



Awareness cum Brainstorming Meeting

on

Access and Benefit Sharing

Striking the Right Balance

Proceedings

India Habitat Centre, New Delhi
October 22, 2016

An event held as a prelude to the
1st International Agrobiodiversity Congress 2016





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Organizers



Knowledge Partners



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PREFACE

This proceeding emanates from the Awareness Seminar cum Brainstorming Meeting on 'Access and Benefit Sharing: Striking the Right Balance' organized jointly by the Organizing Committee of the '1st International Agrobiodiversity Congress (IAC 2016)' and Anand and Anand, a leading full service intellectual property Law Firm and the Indian Society for Plant Genetic Resources (ISPGR). The Trust for Advancement of Agricultural Sciences (TAAS) and the Indian Society of International Law (ISIL) were the knowledge partners for organizing the twin event, held at India Habitat Centre, New Delhi, India on October 22, 2016. Conceived as a pre-event to the 1st International Agrobiodiversity Congress (IAC 2016) held from November 6-9, 2016, New Delhi, the main aim was to bring on board issues related to agrobiodiversity access and benefit sharing (ABS) based on considered views of various stakeholders. The statutes and provisions related to ABS and issues faced by the stakeholders were extensively discussed by the participants, which comprised officials from government departments, subject matter experts, scientists, lawyers, researchers, representatives of the private sector and other stakeholders.

The event provided an excellent opportunity for exchange of views among participants concerning use of genetic resources. The goal was to formulate a Road Map for accelerating the process of ABS for facilitated exchange and better regulated flow of germplasm both within and outside the country keeping in view the larger interest of all stakeholders. Accordingly, recommendations emerging on major issues concerning ABS have been synthesized in this document.

We place on record our deep appreciation to the Organizing Committee of IAC 2016, for planning and conduct of this Awareness cum Brainstorming Meeting in which 93 delegates participated. The event was possible due to the diligence of ISPGR and the knowledge partners (TAAS, ISIL). We thank all the members of the Organizing Committee of Awareness Seminar cum Brainstorming Meeting for their contributions. Anand and Anand in particular facilitated the process of hosting the meeting in Habitat Centre, New Delhi, which is duly acknowledged.

It is hoped that this document would be useful to all the stakeholders, especially for shaping the policy, guidelines and procedures related to ABS arising out of agrobiodiversity exchange and use. It is also our expectation that the benefits through ABS would reach custodians and developers of genetic resources, especially the farmers, tribal communities and the breeders, both in public and private sector.

Editors

ACRONYMS

ABLE-AG	The Association of Biotech-Led Enterprises–Agriculture Group
ABS	Access and Benefit Sharing
ARS	Agricultural Research Service
BDA	Biological Diversity Act, 2002
CBD	Convention on Biological Diversity
DIPP	Department of Industrial Policy & Promotion, Government of India
DST	Department of Science and Technology, Government of India
GIZ	Deutsche Gesellschaft für Internationale Zusammenarbeit GmbH
IAC 2016	1 st International Agrobiodiversity Congress, November 6-9, 2016, New Delhi
ICAR	Indian Council of Agricultural Research
IP	Intellectual Property
IPO	Indian Patent Office
IPR	Intellectual Property Right
ISIL	Indian Society of International Law
ISPGR	Indian Society of Plant Genetic Resources
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
KVK	Krishi Vigyan Kendra
LMOs	Living Modified Organisms
MAT	Mutually Agreed Terms
MoA	Memorandum of Agreement
MoA&FW	Ministry of Agriculture and Farmers Welfare, Government of India
MoEF&CC	Ministry of Environment, Forest and Climate Change, Government of India
MTA	Material Transfer Agreement
NBA	National Biodiversity Authority, Chennai

NBPGR	National Bureau of Plant Genetic Resources, New Delhi
NRDC	National Research Development Corporation, Government of India
PGR	Plant Genetic Resources
PGRFA	Plant Genetic Resources for Food and Agriculture
PIC	Prior Informed Consent
PIL	Public Interest Litigation
PPV&FR	Protection of Plant Varieties and Farmers' Rights Act 2001
PPV&FRA	Protection of Plant Varieties and Farmers' Rights Authority, New Delhi
R&D	Research and Development
SMTA	Standard Material Transfer Agreement
TAAS	Trust for Advancement of Agricultural Sciences
TCL	Tata Chemicals Ltd.
TIFAC	Technology Information, Forecasting and Assessment Council, Government of India
TKDL	Traditional Knowledge Digital Library
USPTO	United States Patent and Trademark Office
WTO	World Trade Organization

BACKGROUND

India has been proactive in implementation of international treaties and conventions including the CBD (1993), WTO (1995) and ITPGRFA (2004) by developing and effectuating compatible legislative, policy, and administrative steps. Facilitated access to bio/genetic resources and equitable sharing of benefits arising from their use figured among the key objectives of CBD, besides conservation for sustainable use of biodiversity and its components. The ABS regime introduced by CBD in 1992 has been elaborated subsequently under ITPGRFA in 2004 and the Nagoya Protocol in 2012 bringing clarity with regard to the national domains of ABS for bio/genetic resources within their own jurisdictions as well as at international levels.

Through enactment of the PPV&FR Act, 2001 and the BDA, 2002, and establishment of PPV&FRA and NBA, India has simultaneously implemented the spirit of WTO (protection for plant varieties) as well as CBD (utilization of genetic resources). Indian regime has created exceptional provisions of farmers' rights and compulsory approval from NBA for patenting related to bio-resources to pave way for equitable sharing of benefits.

