

IGC Conversation hosted by Innovation Council

April 2024

Key Takeaways

On April 23, 2024, Innovation Council hosted an online conversation with experts about the ongoing WIPO IGC negotiations, the focus of a Diplomatic Conference in May 2024.

Innovation Council Director **Jennifer Brant** moderated an online conversation featuring **Dr Malathi Lakshmikumar** and **Dr Axel Braun**. These patent lawyers, both with scientific backgrounds, shared their experience with and insights about patent disclosure requirements (PDR) for inventions that are based on genetic resources (GR) and/or associated traditional knowledge (TK) in different countries. They drew attention to shortcomings of the so-called Chair's text, which is the basis for the WIPO negotiations aimed at delivering a new WIPO international instrument setting forth a PDR.

Dr Malathi and Dr Braun provided specific examples of problems that arise when PDR-related legislation is unclear, sharing perspectives from both the biopharmaceutical and agriculture biotech sectors.

Key takeaways from the discussion include:

- **Legal uncertainty** was the top concern expressed by the experts. They pointed out several flaws in the Chair's text that must be fixed prior to any agreement. If these problems go unaddressed, they warned of complexity for IP offices and innovators that will be difficult if not impossible to manage. They raised the likelihood that, faced with patent-related legal uncertainty for inventions based on GR, innovators would direct R&D investments away from natural resources research programs.
- They highlighted the need for the text to set forth **maximum requirements**, which is not currently the case. Both experts underlined the benefits of PDR harmonization among countries, to provide legal certainty and predictability for innovators engaging with regulations across borders in today's global economy.
- The experts stressed the need to **clarify definitions in the Chair's text**. For instance, they called on negotiators to clearly define important concepts like TK and the trigger.
- They underlined the need to clearly **define the scope of the text**, in relation to various elements including: the trigger for applying the PDR, exclusion of human genetic material (with explanation of what that includes), exclusion of supply chain inputs used to make the invention, exclusion of DSI (digital sequence information) and ABS related requirements, like PIC and MAT. They emphasized that the instrument must have no retroactive application, and that this should be clearly stated in the text.
- They urged negotiators to make sure that **no patent-based sanctions** (such as refusal to grant a patent, or patent revocation) are associated with the PDR. They considered it important that patent applicants have the option to state they do not know the origin or source of the GR and/or associated TK, and to correct issues with the PDR, which the experts viewed as a transparency-related administrative requirement.

Below are the experts' closing remarks:

Dr Malathi: "There has to be clarity for all the definitions, and there has to be consistency. Consistency across all jurisdictions is important. Is it that when I come to India I have a different yardstick, and in other countries I have a different yardstick? It is very difficult to draft patent applications keeping different jurisdictions in mind, like this, especially when laws and their interpretation vary widely. I hope that with this IGC text, if it is adopted, there will be transparency, consistency, and clarity on every aspect of the patent disclosure requirement. Because that is very important for patent advisors and researchers."

Dr Braun: "I agree that what's important is to create consistency. You can only achieve harmonization when you have a maximum standard, when you have clear definitions and clear terms, and when you do not leave room for too much national flexibility. Harmonization is a very important issue. Another key issue is that, because this is a transparency measure, the PDR must be linked to appropriate sanctions. Basically, don't refuse to grant the patent because of the PDR, and no revocation. There should be no patent-based sanctions."

To read the full transcript of this conversation, and for more information about the IGC negotiations at WIPO and the key issues at stake, visit: <https://innovationcouncil.org/ip-natural-resources/>.