Practical IP considerations in ABS agreements

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Preliminaries

- Contracts are established under the general framework of national contract law
- In some cases, a national law on genetic resources might specifically require that the provider and recipient agree on an ABS contract
- In some cases, contracts are likely to be governed by general laws such as the laws of contracts and competition law.

Preliminaries

- Intellectual property (IP) issues arise as one element of the broader framework on access and equitable benefit-sharing.
- IP issues are **only one component** of the full range of practical and legal questions that may need to be addressed in access and benefit-sharing agreements
- IP management in an access and benefit sharing agreement can greatly influence how Parties to a given agreement **achieve their goals and serve their mutual interests.**

Preliminaries

- Preliminary confidentiality agreements
- Shared understanding of value– value of GRs and/or ATK, value of research, development, risks
- Resource review/goal setting
- Physical resources v knowledge resources;
- Factors affecting agreements – Legal landscapes; potential, actual, unforeseen, untested and/or uncertain GR value
- Nature of agreement - Letter of intent, MTAs, licensing, research, confidentiality agreements.

Value identification

- *"This research material represents a significant investment on the part of provider, and is considered proprietary to provider, recipients investigator therefore agrees not to transfer the research material to other people not under her or his direct supervision without advance written approval of provider"**

Model MTA of the Korean Research Institute of Bioscience and Biotechnology

Key IP Issues

Overall, IP issues:

- a) dependent on the mutual understanding and goals set.
- b) Type of agreement and factors affecting same.

General IP questions

General IP questions

- Which IP may result from access and utilization
  - What potential/eventuality *could* and *should* be covered by IP?
  - What should be excluded?
- What conditions or restrictions may apply to seeking IPRs
- Ownership of IPRs, sharing of benefits from the exploitation of IPRs, etc?

Use of Microbial GRs

- The RECIPIENT and the PROVIDER distinguish the following categories of use of MGRs (microbial GRs):
- **Category 1:** Use for test, reference, bioassay, and control (covering only their use within the framework of the corresponding official (inter)natonal test-, bioassay and control protocols); use for training and research purposes;
- **Category 2:** Commercial use . Commercial use of MGRs includes but is not limited to the following activities: sale, patenting, obtaining or transferring intellectual property rights or other tangible or intangible rights by sale or license, product development and seeking pre-market approval.

Use of Microbial GRs

- **For category 1 uses:**

The RECIPIENT will not claim ownership over the MGRs received, nor seek intellectual property rights over them or related information. If the RECIPIENT wishes to utilize or exploit such organisms commercially he will first inform the PROVIDER; when applicable, suitable and adequate recompense to those entitled to be rewarded, and the country of origin will be discussed in the spirit of the Convention on Biological Diversity.

THE RECIPIENT will ensure that any individual or institution, to which the RECIPIENT makes samples of the MGRs available, is bound by the same provision.

- **For category 2 uses:**

In order to ensure adequate benefit sharing with the country of origin and « names of those entitled to be rewarded », according to the principles of the Convention on Biological Diversity, the RECIPIENT will immediately inform the PROVIDER and the country where the MGRs were originally accessed, of the intended commercial use(s) of the MGRs and/or derived technology and/or related information. The terms upon which benefit sharing with the stakeholders takes effect are laid down in annex.

- **For all categories of uses:**

The RECIPIENT will men=on the PROVIDER, the strain reference number and the country of origin in publication presenting scientific results and related information resulting from the use of the MGRs.*

Micro-Organisms Sustainable Use and Access Regulation International Code of Conduct(MOSAICC),

Specific Practical IP Questions

- Right to application
- Ownership
- Licensing arrangements
- Enforcement
- Sublicensing
- Performance standards
- Reporting and disclosure
- IP and related rights (i.e copyright, patents, trademarks and GI's, trade secrets etc.)

Confidential information

- *"...In all oral presentation or written publications concerning the Research Project, recipient will treat in confidence, for a period of three years from the date of its disclosure, any of provider's written information about this research material that is stamped "confidential", except for information that was previously known to recipient or that is or becomes publicly available or which is disclosed to recipient without a confidentiality obligation. Recipient may publish or otherwise publicly disclose the results of the research project, but if provider has given confidential information to recipient such disclosure may be only after r provider has had 30 days to review the proposed disclosure..."**

* *Model Material Transfer Agreement (MTA) of the Korean Research Insttute of Bioscience and Biotechnology, clause 5.*

Licensing agreement

*"...subject to section 4(License) it is understood that the AAFC Inbred Line(s) belong to Agriculture and Agri-Food Canada and that all intellectual property rights related to the AAFC Inbred Line(s) are vested and shall continue to be vested in Agriculture and Agri-Food Canada".**