Indian authorities have also taken up massive awareness programs about the rights of farmers and communities on genetic and bio-resources. However, there are intricacies that demand sensitization of stakeholders, upgradation of skills in implementing agencies and resolution of ambiguities arising in individual cases of agrobiodiversity access and use *vis-à-vis* innovation management. As a result, central and state governments, district administration and the constitutional authorities established to regulate biodiversity and farmers' rights as well as all agrobiodiversity stakeholders need to come forward to harmonize compliant approaches, appropriate processes and good practices that would contribute to the evolution of an effective and efficient ABS domain acceptable to all.

For instance, Indian guidelines on the ABS based on the Nagoya Protocol were issued under BDA by Ministry of Environment, Forests and Climate Change and came into effect in 2014. Matching internal guidelines to deal with system-wide flow of PGRFA for facilitating multilateral access under ITPGRFA have been brought out by the Ministry of Agriculture and Farmers Welfare in 2015,

under section 40 of BDA. However, concerned administrative bodies and the stakeholders are gradually coming to terms with these new developments. It is recognized that paucity of awareness and lack of clarity are creating difficulties in real time handling of cases.

There exists a variety of legal dimensions and instruments in the utilization of genetic resources and associated traditional knowledge at the national as well as international level. They include laws governing administrative processes, intellectual property, environment, contracts, property, etc. Core issue in the area of ABS implementation is integrating multiple statutes, multiple ministries issuing multiple guidelines, and multiple agencies in order to benefit the stakeholders. There is a need to strike the right balance between the 'access' and the 'benefit sharing' concerns, possibly by enhancing tools to analyse such concerns raised by affected stakeholders, and refining the processes and protocols for their adherence to the regulatory norms.

India organized the 1st International Agrobiodiversity Congress (IAC 2016) from November 6 to 9, 2016 (www.iaac2016.in).

More than 60 countries and 1000 participants participated in the congress to deliberate on thematic issues of global importance, with major emphasis on rational and effective use of agrobiodiversity for food, nutrition and environmental security. The program committee gave focused attention to the ABS centric issues and concerns while developing the technical programme of the 4-day congress.

Anand and Anand, a leading full service intellectual property Law Firm (anandandanand.com) has been duly conversant with the developments and also emerging concerns related to ABS in bio/genetic resources post-implementation of relevant acts and guidelines.

Anand and Anand was contemplating having an awareness drive in ABS processes, post Nagoya Protocol, and approached the organizers of IAC 2016 to co-organize a suitable pre-Congress event on ABS issues. Accordingly, this meeting was organized to raise awareness and also brainstorm on the issues related to ABS vis-à-vis the Nagoya Protocol and ITPGRFA, in association with ISPGR, TAAS and ISIL.

OPENING SESSION

Participants of the first of its kind ABS meeting were welcomed by Dr R.K. Tyagi, Principal Scientist and Head, Division of Germplasm Conservation, NBPGR and the Co-organizing Secretary of IAC 2016. He gave a brief background about IAC 2016 scheduled to be organized during November 6-9, 2016. He drew attention to COP13, Cancun, Mexico scheduled immediately after IAC 2016 and possibility of IAC 2016 recommendations setting tone for further deliberations and decision making. Acknowledging the efforts of Dr Neeti Wilson (Anand and Anand) and Dr Sudhir Kochhar (EXICAR), he explained how the meeting was visualized as a precursor to the full-

fledged technical session on ABS during IAC 2016. Dr Tyagi expressed hope that the meeting would come up with specific



Dr R.K. Tyagi giving the opening remarks in the inaugural function, on behalf of IAC 2016



Ms Archana Shanker welcoming the dignitaries and participants on behalf of Anand and Anand

recommendations for implementation of ABS regime in India.

Mr Pravin Anand, Managing Partner of Anand and Anand, put the entire issue of ABS in the perspective of a legal expert. He pointed out that access to innovation/IP can have four broad possibilities viz.



Welcome address by Mr Pravin Anand

no access (trademarks), access with consent (voluntary license), access without consent but with payments (compulsory or statutory licensing), and access without consent and without payments (some instances of copyrights). Mr Pravin Anand raised the practical issues that have arisen in access of IP as a whole, lack of case law in ABS, and how ABS implementation can be shepherded by experience in other IPRs. If the benefit sharing is not forthcoming voluntarily, should owner of the resource prove infringement in litigation as in trademarks? On the other hand claims of benefits cannot be arbitrary but have to be fair as in "fair reasonable and non-

discriminatory terms for compensation" of telecom industry. Third point is to evaluate the contribution of the genetic resource in the final commercial product. There are examples of societies (music industry) collecting tariffs; can farmers' communities assume such and other roles? Share of farmers must be decided on a reasonable, rational and logical basis. IPRs can suffer from defective collection and distribution of benefit share. Mr Pravin Anand hoped that sharing of experiences by practicing IP lawyers and scientists can form a nice amalgam of solutions in the area of ABS.

Mr Rajiv Aggarwal, Joint Secretary, DIPP, was happy to note the seriousness attached to the topic of ABS. Calling upon the participants to find ways to achieve the right balance between access and benefit sharing, he cautioned them to be prepared for not just use, but also for misuse and abuse of resources. As battle for turmeric patent revocation inspired development of TKDL, documentation can become very critical in ABS. He reiterated that



Mr Rajiv Aggarwal giving his comments

India has always maintained right balance and has been proactive in participating in multilateral treaties, enacting legal instruments to protect biological diversity, genetic resources, and farmers' rights, and in recognizing all these diverse issues in the IPR Policy. Mr Aggarwal hoped that the ABS meeting and IAC 2016 not only will bring awareness about ABS but also provide direction for its implementation.

