
K D Raju*
Amity Institute of Global Legal Education and Research, E-25, Defence Colony, New Delhi 110 024

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Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement was one of the most contentious issues in the Uruguay Round of multilateral trade negotiations, which was concluded in 1994 at Marrakech. The commitments under the TRIPS Agreement compelled India to amend its patent regime in 1999, 2002 and 2003 (the Amendment Bill lapsed due to the dissolution of the present Lok Sabha). This paper examines the amendments in the Indian patent system in consequence of TRIPS Agreement, and Indian reaction to the same in substantial and procedural levels. India opted for the setting up of a ‘mail box’ and has taken Exclusive Marketing Rights (EMR) route for the transitional period. The second section analyses the implications of transitional period and to suggest further options available to India. It also looks into the new provisions included in the Patents (Amendment) Bill 2003. This paper, based on a review of amendments to the Indian law, concludes that the Indian patents regime is inadequate to meet the challenges posed by the TRIPS Agreement. It also puts forward some suggestions to improve the patent regime in the country as a whole.

Keywords: TRIPS Agreement, Patent amendment, Mailbox and EMR

The GATT was originally conceived in the early post-war years. The purpose was to establish a legal framework for international trade in goods. In the beginning, intellectual property protection was outside the GATT agenda, but it did take notice of intellectual property protection in Article IX and Article XX. The Agreement on Trade- Related Aspects of Intellectual Property Rights (TRIPS) was one of the most contentious issues in the Uruguay Round (UR) of multilateral trade negotiations, which was concluded among 125 nations, including India, in April 1994 at Marrakech. Almost a decade after coming into effect, the TRIPS Agreement remains a controversial but forceful legacy of the UR trade agreements. However, the Agreement leaves considerable room to deal with the national level issues, such as the definition of an invention, exception to exclusive rights, compulsory licensing, etc. The TRIPS Agreement provides a three-stage time frame for developing countries to comply with its obligations. They are:

† The views expressed in this paper are personal and should not be attributed to the institutions which the author is associated with.
*E-mail: kdr_jnu@hotmail.com
1. Introduction of a ‘mailbox’ facility starting from 1995 to receive product patent application in the field of pharmaceuticals till 31 December 2004. An Exclusive Marketing Rights (EMRs) for a period of five years or till the product patent is granted or patent application is rejected.

2. Other rights related to rights of patentee, term of patent protection, compulsory licensing, reversal of burden of proof, etc., are to be complied with by 1 January 2000.

3. Introduction of product patent protection in all fields of technology from 1 January 2005 including food, drugs, pharmaceuticals and chemicals.

India has complied with most of the obligations and the remaining will be fulfilled with the passing of Patents (Amendment) Bill 2003. The TRIPS Agreement covers seven major IPR areas, viz., patent, copyrights and related rights, trademarks, geographical indications, industrial designs, layout designs (topographies) of integrated circuits, and protection of undisclosed information. India made a series of amendments to its existing laws and enacted new legislations in consonance with the TRIPS commitments. They are:

1. Patents (Amendment) Act, 2002 and Patents (Amendment) Bill 2003 (lapsed due to the dissolution of the Lok Sabha).

2. Trade Marks Act, 1999

3. Designs Act, 2000

4. Copyright (Amendment) Act, 1999

5. Protection of Plant Varieties and Farmers’ Rights Act, 2001


This stocktaking acquires special significance in the wake of the US putting India in the priority watch list under ‘Special 301’ provision of the Trade Act, alleging poor intellectual property protection in India. The US pharmaceutical industry alleges that it currently loses more than $1.7 billion annually because of India’s insufficient intellectual property protection. The western perspective of the Agreement is that, “Intellectual property has become one of the most valuable assets of a large and growing number of domestic and international corporations.”

TRIPS Agreement and Patents (Amendment) Act, 2002: A Comparative Analysis

The Concept of Invention

Article 27(1) of the TRIPS Agreement provides that:

—Patents shall be available for any inventions, whether product or process, in all fields of technology; and
Patent rights shall be enjoyable without discrimination in the field of technology.

