Technology Transfer in India: CBD, institutions, actors, typologies and perceptions

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Sector: Herbal Medicines (biopharmaceuticals, botanicals and personal care products and cosmetics)

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Title

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Abstract

The Convention on Biologcal Diversity (CBD) recognises that both access to and transfer of technologies are essential for the attainment of its objectives. This report explores a number of issues related to technology transfer with a particular focus on India asking questions on: typologies, actors, and institutions, perceptions and mechanisms. The report explores these issues for herbal medicine development and the use of medicinal plants particularly those based on the ancient written Ayurvedic medicinal system.

Key Words

Technology transfer, genetic resources, medicinal plants, biodiversity, traditional knowledge. Convention on Biological Diversity.

Foreword

This report is a contribution to the Indian Centre for Biodiversity Policy and Law (CEBPOL). The Centre has been established in the National Biodiversity Authority (NBA), Chennai, which is a statutory autonomous body of the Ministry of Environment and Forests responsible for implementing the Biological Diversity Act, 2002. CEBPOL is a joint project on technical and institutional cooperation between the Government of Norway and the Government of India as part of the Indo-Norwegian dialogue under the Joint Working Group on Environment.

CEBPOL is meant to be a Centre of excellence focusing on biodiversity law and policy that caters to the needs of national and international rulemaking and subsequent implementation on issues of biodiversity with the following objectives:

1. To provide professional support, advice and expertise to the Government of India and Norway on a sustained basis on matters relating to biodiversity policies and laws at the national level, as well as in international negotiations relating to biodiversity in multilateral forums.

2. To develop professional expertise in biodiversity related policies and laws, inter alia through encouragement of research, development and training in matters relating to Convention on Biological Diversity, as well as its interface with other multilateral environment agreements and United Nations bodies.

3. To develop and implement an array of capacity building programmes through multidisciplinary research and customise training programmes for a wide range of stakeholders focusing on human resource development.

4. To facilitate interactive information sharing through web conferencing, web seminars and virtual meetings involving relevant research centers and environmental law associations within India, Norway and other countries where such expertise is available.

5. To help develop India as a regional and international resource Centre for Biodiversity Policy and Law through provision of training and human resource development.

Technology Transfer in India: CBD, institutions, actors, typologies and perceptions

Sector: Herbal Medicines (*biopharmaceuticals, botanicals*¹ *and personal care products and cosmetics*)

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¹ Including the group called, Nutra-pharmaceuticals.

1 Abstract

The Convention on Biodiversity (CBD), the Convention recognizes that both access to and transfer of technology are essential elements for the attainment of its objectives. The Convention sets-up requirements for obtaining genetic resources, derivatives of biological resources and traditional knowledge – for medicinal development - for both research and commercial purposes. The Convention introduced the concept of technology transfer (Art. 16), separate from ABS (Art. 15) and one which is expanded in the Nagoya Protocol. The concept is, however, one that is very much intertwined in its comprehension and its implementation through ABS. Although technology transfer was seen as one of the main pillars of the CBD, it has been covered only sporadically under the Convention with limited reflection on the types of technology needs of different actors in the steps of product identification to development, how access to technology may be attained, and how technology transfer occurs and is understood. This study explored a number of issues related to technology transfer with a particular focus on India asking questions on: typologies, actors and institutions, perceptions and mechanisms. The paper explores these issues for herbal medicine development and the use of medicinal plants particularly those based on the ancient written Ayurvedic medicinal system.

India has addressed several of the Convention's Provisions in its Biological Diversity Act (BDA) of 2002 recognizing the role technology know-how could play in enhancing development in a mega-biodiversity nation. It has established a National Biodiversity Authority (NBA) to implement the provisions of the BDA. Technology transfer can be defined in various ways. Here its context is anchored in the fact that technology transfer is often, increasingly, being included as part of benefit sharing regimes as in the BDA. India has opted to include technology transfer as under the umbrella of benefit sharing and not as a standalone mechanism. In practice it has been useful to consider access and benefits from the use of medicinal plants in India: the inclusion of technology transfer is a natural part of the discussion over benefit options in bio-prospecting or drug development processes. In addition, importantly, the inclusion of technology transfer as part of the benefit sharing package is generally considered in unison with benefit sharing by international bio-prospectors.

Traditional knowledge (TK) in India is available both as written documents and in oral forms. There are official data bases, data banks and collections of plants in a number of institutions. India has developed a Traditional Knowledge Digital Library (TKDL) which is a digitized database of documented information available in ancient written Indian systems of medicine. The database is primarily aimed for consolidating all TK based knowledge of medicinal plants, providing and identifying TK basis of plants accessed, providing easy and controlled (monitored) access to public at-large and bio-prospectors, and assuring that benefits (and technology transfer) are considered in relation to access to TK based knowledge. Not all information of TK based medicines in consolidated

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to-date. Besides the TKDL there are a number of botanical gardens, herbaria and research institutes which house smaller and regional plant databases and collections. In addition, local communities and ethnic groups form one of the key pools of oral knowledge on medicinal plants. Only the TKDL has a system for extraction of information on herbal plants for international and national (including those collaborating with foreign actors) actors. However the current system was criticized for not having clear provisions or guidelines for its use and contractual requirements between international and national contractors.

The findings of this study also showed that at present there are no specific mechanisms that facilitate interest and increase in technology transfer as part of benefit sharing. The NBA implements the BDA (2002) through a process for agreements for ABS, thus granting access to genetic resources and TK. In respect to these the NBA has a slew of benefit sharing options which are explored as per the BDA, many of which are similar to those suggested in the Bonn Guidelines. Although technology provided as a monetary transfer appears to be preferred by biodiversity prospectors and users, the NBA calls for the setting up of Funds which may be used by suppliers of biodiversity and TK holders. This is the general alternative opted if no decision on what technology transfer options could encompass in an ABS agreement. For many established actors, the preferred technologies can be in the form of sharing of IPR and revenues, and, where possible, scientific publications.

This project showed that there are a range of actors involved as suppliers of genetic resources, TK and those that have potential to receive technology. The major constraints reported by actors with and potential international collaboration for herbal medicinal development are the lack of (i) contracts which may facilitate initial screening (scoping or early research) of biological resources and (ii) understanding and realistic expectations of revenues and thus related benefit sharing. In this regard, the NBA is considering and has recently employed paced contracts (with staggered payments which call for disbursements/payments during the steps of drug development or use of biodiversity) which do not bind the biodiversity prospector or users to one-time or fixed pre-determined payments. Early stage research or scoping (or even screening) as the first step of a 'paced' ABS agreement may be looked upon as a mechanism to encourage bio-prospecting and herbal medicinal development in India.

The actual type of transfer has to be reflected by the nature of the exchange, the needs of the actor, and the ability of the actor to absorb the technology and importantly to adapt it. There are hard technology needs in India specifically among the medium industry and laboratories in academic institutions (universities) and herbaria/gardens, and certainly among the small industry and communities. Among the latter group, supply has to move from raw products to more sophisticated products, which require technology transfer to increase product usability for exploration by both international and sophisticated national actors. All these point to the necessity of assessing what the actual needs are of the actors, through technology need assessments.

There are also needs fortargeted effort put into linking technology transfer options into conservation and sustainable use of genetic resources. The list of technology transfer options in the BDA call for prior informed consent (PIC) and agreement on benefits among the different actors involved: particularly the suppliers and users. There is a clear need for balancing the roles of different actors in collectively deciding technology transfer. Technology for conservation and sustainable use of biodiversity ought to explore wide inroads as challenges for making transfer possible are multi-faceted and cross ABS borders. Pathways to enhance technology transfer ought not to be just confined to the ABS mechanisms and processes. There is a need to look at several other inroads to achieving a momentum in technology transfer processes that makes a contribution to the Convention's aims, in addition, to that of community development.

2 Introduction

The objectives of the Convention on Biodiversity are the conservation of biodiversity, the sustainable use of its components, and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources. For attainment of these objectives, the Convention recognizes that both access to and transfer of technology among Contracting Parties are essential. In the Convention on Biological Diversity (CBD), Article 16 - Access to and Transfer of technology - states that: Each Contracting Party, recognizing that technology includes biotechnology, and that both access to and transfer of technology among Contracting Parties are essential elements for the attainment of the objectives of this Convention, undertakes subject to the provisions of this Article to provide and/or facilitate access for and transfer to other Contracting Parties of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment. Each Contacting party is to facilitate access for and transfer of its components to another Contracting Party.

Noticeably Art 16.2 states that for developing countries the access and transfer of technology shall be provided and/or facilitated under fair and most favorable terms, including on concessional and preferential terms where mutually agreed. Intellectual property may be an issue affecting access and transfer of technology, and thus play a part in structuring the frame of the mutually agreed terms. Furthermore, Art 16.4 proposes that legislative, administrative or policy measures should be taken at the national level, while elaborating on the role of the private sector in the facilitation to the access, joint development and transfer of technology for the benefit of both governmental institutions and private sector of developing countries. Technology transfer falls under the umbrella of benefit sharing, where access is often seen as to be given in exchange for some sort of benefits, technology² being one. India has addressed several of the above themes in its Biological Diversity Act of 2002³ recognizing the role technology know-how could play in enhancing development in a mega-biodiversity nation.

Notably Technology transfer may take place via two avenues where one is under the auspicious of the benefit sharing regimes (Art. 15, ABS) or through other mechanisms, independent of ABS. This report explores the former, particularly as in India technology transfer is embedded in ABS. In addition, in the case of medicinal plants and associated TK, ABS becomes a key mechanism. To achieve sustained technology transfer human and institutional capacity building is seen as a central issue. Capacity building inevitably depends on a vital question of need. Is there a need and, if yes, in which areas and how is the need to be fulfilled? The needs and forms of technology transfer are varied and likely vary across

² Chapters 4 and 7 elaborate on what encompasses technology and its transfer.

³ India's Biological Diversity Act, 2002 interalia provides for the development of

appropriate guidelines to ensure fair and equitable sharing of benefits arising from the use of bio-resources.

actors using biological resources, particularly when knowledge of biodiversity and its components is anchored in traditional knowledge bases and access requires to be granted. The promotion, facilitation, adaptation and maintenance of technology require attention to a number of factors, namely: the capacity for legal and regulatory negotiations; institutional formation; access to raw material (species); drug development; approval (certification) procedures and monitoring; market issues; techniques of material (species) collection and processing; and biodiversity informatics; in addition to the presence of fairness and equity in benefit sharing (see Nagoya Protocol, 2010⁴). It is to be noted that collectively technology transfer is viewed as part of benefit sharing regimes in bio-prospecting.⁵ As exploration of medicinal properties – bioprospecting - entails the use of genetic resources (plants in this study) where innovation structures and processes are central, certain transfers of technology would hinge on specific policy and practical questions. Thus looking at access and transfer of technology would require reflection on intellectual property systems as well.

Technology transfer to developing countries can take place via varied routes and assume various forms: through industry (small to large), academic and research centers, repositories of plant species and as products, instruments, industrial processes or devices, training (capacity/skills building), knowledge and agro-practices. A fundamental distinction in the form of technology transfer involves the difference between the transfer of products vs. skills or know-how. The successful transfer of the latter can have significant implication to development of technologies within the country and its growth, although the adoption of a type of practice can pose complex ramifications when it comes to adaptation.

Countries like India with rich bio-resources may benefit from a nuanced definition of the needs for technology and related capacity in a range of institutions – not merely in the currently present high technology centers - which could trigger, where possible, the development of valued products on a wider scale. Access to raw material like plant species for medicinal development is often linked to traditional knowledge (TK) where some

⁴ Nagoya Protocol, 2010. Art. 5. Fair and Equitable Benefit Sharing with reference to Article 15, paragraphs 3 and 7 of the Convention. See also Art 8 of the Nagoya Protocol on Special Considerations when developing and implementing access and benefit sharing legislation or regulatory requirements, Art. 9 of the Nagoya Protocol on contribution to conservation and sustainable use, and Art. 18. Compliance with Mutually Agreed Terms. www.cbd.org ⁵ ten Kate, K. and S.A. Laird. 1999. The commercial use of biodiversity. Earthscan Publications Ltd., London; Svarstad, H. and S. S. Dhillion (eds.). 2000. Responding to bio-prospecting: from biodiversity in the South to medicines in the North. Spartacus Forlag, Oslo; Alan Hamilton. 2004. Medicinal plants, conservation and livelihoods. Biodiversity & Conservation, 13 (8):1477-1517; Newman, D.J. and G.M. Cragg. 2007. Natural products as sources of new drugs over the last 25 years. Journal of Natural Products, 70:461-477; also benefit sharing options listed in India's BDA (2002) (see Table 2 chapter 4 of this study)

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established use exists:⁶ where owners of TK could benefit from technology transfer in exchange for the raw material or knowledge. India is unique in that it has much of its traditional medicinal knowledge anchored in well-written and organized traditional healing systems, unlike most other nations where traditions exist only or largely in the oral form. The existence and continued practice of traditional healing systems provides for an evolved platter of medicinal plants with traditional uses to choose from – thus jump-starting the search for new medicinal products for interested actors.⁷ Such plants function not only as actual medicinal development specimens but also as clues to related species for potential screening.⁸

Although technology transfer was seen as one of the main pillars of the CBD by developing countries, it has been covered only sporadically under the Convention with very limited guidance as to the types of technology needs by different actors in the steps of product development, how access to technology may be attained, and how technology transfer occurs and is understood. India has a range of public and private actors, including local communities, along with a growing number of publicprivate partnerships involved in the herbal medicinal identification and production process. This array of actors points to the potential existence of diverse technology needs, understanding and practice of technology transfer. Broadly, this report provides a status of the actors, and perceived state of technology transfer in the herbal medicinal sector in India, along with a brief description of the related main institutions and legislation. The study started with the set of questions listed below, which formed the backdrop for understanding technology transfer in India. This study endeavors to address the issues that the questions below point to.