Mr N.K. Anand, Founding Partner, Anand and Anand, expressed happiness to be part of this unique ABS meeting where lawyers and scientists would be brainstorming together. He underscored the importance of lawyers working closely with people from the science, people from institution and the people who are more concerned about ABS other than just law.



Mr N.K. Anand addressing the participants

Dr R.S. Paroda, President, ISPGR and Co-Chair, IAC 2016 gave a succinct account of paradigm shift from genetic resources being “common heritage of mankind” to “regulated access and benefit sharing” within a span of twenty years.



Dr R.S. Paroda addressing the gathering in the inaugural session

As he was part of many of the post-CBD international deliberations that evolved the framework of ITPGRFA and defined rights on the genetic resources particularly farmers' rights, Dr Paroda elucidated the entire process of how we have reached the current state of multilateral agreement on access to PGR and ensuing benefit sharing. He was at the helm of affairs when Biological Diversity Act, 2002 and PPV&FR Act 2001 were drafted. He narrated the challenges in formulating acts and building institutions and urged the participants to make best use of the existing international and national legal framework by increasing the awareness among stakeholders and enhancing the capacity of the personnel. Dr Paroda highlighted that India's food basket is diverse and full due to generous exchanges in the past. He, therefore, advised that the legal frameworks should be employed to facilitate the exchange

of material and to ensure benefit sharing rather than blocking the exchange of germplasm in the name of law. Instead of agonizing over tech-rich countries adopting IP-driven path and patenting of bio-based inventions, India should look to enhance its capacities to harness the potential of biotechnology to enhance the commercial value of genetic resources.

India has a Patent Act and a Plant Variety and Farmers' Right Act and also a Biodiversity Act. With all these, fair treatment of innovations and ownership of genetic resources requires to think globally and act locally. Dr Paroda exhorted participants to strive for a clear understanding of the legalities governing the various processes and work towards harmonizing them. He reiterated the need for capacity building and development of legal expertise on genetic resources. He maintained that Nagoya Protocol was a major step towards fair and equitable

sharing of benefits arising from the utilization of genetic resources, especially for bilateral exchange, by providing greater legal certainty and transparency for both providers and users of genetic resources including researchers and industry. Dr Paroda strongly advocated on having a single window system as a clearing house to facilitate access to genetic resources. Different acts in India are administered by Ministries of Commerce, Agriculture and Environment and as such no easy system exists. If a farmer wants to provide access to his/her material, where does he/she go? How does he/she get benefit? If a private company wants to access a landrace, what is the shortest route? Such facilitation process requires deep awareness among policy makers. Dr Paroda advised that responsibilities of dealing with agrobiodiversity be delegated to MoA&FW, with PPV&FRA and ICAR handling the matter of access and benefit



Ms Neeti Wilson proposing a vote of thanks at the conclusion of the inaugural session

sharing and the five genetic resources bureaux functioning as facilitating points. Finally, Dr Paroda called upon all technical and legal experts to be innovative to ensure effective implementation of legal instruments that are in place, ensuring that the system should act as a facilitator rather than a regulator.

Dr Neeti Wilson, Partner, Anand and Anand and the convener of the ABS meeting acknowledged the time and interest of dignitaries and participants. She thanked the National Steering Committee, IAC 2016 for agreeing to organize the ABS meeting as a pre-IAC 2016 event and also for co-organizing the same.

KEY POINTS

- ◆ ABS legal frameworks should be employed to facilitate the exchange of material and to ensure benefit sharing rather than blocking the exchange of germplasm in the name of law
- ◆ Our preparation for ABS implementation should be not just for fair use, but also to tackle misuse and abuse
- ◆ Sharing of experiences by practicing IP lawyers and scientists can form an effective amalgam of solutions in the area of ABS
- ◆ India is yet to have case law in ABS; its implementation can be shepherded by experience in other IPRs
- ◆ Strive for a clear understanding of the legalities governing the various processes of ABS and work towards harmonizing them
- ◆ Capacity building and development of legal expertise on genetic resources is the need of the hour for successful implementation of ABS
- ◆ India should look to enhance her capacities to harness the potential of biotechnology to enhance the commercial value of genetic resources
- ◆ Establish a single window system as a clearing house to facilitate access to genetic resources
- ◆ Delegation of responsibilities of dealing with agrobiodiversity to Ministry of Agriculture and Farmers' Welfare, with PPV&FRA and ICAR handling the matters of access and benefit sharing and the five genetic resources bureaux functioning as facilitating points

TECHNICAL SESSION 1: INTRODUCTION TO THE KEY STATUTES RELATED TO ABS

The first technical session was moderated by Ms Archana Shanker, Anand and Anand. She identified core issue in the area of ABS implementation to be “integrating an array of multiple statutes, multiple ministries issuing multiple guidelines, multiple agencies” in order to benefit the stakeholders. The moot point was to create a single window system, to disseminate knowledge, and to

understand legislations, formats, agreements, standards of royalties, flow of benefits, etc.

Issues of benefit sharing related to the PPV&FR Act was described by the Registrar General of PPV&FRA, Dr R.C. Agrawal. He said that contributions of the poor farmers who maintained, managed and conserved genetic resources were identified in the CBD and principles



Panelists of Technical Session 1 – Ms Archana Shanker, Drs R.C. Agrawal, P. Nelliya and K.S. Kadam (from left to right)

and guidelines of benefit sharing have been enacted by India. Ownership on a plant variety, given to plant breeders or farmers, is a form of IPR. Because of the nature of the IPR and its administration, PPV&FRA in the MoA&FR has been identified as the responsible agency. The inherent complexities and technicalities of IPR on living and reproducing entities (plant variety) make it a daunting task to identify the legitimate shareholders of the benefits.

