

**Trade Related Aspects of Intellectual Property Rights and Pharmaceuticals:
The Impact of Extended Protection of India**

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List of Abbreviations

Abbreviated New Drug Application	ANDA
Center for Science & Industrial Research	CSIR
Commission of Intellectual Property Rights	CIPR
Convention on Biological Diversity	CBD
Drug Master File	DMF
European Patent Office	EPO
Exclusive Marketing Rights	EMRs
Foreign Direct Investment	FDI
General Agreement on Tariffs and Trade	GATT
Gross Domestic Product	GDP
Indian Drugs Manufactures Association	IDMA
Intellectual Property	IP
Intellectual Property Rights	IPRs
International Monetary Fund	IMF
International Trade Organization	ITO
International Union of the Protection of New Varieties of Plants	UPOV
Less-Developed Countries	LDC
Multinational Company	MNC
Non-Government Organization	NGO
Patent Co-operation Treaty	PCT
Patent Facilitation Center	PFC
Patent Office	PO
Patent Information System	PIS
The Controller General of Patents, Designs & Trademarks	CGPDTM
The Copy Right Enforcement Advisory Council	CEAC
The National Informatics Center	NIC
The Treaty of Intellectual Property in Respect of Integrated Circuit	IPIC
Trade Marks Registry	TMR
Trade-Related Aspects of Intellectual Property Rights	TRIPs
United Nations Organization	UNO
United States Dollar	USD
United States Patent & Trademarks Office	USPTO
World Health Organization	WHO
World Intellectual Property Organization	WIPO
World Trade Organization	WTO

INTRODUCTION

Introduction

Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), which came into effect from 1st January 1995, is to date most comprehensive multilateral agreement of Intellectual Property Rights (IPRs). TRIPs requires all World Trade Organization (WTO) members to provide minimum standards of protection for a wide range of IPRs including copyright, patents, trademarks, industrial designs, geographical indications, semiconductor topographies and undisclosed information. The most sensitive part of TRIPs is regarding product patent issue in various fields of technology including pharmaceuticals. According to the agreement, developed countries were given one-year period to set standards as per TRIPs, while the countries (including India) that did not provide product patent in certain areas of technology as on 1st January 1995 can delay the grant of product patents in those areas till 1st January 2005. Recently some poorer economies were granted extension till 2016. Where a country, like India, does not make available patent protection for pharmaceutical and agricultural chemical products as on 1.1.1995, they have to provide a means for accepting applications for such inventions (mailbox), apply applicable priority rights and provide exclusive marketing rights (EMRs) for such products while they comply with TRIPs.

No country was more actively involved in opposing this component of the General Agreement of Tariffs & Trade (GATT) than India and no part of TRIPs was, and continues to be, more sensitive than the proposal to require product patents for pharmaceutical innovations. The national sentiment on this issue is well captured in an often quoted statement made by Indira Gandhi at the World Health Assembly in 1982: *"The idea of a better-ordered world is one in which medical discoveries will be free of patents and there will be no profiteering from life and death."*

At the time TRIPs went into effect, many low and middle income countries made an exception for pharmaceuticals, even if they recognized product patents in other areas, because low-cost access to life-saving drugs and essential medicines was deemed to be an overriding public policy priority. Even among the developed

countries, pharmaceutical product patent is a relatively recent phenomenon. For instance, pharmaceutical products were excluded from patent protection in Germany until 1968, Switzerland until 1977, Italy until 1978, Spain, Portugal and Norway until 1992, and Finland until 1995. Moreover, in countries with a longer history of pharmaceutical product patents, such as Canada, France and the U.K., compulsory licensing provisions are quite liberal.¹

The negotiations leading up to TRIPs, and in particular the provisions relating to pharmaceuticals were highly contentious. The main point of contention is the claim made by governments of many poor developing economies that unqualified patent protection for pharmaceuticals will result in substantially higher prices for medicines, with adverse consequences for the health and well being of their citizens. Countering this claim, research based global pharmaceutical companies, which have potentially lost billions of dollars because of patent infringement by Third World firms that have reverse-engineered their products, argue that the introduction of product patents is unlikely to significantly raise prices because most patented products have many therapeutic substitutes. Moreover, they claim that the absence of patent protection has served as a disincentive to engage in research on diseases that disproportionately afflict the world's poor, implying that patent protection for pharmaceuticals will actually benefit less-developed economies by stimulating innovation and transfer of technology.

Now when the treaty has been signed, with or against the will of most of the developing countries (most probably as a one of the pre-requisition for WTO membership), where a large part of the world is moving from no protection to full-fledged twenty year protection on intellectual property rights in the one area where, it is thought, patents really matter: pharmaceuticals, developing countries like India, have to go through vast change phase.

This thesis is an attempt to give an overview of what product patent might bring to India in pharmaceutical sector.

The first section is giving introduction to WTO's agreement on Intellectual Property Rights (TRIPs). The second section is giving an overview of current Intellectual Property (IP) legislation and major changes to meet TRIPs obligation in India. While the third section deals with impact of extended protection with regards to pharmaceutical sector in India.

SECTION - I

Overview of TRIPs Agreement

Background^{2,3,4}

After the World War – II, which ended in 1945, many countries in Europe and Asia were ravaged and their economy was shattered. After United Nations Organization (UNO) was born, three bodies, namely World Bank, International Monetary Fund (IMF) and International Trade Organization (ITO) were formed in 1947 to revive the economic disaster, particularly for the developing countries. On 1st January 1948, a treaty called General Agreement on Tariffs and Trade (GATT) was ratified by 23 contracting states including India. From 1948 to 1994, GATT provided the rules for much of world trade and presided over periods that saw some of the highest growth rates in international commerce. It seemed well established, but throughout those 47 years, it was a provisional agreement and organization.

In the early years, the GATT trade rounds concentrated on reducing tariffs. Then, the Kennedy Round in the mid-sixties brought about a GATT Anti-Dumping Agreement and a section on development. The Tokyo Round during the seventies was the first major attempt to tackle trade barriers that do not take the form of tariffs, and to improve the system. The eighth, the Uruguay Round of 1986-94, was the last and most extensive of all. In light of global trade and economic changes, GATT needs to be revised in certain areas and it was felt that it was not as relevant to the realities of world trade as it had been in the 1940s. Such factors led to the WTO and a new set of agreements.

On 1st January 1995, the WTO replaced GATT and upon signing the new WTO agreements (which include the updated GATT, known as GATT 1994), signing governments officially became “WTO members”. Today 147 countries (on 23rd April 2004) are member of WTO. The WTO’s creation marked the biggest reform of international trade since after the World War – II. It also brought to reality - in an updated form - the failed attempt in 1948 to create an International Trade Organization.

The WTO's agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) negotiated in the 1986 – 94, Uruguay Round, introduced intellectual property rules into the multilateral trading system for the first time. TRIPs Agreement adds a significant number of new or higher standards than those covered by the Paris Convention for the protection of industrial property (patents, industrial designs etc.) and the Berne Convention for the protection of literary and artistic work (copyright), which are two main international agreements of the World Intellectual Property Organization (WIPO).

What are the Intellectual Property Rights?

Intellectual Property Rights (IPRs) are not 'natural rights' but statutory privileges granted to reward inventions and provide an incentive. (Because natural rights do not lapse with time) Intellectual Property Rights (IPRs) are the rights given to persons over the creation of their minds. Ideas and knowledge are an increasingly important part of trade. Most of the value of new medicines and other high technology products lies in the amount of invention, innovation, research, design and testing involved. Intellectual Property Rights usually give the creator an exclusive right over the use of his or her creation for a certain period of time. The social purpose is to provide protection for the result of investment in the development of new technology, thus giving the incentive and means to finance research and development activities. Any IPR system has to balance this privilege with public interest, including consumer welfare, the right of other producers to use technology, the right to development, and environmental protection.

Intellectual Property Rights are customarily divided into two main areas:

1. Copyrights and Rights Related to Copyright

In order to encourage and reward creative work, the rights of authors and literary and artistic works, performers, producers of phonograms and broadcasting organization are protected.

2. Industrial Property

These are the protection of distinctive signs in particular trademarks and geographical indications. Other types of industrial property are protected primarily to stimulate innovation, design and the creation of technology. In this category fall inventions protected by patents, industrial designs and trade secrets.

The extent of protection and enforcement of these rights varied widely around the world, and as intellectual property became more important in trade, these differences became a source of tension in international economic relations. The WTO's TRIPs Agreement is an attempt to narrow the gaps in the way these rights are protected around the world and to bring them under common international rules. It establishes minimum level of protection that each government has to give the intellectual property of fellow WTO members. In doing so, it strikes a balance between the long-term benefit and possible short-term cost to society. Society benefits in the long term when intellectual property protection expires and the creations and inventions enter the public domain. Governments are allowed to reduce any short-term costs through various exceptions for example to take care of public health problems.

Provisions for various Intellectual Properties laid down by TRIPs are:^{2,3,4}

- *Copyrights and Related Rights*

Copyright protects the form, in which ideas are expressed, not the ideas themselves. Copyright was and remains the basis for making the publishing of literary and artistic works an economic proposition by preventing copying. Unlike patents, copyright protection does not require registration or other formalities.

Besides complying with provisions of the Berne Convention (1971), the TRIPs Agreement clarifies and adds certain specific points. Article 9.2 confirms that copyright protection shall extend to expression and not to ideas, procedures, and methods of operation or mathematical concept as such.

Article 10.1 provides that computer programs, whether in source or object code, shall be protected as literary works under the Berne Convention. The general term of protection of 50 years applies to computer programs.

Article 10.2 provides that databases and other compilations of data or other material shall be protected as such under copyright even where the databases include data that as such are not protected under copyright.

Article 12 clarifies that whenever the term of protection of work, other than a photographic work or a work of applied art, is calculated on a basis other than the life of a natural person, such term shall be no less than 50 years from the end of the calendar year of authorized publication, or, failing such authorized publication 50 years from the making of the work.

The provision on protection of performers, producers of phonograms and broadcasting organization are included in article 14.

Article 14.1 says that performer shall have the possibility to preventing unauthorized fixation of their performance on phonograms. Article 14.2 and 15.4 deals with granting of exclusive reproduction and exclusive rental rights to producers of phonograms.

Article 14.5 provides that the term of protection is at least 50 years for performers and producers of phonograms and 20 years for broadcasting organization.

- *Trademarks*

The basic rule contained in Article 15 of TRIPs is that any sign, or any combination of signs, capable of distinguishing the goods and services of one undertaking from those of other undertakings, must be eligible for registration as a trademark, provided that it is visually perceptible. Such signs, in particular words including personal names, letters, numerals, figurative elements and combinations of colors as well as any combination of such signs, must be eligible for registration as trademarks.

The TRIPs Agreement contains certain provisions on well-known marks, which supplement the protection require by Paris Convention. Article 15.1, 16.2 and 62.3 say that service marks are to be protected in the same way as marks distinguishing goods.

Article 19 says that use of a trademark by another person, when subject to the control of its owner must be recognized as use of the trademark for the purpose of maintaining the registration.

- *Geographical Indications*

A place name is sometimes used to identify a product. This ‘geographical indication’ does not only say where the product was made. More importantly, it identifies the product’s special characteristics, which are the result of the product’s origins.

Well-known examples include “Champagne”, “Scotch”, “Tequila”, and “Roquefort” cheese. Wine and spirits makers are particularly concerned about the use of place-names to identify products, and the TRIPs Agreement contains special provisions for these products. But the issue is also important for other types of goods.

Using the place name when the product was made elsewhere or when it does not have the usual characteristics can mislead consumers, and it can lead to unfair competition. The TRIPs Agreement says countries have to prevent this misuse of place names.

Apart from complying with minimum provision set by the Paris Convention, article 24 of the TRIPs contains a number of exceptions to the protection of geographical indications, particularly for wines and spirits. For example, members are not obliged to bring a geographical indication under protection where it has become a generic term for describing the product in question.

- *Industrial Designs*

Article 25.1 of the TRIPs Agreement obliges members to provide for the protection of independently created industrial designs that are new or original. While article 26.3 states that the duration of protection available shall amount to at least 10 years, where the wording ‘amount to’ allows the term to be divided into, for example, two periods of five years.

- *Patents*

Article 27.1 requires member countries to make patent available for any inventions, whether product or process, in all fields of technology without discrimination, subject to the normal tests of novelty, inventiveness and industrial applicability. If a patent is issued for a production process, then the rights must extend to the product directly obtained from the process. Patents be available and patent rights enjoyable without discrimination as to the place of invention and whether the product is imported or locally produced and patent protection must be available for at least 20 years.

Article 27.3 and article 33 say that patent protection must be available for both products and processes in all most all field of technology. However government can refuse to issue a patent for an invention if its commercial exploitation is prohibited for reasons of public order of morality. They can also exclude diagnostic, therapeutic and surgical methods, plants and animals (other than microorganisms) and biological processes for the protection of plants or animals (other than microbiological processes)

Plants varieties however must be protected by patents or by a special system such as the breeder's rights provided in the convention of UPOV - The International Union of the Protection of New Varieties of Plants.

Article 31 describes that a patent owner must enjoy minimum rights but certain exceptions are allowed where patent owner could abuse his rights, for example by failing to supply the product to the market. To deal with those possibilities, the agreement says government can issue 'Compulsory Licenses' allowing a competitor to produce the product or use the process under license. But this can only be done under exceptional conditions aimed at safeguarding the legitimate interests of the patent holder.

- *Layout – Designs of Integrated Circuits*

Article 35 of the TRIPs Agreement requires member countries to protect the layout-design of integrated circuit in accordance with the provisions of the IPICT Treaty (The Treaty on Intellectual Property in Respect of Integrated Circuit), 1989.

Article 36 and 37.1 deal with the applicability of the protection to articles containing infringing integrated circuit and the treatment of innocent infringers while article 38, extends term of protection from eight to ten years.

- *Protection of Undisclosed Information*

Undisclosed information - trade secrets or know-how are to be benefited by protection as per TRIPs Agreement.

Article 39.2 describes that the protection must apply to information that is secret and got commercial value because it is undisclosed, and that has been subject of reasonable steps to keep it secret. Undisclosed information are not necessarily treated as a form of property but the agreement requires that a person lawfully in control of such information must have the possibility of preventing it from being disclosed to, acquired by, or used by others without his or her consent in a manner contrary to honest commercial practice.

The Agreement contains provisions on undisclosed test data within application of marketing authorization of pharmaceuticals with new chemical entities. In such situation, the member government in concern must protect the data against disclosure, except when it is required to do for protection of public health.

- *Control of Anti-Competitive Practices in Contractual Licenses*

Article 40 of the TRIPs Agreement recognizes that some licensing practices or conditions pertaining to intellectual property rights, which restrain competition, may have adverse effects on trade and may impede the transfer and dissemination of technology. Member countries may adopt, consistently with the other provisions of the Agreement, appropriate measures to prevent or control practices in the licensing of intellectual property rights, which are abusive and anti-competitive.

SECTION - II

Overview of Current Intellectual Property Legislation and Major Changes to Meet TRIPs Obligation in India

Background⁵

India is a Federal republic

Legal system: English Common Law based

Population: 1,065,070,607 (estimate on July, 2004) Second largest in the world.

GDP per capita 2,900 USD (2003 est.)

GDP composition by sector:

- Agriculture: 23.6%
- Industry: 28.4% (textiles, chemicals, food processing steel, transportation equipment, cement, mining, petroleum, machinery, software)
- Services: 48% (2002 est.)

History of Indian Patent System⁶

- 1856 The act VI of 1856 on protection of inventions based on the British patent law of 1852. Certain exclusive privileges granted to inventors of new manufacturers for a period of 14 years.
- 1859 The act modified as act XV; patent monopolies called exclusive privileges (making, selling and using inventions in India and authorizing others to do so for 14 years from date of filing specification).
- 1872 The Patents & Designs Protection Act.
- 1883 The Protection Of Inventions Act.
- 1888 Consolidated as The Inventions & Designs Act.
- 1911 The Indian Patents & Designs Act.
- 1972 The Patents Act (Act 39 of 1970) came into force on 20th April 1972.
- 1999 On march 26, 1999 patents (amendment) act, (1999) came into force from 1st January 1995 (First Amendment)
- 2002 The patents (amendment) act 2002 came into force from 20th May 2003

Legal Framework

The Indian IP system is over 150 years old and based on British law (1856). The Indian Patents & Designs Act came into force in 1911. India is a member of the following international conventions and treaties regarding industrial property:

- WIPO Convention
- Paris Union
- Berne Union
- Universal Copyright Convention
- Convention for the Protection of Producers of Phonograms
- Patent Cooperation Treaty

Table – 1 summarizes the number of patents granted in selected countries, to residents per million people in 1998⁷. In India there was 1 patent granted per million people in 1998.

