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**TRIPS PATENT SYSTEM AND DOHA
DECLARATION
-IMPLEMENTATION PROCESS BY INDIA**

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**TRIPS PATENT SYSTEM AND DOHA
DECLARATION
- IMPLEMENTATION PROCESS BY INDIA**

***B.K. Keayla**

TRIPS Agreement expects WTO member countries to adopt minimum standards on patent laws as stipulated therein. Doha Ministerial Conference Declaration on TRIPS Agreement and Public Health (November 2001) recognizes the gravity of public health problems afflicting the poor countries, especially those resulting from HIV / AIDS, tuberculosis, malaria and other epidemics. The Declaration also stipulates that in applying the customary rules of interpretation of public international laws, each provision of TRIPS Agreement should be read in the light of object and purpose of the Agreement as expressed, in particular in its objectives and principles. These are contained in Articles 7 and 8 of the TRIPS Agreement. For core areas of concern the Declaration also provides that each member country has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted. In the background of the flexibilities and freedom available as stated, the national legislation on patent laws could ensure that there is complete co-relation of the national patent system with National Health Policy and National Pharmaceutical Policy so that the objectives of these policies are fully accomplished. This would also help in realisation of the Constitutional right of 'right to life' which incorporates also 'right to health' which is guaranteed to the citizens of the country. In fact International Human Right Laws also guarantee similar rights. It is for the nation states to ensure that such rights are fully protected in its laws and policies while implementing the TRIPS Agreement.

Peoples' Commission on GATT (1996) whose members were former learned judges of the Supreme Court of India viz. Justice V.R. Krishna Iyer, Justice O. Chinnappa Reddy and Justice D.A. Desai and Chief Justice of Delhi High Court Justice Rajinder Sachar gave valuable suggestions and pointed out implications of the TRIPS Agreement in their Report as follows:

"It (TRIPS) is questionable whether Intellectual Property so called comes within the founding ambit of GATT in its original structure. Assuming the rather ambiguous and dexterous inclusion of TRIPS is a fait accompli, any structural mutations to be wrought into the Indian Patents Act must be constitution-friendly and socially value based, since imperial occupation through technological invasion is anathema to the spirit of our Founding Deed", (p. 173)

The concluding sentence of this Report also pointed out:

"If the Constitution is what the Judges have told us it is and the text with the Preamble explicate it, the TRIPS part vis a vis Indians will in all probability by *ultra vires*".

Similarly another Peoples' Commission on Patent Laws for India (2003) chaired by

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former Prime Minister of India viz. Shri. I.K. Gujral and top ranking experts as members expressed the following views on amending our Patents Act 1970 in their Report :

"The Commission is of the view that the wider approach needs India's sustained attention so that we are not lost within a host of narrow issues. These arise in two ways. In the first place, TRIPS itself leaves open many matters for future consideration. Secondly, more importantly, treaties evolve and change over time in response to exigent needs. Before 1994, the international patent regime was very different from that which emerged under the aegis of the WTO treaty. A decade is a long time in such matters, India needs to approach the WTO and TRIPS with wide angled lenses so that the long term perspective is as much as they affect India's national interest and the interest of other nations is also not overlooked".

The most important aspect which was also pointed out by the Peoples' Commission on Patent Laws for India in their Report of 2003 relates to certain important aspects of the Indian Constitution relevant to Fundamental Rights guaranteed to its citizens by the Constitution are reproduced as follows:

(i) **Article 13:- Laws inconsistent with or in derogation of the Fundamental Rights :-**

"The State shall not make any law which takes away or abridges the rights conferred by this Part and any law made in contravention of this clause shall to the extent of the contravention, be void."

(ii) **Article 14: - Equality before law: -**

"The State shall not deny to any person equality before the law or the equal protection of the laws within the territory of India."

The equality clause requires that all persons subjected to any legislation should be treated alike under like circumstances and conditions. Equals have to be treated equally and unequals ought not to be treated equally. Globalisation in India will confront the medium and tiny scale enterprises to compete with the giant Trans-national Corporations. This is clearly against the spirit of equality before law in our Constitution.

(iii) **Article 21 : - Protection of life and personal liberty : -**

"No person shall be deprived of his life or personal liberty except according to procedure established by law."

Right to life includes right to health which has been clarified in many judgments of Supreme Court.

Thus any amendment to our patent laws and policies if inconsistent with the provision of the Constitution can be struck down by the Supreme Court and as such amendments to the Patents Act, 1970 should not be constitutionally inconsistent. The basic spirit of the Patents Act 1970 is likely to be affected by certain amendments arising in implementing provisions of the TRIPS Agreement.

While the top legal luminaries, economists, scientists, experts, etc. in India through the Peoples' Commission Reports have cautioned the government for a careful approach in changing our national legislation on patent laws, world-wide also cautious approach has been sounded. The Commission on Intellectual Property Rights established by the British government in its Report of September 2002 pointed out in the Executive Summary on Chapter 2 on health states as follows:

“As intellectual property rights are strengthened globally, the cost of medicines in developing countries is likely to increase, unless effective steps are taken to facilitate their availability at lower cost in developing countries. There are a number of IP policies that both developed and developing countries can adopt to promote cheaper prices for medicines in developing countries which the Commission does not believe will adversely affect the incentives for research on relevant diseases. One means of obtaining medicines at lower prices, amongst others discussed in the report, is for countries to use a mechanism called "compulsory licensing". This allows countries to licence the manufacture of patented medicines to other manufacturers if there are good reasons to do so (e.g. when the government considers the price of a medicine is unjustifiably high). It can also be useful as a bargaining tool in price negotiations with producers of patented medicines. For instance, the US envisaged this possibility when negotiating the price of Cipro following the anthrax attacks last year. The importance of the IP system being used to improve access to medicines and public health was emphasized in a Declaration on TRIPS and Public Health at the WTO Ministerial meeting in Doha last year.”

