifying that the call for ‘mutual supportiveness’ does not mean that the provisions of the Treaty derogate from, or modify, other international agreements.¹⁵⁹ This resulted from the concerns of some Member States about the lack of clarity over the meaning of the term, particularly whether it necessitates the modification of other treaties.¹⁶⁰ Ultimately, work will need to be done to convince the PCT Union to adjust the Regulations or Administrative Instructions so that they confirm to the GRATK Treaty once it enters into force.

On the other hand, the Nagoya Protocol also has a mutual supportiveness clause and there is no inherent conflict between the provisions of the GRATK Treaty and the Nagoya Protocol.¹⁶¹ In fact, it contains a provision on Parties establishing designated checkpoints to collect or receive relevant information, as appropriate, including on the source of GR.¹⁶² In this context, Parties must require users of GR to provide information such as the source of origin at a designated checkpoint, and take appropriate, effective and proportionate measures to address non-compliance.¹⁶³ This language is closely aligned with Art. 5.1 of the Treaty but solely speaks to GR, meaning

that the Treaty goes beyond the Nagoya Protocol in this regard.¹⁶⁴

The information on GR that is disclosed to designated checkpoints will be provided to relevant national authorities, the Party providing access and the ABS Clearing-House, as appropriate and without prejudice to the protection of confidential information.¹⁶⁵ This language is similar to Art. 3.6 of the Treaty, which speaks of protecting confidential information ‘in accordance with patent procedures’.¹⁶⁶ Designated checkpoints must be effective and relevant to the utilization of GR or the collection of relevant information at all stages of research, development, innovation, pre-commercialization or commercialization.¹⁶⁷ Few Nagoya Protocol Parties have designated intellectual property offices as checkpoints.¹⁶⁸

The formal designation of a patent office as a Nagoya Protocol checkpoint is not obligatory, and Parties to both instruments will decide this based on national priorities. In making this decision, Parties must consider whether it adequately balances the need for effective disclosure with the risk of potential delays in patent prosecution. Moreover, over 50 WIPO Member States are not Parties to the Nagoya Protocol, and many have no intention of ratifying in the near future.¹⁶⁹

IX. Conclusion

The current international harmonization of patent law does not result in a unified global system.¹⁷⁰ While the PCT, PLT and TRIPS Agreement establish common rules significantly shaping the global patent system, they only regulate part of the system.¹⁷¹ They leave ample freedom to legislate flexibly in accordance with national interests and political priorities, which has been and always will be central to the international patent system.¹⁷²

In the history of international patent law, ‘international harmonization *per se* has never been the ultimate goal or an end in itself ... [it] has always been a tool to respond to challenges that require international solutions.’¹⁷³ Improving the transparency of the global patent system on GR and ATK is one such challenge and the harmonized international PDR is a tool designed specifically to respond to the task.

The GRATK Treaty is thus a considered step forward in enhancing the transparency and integrity of the patent system concerning GR and ATK. It represents a partial harmonization of PDR rules for GR and ATK, while also

¹⁵⁵ GRATK Treaty (n 1) art 7 footnote 4.

¹⁵⁶ Batista (n 6) 334.

¹⁵⁷ *ibid* 334.

¹⁵⁸ *ibid* 334.

¹⁵⁹ GRATK Treaty (n 1) art 7 footnote 5.

¹⁶⁰ Author’s notes (on file). See Riccardo Pavoni, ‘Mutual Supportiveness as a Principle of Interpretation and Law-Making: A Watershed for the “WTO-and-Competing-Regimes” Debate?’ (2010) 21(3) *European Journal of International Law* 649, 666-72, 678-79; Laurence Boisson de Chazournes and Makane Moïse Mbengue, ‘“Footnote as a Principle”: Mutual Supportiveness and Its Relevance in an Era of Fragmentation’ in Holder P Hestermeyer and others (eds), *Coexistence, Cooperation and Solidarity: Liber Amicorum Rudiger Wolfrum*, vol 2 (Martinus Nijhoff 2012).

