

959

Government of India
Ministry of Commerce & Industry
Department of Industrial Policy & Promotion

An Ordinance, Patents (Amendment) Ordinance, 2004 was promulgated on 26.12.2004. Notice for introduction of the Bill has already been given in Lok Sabha. A bill to replace the Ordinance has been circulated. A copy of the Bill is enclosed.

After consultations with the concerned groups/organizations, some *draft* modifications are proposed in the said bill. A statement is enclosed.

Legislative Department is requested to draft official amendments to the bill. Further approval of competent authority for these amendments will be obtained separately.

Rajeev
17/3/05
(Rajeev Ranjan)
Director

Shri N. K. Nampoothiry, Joint Secretary & Legislative Counsel
Legislative Department, Ministry of Law & Justice, Shastri Bhawan, New Delhi
Department of Industrial Policy & Promotion I.D. No. 12/14/2003-PP&C dated
17th March, 2005

Encl: As above

96

AMENDMENTS IN THE PATENT BILL 2005

1. Scope of patentability

In order to restrict the scope of patentability, the following has been agreed to:

a) Modifying definition Section 2 (ja). "Inventive step" means a feature of an **invention that involves technical advance as compared to the existing knowledge and or having economic significance and that makes the invention not obvious to a person skilled in the art;**

b) New definition Section 2 (la) "New invention" - A new clause may be incorporated as follows:

"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".

c) New definition Section 2 (ta) "Pharmaceutical Substances" - A new clause may be incorporated as follows:

"Pharmaceutical Substances" ^{means} includes new entity ~~(chemical or medical)~~ involving one or more "inventive steps".

d) In order to incorporate the intention of restricting the scope of patentability particularly for pharmaceutical inventions, the following was agreed to (Based on formulation Suggested by Justice V.R. Krishna Iyer):

Section 3 (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 to Section 3 (d): "Salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to safety and/or efficacy.

(Highlighted portion is the new addition)

- e) The word "mere" introduced by the Ordinance before the words "new use" in Section 3 (d) was agreed to be deleted. (This will remove any doubt suggesting that the scope of patentability is being enlarged by narrowing the exceptions to inventions).

2. Strengthening of Pre-grant Opposition:

- a) **Opposition to grant of patent:** The proposed new Chapter heading concerning opposition, namely, "REPRESENTATION AND OPPOSITION PROCEEDINGS" to be substituted with earlier heading, namely, "OPPOSITION TO GRANT OF PATENT". (This will allay the fear that opposition proceedings are being 'diluted').
- b) **Hearing at pre-grant opposition stage:** A provision for hearing at pre-grant opposition stage has been made in the rules. This may be introduced upfront in the law itself, as it would provide a higher comfort level.

It is also proposed to provide a minimum period of 6 months, from the date of publication, for making representation as against the present period of 3 months. This will ensure that the opponents get sufficient time to file the objections.

Since all the time-lines have been provided in the subordinate legislation, this will also be done in the rules. The modified draft could be as under:

" 25 (1) Where an application for a patent has been published but a patent has not been granted, any person may, in writing, represent by way of opposition to the Controller against the grant of patent within the prescribed period on the grounds of

(a)

(b)

and the Controller shall provide him an opportunity of hearing if so requested and dispose of the representation in such manner and within such period as may be prescribed."

- c) **Becoming party to any proceedings:** Section 25 (2) prohibits the persons making a representation from becoming a party to any proceedings under the Act. This provision restricts the scope of opposition. Therefore, in order to strengthen the pre-grant opposition sub-Section (2) of Section 25 can be deleted.

3. **Facilitation of pharmaceutical exports to LDCs:** This new provision (Section 92A) relates to compulsory licence for export of patented pharmaceutical products under Para 6 of Doha declaration, to such countries as have inadequate production capacities. Here the condition of obtaining compulsory licence could be expanded, (in case of LDCs having no Patent Law or provision for compulsory licence) to include an

'authorisation' or notification from such a country. It was agreed to add, in sub-section (1) of section 92A, the following words after the words "provided compulsory licence has been granted by such country".

"or such country has by notification or otherwise allowed importation of the patented pharmaceutical products from India."

- 4. **Amendment to Section 90 relating to compulsory licence:** Section 90 (1) (vii) and (viii) can be modified as follows and a new sub-section 90 (1) (ix) can be introduced as suggested below:

(vii)that the license is granted with a predominant purpose of supply in the Indian market and that the licensee may also export the patented product, if need be in accordance with Sections 84 (7) (a) (iii) and 92 A".

(viii) that in the case of semi-conductor technology, the license granted is to work the invention for public non-commercial use;

(ix) that in case the license is granted to remedy a practice determined after judicial or administrative process to be anti-competitive, the licensee shall be permitted to export the patented product, if need be.

- 5. **Transitional arrangement applications:** It has been suggested that a provision be made in the law so that the companies which are manufacturing the products for which applications are in the mailbox should be able to continue production of the said products on payment of nominal royalty. A 3rd new proviso can be added under section 11 A (7) as follows:

Provided also that after a patent is granted in respect of applications made under sub-section (2) of section 5, the patent holder will be entitled to receive reasonable royalty from such enterprises as made significant investment and were producing and marketing the concerned product prior to 1.1.2005 and continue to manufacture the product covered by patent on and after the grant of patent.

- 6. **Compulsory licensing:** A new Section, namely, 84 (B) has been suggested to enable obtaining compulsory licence on reasonable commercial terms and conditions and prescribing a time limit of 5 months for obtaining such licence. The suggestion can be better incorporated as an explanation to the existing section 84 (6) (iv), before the existing proviso, as under:

"Explanation: The reasonable time period under this clause shall not ordinarily exceed six months".

