Dec 20, 2004

Left Parties on Amendments to the Indian Patent Act

The Group of Ministers had made available to us the draft Patent (Third) Amendment Bill for our consideration and suggestions. We were told about the predicament faced by the Government: 'The Patents Act 1970 had already been substantially altered and diluted by the two amendment bills enacted by the previous NDA government. There was also the so-called deadline of TRIPs to be observed. And hence the need to push through the Third amendment bill as proposed.' Either the reasoning or the conclusions of the Government did not convince us. Nevertheless, we tried to understand the compulsions of the Government and limit our suggestions to the absolute minimum that is needed to be done to safeguard the national interest.

The amendments/modifications that we proposed related to the vital matters of (i) definition and scope of patentability; (ii) the subject matter that is under the mandatory review provided in TRIPs; (iii) eschewing retrospective protection to product patent rights not visualized in TRIPs; (iv) ensuring continued availability, at affordable prices, of medicines brought into the market with due approval of Government during the transitional period between 1995 and 2005; (v) the need to fully exploit the flexibility provided in TRIPs in regard to issue of Compulsory Licenses and also the possibility of exports thereunder; (vi) prescribing a salutary ceiling for payment of royalty to the right holders to avoid escalation of costs of medicines etc. to be produced under Compulsory Licenses; (vii) maintaining the provision in the Act allowing "Pre- Grant Opposition" to avoid /minimize proliferation of non-serious claims for patent rights.; and finally, (viii) permitting "parallel imports".

We regret that the response that we have received from the Government is totally disappointing. Except for the suggestion regarding "parallel imports", not one of our proposals in the core areas mentioned above has found favour with the Government. In a detailed clause by clause analysis appended to this note, we have shown how untenable is the Government reasoning for non-acceptance of our suggestions. We do not wish to summarize or repeat that analysis here. It is a matter of deep concern that the response of the Government shows little awareness of the basic public interest issues involved. It has chosen to follow the line of the previous NDA government without any fresh thinking or reservation, whatsoever. It has also remained oblivious of the sea change that today characterizes the world opinion in regard to the unequal global regime of TRIPs.

Repeatedly, the Government has taken resort to the rather formal argument that: " The issue has been discussed by the JPC (Joint Parliamentary Committee) during the Second Amendment Act." We fail to understand how the deliberations of the JPC constituted to consider the Second Amendment can now be cited as if it had the last word on all matters relating to the Patent Amendments under consideration at present. That JPC is now *functus officio*. Moreover, it was constituted at a point in

time when the composition of the Parliament was different. The last General Elections have brought into office a new government, which is committed to providing a “human face “ to our integration with the global economy. A Common Minimum Programme embodying greater commitment to the provision of health and education facilities to the people has been drawn up as a charter of governance. To honour that commitment the government should confront the attempt of MNCs to strengthen their monopoly position at the cost of our people through imposition of a particularly coercive version of a TRIPs -compliant patent regime. Our suggestions were informed by such an approach. The Government, has however, found our suggestions unacceptable but it has no hesitation in adopting the NDA line lock, stock and barrel.

The last few years starting with the Seattle meeting of WTO in 1999 have witnessed a remarkable change in the world opinion on the issues pertaining to IPRs, particularly where TRIPs regime threatens to adversely affect the human rights in regard to health care. Academics have questioned the rationale of TRIPs having been made part of the world trade order and recognized the unequal nature of the bargain foisted on the peoples of the third world in the process. Activists and statesmen the world over have expressed concern about the anti-people and pro- MNCs tilt of TRIPs. The spreading incidence of HIV-AIDS, particularly in poor African countries, on the one hand, and the tendency of the MNCs to profiteer out of the misery, on the other, has stirred the conscience of the world and exposed the inherent dangers of the IPR regimes constructed mainly to enhance the profits of MNCs. The need to fully exploit the niches of flexibility available in TRIPS so as to redress the tilt in favour of the MNCs has now been universally recognized. In sharp contrast to this changing perception, the Government is adopting a simplistic, conformist approach of hurriedly “aligning “ our Patent Law to the coercive version of TRIPs. The need of the hour is to follow a more creative and independent approach, while still remaining within the broad contours of TRIPs. That is what we had tried to do through our suggestions. Unfortunately, the Government seems to be content with a timid and complacent approach. It has refused to use the available flexibility. What is worse, it has tried to justify its failure in the name of not disturbing the prevailing “balance between the IP protection and the public interest concerns”. In effect, this stance amounts to protecting the tilt in favour of the MNCs and against the people.

