Obviousness Under India Patent Laws

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Broad Comparison

- United States
  - Obviousness left to the judiciary to develop
  - No legislative intervention
  - MPEP the Bible/Gita/Quran for PTO processes
  - Fairly litigious in ALL segments
  - USPTO a profit centre

- India
  - Very little guidance from courts
  - Legislation to 'limit' the scope of protection
  - Limited evolving litigation only in pharma area

Patentability Framework

- Novelty
- Industrial application
- Obviousness
- Exclusion

Patents Act – Amendments History

- **1970: Principal Act**
- **1995(Patents (Amendment) Act, 1999)**

  - Product Patents for drugs, pharmaceuticals and agro chemicals

  - Examination after Dec 31, 2004
- **2002 (Patents (Amendment) Act, 2002)**

  - Process patent for micro organisms

  - 20 year term for all technologies

  - Deferred examination

  - Add non patentable inventions
- **2005 (Patents (Amendment) Ordinance)**

Invention/Inventive step under Patents Act,1970(amended)

- Section 2 (j) "invention" means a new product or process involving an inventive step and capable of industrial application;

(ja) “inventive step” means a feature of an invention that involves technical advance as compared to the existing knowledge or having economical significance or both and that makes the invention not obvious to a person skilled in the art

‘not inventions’ (relevant to obviousness)

The following are not inventions within the meaning of this Act, -

(a) an invention which is frivolous or which claims anything obviously contrary to well established natural laws;

(d) 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 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.

***Explanation*.- 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;**

‘not inventions’ (relevant to obviousness) (Continued…)

Section 3(d) can be viewed as follows:

(a) (1) 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

(2) the mere discovery

i) of any new property or new use for a known substance or

ii) 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.

‘not inventions’ (relevant to obviousness) (Continued…)

(e) a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance;

(f) the mere arrangement or re-arrangement or duplication of known devices each functioning independently of one another in a known way;

(p) an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components.

Changes to Invention/Inventive step (Section 2j)

- **Principal Act, 1970**

2 (j) "invention" means any new and useful-

(i) art, process, method or manner of manufacture;

(ii) machine, apparatus or other article;

(iii) substance produced by manufacture,

Changes to Invention/Inventive step (Section 2j) (Continued…)

- **Patents (Amendment) Act, 2002**

  2 (j) "invention" means ~~any new and useful-~~

  ~~(i) art, process, method or manner of manufacture;~~

  ~~(ii) machine, apparatus or other article;~~

  ~~(iii) substance produced by manufacture~~,

  a new product or process involving an inventive step and capable of industrial application;

  (ja) “inventive step” means a feature that makes the invention not obvious to a person skilled in the art;

Changes to Invention/Inventive step (Section 2j) (Continued…)

- **Patents (Amendment) Act, 2005**

  2 (j) "invention" means a new product or process involving an inventive step and capable of industrial application;

  (ja) “inventive step” means a feature of an invention that involves technical advance as compared to the existing knowledge or having economical significance or both and that makes the invention not obvious to a person skilled in the art;

  2 (l) "new invention" means any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i.e. the subject matter has not fallen in public domain or that it does not form part of the state of the art;

Changes to Section 3(d)

- **Principal Act, 1970**

3(d) 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;

- **Patents (Amendment) Act, 2005**

3(d) the mere discovery of any 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 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;

Explanation.- For the purposes of this clause, salts, esters, ethers, polymorphs, ... and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy;

Changes (relevant to obviousness) (Cont..)

- **Principal Act, 1970**

(a) an invention which is frivolous or which claims anything obvious contrary to well established natural laws;

(e) a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance;

(f) the mere arrangement or re-arrangement or duplication of known devices each functioning independently of one another in a known way;

- **Patents (Amendment) Act, 2002**

(p) an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components.

