Expert Meeting on ABS and Intellectual Property Rights
5th to 9th September 2011
Addis Ababa, Ethiopia

Details of the Workshop

Day Four, 8th September 2011

1. Summary

Day Four first focused on two key topics: (i) disclosure requirement issues alongside the experience of Peru and the Andean Community and (ii) the use of IP systems to track the utilisation of GRs. The rest of the day was devoted to examine the four different "instruments" proposed in the Nagoya Protocol, namely PIC, MAT, Access Permits and International Certificates. A group work enabled the participants to look in depth into each instrument, how they relate to each other and how they could be used efficiently to make the ABS system work. The following questions were provided to the participants as guidance for their brainstorming on the named instruments:

1) What information does an applicant have to provide/give in order for the providers to make an informed decision?
2) Which elements need to be incorporated into MAT to make it a workable agreement?
3) Which elements of all this need to be provided on the access permit/certificate, to make it a useful compliance tool?

2. Plenary Discussion and Question and Answer Session on the Group Work of the Previous Day

Ms Heidbrink introduced the day by inviting the delegates to discuss the work results from the previous day.

Comments and Clarifications during the Question and Answer Session on the Group Work of the Previous Day

- The key fields of work identified re-emphasised the necessity to talk more with businesses and other relevant industry stakeholders. There is a lot of unfolding to do in this regard, for example, how to capacitate provider countries in understanding business models keeping in mind the perspective of fair and benefit sharing. Most of the

points identified in this meeting will be referred to in the next Pan African ABS Workshop and serve as guidance for the ABS Initiative future work on IP.

- The group work on "Monitoring and IP/IP Management" pointed out, that as the focus was supposed to be on IP, they concentrated on this issue from the point of view of (local) communities. The role of customs and other border control agencies is indeed very important and should also be considered.

- Before speculating who will participate in a deal, you need to find who has the rights over particular resources or TK. Then you can start define the contract. If you don't have that it will be difficult to implement ABS/ Nagoya Protocol.

- For example, PIC has to be given by the land owner or the manager of the land but the exit permit is given by relevant national competent authorities.

3. Monitoring and Tracking Genetic Resources

3.1. Disclosure Issues and Requirements: The Experience of Peru and the Andean Community by Manuel Ruiz Muller the Peruvian Society for Environmental Law

Mr Manuel Ruiz Muller introduced his presentation by defining what disclosure was. He highlighted that disclosure was one of the most studied and identified control point for monitoring especially in the context of IPRs. He also explained that disclosure derived from disclosing the invention or innovation so that improvement and further research could be done. Mr Ruiz Muller informed the participants that, in both Peru and the Andean Community, disclosure was a requirement for filling a patent application to ensure that appropriate IPRs were granted. He then put an emphasis on the fact that there were very explicit connections and potential to generate synergies between ABS and IP regimes.

Mr Ruiz Muller told that disclosure was first discussed in the 90's as part of the ABS debate and further consolidated in the Andean Community. Then countries in the region developed their own legislation. Disclosure was incorporated as a control point. Focussing on the disclosure in Decision 391 of the Andean Community on ABS, he indicated that:

(i) If a patent is requested and the applicant does not provide appropriate information about legal access to GRs, the patent is not granted.

(ii) National authorities have the faculty of requesting that the person or institution provide evidence that the material has been obtained legally.
(iii) Same principles are applicable to TK.

Hence, to apply to a patent, it is mandatory to provide evidences that materials and TK have been accessed legally. National authorities would have the right to demand the proof of this.

Mr Ruiz Muller concluded by advising on the prerequisites for the disclosure requirement procedure to operate effectively. These were as follows:

- The disclosure procedure to have be EXTREMELY clear ;
- Clear, transparent and operational ABS and TK frameworks;
- Basic, standardised certificate or instruments which demonstrates legal provenance and origin of GRs and TK;
- Interaction between ABS/TK authorities and IP authorities;
- Universal recognition of disclosure and certificates; and
- Possibility of alleviating tensions and supporting less stringent ABS regimes

3.2. Question and Answer Session

Q1 *With regard to The International Workshop on the Application of Disclosure of Origin Provisions & Legal Provenance in Intellectual Property Legislation which took place in Lima on the 13th and 14th August 2011, could you clarify why benefit sharing, PIC, MAT should not be requested to be verified by the examiners?*

Q1bis*: Examiners can only check the certificate presented and should not be expected to check the permit i.e. the certificate of legal access – was that discussed at all at the workshop?*

A1: The examiners want to know if a simple standardised document has been done and provided. They do not want to see or check the benefit sharing agreement, MAT or PIC that were obtained.

