

The Patents (Amendment) Act, 2005 – A Critique

Presentation at

ASSOCHAM

May 06, 2005

In my view the following issues require (re) consideration

- (1) Definition of 'inventive step' [Sec.2(1)(ja)]
- (2) Definition of 'new invention' [Sec.2(1)(l)] r/w 'invention' in 2(1)(j)
- (3) 'pharmaceutical substance' [Sec.2(1)(ta)]
- (4) Excluded subject-matter in Sec. 3(d) r/w 'Explanation'
- (5) Second Medical Use & Swiss-type claims
- (6) Method of treatment
- (7) Scrapping of 3(k) & (ka)
- (8) Pre-grant Representation (opposition) system
- (9) Foreign Filing License
- (10) Working Requirement – obligations
- (11) Dateline for Publication and RFE
- (12) Re-Publication of PCT Application

The Technical Expert Group on Patent Law Issues - Terms of Reference:

- * Whether it would be TRIPS compatible to limit the grant of patents for pharmaceutical substance to **new chemical entity** or to new medical entity involving one or more inventive steps; and
- * Whether it would be TRIPS compatible to exclude **micro-organisms** from patenting.

- * Would it be TRIPS Compliant if India excludes all inventions except those directed at New Chemical Entities in pharmaceutical arts?
- * Art. 27 (3) (b) of TRIPS mandates the Member Countries not to exclude **micro-organisms** from patenting.

Flawed Definitions!

Definition of 'inventive step' [Sec.2(1)(ja)]

“A feature of an invention:

- (a) that involves technical advances as compared to the existing knowledge; or
- (b) having economic significance; or
- (c) Both of the above; AND
- (d) That makes the invention not obvious to a person skilled in the art

‘New Invention’ & ‘absolute novelty’

“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”.

‘New Invention’ a check on ‘Invention’ in Sec. 2(1)(j)

- * The definition of ‘new invention’ acts as a check on the mandate in Sec.2(1)(j) that an invention to be patentable must be ‘new’.
- * The new requirement is that there must be ‘absolute novelty’ (and not ‘relative novelty’) for an invention to be patentable.
- * An invention will be anticipated by prior public working anywhere in the world (and not just in India).

‘pharmaceutical substance’

- * “Any new entity involving one or more inventive steps’
- * This definition reflects an unfinished agenda!
- * There is no mention of the expression ‘pharmaceutical substance’ in the body of the Act.
- * The definition reads into it the additional limitations brought into defining ‘inventive step’.
- * The only missing link is the absence of limiting product patents to pharmaceutical substance (in the case of inventions in the field of pharmaceutical arts).

3(d) Exclusions

What all Sec. 3(d) excludes:-

- Mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance;
- Mere discovery of any new property for a known substance;
- New use for a known substance;
- 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

More 3(d) Exclusions Specific to Pharmaceuticals

Explanation to Sec. 3(d) excludes:-

- Salts;
- Esters;
- Ethers;
- Polymorphs;
- Metabolites;
- Pure form;
- Particle size;
- Isomers;
- Mixtures of isomers;
- Complexes;
- Combinations & other derivatives of known substances

Unless they differ significantly in properties with regard to efficacy.

No more Swiss-Types Claims

- The Ordinance qualified 'new use' with 'mere' in Sec. 3(d) to permit Swiss-type claims directed at 'second medical use'.
- That is no more the case.

Method of Treatment

- Method of treatment continues to be ‘non-statutory subject matter’.
- An Enlarged Board of Appeal at the EPO is considering the permissible exclusions in relation to methods of treatment.
- The patents act does not strike a proper balance in defining the exclusions in Section 3(i).

Scrapping 3(ka)

- The Ordinance brought in a new sub-section 3 (ka) to cover the excluded subject matter in the field of ‘computing’;
- The 3 (k) as originally introduced by the 2002 amendment act was re-framed to explain what is not *PER SE*;
- The ‘technical effect test’ in the Europe (at EPO) was the basis for the amended 3(k) as in the Ordinance;
- The 2005 Act scrapped it – on what rationale;
- No empirical study has so far been conducted in India to understand what is in the interests of Indian s/w industry – patents or no patents!

