Innovation Council IGC Conversation

Transcript of the online discussion with experts

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Jennifer Brant, Moderator

Hello, everyone. Thank you for joining this conversation today. My name is Jennifer Brant, and I am the Director of Innovation Council in Geneva, a cross-sectoral innovators group with the mission to bring the perspectives of organizations and individuals that are bringing new solutions for society to policymakers. We're active in Geneva as well as other places. We have been engaging with the IGC talks at WIPO, since the outcome could affect the environment for R&D, innovation, and commercialization in certain sectors.

We wanted to host this conversation today in order to flesh out the high-level talking points and arguments about the IGC that you may have already heard. During the next hour or so, you will get the chance to hear from two experts and to ask your questions, as we head into the month of May and the Diplomatic Conference.

I will structure this as a moderated discussion. Please put your own questions in the chat, and feel free to raise your hand and participate in the conversation at any time. I want to make sure that what you are most interested in gets put on the table.

Let me now introduce our speakers very briefly. They are **Dr. Malathi Lakshmikumaran** and **Dr. Axel Braun**. Both are patent lawyers with scientific backgrounds, Axel now retired, with many years of experience working on patent-related matters. Together they bring experience from both the biopharmaceutical and ag biotech sectors. I will give each a moment so they can introduce their backgrounds and experience with genetic resources (GR), associated traditional knowledge (TK), and patenting.

Dr. Malathi

Thank you, Jen. I'm very happy to contribute here. I was a scientist for twenty years, and this is my second career in patent law. I'm now a patent agent and I have a lot of clients in the field of biochemistry and molecular biology. My work focuses on India. Because I've been a molecular breeder and a molecular biologist, I do a lot of work in agribiotech, fermentation, and biotechnology areas, including antibodies. I am a practitioner with knowledge about patent systems as well as research and invention, and I sit at the intersection of law and science. Today, what I plan to do is bring this perspective.

Dr. Braun

Thanks a lot, Jen, and likewise I am very happy to be here today. Actually, I became aware of this issue of patent disclosure of country of origin or source during the early years of 2000. I worked as a patent attorney at Hoffman La-Roche. At that time, there was the revision of the Swiss patent law. And one of the issues in the revision of the Swiss patent law was the introduction of a patent disclosure requirement for genetic resources and traditional knowledge. At this same time, I started following the discussions and negotiations in the IGC and WIPO, at some points very closely. I've been a member of the IFPMA delegation to the IGC, and I have also served as an expert for the WIPO IGC expert group.

Jennifer Brant

Thank you. Here is an introductory question for Axel. Please, can you situate the IGC talks in the broader context. For example, how do these relate to the CBD?

Dr. Braun

I think that's a very important question, especially since the IGC instrument and negotiating text has really evolved over time. Let me explain. For quite some time, at the start, the discussions at WIPO focused in part on ABS (access and benefit-sharing) issues. When the discussions started in the early 2000s at the WIPO IGC, the Nagoya Protocol, under the CBD, the Convention on Biological Diversity, was not yet in place. As you know, the Nagoya Protocol is an instrument to implement the access and benefit-sharing provisions of the CBD, specifically through compliance and monitoring measures. Since then, the discussions at WIPO have largely moved away from this ABS issue. You can see this in the current Chair's text, which is the basic text for the forthcoming negotiations in the Diplomatic Conference. The focus of the talks over the years have evolved to center on a true transparency measure related to the patent system. The focus moved away from the CBD and ABS issues. This makes sense because these are unrelated to the patent system.

Jennifer Brant

Thank you. I have another question, for both of our experts Let's consider two scenarios, one where the IGC instrument would set minimum standards internationally, and a second where the instrument would set both minimum and maximum requirements for the PDR (patent disclosure requirement). What are the implications for the policy landscape of each of those two scenarios? First, Dr Malathi.

Dr. Malathi

To answer this question, we can use the example of the trigger. When I look at the current negotiating text, it says this: the claimed invention in a patent application is materially or directly based on GR. But there are several situations where the trigger can be interpreted on a case-to-case basis. So, the real question is: where do we draw the line? And who will decide the basis for the trigger?

As a starting point, what is the claimed invention? In India, we have two government bodies intervening in cases where an invention and genetic resources were used. We have two government agencies involved: one is the Indian Patent Office, which comes under the Ministry of Commerce and Industry, and the other is the National Biodiversity Authority (NBA), which comes under the Ministry of Environment, Forest, and Climate Change.

