D.O. No. 5101 /RM/2004

सत्यमेव जयते

रक्षा मंत्री, भारत
MINISTER OF DEFENCE
INDIA

2nd December 2004

Sub:- Patent(Third) Amendment Act 2004

My Dear Kamal,

I am enclosing herewith a note received from Shri C. Sitaram Yechury on Patents(Third) Amendment Bill 2003.

You may recall at our meeting with the Left Parties held at 1130 A.M. on 19th November 2004 at my room in Parliament House the Left Leaders were requested to forward the amendments they propose to incorporate in the text of the Bill. Yesterday Shri Yachury handed over the enclosed note to me. Kindly get these examined by your officers to ascertain the WTO compatibility of the suggestions.

With regards,

Yours sincerely,

(Pranab Mukherjee)

Shri Kamal Nath
Minister of Commerce & Industry
Udyog Bhavan
New Delhi

Suggestions for Patents (Third) Amendment Bill to Amend the Indian Patents Act 1970

As per the provisions of the TRIPS agreement under the WTO, India is required to amend its Patent Laws to provide for a TRIPS compliant regime. There has been extensive debate within the country about what the contours of India's Patent Laws should be.

The 1970 Patent Act was formulated after an exhaustive process of discussions within the country – both inside and outside Parliament -- starting from the Justice N. Rajagopala Ayyangar Committee Report of 1959. The 1970 Act served the country well and was instrumental in development of the indigenous industry – *to a point where the Indian pharmaceutical Industry is the leader in the developing world.* It is thus imperative that any fundamental changes in the 1970 Patents Act need to be carefully examined, so as not to compromise the interests of the country, both in terms of our ability to safegaurd the health of our people and our interest in promoting a self-reliant indegenous Pharmaceutical Industry.

Since before the signing of the WTO agreement, and in the ensuing 10 years till date, globally as well as in the country, diverse contentions have emerged about the impact of TRIPS compliant Patent Laws on domestic industry – especially in developing countries. There is, however, a wide consensus that domestic laws, while being TRIPS compliant, need to make full use of "flexibilities" available in the TRIPS agreement. This was reiterated in unequivocal terms by the WTO Doha Declaration on TRIPS Agreement and Public Health (2001), which, *inter alia*, commented that countries have the sovereign right to enact laws that safeguard domestic interests. It recognised the gravity of public health problems in developing countries and clearly provided that the member countries had the right to protect public health and to promote access to medicines for all.

Experience with TRIPS since 1995

It needs to be underlined that a wide body of experience has accrued in a large number of countries since the TRIPS agreement came into force in 1995.

Several economists of repute who otherwise are fully supportive of the free trade theory and the WTO (viz. Jagdish Bhagwati, Dani Rodrik, Michael Finger) have, of late, recognised the inherent inequity in the TRIPS agreement and some have even questioned the logic of incorporating TRIPS into the WTO system in the first place. Similarly, in its report of September 2002, the Commission on Intellectual Property Rights (CIPR) established by the Government of U.K has made a pointed reference to the likely adverse impact of the global enforcement of the new intellectual property regime on the cost and availability of medicines to developing countries and the need to use the mechanism of "compulsory licensing" to mitigate such impact.

The HIV-AIDS epidemic across the globe, and particularly in African countries, has devastated entire countries. The epidemic has served to focus on the inhuman conduct of global pharmaceutical MNCs who continue to sell drugs to treat HIV-AIDS at 20-50 times their actual cost by seeking shelter under laws mandated by the TRIPS agreement. In fact it was left to Indian companies like Cipla to offer these drugs at vastly reduced prices and thereby provide some succour to those affected by HIV-AIDS. The conduct of these MNCs has also led to an upsurge of public opinion the world over, including in the US and EU, questioning its rationale, particularly in the area of public health. Organisations such as the Medecens Sans Frontieres (Doctors Without Borders) have provided a powerful voice to this upsurge and soon became a global force contending the rationale of the new IPR regime. These developments ultimately resulted in the Doha Declaration on TRIPS Agreement and Public Health (November 1999)

seeking to limit, to some extent, the damage done by the TRIPS agreement and its underlying philosophy.

These experiences of the last 10 years clearly call for a independent approach when India is poised to amend its Patent laws to make it fully "TRIPS compliant".

Safeguard National Interests

In pursuance of the necessity to make India's Patent Laws TRIPS compliant, the Indian Parliament has enacted two legislations through the Patents (Amendment) Acts of 1999 and 2002. In order to fulfil the conditions in the TRIPS agreement, a Third Amendment is now to be tabled in Parliament. The CPI(M) and other Left parties were of the opinion that the Patents (Amendment) Bill of 2002 did not make full use of the flexibilities available in the TRIPS agreement, which were further emphasised in the Doha Declaration. It is necessary that the draft Patent Bill 2003 incorporate amendments that address the gaps in the Indian Patent Act 1970 (as amended by the Patent (Amendment) Acts of 1999 and 2002), so that we make full use of flexibilities available in TRIPS. The Left parties have also consistently argued that, it is also necessary to *press for a review of the TRIPS agreement itself – something that is mandated in the original agreement*, but has not been followed up. Such a review, the Left has argued, is necessary to address the imbalance in favour of developed countries inherent in the TRIPS agreement.