Pre-Grant Representation System & Post-grant Opposition

- * The heading of the new Chapter V as proposed in the Ordinance was “REPRESENTATION AND OPPOSITION PROCEEDINGS” – it is now changed to ‘OPPOSITION PROCEEDINGS TO GRANT OF PATENTS’.
- * That means we WERE talking about a Representation System prior to grant like the one available at the EPO;
- * But it is not. It is now ‘opposition pre-grant’ & ‘opposition post grant’.
- * Pre-grant opposition can be instituted by ‘any person’. But, post-grant opposition can be instituted only by “person interested” – why this difference ?

Foreign Filing License

- Section 39 is re-introduced
- A foreign filing permission is required to file patent applications in respect of inventions originating from India
- This is applicable even for PCT International Applications filed at the Indian Patent Office as RO.

Working Statement

It seems we often look at the 'entire' institution of patents only from the perspective of pharmaceutical and chemical inventions.

The 2005 Act amended Section 122 of the Patents Act, 1970. As per the amended provision if a Patentee does not file a Working Statement the penalty is Ten lakh Rupees!

Now how should one file a Working Statement – in Form 27. Look at the form.

FORM 27
THE PATENTS ACT, 1970
(39 of 1970)

No Fee

&
The Patents Rules, 2003

**Statement regarding the working of the patented
invention on commercial scale in India**
[See section 146(2) and rule 131(1)]

1. Insert name, address and nationality.

In the matter of Patent No.....of

I/We¹

2. State the year to which the statement relates

The patentee (s) or licensee (s) under Patent No..... hereby furnish the following statement regarding the working of the patented invention referred to above on a commercial scale in India for the year².....

3. Give whatever details are available.

- { (i) The patented invention:
{ } Worked { } Not worked [Tick (✓) mark the relevant box]
(a) if not worked: reasons for not working and steps being taken for working of the invention.
(b) If worked: quantum and value (in Rupees), of the patented product:
i) manufactured in India
ii) imported from other countries. (give country wise details)
(ii) the licenses and sub-licenses granted during the year;
(iii) state whether public requirement has been met partly/adequately/to the fullest extent at reasonable price.

The facts and matters stated above are true to the best of my/our knowledge, information and belief.

Dated this day of200

4. To be signed by person(s) giving the statement.

Signature⁴

To
The Controller of Patents
The Patent Office
at

Note: (a) Strike out whichever is not applicable."

Need to move beyond pharma – at least when drafting the Act and the Rules

In many areas of technology (as for example telecommunications) it is rather impossible to individuate inventions and quantify the “quantum and value” of the patented product.

A clear case of having ‘pharmaceutical inventions’ on top of the draftsman’s mind!!

RFE

We have a system of 18 months Publication.

