INNOVATION COUNCIL ANALYSIS

WIPO Negotiations on Patents, Genetic Resources and Associated Traditional Knowledge: How Might They Affect Innovation?

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Context for the Analysis

After more than two decades of "IGC" talks at WIPO,[1] the WIPO Member States are now working to finalize the text of an "international instrument" pertaining to Intellectual Property, Genetic Resources (GRs) and associated Traditional Knowledge (TK), for agreement at a Diplomatic Conference (Dip Con) to be held during 2024.

As they carry out this work – with the stated aim of enhancing transparency – it is essential to consider the perspectives of all stakeholders potentially affected by the instrument, while keeping in mind broader shared goals. These include encouraging investments in R&D and innovation and making sure the instrument is feasible and provides the necessary legal certainty.

Innovation Council, established in January 2021, is a cross-sectoral innovators group dedicated to sharing the views and experiences of organizations – including companies, tech transfer offices, funders, incubators, and public-private partnerships – that work to bring new technology solutions to society. This note provides perspectives of such organizations, from sectors such as biopharma and ag biotech where R&D may involve natural resources, regarding certain aspects of the negotiations.

The current basis for the IGC negotiations is essentially the 2019 "Chair's text" which comprises the substantive provisions in Articles 1 – 9, as well as administrative and final provisions.[2] Minor changes to the Chair's text were agreed by WIPO members in September 2023 during the Special

1 The Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore – today, simply referred to as the "IGC", was originally set up by the WIPO General Assembly in 2001 to develop a global agreement pertaining to the protection of genetic resources and traditional knowledge.

2 In July 2022, at the WIPO General Assembly, WIPO Member States "decided to move to diplomatic conferences - or dedicated negotiating rounds where agreements may be concluded - no later than 2024". Before this decision, the former IGC Chair, Amb. Ian Gross, had prepared a draft legal document in 2019 on GRs and associated TK. This draft serves as a basis for the ongoing talks. At the core of the international agreement, or "instrument", under discussion is the notion that when applying for patent protection for an invention that integrates GR and associated TK, the applicant must provide information about the GR and associated TK. This is referred to as a "patent disclosure requirement" (PDR). See: https://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_46/wipo_grtkf_ic_46_chairs_text.pdf.

Session and Preparatory Committee meetings held in Geneva. Those agreed changes slightly update the official negotiating text.

At this late stage of the talks, with a Diplomatic Conference planned already next year, Member States continued during the September 2023 IGC Special Session (which preceded the Preparatory Committee meeting) to table proposals that would fundamentally alter the scope and other elements of the instrument. These proposals will likely remain in play between now and the Dip Con. Some of the proposals are disconnected from how R&D and commercialization of products using natural resources happen in the real economy. Others are intended to inject more clarity and legal certainty into the text. In any event, because no major textual changes were agreed during the fall 2023 meetings, there is much left to be decided and clarified prior to the Dip Con.

This note explains why there is a critical need for much more clarity and legal certainty in several parts of the negotiating text, and in the overall negotiations, before an international instrument can be signed.

The Focus of the IGC on the Patent System

According to WIPO, the talks are aimed at creating an "international instrument", or agreement, that will enhance the efficiency, transparency, and quality of the patent system and thereby enable researchers and innovators to bring innovative health, agriculture and other technology solutions to society while also protecting the interests of biodiversity-rich countries and indigenous communities.

In practice, the central goal is narrower: leveraging the patent system to identify what is being commercialized using natural resources and associated traditional knowledge. The talks are also about preventing the granting of erroneous patents, and, according to some stakeholders, curbing misappropriation of genetic resources and associated TK.

The vehicle for achieving these goals is a "patent disclosure requirement" (PDR) in patent applications that will be filed in those countries that ratify and implement the instrument. Patent applicants would be required to provide information about GRs and associated TK on which their claimed inventions are "materially/directly based". Information provided through the patent disclosure would become part the of patent applications, thereby making information about GR and associated TK use in patented inventions publicly available.