So, the Indian government is looking at these situations from two different angles. The Ministry of Environment, Forest and Climate Change will be looking at the situation as per the CBD and the Nagoya Protocol. They are not focused on IP, but they are involved in regulating ABS for IP based on GR.

The two bodies mentioned above have very different ways of looking at an invention in a patent that uses GR. Therefore, we need to be clear regarding the WIPO IGC text: how do you define a GR and how does it relate to the invention, and therefore, what should be the trigger? And, again, who decides? Should it be the patent office that decides what is an invention based on GR? Should it be the applicant that decides? If I look at India, we talk about "biological resources", which is different

from the WIPO text, which uses the term “genetic resources”. Indian government authorities are going to comply with and carry out regulations based on the Biological Diversity Act in India.

Unless there is uniformity and consistency across jurisdictions, we are going to run into a lot of problems. When it comes to India, you may have other triggers. The law may not align with what gets agreed upon at WIPO.

Let’s say my client wants to patent a chemical, and this is the crux of the invention. Let’s say the chemical can be used to make a cosmetic or any such product. In my dependent claims, I can say that this chemical can be mixed with oils for that purpose, and that I have evaluated its use with oils, and soybean oil in particular. Now, like all practitioners in patent field, we know we can also claim for its use with olive oil or with any other oils along with that soybean oil. My main invention is the chemical – nothing to do with GR – whether it is used in a pharmaceutical or an herbal or a cosmetic composition. But I have to mix it with oils in order to make the formulation for my cosmetic product or any such product. I would be adding an oil, polymer, fiber, or so on to do so. This means that because of these oils, I may be adding GRs to a chemical composition. So, how are we to decide?

At present, in India, any word that refers to a genetic resource, what they call a “biological resource”, can be a sort of trigger for Disclosure Requirement (DR). This could be the soybean oil, or the olive oil recited in the dependent claims in the example that I just gave. How is one meant to evaluate all this information? I have major concerns about the lack of clarity when it comes to who is to decide what is a claimed invention, and how are they to determine whether it is based on GR or not.

So, going back to the original question. It is important for us to have a proper definition of GR and the trigger, and to make all this uniform across jurisdictions. Being a scientist for 25 years, I'm nervous about different disclosure requirements and how the countries will use different approaches to comply with WIPO IGC PDR (patent disclosure requirement).

What will happen if in every jurisdiction I have a different standard for compliance? For applicants, this is really difficult. So, we need to have both the minimum and the maximum requirements in any global agreement for proper compliance.

Jennifer Brant

Thank you. Axel, do you have anything to add regarding the question as to whether we should be setting maximum and minimum standards, or just minimum? And what the impact of either path would be?

Dr. Braun

I fully agree with what Dr Malathi was just explaining. These are really very important issues, specifically the point about the definition for GR, genetic resources. To give an example, we can look at the use of genetic resources in Brazil, which are referred to under the laws as “genetic heritage.” That seems broad and could basically cover DSI (digital sequence information) along with GR which have been accessed in person.

This illustrates the point that the trigger, if broadly defined, would have the potential also to cover DSI. The text at WIPO is, with some exceptions, setting forth only a minimum and not maximum standard. And why is that so? I think there are several reasons. One is there are unclear terms and terminology, as we just discussed.

Another reason is that, for example, looking at Article 3, it's not totally clear what is required in terms of information from the patent applicant, for the PDR. It's required to indicate the country of origin and or the source. And if you don't know that, you can make a declaration. But that's not phrased in the text as a maximum standard. Countries could add more in their national law, creating the confusion and legal uncertainty that Dr Malathi was talking about. Countries could easily come back also to the ABS issues and for example, require, in addition to origin and source, that applicants give some indication of prior informed consent and mutually agreed terms.

Let's look also at other articles in the text like, for example, Article 5 on retroactivity, which specifically refers to national law. If I recall, there's one point in the text where non-retroactivity – independent from existing or future national laws – is not excluded. This is with respect to genetic resources accessed before the instrument came into place. There is actually no cut-off point, which for an applicant can make things very tricky and difficult.

I know from my time working in industry that companies have big collections of data and compounds. Sometimes, since there were no requirements years ago, there may be no indication of origin or even source. Things may have been added without this information in years past.

