An overview of India's approach to key IP issues at home and abroad

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- Why Intellectual Property?
- Why India?

Key IP issues at International Fora: IP and access to medicines

- WTO (TRIPS Council, since late 1990s; DSM cases incl. India and Canada; Compulsory Licenses for Export – para.6 mechanism)
- WIPO
  - Development Agenda, at the Standing Committee on Patents, 2011, on issues of patent and public health, technology transfer, patent quality, opposition systems, exceptions and limitations to patent rights
- WHO (IPRs and R&D since 2003; R&D Treaty for neglected diseases - idea since late 1990s, proposal by scientists supported by Kenya and Brazil in 2005)
  - Support for the WHO R&D treaty not strong (contribution – 0.01% GDP US$ 172,711,110 - yr2010) at the WHO and BRICS Health Ministers in Delhi Jan 2013
- UN Political Declaration on HIV/AIDS and UN Declaration on Non Communicable Diseases (both 2011) – language of Doha flexibilities lost, despite support from India and Brazil
- UNITAID (patent pools since 2008, ideas circulating from 2002)
  - India not a signatory/member

IP and access to medicines in India

- Around 1% GDP spent on healthcare, lack of universal coverage, 68% pay out-of-pocket (50-80% spent on drugs) - hence, reliance on cheap generics (1970 Patent Act) and price controls for essential medicines (though number low)
- Generic industry important to Indian economy (1,55% GDP, 13-14% growth rate, 4.2 million employees); pharmaceutical policy part of industrial policy
- The above, plus keen mobilization by generic industry (IPA) and civil society (NWGP) from mid-1990s instrumental for key flexibilities Indian patent law:
  - Section 3(d) – patentability criteria (but yes to patentability of micro-organisms)
  - Pre- and post-grant opposition
  - Compulsory license (not used until 2012, although 2007-10 1053 patents)
  - Parallel import (exhaustion doctrine) – although not very clear
  - No data exclusivity (Bolar +)

IP and access to medicines in India

- Legal challenges
  - WTO (1999) – mailbox instituted, but only a few EMRs granted (Section 11A)
  - Domestic cases – Novartis (3d, at Supreme Court); Roche (appealing patent rejection for cancer drug); Gilead Science (appealing patent rejection for HIV drug); Bayer appealing compulsory license (against Natco at IPBA and Cipla at Delhi High Court)
- Patent Office interpretation of section 3(d); recently gained status as ISA under the Patent Cooperation Treaty plus foreign PO assistance
- Fragmentation and changes in the generics sector
- Other pressures:
  - US Special 301
  - In-transit drug seizure, EU
  - ACTA, EU-India FTA
  - WTO Trade Review Mechanism
  - Indirect pressure (official trade delegations and industry pressure)

Key IP issues at International Fora: IP and Genetic Resources + Associated Traditional Knowledge

- WTO TRIPS Council
  - Late 1990s, Review of Art 27.3 and relation between TRIPS and CBD – emergence of demands for obligatory disclosure of origin (DOO) since late 1999 (India and Brazil amongst key *demandeurs* as Megadiverse countries)
- WIPO Inter-governmental Committee on GRs, TK and TCE, established since 2000 – slowest progress on GR front
- CDB (1992) – establishes principle of sovereignty rights over GRs and benefit-sharing; several countries, incl. India introduce legislation to regulate such access
  - Signals abandonment of support by developing countries for principle of GRs as common heritage of humankind (as stated in FAO's International Undertaking on Plant GR, 1983 – FAO 2001 Treaty brings the Undertaking in line with CBD)
  - CBD Nagoya Protocol added in 2010 (India played key role) set up system to deal with access and benefit sharing rules – by most accounts, a weak system

IP and Genetic Resources + Associated Traditional Knowledge in India

- High hopes for biotech sector as the next IT; desire to stop ‘bio-piracy’ and cash-in from rich GRs lead to India abandoning support for common heritage and ‘no patenting on life’ principle
- India adopted both offensive and defensive measures to deal with GR and associated TK :
  - Efforts to get TRIPS amended to include DOO/ efforts at WIPO IGC and CBD
  - Challenges to foreign patents based on GRs used widely in India (e.g. turmeric, basmati)
  - Patent Act Amendment excludes TK from patentability (but not GMO)
  - Creates Traditional Knowledge Digital Library (TKDL) to avoid misappropriation and signs memoranda of understanding with key Patent Offices

IP and Genetic Resources + Associated Traditional Knowledge in India

- Biological Diversity Act (2002) pushed for largely by NGOs:
  - Brings Indian law in line with CBD
  - Establishes access and benefit-sharing rules; National Biodiversity Authority (NBA) to oversee system
  - However, no request for PIC (prior informed consent) from communities and differential national treatment
  - NBA rules in 2009 introduce PIC and national treatment
  - Despite the fact that Patent Law excludes TK from patentability, there has been patenting of TK by public institutions, as well as patents on GRs, often without authorization by the NBA
- Complains about the Act (and 2009 Rules) and NBA duties – ongoing efforts to amend the Act and provide a new system for

IP and Genetic Resources – the issue of plant varieties

- India is not a member of UPOV, despite considerable pressure on it and even an announcement (2002) by the government to apply for membership (currently ‘frozen’)
- Language of food security, biotech revolution, seed improvement, improving state of Indian agricultural sector – all played a role on both sides of the debate (between seed companies and NGOs)
- The PPVFR Act of 2001 reflects a compromise between these groups by:
  - Incorporating some UPOV 1978 and 1991 provisions for PBR (initially contemplating patents)
  - Introducing for the first time in a domestic law Farmers Rights to save/exchange/sell seed and apply for protection of their varieties
  - However, FRs provisions for varieties protection are difficult to enact in practice
  - Industry is trying to use the currently debated Seed Bill to claim back some ground on PBR, plus pressure to join UPOV

Some (early) conclusions

- 2010-2020 decade of innovation, IP seen by some as key to ensuring this
- View especially embraced by government and public institutions, e.g. efforts to introduce an Indian Bayh-Dole Act and haste of public institutions to patent
- Focus on patent law has meant some TRIPS + provisions have been introduced in area of plant varieties and copyright
- IP coordination policy in place (DIPP), but different ministries cover different aspects of IP (fragmentation domestically)
- Counterweight by civil society groups weakening more recently due to funding pressure, fragmentation etc
- Indian IP position abroad generally underpinned by industrial sectors' interests and domestic exigencies
- India reputation as leader of developing countries fighting for flexibilities in IP regime will last as long as such positions fit with