Recent Events⁸

- April 15, 1994 - The Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations were authenticated by 117 nations, including India.
- January 1, 1995 - The Final Act came into force. India is one of the countries with a ten-year transition period to implement the treaty requirements. This grace period ends on 31st December 2004.
- January 1 to March 31, 1995 - Patent Ordinance put in place by the government, temporarily implementing the treaty without requiring legislative approval.

- January 1, 1995 - During the transition period, India must accept product patent applications for Pharmaceuticals, so-called 'black box' applications, and grant Exclusive Marketing Rights - EMRs. (See Annex - I for details) These give the patent applicant the exclusive rights to sell and distribute the product for a maximum of 5 years. EMRs can only be obtained after the pharmaceutical product has been granted a patent and has obtained marketing approval in another signatory country and after marketing approval is obtained in India.
- March 1995 - Passage of the Patents (Amendment) Bill in the Lok Sabha (upper house) of parliament by small majority. Could not be introduced in the Rajya Sabha (lower house) due to opposition.
- January 1997 – The United States requests that a WTO dispute panel be constituted to investigate India's failure to pass implementing legislation to enable the acceptance of black-box product patent applications during the transition period. (Although they are, in fact, being accepted at the patent offices in anticipation.)
- India acceded to the Paris Convention with effect from December 7, 1998.
- India also acceded to the Patent Cooperation Treaty effective from December 7, 1998, and began operating as a PCT Receiving Office, Designated Office and Elected Office for the purposes of international applications filed under the PCT. India announced its recognition of Chinese and US Patent Offices as authorized international search and examining authorities, in addition to the Australian, Austrian and European Patent Offices.
- The Copyright (Amendment) Act, 1999 has amended the Copyright Act, 1957, to bring it into compliance with TRIPs Article 14, to extend protection to performers from 25 years to 50 years.

- The Trade Marks Act, 1999, which repeals and replaces the Trade and Merchandise Marks Act, 1958 was adopted.
- The Industrial Designs Act, 2000, replaced the Designs Act, 1911
- Geographical Indications of Goods (Registration & Protection) Act, 1999 and Geographical Indications of Goods (Registration & Protection) Rules 2002, have come into force with effect from 15th September 2003.
- The Monopolies and Restrictive Trade Practices Act, 1969, termed “obsolete” by the government when the Competition Bill, 2001 and thereafter act, was passed. The salient features of this act cover prohibition of anti- competitive agreements, prohibition of abuse of dominance, regulation of combinations (acquisitions, mergers and amalgamations of certain size); establishment of the Competition Commission of India and definition of its functions and powers.
- The Patents (Amendment) Act, 2002 and The Patents Rules, 2003 have come into force with effect from 20 May 2003.
- By December 31, 2004, India must examine and grant pharmaceutical products patents.

Intellectual Property Policy & Administration^{6,9}

The IP policy lead rests with the Minister of Commerce and Industry. The Ministry maintains an extensive and comprehensive inter-ministerial and private sector consultative network. IP policy is linked to economic development through trade and is viewed as an important component of science and technology policy. Thus, other key agencies that are closely involved in the development of IP policy include the Ministry of Science and Technology, the Ministry of Human Resource Development and the Ministry of Agriculture.

The Office of the Controller General of Patents, Designs and Trade Marks is a subordinate Office under the Department of Industrial Policy and Promotion in the Ministry of Commerce and Industry. This Office has statutory responsibility for administration of patents, trademarks and industrial designs and serves as a main source of policy advice to the Government of India on industrial property matters.

The Copyright Office, in the Ministry of Human Resources Development, provides policy advice to Government with respect to copyright and neighboring rights. The Copyright Enforcement Advisory Council (CEAC) is an advisory body established by the Central Government and includes representatives of state police authorities as members.

The Controller General of Patents, Designs and Trademarks (CGPDTM) is the administrative and statutory head of the Patent Office (PO) and the Trade Marks Registry (TMR).

The Patent Office is headquartered in Kolkata and has Branch Offices in Mumbai, Chennai, and New Delhi. The Indian Trademark Registry is headquartered in Mumbai and maintains Branch Offices in Kolkata, Chennai, New Delhi and Ahmedabad.

Government of India, Ministry of Industry, Department of Industrial Development establishment Patent Information System (PIS), in the year 1980 with the objectives of obtaining and maintaining a comprehensive collection of patent specification and patent related literature on a world wide basis to meet the needs for technological information, of various users in R&D establishments, Government Organizations, Private Industries, Business, Investors and other users, also to provide technological information contained in patents or patent related literature through publication services, search services and patent copy supply service; and to meet statutory obligation regarding novelty search under the Indian patent system.

The Government of India supports public education and outreach programs, holding 60 seminars on intellectual property in universities across the country during 2000.

The National Informatics Center (NIC), an agency of the Ministry of Information Technology, maintains significant patent information holdings, including international patent search facilities on its World Wide Web site (Intellectual Property & Know-how Informatics Division).

A Patent Facilitation Center (PFC) of the Technology Information Forecasting and Assessment Council, an agency in the Ministry of Science and Technology, is aimed at providing patenting facilities to scientists and technologists in the country, keeping a close technology watch by taking up patents analysis in specific areas and creating awareness & understanding of patents among the scientific community by arranging workshops and seminars.

The Indian intellectual property legal community is well established. The Controller General, Patents, Designs and Trade Marks maintains a register of practitioners (agents and attorneys) that are qualified and permitted to represent applicants before him/her. The register currently lists 617 individuals who are qualified agents. Many of the firms are of long standing, with the oldest active firm on the register having been established in 1856, at the same time as the patent system was initially established in India.

What is New?

Patents

The new Patents Act uses some of the exceptions and qualifications included in TRIPs to foster public health goals. The controversial nature of these amendments explains in fact why the Government was initially reluctant to accept TRIPs in the WTO context and why Parliament initially refused to adopt the first Patent Amendment Bill in 1995.

While the TRIPs Agreement lays down a number of precise standards and rules, it also includes a number of exceptions and qualifications. Over the years, the exceptions and qualifications have been largely ignored in most developing countries. Following increasing controversies concerning the impact of TRIPs in the health sector, the last WTO ministerial conference addressed the issue of health and adopted a Declaration on the TRIPs Agreement and Public Health (Doha Declaration). The Doha Declaration does not modify TRIPs but restates that member States are allowed to fully use the exceptions provided in the treaty to foster public health goals. In other words the Declaration gives countries like India further authority to fully use the exceptions and qualifications provided in TRIPs.

The new Patents Act is characterized by two main trends. On one hand, it generally follows quite closely the requirements of the TRIPs Agreement. The amendments thus generally alter the balance between the interests of patent holders and the interests of society at large in favor of the former. The duration of patents in the health sector is, for instance, dramatically increased from seven to 20 years. The amendments also strike out an important provision of the Act seeking to oblige patent holders to manufacture their inventions in India.

On the other hand, it uses, for instance, the health-related exceptions, which determines which inventions are not patentable. Some of the most interesting and most controversial new provisions are regarding compulsory licensing. While TRIPs generally imposes a stricter compulsory licensing regime than what was provided

under the Patents Act, 1970, the amendments strive to make use of some of the possibilities opened by the Doha Declaration. Provisions on compulsory licensing mentions that patents granted should not 'impede protection of public health' and should not prohibit the Central Government from taking measures to protect public health. Further, it recalls that patents should be granted to make the benefits of the patented invention available at reasonably affordable prices to the public. The Doha Declaration generally recognizes member States' right to take measures to protect public health. This is not limited to compulsory licenses but applies generally to patenting in the health sector.

On the whole, the amended Patents Act is noteworthy for dismantling most of the specificities of the 1970 Act. The 1970 Act constituted a carefully crafted response to specific socio-economic challenges that has served India well over the past three decades. Further, while India's intellectual property obligations have changed with the TRIPs Agreement, its obligations in the field of health have not changed in recent decades. What these amendments will bring can only be answered after they are in practice. See Annex – II for comparison of Indian Patent Act of 1970 and GATT¹⁰.

Salient Features of the Patents (Amendment) Act, 2002 and the Patent Rules, 2003⁶

(Taken directly from the source reference)

- Term of every patent which is in force including a patent restorable, U/S. 60 as on 20.5.2003 has now become 20 years from date of filing.
- Time for restoration of a ceased patent, U/S 60 has now increased from 12 months to 18 months as such an application for restoration of a patent ceased on or after 20th May, 2003 can be filed within 18 months from the date of ceasession.
- A new definition of "Invention" means a new product or process involving inventive step and capable of industrial application; has now come in force.
- A method or process of testing during the process of manufacture will now be patentable.
- Process defined, U/S 3(i) in case of plants, are now patentable while a process for diagnostic and therapeutic has now been considered as non patentable,
- A list of Authorized Depository Institutions have been notified (annexed hereto) in the Gazette Of India, Part II, Section 3 sub-section (ii) dated 20.5.2003 for depositing the biological materials mentioned in the specification at the time of filing a patent application.
- The source of Geographical origin of the biological material used in invention is required to be disclosed in the specification.
- 18 months publication has been introduced, therefore, every patent (except in which a secrecy direction is given U/S 35) will now be published just after 18 months from the date of filing/priority and will be open for public on

payment. As such the filing intimation being published in the Gazette immediately after filing has been stopped.

- A request for examination system has been introduced and therefore all the patent applications in which First Examination Report has not been issued on or before 19th May 2003 will now be examined U/S 12 only after filing a request for examination on Form –19 with prescribed fee.
- The applications for patent will now be examined in serial order in which the request for examination is filed.
- In case the application has been filed before the commencement of this Act, the request shall be made within a period of twelve months from the date of commencement of the Act i.e. 20th May 2003 or 48 months from the date of application, whichever is later.
- Provision for filing request for examination by any other interested person (other than applicant) also has been introduced.
- Provision for the withdrawal of application by applicant any time before grant has been introduced.
- Time for putting the application in order for acceptance U/S 21 has now been reduced from 15/18 months to 12 months.
- Ground of opposition U/S 25 as well as revocation U/S 64 have been enlarged by adding following grounds:
 - i. Non disclosure or wrongly mentioning the source of geographical origin of biological material used for invention;
 - ii. Anticipation having regard to the knowledge oral or otherwise available with in local or indigenous community in India or elsewhere.

- Section 39 in modified form prohibiting filing patent application outside India, inventions limited to the fields of defense purposes or atomic energy has been reintroduced.
- Opposition Proceedings U/S 25 have been simplified and shortened, fixing hearing is not compulsory, if the applicant does not file reply statement and evidence, application will be deemed to have been abandoned.
- Provision for extension of time up to 6 months for paying the overdue renewal fees initially i.e. renewal fees, which have become due, due to the late grant of patent can now be paid within 9 months from the date of recordal by taking an extension on Form – 4.
- Charges for supplying the photocopies of the documents available in the Patent Office have now been reduced from Rs. 10/- to Rs. 4/- per page.
- Charges for amendments in name, address, nationality, and address for service, payable on Form – 13 have been drastically reduced from Rs. 1000/6000 to Rs. 200/500.
- Patent Applications and other documents (except PCT International application) are now required to be filed only in duplicate. Documents can now be filed 1 copy in electronic form with one hard copy (paper form).
- Fees required to be paid on documents can now be paid within 1 month from its date of filing.
- Provision for allowing Paris Convention Priority has been extended to group or union of countries or inter governmental organizations, therefore, 12 month priority will also be available to applications filed in EPO, AIRPO, OAPI and EAPO.

Also see attached, The Patents (Amendment) Act, 2002, The Gazette of India, published by Ministry of Law, Justice and Company Affairs for further reference.

Copyright

India has one of the most modern copyright protection laws in the world. Major development in the area of copyright during 1999 was the amendment to the Copyright Act of 1957 to make it fully compatible with the provisions of the TRIPs Agreement. Called the Copyright (Amendment) Act, 1999, this amendment was signed by the President of India on December 30, 1999 and came into force on January 15, 2000.

The earlier 1994 amendment to the Copyright Act of 1957 had provided protection to all original literary, dramatic, musical and artistic works, cinematography, films and sound recordings. It also brought sectors such as satellite broadcasting, computer software and digital technology under Indian copyright protection.

The Copyright Act is now in full conformity with the TRIPs obligations.

Trademarks

The Trade and Merchandise Marks Act, 1958 was in its essential features in accordance with TRIPs, except that it did not cover service marks in its scope. This has been done by replacing it with the Trademarks (Amendments) Act 1999.

Geographical Indications

They have been of particular interest to India, especially after a patent was obtained for basmati rice in the United States by Ricetec Inc. Under the TRIPs agreement, each member country must provide legislation to prevent the use of any means in the designation or presentation of a good that indicates or suggests that the good in question originates in a geographical area other than the true place of origin of the good. India has a great interest in this area since there have been reports that Nigerian and Sri Lankan Tea growers have been passing off their tea as Darjeeling Premium Tea (which commands the highest price in the market). Until recently,

protection from such misuse was granted through passing off action in courts or through certification marks. However, in order to provide better protection to geographical indications, the Geographical Indication of Goods (Registration & Protection) Act, 1999 has been enacted in India.

Industrial Design

The essential purpose of design law is to promote and protect the design element of industrial production. It is also intended to promote innovative activity in the field of industries. The existing legislation on industrial designs in India is contained in the New Designs Act, 2000, this replacement Act is aimed to in act a more detailed classification of design to conform to the international system and to take care of the proliferation of design related activities in various fields

Layout Design of Integrated Circuits

India is a signatory to the international agreement administered by WIPO on this subject known as the Washington Treaty. The main obligations of the Washington Treaty are also incorporated in the TRIPs Agreement with some enhancement and cover the protection of the intellectual property in respect of lay-out designs that are original in the sense of being the result of their creator's own intellectual efforts. The obligations include national treatment to foreign right holders and a term of protection for 10 years. The Semiconductor Integrated Circuits Layout-Design act, 2000 is in force in India in these regards.

Protection of Undisclosed Information

The Agreement provides in this area that natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by or used by others without their consent in a manner contrary to honest commercial practices. Further, parties are required to protect

against unfair commercial uses, undisclosed or other data obtained as a condition of approving the marketing of pharmaceutical or of agricultural chemical products.

India is entitled to wait till 2005 for granting product patents for drugs but data exclusivity, which protects the confidentiality of clinical data submitted to regulatory authorities for the drug approval process, is a current obligation under Article 39.3 of the TRIPs agreement.

Data exclusivity did not require legislative amendment in India. There is no separate legislation dealing with trade secrets in India, however common law on the subject is to be observed. But the problem in the case of India, is that the rules and regulations under the 1964 Act governing foods and drugs had been diluted over the years in such a manner that the power of the government to reveal to third parties clinical data submitted by drug companies to regulatory authorities was substantially expanded. This undermined the confidence of innovators in the drug industry for whom confidentiality of the data was crucial for recouping their investments in R & D when the drug came into the market.

In addition to the above legislative changes, the Government of India has taken several measures to streamline and strengthen the intellectual property administration system in the country. Projects relating to the modernization of patent information services and trademarks registry have been implemented with help from WIPO/UNDP.

Indian Pharmaceutical Industry – Today

The Indian Patents Act 1970 was a landmark legislation, which in many ways far exceeded the restrictions put on the patent system by other like-minded countries such as Brazil, Argentina, Chile and China to enable local production and marketing of patented drugs at prices much lower than their counterparts in the patent- strong developed countries. The two stated objectives of the 1970 act were: the development of an indigenous pharmaceutical industry and the provision of low-cost access to medicines for Indian consumers. Consistent with these objectives, and with the broader leftward tilt in policy, a number of other measures were introduced – drug price control, restrictions on capacity expansion, limits on multinational equity shares, etc. – that in the years since have, on one hand, kept pharmaceutical prices low, and on the other, encouraged the development of the Indian pharmaceutical industry. The achievements of the Indian pharmaceutical industry during 1970-95, that is, until the World Trade Organization was set up, is part of history, and they have been rightly and well accepted as one of the success stories of post-independent India.

Today the Indian pharmaceutical industry is a success story providing employment for millions and ensuring that essential drugs at affordable prices are available to the vast population of this sub-continent. See Annex – III for Fact Sheet of Indian Pharmaceutical Industry, 2003, given by Organization of Pharmaceuticals Producers of India (OPPI) 2004¹¹. It is in the front rank of India's science-based industries with wide ranging capabilities in the complex field of drug manufacture and technology. Even while undergoing restructuring, it has established its presence and determination to flourish in the changing environment. The industry now produces bulk drugs belonging to all major therapeutic groups.

Playing a key role in promoting and sustaining development in the vital field of medicines, Indian Pharma Industry boasts of quality producers and many units approved by regulatory authorities in USA and UK. International companies associated with this sector have stimulated, assisted and spearheaded this dynamic

development in the past 57 years and helped to put India on the pharmaceutical map of the world.

According to OPPI, the pharmaceutical industry has a capital investment of 21.50 billion Rupees during 1998-99. In 1965-66, the industry had capital investment of 1.40 billion Rupees. In 1971, out of top 10 only 2 were Indian firms, while in 2003, 8 were Indian firms out of top 10. See table – 2 for list of top 10 firms in 1971 & 2003¹².