¹⁶¹ Nagoya Protocol (n 7) art 4.3: ‘This Protocol shall be implemented in a mutually supportive manner with other international instruments relevant to this Protocol. Due regard should be paid to useful and relevant ongoing work or practices under such international instruments and relevant international organizations, provided that they are supportive of and do not run counter to the [CBD and Nagoya Protocol] objectives ...’. See further Thomas Greiber and others, *An Explanatory Guide to the Nagoya Protocol on Access and Benefit-Sharing* (IUCN 2012) 79-80; Boisson de Chazournes and Mbengue (n 160) 1631-32.

¹⁶² Nagoya Protocol (n 7) art 17.1(a)(i).

¹⁶³ *ibid* art 17.1(a)(ii).

¹⁶⁴ Perron-Welch, ‘Striking a Balance Between Innovation and Tradition in the Global Patent System’ (n 1).

¹⁶⁵ *ibid* art 17.1(a)(iii).

¹⁶⁶ Perron-Welch, ‘Striking a Balance Between Innovation and Tradition in the Global Patent System’ (n 1).

¹⁶⁷ *ibid* art 17.1(a)(iv).

¹⁶⁸ Perron-Welch, ‘Striking a Balance Between Innovation and Tradition in the Global Patent System’ (n 1). These are Bhutan, Kenya, Peru, Uruguay and Switzerland. For the current number, search CBD, ‘Access and Benefit-Sharing Clearing House’ <<http://absch.cbd.int>> accessed 16 September 2024.

¹⁶⁹ eg Australia, Canada, New Zealand, Russian Federation, United States of America.

¹⁷⁰ Miyamoto (n 43) 31.

¹⁷¹ *ibid*.

¹⁷² *ibid*. The Treaty’s general principles for implementation reflect this, see GRATK Treaty (n 1) art 9.2.

¹⁷³ Miyamoto (n 43) 53.

incorporating some visionary aspects. Similar initiatives will build on this successful outcome,¹⁷⁴ including IGC negotiations in the 2024-2025 biennium¹⁷⁵ on the protection of traditional knowledge¹⁷⁶ and of traditional cultural expressions.¹⁷⁷

Reaching international consensus on patent law requires seeking and re-seeking a harmony that involves convergence and divergence, so both vision and modesty are key.¹⁷⁸ In this regard, the GRATK Treaty is modest in that it mainly addresses and converges on the core PDR norm while diverging on sanctions and remedies, information systems, and the material scope. Its visionary or forward-looking elements include the Art. 8 Review mechanism, which formalizes the consideration of innovative technologies, and leaves several avenues for amendment open.

Demonstrating the flexibility of the GRATK Treaty, its general principles on implementation are that Parties undertake to adopt the necessary measures for its application¹⁷⁹ in accordance with their right to determine ‘the appropriate method of implementing the provisions of this Treaty within their own legal systems and practices.’¹⁸⁰ This exemplifies the Treaty’s attempt to balance legal certainty through harmonization with the exercise of national sovereignty.

The GRATK Treaty introduces new challenges and complexities, and its success will depend on the collaborative efforts of international, national, and local stakeholders to implement and adapt its provisions effectively. The harmonized PDR in Art. 3 will gradually enhance legal certainty and foster transparency on GR and ATK in the global patent system,¹⁸¹ but a lower level of harmonization on sanctions and remedies in Art. 5 will need to be navigated as patent law sanctions are still acceptable in certain cases. Patent holders can be assured that conferred rights over bio-based innovations will not be revoked, invalidated, or rendered unenforceable solely on the basis of the applicant’s failure to disclose the information specified by the PDR.¹⁸² However, deception may lead to more significant consequences depending on the legal measures implemented under Art. 5 by the Party involved.¹⁸³

It would be advisable for innovators, patent applicants, examiners, legal practitioners, and academics to monitor developments in this area as they could have significant implications for obtaining patents in the field of bio-based innovation.¹⁸⁴ Four years after the Treaty’s entry

into force, the Art. 8 Review could lead to a significant expansion of its scope. While plant variety protection is not currently within the scope of the Treaty, Parties could include it in a revised Treaty,¹⁸⁵ and Parties could also expand the material scope to include a ‘derivative’ of GR and/or ‘DSI’ on GR.¹⁸⁶

This would exponentially broaden the Treaty’s scope in light of recent developments in bio-based innovation, a field which is rapidly moving from utilizing tangible genetic material to utilizing intangible natural information, big data and AI.¹⁸⁷ Observers should expect continued debate and negotiation on the scope of the PDR in years to come – in the Assembly of the Parties, during the Review, or at a second Diplomatic Conference convened by the Assembly.¹⁸⁸

The GRATK Treaty’s impact on innovation is double-edged. It can promote responsible, equitable and ethical innovation through transparency and monitoring for the purposes of ABS compliance, but it could also deter bio-based innovation if inventors deem compliance to be too onerous. Applicants may face increased administrative and legal costs that could deter investment in bio-based innovation, and Offices must support applicants in complying with the PDR. This calls for supple intervention by regulators rather than a punitive approach primarily driven by sanctions and remedies to obtain compliance.