The TRIPS Agreement does not specify what an ‘invention’ is; national laws can define this concept according to the standards generally applied. But all these are subject to normal tests of novelty and inventiveness capable of industrial application.

There is no obligation under the TRIPS Agreement to adopt an expansive concept of ‘invention.’ While implementing Article 27(1), each country should carefully consider the economic, legal and ethical aspects involved in the patenting of living materials or certain types thereof.

There is no uniform definition available which relates to the distinction between ‘invention’ and ‘discovery.’ According to the basic principles of patent law, the former is patentable and the latter is not. A ‘discovery’ is commonly considered to mean the mere recognition of what already exists. It means that India can legitimately follow a definition of invention that broadly excludes materials pre-existing in nature. For instance, Argentine patents law excludes from the concept of invention “any kind of living materials or substance already existing in nature” (Article 6g).

Indian Practice and Exceptions to Patentability

The Indian Patents (Amendment) Act, 2002 defines an ‘invention.’ Section 3 of the Act enumerates what are not ‘inventions’ and those inventions, which are not patentable. An invention that is frivolous or contrary to well-established natural laws cannot be patentable. An invention intended to commercial exploitation or contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment, is also not patentable. Mere arrangement, rearrangement or duplication of a known device cannot be patented. Mere discovery of a scientific principle or the formulation of an abstract theory or “discovery of any living thing or non-living substance occurring in nature” is not acceptable.

The new clause (j) excludes plants and animals other than micro-organisms in whole or any part thereof including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals. Sub-section (k) excludes a mathematical, business method, computer program or algorithms. Sub-section (l) excludes “a literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever includes cinematographic works and television productions. Sub-section (m) excludes “a mere scheme or rule or method of performing mental act or method of playing game.” Presentation of information and topography are included in sub-sections (n) and (o). Traditional knowledge or traditionally known component is excluded from patenting. This provision may adequately check the piracy of huge Indian traditional knowledge in the sphere of Ayurvedic medicines.

In addition to what is not an ‘invention’, national laws can establish exceptions to the patentability of invention that would otherwise be protectable. There are three permissible exceptions to the basic rule on patentability. Broad ex-
emptions from patentability remain, to protect public order or morality, prevent environmental deterioration and protect animal, human or plant life. This is an area where India can enjoy some room to manoeuvre. The same applies to therapeutic and surgical methods for treatment of humans or animals.16

The controversial exemptions are in Article 27 (3) (b) for biotechnological inventions. It exempts plants and animals, essentially biological processes for the production of plants and animals. The TRIPS Agreement permits the patenting of micro-organisms and non-biological and microbiological processes. Nowadays, biotechnology has become one of the most significant areas of innovative inventions like cloning. In principle, patents must be provided for micro-organisms and biotechnological inventions.17 But at the same time, the ethical, economic and legal implications of allowing the patenting of plants and animals, even if genetically modified, strongly indicate that all patents on life-forms and living processes should be rejected from inclusion in TRIPS.18

The concept of ‘microorganism’ is extensively interpreted under the TRIPS Agreement. Patenting of it is permitted as applicable only to genetically modified microorganisms and not to those existing in nature. This concept should be interpreted, however, in accordance with the scientific concept that may be adopted by national legislation; a ‘microorganism’ is a member of any of the following categories: bacteria, fungi, algae, protozoa or viruses.19 The newly-introduced section 3(b) excludes “inventions primary or intended use or commercial exploitation of which could be contrary to law or morality or which causes serious prejudice to human, animal or plant life or health or to environment.”