The NDA government had circulated the draft Third Patents (Amendment) Bill in 2003. The Bill could not be discussed in Parliament, because of the change in Government. The draft Bill, in our view, was entirely inadequate in addressing domestic concerns relating both to health care and development of the indigenous industry. Further, it seeks to reverse salutory provisions in the original Patents Act of 1970 e.g. by further diluting the provision for "pre-grant opposition".

We understand that the UPA Government is now poised to introduce the same Bill (drafted by the earlier NDA government) in the Winter session of Parliament. *We are strongly of the opinion that any hasty passage of the Bill, without an informed discussion, will not be in the larger interests of the country. We give below a list of amendments that, we feel, need to be incorporated in the existing Indian Patents Act and the draft Bill 2003. These we believe are the minimum that need to be done to safeguard national interests.*

Broad Areas of Concern

The broad areas which require further amendments in the Indian Patent Act 1970 (as amended by the Patents Act 2002) and the draft Patents Bill 2003 are as follows. Specific suggestions for amendments and their justification are provided after this.

Patentable Subject Matter: The term "invention" should be reserved for a "new" product or process involving an inventive step and capable of industrial application". All three criteria, "novelty", "inventive step" and the quality of being "capable of industrial application", must be insisted upon. This is necessary in order to limit the number of applications and to discourage frivolous claims. The Report of the US Federal Trade Commission says that over one thousand patent applications are filed every day in the US. Even in the US, such huge volumes have resulted in many frivolous claims being admitted. With the introduction of product patent in India from 1.1.2005 a similar situation is likely to arise. This would have a serious impact on our industrial economy, creating spurious monopolies for otherwise common products for which people will have to pay high prices.

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What are not inventions (and thus not patentable): The Indian Patent Act allows patenting of "micro-organisms" and "non-biological and microbiological processes". Patenting of these inventions are under mandated review by the WTO since 1999. In the absence of any decision, patenting of these inventions should not have been provided. Further, all life forms and research tools for biotechnology should also be excluded from scope of patentability. A host of developing countries, the African countries in particular, have agreed that life forms of all hue should be excluded from patentability and India has tacitly supported these countries. The draft Bill 2003 has also restricted the scope of exclusion from patentability for computer programmes, and this needs to be remedied so that we do not encourage monoploies by the likes of Microsoft.

Compulsory Licensing: Compulsory Licensing is an instrument available in the TRIPS agreement to safeguard the legitimate interests of consumers by limiting the possibility of monopolies being created in different sectors. Unfortunately the Indian Act has not made full use of the flexibilities available in the TRIPS agreement in this regard. The Indian Act and the proposed amendment provides no scope for the issuing of a compulsory licensing in cases where, notwithstanding the offer of reasonable commercial terms and conditions to the patent holder by an enterprise, the patentee does not respond within a stipulated period of time. Countries like Brazil and China have passed legislations allowing compulsory licensing in such circumstances.

Export by a Licensee: The TRIPS agreement allows exports by manufacturers who produce through a compulsory licence. Unfortunately the Indian Act does not explicitly provide for this. This is of particular importance in the case of pharmaceuticals where Indian licensees can export drugs to the developing country markets at relatively lower prices, to the mutual benefit of both.

Transitional Arrangement and Mailbox: As per the TRIPS agreement, India has provided for the receipt of patent applications through a mailbox between 1.1.1995 to 31.12.2004. These applications are to be examined after 1.1.2005 and patents, if granted, would be effective from the latter date for a period of twenty years from the date of application. In all such cases if any production activity has been started by any enterprise during the transition period, then that enterprise should be allowed to continue production on payment of a nominal royalty to the patent-holder, after the patent has been granted, instead being accused of violating the patent. In the absence of such a provision there would be a spiraling rise in prices of patented products even when Indian companies would be in a position to produce these products at much lower costs. The recent case of an anti-cancer drug called Glivec (where Novartis, after being granted a monopoly through an EMR has restrained six Indian companies from producing the drug and at the same time has hiked the price of the drug far above what was being charged by the Indian companies), points to many such occasions in the future.

Royalty payment: The quantum of royalty payable if a compulsory licence is issued should be explicitly stipulated within a range, say 4-5 percent, of the sales turnover at ex-factory price. This would ensure that costs of drugs produced through a compulsory licence remain within affordable limits and also prevent unnecessary litigation and delays in enforcing of such licences.

Pre-Grant Opposition: The TRIPS Agreement does not preclude the possibility of pre-grant opposition to Patents that are filed. There is no justification for the removal of the existing provision of pre-grant opposition from the Patents Act, as is being proposed in the draft Bill 2003. Many countries, including developed countries like Australia, Japan, Canada and UK provide for pre-grant opposition in their national laws.