Highlighting the uniqueness of India's plant variety act, Dr Agrawal mentioned that India's farmers can register their varieties just as breeders do, license them to seed companies and enjoy the royalty benefits. This provision is in addition to right to sharing of benefits when varieties are developed by others, based on their material. Indian plant variety legislation has simple and clear procedures of

application and examination and allows farmers to use, save and exchange protected varieties, provides procedural and financial exemptions and grants dual IP protection in terms of denomination and the variety. He described these as fundamental steps towards achieving benefit sharing in plant variety protection. Additionally, creation of farmers' variety registry and publication of the plant variety journal allow adequate room for claims by righteous owners of varieties. He also said that over the period, case laws were being developed, appellate tribunal being set up and procedural improvements were being adopted. Due to continuous awareness programs and proactive drive to register farmers' varieties, more than 800 farmers' varieties have been registered by PPV&FRA.

Dr Agrawal explained that governing benefit sharing under the PPV&FR Act is



Dr Prakash Nelliyaat delivering his speech on access and benefit sharing in the jurisdiction of NBA

limited to varieties registered only under the act whereas benefit sharing under the BDA covers all the varieties within Indian territory, irrespective of whether a variety is registered with PPV&FRA or not. He identified jurisdictional issues, possibility of double taxing (in the form of benefit sharing) and modalities of benefit sharing as grey areas for further deliberation and clarification. He called for employing benefit sharing as a tool to facilitate enhanced use of genetic resources and advancement in the agriculture research, rather than as a deterrent.

Access and benefit sharing *vis-à-vis* evaluation of bio-resources in the jurisdiction of NBA was presented by Dr

Prakash Nellyyat, Fellow, NBA. He flagged a number of issues, such as ensuring conservation and sustainable use while awarding benefits, principles of equity and ethical use to balance rights of users and providers, emphasis on the “Prior informed consent” (PIC) and “mutually agreed terms” (MAT), negotiations driven by actual value of the resource, implementing decentralized system for benefit sharing, and learning from case studies.

Dr K.S. Kardam, Deputy Controller, Patent Office, portrayed the perspective of a patent regulator in dealing with ABS issues. Highlighting the fact that Indian patent law, the only one globally, requires declaration of source of biological



A view of dignitaries during the Technical Session 1

material, he asserted that applications from India and abroad are scrutinized alike for its implementation and that the patents were not granted without the permission of the NBA. Based on the cases handled, he identified four critical points for deliberation and action. First was to create, by collaboration between IPO and NBA, a digital register of biological resources in line with TKDL; second to bring clarity to definition of value added bio-products; third to

simplify and expedite the permission grant process and clarify provisional permissions; fourth was to increase coordination between IPO and NBA. Mr Kardam drew attention to the fact that benefit sharing arose only after a patent was granted and commercialization began. Effective benefit sharing could be possible only if IPO and NBA were on the same page regarding provisions and decisions, while working in a time-bound manner.

KEY POINTS

- ◆ In India, ABS is affected by multiple statutes, governed by multiple ministries issuing multiple guidelines, and executed by multiple agencies
- ◆ Coordination and cooperation among agencies (NBA, PPV&FRA and IPO) must for effective implementation of ABS
- ◆ Effective and efficient implementation of ABS requires a single window system
- ◆ Awareness programs at different levels must be organized
- ◆ It is crucial for personnel of implementing agencies to understand legislations, formats, agreements, standards of royalties, flow of benefits, etc.

TECHNICAL SESSION 2: GENERAL ISSUES FACED BY ABS STAKEHOLDERS

Dr Sudhir Kochhar, ARS (Retd.), Ex-ICAR, was the moderator of the session. He said that the previous sessions were insightful to understand the provisions in the legislative domain dealing with ABS as well as to assess the extent of comprehension and performance in implementation.

Dr Pratibha Brahmi, ICAR-NBPGR, spoke about the provisions and the requirements regarding deposition of

material at the designated repositories. With 2016 clarifications, guidelines and a list of designated repositories for different categories of biological materials, NBA has set the tone under section 39. She informed the participants that discoverer of a new taxon, person accessing biological resource, and Indian researcher carrying material abroad for research should deposit the voucher sample of the original material. She also



Panelists of Technical Session 2 – Drs S. Kochhar, P. Brahmi, S.K. Verma and Ms Sheetal Talwar (from left to right)



A view of the audience during Technical Session 2

clarified that ownership remained with the state, and the designated repositories were only the custodians. The deposited material is available for academic purpose to users within the country under section 3(2) of the NBA. For bio-resource related to plants, NBPGR has standards available for deposition of the propagules (samples that can be regenerated and not any bio-material). Any plant material which was being used in a patent application was to be deposited at NBPGR; but now this has been clarified that for patents one does not need to deposit any material. Only in case of accessing or any researcher who is going abroad taking material has to deposit.

Professor Surinder Kaur Verma, ED, ISIL, highlighted the national and international scenario covering ITPGRFA, CBD, and Nagoya Protocol as well as National IPR policy, NBA, Patent Act, PPV&FR Act. She provided the legal jurisprudence with case studies in her detailed presentation. Ms Sheetal Talwar, DGM Legal, TCL, presented specific cases of access to bio-resources by Tata Chemicals and the issues and concerns in context with permissions from NBA. She brought out the fact that industry was willing to pay to access bio-resources or share the benefit, but the systems were not permitting to do the same in an amicable manner.