In the IGC text, we have also articles that simply refer to or leave room for national laws. That's a problem with the present text. Setting a minimum standard only will not be enough for legal certainty and predictability.

Jennifer Brant

Let's follow this line of argumentation. You have mentioned the challenges where there are different definitions, like for the trigger, across jurisdictions. You also talked about specific areas of ambiguity in the text, and about how ambiguity plus minimum standards only could result in a mosaic of different requirements under national laws. We have heard that the translation of the instrument into national law could be variable.

What about the question of DSI (digital sequence information)? You touched on that, and I would like to ask you to speak more about DSI and the scope of the negotiating text for the IGC instrument.

Dr. Braun

I think that's a very interesting point. Here let's look again at the Chair's text which, as you know, has a certain importance for the present talks. When DSI was discussed at the IGC in the past, I really got the sense that there was an overall understanding that DSI should not be covered and should not be part of the trigger. But, as we have seen, if you have an unclear definition of genetic resources (GR), a definition that can be interpreted very differently, this creates confusion. If the definition used in the IGC refers to material of animal, plant or other origin (which is language taken from the CBD), and if the word "material" is not interpreted to be strictly physical material, then all this leads you is that you have the problem that, yes, DSI can be considered to be part of the IGC text.

As I said, there was an understanding that DSI should not be covered, despite all the ambiguities we have in the text. This was even indirectly put into the so-called review clause in Article 9 of the text. Article 9 refers to derivatives, which should also not be covered in the present version of the text. There is also a reference to future technologies, which should exclude DSI.

We have another interesting point, which I should mention, regarding human genetic resources and human DSI. Exclusion of human genetic resources is taken care of in the text by a footnote. This says that “genetic resources” is understood to not include human genetic resources. But for such an important issue, this should be directly in the text, either under the definition of genetic resources or, for example, under the part on exceptions and limitations.

Let’s look at yet another question of scope, and this one is a closely related issue to the treatment of human genetic resources. At one point, I was attending meetings and working on the guidance for the EU Regulation implementing the Nagoya Protocol. A question arose: what do we do with research on the human microbiome? Does that count as human genetic material? In the case of the IGC, if it's human genetic material, would it be excluded? What guidance would we have? Would we have to follow what's available guidance, like the EU guidance? I can see how, if you look at the whole human genome, people might expect that to be excluded from the scope of the IGC text. But if you look at the microbiome, this is in humans but is not obviously excluded. We need more clarity. And a lot of research is now going on in this area.

There are different conversations and examples we could have about the challenges around the lack of clarity and certainty in this text. These are important issues for negotiators.

Jen Brant

Thank you.

Dr Malathi, I wanted to shift over to you because Axel is raising questions about interpretation, clarity in the text, and possible lack of legal certainty. You and I have had conversations about the difficulty in identifying the origin and source of genetic resources in modern R&D programs. Can you please build on what Axel just said?

Dr. Malathi

Listening to Axel talk about these issues and thinking about the question you have just asked me about origin, some thoughts have been triggered. Let me share these. I will first talk about what you have asked me, specifically. Then I want to make a comment also about what Axel said, about research and the human gut microbiome.

What has happened? Let’s look at India. We've had this Biological Diversity Act – the law is very broad. One, I already said that we have “biological resources”, which is broad as compared to GR. And if I look at the Biological Diversity Act, it says any “information” on the biological resources – that is, data on the biological resources – would also get covered under DR.

One of the things that several of our clients, patent applicants, do is to isolate gut bacteria. This is an important area for R&D. Now fecal transplants are there, we know that gut health is what decides your mental health, we know that challenges like obesity can be dependent on your gut health, and so on. There is a lot of research going on. People want probiotics which can be useful for mental health, and for other issues.

So, several of my applicants are trying to isolate these bacteria, which come from the human gut. If bacteria is isolated from the human gut, we said that it is not a GR as it is isolated from humans. In India, “biological resources” covers plants, animals, microbes – but it does not cover human genetic material. So, we thought human genetic material is clearly left out of those regulations for compliance of DR. But the government had a different opinion.

Here is what happens. One is the patent office keeps asking the applicant to provide the source and geographical origin of the bacteria isolated from humans, which in this case they shouldn't, but they do. And the National Biodiversity Authority (the NBA) wants the applicant to provide the source of bacteria (DR) before granting ABS approval.