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Patents Act 1970 (as amemnded by The patents (Amendment Act) 2002	Draft Patents Bill 2003	Amendment Suggested	Comments
I. Section 2: Definitions and interpretation			
Clause (ja): (ja) "inventive step" means a feature that makes the invention not obvious to a person skilled in the art;		(ja) "inventive step" means a feature of an invention that involves important technical advance as compared to the existing knowledge and or having considerable economic significance and that makes the invention not obvious to a person skilled in the art;	
		New clause (la) "New invention" A new clause (la) may be incorporated as follows (la) "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 specifications, i.e. the subject matter has not fallen in public domain or that it does not form part of the state of the art.	*It is important to provide the definition of 'New' invention as it is an important criteria for admitting claims.*

		New clause (ta) **"Pharmaceutical substances"** A new clause (ta) may be incorporated as follows: (ta) "pharmaceutical substances mean new chemical entity or new medical entity involving one or more inventive steps".	*Definition is based upon the recommendations of Pharmaceutical Research and Development Committee headed by Dr. Mashelkar. This would help restrict frivolous claims.*
II. Section 3: What are not inventions			
Clause (j): (j) plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals;		(j) plants, animals and microorganisms in whole or any part or constituent thereof including seeds, varieties and species and any biological, non-biological and microbiological processes for production or propagation of plants, animals and microorganisms (the term microorganism would include viruses)	*Review process of Article 27(3)(b) of TRIPS Agreement for patenting of "micro-organisms and non-biological and microbiological processes" by the WTO is still not complete and as such provisions thereof should be excluded.*
	Clause 3 (k) and (ka) (k) a computer programme *per se* other than its technical application to industry or a combination with hardware; (ka) a mathematical method or a business method or algorithms;	Clause 3 (k) (k) a mathematical method or a business method or a computer programme *per se* or algorithms; Clause (ka) be deleted	*There is no reason to restrict the exclusion from patentability available to computer programmes, so it is suggested that we revert back to the provision in this respect in the Indian Patents Act 1970 (as amended after Patents (amendment) Act 2002*

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III. Section – 5: Inventions are only methods or processes of manufacture patentable			
(1) In the case of inventions - (a) claiming substances intended for use, or capable of being used, as food or as medicine or drug, or (b) relating to substances prepared or produced by chemical process (including alloys, optical glass, semi-conductors and inter-metallic compounds) no patent shall be granted in respect of claim for the substances themselves, but claims for the methods or processes of manufacture shall be patentable. (2) Notwithstanding anything contained in sub-clause (1), a claim for patent of an invention for a substance itself intended for use or capable of being used, as medicine or drug, except the medicine or drug specified under sub-clause (v) of clause (1) of sub-section (1) of section, may be made and shall be dealt, without prejudice to the other provisions of this Act, in the manner provided in Chapter IVA Explanation - For the purposes of this section "chemical process" includes biochemical, biotechnological and microbiological process.	Has been deleted in the Bill	5 (1) Patents shall be available for new inventions in all fields of technologies including pharmaceutical substances as defined in section 2 (ta), but excluding inventions stipulated in Section 3, provided that they are new, involve an inventive step and are capable of industrial application. (2) All product patent applications received during 1.1.1995 to 31.12.2004 shall be examined as provided in sub-clause (1) of this section. (3) There shall be no obligation to restore protection to a subject matter which on 1.1.2005 has fallen in the public domain. Explanation - For the purpose of this section, the term "inventive step" and "capable of industrial application" may be deemed to be synonymous with the term "non-obvious and "useful" respectively.	*Instead of omitting this section as suggested in the draft Bill 2003, the amendment suggested should be substituted.* *All applications received during the transitional period 1.1.1995 to 31.12.2004 according to Article 70.8(b) of TRIPS Agreement are to be examined as provided for in product patent regime from 1.1.2005. Further according to Article 70.3 of TRIPS Agreement any subject matter which had fallen in public domain as on 1.1.2005 i.e. the date of application of TRIPS provision on product patents for applications received during 1.1.1995 to 31.12.2004 shall not be eligible for patent protection.*

IV Section 11 (A): Publication of Applications			
	Clause 11(A) (7) (7) On and from the date of publication of the application for patent and until the date of grant of a patent in respect of such application, the applicant shall have die like privileges and rights as if a patent for the invention had been granted on the date of publication of the application: Provided that the applicant shall not be entitled to institute any proceedings for infringement until the patent has been granted".	**New sub-section (7A)** **Transitional Arrangement Applications.** Section 11 (A) New sub-section (7A) 7(A) However the provisions of sub-section (7) shall not apply to applications during the period 1.1.1995 to 31.12.2004. The patents protection on such applications shall be provided as from the grant of the patents and as such no infringement proceeding shall be instituted against any enterprise which made significant investment and is producing and marketing the concerned product prior to grant patent on such applications. The patent right holder will however be entitled to receive nominal royalty from such enterprises on and after the grant of patent.	*The provision is based upon Article 70.8 (c) of TRIPS Agreement*

V Section 25: Opposition to Grant of Patent			
Clause 25 (2) (2) Where any such notice of opposition is duly given, the Controller shall notify the applicant and may, if so desired, to the applicant and the opponent an opportunity to be heard before deciding the case.	The Bill proposes to change the provisions in Sections 25-28 of the Indian Patent Act 1970 as amended by Patents (Amendment) Act 2002.	Clause 25 (2) (2) Where any such notice of opposition is duly given, the Controller shall notify the applicant and provide to the applicant and the opponent an opportunity to be heard before deciding the case.	*The draft Bill 2003 proposes to completely change the provisions in Sections 25-28 of Patents Act 1970. This is not basd on any requirement in the TRIPS Agreement. This chapter, as provided in the Patents Act 1970 should be retained with the amendment suggested in the previous column.*
VI. Section 53: Term of Patent			
		New sub-section (2) New sub-section (2) may be incorporated as follows (2) In regard to applications received during the period 1.1.1995 to 31.12.2004 for product patents for pharmaceuticals and agricultural chemical, protection would be provided as from the grant of the patent and for the remainder of the patent term counted from the filing date in accordance with sub-section (1) of this section for those of the applications that meet the criteria for protection referred Section 5 of this Act.	*sub-section (2) is based upon Article 70(8)(c) of TRIPS Agreement). Sub-sections (2), (3) and (4) of this section shall be renumbered as (3), (4) and (5)*