See table – 3 for facts and figure about Indian pharma industry with respect to export and import of bulk drugs and finished formulation from 1980. The growth rate has been around 15% for bulk drugs and 20% for formulations during nineties¹³.

The Indian Pharmaceutical sector is highly fragmented with about 250 large units and about 18,000 small-scale units in operation including 5 Central Public Sector Units. It has expanded drastically in the last two decades. Today, India is in a position to meet 70% of the country's requirement of bulk drugs and all the demands for formulations. The leading 250 pharmaceutical companies control 70% of the market with market leader holding nearly 7% of the market share.

In 2005 Indian companies are expected to file 60 Abbreviated New Drug Applications (ANDAs), while Ranbaxy and Dr. Reddy's Labs already have been filling 18-20 ANDAs a year, with 37% share of Drug Master Files (DMFs) filled with US FDA.

The total R & D expenditure in India is relatively low; roughly today it is 2.0% of total sale. See Table – 4 & 5¹¹ for R & D expenditure in India as well as R & D expenditure as % of sale of selected Indian pharma firms. To be globally viable in R & D, high-level expertise and adequate human resources as also modern facilities in specified areas of drug development are required. There is a virtual lack of high quality R & D being undertaken at the moment in India. Universities in India seems

to be caught in a bureaucratic trap, neither receiving funding, not motivated to finish ongoing projects quickly. Council for Scientific & Industrial Research (CSIR) is an autonomous R & D organization providing scientific industrial research for India's economic growth and human welfare. Apart from CSIR, Central Drug Research Institute (CDRI) is involved in R & D. Indian pharmaceutical companies also, in light of globalization, is now becoming more R & D orienting through various international collaborations^{13,14}.

Indian Pharmaceutical industry today is moving up the value chain. From being a pure reverse engineering industry focused on the domestic market, the industry is moving towards basic research driven, export oriented industry with a global presence, providing wide range of value added quality products and services.

SECTION - III

Impact of Extended Protection on India (Regards to Pharmaceutical Sector)

Pharmaceutical sector, among all knowledge-based industry in India, is more concern about impact of extended protection laid down by TRIPs. These concerns are mainly about post-patent regime price and availability of pharmaceuticals, situation of R & D, foreign direct investments, Indian generic market, export market and so on.

On one hand there are evidences that after adopting product patent regime, Jordanian exports of pharmaceuticals increased from 150 million USD in 1999 to 200 million USD in 2001, a significant increase for a country with a population of 5 million. In Jordan, patent-protected medicines have not exceeded pre-patent prices, and prices have actually fallen for medicines on the market before patent protection. The generic industry has also benefited from introduction of patents, as the increase in foreign investment has generated work for Jordanian companies¹⁵. Many countries of the developing world that do not have strong IPR regimes remain mired in economic stagnation and worse yet, have suffered the negative effects of the "brain drain." Talented scientists, engineers, artist and inventors leave their home countries where their work is unprotected and migrate to those countries where it is.

On other hand, one report of the Commission on Intellectual Property Rights (CIPR), set up by the UK Government but independent of it, having members from the US, UK, Argentina and India says that developed countries often proceed on the assumption that what is good for them is likely to be good for developing countries. But rich and poor countries have differing interests, and expanding IPRs makes poverty reduction more difficult. Extended IPRs are unlikely to help most developing countries; instead, it will increase their costs, by making them pay more for medicines and seeds¹⁶.

Impact Determining Factors

There have been much written about the impact of patents and other IPRs with context to pharmaceutical sector in various developed countries. However, developed and developing economies cannot be expected to have the same factors that determine price and other relevant impacts. Developing economy is relatively more price sensitive than developed one. Taking pharmaceutical sector, demand of drugs in developing or less-developed economies differs from that in developed economies in some critical respects.

The first is that households are much poorer in less-developed countries like India, and thus per capita health expenditure are several orders of magnitude lower than in developed countries. Per Capita health expenditure was only 23 USD in 2001 in India while in most of the developed nations such expenditure was more than 1000 USD¹⁷. Table – 6 shows per capita health expenditure during 1997-2001 in selected countries. Although poor countries tend to allocate a smaller share of their GDP to health, income disparities drive these differences. WHO estimates that 17 countries spent no more than 10 USD per capita in 1998 on all health expenditures, not just pharmaceuticals. Over a third of all countries spent less than 50 USD. By contrast, twelve countries are estimated to spend over 2,000 USD per capita on health. Considering case of Luxembourg and Malawi, where former spent 6.0% of its GDP on health for a per capita expenditure of 2,574 USD while Malawi spent 7.2% to manage per capita expenditure of 12 USD¹⁸.

The second crucial difference is that health insurance coverage is much rare in less-developed countries. As a result, the bulk of a household's medical expenditures are met out-of-pocket. WHO report 2000 says that Indian population has to pay 84.6% of total health expenditure out-of-pocket¹⁹. Table – 7 shows health account indicators.

Third, the burden of disease in low-income countries stems from somewhat different causes than in developed countries. In particular, there are certain diseases that are almost

exclusively suffered by Third World Population. See Table – 8 for details of top ten leading causes of burden of disease in 1998 in India, US and Canada and table – 9 for list of disease for which 99% or more of the global burden falls on low-and middle-income countries^{20,21}. The fourth difference is conditions under which drugs are stored, transported or administered are considerable different in less-developed countries.

Apart from these developing country specific factors, under such situation, other factors like, market structure before and after the new patent regime matters crucially. Also the number of firms (home and foreign) competing with rights holder, the nature of that competition, the ease of market entry and exit, quality differentiation among products, openness to trade, and wholesale and retail distribution mechanisms, pricing regulations with respect to pharmaceuticals, competition policies etc. will decide largely the impact of TRIPs in India.

Impact on Price

The absence of product patents and the relative ease of entry into imitative production means that there are significant numbers of small and medium- sized firms producing generics, 'me-too' drugs. To take an example, seven years after its introduction in India, there were 48 firms offering the important on-patent drug Ciprofloxacin for sale in the 1996. The UK multinational Glaxo was faced with several local competitors from the first day that its subsidiary marketed its proprietary drug Ranitidine (Zentac) in India. See table – 10 for year of introduction by patent owner for a newly invented drug, year of introduction in India and lag period between these²². With no product patent protection, it is obvious that with scientific skill, Indian firms were able to produce patented medicines at affordable rates to Indian market. Lanjouw has given detail study report on Indian pharmaceutical market, in which she has compared Indian prices of the four drugs with the largest sale in India among those, which were on-patent in Europe in 1995. This suggests that prices in India for drugs, which are on-patent elsewhere, are substantially lower than in the countries granting protection²². See Table – 11 for this comparison.

Pharmaceutical price also depends on what the patentees would like to do and what they would be allowed to do. Since health insurance coverage is very low in India, Indian market is likely to be more price sensitive and people may tend to switch to less effective but cheaper alternative. Currently many diseases and conditions have multiple alternative drug therapies, which are off-patent and competitively priced. In fact, most of the drugs on the World Health Organization Model List of Essential Drugs are off-patent. So the option to switch to a lower-price drug is open in most of the cases. Also, it is possible to dispense lower priced alternative than the one, which is prescribed in India, due to relaxed control over retail pharmacy practice.

However, there are certain other facts that cannot be overlooked. First is that patentees would like to maximize global profit. Drug prices in developed country markets are being regulated using global reference pricing. For countries which fix

ceiling prices, the price for a newly introduced drug may be linked to its price elsewhere. So foreign patent holder will definitely tend to set higher price for not loosing global profit. Under this situation, if Government imposes very strict price control than a patent owner may refuse to supply drug.

But it is unlikely that either a foreign or a domestic firm would do this. Because in case of a foreign firm, Government would have a good reason for waiving the restrictions on compulsory licensing as allowed by the GATT treaty in case of 'national emergency or other circumstances of extreme urgency'. India has well developed industry that would allow domestic firm to obtain compulsory license and have supply of on-patent drug. Domestic firm would not go for refusal of supply due to political pressure.

However, despite this fact, there is a 'transfer-price-loophole' as described by Lanjouw²². The Indian price control regime is set up such that ceiling prices are determined as a mark-up on input costs. Any MNC may export the patented active ingredient to its Indian subsidiary at an artificially high transfer price and thereby attain a higher controlled price for its formulations. More over, uniform global transfer price issue is still left unclear by GATT, so this possibility cannot be denied. However, there is nothing in the GATT treaty written as well, that can prevent India from exercising more hold on price control if needed.

On the other hand, there are other pressures that could indeed cause prices to rise. One, ironically, is the government's new drug pricing policy of 1994 – and not patent protection. In a bid to attract foreign investment, the government has ended laws that used to discriminate against multinationals, including some price controls. Now, most drugs are exempt from industrial licensing and the number of price-controlled drugs has been reduced from 142 to 73. The underlying rationale behind the 1994 policy is in line with the free market ethos of the country's reform process. It is argued that the decontrolling will in itself lead to a hike in drug prices, irrespective of whether a new intellectual property regime is introduced. Recent market trends seem to confirm this. The price of Alludrox an antacid and Lanoxin a

cardio-vascular drug rose by 114% and 105% after the new drug policy was implemented²³.

It is also crucial to consider that how important patented drugs are in total pharmaceutical sale. S.Chaudhari and P.Goldberg, have given excellent estimation of total welfare loss to India customer after product patent will be in practice, in Quinolone sub-segment of the systemic anti-bacterial segment²⁴. Their estimation say that patent enforcement would result in a total annual welfare loss of 713 million USD for the Indian economy. Four important drugs viz. Ciprofloxacin, Norfloxacin, Ofloxacin and Sparfloxacin, which were still on-patent in US while they were manufactured in India by domestic firms. See Table – 12 for basic information about these drugs. The authors have calculated case-by-case welfare loss, when due to product patent; domestic brands have to be replaced of these drugs.

S.Chaudhari concluded that there are not enough evidences for the claim that TRIPs would have detrimental effects on the Indian pharmaceutical industry. In fact, under some scenarios the profits of domestic firms may even increase, this happens because, when certain domestic products become unavailable as a result of patent enforcement, consumers substitute towards other domestic products containing different molecules, rather than foreign products containing the same molecules. The claim of TRIPs proponents that an adverse effect from the introduction of a patent in a particular market would be mitigated by the availability of close therapeutic substitutes is only valid if there are patent-expired substitutes available within fairly narrowly defined therapeutic categories.

More over, the rate of pharmaceutical innovation is stable over time, in equilibrium the introduction of new-patented drugs will be matched by those going off- patent. So percentage of market under patent protection is unlikely to rise. Drug research in recent years has been relatively unfruitful. Most of the new entities have been ‘me-too’ type rather being truly innovative. Definitely the trend cannot be extrapolated and nothing can be foreseen. Recently, biotechnology and microorganisms as

patentable subject matter, present a whole new opportunity for finding important and patentable new drug therapies.

Currently it seems that at least initially foreign inventors will be benefited²². During the period 1975-1995 only 65 of approximately 100,000 patents granted in the U.S. for drug and health innovations were to Indian inventors. 8 Initial 'black-box' applications to the Indian Patent Office (those submitted after January 1, 1995) suggest too that foreign inventors will be the main beneficiaries of the new product patents regime. Of the drug-related patents granted in 1995 and 1996, and therefore process patents, 39% and 48%, respectively, were to domestic firms or inventors (based on the applicant's address) In a sample (about half) of the patent applications made in the first six months of 1995, again 50% of the applications for process patents were to India resident inventors. However, in contrast, just 14% of the applications for product patents were made by domestic inventors.

The Indian Drug Manufacturers Association (IDMA) protested in 1994 that prices of drugs shall go up by 5 to 20 times as a consequence of accepting the TRIPs proposals²⁵. No doubt that per capita income in India is growing and that alternative off-patent therapy will not be always available, in absence of close substitution for on-patent drug, it is obvious that price would be higher. But we cannot overlook widely spread traditional medicinal system in India (for example, Ayurveda, Naturopathy, Unani, Siddha etc.). They definitely cannot substitute sophisticated on-patent therapeutic drugs but in a country like India traditional medicines would be preferred looking at higher price of modern medicines if time comes. Cost of medicines should be such that poor can afford it because human approach should be on priority than any economic interests, not only in India but also throughout the world.

Impact on Generics

One estimate suggests that only 15% of the Indian drug market will be covered by patents after 2005 and be subjected to price premiums as a result. The remaining 85% of the market will continue to be exposed to the full impact of generic competition, to which patented products will themselves ultimately contribute when their patents expire. In other words, 'the self paying Indian pharmaceutical market will in effect be self-regulating in terms of drug pricing, without the need for government intervention',²⁵

Indian manufacturer have a lot experience in generics and India have proven successfully in last many years this capability. Being first into the market appears to matter. Being based in a country, which does not grant product patents, helps firms to get into the market earlier. Currently, without product patent, Indian firms have two institutional advantages in trying to enter quickly with low costs. The lack of product patents means that an imitating firm can have many years of experience with the commercial production of an on-patent drug before the day that the patent expires in the US, in Europe and elsewhere. Indian firms also benefit from the fact that, in India, changes in a drug's production process do not require that it be re-approved for marketing, as is typically required elsewhere. Thus Indian firms are free to experiment to fine-tune their production processes. Due to this fact, India has enjoyed a handsome export record of on-patent drugs in bulk as well as formulation^{22,24}. Table – 13 shows export of three major on-patent drugs in Europe.

Indian firms are likely to become important players in generic industry. The US FDA, the UK MCA and so on have approved many manufacturing facilities. In generic low manufacturing costs are essential. Low labor cost is India's most obvious advantage. Ghemawat and Kothavala, writes that one Indian firm estimated that its capital costs were also 50-75% lower than those in developed countries²⁷.

Most of the larger Indian firms have ambitious plans to expand their generic drug exports, either as suppliers, through joint venture agreements with foreign firms or

by purchasing formulation plants overseas. For example, Cipla has formed a subsidiary with a local firm in South Africa to sell Cipla products in that country, as well as a marketing alliance with Novopharm, Canada. Ranbaxy has purchased formulation plants in the US and in Ireland, as well as forming a joint venture with Eli Lilly to market joint products in the US. Lupin has alliances with Merck Generics, UK, Fujisawa, US and McGaw Inc., US, to market their cephalosporin products.

Currently, over three-quarters of the bulk drugs and finished formulations consumed in India are produced domestically and most of these are off-patent drugs. There is no reason to expect that granting product patents would effect the production of off-patent drugs for the domestic market. Once patent protection is available, however, patent-owning firms may choose either to export their patented drugs to India, thereby replacing domestic production, or they may choose to produce in India through a subsidiary or under license to Indian firms. In such scenario, on-patented drug might be imported in India.

With product patent regime, Indian firm will no longer be able to export on-patent drugs to other countries. However, according to a recent study by the Indian Drug Manufacturers Association (IDMA), within the next 10 years, patents of most of the world's top 10 drugs will expire. The market for generic drugs will correspondingly increase²⁸.

Impact on Availability of Medicines & R & D

Generally speaking, granting protection may speed the arrival of new drugs on the market by making the process of adapting a product, getting marketing approval, and introducing it to consumers profitable. However, a multinational with a newly patented drug may delay launches in poor countries because of concerns over global price regulations. For example, Bayer chose not to introduce its patented drug Ciprofloxacin in India because it would have had to sell it at what Bayer viewed as, at that time, too low of a price. Instead, Ciprofloxacin was introduced three years after its world launch by the Indian firm Ranbaxy. In 1996, more than eight years after its world launch and long after the entrance of a multitude of local producers, Bayer also began marketing Ciprofloxacin in India. See Table – 10 for information about introduction of newly patented drug in Indian market²⁴. If patentees hesitate to introduce drugs at low prices in the initial years of global marketing, and with imitators prevented from entering, innovative pharmaceuticals may actually become available in poor countries more slowly than they would have in the absence of protection²⁶. Such delay in introduction is said to be largely due to cross-country price comparisons.

Some exceptions to this trend have been also come into picture. For example, until the anthrax scare in October 2001, the drug recommended to combat the disease, Ciprofloxacin, was being sold by the patent owner, Bayer, in the United States at a wholesale price of about 4.60 USD for a 500 mg tablet and at a federal government price of 1.83 USD. Meanwhile, it was being marketed in India by 78 firms, including Bayer, for about 10 cents a tablet²⁶. However there are only a few example of this kind.

The research-intensive pharmaceutical firms that invented these drugs have three concerns about low-cost distribution programs. First, provision at marginal cost or lower adds nothing to their ability to cover the fixed costs of R&D. Second, while they may be willing to circulate their medicines cheaply, the firms are anxious to retain the exclusive distribution rights inherent in patents and EMRs.