A few judicial decisions are also available for considering the determination of invention. An “invention is the act or operation of finding out something new; the process of contriving and producing something not previously known or existing, by the exercise of independent investigation and experiment.”20

Section 2(8) of the Patents and Designs Act, 1911, defines ‘invention’ as any manner of new manufacture and includes an improvement and allied invention. Unlike the Patents Act, 1970, the 1911 Act does not specify the requirement of being useful in the definition of ‘invention.’ But the courts were always of the view that a patentable invention, apart from being a new manufacture, must also be useful.21

Without violating the TRIPS provisions, the Indian courts can interpret what is contrary to morality or what are the kinds of commercial exploitations that can cause serious prejudice to human or animal or plant life. Like the TRIPS provisions, Indian law also does not precisely enumerate what is opposed to public policy. It is for the Indian courts and authorities to interpret and consider each case separately and fix the standards.

Criteria of Patentability

Article 27(1) of TRIPS Agreement provides that patents shall be granted to protect inventions, which are “new, involve an inventive step and are capable of
industrial application.” The Agreement allows Member countries to interpret ‘inventive step’ as synonymous with ‘non-obviousness’. Similarly, a country can consider treating ‘capable of industrial application’ as synonymous with ‘usefulness.’ The latter concept is looking somewhat broader, since it would allow even the patentability of purely experimental inventions. Other options to be considered relates to the concept of ‘prior art’ which may be defined more or less broadly, and to the processes that are not novel but which use or produce a novel product.

Where the invention has not been properly described and will not function in the way claimed by the applicants, the opponents succeed even when they fail to establish “prior publication” as well as “prior public knowledge” and, therefore, the application for grant of patent is liable to be rejected.

**Indian Position**

Section 2 (1)(j) of the Act defines invention as follows, “a new product or process involving an inventive step and capable of industrial application.” According to section 2 (1)(ac), which explains “capable of industrial application, in relation to an invention, means that the invention is capable of being made or used in any kind of industry.”

The interpretation of the words “capable of industrial application” is also subject to judicial scrutiny. An invention, in order to be patentable, must be capable of being made or used in some kind of industry. Hence, ‘industry’ should be understood in its broadest sense as including any useful, practical activity as distinct from purely intellectual or aesthetic activity, and does not necessarily imply the use of a machine or the manufacture of an article.

An ‘invention’ within the meaning of the Act is an invention for a manner of new manufacture that is in some way associated with trade and commerce, meaning traffic in goods, i.e. exchange of commodities for money or other commodities.

The entire definition is dependent on or associated with the word ‘manufacture’ which denotes: (i) either a thing made which is useful for its own sake and vendible as such, or (ii) means an engine or instrument to be employed either in the making of some previously known article or in some useful propose or extending to new process to be carried on by known implements or elements acting upon known substances and ultimately producing some other known substance, but producing it in a cheaper or more expeditious manner, or of a better or more useful kind.

The interpretation of ‘inventive step’ as ‘non-obviousness’ in Article 27(1) of TRIPS Agreement and the consequent Indian provision in Section 2(1)(ja) provides that “inventive step” means a feature that makes the invention not obvious to a person skilled in the art. This definition is ambiguous and holds many implications for India.

**Rights Conferred on the ‘Patentee’**

Article 28 of TRIPS Agreement set forth the rights that a patent should confer on its titleholder by referring to the two
traditional categories of inventions, products and process. Here, an option is open to exclude the extension of protection to the product if the latter is excluded from patentability (e.g., plants or animals, inventions contrary to ordre public, etc.). This is to avoid an indirect ‘product by process’ protection that would nullify the exclusion from protection. The right of patentees are included in the newly created Section 48 (a) and (b) of the Act; the rights are limited by a proviso ‘provided that the product obtained is not a product in respect of which no patent shall be granted under this Act’. This is completely in consonance with the TRIPS provision.

According to Article 6, nothing in the TRIPS Agreement shall be used to address the issue of exhaustion for the purpose of dispute settlement. This means that a member cannot approach the Dispute Settlement Body of the WTO, on the basis that another member provides for international exhaustion of a patent. India can consider an option, which provides for an international exhaustion of rights, in order to allow ‘parallel imports’ of legitimate products from any country and ensure the availability of the product on a competitive basis. The basic concept behind this principle is that once a product has been legitimately introduced in the market, the rights of the patentee are exhausted, since the patentee has already exercised his rights.