Until now, for any research outcome that we want to patent that used biological resources, we need approval from the NBA before the grant of the patent in India or any other country.

Let's look at this more closely. Say I have a client that has isolated bacteria that can have a probiotic value, and they want to produce it. Where do I say they got these bacteria from? From humans? Did I take it from a person in a hospital? Or did I take it from a neighbor? This becomes a problem of privacy if I identify a specific human or patient. However, the authorities insist that I name at least the hospital or institute from where the sample may have been taken.

How do I manage ethics and privacy, and provide the needed correct information? Does human genetic material include things from the human microbiome? Yes, or no? I had issues with the NBA and also with the patent office when I filed applications involving isolated bacteria (also virus) from a human sample. They wanted me to give the source and geographical origin, which I thought was crazy.

Here is a COVID example. During the pandemic, we did assays to identify whether a patient had flu, dengue, or COVID. Indian institutes came up with assays, and they studied them, submitted the papers, filed patent applications for their inventions. Then the authorities said: please tell me the source from where you got the COVID-19 sample. This is a great invention, but what about the source and geographical origin for COVID-19?

I can share another example from my practice that shows why we have a big problem when there is no clarity with these regulations for DR. Let's look at fermentation using E. coli. If I use E. coli mixed with a waste product to make a recombinant E. coli, which is my invention, then I am using inputs that are (1) E. coli and (2) waste material. Where did I get the waste? Do I have receipts? Which vendor? What is the source and origin of the waste material? To what extent do I tell the patent office and the NBA about all these inputs, and their source and origin, that I used in my supply chain to make my invention?

So here comes the question. In one part, we say tools are not required. But will national laws decide on that, country by country, or will we get clarity from a global agreement? Will there be harmonization for DR?

Also, what if I have many assays, or in whatever other case, many different things that go into making my invention. How do I give the origin? Can you realistically track the origin of something? Say I bought the waste that I used for my E. coli invention from someone, and they got it from someone else, and that person or shop had gotten it from another party. This can be a long and opaque supply chain.

You buy inputs from a retailer or a trader if you want to R&D in bulk. And they would likely have collected the product from three or four different sources and sold it to you. So, it's very difficult for me as an inventor to accurately state where my waste material really came from, because it is most likely coming from different sources.

I could give many such examples. For another case, I had media that uses rice flour to make an enzyme. The rice flour went into a hundred-ton fermenter. I had to put tons of rice flour in there to

make the invention. And the authorities asked: Please, tell me, from where did you get this rice flour? I said I bought it from a shop. So, they asked me: Where did the shop source it from? I said: I don't know. I just bought the flour and then put it in my fermenter. And it doesn't stop with that. They could also ask: Please give me the source of all the kilos of the rice flour that went into the fermenter because, without this rice flour, this fermentation would not have worked. It was essential to your invention. But the rice flour was not actually the claimed invention but used as a tool to make an enzyme in a fermenter.

If patent applicants have to start giving such information, giving the source and country of origin, for all these different bio-resources used, it will be difficult to provide the accurate source and origin.

Jennifer Brant

This raises an important point for the IGC talks. Could all the different tiers of the supply chain be covered? And, also, what about scope and research materials?

And also: what do people on this call do with this information we have just heard? This is a problem, but what might be a solution? How do we adjust the text for the IGC to reduce ambiguity. Axel, what do you think?

Dr. Braun

I think there are different issues – and many things you could do. For example, regarding the digital sequence information, I remember there was a good submission some time ago. I think it was from Switzerland. They suggested a criterion for managing these issues, which was also discussed in the Chair's text. For certain reasons, their ideas were not taken up. But if you would use this element they suggested, which basically states that the scope of the IGC text covers only a genetic resource for which you had physical contact, then that would clearly exclude any nonphysical material.

I think it's very interesting what Dr. Malathi just explained. One idea is to change the definition of human genetic resources to specifically exclude other materials obtained from humans.

Dr. Malathi

Let me say something about DSI. This is part of the compliance challenges that I face in India. Why do I say that? Because the Biological Diversity Act says "biological resources," and this has a larger scope than "genetic resources". "Genetic resources" must have functional units of heredity, and this keeps derivatives out. Ideally, we want both derivatives and human material out of scope. But now comes "information" about GR. When they say information about GR, this could mean DNA, RNA, protein, or any chemicals coming from a plant or microorganism or human.

