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Intellectual Property and Public Health: Regional Perspectives

India

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Scope

- Efforts against ‘evergreening’ of patents in the pharmaceutical sector;
- Policy Issues relating to exclusivity of clinical trial data;
- Compulsory licenses;
- Direct Drug Price Control Mechanism

Introduction and Importance

- Rich – poor divide getting steeper in many countries like India;
- Increased privatization (rising costs);
- Health insurance penetration not high in many developing countries
- Raging debate – IP v/s Access to Medicines
  - In the present state of affairs, solution cannot rest in extremes

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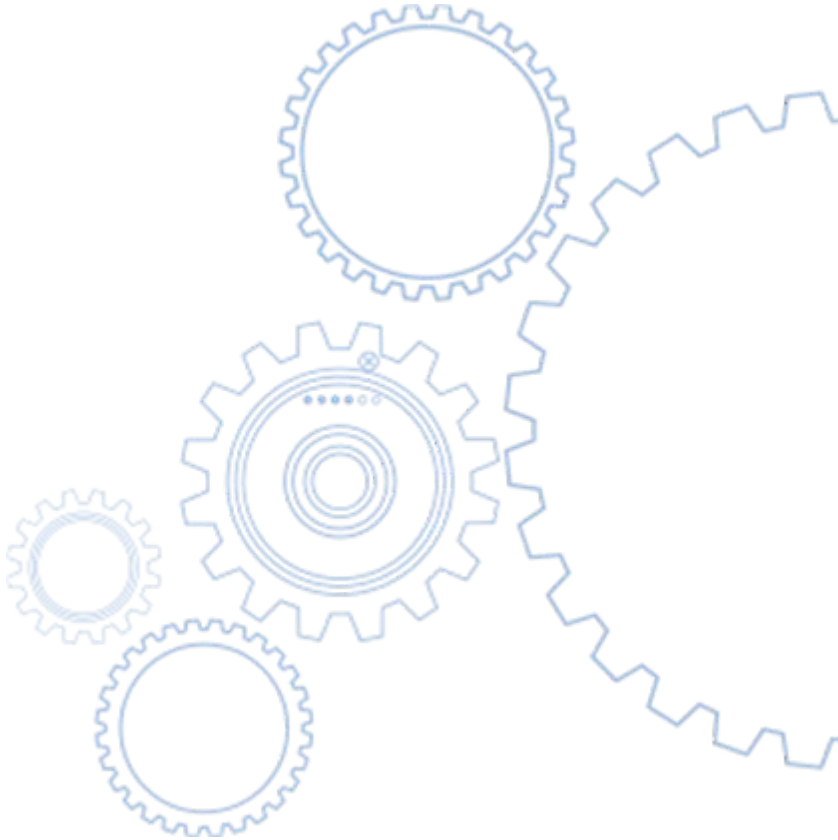

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Anti-‘Evergreening’ of Patents?

Anti-‘Evergreening’ of Patents?

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“**The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance** or …

the mere discovery of any new property or **new use for a known substance** or ….

the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.”

Explanation to Section 3(d).—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

Anti-'Evergreening' of Patents? ...Contd.

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- Section 3(d) held constitutional by Indian Court
- IPAB ruled that mere increase in bio-availability is insufficient to overcome Section 3(d)
  - Decision under appeal before Supreme Court
- Section 3(d) concerned with IMPs (Incrementally modified products) and not New Chemical Entities (NCEs)
- Recently, Argentina and Philippines implemented similar provision; Thailand may follow suit

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Data Exclusivity to Clinical Trial Data

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ldy Committee Report

nded 5 year exclusivity period (follow foot-atch-Waxman Regime in USA)

›position

mently opposed such a clause in ndia-EU FTA negotiations.

een by critics as unnecessary – ttempt to delay generic entry