Q2 *Did you discuss the voluntary and mandatory aspect of disclosure? Why very few applications? When Peru introduced its legislation – was it going further than the UPOV requirements?*

A2: (i) Disclosure is always mandatory. There is a need to have ABS regimes that are operational in practice. (ii) Peru was not part of UPOV. When we developed our national legislation, we had no opposition to include disclosure. This changed and we had to adapt our regulation to comply with UPOV.

Q3: *The meeting of experts mentioned above made some recommendations but did they give specific recommendations on the Peruvian system? Do you have* any feedback on your system from the communities and other stakeholders?

A3: In the case of the Peruvian (and Andean) system of disclosure, there is the need for national IP examiners to have more specific guidance as to exactly what type of patent applications may need to be reviewed with more attention. The first International Workshop for IP Authorities on Disclosure Requisites, provided with some recommendations as to how to improve action by examiners. These included the need to create a certificate, not over burden examiners with additional requisites, not make them responsible for actual benefit sharing, among others.

Q4: *At which level did you involved local communities and what is the importance in understanding this procedure?*

A4: Peru has introduced a protection regime for the collective knowledge of Indigenous Peoples derived from biological resources (Law 27811, 2002). The regime also aims to ensure that the benefits resulting from the use of this knowledge by any type of industry be fairly and equitably distributed among the owner(s) of the knowledge. Representatives of communities have participated in this process. There is a considerable representation of Indigenous Peoples mostly from the Amazon area. Amazon Indigenous Peoples are very active. Other communities do not have so much means.

Q6*: Quite similar disclosure requirements in the African Model Law – to what extent a model law could do the same as the Andean Community and what would be the challenges for the region.*

A6: Regional approach is ideal as you can standardise process. It is the way to go

Q7: *Any association of ILCs?*

A7: Peru has just enacted the Law of Prior Consultation with Indigenous and Original Peoples which requires that they be informed about and consulted on, in a culturally appropriate manner, government projects that will affect their lives, territories and rights of Indigenous Peoples. This new law is being regulated at this moment. Together with the CBD, the United Nations Declaration and ILO 169, this framework for prior consultation sets the bar as to how indigenous peoples should be consulted in regards to their lands and TK. Prior consultation is not the same as prior informed consent which is clearly applicable to situations concerning access and use of TK (and genetic resources). PIC may be a sub set of consultation but is not exactly the same.

3.3. Tracking and Monitoring Genetic Resources in the Patent System by Paul Oldham from the ESRC Centre for Economic and Social Aspects of Genomics (Cesagen) & UNU, UK

Mr Paul Oldham provided a very comprehensive presentation on the potential and effective use of patent databases to track and monitor GRs. He indicated that Article 17 of the Nagoya Protocol talked about enhancing transparency about the uses of GRs and TK in the patent system and the creation of check points. He then pointed out the various challenges of monitoring and tracking GRs. These were:

- Dealing with scale (more than 60 million patent documents in multiple languages)
- Identifying species
- Disclosure of origin
- Addressing distribution
- Regional and national reporting

Mr Oldham highlighted that the patent system was important because (i) the data was already standardised and coded across language, (ii) this information was essential for tracking and monitoring as it could trace where a patent had been filed anywhere in the world through family data. However, this system had some limitations. It is very time consuming, one species per species entry, and costly as commercial database are extremely expensive to access in comparison, maybe, to an ABS system. Mr Oldham pointed out that disclosure happened quite recurrently but in a rather disorganised way.

Mr Oldham then focused on the wilder problem of origin and explained that tracing the source was quite a challenging task due to the fact that:

- Organisms share common genetic components (conserved over evolutionary time);
- Geographic distribution of some species happened in more than one country;
- *In situ* diversification happened through adaptation to local conditions; and
- *T*axonomic information was also often incorrect.