Similarly, the UNDP Report (2003) on 'Trade for Life: Making Trade Work for Poor People' by a team of experts led by Dr. Kamal Malhotra, Senior Advisor of UNDP concludes:

“Global trade rules need to be rewritten in order to benefit poor people. New trade rules should champion diversity and protect the rights of governments and people, especially in the poorest countries, to decide how best to develop their own economic activities. These should ensure that trade is a means to promote sustainable development, not an end in itself.

The flexibilities as clarified in the Doha Declaration on TRIPS and Public Health have provided enormous scope to strengthen public interest provisions in our patent law. Similarly the cautious approach spelt out above should also be kept in view. Thus all the relevant provisions of our Patents Act 1970 have been examined in the minutest possible details. Necessary suggestions have been incorporated in the Annexure attached to this paper. It is extremely important that Chapter XVI of the Patents Act on 'Working of the Patents, Compulsory Licences and Revocation' is given special attention keeping the stipulations in the Doha Declaration that each member has the right to grant compulsory licences and freedom to determine the grounds upon which such licences are granted.

In order to conform the Patents Act 1970 with the TRIPS provisions, the Act has already been amended twice:

- (i) Patents (Amendment) Act 1999
- (ii) Patents (Second Amendment) Act 2002

The Government of India has since started exercise to further amend the Patents Act 1970 to provide for product patent regime from January 1, 2005 in such sectors of inventions which were not so protected. The government is also keen to introduce procedural improvements to make the Patents Act user friendly and simple. The scope of the third amending Bill should thus be quite wide.

There are two major components of the patent system which need to be carefully formulated as the same are extremely important for our country. They relate to the 'scope of patentability' and 'working of patents through compulsory licensing system'. Transfer of technology, parallel imports, and export of patented products are the other important provisions which also need to be appropriately stipulated. All these provisions have been suitably dealt with in this paper and appropriate amendments/additions suggested in the annexed comparative statements.

SCOPE OF PATENTABILITY

To comply with TRIPS requirement, during the transitional period India amended its Patents Act 1970 through Patents (Amendment) Act 1999 and incorporated sub-section (2) under Section 5. This incorporation provided for Mail Box facility from 1.1.1995 for receiving product patent applications for pharmaceuticals and agro-chemical products. It is observed that over 5000 applications have been received up till now under this stipulation for the Mail Box. As against this the new molecules in the pharmaceutical field invented world - wide and which only could have qualified for patentability through Mail Box are averaging between 40 to 50 per annum. The anomaly needs to be rectified through the new Bill.

Article 27 of the TRIPS Agreement deals with the 'patentable subject matter'. Under this Article the patent rights are enjoyable without discrimination as to the field of technology. However, the Doha Declaration on TRIPS Agreement and Public Health has recognized gravity of the public health problems afflicting many developing and least developed countries. In order to promote easy access to medicines for all as stipulated in the Declaration, the inventions relating to pharmaceutical could be singled out for special dispensation. In order to implement the scope of patentability aspects of the patent system, the following three sections of our Patents Act 1970 need to be carefully formulated :

- (i) Section 2 : Definitions and interpretation of technical patent terms (including pharmaceutical)
- (ii) Section 3 : Inventions not patentable
- (iii) Section 5 : Patentable subject matter in the area of pharmaceutical

There are certain important patent terms which should also be carefully defined in our national Patents Act 1970. It is important to do so to avoid representations or disputes due to casual interpretations in the patent laws. In this connection important suggestions have been made in the comparative statement for Sections 2 and 82.

The Pharmaceutical Research and Development Committee headed by Dr. R.A. Mashelkar, Director General CSIR and Secretary to the Government of India in its Report has suggested as part of intellectual property right strategies that for the pharmaceutical sector there is a need to amend section (2) (1) (1) of the Patents Act

1970 to provide for New Chemical Entity (NCE) / New Medical Entity (NME) only to be patentable. In view of this the third patents amending Bill should be amended accordingly.

The latest indications in the US Federal Trade Commission Report are that over 3 lakhs patent applications are being filed in USA annually. Due to this heavy burden of applications, the Commission has recommended that proper application of the statutory requirement is crucial to prevent the issuance of questionable patents, including trivial patents and patents on invention essentially already in the public domain. We have also to ensure that in our country frivolous claims are not entertained and as such sections has to be carefully formulated excluding trivial and questionable claims. Suitable suggestions have been made in the comparative statements annexed for this section. In particular it is important to point out that 'research tools' related to biotechnology inventions should also be specifically deleted, otherwise biotechnology research could be in jeopardy. It is estimated that over seventy percent of the turnover of the drugs and pharmaceuticals in the coming future would be produced through biotechnology route and the use of these technologies being new will also qualify for process patent term of twenty years. Further there is no decision as yet on the mandated review of Article 27 (3) (b) of the TRIPS Agreement on patenting of 'micro-organisms and non-biological and microbiological processes' which was initiated in WTO in 1999. As such there should be no need to make any provision on their patenting and also on any other life-form. Patenting of life form is a critical issue and should not be routinely implemented. Inventions which do not strictly meet the criteria of industrial application e.g. once mouse, stem cell, partial gene fragments, PCR technique, machine based embedded bio-informatics software, genomic information and data bases should also be excluded. Thus exclusion of invention from scope of patentability is also quite important.

