
The TRIPS Regime of Patents and PVPFRA in India

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Yogesh Pai
Assistant Professor of Law
National Law University, Delhi

Outline

- **Patents Act, 1970 (amended in 1999, 2002 and 2005)**
 - Patentability Exclusions- Guidelines on Biotechnology and Traditional Knowledge)
 - Traditional Knowledge Digital Library (TKDL)- defensive mechanism
 - Disclosure Requirement (Linkages with compliance under the Biological Diversity Act, 2002)
 - Revocation in public interest - examples
 - Other public interest provisions- research exemption, compulsory licence etc..
 - **Plant Variety Protection and Farmers Right Act, 2001**
 - Registrations- example of Breeders intending to extend protection
 - Public interest provisions - Farmers Rights, GURTs etc... & compulsory licence
 - Disclosure requirement
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Patents Act, 1970

- **Exclusions from patentability** - Relevant provisions in Section 2 (1) (j), Section 3 exclusions, disclosure requirements under section 10
 - **Guidelines for examining patent application:**
 - *Biotechnology patent applications (2013)*
http://www.ipindia.nic.in/whats_new/biotech_Guidelines_25March2013.pdf
 - *TK based patent applications (2012)*
http://ipindia.gov.in/iponew/TK_Guidelines_18December2012.pdf
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Patents Act, 1970

- ***Tension points - very little experience (lack of case-law jurisprudence)***
 - Exclusion based on morality, public order and serious prejudice to human plant, environment
 - inventions v. discoveries (gene patents)
 - breakthrough v. incremental (admixtures etc...)
 - methods patents - for agriculture, horticulture etc...
 - exclusions based on public policy- plants (or parts thereof), seeds, plant varieties (except microorganisms and microbiological processes)
 - Exclusions based on traditional knowledge content
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TKDL- Defensive Mechanism

- **Novelty & Inventive Step-** *TKDL creates standardised and accessible prior art in different languages - does not document information not in public domain*
 - TKDL database access available to patent offices (USPTO, EPO, JPO, IPO etc...)- *not to general public*
 - Database is not in public domain- patent offices can cite TKDL for examining applications and citing reasons (no fee charged for the database)
 - Examples of patent examination reports citing TKDL: <http://www.tkdل.res.in/tkdل/langdefault/common/ExaminerReport.asp>
 - **Recent example:** *Colgate Palmolive- composition involving Myristica Fragrans spice (Jai Phal) as a mouth-wash formula (June 2015- EPO)*
 - *How do we measure the success of TKDL?- issues relating to misappropriation?*
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Disclosure Requirement

- *Requirement of Prior Approval for applying for IPR under the Biological Diversity Act, 2002 (Section 6)*

Section 10: Disclosure Requirement:

- *Applications pertaining to Biological Material should disclose Source and Geographical Origin of Biological Material*
 - **Form 1 under Patent Rules**
 - *Declaration by Applicant that Biological Material used from India has been obtained after permissions from relevant authority*
 - *No evidence of BD Act permissions however required*
 - **Coordination mechanism: between Patent Office and National Biodiversity Authority**
 - **Implications for patent holders for non compliance**
 - *Revocation- under Section 64 (lack of adequate disclosure)*
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Revocation- public interest

- Revocation in public interest- (section 66)
 - Where in the 'opinion' of the central govt.- patent or mode in which it is exercise
 - mischievous to the state, or
 - generally prejudicial to the public
 - **Two instances where it has been used:**
 - **Agracetus (US based company) Indian Patent Number 168950** titled “A method of producing transformed Cotton Cells by tissue culture” was granted to Agracetus of USA based on the patent application number 919 Cal 87 (filed on 24/11/1987) by the Indian Patent Office.
 - Revoked in 1994 citing - “*because of its far-reaching implications for India's Cotton economy*”.
 - **Avesthagen (Indian company) Indian patent 252093**, “synergistic ayurvedic/ functional food bioactive composition”. (Jamun for treatment of diabetics)
 - Revoked in 2012 citing - lack of novelty and inventive step/ public domain
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PVPFRA

- Registration of several categories of varieties (new variety, farmers variety, essentially derived variety, extant variety)
 - Crop-wise Application status (2007 - August 2015)
 - Public 1424
 - Private 2954
 - Farmer 5693
 - Individuals - 2
 - **1870 PVP Certificates Issues (August 2015)**
 - **Delhi HC (January 2015) (evergreening of PVP protection)**
 - Maharashtra Seed Corporation / Monsanto v. Union of India
 - If hybrid variety already registered, parental lines involving the same cannot be further registered as a new variety
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PVPFRA

“If the provisions of Section 15(3) of the Act are read in a manner as suggested by the petitioners, the effect would be to extend that period of protection many times over. In the first instance, a breeder would get protection in respect of the hybrid variety and assuming that there are two parent lines, the breeder could just before the expiry of the Registration Certificate in respect of a hybrid variety, register one of the parent variety and thus, extend its period of exclusivity for a further period of 15/18 years because protection of even one parent line would practically ensure exclusive rights in relation to the hybrid variety. In the same manner, before expiry of the registration period of that parent line, the breeder could register the other parent line as a new variety. In this manner a breeder could extend the protection for a period up to maximum 45/54 years instead of 15/18 years as contemplated under the Act. Clearly, this is not the legislative intent of the Parliament.”

PVPFRA

Exceptions:

- Section 39(1) (iv) a farmer shall be deemed to be entitled to save, use, sow, resow, exchange, share or sell his farm produce including seed of a variety protected under this Act

Provided that the farmer shall not be entitled to sell branded seed of a variety protected under this Act (excludes branded- such seed is of a variety protected under this Act)

- **Compulsory licence** after three years of registration, if the breeder fails to satisfy the reasonable requirements of the public for the seed or other propagating material or that the seed or propagating material has not been made available to the public at a reasonable price.
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PVPFRA

- **Disclosure requirement:**
 - Section 40. shall disclose in the application the information regarding the use of genetic material conserved by any tribal or rural families in the breeding or development of such variety.
 - reject the application for registration if willfully and knowingly concealed such information
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Thanks!

yogesh.pai@nludelhi.ac.in