VII. (New) Section 84 (B)			
		New Section 84 (B) A new Section 84 (B) may be incorporated as follows (1) Where the proposed user has made efforts to obtain authorization from the patentee to use the patent on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time, the Controller shall at any time after the expiration of three years from the date of grant of patent, grant compulsory licence to the applicant on such terms and conditions as he may deem fit; (2) The reasonable period after which the applicant may approach the Controller would not be less than 150 days from the date he had approached the patentee. The commercial terms and conditions offered by the applicant shall be considered reasonable by the Controller if royalty and other remunerations offered by him are within five percent of the annual sales turnover of net ex-factory sale price.	*The suggested provision is extremely important and is within the framework of TRIPS Article 31 (a) and (b). Other countries like China, Brazil, etc. have made similar provision in their patent laws*

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VIII. Section 90: Terms and conditions of compulsory licenses			
Clause 1 (i) That the royalty and other remuneration, if any, reserved to the patentee or other person beneficially entitled to the patent, is reasonable, having regard to the nature of invention, the expenditure incurred by the patentee in making the invention or in developing it and obtaining a patent and keeping it in force and other relevant factors;		(i) That the royalty and other remuneration, if any, reserved to the patentee or other person beneficially entitled to the patent, is reasonable, having regard to the nature of invention, the expenditure incurred by the patentee in making the invention or in developing it and obtaining a patent and keeping it in force and other relevant factors, and is not in excess of five percent of the annual sales turnover of net ex-factory sale price;	*It is necessary to provide a ceiling n royalty payment that is admissible to ensure affordability of products produced under a compulsory licence, and in order to avoid delays and litigations.*
Clause 1 (vii): (vii) that the licence is granted with a predominant purpose of supplying in Indian market and in the case of semi-conductor technology, the licence granted is to work the invention for public non-commercial use and in the case, the licence granted to remedy a practice determined after judicial or administrative process to be anti-competitive, licensee shall be permitted to export the patented product;		(vii) (a) 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 ; (vii) (b) that in the case of semi-conductor technology the licence granted is to work the invention for public non-commercial use; (vii) (c) 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.	*Clause (vii) as provided in Patents Act 1970 needs to be re-written as in the previous column, clearly providing for each category*

IX. Section 107 A: Certain acts not to be considered as infringement			
Clause 107 A (b): (b) importation of patented products by any person from a person who is duly authorized by the patentee to sell or distribute the product, shall not be considered as an infringement of patent rights.		(b) importation of patented product at cheaper prices or to meet shortages in the country by any person authorized by the Controller from a person who is duly authorized under the law to produce and sell or distribute the product, shall not be considered as an infringement of the patent rights.	*The doctrine of "exhaustion" does not require authorisation of the patentee to import products once they are already in the market (parallel import).*

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MINISTRY OF COMMERCE AND INDUSTRY

On Prime Minister's advice, a meeting with leaders of Left Parties was organized under the Chairmanship of Defence Minister (who is Chairman of the Group of Ministers charged with examining the draft Patents Amendment Bill). During the discussions with the Left Parties it was clarified that two broad parameters would guide our approach to the draft Amendment: (a) the amendment should make the Act TRIPS compliant in a credible manner; and (b) matters that had been discussed and decided upon by the Joint Parliamentary Committee while dealing with the Second Amendment to the Bill in 2002, would not be re-opened.

After detailed discussions it was agreed that within the above two parameters, the Left Parties would propose concrete formulations which they would like to have incorporated in the Amendment Bill. These suggestions were received last week.

Suggestions were made in 9 broad areas of concern. We have examined all these carefully. Of the 9 areas of concern we have been able to accommodate 4½ in a slightly modified form. It is, therefore, proposed to incorporate suitable changes to the draft Bill which would substantially address these concerns.

3½ parts, however, dealt directly with such issues as had been discussed and specifically decided upon by the Joint Parliamentary Committee two years ago, and so it would be inappropriate to re-open these issues.

One part cannot be accepted since this is a suggestion not to delete that section of the Act which currently excludes food, drugs, pharmaceuticals and chemicals from product patents. Since this is the very heart of the Amendment this suggestion cannot be accepted.

Thus it will be seen that 4½ out of the 9 areas of concern indicated by the Left Parties have been accommodated.

The suggestions received from the Left Parties and the detailed analysis by my Ministry is enclosed. I have also sent this detailed analysis to Shri Pranab Mukherjee.

KAMAL NATH
Minister of Commerce and Industry
December 10, 2004

Prime Minister

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मंत्री
वाणिज्य एवं उद्योग
भारत
MINISTER
COMMERCE & INDUSTRY
INDIA

10 December 2004

Dear Pranab de

Please refer to your letter dated 2nd December, 2004 enclosing the note received by you from Shri Sitaram Yechuri containing the suggestions of the leaders of the Left Parties on the Patents Third Amendment Bill.