Suitable suggestions to strengthening section 5 have been made in the comparative statements. The suggestion made in section 5(1) and (2) and subsection 48(2) are extremely important. Particularly subsection 5(2) and subsection 48(2) should have been provided in the Patents (Amendment) Act 1999. These provisions are based upon Articles 70(3), 70(8) (b) and 70(8) (c) of TRIPS Agreement.

WORKING OF PATENTS

Working of patents in a large country which grants exclusive patent rights on the relevant products is important to ensure easy availability and containing of prices of these products through competitive environment. Article 27 of TRIPS Agreement has absolved the patent holders from the obligation of working their patents in the country which grants the patent. They can resort to imports as according to Article 27 'patent rights are enjoyable by them without discrimination whether products are imported or locally produced'. However, working of patent through the domestic enterprises must be ensured under the system of grant of compulsory licences. Presently there are over 20,000 pharmaceutical manufacturers registered in India and hundreds of enterprises are producing the same product and competing amongst themselves and meeting the country's requirements. This phenomenon cannot be equated to the working of patent through imports by the patent holder. Extensive involvement of domestic enterprises in the production and availability of patented products is absolutely necessary for our

vast country.

COMPULSORY LICENSING SYSTEM

Compulsory licensing system is the back-bone of the patent laws. The question of constraints which would emerge after the implementation of TRIPS had been a subject of serious concern and discussed in the TRIPS Council of WTO during the year 2001. The issue was further hotly debated in the Doha Ministerial Conference held in November 2001. The result was the Doha Declaration on TRIPS Agreement and Public Health which clarifies that sufficient flexibilities and freedom to determine the grounds upon which compulsory licences can be granted are available to member countries. It is now for the member countries to exercise their right and make suitable provisions in their national legislations. While enacting the Patents (Second Amendment) Act 2002, this aspect did not receive the due consideration even when the Indian delegation at the Doha Ministerial Conference was the major player in the adoption of Declaration on TRIPS Agreement and Public Health.

There are nine possibilities of structuring the grant of compulsory licences/authorization arising from TRIPS Agreement and Paris Convention. These are:

(i) Voluntary Licences registered by the patent holder, (provision exists in a number of patent laws)

(ii) Authorisation for meeting the government requirements by Government enterprises or third parties authorized by the government.

(Article 31- first para of TRIPS)

(iii) Compulsory Licence due to abuse of patent rights by the patent holder.

(Paris Convention Article 5 and TRIPS Article 8)

(iv) Compulsory licence for reason of unsuccessful attempt by an enterprise to obtain voluntary licence directly from the patent holder.

(Article .31(b) of TRIPS)

v) Authorisation of licence due to National Emergency.

(Article 31 (b) of TRIPS)

(vi) Aurthorisation of licence due to circumstances of extreme urgency

-Article 31(b) of TRIPS

(Health Emergency, Environmental Emergency, etc)

(vii) Compulsory Licence in cases of public non-commercial use

(Article 31(b) of TRIPS)

(viii) Compulsory licence to remedy anti-competitive practices

(Article 31(k) of TRIPS)

(ix) Second patent for an invention involving important technical advance of considerable economic significance over the existing patents. (Article 31(1) of TRIPS)

If all the above possibilities are suitably provided in the national patent laws it would be possible to develop competitive environment about the availability of drugs and pharmaceuticals in the country. In the Patents (Second Amendment) Act 2002 certain possibilities have neither been incorporated nor adequately provided. The framing of appropriate provisions or amendments on this subject in the third amending Bill have been suitably dealt with in the comparative statement.

The TRIPS Agreement in Article 31(b) deals with the contingencies of national emergency or other circumstances of extreme urgency or cases of Public non-commercial use together. In our Patents (Second Amendment) Act 2002 also we have provided accordingly. However, these contingencies arise under different circumstances and should be dealt with under different Sections in the Patent Act as suggested in the comparative statement. These contingencies have also been defined in Section 82 in the statement.

TRANSFER OF TECHNOLOGY

Doha Declaration on TRIPS Agreement and Public Health in Para 5(a) stipulates that "the provision of the TRIPS Agreement shall be read in the light of the object and purpose of the agreement as expressed, in particular, in its objectives and principles". The objectives and principles of TRIPS Agreement are stated in Articles 7 and 8. Article 7 provides for: "The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology". Article 8 provides for: "Appropriate measures may be needed to prevent the abuse of intellectual property rights by the right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology". The provision contained in these two Articles cannot be regarded as "best endeavour" commitments as they form part of the "General Provision and Basic Principles" just as Articles 3 and 4 relating to National Treatment and Most Favored National Treatment are mandatorily enforced. Provisions of Articles 7 and 8 should also be equally mandatorily enforceable about transfer of technology.

Similarly, the reading of the stipulations in the Doha Declaration on TRIPS Agreement unambiguously provide that the patent legislation could incorporate provision for transfer and dissemination of technology and it should be one of the obligation for the patent holder to be fulfilled on issue of compulsory licences within a stipulated period. Similarly, there is also provision that appropriate measures could be taken if international transfer of technology is adversely affected for some reason or the other. If the patent holder does not cooperate in the transfer and dissemination of technology the issue of appropriate measures could be considered by the designated authority.

Patents Act should be explicit on all aspects of transfer of technology. Section 95 has

been proposed in the statement.