With the intended result being increased transparency in disclosure, the GRATK Treaty aims for a facilitative rather than a punitive approach. This is demonstrated by Art. 3(4), which requires Parties to provide guidance to patent applicants on how to meet the PDR and an opportunity to rectify a failure to include required information or correct erroneous or incorrect disclosures, and Art. 5(2) which requires Parties to provide an opportunity to rectify a failure to disclose the information required before directing sanctions or remedies where there is no fraud.

Collaboration among States, IPLCs, and the private sector, a continuous dialogue at all levels, and commitment to ethical practices will be crucial for effective implementation of the GRATK Treaty in a way that facilitates bio-based innovation, supports a sustainable bioeconomy, and helps build compliance for fair and equitable ABS. Ongoing stakeholder engagement and cooperation will be essential in refining implementation over time, addressing emerging challenges and enhancing the Treaty’s contribution to global IP law and bio-based innovation. This will help ensure long-term success in stimulating ethical and equitable innovation, leading to beneficial effects for bio-based innovation.

¹⁷⁴ Oguamanam, ‘The New WIPO Genetic Resources and Associated Traditional Knowledge Treaty’ (n 1).

¹⁷⁵ WIPO General Assembly, ‘64th Meetings: Agenda Item 15(v) Report on the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) – DECISION’ <<https://www.wipo.int/export/sites/www/tk/en/igc/docs/igc-mandate-2024-2025.pdf>> accessed 16 September 2024.

¹⁷⁶ See The Protection of Traditional Knowledge: Draft Articles, WIPO Doc. WIPO/GRTKF/IC/47/4.

¹⁷⁷ See The Protection of Traditional Cultural Expressions: Draft Articles, WIPO Doc. WIPO/GRTKF/IC/47/5.

¹⁷⁸ Miyamoto (n 43) 54.

¹⁷⁹ GRATK Treaty (n 1) art 9.1.

¹⁸⁰ *ibid* art 9.2.

¹⁸¹ Perron-Welch, ‘Striking a Balance Between Innovation and Tradition in the Global Patent System’ (n 1).

¹⁸² GRATK Treaty (n 1) art 5.3.

¹⁸³ *ibid* arts 5.2^{bis} and 5.4.

¹⁸⁴ Perron-Welch, ‘Striking a Balance Between Innovation and Tradition in the Global Patent System’ (n 1).

¹⁸⁵ GRATK Treaty (n 1) arts 8 and 14; Würtenberger and Freischem (n 3) 145.

¹⁸⁶ For a deeper analysis of the debate on DSI, see eg Jorge Cabrera Medaglia, ‘Digital Sequence Information (DSI) and Benefit-Sharing Arising from Its Use: An Unfinished Discussion’ [2020] GRUR International 565; Claudia Seitz, ‘Digital Sequence Information – Legal Questions for Patent, Copyright, Trade Secret Protection and Sharing of Genomic Sequencing Data’ (2020) 482(1) IOP Conference Series: Earth and Environmental Science 012002, 3–5; Margo Bagley, ‘“Just” Sharing: The Virtues of Digital Sequence Information Benefit-Sharing for the Common Good’ (2022) 63(1) Harvard International Law Journal 1, 6–7, 20–22, 44–45, 56, 60; Charles Lawson, Fran Humphries and Michelle Rourke, ‘Challenging the Existing Order of Knowledge Sharing Governance with Digital Sequence Information on Genetic Resources’ (2024) 19(4) JIPLP 337.

¹⁸⁷ Perron-Welch, ‘Striking a Balance Between Innovation and Tradition in the Global Patent System’ (n 1).

¹⁸⁸ *ibid*.