KEY POINTS

- ◆ Improvements in administrative and regulatory systems are necessary for an efficient ABS system
- ◆ Roles and procedures of material repositories are clear
- ◆ Improved awareness of national and international scenario is essential for ABS implementation

BRAINSTORMING MEETING

During a lively brainstorming session view-points, experiences, suggestions of experts cutting across specializations were assembled. They are presented below in the order of speakers:

Dr Neeti Wilson

1. No clarity with respect to pre-NBA access and commercialization of such accessed bio-resources. The grace period from the initiation of NBA should be considered in lines of the extant variety protection provided under the PPV&FR Act.
2. No clarity on how microorganisms are to be treated leading to, among others, companies exploring foreign microorganism instead of bio-prospecting in India.
3. Stringency of filing requests at NBA with respect to authorized signatory, extent of criminal liability and reluctance of authorities to sign the document.
4. Simplification of procedures especially the forms, minimum transparency and reasonable time frame for disposal of applications.

5. Convergence and harmonization of PPV&FR Act and BDA, particularly overlaps and gaps.
6. Clarification on linkage clause of Patents Act with NBA permissions and matters of jurisdiction.
7. Documentation like TKDL, clarity on determination of ownership of genetic resources and evaluation.

Mr Pravin Anand

1. Recognize nature of issues to tackle them; the issues could be substantive (need definition and interpretation), administrative or legislative (require either a change in a law or rule connection).
2. Need time revolution i.e. time taken to deal with cases should be reasonably minimal (requiring change in mind-set and technical knowledge).
3. Case studies have shown that applicants and lawyers can take the route of court of law for clarification on rules, amending them, and even strengthening the hands of regulatory authorities in terms of staff and funds.

4. Stakeholders should not hesitate to go to court of law or a tribunal or a hearing officer to get unambiguous interpretations in the form of orders for everyone down the line to implement in words and spirit.
10. IPRs on innovations in the field of agrobiodiversity conservation and use should be encouraged.

Dr R.S. Paroda

1. First establish modalities for access before we talk of benefit sharing.
2. Creation of a well-defined database of not just resources but also associated traditional knowledge.
3. Clarity on overlapping jurisdictions of NBA and PPV&FR Act in case of “any biological material” vs. “value added product”.
4. Bring in procedural reforms to avoid delay and enhance efficiency through bringing out proper guidelines and harmonization of these acts.
5. Identify grey areas to resolve them gradually.
6. Put in place end-to-end guidelines for access and sharing the benefits.
7. Create a single window system for clearing house.
8. Implement dispute settlement mechanism with the help of legal experts.
9. Innovative approaches to share material with global community (and share benefits) to shed conservative and protectionist image of India.
11. Understaffed NBA is a serious concern; strengthening of NBA secretariat on urgent basis.
12. Execution of issues provided under the law and agreed upon in principle for instance standard material transfer agreement (SMTA) without which access is a non-starter.
13. Immediate action is required on enabling multilateral access to genetic resources committed under Treaty. Benefit sharing will follow.
14. Facilitate access to users within the country including private sector. Only then the private sector can come forward, sign SMTA, and access the material for research. Benefit sharing will follow.
15. When law does not stop anyone to access material and use it (subject to adherence to requirements), we have to embrace all the users and provide mechanisms of access. Create enabling environment, have dialogue with private sector, facilitate the access and then benefit sharing will follow.
16. Technical experts should work on defining what constitutes a “biological resources”, a “genetic material” and a “value added product”.
17. Membership to international fora and ratification, national legal framework, and institutions and authorities

are in place. There is a serious need for accessing bio-resources for research and development in agriculture and health and fortunately public and private organizations are working towards that. It is “now or never” time to move forward for scientists, lawyers and regulators for collective action to ensure protection of biological resources, their conservation, facilitated access and then plough back benefits to the system.

Dr R.R. Hanchinal

1. Time management crucial in dealing with disposal of various applications and requests at IP offices. PPV&FRA is working constantly towards accelerated governance model.
2. Delay should not be due to incomplete and incorrect applications; awareness programs for applicants has improved the situation in PPV&FRA.
3. In addition to functioning as an IP regulator, PPV&FRA also promotes registration of farmers’ varieties by way of special drives in awareness programs.
4. Recognizing, rewarding and hand-holding farmers and communities for innovation and conservation activities enhances likelihood of access and benefit sharing; PPV&FRA has a dedicated Gene Fund for this purpose.

5. Based on the day to day experiences, the procedures need to be corrected, simplified or evolved by amending the rules; PPV&FRA has amended the rules to make the entire process faster, simpler and professional.
6. PPV&FRA is yet to experience full-scale implementation of benefit sharing as only one application for benefit sharing has been received so far; as a proactive step, KVKs are being brought into the loop to educate farmers and communities.
7. Regular and strong interface between PPV&FRA and NBA to iron out gaps and to frame rules and procedures that are non-encroaching, complementary and compliant.
8. Resolution of issues possible only if technical experts and legal experts work as a team towards a common objective.

Dr K.S. Kardam

1. Reforms in administrative procedures at Patent Office taking place to overcome delay.
2. Patent rules amended to enforce timelines on Examiners and Controller.
3. A timeline of three months from start to finish is achievable.

Dr Prakash Nellyat

1. Emphasis on the adherence to the ethical and equity principles in bio-

resources exchange and on following the procedure of obtaining “Prior informed consent” and arriving at “mutually agreed terms”.

2. All the negotiations should be based on the actual value of the bio-resources.
3. NBA needs to be staffed adequately for handling large number of requests of disparate nature.

Ms Archana Shanker

1. We must develop an online integrated platform for cases relating to access to bio-resources and eventual benefit sharing. Different regulatory and approval authorities like NBA, PPV&FRA and IPO will have dedicated modules for administering relevant jurisdictions. For user, it will be a single window system. User is guided at every stage, time-line is determined, over-laps as well as gaps are easily identified and taken care, documentation at every step makes the entire process transparent.

