

# INNOVATION COUNCIL

## **Innovation Council Q&A**

### IGC Negotiations Wend Wendland, WIPO

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nnovation Council sat down with Wend Wendland<sup>1</sup>, Director – Traditional Knowledge Division of the World Intellectual Property Organization, to get his insights on the IGC negotiations based on his many years of leadership and experience working with Genetic Resources and associated Traditional Knowledge.

1 Any views expressed are those of the interviewee and not necessarily those of WIPO or any of its Member States.

#### Please tell me about your role at WIPO and how your work relates to the IGC talks.

direct the WIPO Secretariat's program on genetic resources, traditional knowledge (TK) and traditional cultural expressions. This nexus between program lies at the property biodiversity, intellectual and cultural heritage, agriculture, trade, human health, climate change rights, and sustainable development. The program comprises an intergovernmental negotiation and, distinctly, a large training skills-development program and for Indigenous Peoples and local communities in all countries and government officials. I'm also the Secretary to the WIPO Intergovernmental Committee (the IGC), the forum in which negotiations take place for the finalization of new international legal instruments on these subjects. As the Secretary, my team and I try to create a conducive environment for the negotiations and do what we can to help the countries reach agreement. Organizationally, my team and I comprise the Traditional Knowledge Division, which is situated in the Global Challenges and Partnerships Sector.

#### You have observed the IGC talks for many years. Can you summarize what has happened and where things stand today?

This work has been ongoing for over two decades. At first, the Intergovernmental Committee's focus was on non-normative work, which led to a number of useful practical outcomes. These included concrete first steps towards the defensive protection of

TK (protection against TK being erroneously patented) through enhanced its recognition as prior art. Relatively soon, however, developing countries began to push for work to begin on new international legal instruments, such as treaties. Formally, the Committee began "textbased negotiations" as from 2010. From then on, this became the focus of the Committee's work. Agreeing on suitable working methodologies to conduct negotiations proved difficult, however, and various working methodologies have been tried out. Negotiations relating to genetic resources and associated TK took a leap forward in 2012, with the emergence of a single consolidated draft of an international legal instrument. Options for a new patent disclosure requirement became clearer and pressure mounted for an agreement on this specific question. However, by mid 2018, the negotiators had deadlocked on the Committee's consolidated text. In April 2019, the IGC Chair at that time, Ian Goss, prepared, under his own authority, a draft text (which became known as "the Chair's Text"). Up to that time, the Committee had been addressing its three subjects (genetic resources, TK and traditional cultural expressions) on an equal footing. In July 2022, WIPO Member States decided to fasttrack the negotiations on genetic resources and associated TK by convening diplomatic conference to conclude an international agreement on these matters no later than 2024. The Diplomatic Conference is scheduled for May 13 to 24, 2024, at WIPO Headquarters in Geneva. The negotiations on TK more broadly and traditional cultural expressions will resume towards the end of 2024.

Any memorable moments in the talks so far?

It has been - and continues to be - a fascinating process, with much "back and forth", often more "back" than "forth"! Memorable moments would include the unexpected launch of "text-based negotiations" towards "Diplomatic a Conference" as from 2010; the IGC not meeting at all in 2015 because countries could not agree on the number and length of meetings for that year; the all-night sessions of the WIPO General Assembly to agree on new mandates for the IGC, such as in 2015; and, of course, the decision of the 2022 WIPO General Assembly to convene a Diplomatic Conference in 2024.

#### Much has been done to facilitate the involvement of a variety of stakeholders in the work of the IGC. What has been the impact?

From the very first session of the IGC in April 2001, innovative initiatives have been undertaken to enable previously excluded stakeholder groups to participate as observers, especially representatives of Indigenous Peoples and local communities (IPLCs). As a result, the IGC's negotiations are the first-ever opportunity for IPLCs to participate in WIPO's normative work. A new treaty, should one be adopted by the Diplomatic Conference in 2024, would be the first time that IPLCs have had a say, albeit as observers, in the development of an international intellectual property convention. The involvement of IPLCs has not been limited to the IGC: IPLCs are **beneficiaries** suite of a of skillsdevelopment programs and projects offered by the Traditional Knowledge Division. This has enabled IPLCs to better understand intellectual the current property system and make more effective use of it. We are delighted to be helping Indigenous persons and communities register their first trademarks, collective marks and geographical indications.