You will recall that during the discussions with the Left Parties it was clarified that two broad parameters would guide our approach to the draft Amendment: (a) the amendment should make the Act TRIPS compliant in a credible manner; and (b) matters that had been discussed and decided upon by the Joint Parliamentary Committee while dealing with the Second Amendment to the Bill in 2002, would not be re-opened.

The suggestions have been made in 9 broad areas of concern. We have examined all these carefully. Of the 9 areas of concern we have been able to accommodate 4½ in a slightly modified form. It is, therefore, proposed to incorporate suitable changes to the draft Bill which would substantially address these concerns.

3½ parts, however, dealt directly with such issues as had been discussed and specifically decided upon by the Joint Parliamentary Committee two years ago, and so it would be inappropriate to re-open these issues.

One part cannot be accepted since this is a suggestion not to delete that section of the Act which currently excludes food, drugs, pharmaceuticals and chemicals from product patents. Since this is the very heart of the Amendment this suggestion cannot be accepted.

Thus it will be seen that 4½ out of the 9 areas of concern indicated by the Left Parties have been accommodated.

I am enclosing the detailed analysis as well as a brief ready reckoner which clarifies the situation.

Yours sincerely,

KAMAL NATH

Shri Pranab Mukherjee,
Minister of Defence,
Government of India,
South Block,
New Delhi

Encl: a.a.

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Analysis of suggested amendments to Patents Bill from Leaders of Left Parties

Patents Act, 1970 [as amended by the Patents (Amendment) Act 2002]	Draft Patents Bill 2003	Amendment suggested by Left Parties	*Comments given by Left Parties*	Comments of Department of Industrial Policy & Promotion
I. Section 2: Definitions and interpretation				
Clause (ja): **(ja)** " inventive step" means a feature that makes the invention not obvious to a person skilled in the art;		**(ja)** " inventive step" means a feature of an invention that involves important technical advance as compared to the existing knowledge and or having considerable economic significance and that makes the invention not obvious to a person skilled in the art;		**This issue has been discussed by the JPC during the 2nd Amendment to the Patents Act and the JPC has defined "inventive step"** The existing definition is based on internationally accepted practice and is also as per Article 29 of the TRIPS Agreement.
		New clause (la) "New invention" A new clause (la) may be incorporated as follows: (la) "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.	*It is important to provide the definition of "New" invention as it is an important criteria for admitting claims.*	**This issue has been discussed by the JPC during the 2nd Amendment to the Patents Act, which has defined 'invention' at Section 2 (1)j** The criteria for determining 'prior art' under the Patents Act has been defined under Section 13 of the Patents Act.
		New clause (ta) **"Pharmaceutical substances"** A new clause (ta) may be incorporated as follows: (ta) "Pharmaceutical substances mean	*Definition is based upon the recommendations of Pharmaceutical Research and Development*	It is not possible, in the Definitions Chapter, to introduce a definition that stipulates that a pharmaceutical substance is only 'a new chemical entity'. This would amount to restricting product patents through the backdoor, and would be TRIPS violative.

Analysis of suggested amendments to Patents Bill from Leaders of Left Parties

Patents Act, 1970 [as amended by the Patents (Amendment) Act 2002]	Draft Patents Bill 2003	Amendment suggested by Left Parties	*Comments given by Left Parties*	Comments of Department of Industrial Policy & Promotion
		new chemical entity or new medical entity involving one or more inventive steps".	*Committee headed by Dr. Mashelkar. This would help restrict frivolous claims.*	Novelty, inventive step and industrial application form the internationally accepted premise of patentability of an invention. The TRIPS Agreement does not provide for exclusion of any technology, which meets these criteria of patentability. Since modifications and improvements which enhance efficacy of products can also meet the criteria of patentability, it is not possible to restrict product patent to new chemical entity only. In fact, the Pharmaceutical Research and Development Committee headed by Dr. Mashelkar has recommended that *"A TRIPS compatible IPR legislation, which at the same time protects the interest of consumers and allows a platform for the growth of Indian pharma industry, would need to address the following issues:* *Patentability: Product patent should be granted in India for New Chemical Entity, including new chemical molecules and new chemical formulations only. However, in order to ensure that the legislation remains TRIPS compatible, Section 3 of the present Patent Act, which denies patentability to formulations of drug molecules would need to be re-examined."*