Why do I raise this issue? Because many of us had to furnish this information to the NBA for ABS. An example of a problem I had was this one case – and you can review information about it on the internet – which we call the plasmodium case of Oxford University. Plasmodium is responsible for malaria. They were trying to make a vaccine and they had certain repeats in the plasmodium. We know there are different strains of plasmodium. Every country you go, you have a different strain. The Oxford invention was based on material that they had taken ethically. They had done the sequencing. But when you draft a patent application, you'll say I took a few repeats from a plasmodium species. You give the sequence of the gene. But in the Oxford case, they said in a dependent claim that these repeat sequences can be from any strain of plasmodium; it can be from Thailand, it can be from Africa. And they happened to recite an Indian strain in the claims. Now the

NBA got upset when they saw this and asked how can you just use this information from an Indian plasmodium strain? But this was only information. They had done the actual work on specific strains but not Indian strains of plasmodium. However, in the dependent claims they asserted that their invention was valid for the repeat DNA for several strains of plasmodium. They were ultimately forced to cancel the claims for the Indian strain in the application. They did not actually touch plasmodium from India. They did not use the genetic material from Indian strains. They used the data which was provided by Indian scientists and put up on the internet, where anyone can download the sequences.

So, this is where we are. There is a good reason why DSI and derivatives should not be included. In India, at present, all things are included potentially because the Biological Diversity Act is so broad.

So, I really worry about a lack of clarity with the trigger. What is my trigger? Is it the use of the genetic resources or is it the use of data or information about GR? Or is it the use of DNA sequences, protein sequences or chemicals already out there and publicly available online? Shouldn't this be kept out because derivatives and DSI are out too? We need clarity on this. If not, anybody who goes into different countries will have a problem. In India, DSI is already part and parcel of our patent law and the Biological Diversity Act, and you cannot escape it.

We need harmonization.

Jennifer Brant

I have a question from the chat: "I'm understanding the difficulties of disclosing source and country of origin in certain circumstances. Does Article 3.3 not provide the relief needed? Is there a sense that the amount of due diligence required to comply with 3.1 and 3.2 might introduce legal uncertainty? If you declare the information is not known? "

Dr. Braun

Happy to take that question. I think that's a very valuable point because it raises the important issue of what due diligence you would have to do. I think that for a simple transparency measure, there should be no expectations of due diligence.

Look at all the examples Dr. Malathi was giving. We can give you even more. Here, retroactive application is an important issue. As I said, if genetic resources accessed before the instrument comes into force, and perhaps even before the CBD or the Nagoya protocol took effect, would be covered, then there would be a lot of difficulties to demonstrate due diligence.

I think a correct reading of Article 3 in the Chair's text should be that there is just a need for a declaration according to your best knowledge, which implies due diligence. If the understanding is that the PDR is a transparency measure, an administrative measure, then that declaration should be done according to the best of your knowledge, and this should imply due diligence.

Jennifer Brant

Thank you.

Dr Malathi, you have described the complexity in determining the origin and source in some cases, including when you are made to look at all tiers of the supply chain. In the real world, how do you manage that complexity with your clients? And what are they risking if they're not totally confident

in what they're identifying about source or origin. What if they go forward anyway with the patent prosecution process anyway?

Dr. Malathi

We have actually abandoned the application in some cases, because this affidavit or declaration has to be signed by senior leaders. There has to be an authorized senior signatory because the inventors may have moved on by the time you file and prosecute this application. A senior inventor (professor) is there, and they may not know the details about what was used and how. The question then becomes: can I give this declaration about source and geographical origin?

I understand this personally. I worked as a scientist. I got agrobacterium way back in ’85 and ‘87 that I used in later research projects. And then, in a lab, you just give it to all your friends who are also working in the lab. How do I or others then actually know where this came from? What if ten years later that same agrobacterium or E. coli is being used by my friends from the lab. How do they actually show the source or the origin?

In India, they may say it doesn't matter, just say that you took it from your friend in lab X. But that may not actually be the real “source”. The source may really be somewhere else. Let me tell you that, today, there are more than 500 to a thousand applications in India for which the patents have not been granted because of issues with these disclosure situations. In many cases, with my own clients, we have abandoned the patenting process when this arises.