The recognition of the international exhaustion in the TRIPS Agreement may be seen as logically reflecting the globalization of the economy. This option is not explicitly included in the Indian Act. In these circumstances, as rightly observed by Jayashree Watal “it would be difficult to imagine what an importer would do with patented products if he could not sell or distribute them.” Section 84 (7) retained in the new Act, also sets out the grounds and conditions of compulsory licences, makes it clear that the importation of the patented article or substance made by a patented process is not allowed to such licences as it could constitute infringement of the patentees’ rights.

Compulsory Licensing

The basic objective of granting patent is to encourage inventions and to secure that the inventions are worked in India on a commercial scale, and to the fullest extent under reasonable terms without delay. They are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article.

Article 31 of the TRIPs Agreement ‘on other use without the authorization of the right holder’ contains a detailed set of conditions for the granting of compulsory licence. The TRIPS Agreement refers to five possible specific grounds for the granting of compulsory licences. These are refusal to deal, emergency and extreme urgency, anti-competitive practices, non-commercial use, and dependent patents. The stringent conditions are really for the actual use of the patent and not on the grant of compulsory licences.

It is noted that in some cases, for instance, in emergency and public-non-commercial use, there is no need to have a previously requested voluntary licence as required by article 31(b) of the Agree-
ment. Moreover, in the case of public non-commercial use, the patent holder may be informed after the use of the invention.

The TRIPS Agreement also allows compulsory licences in case of lack of or insufficient working. Article 27(1) of the Agreement stipulates that ‘patent rights shall be enjoyable without discrimination whether the products are imported or locally produced.’ It has been interpreted as a prohibition of any obligation to locally execute a patented invention. This is subject to many criticisms. A possible option is to provide in line with article 8.1 of the TRIPS Agreement for qualified cases of lack of working.

Under compulsory licensing, the patentee will be able to hold and use production of his invention down to the level of maximum profit. But even if it is a monopolistic right for 20 years, many countries want to qualify it for political objectives, such as local working of the invention or protection of consumer interests.

The Indian government reiterated its position that since the enactment of the Patents Act, 1970 there have been no instances of misuse of the provision related to compulsory licensing in India. However, the foreign companies are sceptical that once the product patent regime comes into place, the Government could potentially misuse the same. It is true that 80 per cent of the patents granted in India are owned by foreign multinationals. It is better to wait and see rather than speculate on apprehensions.

Compulsory licences are provided in chapter XVI from sections 82 to 94 of the Act and the Controller of Patents is empowered to grant as well as revoke compulsory licences. Under section 84, an applicant can at any time after expiration of three years from the date of sealing of a patent, apply to the Controller of Patents on any of the grounds provided in the Act. Sufficient safeguards are provided in section 89, which mentions the general purpose and objective of granting compulsory licence.

Transitional Period and Implication for India

The Patents Act, 1970, was amended in 1999 and also in 2002 with a view to fulfilling India’s obligations under Articles 70(8) and 70(9) of the TRIPS Agreement. It was also influenced by the WTO Dispute Settlement Panel’s adverse ruling against India, following complaints made by the US and the European Union that India has failed to meet its commitments under Articles 70(8) and 70(9) of the Agreement. The transition period of 10 years started from the establishment of WTO in 1995 is going to get over soon. This part of the study analyses the implications of transitional period and what would be the strategy for the future negotiations.

Requirements under Articles 70 (8) and 70 (9) of TRIPS

Article 65(2) of the TRIPS Agreement allows developing countries a transitional period of four years with effect from January 1995, to implement the provisions of the TRIPS Agreement as a whole. But article 65 (4) of the Agreement provides for an exception to this
general transition period. Under this provision, if a developing country has not permitted product patent to any class of products under its law as on January 1995, it can take another five more years to amend its law to provide product patents to those classes of products. Therefore, India has availed a transitional period of 10 years, up to December 31 of 2004, to amend its law to extend product patents to food, pharmaceutical products, agrochemicals, microorganisms and seeds.