In the circumstances we reiterate our resolve to oppose the Third Amendment Bill. We appeal to all members of the Parliament to consider the momentous issues at stake and join hands to defeat the proposed Amendment to the Patents Act.

Dec. 20. 2004

Patents Act 1970 (as amemnded by The Patents (Amendment Act) 2002)	Draft Patents Bill 2003	Amendment Suggested	Comments	Comments of Department of Industrial Policy & Promotion	Reply to Comments by Deptt. of Industrial Policy and 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.	The idea was to make the provision more explicit. The proposed definition is not violative of TRIPS. Art. 29 deals with the manner and extent of disclosure, and not with the definition of an inventive step. Patent Laws of many countries have elaborated the concept in even greater detail than what has been suggested.
		New clause (la) "New invention" A new clause (la) may	*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***	Section 13 of the Patents Act lays down the guidelines for the examiner, while what is being proposed is a substantive criterion

		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.		***'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.*	for defining "new" or novel. Most Patent laws do define it specifically in similar manner.
		New clause (ta) **"Pharmaceutical substances"** A new clause (ta) may be incorporated as follows:	*Definition is based upon the recommendations of Pharmaceutical Research and Development Committee headed by Dr. Mashelkar. This would help restrict frivolous claims.*	It is not possible in Definitions Chapter, to introduce a definition that stipulates that a paharmaceutical substance is only 'a new chemical entity' . this would amount to restricting product patents through the backdoor, and would	The U.K. Commission on Intellectual Property Rights (CIPR) suggests that developing countries should "adopt a pro-competitive strategy" by "limiting the scope of subject matter that can be patented". The quote from the

		follows: (ta) "pharmaceutical substances mean new chemical entity or new medical entity involving one or more inventive steps".		be TRIPS violative. 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*	Mashelkar Committee Report in the Ministry's reply also supports the proposed Amendment. The proposed Amendment is intended to prevent an abuse of TRIPS through patenting of frivolous claims and "evergreening" of existing patent monopoly.

				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. "*	

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.*	This issue has been discussed by the JPC during the 2nd Amendment to the Patents Act. The obligations existing in the TRIPS Agreement as on date are to be complied with. As and when provisions of Article 27.3(b) are modified, an amendment of corresponding provision of the patents law could be considered. In any case, it is to be noted that there are emerging opportunities for the growing biotechnological industry in India. Protection of inventions in the biotechnological	In order to maintain a credible position in the ongoing negotiations on review of Art. 27 3(b) it is essential that we do not rush through the Amendment. We do not share the view that the balance of advantage would be in the country's favour if the Patenting of microrganisms and biotechnological processes is allowed as proposed. Let us not forget that the pharmaceutical industry in India was able to grow to present levels because patenting of pharmaceutical products were not allowed.

				sector is in the interest of Indian industry as well as the public interest, so as to encourage investments and commercial exploitation as well as R & D which can address public health concerns.	
	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*	**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.** Section 3 of the Act contains details of items which are not inventions within the meaning of the Act and hence, are not patentable. This section also provides, inter alia, that "a mathematical or business method or	The clause in the Draft Bill reduces the scope of what is not patentable in the area of computer programmes. This is not in the interest of the software industry in India. To the contray, it could promote the interests of monopolies like Microsoft. If the qualification “per se” is creating confusion, the same may be deleted from the original Clause 3 (k) of the present Act, without any other Amendments.

				computer programmes per se or algorithms" are not patentable. However, this provision has been subject to confusing interpretations, (such as whether 'per se' applies only to computers programme, or also to mathematical or business methods. Also, whether technical applications of computer programmes are patentable or not). Given the emerging opportunities in the software sector and growing Indian strength in information technology, it is necessary to clarify the provisions in Section 3 (k) so as to allow patenting of a computer programme only in case it has technical applicatioos to industry or is in	

				combination with hardware. Software alone is already protected under copyright laws. It is also proposed to clarify that a mathematical or business method or algorithm will not be patentable. The Department of Information Technology has suggested the incorporation of such a clarification which is now proposed to be included. The GoM has considered this issue and noted that the proposed clarification is in the larger national interest.	