Mr Oldham pointed out that, because of the multiple references to multiple species in multiple geographical locations, disclosing the source should not actually be a problem but could be solved:

- By enhancing disclosure requirements: specifying which country a species is from and whether ILCs are involved, and

- By introducing a statement on ABS into patent applications detailing the ABS country and agreement number and whether ILCs involved and include this in the MAT.

With regard to regional and national reporting systems, Mr Oldham stated that because species were disturbed in more than one country, a regional approach would make more sense in the context of the ABS and IP. He went on to say that quite a number of species were distributed in Africa and around the world and that the case that a species was unique to a country was rare. A system as an ABS Patent Index will be simple approach to list which kind of species is occurring regionally.

Mr Oldham concluded with few observations such as:

- Patent databases have an important role to play in monitoring and tracking utilisation of genetic resources and TK;

- Enhanced disclosure of origin and a Statement on Access and Benefit Sharing would go a very long way to addressing ABS issues on patents;

- Large scale indexing of patents is a cost effective way of monitoring and tracking and can be expanded and updated over time. Critically, it avoids duplication of effort; and

- ABS Patent Index (ABSPAT) will be made available in a variety of ways in the coming year.

3.4. Question and Answer Session

Q1: *I am confused regarding the wider challenges you mentioned. Why should we be concerned by the similarity and special location of species? Why is the issue of geographic distribution a problem in ABS?*

A1: We could argue that the only thing that could matter is the source of origin and/or collection. However, there is a broader consideration in the share of genes around the world and also the Article 10 of the Nagoya Protocol which talks about transboundary issues and cooperation between countries. Hence a regional approach might make more sense to these kinds of issues. Such a regional approach will help preventing conflicts that might arise between countries. Indeed, it is worth to look at a regional approach.

Q2: *When people indicate Africa or East Africa – are you trying to find the real origin?*

A2: Some companies are very specific on the source – prevention with regard to ABS.

Q3: *One useful component is the obligation to disclose the source, but there is a contractual relation which*

often includes a confidentiality clause. The condition of access could be included in the contract. Is this sufficient or is there a need for more legislation?

A3: Contractual approach combined with relevant regulations would be ideal. However, it takes more time.

Q5: *When you are dealing with genetic sequences or compound utilisation, it is quite complex. With a regional approach combined with a MTA and statement in your patent application, would it be easy to track the source through patent system?*

A5: Yes – absolutely. It is necessary to understand how the patent system works but it is possible. The information will need to be added on the patent form.

4. What is needed in Prior Informed Consent, Mutually Agreed Terms, Access Permits and International Certificates to Make the ABS System Work?

4.1. Group Work

Dr Reyes-Knoche and Ms Heidbrink welcomed the participants to the last group work of the meeting which was dedicated to examining and discussing the contents and elements of PIC, MATs, Access Permits and International Certificates. They invited them to look in more detail at the instruments that have been discussed so far and how one instrument is related to the other.

It was indicated that the participants will be divided in three groups, one group for each instrument, and asked to address the following questions:

1) What is the purpose of this instrument?
2) Who are the players, partners involved?
3) Which aspect/aspects should be covered in order to make the 'system work' in draft agreements such as MAT, PIC, etc…? What is needed?

Dr Reyes-Knoche reminded the participants that each instrument had been mentioned in the Nagoya Protocol and that this exercise will also serve to find out if all aspects have been taken into account in the discussions of the past few days. To this effect, references for each tool in the Nagoya Protocol were provided to the various groups.

4.2. Plenary discussion

Participants discussed the directives given for the exercise. It was suggested to:

- Discuss in the plenary how one instrument is related to the other ones and what their key differences are.
- Construct a flow diagram of how these instruments work together as they are different but much intertwined.
- Do the exercise assuming that none of the participants knew what PIC/MAT, etc… are all about.
- Consider this last task as a capacity development exercise.