Articles 70(8) and 70(9) of the TRIPS Agreement place a limitation on the transition periods allowed under Articles 65(2) and 65(4) of the Agreement in respect of pharmaceuticals and agrochemicals. Article 70(8) establishes ‘mailbox’ mechanism and article 70(9) provides for ‘exclusive marketing rights (EMR)’ to the applicants.

**Mailbox**

Article 70(8) read with articles 65(2) and (4) of TRIPS obliges all the countries that do not provide product patents for pharmaceuticals and agrochemicals as on January 1995 in accordance with article 27, to provide means for the acceptance of applications for product patents. Such applications are to be examined only from the date of January 2005; till then the applications are kept in a ‘mailbox’.³¹ The mailbox system mandates such a facility for the interim period or until the product patent facility is introduced.

**Exclusive Marketing Rights (EMR)**

According to article 70(9) of TRIPS Agreement during the transitional period, EMR is to be granted for a period of five years from the date of obtaining marketing approval in that country or until a product patent is granted or rejected, whichever is shorter. It means India should receive patent applications for pharmaceuticals and agro-chemicals from 1 January 1995 and that exclusive marketing rights should be granted to an applicant, who applies for those rights.

The following criteria are to be fulfilled for granting EMR:

- A product patent has been granted in any WTO country
- A patent application has been filed in any WTO country on or after January 1995
- Marketing approval has obtained in that country
- An application for a product patent should have been filed in India on or after January 1995 under the mailbox facility under article 70(8).

**The Mailbox Dispute in WTO**

The US and EU complained to the WTO Dispute Settlement Body (DSB) regarding the absence of either patent protection for pharmaceutical and agricultural chemical products or formal systems in India that permit the filing of patent applications for pharmaceutical and agricultural chemical products and that provide for the grant of exclusive marketing rights for such products.³² India argued that:

Obligations arising under international agreements or treaties are not, by their own force, binding in Indian domestic law. Appropriate legislative or executive action has to be taken for bringing
them into force. Although not self-executing under Indian law, implementation of a treaty does not require fresh legislative or executive action if existing administrative regulations or statutory or constitutional provisions permit the implementation of the treaty in question. The Indian courts may construe, in this context, statutory or constitutional provisions that pre-exist a treaty obligation in order to render them consistent with such a treaty obligation.33 But the Panel ruled that India has not complied with its obligations under article 70(8) as:

1. It has failed to establish a sound legal basis for adequately preserving novelty and priority vis-à-vis applications for product patents in respect of pharmaceutical and agricultural chemical inventions during the transitional period

2. It has failed to establish a system for the grant of exclusive marketing rights.34

India appealed to the Appellate Body (AB) of WTO on the ruling. But the AB upheld the findings of the Panel.35 After the decision, India was forced to amend its Patents Act in 1999 to avoid trade sanctions. Thus, the Patents (Amendment) Act, 1999 was passed in December 1999 and to include more procedural aspects it was amended again in 2002. Presently, the government is planning to further amend it to include the product patent system.

The real implication of Articles 70(8) and 70(9) is that in respect of pharmaceuticals and agrochemical products for which product applications were filed on or after January 1995, Indian companies will not have the freedom that they had enjoyed under the earlier Patents Act of 1970, to produce and market those products in India or elsewhere without any legal restrictions.36 Indian drugs industry feels that the introduction of the EMR facility would destroy the local industry and the multilateral pharmaceutical giants will take over the domestic market. The net result would be the increase in price of medicines, which cannot be affordable to the common man in India.37 The general trend is that, there are three to five years of gap in introduction of a new-patented drug in the world market and its subsequent introduction in Indian market. The consequence is that people in India have to wait for that particular drug even when it is available in the world market.38

Article XX of the GATT recognizes “the importance of the sovereign nation being able to promote health interests, even if contrary to its general obligations under the WTO agreements.”39 The product patent system has now become an accepted norm even in most of the developing countries. Thailand amended its patents act in 1992 to provide product patents in food, pharmaceutical and chemical sectors. China also amended its patent law in 1992 for providing product patents in the above sectors; China was not even a member of WTO at that time. Turkey, Brazil, Argen-
tina and other Latin American countries have opted to introduce product patents by amending their patent laws.