Ms Sheetal Talwar

1. Involvement of clientele and stakeholders in refining rules should be considered in order to make the process agreed upon by the users.

Dr Prathiba Brahmi

1. Access under multilateral treaty is being done under SMTA, which

is notified and is being used. MTA for bilateral exchange with another country has been drafted in harmony with multi-lateral SMTA, and will be notified by DARE shortly.

Dr Sudhir Kochhar

1. Interpretations of technical phrases of BDA including “occurring In India” and “conventional breeding” should be practical and clear.
2. Who is the National Focal Point for ABS?

Dr Aeshita Mukherji-Wilske

1. There is a dire need of clear and consistent interpretations of act and rules avoiding case-to-case basis differences. Stakeholders would be better equipped if rules are available in simple language, consistency of application improves.
2. It appears that each state has different state biodiversity rules (and in some states they are not passed) causing disparities.
3. Capacity building of stakeholders and having competent people at decision making positions.

Dr Malathi Lakhmikumaran

1. Definition of “conventional breeding” either for research or for commercial utilization needs clarity and consistent application; interpretation of “occurring in India”

in diverse cases can be challenging, needs comprehensive review and clear rules; What is an Indian Company needs revisiting in today's context; "Exemptions" for approval needs clarity and consistency; and jurisdiction of MoA&FW and MoEF&CC on different species as per NBA.

Dr Shivendra Bajaj

1. NBA's permission to access genetic resource (e.g. insect pest or weed) "not to be used to test" as a resource *per se* but "to be used to test against" them for research needs to be revisited and clarified.

Dr Shashank Mauria

1. We should consider filing a PIL to get national authorities implement rules in harmony.

Dr Abha Agnihotri

1. Lack of clarity on need for permission from NBA to access pre-BDA material existing with universities.
2. Inadequate checks and mechanisms to prevent persons taking material out of country illegally.

RECOMMENDATIONS

1. Implement ABS in letter and spirit to ensure protection of bio-resources, their conservation, facilitated access, sustainable use and equitable sharing of benefits

- As there is a serious need for accessing bio-resources for research and development in agriculture and health, that national legal framework, institutions and authorities are in place, it is time to move forward for scientists, lawyers and regulators for collective action to ensure effective implementation of ABS regime.
- The ABS implementation should ensure intended use of accessed material, alongside suitable mechanisms to address misuse.
- There should be opportunities to share experiences by practicing IP lawyers and scientists to form an effective amalgam of solutions for ABS implementation; India is yet to have case law in ABS; its implementation can be shepherded by experience in other IPRs.
- There is a need to put in place adequate checks and mechanisms to prevent illegal export of genetic material out of country.

2. Establish a simplified and enabling system for effective ABS regime

- Simplification of forms and reasonable time-frame for disposal of applications.
- Set up a “Single Window System” as a clearing house to facilitate effective and efficient ABS system as per provisions of the Nagoya Protocol.
- Put in place end-to-end guidelines for access and sharing the benefits.

3. Bring about clarity on critical issues for effective implementation of ABS

- Events of pre-BDA access and commercialization of such accessed bio-resources such as a cut-off date for implementation be considered in line with extant variety protection system provided under the PPV&FR Act.
- Permission to access genetic resource (e.g. insect, pest or weed) “not to be used to test” as a resource *per se* but “to be used to test against” them for research needs to be revisited and clarified.
- Case studies have shown that applicants and lawyers can take the route of court of law for unambiguous interpretations in the form of orders, clarification on rules and amendments.
- Criteria defining an Indian Company according to BDA needs revisiting in today’s context.
- Clarity on overlapping jurisdictions of NBA and PPV&FRA.
- Defining what constitutes a “biological resource”, a “genetic material”, “value added product”, conventional breeding, occurring in India.
- “Exemptions” for approval needs clarity and consistency.

4. Utilize ABS regulations to facilitate the exchange of PGRFA and to ensure benefit sharing rather than slowing down the exchange

- Modalities for access to genetic resources need to be harmonized before benefit sharing issues are implemented.
- MTA for bilateral agreement with another country needs to be drafted in harmony with multilateral SMTA.
- Revisit the stringency of filing requests at NBA with respect to authorized signatory, extent of criminal liability and resultant reluctance of authorities to sign the document.
- Innovative approaches to share material with global community (and share benefits) to ensure access to important material from other countries as well as to shed conservative and protectionist image of India.
- Execution of issues provided under the law and agreed upon in principle (e.g. SMTA) without which access is a non-starter.
- Immediate action on enabling multilateral access to genetic resources committed under Treaty. Facilitate access to users within the country including private sector for research; benefit sharing will follow.

5. Build greater convergence and harmonization among government agencies governing ABS

- In India, ABS is affected by multiple statutes, governed by multiple ministries issuing multiple guidelines, and executed by multiple agencies. Coordination and cooperation among agencies (NBA, PPV&FRA and IPO) must for effective implementation of ABS.
- A strong interface required between PPV&FRA and NBA as well as NBA and IPO to iron out gaps and to frame rules and procedures that are non-encroaching, complementary and compliant through technical and legal experts.
- Ensure same set of biodiversity rules apply in every state such that no disparities exist.

6. Establish systematic and comprehensive system of documentation and database and integrated ABS platform

- Creation of a well-defined integrated database of genetic resources, bio-resources, associated traditional knowledge like TKDL available with all stakeholders including private sector to ensure effective implementation of ABS mechanisms.
 - Need to develop an online integrated platform for cases relating to access to bio-resources and eventual benefit sharing.
- Different regulatory and approval authorities like NBA, PPV&FRA and IPO may have dedicated modules for administering relevant jurisdictions. For user, it shall be a single window system, guided at every stage, time-line determined, over-laps as well as gaps identified and taken care, documentation at every step facilitating transparency.