Five participants (Manuel Ruiz Muller, Pierre du Plessis, Wilson Busienei, Suhel al-Janabi and Susanne Reyes-Knoche) volunteered to re-organise the questions taking into consideration the results of the plenary discussion on the objective of the group work They suggested that each group will look at all instruments as part of a system. They stressed that PIC (informed) & MAT (contract) belong to one system and suggested the participants to explore the direct connections between the two as well as the links to the access permit. The results will then be presented, compared and discussed in the plenary with the view to get a better common understanding of the terms and instruments used. The proposition was well-received and each group was asked to address the following questions:

1) What information does an applicant have to provide/give in order for the providers to make an informed decision?
2) Which elements need to be incorporated into MAT, to make it a workable agreement?
3) Which elements of all this (Q 1 and Q 2) need to be provides on the access permit/certificate, to make it a useful compliance tool?

4.3. Reporting Back

Ms Heidbrink welcomed back the participants and commended each group for their work in addressing the questions. She proposed that, as opposed to presenting the results, to have a twenty minutes exhibition where each group could inform themselves the other groups' results and take notes on issues that stroke them.

Group n°1	Group n° 2	Group n°3
1) What information does an applicant have to provide/give in order for the providers to make an informed decision?		
Information to make an informed decision regarding access	What we find in Art 17.4 of the Nagoya Protocol	TK involved or not
Background information/references (+contract details) of the user + partners	Intention of use	One or more TK
Location of the resource	'type of applicant'	Intent to handle TK
User and provider	Potential impact on species/ecosystem + migration measures	Material : seed flower , quantity (number species, volume, …)
Which resource (quantity, etc…)	Destination of GR/TK? Transfer to third parties?	Confidentiality agreement
Purpose/intent of use	ID + coordinates + authorisation (if institution)	Non-commercial or commercial use
Non-commercial/commercial	Art 6.3 c+f →Clearing House Mechanisms	Detail in use interest (ethical for e.g.)
Project specification and in particular: ▪ Budget, timeline, expected outcomes, location of research, use, etc…	Capability statement	User: direct or not, institutional, affiliate or private sector
	Proof of consultation with and consent of ILCs	Track record, pre-existing works or experiences
	Benefit sharing proposal $ + non -$	Existing/intended collaboration in the country
Use of TK?	Business model/development plan	Where the utilisation will take place? Local/outside
PIC of ILC if TK is involved	GRs and for TK to be accessed – how much – how often – where?	Timeframe, locations: how long time to have access? How many places?
Where did you hear about GR + ATK? (Prior knowledge about GR + ATK?)	Are you working on the same product with other countries?	
Expected result and returns	Are user measures in place in applicant's domicile?	
Agreement between the providers and the user re terms of use (e.g. benefit sharing)	IP policies (especially for research institutions)	
Regarding agreement between user and provider ▪ Option 1: Confirmation that an agreement has been settled ▪ Option 2: Attack agreement	Corporate philosophy, CR+SR policy, mission statements	
	Previous work on this GR/TK?	
Is the GR an endangered species?	Relevant background	
Did you apply for access re this resource in another country?	Urgent exceptions?	
	Local partners	
	Capacity building?	
	ILCs involved? Relationship of applicant to these ILCs	
	Source of funding (+copy of application if applicable)	

2) Which elements need to be incorporated into MAT, to make it a workable agreement?

Provision re benefit (sharing)

Provision re IPRs e.g. Licenses, assignment, joint IPRs ownership

Co-use rights (e.g. non-IP situation)

Confidentiality clause

Monetary /non-monetary benefits

What happens in the case of change of intent?

Reporting scheme (user-provider)

Dispute conflict resolution mechanism

Negotiation situation: limited access vs. for…? Exclusive use

All information provided in application certified as true + correct + incorporate into MAT

Monitoring + project review schedule – reports, meetings, access to lab notes, milestones, etc…

Responsibility for ILC consultations, - organise, costs…

Special considerations re cross-border + shared GR + TK

BS proposal $ + non- $

Third party transfer: permitted? Conditions?

Formula for dividing benefits (other providers, ILCs…)

Conditions re publications of results

MAT with ILCs

Boilerplate

Address *citanti* et executed

Force majeure

Limits of liability

Warranties of fitness

BS on products ("manufactured derivatives", subsequent applications + commercialisation

Surviving provisions/termination/succession

Roles + responsibilities in subsequent commercial development

Art 6.3 g

Open or exclusive collaboration?

