Cabinet Secretariat
Rashtrapati Bhavan
*****

Subject : TRIPS Obligation for India – Third set of Patent Act Amendments.

Kindly find enclosed herewith a copy of a paper on the subject mentioned above.

2. It is requested that comments of Department of Commerce and Department of IPP, on the issues involved, may please be sent for information of Cabinet Secretary urgently.

Encl: As above

(Pravir Krishn)
Director
Tel : 23792204

Department of Commerce
(Kind Attention: Shri S.N. Menon, Secretary)

D/Industrial Policy & Promotion
(Kind Attention : Shri A.K. Jha, Secretary)
Cabinet Sectt. UO No. 082/6/1/2004-CA.IV dated the 1st December, 2004

S.No-21(R)

83 (39)

IP Protection
Priority Issues

India is in the process of enacting its third set of Patent Act amendments to meet its TRIPS obligation to provide patent protection for pharmaceuticals before the January 1, 2005 deadline. India currently lacks TRIPs-level protection, required as of January 1, 2000, for undisclosed or other test data required by the GOI for submission for marketing approval by pharmaceuticals and agricultural chemical companies. To ensure full consistency with WTO TRIPs obligations, the following changes to India's current law should be enacted:

- Patent Protection
  - Eliminate exclusions from patentability for foodstuffs, chemicals and medicines (Section 5, of Chapter II of the Patent Act of 1970, as amended);
  - Streamline standards for patentability to bring India into the mainstream of patent practices (allowing so-called "Second Use" patents, and eliminating hurdles beyond novelty, commercial applicability, and non-obviousness, as in China and other countries);
  - Ensure that compulsory licensing (CL) provisions are TRIPS compliant (Article 31) and do not unnecessarily eat away a patent holder's enjoyment of his rights. The following provisions should be addressed:
    - ✓ Clarification that importation would amount to working of a patent (as required by TRIPS Article 27.1);
    - ✓ Either eliminate mention of price as trigger to CL or clarify what is meant by 'reasonably affordable price'; and,
    - ✓ Remove the numerous triggers that provide a low hurdle to seeking a CL.

- Data Exclusivity
  - India should provide a reasonable period (international standard is 5 years; EU offers 6 years for pharmaceuticals and 10 years for agricultural chemicals) of exclusivity for clinical dossiers required by the GOI for obtaining marketing approval for pharmaceuticals and agricultural chemicals. This protection is separate from patent protection and benefits, both Indian and American innovative pharmaceutical and biotech companies.

CA IV

30/11/04

84 (40)

- This protection, which could be adopted administratively, would act as a confidence building step for both sides, and, with appropriate safeguards, could be supported by the mainstream of Indian firms and the international research-based pharmaceutical industry.

➢ Post Grant Opposition

- TRIPS requires that procedures for granting IP rights such as patents are reasonable and allow granting the right in a reasonable time. India has a pre-grant opposition system whereby the public can oppose or delay substantially the grant of a patent by the Indian patent office. Pre-grant opposition can undermine granting patent protection and interfere with the patent granting process. A post-grant opposition system allows the public to oppose a patent once it is granted without delaying the grant of a patent.

Paper left for Cabinet Secretary by Shri Rowen Sen Indian Ambassador to US

(S. KRISHNAN)
Private Secretary to
Finance Minister
Govt. of India,
North Block, New Delhi.

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SECRET

Ministry of Commerce and Industry
Department of Industrial Policy and Promotion
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Subject:- TRIPS Obligations – Third set of Patents Act amendment.

Cabinet Secretariat may kindly refer to its UO No. 082/6/1/2004-CA.IV dated 1.12.2004 on the subject mentioned above.