Gaps Compared to US Law

- **Does novelty require basis in a single reference/product?**
  - History of obviousness as anticipation-extension
- **Graham vs. John Deere Starting point missing**
- **When can multiple references be combined?**
- **Objective guidance on 'impermissible hindsight construction' lacking**
- **Predictable vs. unpredictable arts (not yet identified)**

IPO Approach

- Would it be obvious to one skilled in the relevant arts?
  - Without undue experimentation

- Absence of a formal framework
  - Draft MPEP attempted
  - Opinion: Required for statutory duty to examine

- Arguments based on any foreign jurisdiction entertained
  - Required to report status of all non-India filings

IPO Approach (Cont..)

- Relies on pre-grant and post-grant oppositions for serious cases
  - Oppositions only in medicine cases
  - Number of iterations with Examiner limited
  - Reasoning almost absent in examination reports
  - Function of available limited resources and skill set

- Controller decisions in opposition
  - Clear identification of features present/missing
  - Clear ‘mental’ effort from PHOSITA viewpoint

IPO Approach (Cont..)

- “Obviousness one of my mind”
  - Cannot be entirely comprehended?
  - “I know it when I see it”

- Frameworks can help
  - sound results
  - more consistent results

Pre-grant opposition-Controller's Decisions

- **NOVARTIS (Applicant) Vs. Ranbaxy Laboratories Ltd.**
  - 1440/MAS/1998 filed on 29th June

  - Routine Experimentation to form crystalline form from amorphous form

  - Being the first person to prepare the crystalline compound of a known amorphous form does not fulfill the requirement of inventive step under the Indian Patents Act

  - Section 3(d): Enhancement in the KNOWN EFFICACY of the known substance, also missing

  - Patent denied

Pre-grant opposition-Controller's Decisions (Continued…)

- **Pfizer Health (Applicants) vs. Ranbaxy Laboratories Ltd**

  - IN/PCT/2001/00788/CHE

  - A water permeable first layer can control the drug release profile of the bead. There are several advantages obtainable of it as stated above. Hence, it is held that it is not obvious to a man skilled in the art to formulate the first layer in the cited document as water permeable to reach the present invention. In fact, the cited document **teaches away** from the present invention by requiring the first layer be impermeable to the water. Hence, the present claims are found to involve an inventive step.

Pre-grant opposition-Controller's Decisions (Continued…)

- **PFIZER (Applicant) vs. OSI PHARMACEUTICALS, INC**

  - 537/Del/1996

  - Lord Westbury LC in Hill Vs. Evans in the following terms:

  'the antecedent statement must, in order to invalidate the subsequent patent, be such that a person of ordinary knowledge of the subject would at once perceive and understand and be able practically to apply the discovery without the necessity of making further experiments.....the information ..... given by the prior publication must for the purpose of practical utility be equal to that given by the subsequent patent'.

  - I am of the conclusion that opponents probably failed to properly evaluate the strength of the invention. Sometimes the modification in the prior art technologies which appear to be minor may bring great revolutions in the world which could never be predicted by the society of intellectuals.

  - And further once the invention has been found inventive the invention can not be Patentable under section 3(d) of the Patents Act. Therefore, I held that the invention can not be held non-patentable under section 3(d) of the Patents Act, 1970.

Pre-grant opposition-Controller's Decisions (Continued…)

- **F.HOFFMANN-LA ROCHE vs. RANBAXY LABORATORIES LTD**.

  - 190/MAS/1998 filed on 29th January 1998

  - The agent for the applicant further stated that the opponent has failed to assess the inventive step on the grounds namely;

  (i) that there is some teaching or suggestion in the cited prior art that would motivate the skilled artisan to modify the prior art;

  (ii) some expectation that such modification would work

  - In the words of the applicant it is the size of the particle or a pellet, which overcomes the problems of chemical stability, picking and sticking phenomena. Comparative examples were provided in the specification with respect to picking and sticking phenomena wherein the results shown proves that the problem of picking and sticking phenomena has been overcome. No substatative explanation has been provided with respect to chemical stability that is achievable from the alleged invention.