- What range and types of Technology Transfer are required and possible in India?
- Are there basic technological transfer needs which need to be fostered that eventually may lead to sophisticated technology⁹ development within India?
- What mechanisms exist for Technology Transfer at different institutional levels?
- What are the legal instruments that can facilitate Technology Transfer?
- Why is Technology Transfer important for Medicinal Plants and where is access granted?

⁶ Interview: IHST (Dr. Shankar) Nov 2013. See also: Sankar, D. and PM. Unnikrishnan. (Eds.). 2004. Challenging the Indian Medical Heritage. Center for Environmental Education. Foundation Books, Bangalore

⁷ ten Kate K. and S. A. Laird. 1999. The commercial use of biodiversity. Earthscan Publications Ltd. London; Cartaxo S.L., Souza M.M., and de Albuquerque UP. 2010. Medicinal plants with bio-prospecting potential used in semi-arid northeastern Brazil. J Ethnopharmacol.131(2):326-42.

⁸ Dhillion S.S. and C. Amundsen. 2000. Bioprospecting and the maintenance of biodiversity. <u>In</u> Svarstad, H. and S. S. Dhillion (eds.). Responding to Bioprospecting: from biodiversity in the South to medicines in the North. Spartacus Forlag, Oslo.

⁹ Given that technological processes may be protected by patents, there is always a need to explore technological pathways and processes.

- How do (eventual) technology transfer mechanisms affect the conservation and sustainable use of genetic resources, and in this case medicinal plants, for example, and the equitable sharing of benefits?
- Do mechanisms allow for the dissemination of new ideas and transfer of knowledge and in course empower India to add value to a prospective product?
- How does or will Technology Transfer address TK, equity and local needs and priorities given the current institutional set-ups and arrangements?
- How does or will Technology Transfer processes include awareness raising, PIC and monitoring?

3 Methods

The description of the perception of technology transfer, needs and processes is based on a literature review and interviews. The interviews were held with a range of actors (Appendix I) involved in (i) biodiversity repositories and laboratories, including those responsible and having access to plant species, (ii) academic research centers with laboratories, (iii) industry, (iv) government/policy makers, and (v) non-government organizations, from November 25 through 03 December, 2013. The visit was preceded with planning and preliminary exchanges with most of the actors. A total of 15 individuals were interviewed representing seven actors (Appendix I). The work focused on the sector which includes biopharmaceuticals, botanicals,¹⁰ personal care products and cosmetics – primarily stemming from Ayurvedic health care systems and local traditional practices. This sector is particularly interesting in the context of the CBD as traditional knowledge and established medicinal systems often are the basis for many of the botanical based products in India and are those of interested to International actors.¹¹ The open-ended interview approach helped in understanding how technology transfer is understood by key actors, thus getting at stakeholder identities and perceptions, interests and needs, and experiences pointing to technology transfer processes (Appendix II).

The aim was to obtain the views of key actors on technology transfer as to provide a general picture of technology transfer in India and not study particular cases at this stage, which would require a keener understanding of actors and the status of technology transfer through case studies in India, and time.

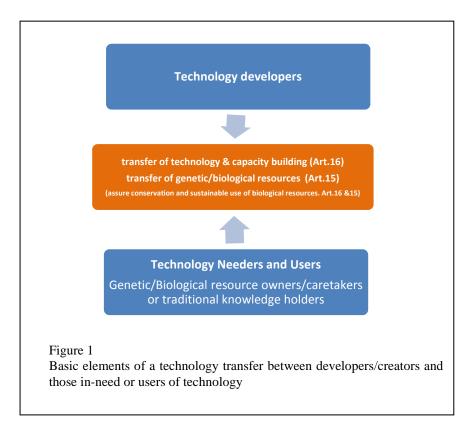
¹⁰ Including the group called, Nutra-pharmaceuticals.

¹¹ Interviews with FICCI, IHST (Drs. D. Shankar and P. Venkat); Natural Remedies (Nov-Dec 2014). IHST and Natural Remedies have both received proposals from international actors for medicinal development.

4 Technology transfer in the CBD and the Nagoya Protocol

4.1 Anchoring Technology Transfer

The CBD and associated triggered policies mark a watershed in the regulation of access to genetic resources and benefit sharing (ABS). The Convention sets-up requirements for individuals, organizations, companies or corporations to obtain genetic resources, derivatives of biological resources and traditional knowledge – for medicinal development - for both research and commercial purposes. Parallel to this the Convention introduced the concept of technology transfer (Art. 16), separate from ABS (Art. 15) but it is one which is very much intertwined in its comprehension and its implementation (through the ABS).



Technology transfer by itself is difficult to separate from ABS in practice, as the provision of access to biodiversity resources (for bio-prospecting) calls for returns in the form of benefits, where technology transfer is one core option (and a term which is often used interchangeably with the term benefit sharing).¹² Importantly, the Convention champions the needs for

¹² The Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization include technology transfer under 46.Types of benefits providing examples in Appendix II (Monetary and Non-Monetary Benefits). These examples point to the inclusion of technology transfer under benefit sharing

the transfer of technology through a variety of modes to those who need and - would - use, the technology (Fig. 1). The group of 'needers and users' is assumed to be composed of suppliers of genetic resources or their products who generally lack or have need for enhancing their quality/range of technology skills and equipment. The technological know-how and sophistication has long been in the hands of actors in the developed nations, in contrast to the bulk of the genetic/biological resources which lie in developing nations and where innate traditional knowledge exists in both oral and written forms. Developing nations like India have long pushed for instruments that would allow for a more balance exchange of technology with genetic resource use.

The Convention on Biodiversity entered into force on 29 December 1993, upon the required ratification by 30 countries, after being open for signature on 5 June 1992 during the UN conference on Environment and Development (Rio Earth Summit). As of November 2013, 193 parties have ratified the Convention. The Convention touches upon a range of activities that relate to the access to genetic resources, training/teaching, including monitoring and assessment for *in situ* and *ex situ* conservation, research, and promotion of equitable exchange. The latter is to be based on mutually agreed terms in exchange for a range of potential benefits: hard technology, shared development and research, training/capacity building, direct financial payments or profit sharing, intellectual property rights (IPR), etc.

International environmental negotiations for several decades have been occupied with the need for provisions for facilitating technology transfer arguing that without the transfer of technologies biodiversity related conservation would be hampered, and as such the goals of the CBD would not be met. The CBD Articles 16, 17, 18 and 19 address technology transfer and cooperation. In addition, while Article 12 addresses training and research activities, Article 16 sets out the basic obligation of all Parties regarding access to, and transfer of, technology and establishes several conditions regarding technology transfer.¹³ However, Art 16 is in itself a complex compromise between the obligation to transfer technology and IPR, and does not limit any intellectual property rights, in particular patents. The obligations apply to states as members of the CBD, whereas the owners of technology, through patents, which are not mainly states, but companies or private enterprises. A core question then arises as to how states can fulfil their obligations and at the same time meet their obligations under the various treaty obligations on IPR.

Technology transfer as stated in Art. 16 is intimately linked to Article 15, where providing access to genetic resources calls for benefits in the form of technology transfer. Article 15 of the Convention states that, 'Each Contracting Party shall endeavor to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting

options. India's ABS agreements/benefit sharing arrangements also include technology transfers under the umbrella of benefit sharing (see Chapter 5 of this report).

¹³ Articles of the Convention can be accessed at

www.cbd.int/convention/convention.shtml

Parties and not to impose restrictions that run counter to the objectives of this Convention'. The conservation goals include not only the in-situ and *ex-situ* conservation of biological diversity, but also with its sustainable use and benefit sharing on mutually agreed terms. Technology transfer as a benefit - for access - under this Article thus allows for both hard and soft technology geared to conservation needs with a wide scope.

The need for development, transfer and adaptation of technology are also echoed in the Rio Declaration on Environment and Development (Principle 9) which calls for States to cooperate to strengthen capacitybuilding for sustainable development through technology transfer. The Agenda 21¹⁴ calls for the guidance for environmentally sound management of biotechnology, where technology transfer is central. To promote the third tenant of the CBD the World Summit on Sustainable Development (WSSD, Johannesburg, September 2002) called for the negotiation of an international regime that would safeguard the fair and equitable sharing of benefit arising from the utilization of genetic resources. The Convention's Conference of the Parties (COP) responded by the elaboration and negotiating of an international regime to effectively implement Articles 15 addressing Access to Genetic Resources and 8(j) on Traditional Knowledge. The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization was adopted at the 10th meeting of the COP on 29 October, 2010, in Nagoya, Japan. It was open for signature from 2 February, 2011 and to date has 92 signatures and 29 ratifications. The 2012 Rio+20 outcome document,¹⁵ The Future We Want, reemphasizes the continued need for technology transfer¹⁶ for sustainable development and that parties should contribute to closing technology gaps between developed and developing countries, and reduce the technological dependence of developing countries using all appropriate measures.

The Nagova Protocol advances the third objective of the Convention by (i) providing a strong basis for greater legal certainty and transparency for

¹⁴ Chapters 23 and 16 provide guidance on technology transfer, capacity building and sound application of biotechnology. ¹⁵ The United Nations Conference on Sustainable Development - or Rio+20 - took place

in Rio de Janeiro, Brazil on 20-22 June 2012.

http://sustainabledevelopment.un.org/futurewewant.html. ¹⁶ http://sustainabledevelopment.un.org/futurewewant.html. 73. We emphasize the importance of technology transfer to developing countries and recall the provisions on technology transfer, finance, access to information, and intellectual property rights as agreed in the Johannesburg Plan of Implementation, in particular its call to promote, facilitate and finance, as appropriate, access to and the development, transfer and diffusion of environmentally sound technologies and corresponding know-how, in particular to developing countries, on favorable terms, including on concessional and preferential terms, as mutually agreed. We also take note of the further evolution of discussions and agreements on these issues since the adoption of the Johannesburg Plan of Implementation.

http://www.un.org/ga/search/view_doc.asp?symbol=A/RES/66/288&Lang=E (specifically see sub-sections B. Technology and C. Capacity-Building under section (VI) on Implementation, pages 51-53).

providers and users of genetic resources, (ii) compliance with domestic legislation and obligations reflected in mutually agreed terms, and (iii) establishing a more predictable conditions ensuring the sharing of benefits with the Providers of genetic resources. The premise is that the promotion of the use of the genetic resources and associated traditional knowledge will translate into enhancing the chances of fair and equitable sharing of benefits. Local and indigenous communities as holders of traditional knowledge and access to genetic recourse identities (the providers) are expected to have enhanced ability to benefit from the use of knowledge, innovations and practices. The Nagoya Protocol also emphasizes adopting monitoring measures to enhance transparency about the utilization of genetic resources through suggesting possible checkpoints (Article 17). In accordance with the Convention's Articles 15, 16, 18 and 19 the Parties are to (Nagoya Protocol, Article 23: Technology Transfer, Collaboration and Cooperation), 'promote and encourage access to technology by, and transfer of technology to, developing country Parties....and such collaborative activities shall take place in and with a Party or the Parties providing genetic resources that is the country or are the countries of origin of such resources or a Party or parties that have acquired the genetic resources'.