Analysis of suggested amendments to Patents Bill from Leaders of Left Parties

Patents Act, 1970 [as amended by the Patents (Amendment) Act 2002]	Draft Patents Bill 2003	Amendment suggested by Left Parties	*Comments given by Left Parties*	Comments of Department of Industrial Policy & Promotion
substances intended for use, or capable of being used, as food or as medicine or drug, or (b) relating to substances prepared or produced by chemical process (including alloys, optical glass, semi-conductors and inter-metallic compounds) no patent shall be granted in respect of claims for the substances themselves, but claims for the methods or processes of manufacture shall be patentable. (2) Notwithstanding anything contained in sub-Section (1), a claim for patent of an invention for a substance itself intended for use or capable of being used, as medicine or drug, except the medicine or drug specified under sub-clause (v) of clause (1) of sub-section (1) of Section 2, may be made and shall be dealt, without prejudice	Bill	including Pharmaceutical substances as defined in section 2(ta), but excluding inventions stipulated in Section 3, provided that they are new, involve an inventive step and are capable of industrial application. (2) All product patent applications received during 1.1.1995 to 31.12.2004 shall be examined as provided in sub-clause (1) of this section. (3) There shall be no obligation to restore protection to a subject matter which on 1.1.2005 has fallen in the public domain. Explanation- For the purpose of this section, the term "inventive step" and "capable of industrial application" may be deemed to be synonymous with the term "non-obvious and "useful" respectively.	*suggested in the draft Bill 2003, the amendment suggested should be substituted. All applications received during the transitional period 1.1.1995 to 31.12.2004 according to Article 70.8(b) of TRIPS Agreement are to be examined as provided for in product patent regime from 1.1.2005. Further according to Article 70.3 of TRIPS Agreement any subject matter which had fallen in public domain as on 1.1.12005 i.e. the date of application of TRIPS provision on product patents for applications received during 1.1.1995 to 31.12.2004 shall not be eligible for patent protection.*	exclusion of product patents in food, medicines, drugs and substances produced by chemical processes. Retaining the Section in order to link it to a newly proposed definition of 'pharmaceutical substances' in 2 (ta) would make it clearly TRIPS violative. (2) & (3). These suggestions, in fact, nullify the very reason for the mailbox. They are contrary to the transition conditions (stipulated in the First Amendment) and in effect not only provide for a discriminatory regime for pharmaceuticals, but also for scrapping of the rights that accrue to applications in the mailbox.

Analysis of suggested amendments to Patents Bill from Leaders of Left Parties

Patents Act, 1970 [as amended by the Patents (Amendment) Act 2002]	Draft Patents Bill 2003	Amendment suggested by Left Parties	*Comments given by Left Parties*	Comments of Department of Industrial Policy & Promotion
to the other provisions of this Act, in the manner provided in Chapter IV A Explanation- For the purposes of this section "chemical process" includes biochemical, biotechnological and microbiological processes.				
IV. Section 11(A): Publication of Applications				
	Clause 11(A)(7) **(7)** On and from the date of publication of the application for patent and until the date of grant of a patent in respect of such application, the applicant shall have the like privileges and rights as if a patent for the invention had been	**New sub-section (7A) Transitional Arrangement Applications.** Section 11(A) New Sub-section (7A) (7A) However the provisions of sub-section (7) shall not apply to applications during the period 1.1.1995 to 31.12.2004. The patents protection on such applications shall be provided as from the grant of the patents and as such no infringement proceeding shall be instituted against any enterprise which made significant investment and is producing and marketing the concerned product prior to grant of patent on such applications. The patent right holder will however be entitled to	*The provision is based upon Article 70.8(c) of TRIPS Agreement.*	**Accepted with minor modifications.** The issue was considered by the Group of Ministers (GoM) which noted that "the demand for waiver from patent infringement for medicines or drugs introduced between 1.1.1995 to 31.12.2004 even if there is a corresponding application for patent in the mailbox and if a patent is subsequently granted, would contravene the rights of patentee under TRIPS. This will also be against the scheme of mailbox for which the Patent Law was amended w.e.f. 1.1.1995". The law cannot provide with one hand and take away with the other, as has been suggested. However, the Left Parties have made a valid point insofar as expressing the apprehension that if a mailbox applicant is permitted to initiate infringement proceedings with effect from a date prior to 1.1.2005 it would amount

Analysis of suggested amendments to Patents Bill from Leaders of Left Parties

Patents Act, 1970 [as amended by the Patents (Amendment) Act 2002]	Draft Patents Bill 2003	Amendment suggested by Left Parties	*Comments given by Left Parties*	Comments of Department of Industrial Policy & Promotion
	granted on the date of publication of the application: Provided that the applicant shall not be entitled to institute any proceedings for infringement until the patent has been granted".	receive nominal royalty from such enterprises on and after the grant of patent.		to having introduced product patents in all fields from 1.1.95 rather than 1.1.2005, and so would be `TRIPS – plus. In order to address this concern it is proposed to add a new proviso as under: *"Provided further that the rights of the patentee in respect of applications received under Section 5 (2) before the commencement of the Patents (Amendments) Act, 2004 shall accrue from the date of grant of the patent".* This proviso to be added to sub-section (7) of Section 11A of the Act would fully address this issue. However, to stipulate nominal royalties even for the period of the patent subsequent to grant of patent would be violative of TRIPS as it would amount to restricting the rights of a class of patent holders, and would be discriminatory against mailbox applicants.
V. Section 25: Opposition to Grant of Patent				
Clause 25(2) (2) Where any such notice of opposition is duly given, the Controller shall notify the applicant and may, if so desired give to the applicant and the opponent an opportunity to	The Bill proposes to change the provisions in Sections 25-28 of the Indian Patent Act 1970 as	**Clause 25(2)** (2) Where any such notice of opposition is duly given, the Controller shall notify the applicant provide to the applicant and the opponent an opportunity to be heard before deciding the case.	*The draft Bill 2003 proposes to completely change the provisions in Sections 25-28 of Patents Act 1970. This is not based on any requirement in*	**Accepted with minor modification.** Section 25 of the Act provides for opposition to a patent application after it has been accepted and published but not yet granted (pre-grant opposition). It is true that the original draft of the Bill proposed to modify pre-grant opposition in