The nature of the relationship between the GR and associated TK, on the one hand, and the claimed invention in the patent application, on the other hand, is known as the "trigger" for the application of the PDR. How the trigger works has yet to be fully clarified, as explained later in this note. Importantly, inventions that use GR and associated TK but are not patented would not be covered by the new PDR.

Patents are critical for managing and incentivizing R&D investments, collaboration, and the commercialization of new products. The IGC talks leverage the central role of patents for bringing inventions to society, linking the use of GR and associated TK with the patent system. It's worth noting, at the same time, that the nature of R&D is uncertain; many research projects do not bear fruit, and many patented inventions (in some sectors, the majority) are never brought to market.

Whether the patent system is the right forum for this effort has not been demonstrated. Arguably, the Convention on Biological Diversity (CBD) framework – particularly the Nagoya Protocol, which had not yet been put in place when the IGC negotiations started – is the most appropriate home for all efforts related to the access to and use of GR and associated TK.[3] However, the patent system is the focus of the IGC because it is viewed by certain parties to be an effective tool for improving

3 The Convention on Biological Diversity, or CBD, (1993) was agreed in order to manage the use and conservation of biological diversity worldwide. The Nagoya Protocol (2010), which is part of this framework, is aimed at ensuring a fair distribution of benefits from the use of genetic resources. The Nagoya Protocol calls for the establishment of official checkpoints in countries where GRs may be accessed for use in R&D programs. These checkpoints are meant to verify whether Prior Informed Consent (PIC), along with Mutually Agreed Terms (MAT) for benefit sharing, has been obtained.

transparency given that, as noted, patents are important for R&D and commercialization. The fundamental question as to whether the patent system should interact with issues that are technically outside of its operation, including arguably transparency around GR and associated TK, remains unanswered.

The Negotiating Text in Relation to R&D and Commercialization

This note unpacks certain elements of the Chair's text and the broader discussions, from the perspective of innovators, patent applicants, and patent owners. It is organized according to:

- Goals and impact,
- Scope,
- Procedural elements, and
- Legal certainty.

Goals and Impact

Legitimate questions have been raised as to whether the present Chair's text is conducive to the achievement of the goals set out in the text itself (and reflected in the introductory remarks made by the Chair in his text).

Article 1, Objectives

The objectives of this instrument are to:

(a) Enhance the efficacy, transparency, and quality of the patent system with regard to GRs and Associated TK; and

(b) Prevent patents from being erroneously granted for inventions that are not novel or inventive with regards to GRs and Associated TK.

The goals cited in the objectives in Article 1 are: to improve efficiency, transparency, and quality in the patent system, and to prevent erroneous patents from being granted.

One challenge is that the transparency-related objectives set forth in the text seem unrelated to the functioning of the patent system. For instance, there is no clear relationship between the proposed PDR on the one hand, for GK and associated TK, and, on the other hand, the criteria for judging whether an invention can be patented ("patentability criteria"). Patentability criteria, along with elements that are central to the nature of the invention and its inventor, are at the heart of patent systems. They are set out in the WTO TRIPS Agreement.

This dissociation matters because one stated goal of the talks, as included in Article 1 of the Chair's text, is to prevent erroneous patents from being granted. This is a notion directly related to patent quality. Patent quality requires that only patents for inventions that meet all the patentability criteria be granted. Patent quality is important for both developers and users of patented solutions, all of whom are poorly served when the environment includes patents with uncertain validity. Under such circumstances, actors in the economy cannot plan investments and other activities with certainty.

Requiring information about the source or country of origin of a GR and its associated TK will do little to help patent examiners assess patent applications against patentability criteria, including novelty and non-obviousness. To assess novelty and non-obviousness, examiners must identify prior art. This process could be supported by increasing transparency around the GR and associated TK that exist across regions, through the creation of further comprehensive databases of GR and associated TK that would be accessible to examiners.[4] However, the creation of this

4 As documented by WIPO, some databases for GR and disclosed TK already exist. See: https://www.wipo.int/tk/en/resources/db_registry.html.

type of broadly available database has been objected to by numerous Member States and other stakeholders, with many of them seeking modification of Article 7.