2. A note on the issues raised therein, relevant to this Department, is enclosed.

RRanjan

(Rajeev Ranjan)
Director
Tel: 2301 0688

Cabinet Secretariat (**Shri Pravir Krishn, Director**), Rashtrapati Bhawan, New Delhi

Department of Industrial Policy & Promotion's I.D. Note No. 12/14/2003-PP&C dated 16.12.2004

Issued
16/12/04

SECRET

Comments on the issues raised by Cabinet Secretariat vide letter dated 1.12.2004

S.No.	Issues	Comments
1.	Eliminate exclusions from patentability for foodstuffs, chemicals and medicines (Section 5, of Chapter II of the Patent Act of 1970, as amended)	This is proposed to be done as a part of implementation of TRIPS obligations scheduled from 1.1.2005.
2.	Streamline standards for patentability to bring India into the mainstream of patent practices (allowing so-called "Second Use" patents, and eliminating hurdles beyond novelty, commercial applicability, and non-obviousness, as in China and other countries)	The definition of the term "invention" contained in the Patents Act is as under: "Invention" means a new product or process involving an inventive step and capable of industrial application". This definition is in accordance with TRIPs Agreement and is in consonance with international practice. This was also considered by the Joint Committee of Parliament along with the exclusions prescribed under the Patents Act that examined the second amendment to the Patents law. Allowing "second use" patent may perpetuate patent monopoly (evergreening) and will not be in the larger national interest. It is being staunchly opposed by Indian industry, and it is not required to meet TRIPS obligation.
3.	Ensure that compulsory licensing (CL) provisions are TRIPS compliant (Article 31) and do not unnecessarily eat away a patent holder's enjoyment of his rights. The following provisions should be addressed: ✓ Clarification that importation would amount to working of a patent (as required by TRIPS Article 27.1) ✓ Either eliminate mention of price as trigger to CL or clarify what is	The provisions relating to compulsory licence and other public interest provisions were comprehensively reviewed and revised by the Joint Committee of Parliament taking also into account the Doha Declaration on TRIPs and Public Health. The existing provisions effectively balance and calibrates IP protection with Public Health, national security and public interest concerns. Therefore, no change is being proposed.

	meant by 'reasonably affordable price'; and ✓ Remove the numerous triggers that provide a low hurdle to seeking a CL.	
4.	Post Grant Opposition - TRIPS requires that procedures for granting IP rights such as patents are reasonable and allow granting the right in a reasonable time. India has a pre-grant opposition system whereby the public can oppose or delay substantially the grant of a patent by the Indian patent office. Pre-grant opposition can undermine granting patent protection and interfere with the patent granting process. A post-grant opposition system allows the public to oppose a patent once it is granted without delaying the grant of a patent.	It is proposed to modify the opposition procedures and review all time-lines with a view to ensuring that patent rights are granted within a reasonable time-frame depending upon the initiatives taken by the applicant and the need for protecting the public interest. Both, pre-grant as well as post-grant opposition will be provided for, but within stipulated time-frames.

(44)

F. No. 29/14/2002-TPD
Government of India
Ministry of Commerce and Industry
Department of Commerce
(Trade Policy Division)

New Delhi, Dated : the 10th December, 2004

OFFICE MEMORANDUM

Subject : TRIPS obligation for India – third set of Patent Act Amendments

The undersigned is to refer to Cabinet Sectt. UO No. 082/6/1/2004-CA.IV dated the 1st December, 2004 on the subject mentioned above and to state that in India, the Drugs and Cosmetics Act, 1940 regulates the import, manufacture, distribution and sale of drugs and cosmetics. Rule 53 of the Drugs and Cosmetics Rules, 1945 creates an obligation on the part of the Drug Inspector to keep the information collected by him in secret. Rule 53 further provides that the officers of Drugs and Controller General of India shall not, without the sanction in writing of their official superior, disclose to any person any information acquired by them in the course of their official duties. Government of India has set up an Inter-Ministerial Committee under the Chairmanship of Secretary in the Deptt. of Chemicals and Petrochemicals to look into the issues relating to adequacy of provisions in the Indian laws regarding protection of test data as required under Article 39.3 of the TRIPS Agreement. Report of the Committee is awaited.

Meanwhile, this Department had earlier submitted its views on this issue to the inter-Ministerial Committee vide letter of even no. dated 6.8.2004. A copy of this letter is enclosed for reference.

On the other issues relating to the amendment of the Indian Patents Act, 1970, Deptt. of IPP is forwarding the comments separately.

(Shashank Priya)
Director
Tel. 23016286

Shri Pravir Krishn,
Director,
Cabinet Sectt.
Rashtrapati Bhawan, New Delhi

Copy for information to :

Shri Rajeev Ranjan, Director, Deptt. of IPP. (It is requested to kindly forward a copy of the reply sent to Cabinet Sectt. to this Department also.)

1743/PP-cell/04
17/12/04