INNOVATION COUNCIL

Innovation Council Q&A

WIPO Negotiations about IP and Genetic Resources

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We sat down with Dr. Axel Braun to discuss the ongoing negotiations at WIPO about genetic resources and associated traditional knowledge, which are expected to produce a new international agreement by next year.

Dr. Braun is a Consultant and Former Swiss and European Patent Attorney

Q Can you please describe your engagement with the WIPO IGC discussions to date?

A I have been following these discussions for many years. I have contributed the perspectives of innovative biopharma companies, first while employed in IP management leadership roles at Roche, then later as consultant to IFPMA and Interpat. I participated in the IGC discussions last year as expert in a virtual International Symposium on IP, TK, and Genetic Resources, which was organized jointly by WIPO and the China National Intellectual Property Administration. This year, I had the pleasure of serving as one of the experts in the virtual technical meeting on possible disclosure requirements, organized by WIPO.

Q What specific perspective and expertise do you bring to the IGC process?

A I bring, above all, a very practical perspective I think. I started following the discussions at the IGC at IGC 6 [2004], if I remember correctly. After so many meetings and exchanges with the member States and stakeholders, I am quite familiar with the issues under discussion, and I understand the impact that different proposals would have for innovators.

I have a scientific background in chemistry and years of experience working in industry as a patent attorney. So, I understand the patent elements and also the technical and R&D elements at play in the IGC. I understand the challenges, of conducting research using natural resources – it's a very complex area. I also followed the negotiations and implementation of the Nagoya Protocol very closely, and I am now engaged with the further negotiations under the CBD for a new system for benefit sharing in cases of use of DSI.

Q What did you learn during the IGC discussions so far that you didn't know before? Anything that surprised you?

A To be honest, having followed the discussions for so many years, nothing surprises me anymore. There is really not anything too surprising to me except that positions on critical issues, things like the definitions of associated TK, trigger and sanctions, are still so far apart.

Q What is at stake in the IGC talks for innovative companies? What risks might there be, depending on the outcome?

A The major issue is really legal certainty. Depending on what the instrument looks like once finalized, there could be important risks for any research with genetic resources. In the extreme case, we may be talking about losing a patent or its enforceability – and thereby losing all the investments that went into developing the patented invention. R&D investments in our sector can be in the billion dollar range and they are made over many years. Patents protect the generation of sufficient income to finance future R&D for drugs for unmet medical needs. Companies will move away from areas of R&D for which they cannot get and use patents, in this case natural resources R&D programs.

Q You are a member of the IGC Expert Group. What did the group endorse?

A I think there was agreement on several issues (but not always by all participants). For example, there was general agreement that TK associated with GR should be included in the scope of the instrument being negotiated, with a clear definition. And that DSI should not be included, but that it could be part of a future review of the instrument. We thought that the country of origin that should be disclosed is the country from which the GR has been obtained. We also proposed a clearer definition of the trigger and recommended that sanctions should not lead to revocation of the patent. Hopefully our work will still be considered by the negotiators.

Q What is the most misunderstood aspect of the IGC talks, in your opinion?

A I think people don't realize how far apart the stakeholders remain even after many years of discussions. Let me give you an example. The Chair's text makes it quite clear that the objectives of the future instrument should be to enhance transparency and help to avoid the erroneous granting of patents. Despite this, I get the impression that there is still an underlying assumption by some participants that the instrument should also be used to regulate certain aspects of access and benefits sharing, or ABS. This is outside the patent system, though.

I think it is important to keep in mind that the patent system should not be used to address non-patent-related issues like ABS. Also, there are now other international instruments for dealing with those issues, which was not the case when the IGC got started.

Looking ahead, the work needs to focus on ensuring clarity, in relation to definitions and scope for instance, and legal certainty.

Q What for you seems to be the thorniest text-related or technical issue to resolve in the talks?

A There are, as I said before, still many critical issues to be resolved. I think the major issue is the one of legal certainty. It's especially important in relation to sanctions and the validity of patents. I keep repeating it because this really matters for those investing in R&D and trying to bring new drugs to market.

Q Tell me more about this. What do natural resource R&D programs look like and why are they unique?

A Simply speaking, natural product research – and here I am focusing on non-human natural products, as the present instrument should do – is more complex than classical approaches to R&D. On the one hand, working with a natural compound has the advantage that you already have a certain degree of knowledge about the function of the compound in the organism from which you have isolated it. However: quite often the chemical structures of such compounds can be very complex and therefore not easy to produce synthetically or work with in order to develop a treatment or medicine. This is one of the reasons why many pharmaceutical companies that have been active in this area of research ended up discontinuing their activities. For the IGC, the point is that it's already more difficult to do natural products research; when you make it harder to patent the research outcomes, it's even harder to justify the R&D investments.

Q Turning to the negotiating text, what is associated traditional knowledge? How does this concept engage with the patent system, and with systems for trade secrets protection?

A TK associated with GRs is basically any knowledge held by indigenous communities that would provide an indication of the potential use of a substance isolated from the associated GR, like for the development of a drug. The more sophisticated question is, however, what is TK and how could it be protected. This is the objective of parallel discussions and negotiations in the IGC.

Q Good policymaking reflects real-world considerations. So far, do the talks reflect the ways that innovators develop new products using natural resources (genetic resources) and how they protect and manage their IP?

A Fully agree. That is the reason why members of IFPMA and other patent users have continued to draw the attention of the negotiators to the more practical issues, and to present the implications of different outcomes in these negotiations. We do this through side events and other ways of communicating our industry perspectives. So, I would say that to a certain degree, the practical issues are being considered in these talks. However, something that is not fully understood by participants, in my mind, is this: a lack of harmonization of legal obligations will inevitably lead to less and not more research in this area, in natural resources.

