

FICPI WORLD CONGRESS
INCREMENTAL PATENTS OR
“EVER-GREENING”

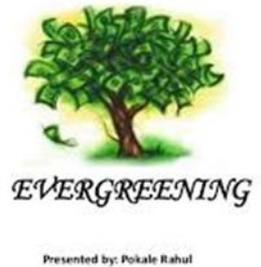
THE PATENT LAW CONTEXT

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Scope: Ever-greening as a patent law issue

Excluded:

- Socio-economic-political issues.
- Use of other IP laws in order to 'extend' or expand patent rights.
- Administrative and legislative attempts to frustrate the rights of inventors.
- Alternative incentives for pharmaceutical innovation.



Patent law issues

- Inventiveness: Incremental and adaptive innovation
- Invention or discovery: Second medical indications



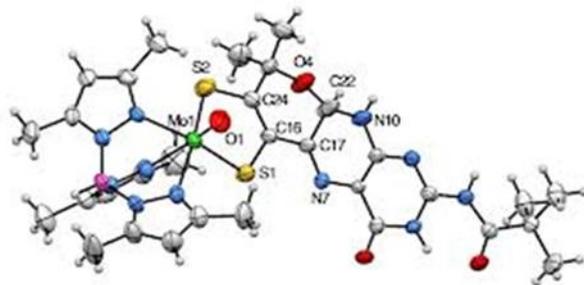
TRIPS art 27

- Patentable inventions must be
 - new,
 - involve an inventive step and
 - are capable of industrial application.
- No discrimination as to the field of technology.
- Exclusion: Diagnostic, therapeutic and surgical methods for the treatment of humans or animals.
- Inclusion: Micro-organisms and non-biological and microbiological processes.
- Distinct patent rules that respond to practical consequences of differences between fields of technology are permitted.

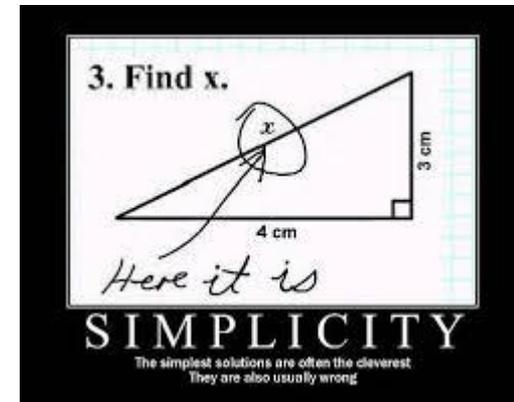


Inventiveness: Incremental and adaptive innovation

A typical nonsensical political statement is that pharmaceutical firms just tweak one molecule when a medicine patent is about to expire and then apply for a new patent.



The obvious answers



- Does not extend the life of the original patent.
- Requires novelty and inventiveness at the date of the application for the new patent.
- If the compound passes that hurdle and is new and inventive and an otherwise valid patent issues, the 'old' compound covered by the expired patent is nevertheless free for all to use.
- Anyone is free to tweak a molecule covered by a patent to prepare a new molecule during the life of the patent and patent the new molecule if it is inventive.
- If the tweaked molecule is obvious anyone would be free to use it during the life of the original patent and thereafter.

Indian solution Brazilian proposal

“inventive step” means a feature of an invention that involves

- (a) technical advance as compared to the existing knowledge or
- (b) having economic significance or
- (c) both and
- (d) that makes the invention not obvious to a person skilled in the art.’

The obvious questions

- ‘Involves technical advance as compared to the existing knowledge’ = ‘step forward’ test = inutility?
- Is a new and otherwise non-obvious analgesic which is no better than say aspirin not inventive? In any event it ought not to change much because non-compliance would probably lead to inutility.
- ‘Having economic significance or both’: who seeks to patent or infringe something that does not have economic significance?

Invention or discovery: Second medical indications

EPC and SA law:

- A new chemical compound (X) can be patented as can its use in the manufacture of a medicament.
- It may not, however, be claimed as a method of treatment.
- But when X is old, a Swiss form of claim confers novelty and yet is not a claim to a method of treatment.



