



INCREASED LEGAL CERTAINTY: INDIA

PANEL DISCUSSION

Side event: IGC on IP, TK, GR & Folklore

WIPO, GENEVA

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C O R P O R A T E L A W G R O U P , N E W D E L H I



OBJECTIVES

- ❑ Patent Act, 1970 (amended in 2002): to provide safeguards for protection of biodiversity and traditional knowledge.
- ❑ Biodiversity Act, 2002 (BD Act): provides mechanism for access to India's biological resources and associated knowledge and for equitable sharing of benefits arising out of utilization of the accessed biological resources and associated knowledge.
- ❑ India for a decade, has led efforts of developing countries in including the protection of TK as a part of the International IP System.
- ❑ Efforts led to **Doha Declaration in 2001 wherein it was decided to establish a relationship between TRIPS and CBD**; and establishment of the IGC on IP, TK, GR and Folklore by WIPO.



Patents Act, 1970

MANDATORY DISCLOSURE REQUIREMENTS

- ❑ **Sec.10(4)(d):** Mandatory disclosure requirements in patent applications of source and geographical origin of biological material;

- ❑ **Form 1:** A declaration by a patent applicant in application for grant of patent: “The invention as disclosed in the specification uses the biological material from India and the necessary permission from the competent authority shall be submitted by me before the grant of patent to me.”

- ❑ **Competent Authority** – National Biodiversity Authority (NBA)



Patents Act, 1970

- ❑ **Sec. 3(p) excludes TK (not defined) from patentability** - “an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components.”
- ❑ **TK Digital Library (TKDL):** prior art evidence: screening. Currently 1384 applications identified.
- ❑ **Guidelines for processing of Patent Applications relating to Traditional Knowledge (TK) and Biological Material – Dec. 2012:** issued to check issuance of patents on use of TK and related to biological resources of India, particularly relating to Indian system of medicines.



Biodiversity Act, 2002

GATEKEEPING BY NBA AT TWO LEVELS

- Prior approval required by a person not a citizen/resident of India before obtaining any biological resource in India or knowledge associated thereto for research or commercial utilisation.
- Prior approval required by all persons before applying for any kind of IPRs (in or outside India) based on any research or information on a biological resource obtained from India.
- Such permission may be obtained before grant of patent.
- The NBA is required to dispose of such an application within 90 days of receipt.



Biodiversity Act, 2002 - RULE 18

- An application in **Form III** - if applying for a patent/IPR based on research on biological material and knowledge obtained from India.
- NBA shall decide on the application, as far as possible, within 90 days from receipt of the same.
- The NBA may grant approval for applying for a patent/IPR and terms of condition will be mentioned in a written agreement signed by the NBA and the applicant.
- The NBA may reject the application after recording the reasons and after giving the applicant an opportunity of hearing.



Biodiversity Act, 2002 – FORM III

- 1. Particulars of applicant**
- 2. Details of invention on which IPRs sought.**
- 3. Details of Biological Resources and/or associated knowledge used in the invention.**
- 4. Geographical location from where the biological resources used in the invention are collected.**
- 5. Details of any traditional knowledge used in the invention and any identified individual/community holding the traditional knowledge.**
- 6. Details of institution where R&D activities carried out.**
- 7. Details of economic, biotechnological, scientific or any other benefits that are intended, or may accrue to the applicant due commercialization of the invention.**
- 8. Declaration that information provided is true and correct.**



Biodiversity Act, 2002

WHAT IS TO BE DISCLOSED?

- ❑ **Sec. 2 (c) Biological Resources**: “means plants, animals and micro-organisms or parts thereof, their genetic material and by-products (excluding value added products) with actual or potential use or value but does not include human genetic material.”
- ❑ **The NBA is advocating the following position:**
- ❑ ‘biological material’ not defined in Patent Act; THEREFORE interpreted as ‘biological resources’ in BD Act;
- ❑ should include **‘human genetic material’** as the latter is dealt with by PO.