7. Strengthen regulatory and implementing agencies with structural reforms

- Regulatory authorities (e.g. NBA) needs to be staffed adequately with competent people.
- Usher in “Time Revolution” i.e. time taken to deal with cases should be reasonably minimal (requiring change in both mind-set and technical knowledge); a time-line should be established. e.g. reforms in administrative procedures at

- IPO and PPV&FRA taking place to overcome delay; rules amended to enforce timelines to make the entire process faster, simpler and professional.
- Recognize nature of issues to tackle them; the issues could be substantive (need definition and interpretation), administrative issues, or legislative (require either a change in a law or rule connection).
- Implement a simplified dispute settlement mechanism with the help of legal experts.
- Delegation of responsibilities of dealing with agrobiodiversity to Ministry of Agriculture and Farmers Welfare with PPV&FRA and ICAR in matters of access and benefit sharing; five genetic resources bureaus functioning as facilitating points.

8. Organize regular programs of promotion, awareness and capacity building

- Awareness programs for stakeholders, industry and academia. e.g. awareness programs for applicants can bring down delay by reducing incomplete and incorrect applications.
- Capacity building for personnel of implementing agencies to understand legislations, formats, agreements, standards of royalties, flow of benefits, etc.
- Recognizing, rewarding and hand-holding farmers and communities for innovation and conservation activities enhances likelihood of access and benefit sharing (e.g. PPV&FRA has a dedicated Gene Fund).

PROGRAM

Awareness Session

Time	Program
9:30	Registration
9:50 - 10:30	<i>Opening Ceremony Lighting of Lamp Welcome Note</i> Dr R.K. Tyagi , Co-organizing Secretary, IAC 2016
	<i>Introductory Remarks</i> Mr Pravin Anand , Managing Partner, Anand and Anand, Co-Chairman ABS Meeting
	<i>Special Address by Special Invitee</i> Mr Rajiv Aggarwal , Joint Secretary, Department of Industrial Policy & Promotion
	<i>Chairperson's Remarks</i> Dr R.S. Paroda , Chairman, ABS Meeting
	<i>Vote of Thanks</i> Dr Neeti Wilson , Partner, Anand and Anand, Convener ABS Meeting
10:30 - 10:50	Tea Break
10:50 - 12:05	Session 1: Introduction of Key Statutes Related to ABS
	<i>Moderator:</i> Ms Archana Shanker , Head-Patents & Designs, Anand and Anand
	<i>Speakers:</i> Dr R.C. Agarwal , Registrar General, PPV&FRA Dr Prakash Nelliyyat , Fellow (ABS), NBA Dr K.S. Kardam , Sr. Joint Controller of Patent and Designs, IPO

Time	Program
12:05 - 13:20	<p>Session 2: General Issues Faced by ABS Stakeholders</p> <p><i>Moderator:</i> Dr Sudhir Kochhar, ARS (Retd), Ex-ICAR</p> <p><i>Speakers:</i> Dr S.K Verma, Secretary General, Indian Society of International Law Dr Pratibha Brahmi, Officer-in-Charge, Germplasm Exchange Unit, ICAR-NBPGR Ms Sheetal Talwar, DGM Legal, Head-Innovation and IPR, Tata Chemicals Ltd.</p>
13:20 - 13:50	<i>Question & Answers and Conclusion</i>
13:50 - 14:30	<i>Lunch</i>

Brainstorming Session

Time	Program
14:30 - 14:45	<p><i>Welcome and Opening Remarks by Chairpersons</i> Dr R.S. Paroda and Mr Pravin Anand</p>
14:45 - 14:50	<p><i>Introduction of Topic by Convenor</i> Dr Neeti Wilson</p>
14:50 - 15:35	<p><i>Comments by Special Invitees</i> Dr R.R. Hanchinal, Chairperson PPV&FRA Dr Prakash Nelliyyat, Fellow (ABS), NBA Dr K.S. Kardam, Sr. Joint Controller of Patent and Designs, IPO</p>
15:35 - 17:15	<i>Open House Discussion</i>
17:15 - 17:25	<p><i>Summary and Conclusion</i> Dr R.S. Paroda and Mr Pravin Anand</p>
17:25 - 17:30	<p><i>Vote of Thanks</i> Ms Archana Shanker</p>
17:30 - 18:00	<i>Tea</i>

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ABS – A PRIMER

“Requiring pre-CBD collections to produce evidence of a legal right to use resources, based on the existence of a sound legal title obtained from a country of origin, would have significant impact on their commercial value. The wide distribution of genetic resources over centuries – many of which are mainstays of global food security – is frequently posited as a reason to avoid extending control over pre-CBD collections.”

– *United Nations University Institute for the Advanced Study of Sustainability*

What is access and benefit-sharing?

Access and benefit sharing is a process by way of which providers and users manage to share, exchange and disseminate genetic resources and the benefits accrued from their use consensually and on mutually agreed terms. There are a total of 34 global biodiversity hotspots. Lately, the importance of these resources has been specially realized specially in the light of the environmental concerns rising.

Regional pre-CBD arrangements

In the 18th century, the Europeans travelled all over the world, discovered the biologically rich parts of the world and brought home with them all kinds of resources with aesthetic, medicinal and industrial viability in exchange of little or no cost, monetary or otherwise. During

the later years of the 20th century, some regions mutually agreed upon access and benefit sharing arrangements. However, these benefits were usually limited to Royalties at the government level. As a result of this traditional knowledge holders were left out of the loop of these benefits and most of the transfer of resources and benefits was one-way and monopolistic.