The Nagoya Protocol defines biotechnology in Article 2^{17} as done in the Convention to mean 'any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use. "Derivative" means a natural occurring biochemical compound resulting from genetic expression or metabolism or genetic resources, even if it does not contain functional units of heredity'. National access and benefit sharing systems are thus obliged to decide on regulating access to derivatives that do not contain functional units of heredity. These derivatives are not 'genetic resources' *per se* according to the CBD. Thus all use of herbals or pharmaceutical medicines which include medicinal active compounds would fall under biotechnology, in the board sense. It is noted that term 'technology' does not only refer to "hard" technology of information and know-how.¹⁸

Intellectual Property Rights

The rational for and structure of IPRs and foremost patents is a recognition of a need for establishing exclusive rights to research results and products as a means to create incentives to innovate and invest in innovation. Whereas, the technology transfer obligations rest on states, the rights holders of IPR are either private persons or companies. In ABS the idea of balance and equity is to be created between the user of the genetic resources and traditional knowledge and its caretaker and

¹⁷ Article 16.1 of the Convention also recognizes that technology includes biotechnology, where it is defined in Article 2 as '*any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes*

*for specific use*². ¹⁸ ten Kate, K. and S.A. Laird. 1999. The commercial use of biodiversity. Earthscan Publications Ltd., London.

provider. This means that if a state shall move to transfer technology to a partner country in the South, and the technique is patented, the state often will be bound by its patent legislation to respect the exclusive right. There are no exploration of whether making an exception from technology transfer under the CBD would be legal under TRIPS Art. 30. Thus the patent holder is according to the patent act entitled to exclude all uses of any patented technique also by its home-state/ government (unless compulsory licenses are granted). This indicates that the patent law restrains on technology transfer as embedded in the CBD.

4.2 Programme of Work on Technology Transfer

A Programme of Work (PoW) on technology transfer and technological and scientific cooperation was adopted by the COP 7^{19} in 2004. The PoW includes elements addressing four themes: (i) technology assessments, (ii) information systems, (iii) creating enabling environments and (iv) capacity-building and enhancement. An implementation strategy was adopted in 2008 to complement the PoW. A small number of critical policy actions were identified.²⁰ An early review of the Programme found that the programme had not yielded ample results that have led to effective technology transfer measures, where (i) technology transfer measures have not addressed CBD objectives and (ii) synergies among existing measures have been lacking. Related to this the COP at its 10th meeting invited Parties along with a wide range of stakeholders (international organizations and initiatives, research institutions and the business sector) to submit to the Executive Secretary information on activities which support, facilitate, regulate or promote technology transfer and technological cooperation of relevance to the convention²¹. Submissions²² were subsequently received from Belgium, Columbia, France, Poland and the UK, along with UNCCD,²³ UNFCCC, UNEP-WCMC. Due the limited number of submissions, a web-based research and consultations were undertaken.²⁴ A total of 127 programmes and initiatives were identified as relevant for analysis. The main results showed that: "(i) while there are activities supporting the transfer of technologies of relevance to the Convention, most do not formally refer to the CBD nor are they connected to it; (ii) some types of support seem to be well-covered for some sectors and types of technologies, but the

²⁰ Decision IX/14 and Annex. www.cbd.org

¹⁹ Conference of Parties (CoP 7) to the CBD in 2004. See Decision VII/29 and Annex. CBD. 2006. Programme of Work on Technology Transfer and Technological and Scientific Cooperation. Secretariat of the CBD, Montreal.

²¹ Notifications 2010-207 (22 Nov. 2010), 2011-094 (05 Apr.2011) and 2011-094 (05 May 2011) (ref. no. SCDB/SEL/ML/GD/74331). CBD Secretariat.

²² Submissions received were made available through the clearing-house mechanism of the Convention (<u>http://www.cbd.int/tech-transfer/gapanalysis/submission.shtml</u>) and are also available under its Programmes listing (see Technology Transfer and Cooperation). ²³ UNCCD, United Nations Convention to Combat Desertification; UNFCCC, United Nations Framework Convention on Climate Change; UNEP-WCMC, United Nations Environmental Programme World Conservation Monitoring Centre.

²⁴ Searchable online database (<u>http://www.cbd.int/tech-transfer/gapanalysis.shtml</u>).

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overall pictures is uneven and patchy (no activities were reported on conservation and sustainable use technologies); (iii) information dissemination leads the largest number of activities, followed by capacity-building and match-making (where most seminars and symposia were not related to CBD-specific technology transfer)."²⁵

The study also revealed that the activities under the CBD focused on training and capacity-building (a form of technology transfer) as a way to enhance the capacity of developing countries for the implementation of the CBD decisions, so these are mostly being organized under each respective programme of work of the CBD. Many regional and subregional capacity-building series organized under the CBD themes had some relevance to certain transfer of technologies (often "soft technologies"): such as the workshops related to the clearing-house mechanism, protected area management, NBSAP and national reporting skills, forest biodiversity and climate change, bio-safety, marine biodiversity, agricultural biodiversity, tourism, traditional knowledge, taxonomy, invasive alien species and issues related to access and benefit-sharing (ABS). Particular emerging issues addressed through capacity-building series, although not always under the auspices of the Convention, included biodiversity safeguards and REDD+, bio-safety and risk assessment of living modified organisms, description of ecologically or biologically significant marine areas (EBSAs), bush-meat, sustainable production and use of biofuel - all of relevance to areas of technology transfer need and could contribute to conservation and sustainable use of biodiversity.

Under the Nagoya Protocol on ABS, capacity-building is currently focusing on the early entry into force of the Protocol. Prior to the adoption of the Protocol, capacity needs were identified on the assessment and inventory of biological resources as well as information management, contract negotiation skills, legal drafting skills, and means for the protection of traditional knowledge associated with genetic resources. All these needs can be part of technology transfer mechanisms. Online e-learning modules and a number of guidelines, principles and tools are available on the CBD's website. The web-based research, including CBD's Technology Transfer database, showed that of many activities that are of relevance to the thematic programmes and issues of the CBD, training on "technology transfer" as a specialized expertise seems to be mostly available under the UNFCCC, where training and capacity-building is organized to support Parties and stakeholders in accessing resources, including funding opportunities, by formulating technology transfer projects in order to meet the needs specified in Technology Need Assessments (TNAs). With regard to the systematic support to technology transfer from researchers to end-users, the knowledge network of CGIAR presents another relevant example. The results of this further support the view that there is lack of focus and interventions that trigger and facilitate technology transfer within the Parties, potentially relevant institutions and initiatives especially targeted to conservation and sustainable use of biological diversity. These are thus other areas where the Convention could put effort in, including drawing

²⁵ UNEP/CBD/COP/11/INF/9 (21 Sept. 2012) (http://www.cbd.int/tech-transfer/)

upon other inroads than just ABS mechanisms in achieving technology transfer.

4.3 **Typology of Technology Transfer**

Technology transfer can be defined in various ways. Here its context is anchored in the fact that technology transfer is often, increasingly, being included as part of benefit sharing regimes as in the Biological Diversity Act (2002) of India, and applied to in the CBD, the Bonn Guidelines and the Nagoya Protocol. For all practical reasons technology transfer is to be "understood as a process and a transaction and needs to be defined accordingly" (Box I)²⁶. It has to be thus wide in its breadth and allencompassing of the range of actors (Fig. 4; Box II). As implied in the Nagoya Protocol, it is important to reflect that the transfer of technology requires attention to a number of factors, namely: the capacity for legal and regulatory negotiations; institutional formation; access to raw material (species); drug development; approval (certification) procedures and monitoring; market issues; techniques of material (species) collection and processing; and biodiversity informatics; in addition to the presence of fairness and equity in benefit sharing.²⁷ Thus the mechanisms and processes for the transfer of technology ought to consider typologies of transfer (Box II) that assure its promotion, facilitation, adapted and maintained. Box I presents a set of working definitions for and an understanding of technology transfer, in the context of processes and transactions.

²⁶ Pyoos, M. 2003. The CBD, technology transfer and the need to understand fully the issue of "Common but Differentiated Responsibilities". Schei, P.J. and O.T. Sandlund (Eds.), Conference Proceedings. The Norway/UN Conference of Technology transfer and Capacity Building, Trondheim, Norway. pages 240. ²⁷ Nagoya Protocol, 2010. Art. 5. (see Footnote no.5).

Box I. Defining and Understanding Technology Transfer

- Technology transfer is the means by which technical knowledge that is lacking in a specific production environment is acquired.
- The technology may be equipment, know-how held in patents and licensed out, available in technical publications, held by experts, or even widely and freely available but not easily accessible because of technical literacy requirements.
- Effective technology transfer should result in the development of sustainable production capacity in manufacturing, farming or even health care.
- Diffusion of the technology happens when the use of the technology becomes widespread, and where relevant reaching all levels of society.
- Technology transfer may be monetary in form: targeted for use for community or group-based interventions
- The needs of technology transfer may benefit from needs assessments.

Source: modified and expanded from Pyoos (2003) by Dhillion (this report)

The question of need is central when deciphering what technology transfer should encompass. Before discussing this it is useful to re-visit the types of technology that are generally discussed (Box II). The list of technology transfer options in the Box II encompasses, although not explicitly, all categories of benefit sharing which the Biological Diversity Act (2002) requires to be explored as part of ABS agreements in India (see Table 1).

Box II. The broad categories of technology transfer may include the following options

- i. Institutional and Human Resource (HR) Capacity Building and Training
- ii. Practical aspects institutional arrangements and access to the resource
- iii. Information technology (e.g., laboratory testing, screening; digital storage of information)
- iv. Products and/or process (e.g., chemical extraction/purification/stabilization, etc.) related IPR (joint ownership of patent rights)
- v. Publications (particularly for experts/academia)
- vi. Involvement in commercialization (direct benefits)
- vii. Sharing of benefits (agreement based; revenue related, fund establishment) which may be targeted to development or otherwise.

4.4 **Other Technology Transfer Activities that May** Contribute to Conservation and Sustainable Use of **Biodiversity**

Pathways to enhance technology transfer are not just confined to the ABS mechanisms and processes. The proposed Convention's Biodiversity Technology Initiative (BTI) which takes into account the Climate Change Initiative (CTI) for promoting and supporting the effective access to and transfer of technology among Parties to the Convention is also a reaffirmation of technology transfer needs²⁸. The BTI aims to facilitate enhanced interaction with Parties with identified capacity/technology building needs and international organizations, Parties, or other relevant organizations, which could assist in capacity building and technology transfer. Activities conducted under other multilateral environmental agreements may contribute to enhancement of and supplementing to technology transfer under the Convention and thus contribute to the conservation and sustainable use of biodiversity. The review conducted by the PoW revealed that several other bodies/MEAs²⁹ (namely, UNCCD, United Nations Convention to Combat Desertification; UNFCCC, United Nations Framework Convention on Climate Change; UNEP-WCMC, United Nations Environmental Programme World Conservation Monitoring Centre) were conducting technology transfer as capacity building and training which were related to biodiversity, although not always connected to the Convention. The climate change and desertification conventions and the Convention on the Law of the Sea to some extent have overlapping goals in that these also call for protection of ecosystems which is central to the Convention. In addition, through, for example, GEF projects and REDD+ initiatives viable links to conservation of ecosystems are clear entry points relevant to TK, medicinal plant habitat conservation and sustainable use at-large. Relevant are also green technologies that aim, among others, to explore the potential to significantly improve environmental performance relative to other technologies. It thus explores the selection of goods and services minimize environmental impacts that including implementing environmental policy instruments, like green procurement and ecolabeling, all which require technological know-how and capability.

²⁸ http://www.cbd.int/<u>decision/cop/default.shtml?id=11657</u>. The Executive Secretary on technology transfer and cooperation called for the establishment of a 'Biodiversity Technology Initiative' (BTI). (UNEP/CBD/WGRI/3/10) ²⁹ MEA = Multilateral Environmental Agreement

5 Legislation, Biodiversity Institutions and **Depositories in India**

Legislation and Institutions 5.1

After ratifying the CBD, India enacted the Biological Diversity Act (BDA)³⁰ in 2002. It laid out the Biological Diversity Rules (BDR) in 2004 to give effect to the provisions of the Convention, including those relating to Access and Benefit Sharing (ABS), and technology transfer.³¹ India was one of the first few countries to have enacted such legislation. The Act provides for setting up of a three-tiered institutional structure, all of which are involved in the consideration of benefit sharing and thus technology transfer options:

- National Biodiversity Authority (NBA)³² at the national level; i.
- ii. State Biodiversity Boards (SBBs) at the state (provincial) level and;
- iii. Biodiversity Management Committees (BMCs) at the local level

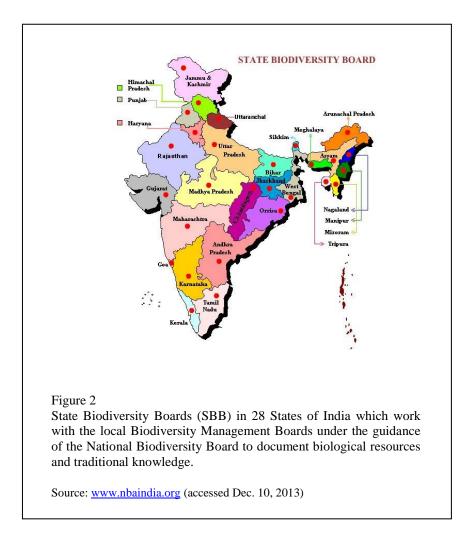
The Act also stipulates preparation of Peoples Biodiversity Registers (PBRs) by the BMCs involving local people and with guidance from SBBs and NBA.³³ SBBs have been established in 28 States and BMCs have been set up in 23 States (Fig. 2). So far, 1314 PBRs have been prepared documenting information on biological resources and associated traditional knowledge. The BMCs and SBBs serve as potential participants in deciding usages of benefits, particularly when technology transfer occurs as monetary funds. The NBA was set up in October, 2003 with its headquarters located at Chennai. The Biological Diversity Act is a legislation, acting as an institutional mechanism for its implementation at all governmental levels (national, state/provincial and local).

