



अशोक झा
ASHOK JHA

सचिव

भारत सरकार

वाणिज्य एवं उद्योग मंत्रालय
(औद्योगिक नीति और संवर्धन विभाग)

उद्योग भवन, नई दिल्ली-110 011

Secretary

Government of India

Ministry of Commerce & Industry
(Deptt. of Industrial Policy and Promotion)

Udyog Bhawan, New Delhi-110 011

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D.O. No. 12/14/2003-PPA C

Dated 19th March, 2005

Dear Shri *Chaturvedi,*

As you are kindly aware, the Patents Act was amended through an Ordinance in December, 2004. Thereafter further discussions with various stake holders have been held and certain amendments have become necessary.

These official amendments would normally be put up to the Cabinet for approval. However, as the Bill to replace the Ordinance is to be taken up for consideration in the Lok Sabha on Monday, the 21st March, 2005, Commerce and Industry Minister has addressed a Note to the Prime Minister to condone a departure under Rule 12 of the Government of India (Transactions of Business) Rules, 1961. The Note along with the enclosures is attached.

I shall therefore, be grateful if the official amendments are kindly approved by the Prime Minister on priority as the Bill is to be taken up in the Lok Sabha on 21st March, 2005.

With kind regards,
Yours sincerely,

Asha
(Ashok Jha)

Encl : as above

Shri B.K. Chaturvedi
Cabinet Secretary
Cabinet Secretariat
Rashtrapati Bhavan
New Delhi

No. 12/14/2003-PP&C
Government of India
Ministry of Commerce and Industry
Department of Industrial Policy and promotion

Subject: Proposal for amendment to the Patents Act, 1970.

The Cabinet in its meeting held on 24.12.2004, considered a proposal for amendment to the Patents Act, 1970, first by promulgation of an Ordinance and subsequently introducing a Bill in Parliament to replace the said Ordinance. Accordingly, an Ordinance, namely, the Patents (Amendment) Ordinance, 2004 (Ordinance No.7 of 2004) was promulgated on 26.12.2004. ✓ The provisions of the Ordinance came into force from 1.1.2005. This was done to meet India's international obligations due from 1.1.2005 under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) which is part of the Agreement establishing the World Trade organization (WTO). A Bill, namely, the Patents (Amendment) Bill, 2005, to replace the said Ordinance, has been introduced in Lok Sabha on 18.3.2005. A copy of the Patents (Amendment) Bill, 2005 as introduced is placed in the file. x

2. As per the provisions contained in Article 123(2)(a) of the Constitution, the provisions of an Ordinance are valid only for a period of 6 weeks from the date of re-assembly of Parliament. The current session of the Parliament commenced from 25.2.2005 and as such the provisions of the Ordinance are valid only up to 8.4.2005. However, both the Houses will adjourn on 24.3.2005 for enabling Department Related Standing Committees to consider the demands for grants and the Houses will meet again from 18.4.2005. As such, there is an urgency to have the Bill passed by the Parliament latest by 24.3.2005.

3. After the issuance of the Ordinance, further discussions have been held with various stakeholders including political parties and representations have also been received from different quarters, expressing concerns that the domestic generic pharmaceutical sector could be hampered and that the supply of medicines to the public could be adversely affected.

These concerns had already been taken into consideration by the Group of Ministers while discussing the draft Bill, subsequently promulgated as the ordinance. However, in view of the strongly expressed concerns, it is proposed to introduce some changes in the provisions of the Bill as introduced in Lok Sabha before it is taken up for consideration, so as to address these concerns unambiguously.

4. It is proposed to make the following amendments:

(a) **Scope of patentability:**

In order to further ensure that frivolous patenting or 'evergreening' of patents is avoided and the interests of Indian industry, including the pharmaceutical sector are secured, definitions of 'inventive step', 'new inventions' and 'pharmaceutical substances' are either proposed to be amended or inserted. Similarly, scope of exclusions from patentability is proposed to be further revised by amending Section 3 (d) and a detailed explanation is proposed to be added based on the formulation suggested by Justice V.R. Krishna Iyer (Retired).

Concerns have also been expressed against the clarification relating to patenting of software related inventions when they have technical applications [Section 3 (k) - Clause 3 (b) of the Bill]. It is proposed to delete the proposed clarification and leave the provision as it was.

(b) **Opposition procedure:**

The Ordinance had streamlined the opposition procedure seeking to provide correctives against delays and introduced a simplified, efficient, cost effective and user-friendly mechanism. However, it has been suggested that the opportunity of hearing, provided for in the subordinate legislation should be in the main statute, and that period for submitting opposition should be extended. These concerns are now proposed to be addressed by strengthening the pre-grant opposition suitably including modifying the language slightly, so as to remove any doubt that opposition procedures were being 'diluted'.

(c) **Export of pharmaceuticals to Least Developed Countries (LDCs):**

It has been represented that the provisions contained in the Ordinance under Section 92A permitting export of patented drugs to countries which do not have adequate manufacturing capabilities, does not cover the situation when a country does not have a patent law or the relevant product is not under patent protection in that country. This is proposed to be addressed through an amendment, so as to amplify the provision.

(d) **Compulsory Licence- related provisions.**

These provisions were comprehensively revised by the Joint Committee of Parliament that examined the second amendment to the Patent Law. However, it has been suggested that certain amendments are needed particularly in Section 84 and 90 to clarify issues like export of products made under compulsory licence and quantifying the time period within which patentee should respond to a request for licence failing which the


applicant can approach the Controller of Patents for issuance of a compulsory Licence. These clarifications are proposed to be incorporated.

- (e) **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 reasonable royalty. This suggestion is proposed to be accepted.

5. A detailed note ✓ on the amendments proposed along with their justification is also placed in the file. (The additions have been shown in bold font). Ministry of Law has also since drafted the official amendments which could be moved in Lok Sabha when the Bill is taken up for consideration.

6. Both the Houses of Parliament will adjourn on 24.3.2005. In view of the critical time constraint, it is necessary that the official amendments are approved at the earliest. These require approval of the Cabinet in normal circumstances. However, Prime Minister, under Rule 12 of the Government of India (Transaction of Business) Rules, 1961 can permit or condone a departure, in any case, to the extent he deems necessary.

7. In view of the circumstances explained above, it is submitted that Prime Minister may kindly approve the official amendments to the Patents (Amendment) Bill, 2005, as drafted by Legislative Department, Ministry of Law. These will be moved when the Bill is taken up for consideration in Lok Sabha for which a notice has already been given to the Secretary General, Lok Sabha.


(Kamal Nath) 19/3/2005

Commerce and Industry Minister

Prime Minister

SECRET/MOST IMMEDIATE

CABINET SECRETARIAT
RASHTRAPATI BHAWAN

Subject: Official Amendments to the Patents (Amendment) Bill, 2005.

The Department of Industrial Policy & Promotion may please refer to their d.o. letter No.12/14/2003-PPR dated 19.03.2005, seeking the approval of the Prime Minister for official Amendments to the Patents (Amendment) Bill, 2005, under Rule 12 of the Government of India (Transaction of Business) Rules, 1961.

- 2. The Prime Minister has approved the above proposal. Further necessary action may be taken accordingly.
- 3. The Department of Industrial Policy & Promotion is also requested to seek the ex-post facto approval of the Cabinet in the matter at an early date.

(K.L.Sharma)

Deputy Secretary(Cabinet)

Tel. No. 2301 5802

Department of Industrial Policy & Promotion [Shri A. K. Jha, Secretary] New Delhi.

Cabinet Secretariat's I.D. No. 83/3/1/2003-Cab. dated 20.03.2005.

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