#### What are the key issues that must be resolved to reach an agreement at the Dip Con next year?

Diplomatic In convening the Conference, the **WIPO** General Assembly decided that "significant convergence" had been achieved around the Chair's Text, which, Member States agreed, is "a focused, effective, and balanced basis for further engagement". Accordingly, they decided that text would "constitute the substantive articles of the Basic Proposal for the Diplomatic Conference". The text was discussed by experts in meetings held earlier in 2023, in which industry representatives participated. It was formally negotiated in September this year in two meetings (one, a Special Session of the IGC on the substantive articles and the second a Preparatory Committee for the Diplomatic Conference on the administrative clauses and final provisions). Few changes were made because any changes required the agreement of all the participating countries. The text is now closed until the start of the Diplomatic Conference. This text - the one the Diplomatic Conference will begin with - is referred to as the "Basic Proposal". There are several key issues that must be resolved to reach an agreement at the Dip Con. On substance, these include the definition of associated TK, the trigger in Article 3, consequences of non-compliance in Article 6 and the scope of the review in Article 9. In addition to the proposed new disclosure requirement, the new instrument would also invite countries to establish databases of genetic resources and TK associated with genetic resources, subject to certain conditions.

I invite your readers to study the text carefully, along with the reports of the experts and records of the two meetings that took place in September, plus other materials we have made available, such as case studies, a laws table and background briefs. The text and other materials are available at <u>https://www. wipo.int/diplomatic-conferences/en/</u> genetic-resources/index.html. What will you and your team focus on between now and the Dip Con?

A Dip Con is a large event that takes place over two weeks attended by some 1000 participants, about 170 of whom are funded. This includes funding for a certain number of IPLC representatives. So, logistically there's a lot to be done. On substance, we will do whatever Member States request us to do to help them prepare. We are, for example, being asked to organize a cross-regional meeting for Member States in March 2024. We are also, upon request, providing many briefings for States and observers, Member and facilitating consultations among them in Geneva and elsewhere. We will in due course start to work closely with the officers-elect of the Diplomatic Conference to help them prepare; this includes the chairs of the main negotiating committees, which are Main Committee I and Main Committee II.

#### Let's look at the substance: can you explain the relationship between CBD, the Nagoya Protocol, and the IGC talks?

There is no direct and explicit relationship. The main idea in the Basic Proposal as it currently reads is a new mandatory disclosure requirement in patent law - this would require patent applicants to disclose the country of origin of the genetic resources and/or the Indigenous People or local community providing the associated TK, if the claimed inventions are "materially/directly based on" genetic resources and/or associated TK. If such information is unknown, the source of the genetic resources or TK should be disclosed. If none of the above information is known, the patent applicant should be required to declare so. Human genetic resources are not intended to be covered. Patent offices should provide certain guidance to applicants, though they would have no obligation to verify the authenticity of the information provided, nor is there any obligation on the patent applicant to show compliance with any national access and benefit-sharing regimes there may be. The Basic Proposal makes no reference to the access and benefit-sharing obligations as found in the CBD and its Nagoya Protocol. Of course, the Basic Proposal is up for negotiation at the Dip Con. Once again, I invite your readers to study the text itself carefully.

#### What benefits do negotiators expect from an international instrument containing a PDR?

As set out in the Basic Proposal, the objectives of the proposed new disclosure requirement are to enhance the efficacy, transparency and quality of the patent system with regard to genetic resources and associated TK, and prevent patents from being granted erroneously for inventions that are not novel or inventive with regard to genetic resources and associated TK. More broadly and taking into account that currently some 35 countries and regional authorities have one form or another of such a patent disclosure requirement, many of which differ, some look forward to the increased legal certainty and predictability that an international instrument might bring.

#### Picking up on what you just said, can you please explain how a mandatory PDR could improve transparency and help prevent the granting of "erroneous patents"?

It is argued by proponents that a mandatory PDR improves transparency by making information available on the source of genetic resources and/or associated TK in relation to an invention, which is not typically made public by patent applicants. This additional information can help patent examiners determine whether an invention is novel or inventive, and who the inventors are. Additional transparency could also mean that third parties could intervene in the rights-granting process (e.g. the postgrant examination phase for patents) where their interests are at stake. These are

some of the arguments put forward by proponents.

#### Industry representatives are expressing concern that the talks could give rise to legal uncertainty. What is your response?

believe that adding Some any additional requirements to the granting of patents leads to legal uncertainty. This is because, it is argued, patent law is already technically complex, and the granting process is expensive, lengthy, and uncertain, so any additional requirement may create unnecessary risk. This is particularly so where the genetic resources or associated TK implicated in an invention came into the applicant's possession with limited identifying information on the source or origin. For instance, the genetic resources and ΤK associated have been may accompanied only by information identifying a broad geographical region. On the other hand, it is countered that these risks are mitigated by the Basic the requirement Proposal making a formality requirement rather than a substantive one and other limits (like Article 3.3 no-known-information on the declaration), facilitating compliance with the rule (for this, see Article 3.4 on providing guidance, rectifying failures and correcting erroneous or incorrect declarations), and not requiring the verification of authenticity (on this point, see Article 3.5). Again, I invite your readers to study the text itself carefully.