³⁰ The Biological Diversity Act, 2002 and Biological Diversity Rules, 2004, National Biodiversity Authority (2004), 74 pages.

³¹ Under benefit sharing options in the BDA (2002). See also Table 2 in this report.

³² The Biological Diversity Act (2002). The Act states in Chapter-III. 8 (1). That a body to be called the National Biodiversity Authority is to be established and 8 (3) its head office shall be located at Chennai. At present the location is: National Biodiversity Authority, 5th floor, TICEL Biopark, Taramani Road, Taramani, Chennai. 600113, India. www.nbaindia.org

www.nbaindia.org, last accessed Dec 10, 2013



Any non-Indian person (or company/institution) who intends to obtain biological resources occurring in India or knowledge associated thereto for research or for commercial utilization or for bio-survey and bioutilization or transfer the results of research and apply for a patent must have approval under the BDR (2004; see Chapter-V (section 19)). Indian partners when partnering with non-Indian partners are required also to approval in the form of an ABS agreement³⁴ between itself and the obtain approval.³⁵ The NBA is required by the BDR (2004) to provide its biodiversity user or prospector that includes the above mentioned terms of utilization of genetic resources and TK, and benefits (including all aspects of technology transfer, as seen possible) arising from such utilization (Rule 14.6 of the BDR (2004). No person who has been granted approval under section 19 shall transfer any biological resource or associated knowledge without the permission of the NBA. The NBA is

³⁴ Rules 14, 17, 18 and 19 guiding Forms 1, 2, 3 and 4, respectively.

³⁵ Non-Indian prospective biodiversity users or prospectors often send in applications with Indian partners, with whom the collaboration is made. (Interviews: Natural Remedies, IHST (Nov., 2013) and FICCI (Dec., 2013)

to also give a public notice of every approval granted. The NBA is to, while granting approvals for the above mentioned use or transfer, ensure that the terms and conditions subject to which approval is granted secures equitable sharing of benefits arising out of use of accessed biological resources (Chapter V (section 21)). This assurance is be in accordance with mutually agreed terms and conditions between the person applying for such approval, local bodies concerned and the benefit claimers. The NBA shall determine the benefit sharing which shall be given effect in all or any of a set of categories (Table 1). These benefit sharing categories are clearly a set of technology transfer options.³⁶ The transfer of technology covers hard technology (equipment), whereas the other options in the list cover a range of soft technologies (BDA (2002), Chapter V. 21. (2): see Table 1).

Table 1: Benefit sharing categories listed in the BDA (2002) that the NBA considers as options as part of the approval to use biological resources and/or associated knowledge

Biological Diversity Act (2002). Chapter V. Approval by the National Biodiversity Authority	
(2)	The National Biodiversity Authority shall, subject to any regulations made in this behalf, determine the benefit sharing which shall be given effect in all or any of the following manner, namely:
А	Grant of joint ownership of intellectual property rights to the National Biodiversity Authority, or where benefit claimers are identified, to such benefit claimers.
В	Transfer of technology.
C	Location of production, research and development units in such areas which will facilitate better living standards to the benefit claimers.
D	Association of Indian scientists, benefit claimers and the local people with research and development in biological resources and bio-survey and bio-utilization.
Е	Setting up of venture capital fund for aiding the cause of benefit claimers.
F	Payment of monetary compensation and other non-monetary benefits to the benefit claimers as the NBA may deem fit.

³⁶ Discussions with: NBA (Drs. Pasupathi and Raghuram; Nov 2013).

(3)	Where any amount of the money is ordered by way of benefit sharing, the NBA may direct the amount to be deposited in the National Biodiversity Fund:
	Provided that where biological resource or knowledge was a result of access from specific individual or group of individuals or organizations, the NBA may direct that the amount be paid directly to such individual or group of individuals or organizations in accordance with the terms of any agreement and in such manner as it deems fit.

A National Biodiversity Fund has been constituted as per the BDA (Chapter VII) where funds credited are to include: (i) any grants and loans made to the NBA by the Central Government; (ii) all charges and royalties received by the NBA under the BDA; and (c) all sums received by the NBA from other sources as may be decided by the Central Government. The Fund is to be applied for: (a) channelling benefits to the benefit claimers; (b) conservation and promotion of biological resources and development of areas from where such biological resources or knowledge associated thereto has been accessed; and (c) socio-economic development of areas referred to in (b) in consultation with the local bodies concerned. In terms of biological resource use, this Fund, for example, is currently being used for holding funds obtained as benefit sharing in a project related to sea weeds (producing carrageen having gelatinous properties) where the decision of how the funds are to be used for the beneficiaries (local communities) is yet to be made.³⁷ This is reportedly the only project which has resulted in funds as part of benefit sharing (see Table 1 for list in BDA, 2002) to local communities over the last seven years. The SSBs (Fig. 2) play an important role in discussions and the decision of how the funds may be used in consultations with BMCs, where relevant. The NBA, through its expert group/committee, has a guidance role in assisting the SSB in this process. For example, in the above case. NBA is in dialog with the BMCs as to how the funds may best be used, where community development interventions and agricultural technology transfer are some options being considered.

In the course of the discussions for this study,³⁸ most of the actors directly involved in herbal medicinal development and having international collaboration tended to dwell on access, use and related 'expected' benefit sharing and technology transfer, in relation to the practice of the NBA based on the requirements of the BDA (2002). These discussion pointed to constraints posed by the NBA for drug development, as perceived by those involved in drug exploration-development nationally and though international collaboration. There appears to be awareness of such constraints among actors interviewed:³⁹ as related to the lack of the type of contracts which may facilitate initial screening

³⁷ Interview NBA, Dr. Raghuram (Nov., 2013)

³⁸ Interviews (Nov. and Dec., 2013)

³⁹ Interviews (Natural Remedies and IHST., Nov., 2013)

(scoping) of biological resources allowing for early-stage research, and realistic expectations of revenues and thus related benefit sharing. The NBA is considering and has recently employed paced contracts (with staggered payments which call for disbursements/payments during the steps of drug development or use of biodiversity) which do not bind the biodiversity prospector or users to one-time or fixed pre-determined payments.⁴⁰ The breaking of phases discussed included scoping/screening, development and actual market value prices (value chain assessments) to determine the potential market to decide upon a benefit sharing regime and thus the type of transfer of technology possible, where relevant.

India has also amended its Patent Act to provide for mandatory disclosure in patent applications that use biological resources, the source and geographical origin of biological material and traditional knowledge used in the invention. The Amended Patent Act also provides for pre- and post-grant opposition of applications and revocation of granted patents on grounds of non-disclosure or wrongful disclosure of source or geographical origin of biological resources and traditional knowledge. In this respect it also aims to assure that technology transfers options are considered where benefits may result from bio-prospecting, through disclosure.

5.2 Databases and Depositories

India has also developed a Traditional Knowledge Digital Library⁴¹ (TKDL) which is a digitized database of documented information available in ancient Indian systems of medicine, specifically the Avurveda, Siddha and Unani. The database is primarily aimed for consolidating all TK based knowledge of medicinal plants, providing and identifying TK basis of plants accessed, providing easy and controlled (monitored) access to public at-large and bio-prospectors, and assuring that benefits (and technology transfer) are considered in relation to access to TK based knowledge. The TKDL includes about 2.50 lakh⁴² (0.250 million)⁴³ medicinal formulations from 148 books available in the public domain. The information is made available to the public in English, French, German, Spanish and Japanese. The TKDL has been established by the collaborative project of the Council of Scientific and Industrial Research (CSIR), Ministry of Science and Technology and the Ministry of Health and Family Welfare's Department of Avurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH). The project was initiated as

⁴² Data accessed January 05, 2014. For prospective interested actors the site provides representative examples of 500 Ayurvedic formulations.

⁴⁰ abid. Case of ABS agreement related to *Dalbergia* spp. and *Satum* spp. seedlings with the University of Oman. This is not a case for herbal medicinal development but an example of how a step wise benefit sharing regime is paced out based on outcomes of the project, that is allowing for early-stage research/testing.

⁴¹ <u>http://tkdl.res.in</u>

http://tkdl.res.in/tkdl/langdefault/Ayurveda/Ayu_Home.asp?GL=Eng. Discussion with experts at IHST pointed to higher numbers as many formulations that have been gathered are not added yet, in addition to many which need gathering/compiling.

 $^{^{43}}$ 1 lakh = 100,000 in metric system (hundred thousand)

a mechanism to safeguard India's traditional knowledge (TK) after several international cases of exploitation of TK and patent grants (e.g., US patent no. 5,401,504 on turmeric; EPO patent no. 436257 on Neem). Such exploitation is believed to be on-going.⁴⁴ Part of the complication with misappropriation of patents is that Indian medicinal TK also exists in different languages (e.g., Sanskrit, Urdu, Arabic, Persian, Tamil, Nepali) that are not understood or fully known by patent offices and examiners, thus making it difficult to trace. Eventually the TKDL is to also serve to overcome this language and access barriers.

Access to the TKDL database is being provided to patent examiners under a non-disclosure agreement, to prevent the grant of patents on nonoriginal inventions. The non-disclosure agreement is between CSIR and the respective International Patent Office, with the conditions that access to the TKDL is granted only for patent search and examination, and examiners do not make third party disclosure of information on species or formulations. The access to the TKDL for International Patent Offices is expected to enhance India's negotiating strength in the international arena for securing benefits, and serve to work as a model to protect TK. The question remains as to when benefit sharing regimes and related technology transfer could kick in when plants in the database are used ("When do you go for the ABS agreement – which phase of development?").⁴⁵

Besides the TKDL there are a number of botanical gardens, herbaria and research institutes which house smaller and regional plant databases and collections:⁴⁶ based on TK from accounts in the written medical systems, in addition to those related to folklore and practice which are not in written form in the hands of practitioners (local communities, healers, ethnic groups, etc). The latter may stem from traditional written systems, but innovation through formulation and new discoveries are expected to have occurred and continue to take place over time^{47,48} (e.g., see the recent find of the *Jeevani* herbal medicinal, Box III). Technology transfer and benefits from medicinal plants and TK accessed from non-TKDL collections may be vulnerable to exploitation where benefits sharing and technology transfer may not take place or may not be on mutually agreed

⁴⁴ Interviews: M.S.S.R.F (Dr. Nambi, Nov., 2013); IFCCI (Dec., 2013)

⁴⁵ Interview. NBA. (Nov., 2013) Out of the current approximately 750 IPR applications 350 are related to medicines, and it is understood that few, if at all, will make commercial profits worth the investments.

⁴⁶ Discussions and observations at IHST, Bangalore. (Nov 2013). Plants in the botanical gardens are also use and accessible easily for exploring different uses, particularly useful also for making different compositions and proportions when conducting clinical trials. It is the differential use of a plant part (or extract) in combination with others which can determine it actual effectiveness. Thus the number of mixtures possible are numerous. See also Box I, Tropical Botanical Garden and Research Institute (TBGRI), Kerala. India. ⁴⁷ Shankar, D. and P.M. Unnikrisnan, (Eds.). 2004. Challenging the Indian Medical

Heritage. Center for Environmental Education. Foundation Books, Bangalore. Interview: IHST, Dr. Shankar (Nov., 2013).

⁴⁸ Interview: IHST, Dr. Venkat (Nov., 2013).

terms and fair. The TKDL aims to also bring all the scattered knowledge into one database.

Box III. An example of the discovery of a herbal medicine from traditional knowledge of tribal communities.

This plant is not in the Ayurvedic medicinal systems per se and its use was known only to the Kani tribals at the time of discovery.