I have seen many applicants face this problem. We don't want oppositions happening later because of it. We don't want to sign a declaration giving incomplete or incorrect answers. The client tells me: Malathi please just abandon this now. Interestingly, in one situation, we abandoned two applications and even then, the authorities came back and told us fine, you abandoned the applications, but your compliance is still not there. Your compliance obligation is to give me the source and geographical origin related to your invention. Because you did research and then you filed a patent application, your compliance should have been there. But we weren’t sure we could do that with confidence, so we had abandoned the application.

The point is that even if I abandon my application, my compliance obligations with regard to source and geographical origin may still remain. So, we have a real issue here.

Jennifer Brant

Okay, thanks. I have a question that's been posted in the chat: “We know that some DSI are taken from public or private databases for which we have no information on the origin. Or that do not even relate to a physical genetic resource. What would be the information to disclose according to the Biodiversity Act in India, especially for inventions that may contain hundreds of digital sequences?” Malathi, can you answer that, please, since it focuses on India.

Dr. Malathi

Everyone thinks DNA from India or from other developing countries is leaving, flowing out. But there are papers that show that researchers in the developing countries, like India, actually source their information from a lot of developed countries. If I don’t know the origin, then I say I don't know from where it came. What we do give is the source in the form of the database or a paper that talks about that sequence. And then we fight for it, because it is actually where we got it. We need to provide information under the Biological Diversity Act.

So many times, I cite the database and I tell them this is where I took the sequence. I accessed the database, modified it, and when I modified the sequence, that made it better. Maybe it is more stable, or it's giving more efficacy. The point is that it doesn't matter where the sequence came from at first. This is now my sequence. I've mutated it and I've done all my research. I changed or improved something. How is this – what I have made – dependent on what the source of the genetic resources or the DSI is?

The NBA has software that just goes through, looking at all the patent applications that are filed in India. As the applicant, you immediately get a letter. You can even get hundreds of letters saying that you've used this, so please provide the source. They have a software which can screen all the terms so it's automated.

Jennifer Brant

Based on what you're saying right now, there's a question here in the chat: "India appears to have the most experience with this type of disclosure obligation. The delegates are routinely told that R&D will adapt moving forward by tracking source and origin in the future, so people will make sure they're retaining this information. To avoid situations where people really don't know. Are the problems you're speaking of where the information was not recorded when the GR or associated TK was accessed an older issue, or is this a contemporary R&D issue as well?"

Dr. Malathi

This is where I find that harmonization is important because in India it doesn't refer to prospectively accessing anything. In India, accessing means using what is in your collection, it means having possession of that knowledge or data or biological resources. Say that I took biological resources ten years back. It's there in my garden, it's there in my laboratory. I just go, pick some leaf and do research. But there is a problem now with the amended Biological Diversity Act, coming into effect from 1st of April. Before, the Biological Diversity Act referred to "obtaining" as something in the future. But now, it's not a question of carefully recording what you will bring in starting right now. They say that even if you possessed it before this Biological Diversity Act came into place, you have obtained it and it's therefore covered in the legislation today. They will ask for the source and geographical origin of that, on this basis. And therefore, we have a problem not just with, in the future, obtaining something and carefully recording the necessary information. Now it is "possessing," and that's where the problem lies. Negotiators have to be careful about this with the IGC.

Jennifer Brant

So you're pointing to a couple of things.

First, the need for clarity and drawing very clear lines. And then also, you are pointing to the need for harmonization. Because if you leave this wide gap between the national legislation and an international agreement, one might expect myriad problems of the kind you're describing for innovators. Different sets of rules, each subject to many interpretations.

Another question: Axel, you have been explaining why it can be hard to identify origin and source. What if companies are not sure to comply even after reasonable due diligence. What's the risk there? What can be the risks for them if they don't get it right?

Dr. Braun

The problem in the end is dependent on the sanctions. If you have sanctions that are not appropriate – and even if you have the possibility to correct the disclosure – then this is a problem.

In the end, everything comes back to the sanctions. And if you're looking at the text, there are still patent-based sanctions. There are two patent-related sanctions that are not linked to fraud like non-enforceability and invalidity.