Innovative firm also have a threat of parallel import from developing country market where they sell their product at low cost. United States and European Union have restricted parallel import even when the first sale of that product abroad was by the patent holder, his licensee or subsidiary. However this is not required by TRIPs. Indeed, this preference to forestall generic competition is the root of the ongoing lawsuit raised by 39 drug makers in South Africa aimed at striking down that country's 1997 Medicines and Related Substances Control Act²⁹. This legislation would permit South Africa's health minister to resort to parallel import in cases where a drug protected by a patent is priced at excessive levels in South Africa. Putting these elements together, drug development and distribution involve tradeoffs that implicate important principles underlying protection of intellectual property rights^{30,31}.

It is however important to realize that TRIPs is a framework agreement; it is to be operationalized via countries' national laws. Moreover, TRIPs does contain (limited) flexibility, as well as some safeguards, which can be used to mitigate the anticipated negative impact on drug prices and on access to drugs¹⁻⁴.

The most important safeguards are: (i) compulsory licensing; (ii) parallel importation; and (iii) provisions for early working (often referred to as "Bolar provision").

The "Bolar provision" allows testing and regulatory approval of generic versions of a drug before its patent expires; thus, it allows generic producers to get ready, so that they can start the production and sale of a generic drug as soon as its patent expires. In this way, a Bolar provision facilitates generic competition.

For Parallel importation, as mentioned above, the TRIPs Agreement states that parallel importation cannot be challenged under the WTO dispute settlement mechanism, thus it gives countries the freedom to choose whether or not to allow parallel importation. Moreover, during the WTO's Ministerial Meeting in November

2001, the Ministers clarified, in the Doha Declaration on the TRIPs Agreement and Public Health, that countries are free to use parallel importation.

A compulsory license can also be used to allow the production and sale of generics before expiry of the patent - thus, again, increasing opportunities for competition. The basic rationale for a compulsory license is that since a patent is a privilege granted by the government, the government retains the right to limit that privilege if necessary. Many countries, including many developed countries, have provisions for compulsory licenses in their national laws, and compulsory licenses are allowed under TRIPs. TRIPs mention that a compulsory license can be issued for reasons of national emergency or extreme urgency, public non-commercial use and other reasons. However, it is important to note that TRIPs does not limit the grounds, or reasons, for issuing a compulsory license. But the TRIPs Agreement does specify conditions, which are to be imposed by governments when issuing a compulsory license. These conditions includes, case-by-case decision, first try to obtain a voluntary license, adequate remuneration to the patent holder, predominantly for the supply of the domestic market, a compulsory license should be non-exclusive and non-assignable. So while these conditions have made the process somewhat cumbersome, it is possible to issue a compulsory license in a TRIPs-compliant way.

However, the safeguards provided for in TRIPs can only be used when incorporated in the national law. Therefore, it is important that countries design and enact legislation, which allows them to protect the public interest, including the public health interest. In India, grounds for invoking compulsory license are national emergency, circumstances of extreme urgency and for public non-commercial use of patented product. Parallel import is also permitted form authorized source, however, there are more flexibilities left out for India.

However, the question availability arises when drugs do exist. Perhaps the most critical task currently facing the global economy is to devise mechanisms that both encourage research aimed at finding treatments for diseases that are common in impoverished nations and that achieve widespread international distribution of these

treatments at sufficiently low costs to be effective and affordable. This issue has achieved prominence by virtue of the severe epidemic of the HIV virus, which inevitably leads to the onset of AIDS, in Sub-Saharan Africa and, increasingly, in South Asia and Southeast Asia.

See Table – 9 for list of diseases, for which 99% of global burden is on developing countries²¹. Introduction of product patent will not be justified if these diseases are not given enough attention. Most of the developed countries have accepted product patent regime when they had substantially high per capita income and most of the developing countries that are going to accept this regime now are economically not sound enough to raise huge fund for R & D that can lead to invent new ray for them²⁶. See table – 15, for development level on adoption of pharmaceutical product patent. Even though it can be justified in the light of globalization that these low-income economies also should be providing full-fledged patent protection, the same time it is reasonable to expect that disease pattern in such countries be thoroughly studied and enough R & D efforts should divert towards them.

HIV/AIDS is not the only disease that plagues poor nations, where malaria, tuberculosis, and other maladies are equally lethal and debilitating. Indeed, HIV/AIDS is unusual in that strong incentives for pharmaceutical companies to develop treatments for sufferers in high-income economies have resulted in medicines that effectively permit patients to function well for many years before onset of the disease. However, this is not so in case of malaria or tuberculosis. Tuberculosis killed 1.7 million people in 1999, with 357,000 in Africa, 59,000 in the Americas, and 723,000 in Southeast Asia. Importantly, Tuberculosis is frequently contracted by HIV/AIDS sufferers and surveys suggest that up to 70 percent of tuberculosis patients are infected with HIV. The WHO in 1996 estimated that of the 56 billion USD spent globally on medical R&D in 1994, less than 0.2 percent was spent on tuberculosis, diarrheal maladies, and pneumonia. Virtually all of the latter research was performed by public agencies and military authorities²¹.

Because serving poor consumers in the developing world is not attractive relative to their other commercial opportunities, commercial pharmaceutical firms have directed a minute fraction of their research expenditure toward creating products for developing country markets. It is often suggested, incorrectly, that pharmaceutical firms located in developing countries concentrate on diseases specific to their domestic markets. In fact they face incentives similar to firms elsewhere. A survey of Indian firms in 1998 found that only 16% of their R&D was directed towards less developed country markets³². Pecoul reported that only eight of 1,233 drugs licensed anywhere in the world from 1975 to 1997, or less than one percent, were developed specifically for tropical diseases in humans³³ (five more were for designed for veterinary uses).

Lanjouw and Cockburn examine basic research activity as evidenced by citations in bibliometric databases covering approximately 3,900 current biomedical journals published in the United States and 70 foreign countries. References to the set of tropical diseases (those with 99% of their burden in poorer countries) occurred in less than one and a half percent of all citations in 1998. Considering patenting activity, which is more closely linked to products, only about one-half of one percent of total pharmaceutical patents in 1996 related to these diseases³².

Sachs have reported that even with full patent protection, market oriented R & D is unlikely to result in new treatments for certain tropical diseases that are exclusively the burden of poor population, has led to calls for increased public funding for such efforts³⁴.

Second, even for a global disease like cancer, the characteristics of some poor countries may make the many products designed for western markets unsuitable. For example, tropical countries with weak infrastructure need pharmaceutical products that can withstand breaks in a distribution cold chain and survive a long shelf life. Drug discoveries that are very cost effective, but less effective overall, may not be acceptable to rich consumers and hence not developed by pharmaceutical firms even though they would be of great benefit to poor consumers. The choice

between vaccines and drug therapies is yet another example. An HIV/AIDS vaccine would be far easier to deliver in a poor country than drug therapy cocktails, but efforts to develop a vaccine have been minimal in comparison to the investment in treatments. Thus, even for a global disease, for which there are many pharmaceutical products, there may be few tailored to the specific needs of the developing world

Increasing the involvement of the private sector could both enlarge the pool of resources directed toward developing country-specific health needs and raise the productivity of public investment. It is important to recognize that just because patent rights are available does not imply private control over innovation. Patents can also be taken out by the government, by universities, and by international organizations. If new products for poor countries health needs are developed within the public sector, the public sector may hold the patents. Here comes the crucial role of Government to design better policies so to take maximum benefit out of such innovations and let poor people enjoy with the help of effective distribution plan.

New investments will not be substantial, of course, unless there is also an increase in resources. The availability of clear and reliable patent rights in India could complement policies to stimulate research with public funding. Patent rights may contribute to the productivity of direct public research funding by lowering the risk associated with investing in this area and facilitating industry involvement. Of course, patents are not the only way of providing incentives for research and innovation. Direct subsidies for research, prizes and tournaments, and patent buyouts are all alternative mechanism for doing so, but patent protection certainly plays a major role.

Question also arise that will the introduction of product patents lead to more R&D being done in India? For MNCs, strong intellectual property laws are certainly a pre-requisite for the choice to locate pharmaceutical R&D facilities in a country. In a World Bank study 81% of US research-based pharmaceutical companies complained that intellectual property protection is too weak in India to permit licensing of their

newest or most effective technology and zero percent would invest in R&D³⁵.

In recent years, Hoechst has been the only MNC with a subsidiary doing basic research in India (with a focus on natural products). The only other example is Ciba-Geigy, which had a basic R&D facility located in India from 1963-1989. That said, even more than in the case of manufacturing facilities, granting and enforcing intellectual property rights is likely to be far from sufficient to attract MNC investment. R&D tends to be quite centralized.

It is frequently argued by proponents of the TRIPs accord that India, once new, WTO-consistent, intellectual property laws are in place, will be very attractive as a location for R&D because, by locating in India, firms can take advantage of a sizable pool of low-cost and technically skilled labor to escape part of the great expense of drug discovery and development. [For example, the rapid growth in the Indian software industry, centered in the city of Bangalore, where a very large number of MNCs have located part of their software development]. However, while considering R & D location, apart from low labor cost other things are equally important like, availability of laboratory equipments and spares, repair and maintenance facility and Indian industry has to grow a lot more to fulfill all these.

On the other hand, the story may well be different for Indian firms. Looking at the domestic pharmaceutical sector today, a handful of firms have already begun increasing their total investment in R&D (from about 1-2% of sales to 5-6% of sales in the past few years) and there are signs that they will be successful in this new direction.

The Indian firms have already demonstrated great expertise at rapidly devising new processes for patent products. A particularly dramatic example is Ranbaxy's development in 1991, after 20 million dollars and three years of effort, of a new process for producing Eli Lilly's patented drug cefaclor. A few companies have also been successful in discovering new products. For example, Reddy's Research Foundation, a separately constituted research center established in 1992 that is a part

of Dr. Reddy's Group, only works on the discovery of new molecules. In June of 1995 they filed their first two product applications in the US (anti-cancer and anti-diabetes substances) and now have ten more patent applications in developed countries. Dabur also has a self-standing research foundation which is 50% devoted to doing discovery research related to anti-cancer drugs.

An important aspect of the R&D being done by MNC subsidiaries and Indian firms in India is the extent of sub-contracting. Discovering a new molecule and bringing it to market involves many stages. Sub-contracting allows firms to focus initially on the parts of the process in which they have gained a comparative advantage. Organizing R&D through networks of research collaborations and joint ventures is becoming increasingly common with the advent of biotechnology firms. Hoffman-La Roche and SmithKline Beecham have sought approval from the Indian government to establish wholly owned subsidiaries for R&D projects, in the latter case to develop new and existing Beecham vaccines³⁷.

However, the other fact is also that the product patents are already available to Indian inventors in much of the rest of the world and without product patent being available in India, large players in pharma industry have done much cooperative R&D arrangements between Indian and foreign firms. But product patent regime certainly will have greater impact of small manufacturers to be R & D oriented.

Maskus have pointed that 'The position that a country takes towards intellectual property may influence whether it is viewed as a favorable location for R & D investment. There may be real economic reasons why intellectual property laws matter to location decisions. Beyond these, a country's stance on intellectual property may be given further importance by being treated as a signal of its business climate more generally'³⁸.

The case of Japan provides an insight into ways in which India's research and development industry can profit from TRIPs^{25,36}. In 1970, Japan was in a similar

situation as India today. As a result of introducing patent protection, research and development expenditure amongst top Japanese drug firms rose from 6% of sales in 1975, to 10.8% in 1990. During the same period, their net profit margins rose from 3.6% of sales to 6.7%. In the 20 years preceding the new patent legislation, Japanese companies introduced 4 new major global drugs. By contrast, during the 10 years following the introduction of patent protection, Japanese drug companies introduced 25 new major global drugs into the market. Foreign investment in Japan also rose dramatically during the new patent regime.

The Japanese case suggests that product patents are a prerequisite to achieving a successful transformation from a copying and parasitic culture, to one of indigenous design and innovation. In Malaysia the level of foreign direct investment increased significantly as a consequence of enforcing the TRIPs Agreement and is currently 11 times the amount India has managed to attract. But the question is does India have the capital and level of technology that Japan had to invest in research and development?

Perhaps India's ongoing liberalization programme has stimulated the process by encouraging further foreign direct investment and capital accumulation in the burgeoning private sector, which can be channeled into research and development projects.

How would be post-2005 scenario for India with respect to Foreign Direct Investments (FDI) and Imports, was well studied by W. Lasser³⁹. He developed a scoring system consists of a 'corruption index', membership in UPOV and the PCT, compliance with TRIPS, and a measure of patent office competency, as proxied by the existence of a web site. The score says that the relationship between the IPR score and both FDI and imports is both positive and significant (at the 10 and 5% levels, respectively). A one-point increase in the IPR score (about 10%) would on average increase FDI by 1.5 billion USD. Refer table – 14 for IPR score of various countries. Of course, this result should not be interpreted to mean that amount would apply to any particular country but the direction of the effect is quite robust.

Lasser further writes that taken in the context of many economical studies, it is evidenced that stronger IPR do indeed provide some domestic benefits for developing countries. The higher tariffs also contribute to greater FDI, likely due to the creation of protected markets.

Utility patents are looked upon as a matter of great concern to India where patents can be granted for discovering new uses for known molecules or products. While India wants to protect its bio-assets from exploitation through second use patents by third parties, it should also consider the possibility of taking patents on new uses for existing products out of its own R&D efforts. TRIPs is silent on this issue, implying that countries are free to decide for themselves whether it is advantageous for them to allow filing and grant of utility patents, like in the US. The utility patents or "Swiss type of Claims" which allows new medical use, if it is entirely new and not predictable from the first use, has now been accepted by many European countries. The 1970 Patents Act and amendments there after have no provisions for utility patents.

The efforts and resources needed to pursue this approach are well within the means of Indian pharmaceutical companies, and therefore, it will be prudent to accept such claims on new uses of known molecules, while granting patents.

In the prevailing western model of new drug research, it is estimated that the costs involved in drug discovery and marketing for a new molecule is as high as 600 million USD, figures outside the reach of any Indian company or consortium of companies. It would be prudent to work towards discovery of new indications for marketed drugs or known molecules, where the costs for such efforts could be a fraction of what it costs for total drug development. Analogue research, development of novel drug delivery system, in-licensing alliances, co-marketing alliances etc. are looked upon as new trends in post-patent years.

In one of the interviews, Dr M Venkateswarlu, Dy. Drug Controller of India said that, ' There's no doubt about the future of Indian pharmaceutical industry which is

mature enough to face the challenges and grab the opportunities by interacting with the global industry and taking advantage of the facilities, manpower and the information technology base of the country.’ In fact opportunity for India in 2005 lies in identifying current strength of India and diverting it to make India a global player⁴⁰.

Issue of Patenting Life Forms & Biotech in India

Nutraceuticals have a global mark of 86 billion USD and the herbal products can take substantial share in the nutraceutical markets. The herbal markets in Europe and Japan are 6500 million USD and 2500 million USD respectively, compared to only 6.5 billion Rupees for Indian market in 1997. India is the land of traditional medicinal system such as Ayurveda and has rich heritage of medical plants. Indian companies have plenty of opportunities in this direction, however standardization of traditional medicine as per international rule is a problem. India is an agro-based country. There is enough scope for developing cultivation of medicinal plants and the cultivation through co-operative sectors on scientific basis, as there is large demand for medicinal plants in the global herbal pharmaceutical/ nutraceutical industry.

India also has varying climates within the country to meet the specific requirements of different medicinal plants. It also has a large coastline but not much has been done to develop marine products for pharmaceutical use.

Among patent issues related to traditional knowledge, an article written by R.V. Anuradha is quite interesting⁴¹. In 1995, two US based Indians were granted US Patent 5,401,504 on Use of Turmeric in wound healing, (popularly known as the Turmeric patent), which was assigned to the University of Mississippi Medical Center, US. The invention claimed under the patent was the use of turmeric at the site of an injury and/or its oral intake to promote the healing of a wound. Turmeric is a traditional plant used in all regions of India for many centuries. Normally it is used in kitchen as a normal spice and is a well-known house hold Ayurvedic medicine to stop bleeding, blood purification, anti-diabetic, as a cough remedy etc. Considering traditional use of turmeric by Indians, the Center for Scientific and Industrial Research (CSIR), an autonomous institution under the Department of Science and Technology, Government of India, decided to file for re-examination of the patent at the United States Patent and Trademark Office (USPTO). After an extensive search, 32 references were located, some of which were more than 100 years old, and in languages other than English. The USPTO revoked the patent,

stating that the claims made in the patent were obvious and anticipated, and agreeing that the use of turmeric was an old art of healing wounds.

Patents, by definition, cannot be granted over something that is obvious; that is known or anticipated by prior use; that is a product of nature, and not a product of human creativity. However, laws of different countries vary in the criteria used for assessment of the degree of human innovation that is required for qualifying for a patent.

In the turmeric case, it was possible for the CSIR to establish that the patent claim was not "new". However, it may not be possible to establish this in most of the cases. Simply because there is a wide gap in the availability of information in countries like the United States for patent examination purposes pertaining to traditional knowledge base from biodiversity-rich countries. The insistence on written published information, as opposed to oral knowledge, could make challenges to such patents difficult. The need for greater scrutiny of patent applications pertaining to biological resources, and the need to consult the source of the biological resource and knowledge pertaining to the same is, therefore, imperative.