PARALLEL IMPORTS

The need for parallel imports arises when availability of patented product is not sufficient to meet the domestic demand. This type of contingency can arise similar to the situation as it arose in USA about the availability of 'Anthrax' drug, availability of HIV/AIDS drugs in African countries and the drugs needed for most recent phenomena of SARS in China and Hong Kong and Dengue fever in Indian cities. To meet such a contingency it is important that the Patents Act must provide for a clear cut provision so that no constraint is raised when parallel imports are authorized. Similarly, it should also be possible to import patented products if they are available in the foreign markets at prices lower than the prices at which the same are being marketed by the patent holders in the country. According to Doha Declaration on public Health the member countries are free to establish their own regime for such exhaustion of right without challenge, subject to National Treatment and Most Favoured Nation Treatment under provisions of Articles 3 and 4 of the TRIPS Agreement. Accordingly, provision should be made in the Patents Act for parallel imports stating the circumstances under which parallel imports would be authorized. Such imports could be made from authorized sources producing patented product under compulsory licence or from the authorized traders of the patent holder or the licensee. Section 107A has accordingly been amplified in the statement to take care of this issue.

EXPORT OF PATENTED PRODUCT

The compulsory licence granted should have clear right to produce the patented products predominantly for the domestic market and also some quantity for exports when required. The spirit of Article 31 (f) of TRIPS Agreement on the use of word 'predominant' permits production mainly for domestic markets as well as for other markets. Even Article 8 of TRIPS Agreement also provides that appropriate measures could be provided to prevent resort to practices which unreasonably restrain international trade. Exports are possible only when provision for parallel imports (under doctrine of exhaustion) is available in the importing countries in their national patent laws. For India it is important to have suitable provisions in its Patents Act for exports as domestic industry has strong potential to produce enough to meet export demands also. Similarly the importing countries should also have specific provision for parallel imports. The spirit of Para 6 of Doha Declaration on Public Health can be accomplished only when exporting and importing countries stipulate appropriate provisions in their Patent laws. The procedure as advocated by USA on the problem stated in Para 6 of the Doha Declaration has certain practical difficulties which needs to be resolved. Section 90 clause vii has been amended accordingly.

CONCLUSIONS

International Human Right Law is becoming a focus issue in relation to implementation of TRIPS Agreement on many basic and fundamental rights of human being. These rights relate to right to health and right to food. In relation to monopolization factor under the TRIPS Agreement these issues are becoming crucial and are being debated worldwide. Patents to protect innovation could be supported, but the system should not be a devise to restrict competition and allow creation of

monopolies under any special circumstances. The origination of inventions should get their just reward by way of suitable royalties and there should be no grudge in providing the same. The doors should be opened for obligatory licensing involving the domestic enterprises in the production of patented drugs. The suggestions made in this Paper are within the frame- work of the TRIPS is Agreement. Judicious and careful implementation of TRIPS is needed for its smooth application and balancing of rights and obligation of the patent holder in a manner conducive to social and economic welfare as stipulated in Article 7 of TRIPS Agreement.

**COMPARATIVE STATEMENT OF AMENDED PATENTS ACT 1970
(AFTER 1999 AND 2002 AMENDMENTS) AND SUGGESTED
PROVISIONS FOR PATENTS (AMENDMENT) BILL 2003**

SI. No.	Existing provisions of Patents Act 1970 after Amendments (1999 & 2002)	Suggested provisions for Patents (Amendment) Bill 2003
1.	2.	3

CHAPTER I: PRELIMINARY

Section 2: Definitions and interpretation

Sub-section 1

1. Clause (ac)

(ac) "capable of industrial application", in relation to an invention means that the invention is capable of being made or used in an industry;

Section 2: Definitions and

Sub-section 1

Clause (ac)

(ac) "capable of industrial relation to an invention means invention is capable of being or used in any industry;

(Remark: use of word 'any' will have a broader application)

(Note: Underlined portions on all pages signify proposed changes or additions)

2. Clause (f):

(f) "exclusive licence" means a licence from a patentee which confers on the Controller which on licensee, or on the licensee and persons authorised by him, to the exclusion of all other persons (including the patentee), any right in respect of the patented invention, and exclusive licensee shall be

Clause (f):

(f) "exclusive licence" means a patentee or the the licensee, or on the person authorised by him, exclusion of all other (including the patentee), respect of the patented

invention, and
construed accordingly ;

exclusive licensee shall
be construed
accordingly.
(Remark: except the
voluntary licence all other
licences will be granted by
the Controller)

3. Clause (j):

(j) "invention" means a new product
new product
or process involving an inventive step

and capable of
chemical process

Clause (j):

(j) "invention" means a

including machine
apparatus or other
article

or process including

involving inventive steps
and

capable of industrial
application;

(Remark: expanded version will be
more explicit)

4. Clause (ja) :

(ja) "inventive step" means a feature
feature of an

that makes the invention not obvious
important

to a person skilled in the art;
compared to the

Clause (ja):

(ja) "inventive step" means a

invention that involves

technical advance as

existing knowledge and or
having considerable
economic significance and
which makes the

invention not obvious to a
person skilled in the art;

(Remark : expanded version
is needed)

5. Clause (1):

(1) "medicine or drug" includes -
substituting

(i) all medicines for internal or external
added.

use of human beings or animals ;

(ii) all substances intended to be used for or
in the diagnosis, treatment, mitigation
or prevention of diseases in human
beings or animals;

Clause (1):

May be deleted : A

clause (ta) has been

- (iii) all substances intended to be used for or in the maintenance of public health, or the prevention or control of any epidemic disease among human beings or animals;
- (iv) insecticides, germicides, fungicides, weedicides and all other substances intended to be used for the protection or preservation of plants;
- (v) all chemical substances which are ordinarily used as intermediates in the preparation or manufacture of any of the medicines or substances above referred to ;

6. New Clause (1a):

A new clause (1a) may be incorporated as follows:

(1a) "new or novel 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.