This raises a critical conceptual challenge in the talks, that is, the substantial difference in how stakeholders perceive the nature of associated TK. The indigenous and local communities make it clear that without any substantial protection of their traditional knowledge, registration of their associated TK in a database may directly lead to misappropriation, which they wish to prevent.[5] Other stakeholders, and some Member States, endorse the creation of comprehensive databases for examiners as efficient tools for preventing the issuance of erroneously granted patents not meeting patentability criteria.

Turning back to transparency in the international patent system, proponents of the instrument argue that this would be realized through the creation of a body of information about GR and associated TK, made available through the PDR. However, again, the PDR envisioned for the international instrument does not relate to patentability criteria, including novelty and inventive step. And certain stakeholders do not agree with creating more databases for use by examiners of prior art related to GR and associated TK without separate legal protection for the underlying TK.

It is not unreasonable to conclude therefore that transparency generated through the PDR would not improve the functioning of the patent system per se, or the quality of the rights granted by national IP offices. The databases envisioned in Article 7 could improve transparency while also helping to prevent the granting of erroneous patents. However, it is not certain that more databases will be created under the instrument.

Efficacy is also cited as a goal in Article 1 of the text. The Chair notes accompanying his text state that any PDR should be effective, practical, easy to implement, and not unduly burdensome for applicants. This is unrelated to improving the operation or efficacy of the patent system. Rather, it seems aimed at ensuring *the PDR* is effective and feasible to implement. These are two different things; again, there appears to be a conceptual problem affecting these talks.

Clarifying the Scope

Whether the international instrument sets a ceiling or floor, and what specific situations would trigger application of the PDR it contains, are foundational issues that have yet to be clarified.

The basic text for the Diplomatic Conference sets out, with some exceptions, what could be viewed as a floor for global PDRs. It provides baseline guidance for WIPO Member States instituting a patent disclosure requirement and reference is made in the text to national law, like in the case of Article 5 on non-retroactivity. However, this approach of setting a floor means that researchers and innovators will continue to face differing patent disclosure requirements for GR and associated TK globally. Member States will continue to keep (and be able to establish in the future) additional obligations or procedures in their national laws.

The above risks creating substantial administrative burdens and compliance challenges, in addition to legal uncertainty. In contrast, the text should create a ceiling for disclosure requirements, so Member States are guided as well as bound by what is in the international instrument.[6]

Delineating the scope of any international agreements' application is essential. This has yet to happen in relation to certain critical topics in the IGC talks, for instance, the treatment of Digital Sequence Information (DSI). Modern R&D programs related to natural resources involve

5 They wish to prevent misappropriation of Traditional Knowledge through agreement of an international instrument focused only on the protection of TK. This is still under negotiation at WIPO in a separate and parallel process and not ready for a Diplomatic Conference.

6 An example of this approach is found in Article 6 of the text, which clarifies that only in cases of fraud, invalidation or un-enforceability as sanction may be foreseen in national law. This is not to say this language should be retained in the final text. As explained below, such sanctions themselves create further major challenges for patent applicants.

researchers accessing the DSI of genetic resources from online databases. During the R&D process they will likely interact with hundreds if not thousands of different sequences, in the form of DSI.

The text seems, through the review clause in Article 9, to exclude DSI from the scope of the international instrument. This is appropriate given how DSI is used in modern R&D programs. However, the treatment of DSI is far from clear and certain. During meetings, Member States continue to either interpret the trigger to include DSI or ask that DSI be explicitly referred to in the scope; both constitute a major change to the text. It is essential that there be total clarity on this point prior to any instrument being signed. Innovators and patent owners have been clear in endorsing application of the instrument only to physical access to and use of GR, as stated by the Chair in his remarks to his text. Its application to DSIs, in light of how they are accessed and used in R&D today, does not seem feasible.