**Exclusive Variety License Agreement between her Majesty the Queen in Right of Canada, as represented by the Ministry of Agriculture and Agri-Food (AAFC), and the Company, Clause 1.*

Strategic planning for potential IP considerations

- Possible IP outcomes from collaborations
- Ownership?
- Ownership of improvements and future developments
- Sharing of benefits from successful exploitation of IPRs
- Legislative considerations: national, regional, international laws

Change of intent

- *“ If the recipient, as the results of the field trials, has interest to develop the material in the commercial market, the recipient agrees to negotiate in good faith with INIA, **prior to marketing** of such products, the compensation to be paid by the recipient to INIA. Such compensation may include **royalties** on the gross sales value of such products derived from the material”*

Material Transfer Agreement (MTA): Restricted License for non-profit purposes of the National Agricultural Research Institute (INIA Uruguay), Clause 10

Benefit sharing from the exploitation of IPRs

- Broad understanding of benefits: a public agency v. an individual/community.
  - Specific monetary benefits (license fees, sale price, royalties, salaries of staff ect.)
  - Specific non-monetary benefits
- Responsibility for filing, maintenance, enforcement of IPRs, capacity building

IP and benefit sharing

"...a separate chapter for benefit sharing has been included in the Contract. Following are the main points of this chapter regarding non-monetary benefits.

1. The technical expertise of local people and farmer community will be preferred for development of 50 hectare Botanical Garden in Karimabad

2. The agricultural graduates and botanical experts of local area will be preferred for research work on Hania plant in the said Botanical Garden and they will be trained by experts of NIH and Astra Zeneca to develop their negotiation capacity

3. Special IP training courses will be conducted for officials of local government to develop their capacities for royalty and other arrangements

*4. The technology should be transferred automatically to the local government after the expiration of 25 years of the contract..."**

Model Project on "GeneFc ModificaFon of hyaluronidase inhibitor glycoprotein (WSG) in the roots of Withania Somnifera (Hania plant) for AnF Vanum Treatment" between the Astra Zeneca (Medicine Company), UK, the NaFonal InsFtute of Health (NIH), Islamabad and the Local Government, Karimabad (Hunza Valley, Pakistan)

IP and enforcement of ABS Agreements

- Dispute settlement
- Mediation, arbitration, litigation etc.
- Where ABS is regulated under national laws, mandatory requirement may exist for dispute settlement.
- The more the specific terms based on shared and full prior understanding, the less likelihood of disputes
- Some IP issues may require dispute settlement
  - Can IP protection be sought for part. Innovation?
  - Is an outcome derived from the use of GR?

Dispute settlement

Text Box 6: DISPUTE SETTLEMENT
A.17 Arbitration

Applicable to agreements with private parties in India

A.17.1 Except as hereinbefore provided, any dispute arising out of this Agreement, the same shall be referred to the arbitration of two arbitrators, one to be appointed by each party to the dispute, and in case of difference of opinion between them to an umpire appointed by the said two arbitrators before entering on the reference, and the decision of such arbitrators or umpire, as the case may be, shall be final and binding on both parties. The venue of arbitration shall be at such place as may be fixed by such arbitrators or umpire and the arbitration proceedings shall take place under the Indian Arbitration Act, 1940.

A.17.2 Any legal appeal over the arbitrators' award arising out of or in any way connected with this agreement shall be deemed to have arisen in Thiruvananthapuram and only the courts in Kerala shall have the first jurisdiction to determine such matters.

Reference : Know How Licensing Agreement between The Tropical Botanic Garden and Research Institute, Kerala, India (TBGRI) and The Arya Vaidya Pharmacy (Coimbatore) Ltd. Coimbatore, India (the PARTY), dated November 10th, 1995 available at http://www.wipo.int/tk/en/databases/contracts/summaries/tbgri.htm

Recap & Conclusion

- **General IP questions**
  - Which IP may result from access, what conditions or restriction may apply to seeking IPRs,
- **Specific Practical IP Questions**
  - Ownership, licensing, performance standards, enforcement, copyright, patents, trademarks and GI's, trade secrets etc.
- **Potential IP considerations**
  - Possible IP outcomes, national regulatory considerations, licensing agreements etc.
- **Benefit sharing from the exploitation of IPRs**
  - Monetary or non-monetary etc.
- Dispute settlement
  - Mediation, arbitration, litigation etc.
- **IP issues generally permeate through all sectors**
  - Pharmaceutical and biotech, food and agriculture, non-commercial research, ex-situ conservation.

Thank you…