(Remark : It is important to provide the definition of 'New or novel' which is an important criteria for admitting claims)

7. New Clause (ta):

A new clause (ta) may be incorporated as follows:

(ta) "pharmaceutical substance" includes, new chemical entity or new medical entity or new bulk drug involving inventive steps".

(Remark : Proposed definition is based upon the recommendations of Pharmaceutical Research

and Development
Committee headed by Dr.
R.A. Mashelkar)

8. New Clause (xa):

A new clause (xa) may be incorporated as follows :
(xa) 'register of licences' means the register of licences granted under various sections of Chapter XVI
(Remark : There is a need to have separate register for all licences issued for use of patents)

CHAPTER II: INVENTIONS NOT PATENTABLE

Section 3 : What are not inventions

9. Clause (b):
- (b) an invention the primary or exploitation of which could be contrary to public order or order or morality or morality or which causes serious prejudice to human and the environment prejudice to human, animal or plant life or health or to the environment;
- Clause (b)
- (b) an invention the primary or intended use or commercial exploitation of which could be contrary to public which causes serious animal health or plant life or to
10. Clause (d):
- (d) the mere discovery of any new property new property or new use for substance or a a known substance or of the drugs or a new mere use of a known process, drug, or a new machine or apparatus unless such an existing known process results in a new product a known or employs at least one new reactant;
- Clause (d)
- (d) the mere discovery of any or new use for a known combination of known formulation of existing variant or polymorph of drug or of the mere use of process, machine or apparatus unless such known process results in a new product or employs atleast one reactant;

(Remark : There is a need for excluding frivolous claims as suggested)

11 New Clause (da) incorporated as follows:

New clause (da) may be

- (da) formulations in any form meant for use as medicine or drug for internal or external use other than such formulations which involve innovative technologies would be covered by process patents;

Explanation : innovative technologies for formulations could be such as 'new drug delivery form' developed on the basis of a novel platform technology and should be covered by process patent.

12 Clause (i):
(i) any process for the medicinal, medicinal, surgical surgical, curative, prophylactic diagnostic diagnostic therapeutic other treatment treatment of human beings or process for any process for a similar treatment animals, of animals to render them free of free disease or to increase their their economic value or that of their their product; products ;

Clause (i):
(i) any process for the curative, prophylactic or other therapeutic or of human beings or any a similar treatment of or plants to render them of disease or to increase economic value or that of

(Remark: inclusion of treatment of 'plants' is also necessary)

Clause (j):

13. (j) plants and animals in whole microorganisms or any part thereof other than constituent thereof micro-organisms but including and seeds, varieties and species and including essentially biological processes production for production or propagation of plants and animals ;

14. New Clause (ja):

15. New Clause (jb):
incorporated as follows:

(j) Clause (j):
plants, animals and
in whole or in part or
including seeds, varieties
species and any process-
biological processes for
or propagation of plants,
animals and
microorganisms (the term
microorganism here would
include viruses);
(Remark : Review process
of Article 27(3) (b) of
TRIPS for patenting of
"microorganisms and non-
biological and
microbiological processes"
by WTO are still not over
and as such should remain
excluded)

New clause (ja) may
be incorporated
as follows:
(ja) inventions which do not
strictly meet the
criteria industrial
application e.g. onco
mouse, stem cell partial
gene fragments, research
tools. PCR technique,
machine based embedded
bio-informatics software,
genomic information and
data bases ;

New clause (jb) may be

(jb) all or parts of natural
living beings, micro-
organisms in any form and
biological materials found
in nature or isolated there-
from including germ
plasm of any living being
and any biological
process, single nucleotide
polymorphisms, naturally

occurring
macromolecules such as
DNA, proteins or
modified proteins:

16. New Clause (jc):
incorporated as follows :

New clause (jc) may be

(jc) biotechnological inventions
needing the use of
biological resources ;

17. Clause (p)
an invention which in effect,
is traditional knowledge or
having
which is an aggregation or
oral
duplication of known properties of
within any local or
traditionally known component or components.

Clause (p):
an invention which, in
effect is anticipated
regard to the knowledge,
or otherwise, available
indigenous community in
India or elsewhere is
traditional knowledge or
which is an aggregation or
duplication of known
properties of traditionally
known components or
compounds.

18. Section-5
(1) In the case of inventions -

Section-5
Sub-clause (1) of the
Principal Act and sub
clause (2) as introduced
through the Patents

(a) claiming substances intended for use, or
capable of being used, as food or

(Amendment) Act, 1999
and the explanation
as incorporated through
Patents (Second
Amendment) Act 2002
may be substituted as
follows :

(b) relating to substances prepared or produced by
available for
chemical processes (including alloys, optical
substances and other
glass, semi-conductors and inter-metallic
or processes in all
compounds) no patent shall be granted in
excluding inventions
respect of claim for the methods or processes
provided that they are

"5.(1) Patents shall be
pharmaceutical
inventions whether products
fields of technology,
listed under section-3

of manufacture shall be patentable.

new, involve an inventive step and are capable of industrial application".

- (2) Notwithstanding anything contained in subclause (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 IV A "Explanation - For the purpose of this section, "chemical process" includes biochemical, biotechnological and microbiological process.

- (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. There shall be no obligation to restore protection to subject matter which on 1.1.2000 had fallen into 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.

(Remark : All applications received during the transitional period 1.1.1995-31.12.2004 would be examined as provided for product patent regime from 1.1.2005. Act 70.8 (b) Any subject matter which had fallen in public domain as on 1.1.2000 shall not be eligible for patent protection - refer Article 70.3 of TRIPS).