**EMR vs Product Patent**

Many scholars are arguing for introducing product patent system straight away for pharmaceuticals and agrochemicals. The rationale for introducing the product patent system may lie around the fact that the acceptance of product patent applications from 1 January 1995 itself means the de-facto introduction of the product patent system for these two products from that date onwards.

Jayashree Watal observed that EMRs are at least equivalent to patents and delaying legislation on product patents, for another five years, would benefit neither Indian industry nor consumers. This is because domestic reverse engineering of a product covered by a patent application would take place only after the product appears in the world market and is considered successful. By the time the EMR or patent would be granted or about to be granted in India, the investment for such reverse engineering would not be made. Moreover, it will give monopoly for a period of five years without examining the patents or its contents.

The implications are severe for instance, turmeric or neem patented in US or products based on Indian medicine (traditional), the EMR route would make it obligatory for India to grant marketing right on any such application till 2004. Product patent system can give thorough examination under the Indian Act, and the Indian patent office can reject or accept the application without waiting for the transitional period.

Another important issue in the field of EMR is the applicability of compulsory licences. Compulsory licences for manufacturing cannot be granted in case of EMRs, since it would not be possible to grant licence for rights, which have not been conferred on the product patent applicant.

**Patents (Amendment) Bill 2003**

It is not unforeseen that India is amending its patent laws for including product patents within the country to meet the deadline of ushering in the product patent regime from 1 January 2005. The Government introduced the Bill in the Lok Sabha on the very first day of winter session. But unfortunately the Bill was lapsed due to the dissolution of the thirteenth Lok Sabha on 6 February 2004. It is expected that the new government will introduce it again in near future.

**Salient Features of the New Bill**

— The statement of objects and reasons for the Bill says, efforts have been made not only to make the law TRIPS compliant but also simplify and rationalise the procedures governing grant of patents so as to make the system more user-friendly.

— The Bill included product patent protection in all fields of technology as per article 27 of the TRIPS Agreement.
— It deleted the provision for EMR and introduced a transitional provision for safeguarding EMR already granted.

— Strengthening the provision with regard to national security. Enlarged the powers of the Appellate Board with a view to extending its jurisdiction to revocation of patents also.

— Certain provisions to harmonize the Act with the Patent Cooperation Treaty to which India is a signatory.

— A provision-enabling grant of compulsory licence for export of medicines to countries, which have insufficient, or no manufacturing capacity to meet emergent public health situations. This provision is in accordance with the truce concluded on 30 August 2003 just before the Cancun Ministerial for the implementation of paragraph 6 of the Doha Declaration on TRIPS and Public Health.

— The Bill also provides for simplifying and rationalizing the procedure and time limit with a view to introducing flexibility and reducing processing time, which will benefit the users.

— The Bill also proposes to drop the present provision for ‘pre-grant opposition’ and substitute it with ‘pre-grant representation.’ The consequence of this provision is that, in future, objections to a patent before grant would be no longer be a legal right. The earlier provision allows opposition to likely granting of a patent and, legally, arbitration can be sought in four months after the Patent Controller makes the application public.

— The Patent Controller is empowered to dispose off the representation and can go ahead with sealing of the patent.

It seemed that the Indian pharmaceutical industry has welcomed the government’s initiative to grant EMR. But the MNCs fear that the new drug price control order will curtail the freedom under the EMR facility. But the moot question is whether the new order is a violation of TRIPS Agreement.

Conclusion and Suggestions

The objective of the TRIPS Agreement is to enforce globally tough standards in respect of several forms of intellectual property, which include patents, trademarks, protection of undisclosed information, and so on. It prescribes the maximum standards that will substantially increase the degree of harmonization of intellectual property, but it does not provide a uniform law. Even the protection is on a universal scale leaving considerable room for national laws to define a number of important aspects.