So, the patent could be granted in any case but then the authorities could decide later that, because of an issue with the disclosure, the PDR, that there will be a transfer of your patent to a different patent owner, for example to the one from whom it was assumed that the genetic resource was misappropriated. Another possibility, of course, would be for the authorities to grant a compulsory license on your patent in this situation.

The part of the IGC text about sanctions right now contains a lot of flexibility. It even includes criminal sanctions. All this would be a serious exposure for a company. And basically, if it's too complicated, if there is too much risk, in the end the result is the same as Malathi was saying. The patent would probably be abandoned.

Something I want to point out, also, is that depending on the company, natural product research is not really a significant work stream. So, imagine it is not a significant part, plus it's already from a chemical point of view very tricky. Then you add additional uncertainties in the patenting process and the risk of losing your patent. This could mean the significant costs and financing put behind an invention based on genetic resources would be at risk. With all this, clearly you would not follow a path of pursuing R&D and patenting in this area.

About a decade ago, biopharma organizations organized a side event to the IGC and were talking about these issues. It can be interesting to look at the number of companies that are doing actually natural product research. From 1992, at the time the CBD came into force, until 2012, we see that basically half of the big pharmaceutical companies, more or less, left this area of natural product research. Of course, there is a certain degree of this type of R&D still related to infectious diseases, but in other areas, people left. This was for some of the reasons I indicated.

All this is to say that it’s really important, if you want to set this up as a transparency measure, to have the appropriate sanctions. No patent-related sanctions.

Jennifer Brant

I have a couple of questions in the chat that are related to what you were just saying. First: “Dr Malathi, do you have experience with fraud in relation to the disclosure requirement in India? What might constitute fraud in this regard, and is willful disregard considered as fraud?”

That's my first question to Dr Malathi. Then I'll read the second one.

Dr. Malathi

I don't have any, no. I've worked with more than hundreds of these cases, but we have not had any case where it was deemed fraud. This is an important issue. Previously, criminal

proceedings were possible for issues with disclosure. So, people were very worried and abandoned applications if there was any uncertainty. From 1st of April 2024, the possibility of criminal proceedings has been done away with. However, there are other penalties to make people comply with the law.

Jennifer Brant

Thank you. For the other question, I'll ask you that one, Axel. It is: "What would be the social value of having a very wide scope of application, all the way up the different tiers of the supply chain, for the patent disclosure requirement? For example, every ingredient, every input that you used, every research tool. Is there a social value associated with that kind of broad scope?

Dr. Braun

It's very difficult to answer that last question in principle. I think that question is best asked to representatives of governments, because the social value is something that governments are most concerned about.

I can speak to the innovators' perspectives. The problems faced by companies are clear, and these get harder to manage when more is covered. Clearly there could be different interests in covering as much as possible. But on the other hand, as I was saying, the more you cover, the more complexities you put into the system. And the more complexities you put into the system, the more you create legal uncertainty. The result is that certain investments will simply not be made.

One might argue that covering a lot could bring a lot more social value. But, on the other hand, if the R&D investments decline and inventions are not made, if the benefits for society are not generated, then the question becomes: how much social value have you created?

Jennifer Brant

Thank you. I have another question in the chat: "What delays, if any, could this disclosure obligation introduce in the processing of patent applications? It seems that, in some systems, the ABS authority might be assessing disclosure or related requirements before the patent office can proceed. Is this correct? Can you comment on any delays in processing patent applications that could result from a PDR?"

Dr. Malathi

According to the Indian Patent Office, there are as many as 1000 applications pending because the applicants haven't given the source and geographical origin. And remember that for "source" and "geographical origin", we have no clear definition in the Biological Diversity Act or the Patents Act.

To date, there's a backlog of about a thousand cases just with the old regime which, as I said, was recently modified. We have a new regime from 1st of April 2024. I can give you an older example. I have a client who worked on brassica, and they showed that they improved it. They worked with just one type of brassica. They took the sequence, improved it and filed a patent. In the dependent claims, we said this improvement could be used in any – even all – of the brassica species, whether cauliflower or cabbage or capers.

Next, the NBA said you've given a sequence, which is fine, and this is *Brassica juncea*. However, you are claiming that your improvement is applicable for all the other brassica species as well. Yes, as a patent attorney and scientist, if the modification works in one brassica, then I expect it will work in the others as well because they are highly interrelated. The authorities wanted the source and geographical origin of all the Brassica species that were listed in my dependent claims. But then I clarified that I had not actually used those. The response? Then how are you claiming for it.