In the case of the benefit sharing and technology transfer with the Kani tribals of the western Ghats in Kerala, India, a drug called Jeevani from Trichopus zelanicus was developed in 1995, and further studied for about 10 years. A rhizomatous and perennial herb, the plant is endemic to Kerala and regarded as a sacred plant by the Kani. It contains glyucocids and non-steroidal compounds: anti-stress and immune-restorative properties. Only leaves are required although the whole plants were uprooted for several years. Kani tribals are recognized as custodians of the knowledge and live in a Forest Reserve (Indian Forest Act, 1927). Designation of Forest Reserve as the Agasthyavanum Biological Park is planned. The researchers and botanists of the Tropical Botanical Garden and Research Institute (TBGRI), Kerala (largest botanical garden in Asia) accidentally noted its affect among the Kani while on a medicinal plant collecting field trip. The herbal medicine required the use of newer technologies for purification and processing which the Kani lacked. Thus the TBGRI conducted the testing and clinical studies. The technology of extraction and processing was transferred to an Ayurvedic drug manufacturing company, Vaida Pharmacy (Coimbatore) Ltd. A contract for benefit sharing lasted for 7 years: with the company and the Kani, with the TBGRI being the facilitator (in 2004). The Kani remained the suppliers. The IPR license was not shared with the Kanis but a trust fund was established as part of the benefits package. Attempts of cultivation by the Kani were successful but reportedly poor quality. The State forest department did not allow further cultivation or harvesting from the wild due to over-exploitation reports, resulting in the halting of the project.



Sources: Vijayan, A., V.B. Liju, J.V. Reena John, B. Parthipan and C. Renuka. 2007. Traditional remedies of the Kani tribes of the Kottoor reserve forest, Agasthyavanam, Triruvananthapuram, Kerala. Indian Journal of Traditional Knowledge. Vol. 6 (4):589-594;

Gupta, A.K. (updated report). Value addition to local Kani tribal knowledge: patenting, licensing and benefit sharing; see case reports on

www.uclan.ac.uk/genbenefit (Lessons learned for the Kani Case, Chaturvedi, S. 2008).

6 Diversity, traditional knowledge and health systems in India

6.1 Diversity: Is it of interest?

The vast majority of plants have yet to be screened for bioactive compounds, the knowledge of which requires basic to highly sophisticated technologies. It is estimated that more than two-thirds of the globally estimated number of higher plants species (250,000- 500,000) may have some compounds or chemical make-ups of interest singly or incombination with other active ingredients.⁴⁹ A small proportion of species have been used traditionally in India, in some case through simple extraction/combining technologies or in most cases without any technology at all. This use has resulted in a myriad of formulations, for mental, physical and social well-being: compositions based on properties of different plant species and parts, age and combined activity, and ailments and patient age to mention a few.⁵⁰ Both oral and written traditions exist in India.⁵¹ Plants and their components also make a vital contribution at the household level for food and nutritional aspects. In addition, home cures (often having a basis established herbal medicinal systems) are customarily used on a daily basis: with adjustments made in - standard and basic - formulations of remedies based on symptoms and at times in consultation with healers. Notably the special ailments and complicated symptoms fall under the realm of healers with traditional know-how acquired from traditional training under a guru,⁵² encompassing intensive training and oral teaching usually spanning a number of years. Healers draw from such traditional learning which is often only in oral form, while some healers also draw from written forms of pharmacopoeia (information that, which is to the point comprehensible). A different group, the most sophisticated healers or physicians are trained from the different written pharmacopoeias of India which require rigorous training over several years in established institutions of higher education in order to achieve their holistic approach. The wide use of medicinal plants through the various types of healers has at times led to over-exploitation. At the national level, India has funded (and continues to do so) technology transfer to medicinal plant production, to some extent through agricultural technologies for communities.³³

⁴⁹ Fransworth et al., 1985. Medicinal plants in therapy. World Health Organization, Vol.63:965-81

⁵⁰ ten Kate and S. A Laird. 1999. Shankar and Unnikrisnan, (eds.) 2004. Interviews: Natural Remedies and IHST (Nov 2013).

⁵¹ Personal observation. Interviews: IHST (Dr. Shankar), Natural Remedies and NGO. (Nov 2013)

⁵² Which is the traditional way of learning and transferring of the skills of medication and healing.

⁵³ See examples at the national level on the Council of Scientific and Industrial Research (CSIR)

http://www.csir.res.in/External/Utilities/Frames/achievements/main_page.asp?a=topframe .htm&b=leftcon.htm&c=../.././Heads/achievements/major_achievements.htm (accessed April 19, 2014)

In the recent years, international actors both from the pharmaceutical and herbal sectors, along with cosmetic and health sectors have shown increased interest⁵⁴ in learning and exploring the wide range of traditional practices and related diverse genetic resources bases. Interest is rooted in their potential for providing clues to: (i) species identities; (ii) species compositional knowledge based on use (treatment locally); (iii) knowledge of variation in efficacy related to type of symptoms and patient-age; and (iv) efficacy related of species in terms of habitat (locality), season and ecosystem.⁵⁵ For use of any species based on these clues would require technologies which would render products marketable in foreign markets: thus making transfer of technology an essential facet of TK based (or otherwise) medicinal prospecting and development. Notably technologies would be acquired within India for some areas or certainly, where amiable, through international collaboration.

The ethnic diversity in India is high and estimated as over 4,000 communities, mostly living in rural or in forested areas. There are reportedly varied medicinal practices based on the plant resources in environments where these communities live. The vast knowledge of healing often comprises of different sets of specializations, linked to different traditional vocations and traits of daily responsibilities. For example (not exhaustive): the Ambattaiva and Uppara women serve as birth attendants; the Kurubas community involved in cattle rearing make up most of the veterinarians; specialists for poisonous snake bites (visa vaidyas); and bone setters.

Local communities and ethnic groups thus form one of the key pools of knowledge which is attractive to both international and national herbal medicinal development sectors. Interest of the traditional knowledge users and Ayurvedic herbal medicinal producers in modern technologies is acknowledged by some actors interviewed for this study. Over time TK based herbal medicine development has benefited from new technologies particularly in yielding purer forms of active compounds. Thus the requirement for technology transfer among traditional practitioners, producers and knowledge holders is high. Agricultural technology for production of plants is also, generally, poor or lacking, especially where sound production systems may help in increased yields and viable quality of plants, and importantly reduce pressure on wild plants - thus contributing to conservation and sustainable use.⁵⁶ Similarly the profound knowledge base may potentially be obtained by international actors via technology transfer (i.e., through benefit sharing agreements in India) thus knowledge may be sought in both directions. The nature of the need and interest from both sides may well be the subject of technology transfer agreements.

⁵⁴ Interview: Natural Remedies and IHST (Dr. Venkat) (Nov 2013). FICCI (Dec 2013). Unpublished report (FICCI, 2011).

⁵⁵ Discussion with: IHST (Dr. Venkat), Natural Remedies, and NGO. See also discussions in chapters (5. Dhillion and Ampornpan; 8. Dhillion and Amundsen) in Svarstad, H. and

S. S. Dhillion (eds.) 2000. Responding to bio-prospecting: from biodiversity in the South to medicines in the North. Spartacus Forlag, Oslo.

⁵⁶ Interview: Natural Remedies (Nov 2013).

6.2 Traditional Health Systems, Knowledge and Ayurveda

Traditional health systems make use of a wide range of approaches covering physical, physiological and spiritual through the use of a spectrum of natural resources. Plants and their components are the most important ingredients of most medications in pharmacopoeia. India, like China, has several well established written traditional systems, e.g., Ayurveda, Siddha and Unani (Fig. 3). In addition, there are oral traditions which are kept alive and undergo innovation through generations. India thus provides a unique opportunity based on the written traditional pharmacopeias for exploration for modern drug development: from traditional methods in combination with or only use of new technologies.⁵⁷ There are estimated 50,000 herbal formulations documented in Indian texts based on 2600 plants,⁵⁸ all anchored in traditional methods, holistic approaches and on complex physical and non-physical interactions. Of the traditional systems of medicine existing in India, the Ayurveda system is the most known and best documented, and the one of much interest to International actors.⁵⁹ It is also perhaps the system that lends itself to exploration both through basic technology transfer, one that may be utilized communities and by small producers, and highly sophisticated technologies.

The Indian pharmacopoeia of *Ayurveda*, like the other Indian systems, has an age long unbroken history rooted in the Indian subcontinent with off-shoots forming local medicinal systems in the middle-east and south-east Asia. The oldest existing document on available plants is the *Ausadhi* sukta in the *Rig Veda*,⁶⁰ in which the hymns (*Mandalas*) provide plant

⁵⁷ Recognizing the profound influence of R&D on the prospects and opportunities for the growth of the Indian Drug Industry, Department of Science and Technology (DST), Government of India mounted a programme on drug development during 1994-95 for promoting collaborative R&D in drugs and pharmaceuticals sector (including herbal and traditional system based medicine) with the following specific objectives. Although the focus has been almost entirely national there is room for collaborative work with international actors. During January 2004, Government of India established Drug Development Promotion Board (DDPB) under the administrative control of DST for supporting R&D projects jointly proposed by industry and academic institutions/ laboratories and to extend soft loans for R&D to the drug industry. Many projects have been started on Ayurvedic medicinal. http://www.dst.gov.in/scientific-programme/td-drugs.htm (accessed April 14, 2014). See also more details on the website of the Ministry of Science and Technology, Department of Science and Technology (DST).

P.M.Unnikrisnan. 2004. *Challenging the Indian Medical Heritage*. Centre for Environmental Education. Foundation Books, Bangalore.

⁵⁹ Interview: FICCI (Dec 2013); Natural remedies and IHST (Dr. Venkat) (Nov 2013). Unpublished report (FICCI, 2011).

⁶⁰ Rig Veda, Section 10, Chapter 97, Verses 1-23. For Vedic hymns see accompanying documents. The Rig Veda is one of the oldest extant texts in an <u>Indo-European language</u> (<u>Sanskrit</u>) composes in the north-west India during the early Vedic Period, 1700-1100 BC. It is a sacred collection of <u>Vedic Sanskrit hymns</u> (*Mandalas*), many of which are still recited on a daily basis by individuals and during religious rituals including weddings, births and cremation ceremonies. It is counted among the four canonical sacred texts (<u>śruti</u>) of <u>Hinduism</u> known as the <u>Vedas</u>. The Vedas contain mythological and poetical

morphological characteristics, their habitat occurrence and therapeutic use classification based on effects on other species. The post-Vedic period is believed to have given rise to a unique way of understanding plants organized as a pharmacopoeia called the Avurveda. The earliest available text of the Ayurveda is the Caraka Smahita (1500 BC - 400 AD), providing a detailed description and medicinal value of approximately 600 plants. The Caraka Samhita forms the start of a large number of texts of the Ayurveda Pharmacopoeia (e.g., the samhitas (treaties); samgrahas (compendiums); nighantus (lexicons); vyaskhyas (critical treaties); the pharmacy specialists (Bhaisajya kalpana on pharmacy text). Ayurveda is also unique in that classification and nomenclature serve different purposes in medication,⁶¹ which makes the knowledge system complex and rich with medicinal compositions. The system, like other traditional systems, is not based on modern technologies (and methodologies) and thus the Ayurvedic formulations still require validation⁶². For most cases the use of modern technologies would provide acute insights to the efficacy of the formulations or rather their components.⁶³ Given this, the need for sophisticated technologies cannot be underestimated.

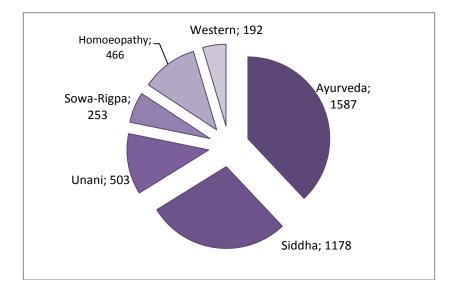
The need for technology in Ayurvedic medicinal applications is high. Despite recorded and established medicinal systems being in use for more than 3000 years, few properly designed trials have scientifically examined the clinical potential of Ayurvedic and other medications.⁶⁴ Thus there has been a gradual surge of interest in traditional medicine in the pharmaceutical industry (including herbal) as evidence-based studies using sophisticated technologies - on the efficacy and safety of traditional Indian medicines become essential to the success of a drug. Furthermore, the proportions of essential ingredients in most traditional written formulations are not precisely defined and are thus subjectively used, in practice, apparently relying on the experience of the Ayurvedic expert and severity of the ailment: this is where innovation occurs through experience and trails. Given this, there is an undisputed necessity to revisit actual ingredients as practiced today through the use of newer technologies, which appear to be often lacking at present. This opens up for the need for pharmaceuticals to conduct field studies (interviews, inpractice observations and new collections) and scientific tests/trails requiring technology (for trials using local - traditional - knowledge, resource access, sophisticated extraction techniques, and testing

accounts of the origin of the world, honoring gods, and ancient prayers for life, prosperity, longevity, health, etc.

⁶¹ Lal, B.B. 2005. The Homeland of the Aryans. Evidence of Rigvedic Flora and Fauna & Archaeology, New Delhi, Aryan Books International. IHST Institute Library, Nov., 2013
⁶² Validation would include a wide range of technologies and methods, ranging from sustainable collections in the wild, approved drying techniques/equipment, extraction and purification techniques to importantly sophisticated testing. All these basic steps require technologies which are acceptable internationally and thus call for technology transfer, capacity/skill building, and adaptability.