Biodiversity Act, 2002

WHAT IS EXCLUDED FROM DISCLOSURE

- ❑ **Value Added Products:** “means products which may contain portions or extracts of plants and animals in unrecognizable and physically inseparable form.”
- ❑ **Collaborative research** between Indian and foreign institutions that conform to the notified guidelines by the Ministry of Environment and Forests, Government of India.
- ❑ **Human Genetic Material** – Reliance Case (PO Decision in March 2013) (*Application for Patent of Addition No. 652/MUM/2007*)

Source: Access and Benefit Sharing: Experiences from India. NBA: Oct. 2012



Biodiversity Act, 2002

WHAT IS EXCLUDED FROM DISCLOSURE

- Plant Variety Rights (PVR). When granted, NBA is required to be notified.**
- Vide Notification dated Oct. 26, 2009, Ministry of Environment & Forests 190 biological resources were exempted from purview of the BD Act, provided they are traded as commodities.**
- Vide a Clarification dated Feb. 16, 2010 it was clarified that the notification applies only for export of these 190 items and these exports would not require prior permission of the NBA.**
- GMOs covered under Environment Protection Act, 1986.**



Biodiversity Act, 2002 - Benefit Sharing

NBA will ensure equitable sharing of benefits arising out of

- (i) the use of accessed biological resources,**
- (ii) their by-products,**
- (iii) innovations,**
- (iv) practices associated with their use, and**
- (v) applications and knowledge relating thereto.**

□ Mutually agreed terms b/w the applicant, concerned local bodies and benefit claimers.



Biodiversity Act, 2002 - Benefit Sharing

- 1. Payment of monetary compensation: benefit sharing fee; royalty; sharing of profits.**
- 2. Grant of joint ownership of IPRs to NBA, or to benefit claimers where identified.**
- 3. Transfer of technology.**
- 4. Location of production, R&D units in such areas which will facilitate better living standards to the benefit claimers.**
- 5. Association of Indian scientists, benefit claimers and local people with R&D in biological resources and bio-survey and bio-utilization.**
- 6. Setting up of venture capital fund for aiding the cause of benefit claimers.**
- 7. Moneys to be deposited in the NBA Fund if not otherwise directed.**



READY TO APPLY ABS FORMULA

Annual royalty payment during the term of the Agreement”

- 1. For product derived from the use of the biological resource and/or associated knowledge accessed: 2% - 5% of the gross ex-factory sale.**
- 2. For product derived from the use of biological resources and associated knowledge accessed (as ascertained from the annual progress reports of the user duly certified by chartered accountants): 5% of the total ex-factory sales.**

Source: Access and Benefit Sharing: Experiences from India. NBA: Oct. 2012



READY TO APPLY ABS FORMULA

Annual royalty payment during the term of the Agreement”

- 3. For transfer/license of patent by researcher: 5% of upfront payment & 5% of the ex-factory sales in event of commercial production.**

- 4. For exporter: 5% of FoB value of the export consignments as evidenced by a copy of the shipping bill and CA certificate, subject to licensing by Director General of Foreign Trade (DGFT).**

Source: Access and Benefit Sharing: Experiences from India. NBA: Oct. 2012



Patents Act - SANCTIONS & REMEDIES

Pre-grant & post grant opposition & Revocation

- ❑ In the event of non- disclosure or incorrect disclosure in respect of source or geographical origin of biological material used for the invention.**
- ❑ In the event where invention is anticipated having regard to knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere.**



BIODIVERSITY ACT -SANCTIONS & REMEDIES

- Contravention or attempt to contravene shall be punishable with imprisonment for a term of 5 years or with fine which may extend to INR 10 lacs up to fine commensurate with damage caused.**
- For contravening direction of NBA and State Biodiversity Boards – fine of INR 1 lac;**
 - ✓ **for subsequent offence - fine of INR 2 lacs;**
 - ✓ **For continuous contravention – fine of INR 2 lacs everyday till the default continues.**
- Offences are cognizable and non-bailable.**
- A court can take cognizance of an offence under this Act if the complaint is made by Central Government or by any benefit claimant.**



Form III Applications to NBA

Year	Number of Form 3 Applications Received	Number of Form 3 Applications Cleared (Provisional)	Number of Form 3 Applications Under process at various levels	Number of Form 3 Applications Closed	Agreement signed by applicant with NBA (MAT)
2003-2004	0	--	---		
2004-2005	1	---	----		
2005-2006	0	----	----		
2006-2007	94	0	----		0
2007-2008	174	223	----		11
2008-2009	58	41	----		21
2009-2010	97	16	----		9
2010-2011	15	9	----		4
2011-2012	35	39	----		6
2012-2013	54	38	----		8
Total	528	366	143	26	59