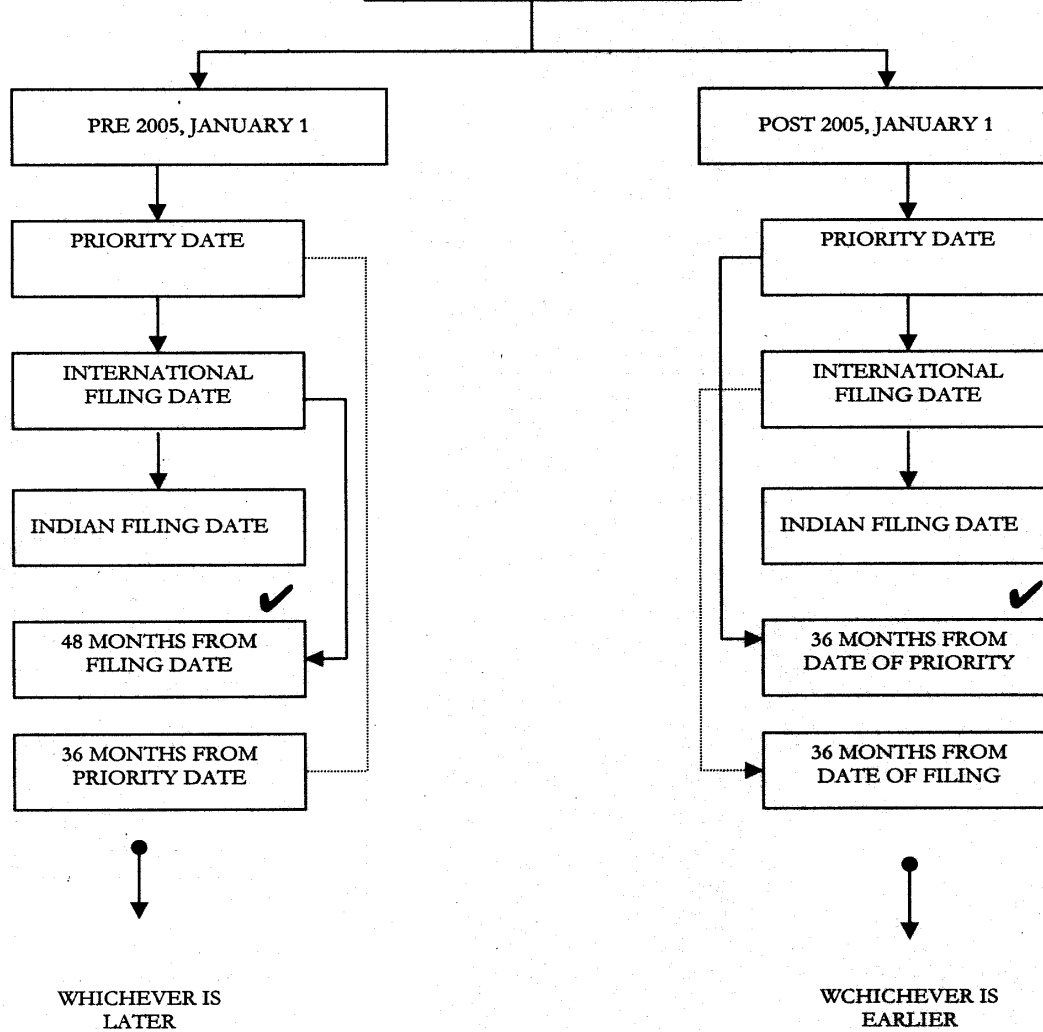
We also have a system of Request for Examination (RFE).

We have a rather complicated deadline to file RFE.