Q Legal uncertainty has been raised as a possible consequence of the IGC talks. What does this mean, in a practical sense? What would give rise to legal uncertainty, potentially?

A Put simply: the more legal uncertainty exists, the less likely research will be undertaken with GR. Consider that the development of a new drug requires investments in the billion dollar range. For companies to put this amount of resources towards R&D, obviously there is a need to reduce any legal uncertainty as much as possible. Any unclear legal term, any unclear legal obligations, a reference to national law instead of harmonization, or the retroactive application of rules – all these types of things – would automatically lead to more legal uncertainty.

Q During the IGC Special Session in September 2023, a number of delegations opposed patent revocation or unenforceability in cases of inadequate disclosure. Thoughts?

A This is important. Such measures are inadequate and disproportionate for a formal transparency measure like a new patent disclosure requirement, which is basically an administrative requirement. Also, those types of sanctions could raise doubts as to TRIPS compliance. In addition, the consequences of any legal uncertainty related to the new disclosure requirement would be significantly increased. This could lead to less research in this area.

Q What about not getting a chance to correct a disclosure deemed insufficient?

A I think there is a growing understanding that there should be the possibility to correct any disclosure before and after a patent has been granted.

Q Some delegations also opposed the notion of fraudulent intent in the text. Can you comment on this?

A Not all national legal systems use the concept of fraud. More importantly, the notion of fraud has been opposed because it is linked in the text to invalidity and lack of enforceability. In addition, what would be the standard to consider an action of the patent applicant to be fraud?

Q Are there any other procedural issues that jump out at you in the talks and/or proposed text?

A Well, in addition to invalidation and rendering a patent unenforceable, there are also other sanctions that are not explicitly excluded that could have a serious impact on the future owner or holder of a patent. An example is the forced transfer of the ownership to another party, normally the provider of the GR or the holder of TK that is associated with the GR. Another example is the granting of a compulsory license. In the end, the owner or holder of the patent would no longer be able to benefit from their IP right. It's the same as in the case of invalidation.

Q Looking at the text, it's not clear whether it's a minimum, maximum or something else that is being agreed? What is your take?

A According to the introductory remarks in the Chair's text, the new international patent disclosure requirement should harmonize existing national laws and thereby increase legal certainty. This means, in my mind, that the new instrument should provide a ceiling in terms of what can be required from the applicant under national laws or regulations. However. the present text for the forthcoming Diplomatic Conference, which is based on the Chair's text, does overall not reflect this intention. One notable exemption is the limitation of invalidation and un-enforceability to cases of fraud; here the text does set a sort of ceiling, which is the right approach even though that particular Article itself is problematic.

Q Sometimes the talks are framed as a North-South issue. Why this dynamic? How might an international instrument with mandatory disclosure help developing countries?

A I think one of the reasons for this dynamic is that countries in the "South" are often viewed as being particularly biodiversity rich – and therefore they are assumed to be the providers of GR. Countries in the "North" are seen as having economies based on a higher degree of industrialization and are considered users of GR. This may be overly simplistic, but I think it's what people assume. It's worth noting that North countries can also be biodiverse. Obviously, there are different priorities expressed by providers and users of GR and associated TK, and the differences give rise to different country positions. If the new instrument would lead to an overall harmonization and simplification of existing national patent disclosure requirements, this would increase legal certainty for everyone – users, providers, companies, governments, and others. I believe this would also lead to more research with GR and associated TK, to the benefit of providers and society at large.

Q What about situations where the GR are not physically accessed? How do these relate to the talks?

A I think you are talking here about DSI, digital sequence information. I think it is important to know that, so far, only about 20% of DSI in databases has any indication as to the country of origin. This means that in the majority of cases, only the source – that is, the database from which the DSI has been obtained – could be identified with certainty. In addition, it is rather rare that research is done with only

a single sequence. In R&D, it is therefore not straightforward to identify what relationship what sequence has, if any, to the claimed invention. Because of this, including DSI in the scope of the instrument would add complexity and confusion to what already exists with the patent disclosure requirement for physical material. This is the reason why, at least for now, there seems to be some degree of consensus not to include DSI.

Q During the last meeting, some countries underlined that a disclosure requirement is a way to enhance transparency. Is transparency the goal of the talks?

A Yes, I think this seems to be the present understanding of the current text, which is based on the Chair's text. Transparency is also referred to under the objectives in Article 1. It is mentioned all the time.

Q What impact on R&D decision-making, or on IP management, might one expect as the result of this international instrument? Does it depend on what exactly is agreed?

A You have already given my answer! If the negotiators cannot provide more clarity on key terms, like "associated TK", the trigger, and the "source" of GR. If the instrument would apply retroactively, including to GR that was obtained before the instrument enters into force. If there are sanctions for insufficient disclosure that include invalidation, un-enforceability, forced transfer of ownership, or compulsory licenses. If overall the instrument would not harmonize existing national disclosure requirements to a defined maximum level. If all this is in that final instrument, then it would have a significant impact on the future of innovation with GRs and associated TK. It would be a negative outcome for innovation.

Q What key message would you communicate to those negotiating the instrument?

A Any new instrument should enhance legal certainty and not create any hurdles for the patenting of future inventions that are made with GR, and TK associated with GR. This is in the interest of providers of GR, users of GR, TK holders and users, and also those involved in the administration of IP rights. It's also for the overall benefit of society at large.