So, then we are stuck. We're not able to move forward because we're not able to give a source and geographical origin, and we're not able to proceed after saying that we didn't actually work on all the brassicas. But we know – and this is what we said in the application – that based on sequence data, we would be able to apply the improvement for the other brassica species. There are other examples as well.

Jennifer Brant

Axel, do you have anything to add?

Dr. Braun

Yes, I want to draw your attention to a study that was commissioned by CropLife and IFPMA around 2016 to Steward Redqueen (*note: this is available on the Innovation Council website, see link at the end of transcript*). It looked at the laws in India and Brazil, and at the impact of patent disclosure requirements in combination with ABS requirements. The authors found that in cases where you are required to wait for prior informed consent, PIC, and complete other requirements before filing the patent application, there were significant delays. After that, Brazil changed the system, so the impact may be different today. In any event, it's important to keep in mind that any delays where you have to wait for evidence or approval, or to complete an ABS-related administrative requirement, prior to filing can cause significant delays in patent processing. And in fields like biotech, priority is very important. A delay of even one day can be critical.

I have seen that so often in pharma. The targets for specific medical indications are quite often the same, so several companies are working on the same ones. And there is an enormous risk that, one day, the other companies will come up with a solution and file first. And therefore, if you have a delay because of an administrative issue, this can be a nightmare for IP counsel in the company with the application that was delayed.

Jennifer Brant

Thank you, Axel. Dr Malathi, do you have any closing remarks?

Dr Malathi

There has to be clarity for all the definitions, and 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.

Jennifer Brant

We have one last question in the chat. Also, Axel, I would like to ask you to comment on the goal of the instrument being transparency, since we did not discuss that until now. The question is this: "What added social value exists in relation to disclosing the origin and source of DSI? How would the inclusion of databases add value?"

Dr Malathi

This is an issue. What if I don't know the geographical origin? The authorities may tell me to at least say the source and from where we took this data, which is actually information. Maybe an applicant will just say: it's this database, but I don't know the geographical origin. But then that application may not go further. We can also think about the case of a scientific paper. Again, here we are talking about information and data – not actual genetic resources.

We also have to think about DSI. Like I said, there must be transparency and consistency. My view is that DSI, human samples and research tools should be out of the purview. If we can get clarity on these three things, and if we can say to each country that everyone needs to follow the same yardstick, I think we'll be in a better place. Harmonization would be very helpful.

Dr. Braun

First, a short comment regarding transparency and the present instrument. As I explained, the discussions at WIPO moved steadily away from the CBD, so the talks are no longer about transparency in the context of ABS. Rather, the talks are now about transparency for the patent system. And therefore, I think what's important to keep in mind is this: what would be the objective of this transparency? This question links to the second objective, namely, to avoid the granting of erroneously granted patents. This could be done by identifying more prior art than before; however, for me, it's questionable whether the IGC agreement could help in this area. I haven't seen evidence about how indicating source and origin of a genetic resource that an invention was based on would provide this prior art. But on the other hand, I think regarding TK that could be interesting.

However, there is a challenge related to the TK. If you put the TK into databases, there are concerns among TK holders that these databases may not be used only for the purpose I was saying, namely, to identify additional or new prior art. They are concerned that putting the TK in databases could provide an opportunity for misappropriation. The only thing you could do here is to provide an instrument for the protection of TK. In this way even if you created databases of TK, there would be protections available for the TK. As we know, there is a second process underway at WIPO that deals exactly with that point. But I think that for now it's hard to say when those negotiations would be concluded.

Jennifer Brant

I have provided both of your emails in the chat. So, please prepare to receive questions when people realize what they forgot to ask today.

Dr Braun

I think that what's really 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, linking the PDR to appropriate sanctions is necessary. Basically, don't refuse to grant the patent because of the PDR, and no revocation. As I said before, there should be no patent-based sanctions.

Jennifer Brant

Thank you to everyone for joining. If you have further questions, you can contact me or the experts by email. And, and thank you so much, Dr Malathi and Dr. Braun, for participating in this conversation today.

For more information about the IGC negotiations at WIPO, and the key issues at stake, visit: https://innovationcouncil.org/ip-natural-resources/.