To cope up with this particular challenge, at the Earth Summit held in 1992, the Convention on Biological Diversity (CBD) was concluded, to which India is a party. The basic objectives of the CBD are: conservation, sustainable use of biological diversity and equitable sharing of benefits arising from the use of biodiversity.

NGOs and institutions in India are attempting to document the knowledge, skills and techniques of local communities related to biological resources through the Community (or People's) Biodiversity Register, in the belief that such documentation would be a deterrent to bio-piracy; as well as for instilling a greater sense of pride among local communities over the knowledge they possess.

Another point is, that, although remedy is available in the laws of developed countries, such as the re-examination proceedings in the US, the financial, technical and legal costs for initiating such proceedings are exorbitantly high. As pointed out

by India in one of its papers to the WTO, it would be more cost-effective to establish an internationally accepted solution to prevent bio-piracy than to divert national resources to expensive judicial processes for the revocation of patents.

The TRIPs Agreement that seeks to harmonize the Intellectual Property laws of WTO members does not address this issue. India and other developing countries have emphasized in various communications to the WTO that the rights of holders of traditional knowledge to share benefits arising out of innovation on the basis of their knowledge and the biological resources nurtured by them, should be recognized. They have also recommended that applications for patents should mandatory disclose the source of origin of the biological resource and knowledge pertaining to it, so as to facilitate benefit sharing with the originators of the knowledge and resource. The United States has strongly opposed this as a "legal and administrative nightmare". In India, in amended Patents Act, it is mandatory to disclose geographical origin of the biological material used in the invention. Certainly there is a need for internationally harmonized rules to prevent bio-piracy.

An article in Bio-Spectrum is reporting that the number of patents on living organisms and their parts continues to grow. The international group Action Aid's 2002 research revealed that six agrochemical companies hold over 900 patents on varieties of the world's five major staple food crops. In 2001, the US Patent Office awarded 20,000 gene patents and another 25,000 were pending⁴².

Article 27 of TRIPs, which deals with the patentability issues, has a major bearing on the biotechnology industry. According to this Article, distinction is made between biological matter produced by biological processes and those produced by essentially non-biological routes; only the latter belonging to patentable subject matters. Thus natural material of any kind would be non-patentable. While the TRIPs Agreement is silent on the patenting of gene and DNA sequences. New plant varieties have to be protected under patents or a special legislation (*sui generis* system). India has legislated Plant Varieties Protection and Farmers Rights Act under the *sui generis* system, which is deemed to protect both the plant breeder's and farmer's rights to the new variety.

Biotech industry in India at present is at the threshold of tremendous growth. For example, in the human and animal products segment of the industry alone, the vaccines market alone is valued at 230 million USD and is growing at 20 per cent. The success of firms like Shanta Biotech and Bharat Biotech emphasize the fact. India's first genetically engineered vaccine, Shanta Biotech's Shanvac against Hepatitis B, costs 4 USD, less than half the price of similar vaccines marketed by multinational companies.

The consumption of biotech products in India was 1789 million USD during 1999, which is expected to grow up to the tune of 4270 million USD by the end of year 2010. Even though in the global biotech market, Indian share is presently just about 2%, the future seems very bright for the country. Biotechnology is a fast emerging sector in India. Revised patent policies can play a major role in growth of the Indian bio-pharmaceutical and biotechnological industry⁴³.

CONCLUDING COMMENTS

Concluding Comments

It is perhaps too soon to draw any strong conclusion about effects of introduction of pharmaceutical product patents on India. None of the effects will be absolute rather relative to one another. Of drugs currently on the market, just fewer than ten percent are on-patent in Europe. Even if this percentage may rise, means that even if product patents result in significantly higher prices, much of the pharmaceutical market will not be affected. We should not expect however that the remaining market segment would have no price increase. The patent-owning firm will set drug price to maximize global profit and the politics of drug price regulation may decide a limit to how low they will be willing to set prices in India. Low income and less medical insurance coverage might not be successful in deciding lower price for drugs due to transfer price loophole. However, price regulation policy of Government of India will have most prominent impact on deciding price.

Indian generic pharmaceutical industry will face very negligible losses due to introduction of product patent regime. It may become somewhat less profitable, since speed into the market seems to be important, but there is no reason to expect that they will not be successful in increasing their global share. Their low manufacturing costs will continue to give them advantage.

There is no point to conclude that upcoming introduction of product patents will make much difference to the amount and type of R & D being done by Indian firms. Already the larger firms are increasing their R & D expenditure as a percentage of sale and they are beginning to move in the direction of new molecule discovery rather than concentrating solely on development research. About MNCs to choose India as R & D location, product patent will make Indian environment more appealing for MNCs but it is unlikely that it will make a dramatic difference to their choice. R & D being of centralized nature, low cost stuff in India may not be able to attract MNCs.

About availability and diffusion of on-patent drugs in the market as a whole, scenario is definitely going to be change. Currently Indian firms are quite quick to

bring imitations of on-patent drugs to the market at affordable price for poor economies. With imitations prevented from entering because of the new patent law, innovative pharmaceuticals may actually become available to Indian consumers more slowly. On the other hand, stronger patent protections might provide an assurance to innovative firms about market exclusivity and result in early introduction. Once the crutches of weak patent law are removed, India can successfully negotiate with research-based international companies to boost export earnings, create more employment and benefit from the transfer of technology.

Introduction of product patent however, in India could create a substantial incremental increase in profits and encourage more commercial interest in discovery and development of medicines for diseases which are relevant to Indian patients but which are not important to consumers in developed countries.

SUMMARY

Summary

Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), which came into effect from 1st January 1995, is to date most comprehensive multilateral agreement of Intellectual Property Rights (IPRs). TRIPs requires all World Trade Organization members to provide minimum standards of protection for a wide range of IPRs including copyright, patents, trademarks, industrial designs, geographical indications, semiconductor topographies and undisclosed information. The most sensitive part of TRIPs is regarding product patent issue in various fields of technology including pharmaceuticals and this part gave rise to an acrimonious debate between the developed countries and less developed countries (LDCs). No country was more actively involved in opposing this component of General Agreement on Tariffs and Trade (GATT) than India and no part of TRIPs was, and continues to be, more sensitive than the proposal to require product patent for pharmaceutical innovations.

On one hand, patent is reviewed as ‘innovation encouraging’ by means of giving exclusive marketing rights to the patent owner and thus providing optimal incentive to invest in the research and development to discover, test and bring innovations to market. On the other hand, many poor developing economies claim that patent protection for pharmaceuticals will result in substantially higher prices for medicines, with adverse consequences for the health and well being of their citizens.

This thesis focuses on impact of extended patent protection for pharmaceuticals in India. Before TRIPs came in to existence, India was not recognizing product patents in pharmaceuticals and agricultural sector, but only process was patentable. When India is approaching deadline for product patent recognition, future consequences are still not predictable. Price for medicines are likely to increase while generic industry will have no adverse effects. Large pharmaceutical companies have already invested in R & D, while smaller players have to move to either generic market or have to look for contract manufacturing. It is unlikely that low labor cost in India will be able to attract MNCs to choose India as preferred location for R & D, looking towards centralize nature of R & D. Contract manufacturing, mergers and co-marketing alliances will likely to be successful in terms of foreign investments. It is also expected that better patent protection will divert more R & D efforts towards developing countries needs.

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TABLES

Table – 1**Patents granted to residents per million people 1998**

Country	Patents granted to residents per million people, 1998	Country	Patents granted to residents per million people, 1998
Japan	994	Poland	30
South Korea	779	Czech Republic	28
United States	289	Lithuania	27
Sweden	271	Hungary	26
Germany	235	Uzbekistan	25
France	205	Slovakia	24
Luxembourg	202	Malta	23
Netherlands	189	Iceland	15
Finland	187	Kyrgyz Stan	14
Switzerland	183	Italy	13
Austria	165	Turkmenistan	10
Russia	131	Croatia	9
Ireland	106	Argentina	8
Slovenia	105	Armenia	8
New Zealand	103	Singapore	8
Norway	103	Portugal	6
Ukraine	84	Morocco	3
United Kingdom	82	Uruguay	2
Australia	75	Tajikistan	2
Israel	74	Brazil	2
Belgium	72	Botswana	1
Latvia	71	China	1
Romania	71	Gambia, The	1
Georgia	67	Iran	1
Mongolia	56	Estonia	1
Kazakhstan	55	Thailand	1
Denmark	52	Colombia	1
Belarus	50	India	1
Spain	42	Mexico	1
Canada	31	Estonia	1

Source: World Intellectual Property Organization 2001, *Intellectual Property Statistics*, Publication A, Geneva.

Table – 2

Top 10 Firms by Pharmaceutical Sale

2003 versus 1971

Rank	Company – 2003	1998 Sale (Billion of Rupees)	Company – 1971
1	GlaxoSmithkline	12.97	Sarabhai*
2	Cipla*	9.08	Glaxo
3	Ranbaxy*	8.55	Pfizer
4	Zydus Cadila*	7.41	Alembic*
5	Nicholas Piramal*	6.75	Hoechst
6	Sun Pharmaceuticals*	5.80	Lederle
7	Aventis Pharma	5.51	Ciba
8	Dr. Reddy's Labs*	4.98	May & Baker
9	Wockhardt-Merind*	4.81	Park Davis
10	Alkem*	4.32	Abbott

Note: * indicates an Indian firm

Source: IMS Plus September 2003

Table – 3

**Production, Export and Imports of Bulk Drugs and Formulations
(Billions of Rupees)**

Year	Bulk Drugs			Formulations			Total	
	Prod'n	Exports	Imports	Prod'n	Exports	Imports	Exports	Imports
1980-81	2.4	0.11	0.87	12.00	0.35	0.096	> 0.46	0.966
1981-82	2.89	0.15	1.05	14.34	0.69	0.019	> 0.84	1.069
1982-83	3.45	0.11	1.15	16.60	0.54	0.054	> 0.65	1.204
1983-84	3.55	0.18	1.23	17.60	0.61	0.034	> 0.79	1.264
1984-85	3.77	0.29	1.78	18.27	0.99	0.101	> 1.28	1.881
1985-86	4.16	0.33	2.08	19.45	1.06	0.158	> 1.39	2.238
1986-87	4.58	0.87	2.07	21.40	1.02	0.218	> 1.89	2.288
1987-88	4.80	1.39	2.34	23.50	0.88	0.214	> 2.27	2.554
1988-89	5.50	2.42	3.28	31.50	1.57	0.354	> 4.00	3.634
1989-90	6.40	3.50	4.25	34.20	3.14	0.550	> 6.64	4.800
1990-91	7.30	4.13	3.22	38.40	3.71	0.849	> 7.84	4.069
1991-92	9.00	7.22	4.58	48.00	5.58	0.961	> 12.81	5.541
1992-93	11.50	4.09	5.08	60.00	9.65	1.19	> 13.75	6.270
1993-94	13.20	5.30	6.12	69.00	13.10	1.38	> 18.41	7.500
1994-95	15.18	7.60	8.11	79.35	15.05	1.73	> 22.65	9.84
1995-96	18.22	11.32	16.30	91.25	20.44	2.70	> 31.77	19.00
1996-97	21.86	15.81	17.05	104.94	25.09	3.45	> 40.90	20.50
1997-98	26.23	21.73	18.27	120.68	31.80	4.30	> 53.53	22.57
1998-99	31.48	27.64	19.18	138.78	31.94	5.40	> 59.59	24.58
1999-00	37.77		20.25	159.60		6.80	> 66.31	27.05
2000-01	45.33	27.32	32.86	183.54	19.95		> 47.27	> 32.86

Source: Website of Pharmaceuticals and Drug Manufactures, India

Table – 4

R & D Expenditure in India

R & D Expenditure (Billion Rupees)	
1994-95	1.40
1995-96	1.60
1996-97	1.85
1997-98	2.20
1998-99	2.60
2003-04	6.20
R & D Expenditure as % of Sales	2.0 %

Source: Organization of Pharmaceutical Producers of India, 2004

Table – 5

R & D Expenditure as % of Sale during 1998-99

Company	R & D Expenditure as % of Sale
Torrent Pharma	11.25
Wockhardt	10.79
Lupin Labs	3.19
Dr. Reddy's Labs	2.49
Ranbaxy	4.30
Cipla	4.02

Source: Organization of Pharmaceutical Producers of India, 2004

Table – 6
Annual Drug Expenditure Per Capita – 1997 – 2001

Country	Expenditure (USD)				
	1997	1998	1999	2000	2001
United States of America	3939	4095	4287	4540	4887
Switzerland	3762	3909	3881	3574	3774
Norway	2797	2867	3025	2817	2981
Germany	2753	2773	2731	2408	2412
Japan	2337	2216	2634	2890	2627
Canada	1864	1835	1949	2102	2163
United Kingdom	1563	1683	1792	1783	1835
New Zealand	1301	1125	1169	1054	1073
Saudi Arabia	432	368	340	376	375
Brazil	362	348	246	265	222
Costa Rica	236	254	268	280	293
Morocco	52	56	54	54	59
China	33	36	40	45	49
Kenya	29	33	28	30	29
Indonesia	26	11	17	20	16
India	23	22	23	23	24
Pakistan	19	19	18	18	16
Bangladesh	10	10	11	13	12
Ethiopia	4	4	3	3	3
Liberia	1	1	2	2	1

Source: The World Health Report, 2003

Table – 7

Health Accounts Indicators, estimates for 1997

Country	Health Expenditure (%)		
	Total health expenditure as % of GDP	Out-of-pocket expenditure as % of total health expenditure	Social security expenditure as % of public health expenditure
United States of America	13.7	16.6	42.1
Switzerland	10.1	29.7	77.9
Norway	6.5	18.0	-
Germany	10.5	11.3	76.6
Japan	7.1	19.9	84.7
Canada	8.6	17.0	1.1
United Kingdom	5.8	3.1	-
New Zealand	8.2	22.0	-
Saudi Arabia	3.5	6.3	-
Brazil	6.5	45.6	-
Costa Rica	8.7	22.3	83.8
Morocco	5.3	59.3	51.2
China	2.7	75.1	-
Kenya	4.6	35.9	-
Indonesia	1.7	47.4	-
India	5.2	84.6	-
Pakistan	4.0	77.1	-
Bangladesh	4.9	54.0	-
Ethiopia	3.8	63.8	-
Liberia	3.0	33.3	-

Source: The World Health Report, 2000

Table – 8

Top Ten Leading Causes of Burden of Disease in 1998: All Ages

India		US and Canada	
Cause	DALYs (000)	Cause	DALYs (000)
Acute lower respiratory infection	24,806	Ischaemic heart disease	2,955
Perinatal conditions	23,316	Unipolar major depression	2,511
Diarrhoeal diseases	22,005	Alcohol dependence	1,736
Ischaemic heart disease	11,697	Road traffic injuries	1,670
Falls	10,897	Cerebrovascular disease	1,651
Unipolar major depression	9,679	Osteoarthritis	1,029
Tuberculosis	7,578	Diabetes mellitus	1,017
Congenital abnormalities	7,454	Trachea/bronchus/lung cancers	996
Road traffic injuries	7,204	Dementias	940
Measles	6,474	Self-inflicted injuries	858

DALY stands for “Disability-Adjusted-Life-Year”.

Sources: The World Health Report, 2002

Table – 9**Disease for which 99% or More of the Global Burden Falls on Low-and Middle-Income countries, 1990**

Disease	Developing Country Burden as a % of Total
Changas Disease	100
Dangue	100
Ancylostomiasis and Necatoriasis	100
Japanese Encephalitis	100
Lymphatic Filariasis	100
Malaria	100
Onchocerciasis-river blindness	100
Schistosomiasis	100
Tetanus	100
Trachoma	100
Trichuris	100
Trypanosomiasis	100
Leishmaniasis	99.9
Measles	99.9
Polio	99.9
Syphilis	99.9
Diphtheria	99.8
Leprosy	99.7
Pertusis	99.6
Diarrhoeal Disease	99.5

Source: Investing in Health Research and Development: *Report of the Ad Hoc Committee on Health Research Relating to Future Intervention Options*, 1996, Geneva.