Please see these charts –

**REQUEST FOR
EXAMINATION FOR PCT
NATIONAL PHASE
APPLICATION**

**PCT NATIONAL PHASE
APPLICATION**



REQUEST FOR EXAMINATION FOR CONVENTION APPLICATION

CONVENTION APPLICATION

PRE 2005, JANUARY 1

POST 2005, JANUARY 1

CONVENTION PRIORITY DATE

CONVENTION PRIORITY DATE

INDIAN FILING DATE

INDIAN FILING DATE

18 Months

18 Months

PUBLICATION

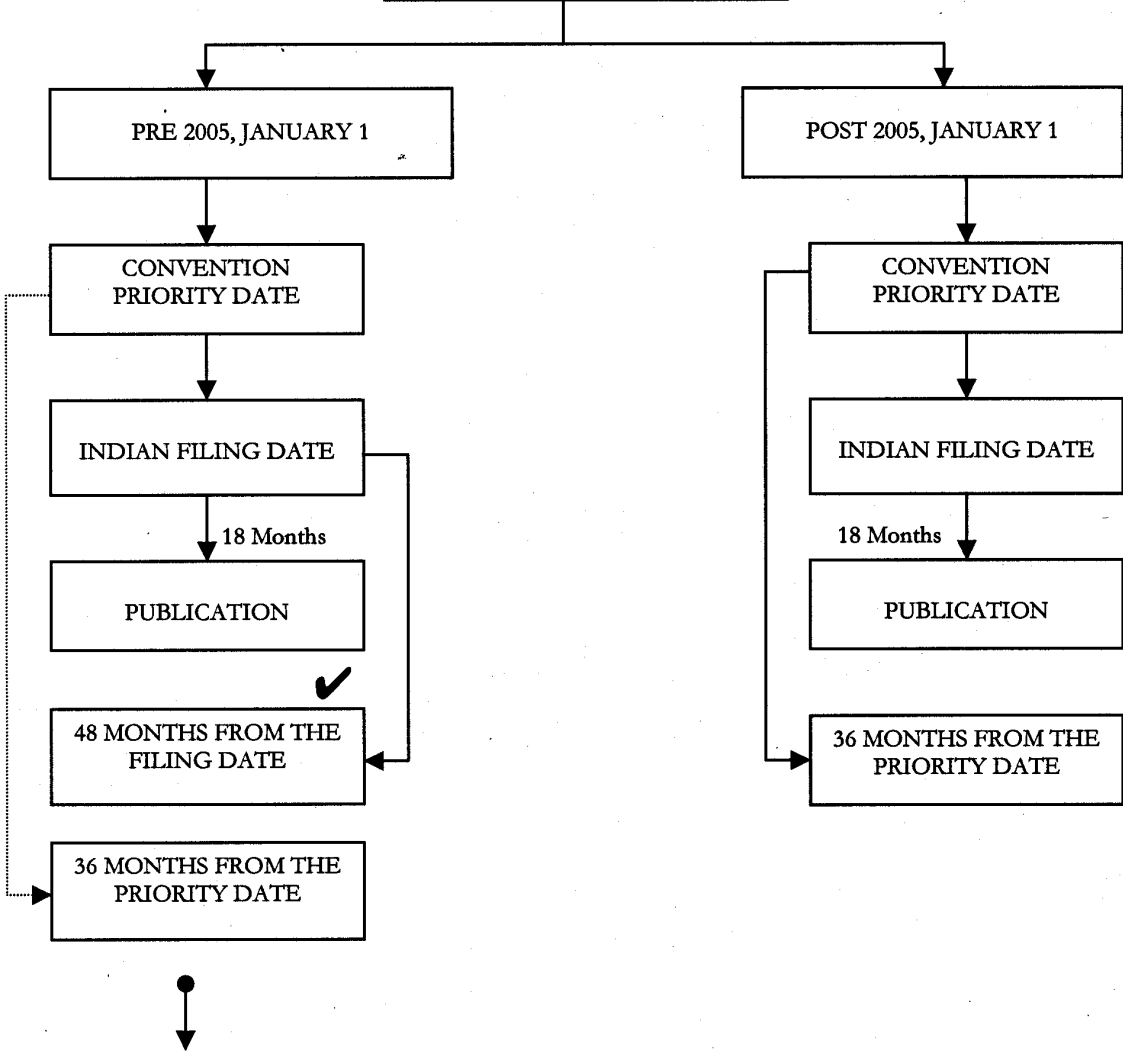
PUBLICATION

48 MONTHS FROM THE FILING DATE

36 MONTHS FROM THE PRIORITY DATE

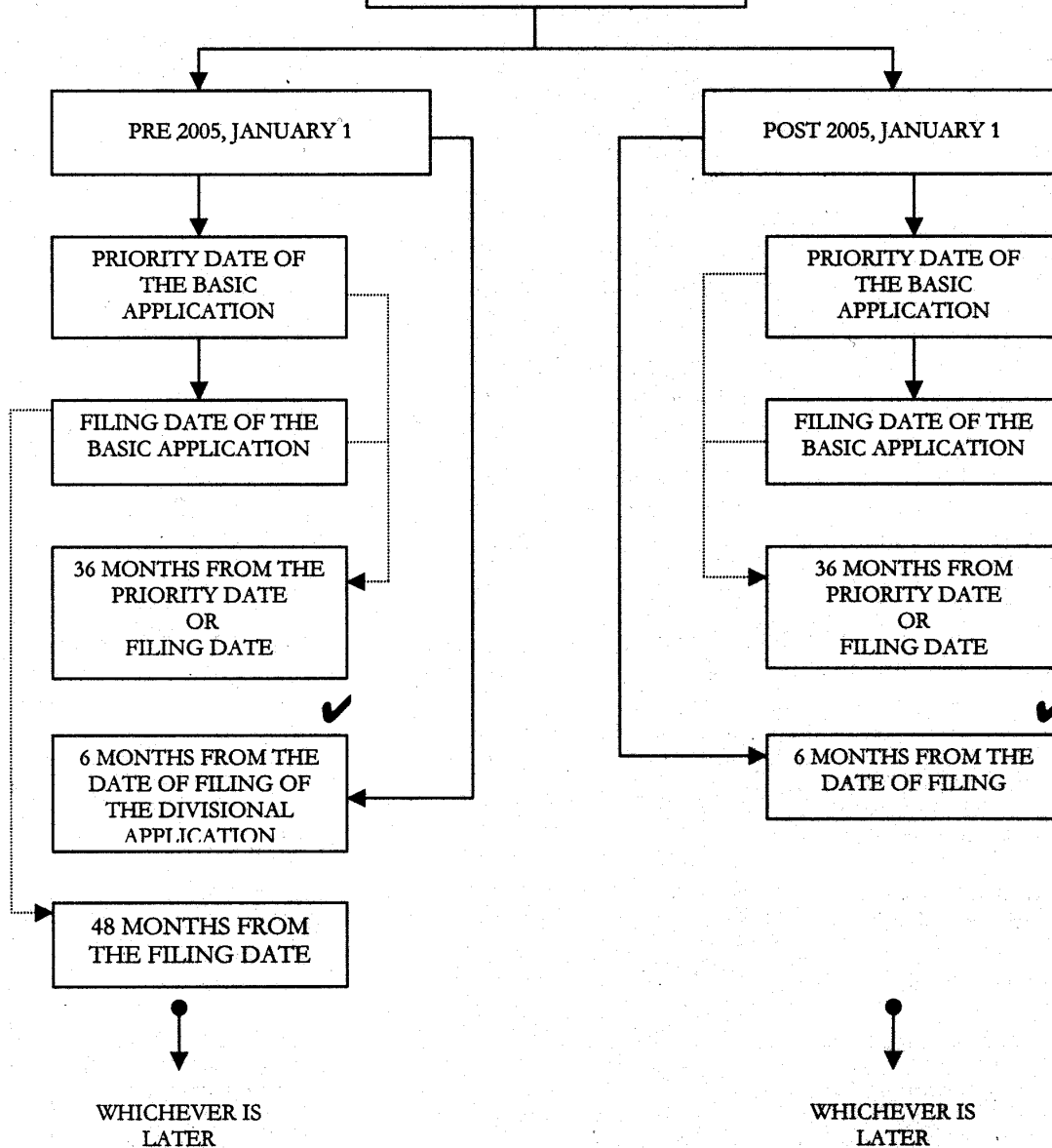
36 MONTHS FROM THE PRIORITY DATE

WHICHEVER IS LATER



**REQUEST FOR
EXAMINATION FOR
DIVISIONAL APPLICATION**

DIVISIONAL APPLICATION



RFE Deadline

- * A PCT National Phase Application enters NP in India on 31 months of its date of priority.
- * The projected publication date for all Indian patent applications is 18 months on filing the application in India, as I said.
- * As per the existing law the Request for Examination must be filed after publication and within 36 months from priority.
- * How is this possible in PCT National Phase Applications?

Briefly ..

- * Is the Patents Act, 1970 as amended by the Patents (Amendment) Act, 2005 TRIPS compliant?
- * Can micro-organisms be excluded from patentability without violating TRIPS Agreement?
- * Can patentability be limited only to 'New Chemical Entities' without violating TRIPS Agreement.
- * Are the amendments in the definitions (including the newly added definitions) self-defeating in nature?

Thank You