 ⁶³ Biswas TK and B. Mukherjee (2003). Plant medicines of Indian origin for wound healing activity: a review. Int. J. Low Extreme Wounds. 2(1):25-39; Lodha R. and A. Bagga 2000. Traditional Indian medical systems. Ann Acad Med Singapore. Jan;29(1):37-41. Interviews: IHST (Nov 2013)
 ⁶⁴ Ibid.

arrangements). Thus the need for technology transfer within India and from abroad can be seen as significantly high. In addition, local oral traditional healing and medicaments abound, as mentioned earlier, especially among the many ethnic groups in India. These continue to form a pool of underestimated and unwritten knowledge base which has a high potential for exploration (for example, the new Ayurvedic herbal Jeevani, Box III). Several actors reiterated the importance of this oral knowledge base as a source for - new and refined - herbal medicinal development, where obvious technology needs arise. One actor,⁶⁵ however, expressed that traditional remedies were well known ('old') as they are written and known to all (for example, the Ayurvedic formulations are in the public domain) and thus exhausted for any new or unknown uses (with no innovation occurring). This opinion condones the idea (of some actors) of less stringent needs for protection of existing written documentation of traditional medicinal systems and easier openings for agreements (i.e., ABS ones) for further study (medicinal development) and thus technology transfer for both national and international companies.





⁶⁵ Interview: IFCCI (Dec. 2013).

⁶⁶ From Sudharkar Johnson, T., R.K Agarwal and Amit Agarwal. 2013. Non-timber forest products as a source of livelihood option for forest dwellers: role of society, herbal industries and government agencies. Current Science Vol. 104 (4): 440 - 443.

7 Actors, Typology, Perceptions and Experiences

7.1 Actors, Their Activities and Possible Technology Transfer

Technology needs may be best mirrored through the actors involved in herbal/Avurvedic plant identification, collection and production, development and market, ranging from large scale industry, government laboratories to households (Box IV). The private industry in India stands independently with its own drug development laboratories and it perhaps has the highest potential for forming liaisons with foreign companies, particularly where the interest from foreign industries is in TK based medicines. The challenge here lies in getting joint access to the TK and genetic resources for medicinal development, based on tangible and realistic technology transfer and benefit sharing. Herbaria and botanical gardens are attractive repositories of information, some of which have laboratories of their own (e.g., IHST (FLHRT); TBGRI,67 MSSRF) where screening of plant components for active compounds and extractions are carried out on a routine basis. Some of the researchers have a significant international publication record, making them attractive for collaboration for international actors (particularly laboratories, pharmaceutical companies, universities and health product developers). There are also innovative constellations of some of the institutions: where public herbaria are institutions of learning offering degree level education (up to doctoral level) and also have laboratories which are open to soliciting collaboration for drug development with foreign industry. One example is that of the IHST,⁶⁸ which has explored such ventures, although, there was clear expression for the need for expert legal and negotiation advice when it comes to international actors. In addition, a need for clearer guidelines of how one is to operate with 'stronger and experienced' international actors, was voiced. The latter is seen as a particular need among the actors which are not organized,⁶⁹ these being the medium to small industries, small businesses (some set-up on an ad hoc basis⁷⁰), and communities and ethnic groups. There is apparently a lack of knowledge on how to deal with genetic resources when approached by international actors where 'leakages' (of genetic resources and TK) are common: especially among small industry and suppliers⁷¹. The movement of genetic resources or their products (for example, extractions) from the national arena to the international is unmanaged at present⁷² (Fig. 4). It is not clear how the smaller actors (particularly suppliers) are organized, although the government institutions and large industries are organized⁷³ and appear to be more aware of government regulations (i.e.,

⁶⁷ IHST (previously FRLHT/I-AIM) – The Institute of Trans-disciplinary Health Sciences and Technology (visited in Nov 2013) and TBGRI – Jawaharlal Nehru Tropical Botanic Garden and Research Institute. <u>http://www.jntbgri.in</u> (located at Palode,

Thiruvananthapuram, Kerala, India.

⁶⁸ Interview: IHST (Dr. Venkat, Nov., 2013)

⁶⁹ Interviews: Natural remedies, MSSRF, IHST (Dr. Venkat) (Nov, 2013)

⁷⁰ Interview: NGO (Nov., 2013) and personal observations (May 2013)

⁷¹ Interviews: Natural remedies, (Nov., 2013)

⁷² Interviews: Natural remedies and MSSRF, (Nov., 2013) and IFCCI (Dec., 2013)

⁷³ As associations.

those under the governance of the NBA) and procedures for genetic resource transfer across borders.⁷⁴ There are also actors which function as facilitators, working as inter-mediatory agents between communities and users (for example, industry and academia).⁷⁵

Box IV. The types of actors supplying genetic resources point to the likely technology needs in India. Actors involved in the herbal medicinal sector in India and those who are likely suppliers of genetic resources in the form of identities, use, extracts and products in exchange for technology transfer. Note that there are also actors who are only users of genetic resources or both users and suppliers (see Figure 4) i. Industry (large, medium and small) Local and ad hoc businesses (herbal suppliers and collectors, ii. middlemen) iii. Ayurvedic pharmacies/treatment centers iv. Health-cosmetic providers and practitioners (including spas) v. University and research institute laboratories Government laboratories without data bases vi. Government institutions with data bases vii.

- Botanical gardens and herbaria/repositories with laboratories viii.
- Botanical gardens and herbaria/repositories without laboratories. ix.
- Communities and ethnic groups (TK bearers; specific and general x. healers; folklore based healers; cooperatives; households; growers; collectors)

Source: observations and interviews (this study, Dhillion)

Increasing the quality of genetic material and derivatives can allow for greater options in technology demands, or at least negotiating leverage. One of the interesting aspects of the industry sector in India is that it has been active in establishing standards for extraction qualities, which are vital and attractive for foreign actors (e.g., Natural Remedies Pvt. Ltd. has been recognized internationally for setting standards, making it attractive for international actors to call upon for testing extractions for herbal drugs). For example, "Many large Indian companies maintain highest standards in Purity, Stability and International Safety, Health and Environmental (SHE) protection in production and supply of bulk drugs even to some innovator companies. This speaks of the high quality standards maintained by a large number of Indian Pharmaceutical companies as these bulk actives are used by the buyer companies in manufacture of dosage forms which are again subjected to stringent assessment by various regulatory authorities in the importing countries. More Indian

⁷⁵ IHST and Natural Remedies (interviewed). NBA (2012). Community Based experiences on access and benefit sharing. See also example of the Jeevani (Box III).

⁷⁴ Interviews: IFCCI (Dec., 2013), Natural Remedies and NGO (Nov., 2013)

companies are now seeking regulatory approvals in USA in specialized segments."⁷⁶ The purely herbal companies are also included in this group of Indian companies and thus establishing high standards, for example., Natural Remedies, visited in Nov 2013 has established standards for biochemical and ADME assays for 80 chemicals all of which have a pharmacological relevance, including diabetes, cholesterol lowering, antibacterial, and atherosclerosis, to mention a few.⁷⁷ It also has reference substances for Quality Control and Standardization of herbal products with a purity high level of purity (Purity > 95%) which is attractive for international partnership for herbal medicinal development. These standards of international ranking are beginning to serve as benchmarks for the actors in the sector, in India.

Private industry is self-investing in herbal medicinal development,⁷⁸ although apparently there are some start-up funds available from the authorities. The major part of the funds for public actors (for example, government institutes, some universities and laboratories, databanks and herbaria) are from government sources while donors have been an important source as well.⁷⁹ It is also noted that herbal medicinal development projects may be instigated through joint ventures, i.e., public-private partnerships (for example: industry with (i) herbaria which have laboratories, (ii) *Ayurvedic* treatment centers, Universities and government laboratories, and (iii) communities).

Given that Ayurvedic treatments are more than 5,000 years old in India the whole sub-continent region has an Ayurvedic treatment market, presumably concentrated in South India although the North abounds of Ayurvedic treatment and training centers. Most hospitals in India have Ayurvedic treatment sections and wards. There are large markets in the surrounding nations and in south-east Asia, apart from growing markets in Europe and North America. There is trend in health and recreation investing through mergers with Ayurvedic pharmacies, supplies and treatment centers (some of which are in government Ayurvedic training institutions).⁸⁰ The Ayurvedic market (which is also a part of the Beauty and Rejuvenation market) is estimated at INR 40 billion in 2009.⁸¹ India is a popular and growing destination for Ayurvedic therapies not only for Indians but to a large number of foreign tourists. The number of growing local spas and Ayurvedic treatment centers are a clear attest to this. In addition, medical tourism in India is therefore growing at a rate of 12 percent per year, and its export is increasing sort after although it is hindered by the fact that herbals are not allowed for production abroad if there is transport of genetic material.⁸²

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⁷⁶ <u>http://indiainbusiness.nic.in/industry-infrastructure/industrial-sectors/drug-pharma.htm</u> (accessed Nov. 18, 2013).

⁷⁷ Interview: Natural Remedies (Nov., 2013). www.naturalremedy.com.

⁷⁸ Ibid.

⁷⁹ Interviews: IHST (Dr. Venkat, Nov., 2013) and IFCCI (Dec., 2013)

⁸⁰ Similar to western medical schools which are often affiliated with hospitals.

⁸¹ Research on India, Wellness Services Market Report, 2010

⁸² Interview: IFCCI (Dec., 2013) and personal observations.

Technology transfer needs in India can also be understood better by identifying the actors in the domestic and international medicinal markets, where there are both suppliers and users of products of genetic resources. The national (domestic) market is composed of raw material collectors and cultivators supplying herb middlemen and suppliers, and research institutes and herbaria (Fig. 4). The domestic market actors supply to a range of actors, catering to different needs: research, health and beauty, and healers. The largest share, however, goes to the established herbal companies and research institutes. The latter two further feed the international export market through a variety of mechanisms. Some domestic suppliers also reach out to the international market, especially for herbal (beauty) cosmetics and spas, along with some herbal medicines.⁸³ The scope of technology transfer types has to be made sensitive to the type and role of actors involved in the transfer of genetic resources or derived products, their precise activities in the supply chain and importantly their ability to absorb and adapt technology. Thus technology and its transfer have to be tailored to the actor/s involved in the transactions: where not all types of technology may apply.

⁸³ Interview: IFCCI (Dec., 2013)

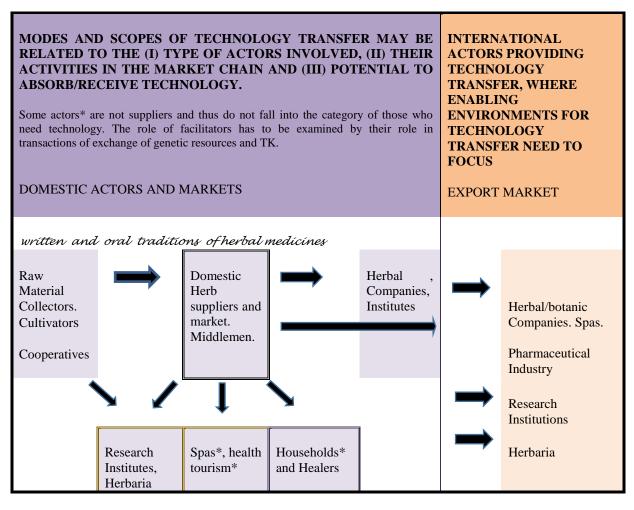


Figure 4

Traditional medicinal (*Ayurvedic*) pathways and actors in the national and international markets point to the potential scope of technology transfer

7.2 Typologies of Technology Transfer in the Indian Setting

During the life-time of the Convention the technology transfer has not been an easy process particularly when it comes to transactions involving traditional knowledge. Governments, as in India, are required to facilitate transfer and not impede the flow of knowledge.⁸⁴ The current process involves the NBA deciding on the type of benefit sharing or technology transfer which would be appropriate for a specific application for use of a genetic entity or product.

In India, almost all actors interviewed and reports point to experiences (direct or indirect) that have encompassed the above types of technology in one way or another, over time, although specific identities of techno-

⁸⁴ Interviews: Natural Remedies (Nov., 2013) and FICCI (Dec, 2013)

logies were not always very clear and, in fact, if technology transfer actually took place. It was obvious that actors are open to a wide range of possibilities within certain limits and keeping with potential market values, while equity and community concerns were important to some of the actors. Nevertheless, the most preferred and relevant current technology transfer was related to the sharing of patents⁸⁵ (and related revenues), at least among actors involved in development and screening processes. This interest is partly due to the fact that in-house (national) technology status (skills, know-how and competencies) are of a high standard, as India has in the last decade managed to encourage the establishment of highly skilled laboratories in the public and private sector: and thus attempted to create an enabling environment for international collaboration.⁸⁶ There is less need for the established actors to search for training from abroad for a number of technologies. This, however, does not include many of the medium and small size industries and many poorly financed government laboratories and learning institutions, which would still benefit highly from training skilled workers and obtaining expensive equipment in exchange for genetic resources, TK and their products.