Clarity with respect to definitions is also lacking. This is both because the existing text is not clear and because Member States are still proposing adjustment of the definitions prior to an agreement. One example is "associated TK", which remains undefined, with perceptions of its nature and definition differing significantly among stakeholders. Another is "materially/directly based on", a definition that provides the crucial nexus between the claimed invention in the patent, and any GR or associated TK integrated into it, and therefore the "trigger" for the PDR.

Regarding the trigger, some clarity was provided by the expert group by linking both alternatives of "material and directly based" in the definition in Article 2 of the text. However, this excludes neither DSI nor so-called derivatives of GRs even though, according to Article 9, they are not meant to be within the scope of the present instrument. Unfortunately, WIPO Member States have not agreed to integrate any of the clarifications provided by the experts into the present text. Also, certain Member States continue to argue that DSI should be covered by the instrument.

Clear and agreed definitions are central to any international agreement, providing critical legal certainty to countries and stakeholders. IGC negotiators must prioritize this in the coming months.

Non-retroactivity is another element necessary for legal certainty. Here too, the present text leaves space for more far-reaching national requirements. Member States must confirm the timeline for applying the instrument and its PDR. In the talks, there remain divergent views on this. Will the instrument apply only to GR that were ***accessed*** following ratification or the entry into force of the instrument? Only to patents ***filed after*** ratification or entry into force, regardless of when the GR were accessed? Application should be in relation to GRs accessed after the entry into force and to patent applications or their priority applications filed after entry into force. In any event, before the international instrument can be signed, the timing of its application must be clearly defined, to forestall the introduction of divergent broader national requirements in this regard.

Procedures and Legal Concepts

Fair and transparent administrative procedures, due process, proportionality, and other elements must be clarified and confirmed prior to any instrument being signed.

The nature of the patent disclosure requirement is a central element of the instrument. However, there are key aspects of Article 3, which sets out the PDR, that still require clarification.

Member States should confirm that applicants will be able to declare, to the best of their knowledge, that they do not know for certain the country of origin or source of the GR. Some Member States continue to challenge this as an unreasonable loophole, but the reality is that innovators will not always be able to state with certainty where something came from – and not even the source in some cases. In this case, they should be able to declare this fact, in relation to both GR and associated TK. Difficulty in identifying the source of GR with certainty is compounded by the reality that R&D projects may involve decades of work.

There must also be fair procedures for remedying disclosures deemed by authorities to be insufficient. This is addressed in Article 6 of the Chair's text, which relates to sanctions and remedies for insufficient disclosure. Fairness and due process dictate that applicants be given at least one chance to remedy a mistake related to PDR on a patent application or a granted patent, particularly given that the PDR is unrelated to patentability criteria and is therefore a pure formality requirement. In no case should a patent for an invention that meets the criteria for patentability and other requirements imposed by an IP Office, be refused only due to issues with the PDR. This would undermine the operation of the patent system, rather than enhance it, in contradiction to the goals of the talks.

Further, it is important that Member States confirm that revocation, non-enforceability of a patent, and also the mandatory transfer of a patent to a third party, such as the provider of the GR or associated TK are off the table as sanctions under Article 6 of the final text. The possibility that non-compliance with the PDR could constitute grounds for granting a compulsory license should be excluded. All these sanctions, which prevent the patent owner from exercising their legitimate rights under the patent, would constitute disproportionate penalties and create significant legal uncertainty. At the time of writing, Member States have not confirmed that such sanctions will be excluded from the final instrument.

Finally, innovators have suggested that the notion of "fraudulent intent" be removed from the text, given the reality of different legal statutes and different standards of evidence in different legal jurisdictions. This could give rise to uncertainty for patent applicants and owners – and potentially also to disproportionate penalties for certain acts of non-compliance with the PDR. The same holds for the notion that dedicated dispute settlement mechanisms should be put in place by WIPO Member States to address issues related to the GR and associated TK patent disclosure requirement. Arguably, usual administrative procedures for addressing administrative issues in patent applications would be sufficient.