Table – 10

**Introduction of On-Patent Drugs
In the Top 500 Brands by Pharmacy Sales, 1993**

Drug Name	Year of World Introduction or by Inventor	Year of Indian Marketing Approval or Introduction by Indian Firm	Introducing Lag (Years)	Year of European Patent Expiry
Cefuroxime Sodium	1978	< 1988	< 10	1994
Cefaclor	1979	1991	12	1994
Netimicin	1980	< 1988	< 8	1994
Albedazole		< 1988		1995
Fluoxetine		1990		1995
Aciclovir	1981	1988	7	1995
Ranitidine	1981	1985	4	1997
Cefotaxime Sodium	1980	< 1988	< 8	1997
Cefuroxime Axetil	1988	1990	2	1997
Ketorolac		1992		1997
Cefotaxime	1980	< 1988	< 8	1997
Captopril	1980	1985	5	1997
Norfloxacin	1984	1988	4	1998
Pefloxacin		1991		1998
Ketoconazole	1981	< 1988	< 7	1998
Femotidine	1984	1989	5	1999
Enalapril Maleate	1984	1989	5	1999
Omeprazole		1991		1999
Astemizole	1983	1988	5	2000
Ceftamizole	1983	1988	5	2000
Ciprofloxacin	1986	1989	3	2001
Ofloxacin		1990		2001
Roxithromycin		1992		2001

Source: Jean Lanjouw, (1998) 'The Introduction of Pharmaceutical Product Patents in India: Heartless Exploitation of the Poor and Suffering?' *National Bureau of Economic Research Working Paper 6366*.

Table – 11

Price Comparisons - Four Largest ‘On-Patent’ Drugs by Sales in India

Drug Name	Dosage	Price in India (Rupees)	Times Costlier In:		
			Pakistan	U.K.	U.S.A.
Ranitidine	300 tabs/10 pack	18.53	14.1	26.1	56.7
Famotidine	40 tabs/10 pack	18.61	14.0	27.1	54.0
Ciprofloxacin	500 mg/4 pack	28.40	8.3	10.3	15.4
Norfloxacin	400 mg/10 pack	39.00	3.2	6.5	23.2

Source: Jean Lanjouw, (1998) ‘The Introduction of Pharmaceutical Product Patents in India: Heartless Exploitation of the Poor and Suffering?’ *National Bureau of Economic Research Working Paper 6366*.

Table – 12

Basic Information About Some Fluoroquinolone Molecules

	Ciprofloxacin	Norfloxacin	Ofloxacin	Sparfloxacin
U.S. or European patent-holder	Bayer	Merck	Ortho-McNeil	Rhone-Poulenc
Year of U.S. patent expiry	2003	1998	2003	2010
Year of US-FDA approval	1987	1986	1990	1996
Year first introduced in India	1989	1988	1990	1996
No. of domestic Indian firms	75	40	17	25
No. of foreign subsidiaries	8	2	2	1
No. of products of domestic firms	90	48	21	30
No. of products of foreign subsidiaries	10	2	2	1
Sales weighted average price per-unit API of products produced by:				
Domestic Indian firms	11.23	9.04	88.73	78.11
Foreign subsidiaries	10.29	4.99	108.15	.

Source: Shubham Chaudhari & Pinelopi Goldberg & Panle Jia, (2003) 'The Effects of Extending Intellectual Property Rights Protection on Developing Countries: A Case Study of the Indian Pharmaceutical Market', *NationalBureau of Economic Research Working Paper 10159*.

Table – 13

**Export of Three Major Drugs On-Paten in Europe
(Millions of Rupees)**

Drug Name	April 1992-March 1993		April 1995-March 1996 (Est.)	
	Exports	Main Destinations ¹	Export	Main Destinations
Ranitidine Bulk	144.8	Bangladesh Germany Spain Switzerland	243.4	Bangladesh Mexico Canada Spain
Ranitidine Formulations	39.9	Bangladesh Mexico Germany Spain	202.0	Canada Ireland Spain
Norfloxacin Bulk	49.7	Thailand Jordan U.S. Italy Germany Spain Switzerland	86.3	Korea Mexico U.A.E. Jordan Germany Spain Switzerland
Norfloxacin Formulations	7.2	Kenya U.A.E. Venezuela Italy Spain	58.9	Kenya Vietnam Sudan Iran Germany Belgium
Ciprofloxacin Bulk	108.3	Bangladesh Hong Kong Taipei Switzerland	121.3	Bangladesh Sri Lanka Venezuela Switzerland
Ciprofloxacin Formulaitons	59.5	Hong Kong Taipei C.I.S. Chad Spain	94.8	Hong Kong Vietnam Egypt Russia Chile
Total	405.3		806.7	

Note: 1) Includes destinations representing 5% or more of total exports of the indicated drug.

Source: Jean Lanjouw, (1998) 'The Introduction of Pharmaceutical Product Patents in India: Heartless Exploitation of the Poor and Suffering?' *National Bureau of Economic Research Working Paper 6366*.

Table – 14**Intellectual Property Score, 1998**

Country	IP Score	Country	IP Score
Chile	7.2012	Guatemala	2.9264
Botswana	5.7584	Argentina	4.8960
Costa Rica	6.1424	Nicaragua	2.8320
Namibia	5.0032	Thailand	3.3060
S. Africa	7.3548	Egypt	2.7376
Mauritius	4.7200	India	3.5936
Tunisia	4.7200	Bolivia	3.4252
Jordan	4.4368	Pakistan	2.5488
Peru	4.7220	Kenya	4.8060
Uruguay	4.8412	Vietnam	2.3600
S. Korea	6.1028	Ecuador	3.7612
Zimbabwe	4.8208	Venezuela	2.1712
Malawi	4.7264	Colombia	2.8588
Brazil	6.6960	Indonesia	4.2148
Jamaica	3.5872	Nigeria	1.7936
Morocco	4.3488	Tanzania	1.7936
El Salvador	3.3984	Honduras	1.6048
Zambia	3.3040	Paraguay	2.1980
Ghana	3.9712	Cameroon	2.1776
Philippines	3.5892	Malaysia	5.4772
Senegal	3.9712	Mexico	6.0352
Cote d'Ivoire	3.7824	China	5.4160

Source: W. Lasser (2001), 'The Effect of TRIPs-Mandated Intellectual Property Rights on Economic Activities in Developing Countries', *report prepared under WIPO Special Service Agreement*.

Table – 15

Development Level on Adoption of Pharmaceutical Product Patent

Panel A: OECD Adapters		
Country	Year of Adoption	GDP per capita (2001 USD)
West Germany	1968	11,601
Japan	1976	27,940
Switzerland	1977	42,956
Italy	1978	15,651
Holland	1978	24,265
Sedem	1978	25,445
Canada	1983	18,937
Denmark	1983	32,170
Austria	1987	29,167
Spain	1992	16,769
Portugal	1992	12,165
Greece	1992	12,664
Norway	1992	35,314
Panel B: Recent Adapters		
China	1992/3	523
Brazil	1996	5,209
Iceland	1997	33,207
Argentina	2000	9,413
Uruguay	2001	7,214
Guatemala	Future	1,795
Egypt	Future	1,384
Pakistan	Future	590
India	Future	523
Malawi	Future	181

Source: Jean Lanjouw (2002), 'Intellectual Property and the Availability of Pharmaceuticals in Poor Countries', drafted for *Innovation Policy and the Economy*, vol.3.

ANNEXURE

Annex – I

Exclusive Marketing Rights

This new provision has been incorporated in the Patents Act, 1970 as amended by The Patents (Amendment) Act, 1999 with effect from 1st January 1995. Under this amendment to the Patents Act, 1970 it is now possible to make an application for patent claiming for a substance itself intended for use or capable of being used as Medicine or Drug, excepting the intermediate for the preparation of drug. However that India has the privilege, under WTO regime, of a ten years transition period. Thus application for product claims for medicine or drug will not be processed until the end of 2004. But Exclusive Marketing Rights (EMR) can be obtained for that application if certain conditions as stated below are fulfilled:

1. Where an invention has been made in India or outside India and before filing such a claim in India, application for the same invention claiming identical article or substance in a Convention Country (WTO) has been filed on or after 1st January, 1995 and a patent has been granted on or after the date of making a claim for article or substance in India and approval to sell or distribute has been obtained in the said Convention Country on the basis of the test done on or after 1st January, 1995.
2. Where an invention has been made in India and before filing such a claim the applicant has made an application for patent on or after 1st January, 1995 for method or process of manufacturing the identical article or substance and patent has been granted in India on or after the date of making of the product claim.
3. Marketing approval of the article or substance has been obtained from the appropriate authority in India provided that the application for patent has not been rejected by the Controller on the basis of the report of the Examiner that the invention is not an invention (Section - 3) or the invention is an invention on which no patent can be granted (Section - 4).

Duration

EMR will be valid for a period of five years or till the date of grant of the patent or date of rejection of the application for the grant of patent whichever is earlier.

Source: Website of Controller General of Patents, Designs & Trademarks, India.

Annex – II

Patent Legislation

Indian Patent Act of 1970 versus GATT

Patent Act	GATT
1. No product patents allowed for pharmaceuticals, food products and agrochemicals. Only process patents. No patents for micro-organisms.	Both product and process patents for pharmaceuticals, food products and agrochemicals, and micro-organisms.
2. Process patents for the above have a statutory term limit of the shorter of 7 years from application or 5 years from granting.	All patents have a term of at least 20 years from filing.
3. Government retains wide powers to grant (non-exclusive) compulsory licenses 3 years after granting. In the case of pharmaceuticals, licenses are automatic, i.e. with no consideration of local working by the patentee or the ability of the licensee to produce. Maximum royalty of 4% of ex factory price in bulk form [compared to typical royalty rates of 10-15%].	No automatic licenses. Compulsory licenses only in cases of national emergency, for public non-commercial use, or to remedy a practice found after judicial review to be anticompetitive. A non-exclusive compulsory license may be granted only after a license sought on commercial terms from the patentee and remuneration should reflect the economic cost of the license to the patentee.
4. Importation does not fulfill working requirement.	No discrimination between domestic production and importation.
5. In all cases, the burden of proof in an infringement case falls on the patentee.	In the case of process patents, the burden of proof lies with the alleged infringer. (Reversal of the burden of proof.)

Source: Iyer, V.R. Krishna, O. C. Reddy, D.A. Desai and Rajinder Sachar (1996) Peoples' Commission on GATT: On the Constitutional Implications of the Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations. *Center for Study of Global Trade System and Development*. New Delhi.

Annex – III

Indian Pharmaceutical Industry

Fact Sheet – 2003

- **Annual Turnover:** Rs.226 billion; Growth 5.1%
- **Exports:** Rs.141 billion - Over 65 countries
- **Outsourcing Opportunities:** Excellent outsourcing opportunities for clinical trials, R&D, custom synthesis, technical services, e.g. Bioinformatics, etc.
- **Future Market Size:** McKinsey Projection 2010 - 25 Billion USD
- **Bulk Drugs Production:** Rs. 78 billion. Over 400 Bulk drugs manufactured
- **Manufacturing Facilities:** Largest number of US FDA approved manufacturing facilities outside US
- **No. of DMFs (Drug Master Files) filed with US FDA:** 126, higher than Spain, Italy, China and Israel
- **Per Capita Drug Expenditure:** Rs.220 per year
- **Share of World Pharmaceutical Market:** 1.0% in value, 8% in volume terms
- **Global Ranking** in Volume terms – 4th, Value terms – 13th
- **Number of Generic Brands:** Over 60,000 in 60 therapeutic categories
- **Capital Investment:** Rs. 45 billion
- **R&D Expenditure:** Rs. 6.6 billion, about 2% of sales (However, some research based companies are spending over 6% of sales on R&D)
- **Ancillary Industry:** Extremely well developed. All manufacturing equipment and machineries locally available.
- **Number of Units:** About 10,000, out of which around 300 units in the organized sector
- **Intellectual Capital:** Third largest English speaking scientific and technical manpower in the world (highest intellectual capital per USD)

- **Employment:** Direct - 5,00,000
Indirect - 24,00,000
- **Price Control** – 3-tier control – on Bulk Drugs, Formulations and Overall Profitability. Currently, 74 drugs under price control (40% of retail market) – New Pharmaceutical Policy 2002 is currently under judicial review in Supreme Court. , If cleared, likely to reduce number of drugs under price control from 74 to about 25.
- **OTC Market:** Approx. Rs.35 billion, Growth 18-20%
- **Alternative Medicine:** Herbal, Ayurvedic, etc. – about Rs.38 billion
- **Health Infrastructure:** No. of doctors – 5,00,000; No. of nurses – 7,37,000
- **No. of Hospitals** – 16,000; No. of Retail Chemists – 5,00,000; Medical Colleges – 171; Primary Health Centers – 1,64,000
- **Top 10 Companies** *: Sun Pharma, Pfizer, Dr. Reddy's, Zydus Cadila, Abbott India, Aventis
- **Top 10 Brands***: Corex (Chlorpheniramine Maleate); Voveran (Diclofenac Sodium); Becosules, (Vitamin B Complex, Vitamin C); Taxim (Cefotaxime); Human Mixtard (Insulin); Althrocin (Erythromycin); Sporidex (Cephalexin); Asthalin (Salbutamol); Betnesol (Betamethasone); Cifran (Ciprofloxacin)

*Based on retail sales

Note: Average Exchange Rate during 2003 – 1 USD = Rs.45.40

Source: Organization of Pharmaceutical Producers of India, 2004

The Patents (Amendment) Act, 2002, India



भारत का राजपत्र
The Gazette of India

असाधारण

EXTRAORDINARY

भाग II — खण्ड I

PART II — Section 1

प्राधिकार से प्रकाशित

PUBLISHED BY AUTHORITY

सं. 42] नई दिल्ली, मंगलवार, जून 25, 2002/ आषाढ़ 4, 1924
No. 42] NEW DELHI, TUESDAY, JUNE 25, 2002/ ASADHA 4, 1924

इस भाग में भिन्न पृष्ठ संख्या दी जाती है जिससे कि यह अलग संकलन के रूप में रखा जा सके।
Separate paging is given to this Part in order that it may be filed as a separate compilation.

MINISTRY OF LAW, JUSTICE AND COMPANY AFFAIRS
(Legislative Department)

New Delhi, the 25th June, 2002/Asadha 4, 1924 (Saka)

The following Act of Parliament received the assent of the President on the 25th June, 2002, and is hereby published for general information:—

THE PATENTS (AMENDMENT) ACT, 2002

(No. 38 of 2002)

[25th June, 2002.]

An Act further to amend the Patents Act, 1970.

Be it enacted by Parliament in the Fifty-third Year of the Republic of India as follows:—

1. (1) This Act may be called the Patents (Amendment) Act, 2002.

(2) It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint; and different dates may be appointed for different provisions of this Act and any reference in any such provision to the commencement of this Act shall be construed as a reference to the coming into force of that provision.

Short title and
commence-
ment.

Substitution of certain words for the words "High Court" and "Court".

Amendment of section 2.

2. In the Patents Act, 1970 (hereinafter referred to as the principal Act), for the words "High Court" wherever they occur in sections 21, 43 and 71 and the word "Court" occurring in sections 21 and 71, the words "Appellate Board" and "Board" shall respectively be substituted.

39 of 1970.

3. In section 2 of the principal Act, in sub-section (1),—

(a) for clause (a), the following clauses shall be substituted, namely:—

'(a) "Appellate Board" means the Appellate Board referred to in section 116;

(ab) "assignee" includes an assignee of the assignee and the legal representative of a deceased assignee and references to the assignee of any person include references to the assignee of the legal representative or assignee of that person;

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

(b) for clause (d), the following clause shall be substituted, namely:—

'(d) "convention country" means a country or a country which is member of a group of countries or a union of countries or an Inter-governmental organisation notified as such under sub-section (1) of section 133; ;

(c) for clause (g), the following clause shall be substituted, namely:—

'(g) "food" means any article of nourishment for human consumption and also includes any substance intended for the use of infants, invalids or convalescents as an article of food or drink; ;

(d) in clause (i),—

(i) in sub-clause (i), for the words "Union territory of Delhi", the words "National Capital Territory of Delhi" shall be substituted;

(ii) for sub-clause (ii), the following sub-clause shall be substituted, namely:—

"(ii) in relation to the State of Arunachal Pradesh and the State of Mizoram, the Gauhati High Court (the High Court of Assam, Nagaland, Meghalaya, Manipur, Tripura, Mizoram and Arunachal Pradesh); ;"

(iii) in sub-clause (v), for the words "Union territory of Goa, Daman and Diu", the words "State of Goa, the Union territory of Daman and Diu" shall be substituted;

(e) after clause (i), the following clause shall be inserted, namely:—

'(ia) "international application" means an application for patent made in accordance with the Patent Cooperation Treaty; ;'

(f) for clause (j), the following clauses shall be substituted, namely:—

'(j) "invention" means a new product or process involving an inventive step and capable of industrial application;

(ja) "inventive step" means a feature that makes the invention not obvious to a person skilled in the art; ;'

(g) for clause (m), the following clause shall be substituted, namely:—

'(m) "patent" means a patent granted under this Act; ;'

(k) after clause (o), the following clause shall be inserted, namely:—

'(oa) "Patent Cooperation Treaty" means the Patent Cooperation Treaty done at Washington on the 19th day of June, 1970 as amended and modified from time to time; ;'

(i) for clause (u), the following clause shall be substituted, namely:—

'(u) "prescribed" means,—

(A) in relation to proceedings before a High Court, prescribed by rules made by the High Court;

(B) in relation to proceedings before the Appellate Board, prescribed by rules made by the Appellate Board; and

(C) in other cases, prescribed by rules made under this Act.'