CHAPTER IV: PUBLICATION AND EXAMINATION OF APPLICATION

19. Section 11 (A)

Sub-section (5)

"(5) The particulars of every application under this section shall include the particulars of the date of application, number of application, name and address of applicant identifying the application and an abstract"

Section 11 (A)

Sub- section (5):

"(5) The particulars of every application under this section shall include the particulars of the date of application, number of application, name and address of the applicant identifying the application and an abstract of invention disclosed and other information that the Controller in the circumstances deem fit".

CHAPTER IV: EXCLUSIVE MARKETING RIGHTS

20. The Patents (Amendment) Act 1999 may be repealed, excepting .

Section 24 (B) as amended Section 24B: Grant of exclusive rights.

The exclusive marketing rights granted upto 31.12.2004 on any application filed for a claim for patent of an invention shall remain valid from the date of approval granted by the Controller in this behalf till a period of five years or till the date of grant of patent or the date of rejection of application for the grant of patent, whichever is earlier.

CHAPTER VII : PROVISION FOR SECRECY OF CERTAIN INVENTIONS

21. Section 39 :

Sub-section (1)

(1) No person shall, except under the authority of a written permit granted by or on behalf of the Controller, make or cause to be made any application outside India for the grant of a patent for an invention relevant for defence purposes or related to atomic energy unless -

Section 39 :

Sub-section (1)

(1) No person shall, except under the authority of a written permit granted by or on behalf of the Controller, make or cause to be made any application outside India for the grant of a patent for an invention relevant for defence purposes or related to atomic energy or biological materials or traditional knowledge and any other subject matter of strategic importance that may be notified by the government from time to time unless -

(Remarks: It is important to expand the coverage of inventions as suggested above).

CHAPTER VIII : GRANT AND SEALING OF PATENTS AND RIGHTS CONFERRED THEREBY

Section 47:

22. Sub-section (3):

(3) Any machine, apparatus or other article in respect of which the patent is granted or any article made by the use of the process in respect of which the patent is granted, may be made or used, and any process in respect of which the patent is granted may be used, by any person, for the purpose merely of experimenting or research including the imparting of instructions to pupils; and

Section 47:

Sub-section (3):

3) Any machine, apparatus or other article in respect of which the patent is granted or any article made by the use of the process in respect of which the patent is granted, may be made or used, and any process in respect of which the patent is granted may be used, by any person, for the purpose of experimenting or research including the imparting of instructions to pupils; and

(Remarks: The 'word' merely has been deleted as the same can be misused)

New Section 48 (A) may be incorporated as follows:

23. New Section 48 (A):

"48 (A) When products protected under clause (a) or (b) of Section 48 are lawfully imported into the country by any person or an enterprise

directly from the patentee or his licensee or their authorised dealers the imports of these products shall not constitute infringement of patentee's rights".

(Remarks: The above provision relates to exhaustion of rights and is in keeping with Article 6 of the TRIPS Agreement and para 5 (d) of Doha Declaration on TRIPS Agreement and Public Health).

24. 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, 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 to in Section 5 of this Act.

(Remark: sub-section (2) is based upon Article 70(8)(c) of TRIPS Agreement)

CHAPTER XII: SURRENDER AND REVOCATION OF PATENTS

25. Section 66 Revocation of patents in public interest:

New Sub-section (2):

A new sub-section (2) may be incorporated as follows:

"(2) Where supply of any patented material/ substance is blocked for political or any other reason by the patentee the central government shall revoke the patent without giving any reason or notice".

CHAPTER XVI : WORKING OF PATENT COMPULSORY LICENCE AND REVOCATION

26. Section 82 : Definitions :

82 In this Chapter unless the context otherwise requires, -

- (a) "patented articles" includes any article made by a patented process ;
- (b) "patentee" includes an exclusive licensee

27. Section 83

Sub-section (f)

- (f) that the patent right is not abused by the patentee or person deriving title or interest on patent from patentee, and the patentee or a person deriving title or interest on patent from the patentee does not resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology ; and

Section 84: Compulsory Licences

- 28. Sub-section (1) (c)

Section 82 : Definitions :

82. In this Chapter unless the context otherwise requires -

- (a) "patented article" includes any article made by a patented process;
- (b) "patentee" includes an exclusive licensee ;
- (c) "national emergency" - the circumstances of national emergency include grave emergency whereby security of the country or any part of the territory thereof is threatened either by war or external aggression or by armed rebellion ;
- (d) "circumstances of extreme emergency" include public health crises relating to HIV/ AIDS, malaria, tuberculosis or prevention or control of any other epidemic among human beings or animals, and control of crisis relating to pollution of air or water or soil or any other circumstance of extreme urgency;
- (e) "public non-commercial use" - in eludes use of any patented substances to produce (c) that the patented invention is not worked in the territory of India.

products from such substances for distribution on public non-commercial basis i.e. at no profit no loss basis,

- (f) "working of patent or invention" shall be deemed to be production of the patented product or substances in different regions in the territory of India.

(Remark : It is important to define the above patent related terms to avoid any ambiguity.)

Sub-section (f)

- (f) that the patent right is not abused by the patentee or person deriving title or interest on patent from the the patentee, does not resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology; and

(Remark: The underline portion being repetition has been deleted).

Sub-section (1) (c)

(c) that the patented invention is not worked in different regions in the

territory of India

(Remark: working in different parts of the country is needed to meet the demands of our large country)

29. Sub-section (2)

To be amended as suggested

Sub-section (2)

'in different regions' may be added after the words "that the patented invention is not worked"

30. Sub-section (5)

Where the Controller directs the patentee to grant a licence he may as incidental thereto exercise the powers set out in section 88.

Sub-section (5)

Where the Controller grants a licence he may as incidental thereto exercise the powers set out in section 88.