Recently the UN Commission on Human Rights in its 52nd session adopted a resolution, which noted that the TRIPS Agreement constitutes contravention of international human rights law. Now, the framework of IPRs is suited for indus-
trialized countries. This conclusion is based on their share in the world R&D expenditure. The contribution of developing countries is only four per cent.

In accordance with the preamble, the main goal of the TRIPS Agreement is “to reduce distortion and impediments to international trade.” This mandate is contained in articles 7 and 8 of the Agreement. In fact, the Agreement catalyses monopolies, inhibits competition and freezes the initiative of scientists and technologies in providing cheaper and better products through more and finer processes in the developing countries. The TRIPs Agreement, in its restrictive provisions, sabotages developmental objectives of countries like India through TRIPs taboos and WTO handcuffs.45

The apprehension of J H Reidman become true that, “in advocating an ‘even handed approach’ to international intellectual property relations, I argued that it would violate fundamental precepts of international economic law if the developed countries failed to differentiate between developing and least-developed countries (LDCs) when formulating minimum standards under the TRIPS Agreement.”46

The Indian Patents Act has been amended a number of times to comply with the TRIPS Agreement. But still the management of the patent regime in India is not satisfactory. The pending patent applications are increasing day by day. Recently, India constituted a Patents Appellate Tribunal with appellate jurisdiction on the decisions of the Patent Commissioners all over the country. Even within the limits, there is space for India to interpret each and every provision.

As a nation committed to the interests of its people, India has to use all options to minimize the lethal consequences of TRIPS regime. As a party to the Alma Ata Declaration of 1978,59 which states the right to health as a part of fundamental rights, India is committed to the cause of protecting the health of its citizens. Right to health is a fundamental right as part of article 21 of the Indian Constitution, which ensures right to life of all persons.50 This right also includes the right to food, clothing and maintenance and improvement of public health. The WTO Doha Ministerial Conference Declaration on TRIPS was on a right direction to ensure the availability of essential medicines in developing and least developed countries. But the attitudes of the devel-
oped nations like the US and those of the EU are in a backward direction.

Our cultural cornerstone, the Rig-Veda says, ‘let noble thoughts come to us from every side.’ Patenting intellect or its products is sacrilegious and a social outrage. The west cannot claim legitimacy for a stranglehold on Indian progress, using patent rights as an iron curtain. Law is for life, science is for man, and the dignity and worth of the human person shall not suffer from ‘patent servitude.’

Suggestions

It seems that many more sections of the Act are to be amended to make it user-friendly or more transparent and feasible. The following principles of Doha declaration can be included in the new Bill:

— Implementation and interpretation of TRIPS provisions for promoting both access to existing medicines and the creation of new medicines.

— TRIPS Agreement should not prevent member governments from protecting public health.

— TRIPS Agreement to be read in light of its objectives and principles.

— International transfer of technology.

The following options can also be considered in the new Bill:

— The recommendation of Pharmaceutical Research and Development Committee headed by Dr R A Mashelkar, that there is a need to amend section 2(1)(i) of the Patents Act to make “new chemical entity or new medical entity” alone to be patentable.51

— The formulations and combinations of drugs, changes in dosage, new use, etc., should not be patentable as there is no inventive step involved in it.

— The patenting of microorganisms and non-biological processes should be excluded. Similarly in principle, bio-technological inventions should be made patentable.

— Patenting of life-form genes should be specifically excluded. There is no such direct obligation to grant patenting to life forms.

— The terms such as novelty, circumstances of national emergency and extreme urgency, and public non-commercial use should be defined clearly in the Bill.

— The working of patents through domestic firms should be made compulsory.

— Right to protect health as a fundamental right.

— Right to grant compulsory licences is in the present Act, but this measure is rarely invoked in India. In the coming years this option should be used if and when needed.