4. In section 3 of the principal Act,—

Amendment of
section 3.

(a) for clause (b), the following clause shall be substituted, namely:—

“(b) an invention the primary or intended use or commercial exploitation of which would be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment;”;

(b) in clause (c), after the words “an abstract theory”, the words “or discovery of any living thing or non-living substance occurring in nature” shall be inserted;

(c) clause (g) shall be omitted;

(d) in clause (i),—

(i) after the word “prophylactic”, the words “diagnostic, therapeutic” shall be inserted;

(ii) the words “or plants” shall be omitted;

(e) after clause (i), the following clauses shall be inserted, namely:—

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

(k) a mathematical or business method or a computer programme *per se* or algorithms;

(l) a literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever including cinematographic works and television productions;

(m) a mere scheme or rule or method of performing mental act or method of playing game;

(n) a presentation of information;

(o) topography of integrated circuits;

(p) an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components.”.

5. In section 5 of the principal Act, after sub-section (2), the following *Explanation* shall be inserted, namely:—

Amendment of
section 5.

‘*Explanation*.—For the purposes of this section, “chemical processes” includes biochemical, biotechnological and microbiological processes.’.

6. In section 7 of the principal Act, after sub-section (1), the following sub-section shall be inserted, namely:—

Amendment
of section 7.

“(1A) Every international application under the Patent Cooperation Treaty for a patent, as may be filed designating India, shall be deemed to be an application under this Act, if a corresponding application has also been filed before the Controller in India.”.

7. In section 8 of the principal Act,—

Amendment
of section 8.

(a) in sub-section (1),—

(i) in the opening portion, after the words "he shall file along with his application", the words "or subsequently within such period as the Controller may, for good and sufficient reasons, allow" shall be inserted;

(ii) for clause (a), the following clause shall be substituted, namely:—

"(a) a statement setting out detailed particulars of such application; and";

(iii) in clause (b), for the words "details of the nature referred to in", the words "detailed particulars as required under" shall be substituted;

(b) for sub-section (2), the following sub-section shall be substituted, namely:—

"(2) At any time after an application for patent is filed in India and till the grant of patent or refusal to grant of patent is made thereon, the Controller may also require the applicant to furnish details, as may be prescribed, relating to the processing of the application in a country outside India, and in that event the applicant shall furnish information available to him to the Controller within thirty days from the date of receipt of the communication requiring such furnishing of information or within such further period as the Controller may, for good and sufficient reasons, allow."

Amendment
of section 10.

8. In section 10 of the principal Act,—

(a) in sub-section (4), after clause (c), the following clause shall be inserted, namely:—

"(d) be accompanied by an abstract to provide technical information on the invention.

Provided that —

(i) the Controller may amend the abstract for providing better information to third parties; and

(ii) if the applicant mentions a biological material in the specification which may not be described in such a way as to satisfy clauses (a) and (b), and if such material is not available to the public, the application shall be completed by depositing the material to an authorised depository institution as may be notified by the Central Government in the Official Gazette and by fulfilling the following conditions, namely:—

(A) the deposit of the material shall be made not later than the date of the patent application in India;

(B) all the available characteristics of the material required for it to be correctly identified or indicated are included in the specification including the name, address of the depository institution and the date and number of the deposit of the material at the institution;

(C) access to the material is available in the depository institution only after the date of the application for patent in India or if a priority is claimed after the date of the priority;

(D) disclose the source and geographical origin of the biological material in the specification, when used in an invention."

(b) after sub-section (4), the following sub-section shall be inserted, namely:—

"(4A) In case of an international application designating India, —

(i) the title, description, drawings, abstract and claims filed with the application shall be taken as the complete specification for the purposes of this Act; and

(ii) the filing date of the application and its complete specification, processed by the patent office as designated office or elected office, shall be the international filing date accorded under the Patent Cooperation Treaty.”;

(c) for sub-section (5), the following sub-section shall be substituted, namely:—

“(5) The claim or claims of a complete specification shall relate to a single invention, or to a group of inventions linked so as to form a single inventive concept, shall be clear and succinct and shall be fairly based on the matter disclosed in the specification.”.

9. In Chapter IV of the principal Act,—

Amendment
of Chapter
IV.

(a) for the Chapter heading “EXAMINATION OF APPLICATIONS”, the following Chapter heading shall be substituted, namely:—

“PUBLICATION AND EXAMINATION OF APPLICATIONS”;

(b) before section 12, the following sections shall be inserted, namely:—

“11A. (1) Applications for patents shall not be open to the public for a period of eighteen months from the date of filing or date of priority, whichever is earlier.

Publication of
applications.

(2) Except when a secrecy direction is given under section 35, every application for a patent shall, on the expiry of the period as specified in sub-section (1), be published.

(3) The publication of every application for a patent shall be notified in the Official Gazette.

(4) In case a secrecy direction has been given in respect of an application under section 35, then, it shall be published after the expiry of the period of eighteen months or when the secrecy direction has ceased to operate, whichever is later.

(5) The publication 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.

(6) Upon publication of an application for a patent under this section—

(a) the depository institution shall make the biological material mentioned in the specification available to the public;

(b) the patent office may, on payment of such fee as may be prescribed, make the specification and drawings, if any, of such application available to the public.

11B. (1) No application for a patent shall be required to be examined unless the applicant or any other interested person makes a request in the prescribed manner for such examination within forty-eight months from the date of filing of the application for patent.

Request for
examination.

(2) In case of an application filed before the commencement of the Patents (Amendment) Act, 2002, a request in the prescribed manner for examination shall be made by the applicant or any other interested person within a period of twelve months from the date of such commencement or within forty-eight months from the date of the application, whichever is later.

(3) In case of an application in respect of a claim for a patent covered under sub-section (2) of section 5, a request in the prescribed manner for examination shall be made by the applicant or any other interested person within a period of twelve months from the 31st day of December, 2004 or within forty-eight months from the date of the application, whichever is later.

(4) In case the applicant or any other interested person does not make a request for examination of the application for a patent within the period as specified under sub-section (1) or sub-section (2) or sub-section (3), the application shall be treated as withdrawn by the applicant:

Provided that—

(i) the applicant may, at any time after the filing of the application but before the grant of the patent, withdraw the application made by him; and

(ii) in a case where a secrecy direction has been issued under section 35, the request for examination may be made within forty-eight months from the date of revocation of the secrecy direction."

Amendment
of section 12.

10. In section 12 of the principal Act,—

(a) in sub-section (1),—

(i) for the words "When the complete specification has been filed in respect of an application for a patent, the application and specification relating thereto", the words, brackets, figures and letter "When a request for examination has been made in respect of an application for a patent in the prescribed manner under sub-section (1) or sub-section (2) or sub-section (3) of section 11B, the application and specification and other documents relating thereto" shall be substituted;

(ii) in clause (a), for the words "specification relating thereto", the words "specification and other documents relating thereto" shall be substituted;

(b) in sub-section (2), for the words "specification relating thereto", the words "specification and other documents relating thereto" shall be substituted.

Amendment
of section 13.

11. In section 13 of the principal Act, in sub-section (2), the words "as the Controller may direct" shall be omitted.

Substitution of
new section
for section 15.

12. For section 15 of the principal Act, the following section shall be substituted, namely:—

Power of
Controller to
refuse or
require
amended
applications,
etc., in
certain cases.

"15. Where the Controller is satisfied that the application or any specification or any other document filed in pursuance thereof does not comply with the requirements of this Act or of any rules made thereunder, the Controller may require the application, specification or other document, as the case may be, to be amended to his satisfaction before he proceeds with the application or refuse the application on failure to do so."

Amendment
of section 17.

13. In section 17 of the principal Act, for sub-section (2), the following sub-section shall be substituted, namely:—

"(2) Where an application or specification (including drawings) or any other document is required to be amended under section 15, the application or specification or other document shall, if the Controller so directs, be deemed to have been made on the date on which the requirement is complied with or where the application or specification or other document is returned to the applicant, on the date on which it is refiled after complying with the requirement."

Amendment
of section 21.

14. In section 21 of the principal Act,—

(a) in sub-section (1), for the portion beginning with the words "fifteen months" and ending with the words "of this section", the words "twelve months from the date on which the first statement of objections to the application or complete specification or other documents relating thereto is forwarded to the applicant by the Controller," shall be substituted;

(b) sub-section (2) shall be omitted;

(c) in sub-section (3),—

(i) for the words, brackets and figure "fifteen months specified in sub-section (1) or the extended period", the words "twelve months" shall be substituted;

(ii) for the words "fifteen months or the extended period, as the case may be", the words "twelve months" shall be substituted;

(d) in sub-section (4), for the words "fifteen months, or as the case may be, the extended period, until the expiration of", the words "twelve months to" shall be substituted.

15. In section 22 of the principal Act, in the proviso, for the words "eighteen months", the words "twelve months" shall be substituted. Amendment of section 22.

16. In section 23 of the principal Act, for the words "filed in pursuance thereof", the words "as accepted by the Controller along with other documents filed by the applicant in pursuance thereof" shall be substituted. Amendment of section 23.

17. In section 24C of the principal Act,—

(a) in clause (c), for the word and figures "section 85", the word and figures "section 84" shall be substituted; Amendment of section 24C.

(b) for clause (d), the following clause shall be substituted, namely:—

"(d) clause (e) of sub-section (7) of section 84 shall be omitted."

18. In section 25 of the principal Act,—

(a) in sub-section (1), after clause (i), the following clauses shall be inserted, namely:— Amendment of section 25.

"(j) that the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention;

(k) that the invention so far as claimed in any claim of the complete specification is anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere,";

(b) in sub-section (2), for the words "shall give", the words "may, if so desired, give" shall be substituted;

(c) in sub-section (3), after the words "shall be taken of any", the words "personal document or secret trial or" shall be inserted.

19. In section 35 of the principal Act, in sub-section (1), the words "to any person or class of persons specified in the directions" shall be omitted. Amendment of section 35.

20. In section 36 of the principal Act, for sub-section (1), the following sub-section shall be substituted, namely:— Amendment of section 36.

"(1) The question whether an invention in respect of which directions have been given under section 35 continues to be relevant for defence purposes shall be reconsidered by the Central Government at intervals of twelve months or on a request made by the applicant which is found to be reasonable by the Controller and if, on such reconsideration it appears to the Central Government that the publication of the invention would no longer be prejudicial to the defence of India or in case of an application filed by a foreign applicant it is found that the invention is published outside India, it shall forthwith give notice to the Controller to revoke the direction and the Controller shall thereupon revoke the directions previously given by him."

- Insertion of new section 39.
Prohibition to apply, under certain circumstances, for patents relevant for defence purposes, etc.
21. After section 38 of the principal Act, the following section shall be inserted, namely:—
- “39. (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—
- (a) an application for a patent for the same invention has been made in India, not less than six weeks before the application outside India; and
- (b) either no direction has been given under sub-section (1) of section 35 in relation to the application in India, or all such directions have been revoked.
- (2) The Controller shall not grant written permission to any person to make any application outside India without the prior consent of the Central Government.
- (3) This section shall not apply in relation to an invention for which an application for protection has first been filed in a country outside India by a person resident outside India.”
- Amendment of section 40.
22. In section 40 of the principal Act, after the words and figures “under section 35”, the words and figures “or makes or causes to be made an application for grant of a patent outside India in contravention of section 39” shall be inserted.
- Amendment of section 43.
23. In section 43 of the principal Act, in sub-section (1),—
- (a) in clause (c), the word “or” shall be inserted at the end;
- (b) after clause (c), the following clause shall be inserted, namely:—
- “(d) the application has not been found to be in contravention of any of the provisions of the Act.”
- Amendment of section 45.
24. In section 45 of the principal Act, for sub-section (1), the following sub-section shall be substituted, namely:—
- “(1) Subject to the other provisions contained in this Act, every patent shall be dated as of the date on which the application for patent was filed.”
- Substitution of new section for section 48.
25. For section 48 of the principal Act, the following section shall be substituted, namely:—
- “48. Subject to the other provisions contained in this Act and the conditions specified in section 47, a patent granted under this Act shall confer upon the patentee—
- (a) where the subject matter of the patent is a product, the exclusive right to prevent third parties, who do not have his consent, from the act of making, using, offering for sale, selling or importing for those purposes that product in India;
- (b) where the subject matter of the patent is a process, the exclusive right to prevent third parties, who do not have his consent, from the act of using that process, and from the act of using, offering for sale, selling or importing for those purposes the product obtained directly by that process in India:
- Provided that the product obtained is not a product in respect of which no patent shall be granted under this Act.”
- Rights of patentees.
- Amendment of section 50.
26. In section 50 of the principal Act, in sub-section (2), for the words “make, use, exercise and sell the patented invention”, the words and figures “the rights conferred by section 48” shall be substituted.

27. In section 53 of the principal Act,—Amendment
of section 53.

(a) for sub-section (1), the following sub-section shall be substituted, namely:—

“(1) Subject to the provisions of this Act, the term of every patent granted, after the commencement of the Patents (Amendment) Act, 2002, and the term of every patent which has not expired and has not ceased to have effect, on the date of such commencement, under this Act, shall be twenty years from the date of filing of the application for the patent.”;

(b) after sub-section (3), the following sub-section shall be inserted, namely:—

“(4) Notwithstanding anything contained in any other law for the time being in force, on cessation of the patent right due to non-payment of renewal fee or on the expiry of the term of patent, the subject matter covered by the said patent shall not be entitled to any protection.”.

28. In section 57 of the principal Act,—Amendment
of section 57.

(a) in sub-section (1), after the word “specification” at both the places where it occurs, the words “or any document relating thereto” shall be inserted;

(b) in sub-section (2), for the words “or a specification”, the words “or a complete specification or any document relating thereto” shall be substituted;

(c) for sub-section (3), the following sub-section shall be substituted, namely:—

“(3) Any application for leave to amend an application for a patent or a complete specification or a document relating thereto under this section made after the acceptance of the complete specification and the nature of the proposed amendment may be advertised in the Official Gazette if the amendment, in the opinion of the Controller, is substantive.”;

(d) in sub-section (6),—

(i) after the words “amend his specification”, the words “or any document relating thereto” shall be inserted;

(ii) after the words “acceptance of the complete specification”, the words “along with other documents filed by the applicant” shall be inserted.

29. In section 59 of the principal Act,—Amendment
of section 59.

(i) for sub-section (1), the following sub-section shall be substituted, namely:—

“(1) No amendment of an application for a patent or a complete specification or any document relating thereto shall be made except by way of disclaimer, correction or explanation, and no amendment thereof shall be allowed, except for the purpose of incorporation of actual fact, and no amendment of a complete specification shall be allowed, the effect of which would be that the specification as amended would claim or describe matter not in substance disclosed or shown in the specification before the amendment, or that any claim of the specification as amended would not fall wholly within the scope of a claim of the specification before the amendment.”;

(ii) in sub-section (2),—

(a) for the words “complete specification, any amendment of the specification”, the words “complete specification along with other documents relating thereto, any amendment of the specification or any other document relating thereto” shall be substituted;

(b) in clause (a), for the word “specification”, the words “specification along with other documents relating thereto” shall be substituted;

(c) in clause (b), for the word “specification”, the words “specification or any other document relating thereto” shall be substituted.

Amendment
of section 60.

30. In section 60 of the principal Act,—

(a) in sub-section (1), for the words "one year", the words "eighteen months" shall be substituted;

(b) sub-section (2) shall be omitted.

Amendment
of section 64.

31. In section 64 of the principal Act,—

(a) in sub-section (1),—

(i) the proviso to clause (b) shall be omitted;

(ii) the proviso to clause (e) shall be omitted;

(iii) the proviso to clause (f) shall be omitted;

(iv) in clause (n), after the words and figures "under section 35", the words and figures "or made or caused to be made an application for the grant of a patent outside India in contravention of section 39" shall be inserted;

(v) after clause (o), the following clauses shall be inserted, namely:—

"(p) that the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention;

(q) that the invention so far as claimed in any claim of the complete specification was anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere.;"

(b) in sub-section (2), in clause (a), for the words "secret use", the words "personal document or secret trial or secret use" shall be substituted.

Amendment
of section 67.

32. In section 67 of the principal Act, for sub-section (4), the following sub-sections shall be substituted, namely:—

"(4) Notwithstanding anything contained in sub-section (1), it shall be lawful for the Controller to keep the register of patents or any part thereof in computer floppies, diskettes or any other electronic form subject to such safeguards as may be prescribed.

(5) Notwithstanding anything contained in the Indian Evidence Act, 1872, a copy of, or extracts from, the register of patents, certified to be a true copy under the hand of the Controller or any officer duly authorised by the Controller in this behalf shall, in all legal proceedings, be admissible in evidence. 1 of 1872.