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be heard before deciding the case.	amended by Patents (Amendment), Act, 2002.		*the TRIPS Agreement. This chapter, as provided in the Patents Act 1970 should be retained with the amendment suggested in the previous column.*	line with the international trend. But the GoM after detailed discussion recommended that pre-grant opposition be retained. So this is being done. However, there is no prescribed time-limit for final disposal in the present provision. Therefore, theoretically, if opposition proceedings continue indefinitely the patent application can also remain unresolved indefinitely. Furthermore, there is no provision for post-grant opposition in the Patent Office in the present system. The only recourse is to a court of law. It is, therefore, proposed to modify the provisions by installing a two-tier mechanism providing for both pre-grant as well as post-grant opposition, and tightening the timelines on these, while also prescribing a time limit for final disposal of representations. The following procedure is proposed to be provided for: **Pre-grant Opposition:** Any person, on initial publication of a patent application may represent by way of opposition within a specified period against its grant on grounds relating to patentability, (that is, lack of novelty, inventiveness and industrial applicability), or non-disclosure or wrongful disclosure of source of geographical origin of biological material used in invention, or

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				anticipation of invention by traditional knowledge. A provision for hearing before grant of patent is being proposed in the Rules. Such representations would be disposed of in a time bound manner by a composite order either rejecting the contention and granting the patent or accepting the contention and rejecting the patent application. **Post-grant Opposition:** Any person may also file his opposition to a patent after it has been granted. This facility will be without prejudice to the option of challenging a patent in the appropriate judicial forum. The proposed system would, therefore, make available both pre-grant and post-grant opposition avenues, which is more than what the present law provides, but would remove the 'open endedness' that currently exists, and introduce timeframe for examination of patents in a cost effective manner while taking care of public interest.
VI. Section 53. Term of Patent				
		New sub-section (2) New sub-section(2) may be incorporated as follows: (2) In regard to applications received	*Sub-section (2) is based upon Article 70(8)(c) of TRIPS Agreement. Sub-sections (2), (3) and*	**Accepted with minor modification.** [Please also refer to comments on Part IV. Section 11 (A) above]. In order to prevent infringement proceedings

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		during the period 1.1.1995 to 31.12.2004 for product patents for pharmaceuticals and agricultural chemical, protection would be provided as from the grant of the patent and for the remainder of the patent term counted from the filing date in accordance with sub-section (1) of this section for those of the applications that meet the criteria for protection referred in Section 5 of this Act.	*(4) of this section shall be renumbered as (3) (4) and (5).*	from being initiated for the use of inventions such as pharmaceuticals, during the period 1.1.1995 to 31.12.2004, it is proposed to insert a specific provision. This is being done vide Clause 10 of the Bill, under Section 11 (A), sub-section 7 as a proviso which reads as under: *"Provided that the rights of the patentee in respect of applications received under Section 5 (2) before the commencement of the Patents (Amendments) Act, 2004 shall accrue from the date of grant of the patent".* This fully addresses the concern expressed in this suggestion.
VII. (New) Section 84 (B)				
		New Section 84 (B) A new Section 84(B) may be incorporated as follows: (1) Where the proposed user has made efforts to obtain authorization from the patentee to use the patent on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time, the Controller shall at any time after the expiration of three years from the date of grant of patent, grant compulsory licence to the applicant on	*The suggested provision is extremely important and is within the framework of TRIPS Article 31(a) and (b). Other countries like China, Brazil, etc. have made similar provision in their patent laws.*	**This issue has been discussed by the JPC during the 2nd Amendment to the Patents Act.** The provisions relating to compulsory licence and other public interest provisions were comprehensively reviewed and revised by the Joint Committee of Parliament while considering the Second Amendment, taking also into account the Doha Declaration on TRIPS and Public Health. The provisions effectively balance and calibrate IP protection

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Patents Act, 1970 [as amended by the Patents (Amendment) Act 2002]	Draft Patents Bill 2003	Amendment suggested by Left Parties	*Comments given by Left Parties*	Comments of Department of Industrial Policy & Promotion
		such terms and conditions as he may deem fit; (2) The reasonable period after which the applicant may approach the Controller would not be less than 150 days from the date he had approached the patentee. The commercial terms and conditions offered by the applicant shall be considered reasonable by the Controller if royalty and other remunerations offered by him are within five percent of the annual sales turnover of net ex-factory sale price.		with Public Health, national security and public interest concerns. It would not now be appropriate to interfere with this balance by introducing a specific 'royalty cap' and declaring it to be 'reasonable commercial terms, and further providing for grant of compulsory licence if such commercial terms are not accepted. Compulsory licensing should be linked essentially to public interest exigencies, and not to all or any products which may be under production by persons not holding patents. Therefore, no change is being proposed.
VIII. Section 90: Terms and conditions of compulsory licenses.				
Section 90 (1) (i) That the royalty and other remuneration, if any, reserved to the patentee or other person beneficially entitled to the patent, is reasonable, having regard to the nature of invention, the expenditure incurred by the patentee in making the invention or in developing it and obtaining a patent and keeping it in		(i) That the royalty and other remuneration, if any, reserved to the patentee or other person beneficially entitled to the patent, is reasonable, having regard to the nature of invention, the expenditure incurred by the patentee in making the invention or in developing it and obtaining a patent and keeping it in force and other relevant factors, and is not in excess of five percent of the annual sales turnover of net ex-factory sale price;	*It is necessary to provide a ceiling on royalty payment that is admissible to ensure affordability of products produced under a compulsory license, and in order to avoid delays and litigations.*	**This issue has been discussed by the JPC during the 2nd Amendment to the Patents Act, and the existing formulation had been agreed upon.** The payment of royalty will depend upon circumstances of each case such as the nature of invention, expenditure incurred by patentee in developing it and obtaining a patent, and keeping it in force etc. The royalty thus is to be fixed taking into consideration these aspects on case-by-case basis. Article 31 (h) of the TRIPS Agreement mandates payment of adequate remuneration based on the circumstances of each case,