Avoiding Legal Uncertainty

Technology developers and users require legal certainty, as do other actors in the economy. Vague definitions and poorly defined requirements create an environment not conducive to investments in R&D involving natural resources.

The above issues, especially in combination, could create substantial legal uncertainty for researchers and innovators, and their partners, as well as indigenous and local communities and other actors in the economy. They exacerbate the striking lack of common ground, conceptually, among Member States and stakeholders in relation to the goals, purpose, and parameters of the international instrument, as set out above.

Transparency, as noted, is one stated objective of the talks. If appropriately calibrated, a PDR aimed purely at transparency, implemented separately from the assessment of patentability, without undue burdens for patent applicants and offices, and treated as a purely administrative requirement in patent applications, could be hoped to not negatively affect R&D investments and innovation. It should be expected to create costs and compliance challenges, however – and it's important that negotiators recognize this burden for patent applicants and make efforts to minimize it.

Any linkage with patentability, on the other hand, is not only outside the scope of these talks but should also be expected to set back investments in innovation involving GR and associated TK.

To commit financial and other resources to R&D and commercialization, with a medium- to long-term timeframe of 10 - 20 years, or more, companies and other actors need certainty and stability. Patents are used to manage investments and collaboration throughout the innovation and commercialization process. If they become harder to obtain for natural resources-related solutions – more costly, undue delays, or undue burdensome administrative requirements, and more uncertainty –the relevant R&D programs are likely to be de-prioritized.

The existence of such challenges within specific countries' patent systems alters decision-making as to where to invest or work with partners. Investments in R&D with natural resources and the commercialization of products developed from natural resources in countries with unduly burdensome PDR could become disproportionately unattractive.

Patent applicants currently face a mosaic of different rules in relation to the disclosure of GR and associated TK. As confirmed by WIPO, more than 30 developing and developed countries already have or are in the process of creating such patent disclosure requirements in their national laws.[7] The requirements and legal consequences differ significantly from country to country. An appropriately crafted international agreement with a clear ceiling could help to reduce such complexity and provide more certainty for patent applicants by harmonizing the respective administrative requirements.

The reality is that R&D involving non-human genetic resources[8] has already been under pressure in recent years, due to various factors, including greater inherent complexities of natural substances and thereby greater challenges in analyzing, synthesizing and modifying such substances to develop new products. In the field of biopharma research, anecdotal evidence points to such programs steadily receiving fewer resources and less attention within innovative organizations over time. They will undoubtedly be further de-prioritized if it becomes more difficult to secure and maintain patent protection for the relevant R&D outcomes. Innovators across sectors have warned of this possibility, which would undermine the goal of encouraging innovation that leverages GR and associated TK – and ultimately undermining what is available for ABS.

Conclusions and Next Steps

Above we review elements of the text for the forthcoming Diplomatic Conference – which is based on the slightly updated Chair's text and overall IGC talks from an innovator/patent applicant/owner perspective. We have identified critical elements that require a closer look, clarification, and/or appropriate modification of the text during the time between now and the Dip Con, which is scheduled to take place in 2024.

There is the likelihood that acceptance of the current text could create more legal uncertainty, negatively affecting innovators as well as other actors in the economy – and without achieving the goals in Article 1. Various Member States continue to propose modifications to the text, creating further complexity. At this crucial stage of the talks, negotiators must be fully aware of the likely consequences of different choices and provisions on R&D and the commercialization of innovative products using natural resources. This views in this note are provided in this spirit of contributing to awareness.

7 To inform the forty-sixth session of the IGC, which took place in February 2023, WIPO provided a comprehensive report about the PDRs in a range of jurisdictions. See: https://www.wipo.int/edocs/pubdocs/en/wipo_pub_1047_19.pdf.

8 It's worth noting that this is another point lacking clarity in the text, given the present text still does not explicitly exclude human GR from its scope.