Swiss form claims

- The generalised form of a Swiss form claim is ‘the use of compound X in the manufacture of a medicament for a specified (and new) therapeutic use.’
- The justification for novelty is the new therapeutic use.
- And since the claim is to the manufacture of the compound, it was not a claim to a method of treatment.
- Because the claim is limited to manufacture and not to use it is of limited value except against the manufacturer.

Indian discovery 1



- Redefine “discovery”:
‘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’ is not an invention.
- ‘Salts, esters, ethers, etc and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.’
- Question: will these instances not have been obvious?

Meaning of “efficacy”

“The test of efficacy depends upon the function, utility or the purpose of the product.

For a medicine the test is therapeutic efficacy, and for a vaccine prophylactic efficacy.”

Indian discovery 2

“The mere discovery of any new property or new use for a known substance or of 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” may not be patented.

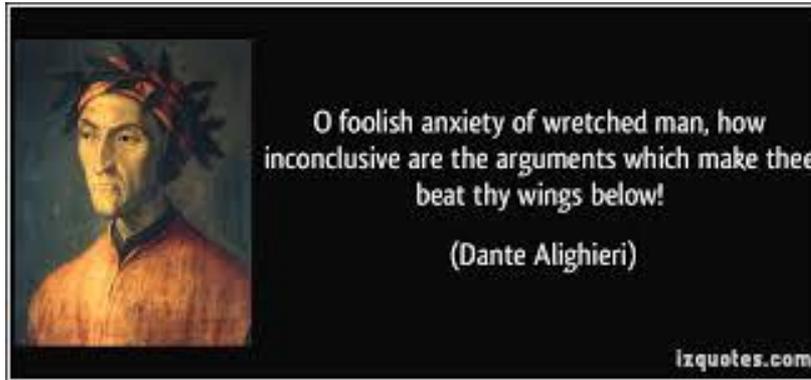
Step forward or backward?

- Reverts to pre EPC: “A thing is either old or it is not. If it is old, then a claim to the thing itself cannot be made novel by qualifying it with words specifying an intended use however inventive that use may have been.”
- Excludes a first medical use for an old substance.
- Removes apparent distinction between “substance or composition for use in a method of treatment of the human or animal body” and other inventions.

Solution?

- What are we demanding?
We demand that government fix our national patent laws. The specific law is called the Patents Act 57 of 1978. This law must be changed so that it balances the rights of patients with the rights of patent-holders in a way that is consistent with our constitution. The law must be changed to include all the life-saving provisions in the TRIPS agreement.





- Incremental and adaptive innovation: it is a no-brainer
- Second medical indications: political decision hinging on whether a country innovates or uses innovation.

Main source material

- Max Planck : “Declaration on Patent Protection” at <http://www.ip.mpg.de/en/pub/news/patentdeclaration.cfm>
- India: “National IPR Policy” (first draft) IPR Centre Think Tank, 19 December 2014.
- Brazil’s Patent law Reform: “Innovation towards National Competitiveness”, 2013, at [http://infojustice.org/wp-content/uploads/2013/09/Brazilian Patent Reform.pdf](http://infojustice.org/wp-content/uploads/2013/09/Brazilian_Patent_Reform.pdf) .
- South Africa: “Draft National Policy on Intellectual Property”, *Government Gazette* September 4, 2013 at www.gpwonline.co.za.
- WHO – WIPO – WTO: “Promoting Access to Medical” at http://www.wto.org/english/res_e/booksp_e/pantiwhowipowtweb13_e.pdf pp 125 to 137 and 171 to 190.
- *Actavis UK Limited v Merck & Co Inc* [2008] EWCA Civ 444.
- *Warner-Lambert Company, LLC v Actavis Group PTC EHF* [2015] EWHC 72 (Pat).
- *Novartis AG v Sun Pharma* Rechtbank Den Haag: C/09/460540 / KG ZA 14-1 \$5, 27 januari 2015
- *Warner-Lambert Company, LLC v Actavis Group Ptc EHF & Others* [2015] EWHC 223 (Pat) and [2015] EWHC 485 (Pat) (02 March 2015).