Material Transfer agreement

Describing GR/TK

Obligations of both users and providers

Terms of access

Transfer to third party

Jurisdiction, law

Dispute resolution

Mediation and arbitration

Terms of benefit sharing

Benefits: monetary /non-monetary

IP clause/disclosure clause

Change of intent

Exclusivity or not

Transfer of technology

Derivatives, secondary products

Ownership of the result or of the end product

Review clause

Confidentiality Clause

Timeframe with provision for extension

Real investment (cause for early termination)

Termination of contract

In time

Before time

Ownership of the material/TK during /after the end of contract

Penalties

	Purpose Conditions Future procedure IP ownership, licensing, costs for maintenance + defence Types of IP/IP options How to deal with confidential information? How to deal with confidential information? IT disclosure requirements/obligations Obligations to negotiate in good faith if intention changes Rules for re-negotiating changing MAT	Reciprocal information on national law and evolution (ABS, IP, Phyto.., export, import, GMO…) Reporting conditions Dedicating BS to GR/TK conservation National activity in the provider country
3) Which elements of all this need to be provides on the access permit/certificate, to make it a useful compliance tool?		
Minimum info: ART 17.4 of Nagoya Protocol Transboundary issues/multiple origins Which information cannot be confidential? Open issues: ▪ Effectives trading? ▪ Prior art? ▪ Quality control?	Art 17.4 Third party transfer permitted of not? Special conditions (or reference to them if confidential)	Establish MAT Obtain PIC Permit/equivalent - formal document or not Permit number or not National competent authority issuance, signature and official seal User Provider Date of issuance of permit or PIC/MAT GR + ATK and subject matter (TK?) Subject matter – no detail which are confidential Intent of use: commercial/non-commercial Used or not for export/import formalities Permit duration, subject to renewal (link to contract duration) Notification or not to Clearing House Mechanisms and National Competent Authorities.

4.4. Summary of Comments regarding Key Points Arising from the Plenary Discussion that Followed

- ***PIC***

How much information the user is expected to provide? Or is it the responsibility of the provider?
Protection of the resource is the responsibility of the provider (via national requirements/legislation law) then the user will have to make a compliance commitment.

- ***Benefits***

How to share the benefits between concerned communities (e.g. beneficiaries of Teff)?
The sharing of the benefits has to be decided / resolved at national level.

- ***Derivative***

What does derivative means in this context?
There are two different kind of understanding of derogative:

(i) For compounds, and
(ii) For something that you made – modified version of the initial compound. It does not qualify for PIC but is relevant for Benefit Sharing.

One should refer to Article 2 and Article 5.1 of the Nagoya Protocol. Derivative has to be specified in MAT.

- ***Access Permit & International Certificate***

When does a national access permit qualify to become an international recognised certificate?
Article 17.4 of the Nagoya Protocol prescribes the minimum information one should provide on the certificate. When a PIC is granted at national level, one has the option not to register to the Clearing House Mechanism; your permit can go as much as you want nationally. Article 17.4 also mentioned 'subject matter' – parties to the CBD have not fully decided on this matter as yet. This point is therefore an open door to introduce TK. ILCs were not ready to provide any information during the negotiations regarding this issue. Under the Nagoya Protocol, there are a lot of undefined legal terms to open the possibility a little bit more (at the countries' discretion).

There are also cases where specification of 'subject matter' cannot be explained in detail for business confidentiality reasons. Though it is understandable that details have to be kept confidential, they nevertheless should be specified if associated to TK.

What were the pros and cons on the above points during negotiation time on this policy option?

(i) To provide clarity, the permit should always specify if third parties transfer permitted or not permitted.

(ii) Whether the source is a confidential information or not. It also depends on the countries and cases. From a Namibian point of view, we think that this information should not be confidential. Canada holds the opposite position.

- ***Monetary Commitment***

Monetary commitment must be discussed on case by case basis or indeed on a step by step basis. Commitment on costs from third party is very difficult to make therefore it is challenging to precise the return. Return is not easily quantified. This will slow down the negotiation process.

- ***Local Permit vs. International Permit***

It is important to distinguish local permits from international permits. One should not confuse them. The latter should be a very simple form to facilitate checking points and the efficiency of the process.

End of Day Four