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force and other relevant factors;				taking into account the economic value of authorisation. Prescribing a ceiling would be violative of TRIPS.
Section 90 (1) (vii): (vii) that the licence is granted with a predominant purpose of supplying in Indian market and in the case of semi-conductor technology, the licence granted is to work the invention for public non-commercial use and in the case, the licence granted to remedy a practice determined after judicial or administrative process to be permitted to export the patented product;		(vii) that the licence is granted with a predominant purpose of supply in Indian market and that the licensee may also export the patented product, if need be; (vii)(b) that in the case of semi-conductor technology, the licence granted is to work the invention for public non-commercial use (vii)(c) 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.	*Clause (vii) as provided in Patents Act 1970 needs to be re-written as in the previous column, clearly providing for each category*	**Accepted with minor modifications.** The revised provision is proposed as under: (vii) that in the case of semi-conductor technology, the licence granted is to work the invention for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive; (viii) that the licence is granted with a predominant purpose of supplying in the Indian market, Provided that the licensee may also export the patented product in accordance with Section 92 A. Provided further 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.
IX. Section 107A: Certain acts not to be considered as infringement				
Clause 107 A(b): (b) Importation of patented products by any person from a person, who is duly authorized by the patentee		(b) Importation of patented product at cheaper prices or to meet shortages in the country by any person authorized by the Controller from a person who is duly authorised under the law to	*The doctrine of "exhaustion" does not require authorisation of the patentee to import*	**Accepted with minor modifications.** The following has to be considered : i) Though the import of products at cheaper prices or to meet shortages is among the

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Patents Act, 1970 [as amended by the Patents (Amendment) Act 2002]	Draft Patents Bill 2003	Amendment suggested by Left Parties	*Comments given by Left Parties*	Comments of Department of Industrial Policy & Promotion
to sell or distribute the product, shall not be considered as an infringement of patent rights.		produce and sell or distribute the product, shall not be considered as an infringement of the patent rights.	*products once they are already in the market (parallel import).*	intended purposes of the provision, only specifying certain conditions under which import can be made would actually restrict the scope of the provision. ii) The existing provision in the law for import is independent of any authorisation. The suggestion that authorisation should be obtained from the Controller could lead to delay in implementation. Further Government has powers under section 47 (4) for import of medicine or drug for distribution in dispensary, hospital etc. Therefore, the revised provision is proposed as under: Clause 107 A (b): "Importation of patented product by any person from a person, who is duly authorised under the law to produce and sell or distribute the product, shall not be considered as an infringement of the patent rights."

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Patents Act, 1970 [as amended by the Patents (Amendment) Act 2002]	Comments of Department of Industrial Policy & Promotion
I. Section 2: Definitions and interpretation	
Clause (ja): Inventive steps	This issue has been discussed by the JPC during the 2nd Amendment to the Patents Act.
(ja) New Invention	This issue has been discussed by the JPC during the 2nd Amendment to the Patents Act, which has defined 'invention' at Section 2 (1)j
II. Section 3: What are not inventions	
Clause (j): Micro organism patenting	This issue has been discussed by the JPC during the 2nd Amendment to the Patents Act.
(j) Patenting of software	This issue has been discussed by the JPC during the 2nd Amendment to the Patents Act. The proposed changes are more in the nature of a classification, due to confusing interpretations that have arisen.
III. Section – 5: Inventions where only methods or processes of manufacture patentable	
(1) Rewording of Section 5 (2) (2) & (3) Patentability of mailbox applications	(1) Deleting Section 5 is the very heart of this Amendment. (2) & (3) These suggestions, in fact, nullify the very reason for the mailbox.
IV. Section 11(A): Publication of Applications – Transitional arrangements	• **Accepted with minor modifications.**
V. Section 25: Opposition to Grant of Patent	
Clause 25(2) - pre-grant opposition	• **Accepted with minor modification.**
VI. Section 53. Term of Patent – Mailbox application	• **Accepted with minor modification.**
VII. (New) Section 84 (B) – CL for commercial use	This issue has been discussed by the JPC during the 2nd Amendment to the Patents Act.
VIII. Section 90: Terms and conditions of compulsory licenses.	
Section 90 (1) (I) – Cap on royalty	This issue has been discussed by the JPC during the 2nd Amendment to the Patents Act, and the existing formulation had been agreed upon.
Section 90 (1) (vii): - Drafting suggestion	• **Accepted with minor modifications.**
IX. Section 107A: Certain acts not to be considered as infringement	
Clause 107 A(b): - Parallel importation	• **Accepted with minor modifications.**

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