— Sufficient safeguards should be
provided against the misuse of compulsory licensing based on any reasons whatsoever.

— All compulsory licences should transfer the technology and know-how related to that technology.

— There should be a common policy on patents and Indian pharmaceutical industry.

— The provisions made in the Patents (Amendment) Act, 2002 for parallel imports should be strengthened, as they are insufficient now.

— The Member should be given freedom to establish its own regime in case of the exhaustion of patents and no double royalty should be provided for imports.

— The product patent protection would be applicable from the date of sealing of a patent.

— All applications (nearly 5000) kept in the ‘mailbox’ from 1 January 1995 would fail if the subject matter has been used anywhere in the world prior to 2005. Such a provision is permitted under the TRIPS also. Because article 70(3) of the TRIPS provides that “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.”

This provision can be made applicable to the transitional arrangement in India, which is TRIPS compatible.

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20 Nichols Smith V, 88 US 22 L Ed.566; Hollister v Mfg Co, 113 US 28 L Ed.901

21 Biswanath Prasad Radhey Shyam v Hindustan Metal Industries, AIR 1982 SC 1444

22 Footnote 5 to TRIPS Agreement

23 Abid Kagahwala v Edgar Huddley Co (P) Ltd, 1984 PTC 234 (PO)

24 Sri Gajalakshmi Ginning Factory Ltd v CIT (1952) 22 ITR 502 (Mad)


26 Watal Jayashree, Implementing the TRIPS Agreement, policy option open to India, Economic and Political Weekly, 27 September 1997

27 Article 27.1 provides that: Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced


29 The Indian Parliament passed the Patents (Amendment) Act, 2002 and it received the assent of the President on 25 June 2002


31 S.24A of the Indian Patents (Amendment) Act, 1999, this system enables the filing of patent applications for chemicals, food and drugs till 2005 for India

32 Supra note 26, India–Patent Protection for Pharmaceutical and Agricultural Chemical Products, WT/DS50, WT/DS79

33 Panel Report in WT/DS79, p 2

34 Ibid, para. 9.1


36 Ganesan A V, Implication of the Patents (Amendment) Ordinance, 1999 (ICRIER, New Delhi, 1999) (Copy on file with the author)

37 The related paper is available at http://www.iprlawindia.org. See also Julio Nogues, ‘Patents and pharmaceutical drugs: understanding the pressures on developing countries, Journal of World Trade, 24 (6) 1990, 86

38 http://www.indiaonestop.com

39 Correa Carlos M, Implementing national public health policies in the frame work of WTO agreements, Journal of World Trade,
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Watal Jayashree, Pharmaceutical patents, prices and welfare losses: A simulation study of policy options for India under the WTO TRIPS Agreement, World Economy, 23 (5) 2000, 733-752

41 Business Line, New Delhi, 23 December 2003

42 See http://www.news.helpline.com

43 Shah G D, Secretary General, Indian Pharmaceutical Alliance, www.hindubusinessline.com 29 December 2003


46 Reidman J H, Compliance with the TRIPS Agreement: Introduction to a scholarly debate, Vanderbilt Journal of Transnational Law, 29(3) 1996, 373

47 Oh Cecilia, TRIPS, Patents and Access to Medicines: Proposals for Clarification and Reform, Third World Network Briefing Paper, 2001, p 1

48 Correa Carlos M, TRIPS, Patents and Access to Essential Drugs, South Centre Bulletin No 2, Geneva, Southcentre.org

49 The International Conference on Primary Health Care, meeting in Alma-Ata on 25 September 1978. The conference organized under the auspices of WHO which mainly focussed on primary healthcare called for urgent and effective national and international action to develop and implement primary health care throughout the world and particularly in developing countries in a spirit of technical cooperation and in keeping with a new international economic order

50 Francis Coralie Mullin v The Administrator, Union Territory of Delhi (1981) 2 SCR 516

51 Some of these suggestions are already proposed by B K Keayala, Convener, National Working Group on Patents, New Delhi, www.expresspharmapulse.com