

Incentivizing Innovation and Serving the Public Good: Extending the Patent Regime to Nanotechnology in India

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The patent regime and new technologies

- In theory, patent system geared towards providing 'technology-neutral protection' (Lemley and Burk, 2003); for 'anything under the sun made by man' (Diamond v. Chakravorty)
- In practice, always difficult to fit new technologies into old concerns as each new technology presents unique problems (Almeling, 2004)
- WIPO Standing Committee on the Law of Patents (2009): '*the patent system constantly faces the question as to whether and how it can adapt itself to new technologies...*'
- Harmonization between two, sometimes conflicting imperatives: sufficient rewards to the inventor as well as the public good (affordable access, avoiding a 'tragedy of the anti-commons' particularly in the developing country context)

Patents in nanotechnology: trends



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- Have acquired a 'tsunami-like' strength since the early 1990s and increasingly growing (ETC Group, 2005).
- Highest number of nano-patents owned by the United States, followed by Japan and Germany (OECD, 2009).
- Korea and China characterized by rapid patenting trends over the last decade (ObservatoryNano Briefing 2011)

NT patents in South Asia



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- Developing countries progressively joining the nano-patents 'race'
- Indian patenting activity has grown exponentially between 2001-07 (Gupta, 2009). Could be attributed to increased funding and policy support.
- Government funded institutions particularly the research laboratories under the Council of Scientific and Industrial Research top NT patent assignees in India, followed by industry (Liu et al., 2009)
- Focus areas- drugs and pharmaceuticals, chemical sciences and technologies.
- Sri Lanka- new player; patenting activities spearheaded by SLINTEC, a public-private venture.
- Five patents filed at the USPTO; focus on nano fertilizer, nano rubber and carbon nanotubes.

Problems in patenting NT innovations



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- Multi-disciplinary nature and span across a broad spectrum of industries.

Example: a US nano-patent (US 5874029) has usages for the pharmaceutical, food, chemical, electronics, catalyst, polymer, pesticide, explosives, and coating industries.

-Implication: Difficulties for patent offices, courts and patentees who must search for 'prior art' in widely disparate fields.

- Being a new field, most patents being taken on basic inventions and for broad claims

-Implication: patenting of inventions bordering closely on discoveries and patents on basic inventions or building block patents. Could result in thickets, impediments to downstream research and lawsuits over overlapping claims.

Problems in patenting NT innovations

- Universities and government funded institutions patenting in record numbers. Many universities having crucial, foundational patents have preferred to exclusively license these to the industry (Featherstone and Specht, 2004)
 - Implication:** hinders access to research tools critical for developing further innovations. Tax-payer may end up paying double- both for the research as well as for the products of the research
- 'Nanotechnology' loosely defined; 'nano' on its own not an adequate search term
 - Implication:** creates difficulties for inventor and patent examiner and leads to patent overlaps and broad claiming.

Patentability criteria and nano- patents



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- Difficulties in fulfilling the patentability requirements of novelty, non-obviousness and industrial application (even in the United States, where these are perceived to be liberally interpreted)
- Evident in *Elan Pharma International Ltd. v. Abraxis BioScience Inc.*
- Issue was Abraxis' alleged infringement of Elan's Patent for the nanoparticle formulation of the breast cancer drug Abraxane. Abraxane's claim that its invention delivers the active ingredient in an efficient fashion while minimizing unwanted side effects failed to satisfy the court on the ground of novelty.
- Earlier case law suggest that an invention may not be patentable where the sole element of novelty is a difference in size, since a mere change in size may be viewed as 'obvious'.

Patentability criteria and nano- patents



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- Patentability criteria more stringent in India
- Section 3(d) of the Patents Amendment Act of 2005- a double edged sword?
 - prohibits the grant of a patent on a derivative form of a known substance unless the derivative form has significantly enhanced efficacy. Prohibits 'new use' patents. Many NT patents may fail to pass the efficacy test
 - At the same time, a very important tool to prevent frivolous grant of patent and curb 'ever-greening'
 - Courts have chosen to take a tough stand on s 3(d) in recent decisions in the public interest

Steps towards adapting the patent regime for NT

- Leading patent offices have initiated preliminary steps in terms of separate classifications and capacity building initiatives
- Collection of all nano-related patents in one single patent class (USPTO's Class 977, with 263 sub-classes, EPO's Y01N, JPO's ZNM)
- Capacity enhancing frameworks in leading patent offices
- Enabling patent legislation which reconciles public good with incentives to innovators

Developing country concerns

- Developing and least developed countries- irrespective of technological advancement, and capacity of the domestic regime- obliged to confer IPRs in the new technology.
- Participation in the proprietary nanotech revolution likely to be highly restricted by patent tollbooths, obliging payment of high royalties and licensing fees to gain access.
- Could also reinforce and magnify existing disparities between developed and developing countries ('nano divide').

How well equipped is the Indian patent law?

- Enough flexibilities and exemptions in the law itself
- Post-grant opposition clause enshrined in section 25(2) can be used to eliminate low quality patents *ex post*. In practice, India has not seen much active opposition to patents, pre or post grant (Basheer, 2010)
- A counter strategy to tackle the issue of broad claims is through a strong enablement clause or disclosure standard. In India, insufficiency of disclosure valid ground for pre and post grant opposition (sections 25(1)(g) and (2)(g)). Backed by case law.
- Patent thicket like situation with hurdles for developing country NT researchers could be circumvented through a strong experimental use exception or Bolar exemption. Indian patent law provides for Bolar plus.
- Compulsory licensing continues to remain an important tool to deal with thickets and when patent holders tend to refuse licenses or license with onerous conditions

Some challenges



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- Many of the public interest provisions in patent law not implemented and would be difficult to implement, owing to lack of political will, pressure from developed countries
- India yet to take steps in the direction of a separate classification for NT patents
- Indian Patent Office on the verge of a human resources crisis, no patent examiner with specialization in NT.
- Judiciary not sensitive to the special problems with new technologies

The Way Ahead

- Separate classification for nano patents, on the lines of the USPTO and the EPO.
- Policy intervention to view NT patents as a separate category, distinguishing these from traditional patents.
- An IP strategy combining patents judiciously with trade secrets, copyright, designs, licenses as well as contractual obligations.
- Courts and patent offices would do well to adopt a middle ground in applying patentability tests and adhere to a case specific approach
- Policy support for technology sharing through patent pools, non-exclusive licensing of foundational patents etc.