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American BioIndustry Alliance

Mandatory Patent Disclosure: The Threat to Biotech Patents

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Key Points

- Additional, mandatory patent disclosure obligations burden biotech entrepreneurs in developing countries
- Domestic regimes
 - go well beyond Convention on Biological Diversity (CBD)
 - mandatory patent disclosure obligations chill biotech investment
 - 2003 Indian Second Patent Amendments Act
 - 2005 South African Patent Amendment Act
 - Draft Chinese Patent Amendments
- Mandatory disclosure cuts to the heart of industry's critical need for patent protection
 - Only your national governments can provide the necessary enabling environment

American BioIndustry Alliance (ABIA): Source for Accurate, Timely Information

- *ABIA Website*: Launched 12/05; now primary source for industry Access and Benefit Sharing (ABS) views
 - *ABIA Publications*: Essays, positions, views gain coverage from major trade journals and on-line pubs
 - *ABIA Events*: Provide educational information at multilateral events, and in key capitals.
 - *Survey of Developing Country Delegates*
 - ABIA is an important, reliable source of information: “that provides a counterview on disclosure of origin for genetic resources.”
- NGOs, Intellectual Property Rights and Multilateral Institutions,
Duncan Matthews, December 2006, pp. 14 and 28

Comparison of CBD with Domestic Patent Disclosure

Provisions	Brazil	India	China*	South Africa
CBD Treaty Limits				
Plant/Animal GR (non-human)	✓	NO	NO	NO
Post-1994 GR	NO	NO	NO	NO
In-Situ GR	NO	NO	NO	NO
Prior Informed Consent	Mandatory #	#	Unclear #	#
Proof of Benefit Sharing	Mandatory #	#	Unclear #	#
Other GR/TK Patent Dilution				
Source or Origin	Origin	Origin	Source	Unclear
Condition of Patentability	✓	✓	✓	✓
Grounds for Patent Revocation	✓	✓	unclear	✓
Open-ended Challenge Grounds	✓	✓	unclear	✓
Inclusion of TK	✓	✓	GR Only	✓
Inclusion of derivatives	✓	✓	GR Only	✓

India 2nd Patent Amendments

- **2002 Patents (Amendments) Act**
 - “Every complete specification shall... disclose the source and geographical origin of the biological material in the specification, when used in an invention.”
(2002 Patents (Amendment) Act)
 - Two new grounds for revocation:
 - “The complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention.”
 - “The invention so far as claimed in any claim of the complete specification was anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere.”
- **2002 Biological Diversity Act**
 - Requires all inventors to obtain consent of National Biodiversity Authority (NBA) before applying for patents where the invention is based on any biological resource
 - Grants NBA power to impose benefit sharing fee (or royalty) or conditions, such as the sharing of financial benefits arising out of commercial utilization.

South Africa: Patent Amendment Act, 2005

- Adds new, additional mandatory disclosure obligations for all patent applications relating to “indigenous biological resource, genetic resource or traditional knowledge or use.”
(3A, insertion into Section 30 of Act 57 of 1978, as amended)
 - No patent without disclosure of origin
 - Broad application: *in situ* and *ex situ*, no time limitations, etc.
- Mandatory disclosure obligation includes
 - *Proof of legal title*
 - Proof of legal provenance or ownership of the right to make use of the resource or traditional knowledge: “(3B) The registrar shall call upon the applicant to furnish proof in the prescribed manner as to his or her title or authority to make use of the indigenous biological resource, genetic resource, or of the traditional knowledge or use”
 - *New ground for patent revocation based on failure to disclose or false disclosure at any time during life of patent*
 - On basis that: “the statement lodged in terms of section 30 (3A) contains a false statement or representation which is material and which the patentee knew or ought reasonably to have known to be false at the time when the [declaration] statement or representation was made.”

Draft Chinese Patent Amendments

“For an invention-creation, the completion of which depends on acquisition and exploitation of genetic resources, but the acquisition and exploitation of said genetic resources are contrary to relevant laws and regulations of the State, no patent right shall be granted.”
Article 25, A2, Amended Patent Law (Draft), as of July 31, 2006

“For an invention-creation, the completion of which depends on acquisition and exploitation of genetic resources, the applicant shall indicate the source of said genetic resources in the description.”

Article 26, Amended Patent Law (Draft), as of July 31, 2006

WTO TRIPS: Patent Disclosure Proposal*

- Any applicant for patent relating to biological materials or to traditional knowledge (TK) shall provide
 - Source and country of origin of biological resource and TK used in the invention
 - Evidence of prior informed consent (PIC) from authorities under relevant national regime
 - Evidence of fair and equitable benefit sharing under the relevant national regime
 - Human vs. non-human
 - Source vs. country of origin
 - Information that applicant knew or should have been known to him
 - Who gives consent if there is no national regime?

Opportunities for Change

- Growing awareness of need for enabling environment for biotechnology
 - *Current policies seen as stalemate; blind alley*
- CBD members seek to improve ABS regimes to increase demand GR/TK demand side
- Unique opportunities for domestic “favorite daughters/sons” to seek improved IP, regulatory support for biotech from national governments

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