31. Sub-section (6) (iv)

as to whether the applicant has made efforts to obtain a licence from the patentee on reasonable terms and conditions and such efforts have not been successful within a reasonable period as the Controller may deem fit: Provided that the clause shall not be applicable in case of national emergency or other circumstances of extreme urgency or in case of public non-commercial use or on establishment of a ground of anti competitive practices adopted by the patentee, but shall not be required to take into account matters subsequent to the making of the application

(Remarks : Since the compulsory licences will be granted by the Controller, there should be no requirement of directing the patentee to grant compulsory licence.)

Sub-section (6) (iv)

(iv) May be deleted.

(Remark: The entire Sub-section along with the proviso may be deleted. There is no question of justifying the abuse to the patentee by the applicant. There is no logic in this condition)

32. **New Section 84 (A):**

New Section 84(A):

A new section 84(A) may be incorporated as follows:

- (1) Any patentee may apply to the Controller for an entry to be made in the register of licences to the effect that any person may obtain licence of his patented substance or technology
- (2) The Controller shall grant a licence under the patent to any person who applies for such a licence on such conditions, restrictions and royalty term as may be agreed upon by the patentee and the applicant. If the patentee and the applicant are unable to agree within a period of 90

days the Controller shall grant the licence
on such conditions, restrictions and

royalty terms as he may deem appropriate.

(Remark: This is an optional provision. It is open for the patentee to avail this provision or not. Some incentives could be provided in the Patent Rules to attract patentees to offer their patents for voluntary licence. Voluntary licence provision is prevalent in some Patent Laws and may be used by any Patent holder who may not like to promote his product himself; he would however be interested to receive royalty from those who exploit his patent)

33. New Section 84(B)

Section 84 (B)

Section 84 (B) may be incorporated as follows:

- (1) Where an individual merits of an applicant have been determined by the Controller to use the patented invention and that 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 sealing of the 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 exfactory sale price. The term of the licence shall be coterminous with the patent term available to the patentee.

(Remark: The suggested provision is extremely important and is within the framework of TRIPS Article 31 (a) and (b). Many other countries have also provided such a provision in their patent laws)

Section 85: Revocation of Patent or patents by the Controller for non-working:

34. (1) Where, in respect of a patent, a compulsory licence has been granted, the Central Government or any person interested may, after the

Section 85: Revocation of licence by the Controller for non-working:

- (1) Where in respect of a patent, a compulsory licence has been granted, the Central Government or any person interested may, after the expiration of two years from the date of the order granting the

expiration of two years from the date of the order granting the first compulsory licence, apply to the Controller for an order revoking the patent on the ground that the patented invention has not been worked in the territory of India or that reasonable requirements or that the patented invention is not available to the public at a reasonable affordable price.

Sub-section 3

35. (3) The Controller, if satisfied that the requirements of the public with respect to the reasonable patented invention has not been satisfied or that patented invention has not been worked in the territory of India or that the patented invention is not available to the public at a reasonably affordable price, may make an order revoking the patent.

Section 89:

Clause (a)

36. (a) that patented inventions are worked on a commercial scale in the territory of India without undue delay and to the fullest extent that is reasonably practicable ;

Section 90

Sub-section (1) Clause (ii) z:

37. (ii) that the patented invention is worked to the fullest extent by the person to whom the licence is granted and with reasonable profit to him

compulsory licence, apply to the Controller for an order revoking the licence on the ground that the patented invention has not been worked in the territory of India.

(Remark : Revoking of the compulsory licence for any reason other than non-working would not be justified. Under other circumstances the justification could be for grant of more compulsory licences.)

Sub-section (3) may be amended as follows:

(3) The Controller, if satisfied that the reasonable requirements of the public with respect to the patented invention has not been satisfied or that patented invention has not been worked in the territory of India or that the patented invention is not available to the public at a reasonably affordable price either by the patentee or by the licensees may order forfeiture of the patent.

(Remark : The amendment proposed is based upon Article 5(3) of Paris Convention)

Section 89

Clause (a) :

(a) that patented inventions are worked on a commercial scale in the territory of India without undue delay and to the maximum extent that is reasonably practicable ;

(Remark: For a large country like India a particular compulsory licence can not be worked to meet the fullest requirement of the country).

Clause (ii):

(ii) that the patented invention is worked to the maximum extent possible by the person to whom the licence is granted and with reasonable profit to him ; (vi) that the licence is for the balance term of the patent.

Section 90

Sub-section (1) Clause (ii) :

37. (ii) that the patented invention is worked to the fullest extent by the person to whom the licence is granted and with reasonable profit to him

Clause (vi):

38. (vi) that the licence is for the balance term of the patent unless a shorter term is consistent with public interest.

Clause (vii)

39. (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;

40. (3) Notwithstanding anything contained in sub-section (2), the Central Government may, if in its opinion it is necessary so to do, in the public interest, direct the Controller at any time to authorize any licensee in respect of a patent to import the patented article or an article or substance made by a patented process from abroad (subject to such conditions as it considers necessary to impose relating among others matters to the royalty and other remuneration, if any, payable to the patentee, the quantum of import, the sale price of the imported article and the period of importation), and thereupon the Controller shall give effect to the directions.

Clause (ii) :

- (ii) that the patented invention is worked to the maximum extent possible by the person to whom the licence is granted and with reasonable profit to him ;

Clause (vi) :

- (vi) that the licence is for the balance term of the patent.
(Remark : A shorter term cannot be determined and as such should not be prescribed. The requirement of shorter term can be satisfied by section 94 regarding termination of compulsory licence. The spirit of Article 31(g) also does not stipulate 'shorter term').