  - The invention as disclosed passes the Novelty test but lacks in Inventive step.

Pre-grant opposition-Controller's Decisions (Continued…)

- **NOVARTIS AG vs. M/s TORRENT PHARMACEUTICALS LIMITED**

  - IN/PCT/2001/00864/CHE

  - A pharmaceutical composition in the form of a tablet for the treatment of invasive lung cancer comprising a therapeutically effective amount of valsartan or pharmaceutically acceptable salt thereof and comprising auxiliary microcrystalline cellulose

  - New use of a known substance is not allowable under Section 3(d)

  - Imagine that the claim is devoid of words, "FOR THE TREATMENT OF INVASIVE LUNG CANCER"

  - composition being not inventive [as valsartan and microcrystalline cellulose are known compounds]

  - Opposition sustained

Pre-grant opposition-Controller's Decisions (Continued…)

- **PFIZER HEALTH AB/ PHARMACIA & UPJOHN vs. RANBAXY LABORATORIES LTD**
  - IN/PCT/2000/00084/CHE
  - The composition as claimed therein is not a mere admixture but it is a synergistic composition
  - Reduced the number of urge incontinence episodes per week by 71% in relation to Placebo
  - Patent allowed

- **M/s J.Mitra & Company vs. M/s Qualpro Diagnostics**
  - 2382/DEL/2004
  - All features individually found in different prior art references
  - When a alleged invention is prima facie obvious having regard go the prior art nevertheless it is some time possible to prove inventiveness by comparative test showing **significant improvement over the closest prior art**

Pre-grant opposition-Controller's Decisions (Continued…)

- **BOEHRINGER INGELHEIM PHARMA GMBH vs. CIPLA Ltd.**

  - 2632/DELNP/2005

  - To a person skilled in the art, it is obvious to combine the teaching of D7, D8 or D9 with the proposed active substance (salmeterol xinafote and a titropium salt) combination and method of production of D6 (or D3-D5) so as to arrive at the alleged invention as provided in the 2632 application

Case Law- Supreme Court of India

- *M/s. Bishwanath Prasad Radhey Shyam Appellant v. M/s. Hindustan Metal Industries, [Pre-1970 Patents Act]*
- *Held:* "It is important that in order to be patentable an improvement on something known before or a combination of different matters already known, should be something more than a mere workshop improvement; and must independently satisfy the test of invention or an 'inventive step'. To be patentable the improvement or the combination must produce a new result, or a new article or a better or cheaper article than before. The combination of old known integers may be so combined that by their working interrelation they produce a new process or improved result. Mere collection of more than one integers or things, not involving the exercise of any inventive faculty, does not qualify for the grant of a patent.“

- *Dicta*: To decide whether an alleged invention involves novelty and an inventive step, certain broad criteria can be indicated. … Secondly, the alleged discovery must not be the obvious or natural suggestion of what was previously known.

Case Law- High Courts of India

- **Press Metal Corporation Limited v. Noshir Sorabji Pochkhanawalla (Bombay High Court, 1973)**
  - improvement in or relating to Muffler and Exhaust silencer for internal combustion engines
  - Found to be a workshop improvement over art of record
  - Anticipation

Case Law- High Courts of India (Continued…)

- **Shri Surendra Lal Mahendra v. M/s Jain Glazers (1981 PTC 112, High Court of Delhi)**

  - pertaining to laminating apparatus

  - invention claimed by the plaintiff involves nothing which is outside the probable capacity of skilled craftsman having regard to what was already known in the country and there being no new manner of manufacture or a distinctive improvement on the old contravene involving novelty or inventive steps

- **Novartis vs. Union of India (Madras High Court, 2007)**

  - Section 3D found constitutional
  - TRIPS compliance: Outside of their jurisdiction

Thank you!