The typologies of technology transfer that are negotiated depend highly on the recipient and, in practice, where the need may often be short-term based and product oriented. Rarely are long-term perspectives included or considered.⁸⁷ Need assessments are rarely done to decide on what technology would be sustained over time and possibly transferable. Recent global discussions call for a closer look at needs assessments for technology transfer⁸⁸ which was also seen as vital by several Indian actors. Some actors⁸⁹ and the NBA expressed that benefits or technology transfer may be more directed to development aspects for communities, where relevant. However, there is concern over what such benefits could encompass and when these should be expected in the time-line of the drug development process. Decisions are believed to be best made when some prospective drug development is seen as plausible after initial screening.⁹⁰ International actors are not willing to commit to technology transfer agreements without having some clue of possible products. Several actors reported on international actors pulling away after understanding the binding ABS requirements required at the onset of the herbal medicinal development process. Several actors suggest the need for more openness in granting plant screening or testing of single species

⁸⁵ What circumstances prescribe joint ownership? This is particularly complicated if the product is unmodified and it has roots (or similar use) in traditional knowledge. See also WIPO/GRTKF/IC/7/9 where ramifications are discussed.

⁸⁶ Discussions with: IFCCI (Dec., 2013) and IHST (Nov., 2013)

⁸⁷ Discussions with: NBA, MSSRF and IHST (Nov, 2013), IFCCI Dec, 2014)

⁸⁸ Pisupati, B. 2010. Technology transfer and cooperation under the Convention on Biological Diversity. IUCN, Kenya.

⁸⁹ Interviews: Natural Remedies (Nov., 2013) and IFCCI (Dec., 2013)

⁹⁰ Interview: Natural Remedies (Nov., 2013)

⁹¹ Discussion with Natural Remedies, IFCCI and IHST.

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extractions:⁹² that is, easing the early development or bio-prospecting process (i.e., early stage research process). Conditional or paced agreements on benefit sharing prospects as suggested by NBA are not always seen as conducive to international and national actors when no initial tests of the raw product (extract) are done: "*it is always too early to foresee what benefit sharing would result in, and it is not right to increase expectations of communities and suppliers*", explained one actor⁹³ directly involved in such transactions. Initial screening (initial testing) is still largely done by the international actors (in-house) to assure quality, although there is apparently a gradual increase in trust among international actors on the quality of materials from national actors (due to established standards).

Typologies of technologies related to herbals and medicinal plants have been rather generic and technical based (e.g., equipment, training, basic laboratory processes, education) with less focus on precise needs or potential spin-offs for broader benefits or capacity building aimed at local actors (knowledge holders, collectors, growers, suppliers, Fig. 5).⁹⁴ Its functional role as a trigger to development in India is uncertain, particularly in relation to the unorganized actors (suppliers of genetic resources) of the sector: the growers, supplies and knowledge holders.⁹⁵ Access to and the use of biodiversity are said to be significant constraints to development as these differ for and among product developers, as the ability of suppliers to process the raw product into the development line varies.⁹⁶ The requirements of the BDA (2002), and that the adequacy of benefit sharing options (see Table 2) are to be analyzed and decided by the authorities of the NBA are seen as stringent and "unreasonable" by some actors⁹⁷.

Actors interviewed in this study provided their perceptions of where constraints and bottlenecks may occur in the process of gaining technology or benefit sharing in general (Appendix III, Table 1). The main issues raised were, that when working with international actors there is a need: (i) of understanding of the regulating requirements and options for the transfer of technology, as this is lacking across many actors; (ii) for obtaining legal assistance in negotiating and contractual aspects allowing for maximizing technology transfer and equity; (iii) for easing the requirements and process for conducting early screening or research (consider having specifically designed contracts); (iv) for the finalization

⁹² There have been cases where interested international actors (industry) have not been granted the possibility of conducting an initial screening for checking the purity of an extract. This was partly to be done to check the quality of material and extracts that the prospective Indian industrial partner would deliver. Interviews with: Natural Remedies, IFCCI and HIST (Nov. – Dec. 2013)

⁹³ Natural Remedies (Nov. 2013); point also supported by IFCCI (Dec., 2013)

⁹⁴ See technology transfer in <u>www.cbd.org</u> and discussions in Schei, P.J. and O.T. Sandlund (Eds.), Conference Proceedings. The Norway/UN Conference of Technology transfer and Capacity Building, Trondheim, Norway. pages 240. Discussions with: FICCI and IHST (Nov-Dev 2013)

⁹⁵ Discussions with: FICCI, Natural Remedies, NBA (Dr. Raghuram) and IHST (Dr. Venkat) (Nov-Dec 2013)

⁹⁶ Discussions with: FICCI (Dec 2013) and Natural Remedies (Nov 2013)

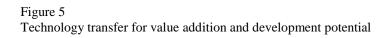
⁹⁷ Discussions with: FICCI (Dec., 2013) and Natural Remedies (Nov., 2013)

of Indian red species lists; (v) for assurance of equity (for communities); (vii) for information to communities/individuals who are suppliers or proprietors of TK/genetic resources on technology options, and; (viii) of attention on gender sensitive technology options. These issues were seen as those calling for attention of and action from the NBA by the stakeholders requiring access to genetic resources associated TK.

Several of those interviewed emphasized the need to focus on community development and capacity building as a key technology transfer or benefit sharing option, however, there are uncertainties of how these would be manifested. This point of view touches on those iterated by global community discussions on the fact that there are few illustratively good and sustainable public-private partnership and related development benefits to rural communities and to those who harbor traditional knowledge. Development here included capacity building in the chain of herbal medicinal development as well as contributing to rural community development in terms of health, education, infrastructure and agricultural technologies. Further exploration of potential areas of technology transfer along a pathway for herbal medicinal development and bio-prospecting at-large where spin-offs for communities can result is needed (Fig. 5).⁹⁸

⁹⁸ Discussions with: NBA, Natural Remedies, IHST (Dr. Shankar) (Nov. 2013) and IFCCI (Dec. 2013).

P		Examples of levels of medicinal development and areas of technology transfer requiring knowhow and for yielding products: pointing to potential development spin-offs for local actors and holders of traditional knowledge		
		Level 7	Producing high quality phyto /herbal medicines meeting regulatory requirements and with major marketing potential.	
	ospecting a	Level 6	Technology transfer to medium to large industry. Producing herbal medicines, cosmetics, purified and isolated compounds. Technology transfer to small – large industry.	
er for bio-pr		Level 5	Producing dietary or veterinary feed supplements. Technology transfer at the industry and community levels, and research institutions. Low development potential at the community level.	
	ology trans	Level 4	Producing purified extracts Technology transfer at the community level, small- medium industry and research institutions. Some development potential in local communities.	
	Increasing value addition through technology transfer for bio-prospecting and herbal medicinal development	Level 3	Producing sorted, clean and dry plant parts . Technology transfer at the community level and small- medium industry. High development potential in local communities.	
	dition t	Level 2	Production and harvesting techniques (agriculture technology).	
	lue ad nal d		Technology transfer at the community level or individual level. High development potential in local communities.	
Increasing value addition thro herbal medicinal development		Level 1	Collection harvesting techniques. Technology transfer at the community or individual level. High development potential in local communities.	
	Inc			



8 Conclusion

This study explored a number of issues related to technology transfer with a particular focus on India asking questions on, mainly: the typologies, actors and institutions, perceptions and mechanisms. The paper explores these issues for herbal medicine development and the use of medicinal plants.

There are a range of actors involved as suppliers of genetic resources, TK and those that have potential to receive technology. The option of the technology has to be tailored to the nature of the actor involved in the transaction. Although technology provided as a monetary transfer appears to be preferred, the NBA calls for the setting up of Funds which may be used by suppliers. For suppliers like the industry or university laboratories (generally through collaboration) the transfers are specific to agreements based on contractual negotiations. The preferred technologies can be in the form of sharing of IPR and revenues, and, where possible, scientific publications. Nevertheless the actual type of transfer has to be reflected by the nature of the exchange, the needs of the actor, and the ability of the actor to absorb the technology and importantly to adapt it. There are hard technology needs in India specifically among the medium industry and laboratories in academic institutions (universities) and herbaria/gardens, and certainly among the small industry and communities. Among the latter group, supply has to move from raw products to more sophisticated products, including high quality extractions, drying techniques, propagation, cultivation and harvesting techniques, and agricultural production of herbs: thus traditional knowledge based medicinal suppliers (lower part of the chain, including communities) require technology transfer to increase product usability (value addition technologies) for exploration by both international and sophisticated national actors. All these point to the necessity of assessing what the actual needs are of the actors, through the Technology Need Assessments (TNAs). Such assessments cannot be simply sweeping generalizations, and do require inclusion of participatory approaches. The wider applicability and sustainability of technology transfer should also be a vital consideration. Technology transfer or benefit sharing may not be absolutely clear at the onset for any herbal medicinal development project (as pointed out by several actors), like drug development, it moves through several steps, including scoping/screening/research, development and actual marketing. These steps may need to be considered closely and value chain assessments conducted to determine a benefit sharing and technology sharing regime in each case, something that actors call for in India. The ramifications of increasing expectations of benefits among suppliers have to be considered through mechanisms of information provision and sharing of real scenarios/cases.

At present there are no specific mechanisms that facilitate interest and increase in technology transfer as part of benefit sharing. The NBA implements the BDA (2002) through a process for agreements for ABS, thus granting access to genetic resources and TK. In respect to these the

NBA has a slew of benefit sharing options (categories listed in the BDA, Table 1) which are explored. The major hindrance and constraints reported by actors with and potential international collaboration for herbal medicinal development are the lack of (i) contracts which may facilitate initial screening (scoping) of biological resources and (ii) understanding and realistic expectations of revenues and thus related benefit sharing. In this regard the NBA is considering and has recently started to employ paced contracts: allowing for payments during the steps of drug development or use of biodiversity, thus not binding the biodiversity prospector or users to one-time or fixed pre-determined payments. At present such contracts appear to be done on an individual basis, are not the norm, and there are no related application forms or guidelines available.

There are official data bases, data banks and collections of plants based on TK at-large and Ayurvedic systems in a number of institutions. Only the TKDL has a system for extraction of information on herbal plants for international and national (including those collaborating with foreign actors) actors. However the current system was criticized for not having provisions or guidelines for its use and contractual requirements between international and national contractors: thus making it difficult for some national actors to explore benefit sharing and thus technology transfer possibilities, let alone negotiate contracts with international actors.

There needs to be targeted effort put into linking technology transfer options into conservation and sustainable use of genetic resources. The potential to allow for substitutions of extracts from plants in Ayurvedic medications that may require conservation or those which are threatened needs to be explored. Substitutions could allow national and international actors to market the product as Ayurvedic even though some of the extract is substituted. Funds and technologies may be directed to conservation of ecosystems or habitats from which specific plants are used rather than just be targeted to one species. Important, is also the issue of an incomplete list of red species in India, which may be used as a vardstick for allowance of use and monitoring. The list of technology transfer options in the BDA call for prior informed consent (PIC) and agreement on benefits among the different actors involved: particularly the suppliers and users. The roles of middlemen/facilitators, and BMCs and SSBs is perceived as vague by several of the actors (users) who require access and use of the plants. A closer study is required of the role of the users in negotiating and deciding on the technology transfer options that the suppliers may consider. There is a clear need for balancing the roles of different actors in collectively deciding technology transfer.

Key consideration and reflection is required on facilitating technology transfer based on where there is a lack of appreciation and knowledge in India. Key issues that need further study and understanding include:

i. Knowledge of different actors on access and use regulations and procedures, elaborating on different natures of the genetic resource in question.

- ii. Reflections on factors that affect technology transfer, like needs (long and short-term), the nature of the actor and ability to accept/absorb and adapt the technology in question. Technology needs assessments must be sensitive to these factors.
- iii. Role of the different actors, including middlemen and facilitators as providers of genetic resources and traditional knowledge based herbal medicinal information
- iv. Role of Communities/Stakeholders as providers and holders of knowledge.
- v. Technology transfer mechanisms that have worked and those that may work in the future, with an acute understanding of the likelihood of benefits from different stages in India: e.g., herbal medicine screening, development and revenue generation. Information on these has to be shared. Clear elaboration of past or existing examples illustrating time-lines for development, range of transactions and contracts, and benefit sharing for sharing with actors (particular communities)
- vi. Establishment of independent committees to assist with negotiating and deciding on technology transfer (and benefit sharing) options. All relevant actors should be allowed to participate in decision making, where possible. Make absolute clarity (transparent) in process that is used at present.
- vii. Revisit typologies of technology transfer to include those which directly contribute to conservation and sustainable use of medicinal plants and related ecosystems. Explore wider inroads and not limit contributions to conservations and sustainable use only to those related to ABS agreements.
- viii. Set-up clear monitoring and compliance processes.
- ix. Working towards completing red list species and revisit the idea of substitution of components of traditional medicinal recipes when these contribute to conservation and sustainable use of biodiversity of threatened species.