Out of 360 , 7 applications cancelled after clearance due to not agreed terms and conditions

Source: NBA website

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The NBA has received the following royalty for the agreements signed:

	FORMS	Total Amount Received (INR)
1.	Form I , IV (combined) (For Commercialization and Third Party Transfer)	39,09,765
2.	Form I (Access for Commercialization)	4, 25, 993
3.	Form III (commercialization of IPR)	3,940
	TOTAL	43,39,698

Source: Access and Benefit Sharing: Experiences from India. NBA: Oct. 2012 ¹⁸



PATENTS GRANTED BASED ON THE APPROVAL OF NBA AS ON March 31, 2010

S. No.	Application no. & Applicant name	Details of Invention
1	NBA/Tech appl/9/129 Mr. P.M.Murali	Herbal composition for respiratory disorders such as chronic obstructive pulmonary disease and bronchitis based on the presence of active ingredients in the plant extracts
2	NBA/Tech appl/9/118 Dr. Anilkumar Vaidya	Preparation of a herbal formulation for the treatment for asthma acute bronchitis and lung disease
3	NBA/Tech appl/9/157 Dr. Polok Kumar Mukherjee	A process of preparing herbosomes with andrographolide having increased hepatoprotective activity and product thereof
4	NBA/Tech appl/9/171 Shri. Amin Jyoti	Antiestrogenic phytosterol extract from fenugreek seeds
5	NBA/Tech appl/9/185 Shri. D. S Prabhakar	A medicinal composition of nut kernel of <i>Caesalpinia bonduca</i> (L.) Roxb. for diabetes in mammals
6	NBA/Tech appl/9/208 M/s. Bose Institute	A new mannose binding insecticidal lectin isolated from seeds of <i>Annona squamosa</i> , and process for its preparation

Source: NBA website



Patents Granted Based On The Approval Of NBA as On March 31, 2010

S. No.	Application no. & Applicant name	Details of Invention
7	NBA/Tech appl/9/100 Mr. Manish Saurastri	Invention relates to composition and a process for preparation of a composition for manufacturing textured soluble container using herbal texturing agent.
8	NBA/Tech appl/9/205 Dr. Mrs.Geeta Pandurang Pawar	Preparation of an Ayurvedic anti snake venom comprising four medicinal plants.
9	NBA/Tech appl/9/229 Prof. Dr. S. K. Nayak	Hybrid composites comprising polypropylene (PP), natural an synthetic fibers, and more particularly referring to a low-cost pineapple leaf-fiber (PALF) based polypropylene composite with material hybridization with glass fibers and material layout for improved behavior that leads to enhanced mechanical properties resulting in lower cast and reduced environmental impact.
10	NBA/Tech appl/9/230 Prof. Dr. S. K. Nayak	A rheological process has been developed wherein natural fiber PALF (Pineapple leaf fiber) has been dispersed with a thermoplastic matrix.
11	NBA/Tech appl/9/131 Ms. Kalpana Bhupendra Katka	A process for preparing the composition for purifying and adding medicinal properties to the air in the form of air freshner

Source: NBA website



HAVE THE OBJECTIVES BEEN ACHIEVED?

- NBA has received only 528 applications since 2004.
- It has finally cleared only 59 applications after ABS agreement was signed.
- PO has granted still fewer patents after MAT submitted and NBA approval.
- PO – screening of 1384 application using TKDL.
- No grant since July 1, 2012: TK Guidelines.
- Majority of applications filed by Council of Scientific and Industrial Research (CSIR), Ministry of Science and Technology of Government of India.



HAVE THE OBJECTIVES BEEN ACHIEVED?

- ❑ While the objectives are laudable, the realization of objectives has been modest.**
- ❑ Disclosure requirements and prior approval of NBA imposes unreasonable burden.**
- ❑ NBA takes unduly long time to grant approval.**
- ❑ TK being excluded from patentability myopic.**
- ❑ Most affected – Indian researchers and government organizations like CSIR.**
- ❑ In the absence of a patent conducive environment, inventions are not commercialized, no sharing of economic benefits occurs, and the consumer and holder of the resource gain nothing**

THANK YOU



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