#### Associated TK is part of the GR talks, in addition to being the focus of separate, parallel negotiations at WIPO. How is associated TK defined in both contexts?

"Traditional knowledge" more broadly is under negotiation in a separate track of the IGC's negotiations. In short, TK refers to knowledge of Indigenous Peoples as well as local communities relating to land and the environment, health, climate change, agriculture and other such topics. For more details, the current draft text – in the document WIPO/ GRTKF/IC/47/14 – contains a proposed definition of TK as well as related terms such as secret TK, sacred TK and so on. It also contains draft "eligibility criteria" for TK that would be protected. The text is available on the <u>website</u>.

#### What relationship is there between the two tracks – and how can Member States ensure coherence between them?

In fast-tracking the negotiations on genetic resources and associated TK convening Diplomatic bv a Conference to conclude an international agreement on these matters no later than 2024, we do not understand that the member countries wish to affect or impede the parallel negotiations on TK more broadly and traditional cultural expressions. I believe Member States will ensure there is coherence between the tracks of the negotiations. In July 2023, countries agreed to renew the mandate of the IGC for the biennium 2024/2025, and they requested the Committee to continue its negotiations on TK more broadly as well as those on cultural expressions. traditional The relationships between intellectual property and genetic resources, TK and traditional cultural expressions are distinct vet interlinked. My team and I will continue to create a conducive environment for the negotiations, and we will do what we can to help the countries reach an agreement if they so wish.

The support from your team has certainly been impressive, particularly the broad range of publications and research. I recently reviewed information from WIPO about national laws on GR and associated TK. What trends can be observed at the national level?

There are now some 35 countries and regional authorities that have a PDR in one form or another. We maintain a <u>table of the various laws and</u> instruments. Some countries are also developing databases and registries to document and track genetic resources and associated TK. Examples include India, Nepal, Peru, and South Africa.

#### Is it possible to identify emerging best practices? For example, what would be the elements of an effective and easy-to-implement PDR, based on WIPO research and analysis

I invite your readers to consult our publication "Key Questions on Patent **Disclosure Requirements for Genetic** Resources and Traditional Knowledge". This is a very useful guide as to how different jurisdictions have introduced a PDR, including their lessons learned.

Given your longstanding involvement with the IGC, I would like to ask: how has the evidence base grown and changed over the years? Do we know more today -20+ years on – about genetic resources, associated TK, and IP management?

The IGC first met in 2001, and there have been several important developments since then. Numerous WIPO Member States have adopted PDRs in their national laws. These include patent laws, sui generis regimes for the protection of TK, and laws on biodiversity or ABS. One major influence on the global governance of genetic resources and associated TK was the adoption of the Nagoya Protocol in 2010, as are the technological and commercial innovations in recent years gene editing, synthetic biology, and gene sequencing. The two decades of discussions at the IGC have narrowed the scope of discussions to the point where members have convened a diplomatic conference to adopt an international legal instrument.

> What is the one publication that you recommend someone read in order to understand these negotiations?



There is actually a whole list of essential reading. They can start with these WIPO publications:

WIPO Background Brief 2: https://www.wipo.int/publications/en/ details.jsp?id=4682

WIPO Background Brief 10: https://www.wipo.int/publications/en/ details.jsp?id=4683

"Is an international agreement on IP, GRs and associated TK finally in sight?" https://www.wipo.int/wipo\_magazine\_ digital/en/2023/article\_0003.html

Key Questions on Patent Disclosure **Requirements for Genetic Resources and** Traditional Knowledge:

https://www.wipo.int/publications/en/ details.jsp?id=4498

#### Sometimes at WIPO, the policy discussions and negotiations can reflect a North-South divide. Is this the case at the IGC?

The negotiations are not neatly divided along North-South lines. The records of the negotiations can be examined to see the various viewpoints that show this.

#### What is your top message for innovators and patent owners, which make up the Innovation Council membership, as we head towards the Dip Con?

Please participate through the many organizations that are accredited to attend the Dip Con. Innovators and patent owners have practical experience with R&D, innovation and the patent system, and your expertise and suggestions would be very welcome and valuable.