India has opted to include technology transfer under the umbrella of benefit sharing and not as a standalone mechanism. The Convention and the Nagoya Protocol deal with the technology transfer and ABS separately as distinct issues. In practice it has been useful to consider access and benefits for medicinal plants in India: the inclusion of technology transfer is a natural part of the discussion over benefit options in bioprospecting processes. In addition, importantly, the inclusion of technology transfer (see typologies in Box II) as part of the benefit sharing package is generally considered in unison with benefit sharing by international bio-prospectors in India. The typologies for benefit sharing (including technology transfer) in the BDA (2002) include most of the categories suggested in the Bonn Guidelines, although as pointed out above there is a need for flexibility depending on the nature of the project, need, capacity and adaptability. For medicinal plant use (bioprospecting) based on TK, India's strategy of a utilizing an overall benefit sharing regime has worked so far although there are several elements which need further nuance (see list above). As for other areas than bio-prospecting, technology transfer may need to be considered separately, for example, for ecosystems services, protected areas and conservation at-large. Here other pathways to stimulate transfer of technology have to be considered.

Linking other international activities and that of the Convention

Technology for conservation and sustainable use of biodiversity ought to explore wider inroads as challenges for making transfer possible are multi-faceted and often cross ABS borders. Pathways to enhance technology transfer need not to be just confined to the ABS mechanisms and processes. There is a need to look at several other inroads to achieving a momentum that makes a contribution to conservation and sustainable use of biodiversity. Activities conducted under other multilateral environmental agreements ought to be used as learning platforms to trigger technology transfer, through complementing or supporting these through the Convention. The review conducted by the PoW revealed that several other bodies/MEAs were conducting technology transfer activities (such as capacity building and training) which were related to biodiversity, although not always connected to the Convention. The typologies of technology transfer may be extended through indirect mechanisms associated with other international initiatives and activities of MEAs. For example; conservation of biodiversity and ecosystems is often in-build in climate activities which call for adaptation mechanisms: biodiversity conservation is a pivotal goal, through soil and biota management, to retard desertification processes; REDD+ initiatives which have implicit biodiversity conservation and habitat/ecosystem components; impact assessment requires the handling of the conservation of a wide range of biota (fauna and flora, including avifauna and aquatic species), and; green technologies which build on the assumption that conservation is central to their success. The typologies of technology transfer that the Convention can further explore and extend into require a detailed analysis of activities of other MEAs and global initiatives. COP activities could explore such linkages for addressing technology transfer objectives.

8 Acknowledgements

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9 Appendices

Appendix I. Interview list

Appendix II. Questions to Guide Open-Ended Discussions

Appendix III. Some Perceptions from Actors

Appendix I Institutions Visited, and Names and Addresses of Interviewed Experts

No	Institution	Name and Title/Position	Address and Contact	Date (2013)	Comments
1	National Biodiversity Authority (NBA)	Dr. Balakrishna Pisupati Chairman of NBA	National Biodiversity Authority (NBA). 5th Floor, TICEL Bio Park, CSIR Road, Taramani, Chennai - 600 113. <u>www.nbaindia.org</u>	Nov. 25 and 27	Government Agency Funding government and donors.
	(location for CEBPOL)		Tel: +91 44 2254 1805. Fax: +91 44 2254 1073. E-mail: <u>chairman@nbaindia.com</u>		
2		Dr. C. Thomson Jacob, Consultant	UNEP-GEF ABS Project and Coordinator of CEBPOL <u>ecbd@nbaindia.in</u> 9003071833 (mob)	Nov . 25	
3		Dr. J. Soundrapandi Consultant (EC)	Medicinal Plant Expert, NBA <u>ecmedplant@nbaindia.in</u> 9841951267	Nov. 25	
4		Ms. Alphonsa Jojan, Junior Legal Consultant	Jrcl2@nbaindia.org 9025253675	Nov. 25	
5		Dr. K. P Raghuram. Technical Officer	tech@nbaindia.in +91 44 22542777	Nov. 25	

No	Institution	Name and Title/Position	Address and Contact	Date (2013)	Comments
6	M.S.Swaminathan Research Foundation (MSSRF)	Dr. Ajay Parida, Executive Director	M S Swaminathan Research Foundation Third Cross Street, Institutional Area, Taramani, Chennai 600113. <u>www.mssrf.org</u> Tel: +91 44 2254 1229, 1698. Fax: +91 44 2254 1319. Direct: +91 44 22542702 <u>ajay@mssrf.res.in, executivedirector@mssrf.res.in</u>	Nov. 26	Private, donor projects and private funding
7		Dr. V. Arivudai Nambi Director- Biodiversity (and Member of Tamil Nadu Biodiversity Board (TNBB))	Direct: +91 44 65481522 nimbi@mssrf.res.in		
8		Ms. Manjula Traditional knowledge Expert			New to institute
9		Dr. A. Arivudai Nambi Director- Climate Change Programme	anambi@mssrf.res.in, arnambi@yahoo.com Tel: +91 44 2254 1229, 2698, 2254, extn.:411 Direct: +91 44 6528 4773		
10	UNU-IAS	Dr. Suneetha Subramanian	Mob:+91-9840574184	Nov 27	
11	PLANT (an NGO)	Dr. R. T. John Suresh Executive Director	PLANT – Participatory learning Action Network & Training. <u>www.plantindia.org</u> No. 52A-1, Orgadam Road, Venkatapuram,	Nov. 27	

No	Institution	Name and Title/Position	Address and Contact	Date (2013)	Comments
			Ambattur, Chennai-600 053. Tel: 91 44 26570929. Mob:09840740929 <u>Plant_suresh@yahoo.com</u> , <u>plant@plantindia.org</u>		
12	IHST (previously FRLHTI/I-AIM)	Dr. Padma Venkat Director, Institute of Ayurveda and Integrative Medicine (I-AIM)	IHST – www.ihstuniversity.org (previously listed as: FRLHTI, Foundation for Revitalization of Local Health Traditions) 74/2, Jarakabanda Kaval, Post Attur, Via Yelahanka, Banagalore-560 064. Tel: 080-28565708 tel. +91 802856 8000/8001/8002/7926. www.ihstuniversity.org Direct (mob) 9482582825 padma.venkat@frlht.org, padmavenkat@rediffmail.com	Nov. 28	Charitable organization, private. Funding from projects and donors, and industry
13		Dr. Darshan Shankar Managing Trustee	IHST Darshan.shankar@frlht.org	Nov. 28	
14	Natural Remedies Pvt. Ltd.	Dr. Amit Agarwal, Director, Human Health Products and Regional Secretary of	Natural Remedies Pvt. Ltd. Plot no. 5B, Veerasandra Industrial Area, 19th Km Stone, Hosur Road, Electronic City Post, Bangalore 560100. Phone: +91 80 4020 9703 (Direct) /9999	Nov. 29	

No	Institution	Name and Title/Position	Address and Contact	Date (2013)	Comments
		Ayurvedic drug Manufacturers' Association (ADMA)	Mobile: +91 9845008951 Fax: +91 80 4020 9817 Prathima (secretary for Agarwal) at +919845351672		
	(ADMA)		Ayurvedic drug Manufacturers' Association (ADMA) Unit no. 227, T.V Industrial Estate, 248/A, S.K. Ahire Marg, Worli, Mumbai – 400 030. Tel: +91 2498 4405 Fax +91 2498 3658 admaindia@vsnl.net	Nov. 29	
15	FICCI	Ms. Sheetal Chopra Joint Director and Head, IPR Division/IP Facilitation centre (IPFC) IP Education Centre (IPEC) National Initiative Against Piracy (NIAP)	Federation of Indian Chambers of Commerce and Industry (FICCI) Federation House, Tansen Marg New Delhi 110 001. <u>www.ficci.com</u> Tel: +91 11 2376 69301 Tel: +91 11 2348 7368 Mob: 91 98 1072 7714 <u>sheetal.chopra@ficci.com</u>	Dec. 2	

Appendix II Questions to Guide Open-Ended Discussions

1

Organization Type?

Private/Public/Charity (Financing agent) / combination

2

- a. Type of resources needed (only plants)
- b. How do you obtain the raw products/species?
- c. Access to resources (how should it be different from practice)
- d. What use of resource/species?
- e. Transfer at what stage. Practice and preferred stage. How product specific?
- f. What circumstances call for TT?
- g. Is TT part of BS?

3

- a. Partners who you work with in the past and plan to?
- b. Which type of actors would like to Collaborate/work with?
- c. Why? Rational? Does TT come into the picture?

4

- a. Products that you develop with partners?
- b. What ownership arrangement/agreement? Constrains in reaching agreements?
- c. What if the product has roots in Ayurvedic (other traditional health systems)? Or is related to TK and use by local communities?
- d. Does geographic occurrence play a role in access to raw products?
- 5
- a. What type of technology enhancement do you need?
- b. Types of TT that are acceptable and those that often occur. (examples)
- c. (see also list of typologies)- When should it occur?
- d. What are the circumstances when there should be TT?
- e. How attractive is it to have projects in India. Are conditions amiable? Facilitating or stringent TT? If the later why? IPR?
- f. Facilitation (legal)

6

- a. Satisfied with the TT as it is: practice
- b. If not, explain?
- c. Should there any explicit guidelines? (sector related?)
- d. Specify?
- e. Have you discussed with authorities species and arrangements?

TT = technology transfer; TK = Traditional Knowledge

BS = Benefit Sharing; IPR = Intellectual Property Rights

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Appendix III Some Perceptions from Actors

Table 1. Some perceptions from actors on elements of technology transfer which need attention when considering collaboration with international actors

Perception from Researchers / Herbarium / University	Perception from Industry	Perception from an NGO
Full understanding of regulatory requirements for use of a wide range of biological resources, as well as to which types of technology transfer to consider in agreements.	Full understanding of regulatory requirements for use of a wide range of biological resource, and that industry to decide on technology transfer and benefit agreements.	Gender focus requires inclusion in technology transfer discussions.
Legal assistance with negotiating for technology transfer under the umbrella of benefits/returns. Indian actors are seen as weak and naive, which is demoralizing and discouraging for research institutions.	Ability to conduct pre-testing (screening/scoping/surveys) without long-term agreements on technology transfer and benefit sharing. Thus having allowance to export 'small amounts ' of genetic resources or products for pre- testing/screening by international actors, without ABS agreements or rather commitments for any or fixed technology transfer or benefits at an early stage.	Communities need to be better informed of the limitations of success of commercial drugs in India or aboard: many misconceptions exist. International actor involvement increases expectations for benefits including technology transfer, significantly.
Legal assistance with IPR negotiations and thus benefits or technology transfer. Unable to negotiate for joint partners on IP as part of technology transfer.	Clarity in status and finalization of Indian Red List plants so that prospectors know what is " <i>off-limits</i> ".	NGOs should continue and be allowed to be suppliers to herbaria, bioprospectors, and acts as communicators with the communities.
Assistance is needed in acquiring an acute understanding of how equity (in terms of technology transfer or potential revenues) is to be decided, when only a small part of the resource is being used. Questions that there is little or no knowledge of are: How is equity to the providers and sharers of knowledge to be decided?; How is technology transfer to be measured and how does have to occur?	There is a need to experiment with a range of contracts and benefit sharing regimes to be realistic. All actors should be brought into the decision making process for technology transfer needs and benefit sharing when it comes to traditional knowledge. Decision making has to be decentralized.	Fairness has to be explained better to suppliers and caretakers of medicinal plant knowledge (TK).
More realistic technology transfer options are needed.	NBA should function as an information providing organ (including technology transfer	NBA should function as an information providing organ.

	options), be proactive, and not a decision making organ.	
CSIR / AYUSH need to have defined ways of how TK information may be used, in relation to information located in other bodies in India (e.g., herbaria, botanical gardens), and how these can yield development of "deals". Research laboratories and academia have specific technology needs, different from others.	NBA should promote use of traditional medicines and knowledge databases (information banks) rather than focus only on conservation.	
	Allowing substitution of species in tradition Ayurvedic formulations to reduce pressure on wild species and ease contractual requirements (to NBA). These could be still labeled as Ayurvedic products.	
	Allowing international actors to contact BMCs and SBBs directly.	
*Source: interviews (Nov. and Dec., 2013)	

The Fridtjof Nansen Institute is a non-profit, independent research institute focusing on international environmental, energy, and resource management. The institute has a multi-disciplinary approach, with main emphasis on political science and international law. It collaborates extensively with other research institutions in Norway and abroad.



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