Ministry of Law and Justice
Legislative Department

963

Subject:- The Patent (Amendment) Bill, 2005.

The list of amendments suggested by the Department of Industrial Policy and Promotion has been perused in this Department.

2. It is noted that the administrative Ministry has suggested incorporation of definitions of "new invention" and "pharmaceutical substances" among other amendments. It may please be ensured that the said definitions will have use at least once in the Patents Act, 1970.

Another suggestion is to omit clause 22 of the Bill. In this connection it may be noted that withdrawal of a clause of a Bill is inadmissible as per the provisions contained in sub-rule (2) of rule 344 of the Rules of Procedure and Conduct of Business in Lok Sabha which reads as under:-

"(2) An amendment shall not be moved which has merely the effect of a negative vote."

3. In view of the procedural provision as explained above, the right course of action for the administrative Ministry is to get the support of the treasury in voting down clause 22 of the Bill as and when the same is put down for voting by the Hon'ble Speaker so that clause 22 of the Bill may not be adopted by the House.

4. In view of the extreme urgency expressed by the administrative Ministry, this has not been submitted to the Secretary for approval. The administrative Ministry may satisfy that the draft of the official amendments suggested as per the enclosed notice meets with their requirements and intentions adequately. We may carry out drafting improvements and consequential changes at the appropriate time.

5. Incidentally, it may be mentioned here that moving of official amendments which are not of a formal nature requires approval of the Cabinet. In case the time available is very short, the Minister in charge of the Bill may seek the approval of the Hon'ble Prime Minister and seek *ex post facto* approval of the Cabinet.



(N.K. Nampoothiry)

Joint Secretary and Legislative Counsel
17-03-2005

Department of Industrial Policy and Promotion

R.Rajam
17/3

US1 HKY

To

The Secretary General,
Lok Sabha,
New Delhi.

Sir,

I give notice of my intention to move the following amendments after the adoption of the motion that the Patents (Amendment) Bill, 2005 be taken into consideration, namely:—

AMENDMENTS

Serial Number	Text of Amendments	Clause number
1.	Page 2, <i>after</i> line 25, <i>insert</i> — (f) for clause (ja), the following clause shall be substituted, namely:— '(ja) "inventive step" means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art;'	2
2.	Page 2, line 26, <i>for</i> "(f)", <i>substitute</i> "(g)"	2
3.	Page 2, <i>after</i> line 26, <i>insert</i> ,— '(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, that is, the subject matter has not fallen in public domain or that it does not form part of the state of the art;'	2
4.	Page 2, line 27, <i>for</i> "(l)", <i>substitute</i> "(la)"	2
5.	Page 2, <i>after</i> line 29, <i>insert</i> ,— '(h) after clause (t), the following clause shall be inserted, namely:—	2

‘(ta) “pharmaceutical substance” means any new entity involving one or more inventive steps;’

6. Page 2, *for* lines 31-36, *substitute*— 3
- Amendment of section 3 3. In section 3 of the principal Act, for clause (d), the following shall be substituted, namely:—
- “(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;”
7. Page 5, *after* line 10, *insert*— 10
- “Provided also that after a patent is granted in respect of applications made under sub-section (2) of section 5, the patent holder shall only be entitled to receive reasonable royalty from such enterprises which have made significant investment and were producing and marketing the concerned product prior to 1st day of January, 2005 and which continue to manufacture the product covered by patent on the date of the grant of patent and no infringement proceedings shall be instituted against such enterprises”.
8. Page 7, line 38,— 23
- for* “the Controller shall consider and dispose of”, *substitute* “the Controller shall, if requested by such person for being heard, hear him and dispose of”
9. Page 7, *omit* lines 40 to 42 23
10. Page 7, line 43, *for* “(3)”, *substitute* “(2)” 23
11. Page 9, line 1, *for* “(4)”, *substitute* “(3)” 23
12. Page 9, line 10, *for* “(5)”, *substitute* “(4)” 23
13. Page 9, line 13,— 23
- (i) *for* “(6)”, *substitute* “(5)”;

(ii) for "(5)", substitute "(4)"

14. Page 9, line 14,- 23
 for "(3)", substitute "(2)"
15. Page 9, line 23, for "(3)", substitute "(2)" 23
16. Page 14, after line 9, insert- 52A
 (New clause)
- Amendment of section 84. '52A. In section 84 of the principal Act,-
- (a) in sub-section (1), for the word "sealing", the word "grant" shall be substituted;
- (b) in sub-section (6), the following *Explanation* shall be inserted at the end, namely.-
- Explanation.*-For the purposes of clause (iv), "reasonable period" shall be construed as a period not ordinarily exceeding a period of six months.'
17. Page 14, for lines 15-24, substitute- 53
- "(vii) that the licence is granted with a predominant purpose of supply in the Indian market and that the licensee may also export the patented product, if need be in accordance with the provisions of sub-clause (iii) of clause (a) of sub-section (7) of sections 84;
- (viii) that in the case of semi-conductor technology, the licence granted is to work the invention for public non-commercial use;
- (ix) that in case the licence is granted to remedy a practice determined after judicial or administrative process to be anti-competitive, the licensee shall be permitted to export the patented product, if need be."
18. Page 14, lines 30-31,- 54
- for "provided compulsory licence has been granted by such country", substitute "provided compulsory licence has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India."
19. Page 15, line 30, for "(5)", substitute "(4)" 60

Yours faithfully

KAMAL NATH