Clause (vii)

- Clause (vii) needs to be re-written stipulating export provision in an unambiguous manner as follows :
- (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;
- (vii) (c) that in the 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.

Sub-section (3)

- (3) Notwithstanding anything contained in

do, in the public interest, direct the Controller at any time to authorise any licensee in respect of a patent to import the patented article or an article or substance made by a patented process from abroad (subject to such conditions as it considers necessary to impose relating among other matters to the quantum of import, the sale price of the imported article and the period of Importation), and thereupon the Controller shall give effect to the directions.

(Remark : The question of paying any royalty and other remuneration on imported patented product will not arise as imported price would have already included the element of royalty)

subsection (2), the Central Government may, if in its opinion it is necessary so to

41. **Section 92:**

- (1) If the Central Government is satisfied, in respect of any patent in force, in circumstances of national emergency or in circumstances of extreme urgency or in case of public non-commercial use, that it is necessary that compulsory licences should be granted at any time after the sealing thereof to work the invention, it may make a declaration to that effect, by notification in the Official Gazette, and thereupon the following Provisions shall have effect, that is to say -

Section 92:

- (1) In the circumstances of notification of the national emergency, the Controller of Patents may issue authorization of rights at any time during the national emergency for working of any patent in the country on application by any enterprise interested to use the patent on such terms and conditions as the Controller of Patents may deem fit;
- (2) In the circumstances of extreme urgency as notified by the Health authorities which may arise as the case may be including prevention

- (1) the Controller shall on application made at any time after the notification by any person interested grant to the applicant a licence under conditions as he thinks fit;
- (2) in settling the terms and conditions of a licence granted under this section; the Controller shall endeavour to secure that the articles manufactured under the patent shall be available to the public at the lowest prices compatible with the patentees deriving a reasonable advantage from their patent rights.
- (2) The provisions of sections 83, 87, 88, 89 and 90 shall apply in relation to the grant of licences under this section as they apply in relation to the grant of licences under section 84.
- (3) Notwithstanding anything contained in subsection (2), where the Controller is satisfied on consideration of the application referred to in clause (i) of sub-section (1) that it is necessary in-
- (i) a circumstance of national emergency;
 - (ii) a circumstance of extreme urgency ; or
 - (iii) a case of public non-commercial use, Which may arise or is required as the case may be, due to public health crises, including those relating to Acquired Immuno Deficiency Syndrome, Human Immuno deficiency Virus, tuberculosis, malaria or other epidemics, he shall not apply any procedure specified in section 87 in relation to that application for grant of licence under this section.
- Provided that the Controller shall, as soon as may be practicable, inform the patentee of the patent relating to the application for such non-application of section - 87."
- or control of HIV/AIDS, malaria, tuberculosis or any other epidemic among human beings or animals and control of crisis relating to pollution of air or water or soil as notified by the concerned authorities in the Government. The urgency may be for the country as a whole or any region of the country. The Controller of Patents shall issue authorisation of rights on relevant patented products to any enterprise interested on such terms and conditions as he may deem fit;
- (3) (a) At any time after the expiration of three years from the date of sealing of the patent any enterprise may make an application to the Controller of Patents for grant of compulsory licence for using any patented substances to produce finished formulations for distribution/ sale on public non-commercial basis i.e. on no profit no loss basis;
- (b) that the concerned enterprise shall furnish a certificate to the Controller at the end of each year that the product has been used on public non-commercial purposes;
- (c) that the term of the licence will be as may be requested by the applicant and may extend to the term as available to the patentee. The royalty payable to the patentee shall be decided by the Controller of Patents in consultation with the patentee.
- (4) The provisions of sections 83, 88, 89 and 90 shall apply in relation to issue of authorization of rights under subsections 1 and 2. Any procedure specified in section 87 shall not apply to each authorization under these subsections.
- (5) In settling the terms and conditions of authorisations issued under the such subsections (1) and (2), the Controller of Patents shall endeavour to secure that the articles manufactured under the

authorisations shall be available to the public at the lowest prices consistent with the patentee deriving a reasonable advantage from their patent rights

Provided that the Controller of Patents shall, as soon as may be practicable, inform the patentee of the authorisations issued granted under subsection (1) and (2).

42. **New Section 95**

Section 95: Transfer of technology:

A new section 95 may be incorporated as follows:

(95) It shall be incumbent upon the patentee to transfer technology to the licensee to manufacture the patented product for which a compulsory licence has been granted by the Controller. If the patent holder does not cooperate in the transfer and dissemination of technology the issue of appropriate measures could be considered by the designated authority.

(Remarks: Application of Doha Declaration on TRIPS para 5(1) and Articles 7 and 8 of TRIPS would fully justify transfer and dissemination of technology and taking of measures necessary where the patentees do not co-operate).

CHAPTER XVIII: SUITS CONCERNING INFRINGEMENT OF PATENTS

Section 107 A : Certain acts not to be considered as infringement

43. 107 A. For the purposes of this Act,-
(a) any act of making, constructing, using or selling a

patented invention solely for uses reasonably related to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, or in a country other than India, that regulates the manufacture, construction, use or sale of any product;

(b) importation of patented products by any person from a person who is duly authorised by the patentee to sell or distribute the product, shall not be considered as an infringement of patent rights.

Section 107 A : Certain acts not to be considered as infringement.

107 A For the purposes of this Act, -
(a) any act of making, constructing,

using or selling a patented invention for uses reasonably related to the development and submission of information required under any law for the time being in force, in India, that regulates the manufacture, construction, use or sale of any product;

(b) importation of patented products at cheaper price or to meet the shortages by any person authorised by the Controller of patents 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 patent rights.