Convention on biological diversity (<https://www.cbd.int>)

The Convention on Biological Diversity instituted and facilitated under the International Treaty on Plant Genetic Resources for Food and Agriculture was the first international instrument legislating on Access and Benefit Sharing. Enforced on 29th December 1993, this treaty has three main objectives:

The conservation of biological diversity; the sustainable use of the components of biological diversity; and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources.

Article 15 of the convention stipulates provisions regarding access to genetic resources, article 16 talks about access to and transfer of technology and article 19 deals with handling of biotechnology and distribution of its benefits. The enforcement of these provisions involves the providers and users of genetic resources, national focal points and competent national authorities.

Two protocols have been enforced as a result of the CBD namely, the Cartagena Protocol on Biosafety and the 'Nagoya Protocol'.

Cartagena Protocol on biosafety (<https://bch.cbd.int/protocol>)

The Cartagena Protocol deals with the transport, transfer and handling of live modified organisms resulting from modern biotechnology. It was added as a supplement to the Convention on Biological diversity on 29th January 2000 and enforced on 11th September 2003. The Intergovernmental Committee for the Cartagena Protocol on Biosafety was established to organize the first meeting for the adoption of the protocol. It includes provisions for advance informed agreement procedures for imports of LMOs, risk assessment and management in their handling, transfer and use. It

also provides for the establishment of a biosafety clearing house.

Nagoya Protocol on ABS (<https://www.cbd.int/abs>)

Inspired and drawn from the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising Out of their Utilization of 2002 the Nagoya Protocol supports the basic provisions of the CBD on ABS arising due to sharing of genetic material and Traditional Knowledge. This read in conjunction with the CBD operates as the nucleus of the working of the ABS system.

Article 5 of the Protocol stipulates provisions for fair and equitable benefit sharing and article 6 deals with access to genetic resources. The two basic principles that drive the working of the access to biodiversity system though are 'Prior Informed Consent' (PIC) and 'Mutually Agreed Terms' (MAT). The competent authority grants a permit for access when it is satisfied that PIC and MAT requirements under national law have been met.

The protocol provides for the establishment of an ABS clearing house to facilitate legitimate movement across borders and discourage misappropriation.

The Nagoya Protocol on Access and Benefit Sharing (ABS) entered into force on 12 October 2014, 90th day of receiving the required 50th instrument of ratification on 14th July 2014 while the United States of America continues to be a non-party to the protocol.

Access and Benefit Sharing in India

Biological Diversity Act, 2002
(www.nbaindia.org)

Access to biological diversity is regulated/facilitated by the National Biodiversity Authority of India, Chennai. NBA has very immaculately laid down the procedure to obtain permission for access to biological resources and related traditional knowledge. NBA has defined the term 'commercial utilization'. The form of the agreement includes, in spirit, purpose of seeking approval; description of the biological resources; intended uses (research, breeding, commercial utilization etc.); intellectual property rights; monetary and other incidental benefits; restriction to transfer the accessed biological resources and the traditional knowledge to any third party; quantity and quality of biological resources; guarantee to deposit a reference sample with the designated repositories; submitting a regular status report of R&D; commitment to conservation and sustainable use of biological resources accessed and to minimize environmental impacts of collecting activities.

Section 4 describes procedure for seeking approval for transferring results of research; Section 5 describes exemptions to collaborative research projects between institutions, Indian or otherwise, government sponsored or otherwise involving transfer or exchange of biological information or resources; Section 6 contains provisions regarding IP arising out of the use of biological resources, its registration, and exploitation, payment

of royalties and related approvals and permissions. NBA has issued guidelines on access to biological resources and associated knowledge and benefits sharing regulations, 2014.

Protection of Plant Variety and Farmers Rights Act (plantaauthority.gov.in)

The provisions are implemented by Protection of Plant Variety and Farmers' Rights Authority, New Delhi. Section 26 and Section 45 of the PPVFR Act, 2001 discuss the provisions of benefit sharing. The amount of benefit sharing under section 26 shall be determined by the breeder by way of the provisions of Section 41 in the National Gene Fund and shall be collected as an arrear of the Land revenue by the District Magistrate. The amount from this fund shall be used to cater for the expenditures of the schemes relating to benefit sharing framed under section 46. Chapter IV Rules stipulates provisions regarding registration and benefit sharing.

Designated Repositories

Any person who discovers a new taxon of biological resources occurring in India, Persons/entities, as identified u/s 3(2), accessing biological resources occurring in India and Indian citizens/entities taking/sending abroad biological resource for non-commercial research are required to notify it to the relevant repository and deposit its holotype/isotype/paratype there. Guidelines for Designated Repositories are available at: http://nbaindia.org/uploaded/pdf/guidelines_for_designated_repositories.pdf





An overview of th Brainstorming Session



1st International Agrobiodiversity Congress : Science, Technology, Policy and Partnership. This event was held at New Delhi from November 6-9, 2016, to provide a common platform to share experience and knowledge on the sustainable conservation and use of agrobiodiversity. (<http://ispgr.nbpg.ernet.in/IAC>)



Indian Society of Genetic Resources (ISPGR) is a multidisciplinary scientific body involved in various values related to plant genetic resources. It is located at ICAR-National Bureau of Plant Genetic Resources, New Delhi, India.

(<http://ispgr.nbpg.ernet.in>)



Anand & Anand is a full-service intellectual property (IP) law firm providing end-to-end legal solutions covering all cross-sections of IP and allied areas.

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