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	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.	*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	(1) Deleting Secton 5 is the very heart of this Amendment. Section 5 provides for 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	We understand the Government's compulsion to provide for product patents in the area of food, medicines, drugs and substances produced by chemical processes" and are not arguing to the contrary. The Amendment suggested is not violative of TRIPS. The rationale of 2 t(a) has already been explained earlier. The Amendment suggested is clearly indicated by Art. 70 (3) of TRIPS which says: "There shall be no obligation to restore protection to subject matter which on the date of application of this Agreement for the Member in question has fallen into the public domain." (the

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.		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.	patents for applications received during 1.1.1995 to 31.12.2004 shall not be eligible for patent protection.	for a discriminatory regime for pharmaceuticals, but also for scrapping of the rights that accrue to applications in the mail box.	date of application in this case is 1.1.2005 for India).

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	*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	The principle aim of the suggested Amendment was not merely to protect some producers from possible infringement proceedings. This matter pertains to broader public interest, namely ensuring continued availability of medicines at affordable prices. Many medicines which may be provided Patent protection after 1.1.2005 have already received marketing approval from the Govt. and are being marketed in the country by generic producers – some of them being vital drugs. If no solution is provided, the sales would have to stop and in all probability the patentee would market the same drugs at much higher

		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.		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 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*	prices (the Glivec case is before us to understand what might happen). This would lead to a sharp rise in prices of drugs already available and would lead to a maze of litigations. It is in this context that the amendment was suggested, whereby the generic producers could be allowed to continue production on payment of royalty, even if a Patent is granted.

				(Amendments) Act, 2004 shall accrue from the date of grant of the patent". This proviso to be added to sub-section (7) of Section 11 A 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	The Bill proposes to change the provisions in Sections 25-28 of the Indian Patent Act 1970 as amended by	Clause 25 (2) (2) Where any such notice of opposition is duly given, the	*The draft Bill 2003 proposes to completely change the provisions in Sections 25-28 of Patents Act*	**Accepted with minor modification.** Section 25 of the Act provides for	We would still argue that the substitution of the word "opposition" by "representation"

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.	Patents (Amendment) Act 2002.	Controller shall notify the applicant and provide to the applicant and the opponent an opportunity to be heard before deciding the case.	*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.*	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 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	constitutes a weakening of the process of challenge. We reiterate that the original chapter 5 opposition to grant of patent be retained as it is and there is no TRIPS requirement to change any provision in this regard.

				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 postgrant opposition, and tightening the time lines 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 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 ended ness' 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 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	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)*	**Accepted with minor modification.** [Please refer to comments on Part IV. Section 11 (A) above] In order to prevent infringement proceedings from being initiated for the use of inventions such as pharmaceuticals, during the period 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	The modification is acceptable.

		meet the criteria for protection referred Section 5 of this Act.		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 such terms and conditions as he may deem fit:	*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 with Public Health, national security and public interest concerns. It would not now be appropriate to	The language of the Amendment suggested strictly follows Art. 31(b) of TRIPS. A very large number of countries (including Argentine, Brazil, Canada, China, France, Germany, Imdonesia, Israel, Thailand, and U.K.) have similar provisions in their Patent legislation. The Amendment suggested is entirely in public interest as promotion of competition curbs monopoly practices and ensures indigenous diffusion of technology. This would lead to easy availability of products at affordable prices.

		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.		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.	Art 31(b) is vital for maintaining the balance between IP protection and public interest as visualised in TRIPS

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.*	**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, taking into account the	Considering the large volumes involved in the Indian market, a 5% royalty cap is extremely reasonable. The suggestion is based on prevalent practices in a large number of countries

				economic value of authorisation. Prescribing a ceiling would be violative of TRIPS.	
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-	*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	**Modification is not acceptable – in fact the new formulation would have dangerous consequences**. Art. 31(f) of TRIPS allows exports of products manufactured under a Compulsory License. By qualifying that export be linked with provisions of proposed Section 92A it would restrict exports to only pharmaceutical substances and to countries that have no manufacturing capability. We are not required to provide for such restrictive terms for exports under TRIPS. Further, the second proviso as suggested needs to be a separate sub section and cannot be a proviso to proposed sub section (viii). We

		competitive, the licensee shall be permitted to export the patented product if need be.		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.	hence insist that the Amendment suggested by us be accepted.

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).*	**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 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	Modification is acceptable to us

				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."	