(6) In the event the register is kept wholly or partly in computer floppies, diskettes or any other electronic form,—

(a) reference in this Act to an entry in the register shall be deemed to include reference to a record of particulars kept in computer floppies, diskettes or any other electronic form and comprising the register or part of the register;

(b) references in this Act to particulars being registered or entered in the register shall be deemed to include references to the keeping of record of those particulars comprising the register or part of the register in computer floppies, diskettes or any other electronic form; and

(c) references in this Act to the rectification of the register are to be read as including references to the rectification of the record of particulars kept in computer floppies, diskettes or any other electronic form and comprising the register or part of the register."

33. In section 68 of the principal Act, for the words "the Controller within six months from the commencement of this Act or the execution of the document, whichever is later or within such further period", the words "the Controller within six months from the execution of the document or within such further period" shall be substituted. Amendment of section 68.
34. In section 72 of the principal Act, after sub-section (2), the following sub-section shall be inserted, namely:— Amendment of section 72.
- "(3) If the record of particulars is kept in computer floppies or diskettes or in any other electronic form, sub-sections (1) and (2) shall be deemed to have been complied with if the public is given access to such computer floppies, diskettes or any other electronic form or printouts of such record of particulars for inspection."
- 43 of 1958. 35. In section 73 of the principal Act, in sub-section (1), for the words and figures "section 4 of the Trade and Merchandise Marks Act, 1958", the words and figures "section 3 of the Trade Marks Act, 1999" shall be substituted. Amendment of section 73.
- 47 of 1999.
36. In section 76 of the principal Act,— Amendment of section 76.
- (a) for the words "Central Government", the words "Central Government or Appellate Board" shall be substituted;
- (b) in clauses (a) and (b), the words and figures "or under the Indian Patents and Designs Act, 1911" shall respectively be omitted.
- 2 of 1911.
37. In section 78 of the principal Act, in sub-section (1), after the words "complete specifications", the words "or other documents relating thereto" shall be inserted. Amendment of section 78.
38. In section 80 of the principal Act, the following proviso shall be inserted at the end, namely:— Amendment of section 80.
- "Provided that the party desiring a hearing makes the request for such hearing to the Controller at least ten days in advance of the expiry of the time-limit specified in respect of the proceeding."
39. For Chapter XVI of the principal Act, the following Chapter shall be substituted, namely:— Substitution of new Chapter for Chapter XVI.

CHAPTER XVI

WORKING OF PATENTS, COMPULSORY LICENCES AND REVOCATION

82. In this Chapter, unless the context otherwise requires,— Definitions of "patented articles" and "patentee".
- (a) "patented article" includes any article made by a patented process; and
- (b) "patentee" includes an exclusive licensee.
83. Without prejudice to the other provisions contained in this Act, in exercising the powers conferred by this Chapter, regard shall be had to the following general considerations, namely:— General principles applicable to working of patented inventions.
- (a) that patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay;
- (b) that they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article;
- (c) that the protection and enforcement of patent rights contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations;

(d) that patents granted do not impede protection of public health and nutrition and should act as instrument to promote public interest specially in sectors of vital importance for socio-economic and technological development of India;

(e) that patents granted do not in any way prohibit Central Government in taking measures to protect public health;

(f) that the patent right is not abused by the patentee or person deriving title or interest on patent from the 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

(g) that patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public.

Compulsory
licences.

84. (1) At any time after the expiration of three years from the date of the sealing of a patent, any person interested may make an application to the Controller for grant of compulsory licence on patent on any of the following grounds, namely:—

(a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or

(b) that the patented invention is not available to the public at a reasonably affordable price, or

(c) that the patented invention is not worked in the territory of India.

(2) An application under this section may be made by any person notwithstanding that he is already the holder of a licence under the patent and no person shall be estopped from alleging that the reasonable requirements of the public with respect to the patented invention are not satisfied or that the patented invention is not worked in the territory of India or that the patented invention is not available to the public at a reasonably affordable price by reason of any admission made by him, whether in such a licence or otherwise or by reason of his having accepted such a licence.

(3) Every application under sub-section (1) shall contain a statement setting out the nature of the applicant's interest together with such particulars as may be prescribed and the facts upon which the application is based.

(4) The Controller, if satisfied that the reasonable requirements of the public with respect to the patented invention have not been satisfied or that the patented invention is not worked in the territory of India or that the patented invention is not available to the public at a reasonably affordable price, may grant a licence upon such terms as he may deem fit.

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

(6) In considering the application filed under this section, the Controller shall take into account,—

(i) the nature of the invention, the time which has elapsed since the sealing of the patent and the measures already taken by the patentee or any licensee to make full use of the invention;

(ii) the ability of the applicant to work the invention to the public advantage;

(iii) the capacity of the applicant to undertake the risk in providing capital and working the invention, if the application were granted;

(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 this 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.

(7) For the purposes of this Chapter, the reasonable requirements of the public shall be deemed not to have been satisfied—

(a) if, by reason of the refusal of the patentee to grant a licence or licences on reasonable terms,—

(i) an existing trade or industry or the development thereof or the establishment of any new trade or industry in India or the trade or industry of any person or class of persons trading or manufacturing in India is prejudiced; or

(ii) the demand for the patented article has not been met to an adequate extent or on reasonable terms; or

(iii) a market for export of the patented article manufactured in India is not being supplied or developed; or

(iv) the establishment or development of commercial activities in India is prejudiced; or

(b) if, by reason of conditions imposed by the patentee upon the grant of licences under the patent or upon the purchase, hire or use of the patented article or process, the manufacture, use or sale of materials not protected by the patent, or the establishment or development of any trade or industry in India, is prejudiced; or

(c) if the patentee imposes a condition upon the grant of licences under the patent to provide exclusive grant back, prevention to challenges to the validity of patent or coercive package licensing, or

(d) if the patented invention is not being worked in the territory of India on a commercial scale to an adequate extent or is not being so worked to the fullest extent that is reasonably practicable, or

(e) if the working of the patented invention in the territory of India on a commercial scale is being prevented or hindered by the importation from abroad of the patented article by—

(i) the patentee or persons claiming under him, or

(ii) persons directly or indirectly purchasing from him; or

(iii) other persons against whom the patentee is not taking or has not taken proceedings for infringement.

85. (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 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 of the public with respect to the patented invention has not been satisfied or that the patented invention is not available to the public at a reasonably affordable price.

Revocation of patents by the Controller for non-working.

(2) Every application under sub-section (1) shall contain such particulars as may be prescribed, the facts upon which the application is based, and, in the case of an application other than by the Central Government, shall also set out the nature of the applicant's interest.

(3) The Controller, if satisfied that the reasonable requirements of the public with respect to the patented invention have 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.

(4) Every application under sub-section (1) shall ordinarily be decided within one year of its being presented to the Controller.

86. (1) Where an application under section 84 or section 85, as the case may be, is made on the grounds that the patented invention has not been worked in the territory of India or on the ground mentioned in clause (d) of sub-section (7) of section 84 and the Controller is satisfied that the time which has elapsed since the sealing of the patent has for any reason been insufficient to enable the invention to be worked on a commercial scale to an adequate extent or to enable the invention to be so worked to the fullest extent that is reasonably practicable, he may, by order, adjourn the further hearing of the application for such period not exceeding twelve months in the aggregate as appears to him to be sufficient for the invention to be so worked:

Provided that in any case where the patentee establishes that the reason why a patented invention could not be worked as aforesaid before the date of the application was due to any State or Central Act or any rule or regulation made thereunder or any order of the Government imposed otherwise than by way of a condition for the working of the invention in the territory of India or for the disposal of the patented articles or of the articles made by the process or by the use of the patented plant, machinery, or apparatus, then, the period of adjournment ordered under this sub-section shall be reckoned from the date on which the period during which the working of the invention was prevented by such Act, rule or regulation or order of Government as computed from the date of the application, expires.

(2) No adjournment under sub-section (1) shall be ordered unless the Controller is satisfied that the patentee has taken with promptitude adequate or reasonable steps to start the working of the invention in the territory of India on a commercial scale and to an adequate extent.

87. (1) Where the Controller is satisfied, upon consideration of an application under section 84, or section 85, that a *prima facie* case has been made out for the making of an order, he shall direct the applicant to serve copies of the application upon the patentee and any other person appearing from the register to be interested in the patent in respect of which the application is made, and shall advertise the application in the Official Gazette.

(2) The patentee or any other person desiring to oppose the application may, within such time as may be prescribed or within such further time as the Controller may on application (made either before or after the expiration of the prescribed time) allow, give to the Controller notice of opposition.

(3) Any such notice of opposition shall contain a statement setting out the grounds on which the application is opposed.

(4) Where any such notice of opposition is duly given, the Controller shall notify the applicant, and shall give to the applicant and the opponent an opportunity to be heard before deciding the case.

88. (1) Where the Controller is satisfied on an application made under section 84 that the manufacture, use or sale of materials not protected by the patent is prejudiced by reason of conditions imposed by the patentee upon the grant of licences under the patent, or upon the purchase, hire or use of the patented article or process, he may, subject to the provisions of that section, order the grant of licences under the patent to such customers of the applicant as he thinks fit as well as to the applicant.

(2) Where an application under section 84 is made by a person being the holder of a licence under the patent, the Controller may, if he makes an order for the grant of

Power of Controller to adjourn applications for compulsory licences, etc., in certain cases.

Procedure for dealing with applications under sections 84 and 85.

Powers of Controller in granting compulsory licences.

a licence to the applicant, order the existing licence to be cancelled, or may, if he thinks fit, instead of making an order for the grant of a licence to the applicant, order the existing licence to be amended.

(3) Where two or more patents are held by the same patentee and an applicant for a compulsory licence establishes that the reasonable requirements of the public have not been satisfied with respect to some only of the said patents, then, if the Controller is satisfied that the applicant cannot efficiently or satisfactorily work the licence granted to him under those patents without infringing the other patents held by the patentee and if those patents involve important technical advancement of considerable economic significance in relation to the other patents, he may, by order, direct the grant of a licence in respect of the other patents also to enable the licensee to work the patent or patents in regard to which a licence is granted under section 84.

(4) Where the terms and conditions of a licence have been settled by the Controller, the licensee may, at any time after he has worked the invention on a commercial scale for a period of not less than twelve months, make an application to the Controller for the revision of the terms and conditions on the ground that the terms and conditions settled have proved to be more onerous than originally expected and that in consequence thereof the licensee is unable to work the invention except at a loss:

Provided that no such application shall be entertained a second time.

89. The powers of the Controller upon an application made under section 84 shall be exercised with a view to securing the following general purposes, that is to say,—

General purposes for granting compulsory licences.

(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;

(b) that the interests of any person for the time being working or developing an invention in the territory of India under the protection of a patent are not unfairly prejudiced.

90. (1) In settling the terms and conditions of a licence under section 84, the Controller shall endeavour to secure—

Terms and conditions of compulsory licences.

(i) that the royalty and other remuneration, if any, reserved to the patentee or other person beneficially entitled to the patent, is reasonable, having regard to the nature of the invention, the expenditure incurred by the patentee in making the invention or in developing it and obtaining a patent and keeping it in force and other relevant factors;

(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;

(iii) that the patented articles are made available to the public at reasonably affordable prices;

(iv) that the licence granted is a non-exclusive licence;

(v) that the right of the licensee is non-assignable;

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

(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.

(2) No licence granted by the Controller shall authorise the licensee to import the patented article or an article or substance made by a patented process from abroad

where such importation would, but for such authorisation, constitute an infringement of the rights of the patentee.

(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 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 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.

Licensing of
related patents.

91. (1) Notwithstanding anything contained in the other provisions of this Chapter, at any time after the sealing of a patent, any person who has the right to work any other patented invention either as patentee or as licensee thereof, exclusive or otherwise, may apply to the Controller for the grant of a licence of the first-mentioned patent on the ground that he is prevented or hindered without such licence from working the other invention efficiently or to the best advantage possible.

(2) No order under sub-section (1) shall be made unless the Controller is satisfied—

(i) that the applicant is able and willing to grant, or procure the grant to the patentee and his licensees if they so desire, of a licence in respect of the other invention on reasonable terms; and

(ii) that the other invention has made a substantial contribution to the establishment or development of commercial or industrial activities in the territory of India.

(3) When the Controller is satisfied that the conditions mentioned in sub-section (1) have been established by the applicant, he may make an order on such terms as he thinks fit granting a licence under the first-mentioned patent and a similar order under the other patent if so requested by the proprietor of the first-mentioned patent or his licensee:

Provided that the licence granted by the Controller shall be non-assignable except with the assignment of the respective patents.

(4) The provisions of sections 87, 88, 89 and 90 shall apply to licences granted under this section as they apply to licences granted under section 84.

Special
provision for
compulsory
licences on
notifications
by Central
Government.

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,—

(i) the Controller shall, on application made at any time after the notification by any person interested, grant to the applicant a licence under the patent on such terms and conditions as he thinks fit;

(ii) 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 consistent 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 sub-section (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; or
- (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, including public health crises, relating to Acquired Immune Deficiency Syndrome, human immunodeficiency 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.

93. Any order for the grant of a licence under this Chapter shall operate as if it were a deed granting a licence executed by the patentee and all other necessary parties embodying the terms and conditions, if any, settled by the Controller.

Order for licence to operate as a deed between parties concerned.

94. (1) On an application made by the patentee or any other person deriving title or interest in the patent, a compulsory licence granted under section 84 may be terminated by the Controller, if and when the circumstances that gave rise to the grant thereof no longer exist and such circumstances are unlikely to recur:

Termination of compulsory licence.

Provided that the holder of the compulsory licence shall have the right to object to such termination.

(2) While considering an application under sub-section (1), the Controller shall take into account that the interest of the person who had previously been granted the licence is not unduly prejudiced."

40. In section 99 of the principal Act, sub-section (2) shall be omitted.

Amendment of section 99.

41. In section 100 of the principal Act,—

Amendment of section 100.

(a) in sub-section (3), for the proviso, the following proviso shall be substituted, namely:—

"Provided that in case of any such use of any patent, the patentee shall be paid not more than adequate remuneration in the circumstances of each case, taking into account the economic value of the use of the patent."

(b) in sub-section (3), for the words "unless it appears to the Government that it would be contrary to the public interest so to do", the words "except in case of national emergency or other circumstances of extreme urgency or for non-commercial use" shall be substituted;

(c) in sub-section (6), for the words "right to sell the goods", the words "right to sell, on non-commercial basis, the goods" shall be substituted.

42. In section 101 of the principal Act,—

Amendment of section 101.

(a) in sub-section (1),—

(i) the words " , whether before or after the commencement of this Act," shall be omitted;

(ii) the brackets and words "(including payments by way of minimum royalty)" shall be omitted;

(b) in sub-section (2), the brackets and words "(including payments by way of minimum royalty)" shall be omitted;

(c) in sub-section (3), in clause (b), the words "(including payments by way of minimum royalty)" shall be omitted.

Insertion of new section 104A.

43. After section 104 of the principal Act, the following section shall be inserted, namely:—

Burden of proof in case of suits concerning infringement.

"104A. (1) In any suit for infringement of a patent, where the subject matter of patent is a process for obtaining a product, the court may direct the defendant to prove that the process used by him to obtain the product, identical to the product of the patented process, is different from the patented process if,—

(a) the subject matter of the patent is a process for obtaining a new product; or

(b) there is a substantial likelihood that the identical product is made by the process, and the patentee or a person deriving title or interest in the patent from him, has been unable through reasonable efforts to determine the process actually used:

Provided that the patentee or a person deriving title or interest in the patent from him, first proves that the product is identical to the product directly obtained by the patented process.

(2) In considering whether a party has discharged the burden imposed upon him by sub-section (1), the court shall not require him to disclose any manufacturing or commercial secrets, if it appears to the court that it would be unreasonable to do so."

Insertion of new section 107A.

44. After section 107 of the principal Act, the following section shall be inserted, namely:—

Certain acts not to be considered as infringement.

"107A. For the purposes of this Act,—

(a) any act of making, constructing, using or selling a patented invention solely for uses reasonably relating 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, 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."

Amendment of section 108.

45. Section 108 of the principal Act shall be numbered as sub-section (1) thereof, and after sub-section (1) as so numbered, the following sub-section shall be inserted, namely:—

"(2) The court may also order that the goods which are found to be infringing and materials and implement, the predominant use of which is in the creation of infringing goods shall be seized, forfeited or destroyed, as the court deems fit under the circumstances of the case without payment of any compensation."

Omission of section 112.

46. Section 112 of the principal Act shall be omitted.

Substitution of new Chapter for Chapter XIX.

47. For Chapter XIX of the principal Act, the following Chapter shall be substituted, namely:—

"CHAPTER XIX
APPEALS TO THE APPELLATE BOARD

47 of 1999. 116. (1) Subject to the provisions of this Act, the Appellate Board established under section 83 of the Trade Marks Act, 1999 shall be the Appellate Board for the purposes of this Act and the said Appellate Board shall exercise the jurisdiction, power and authority conferred on it by or under this Act: Appellate Board.

Provided that the Technical Member of the Appellate Board for the purposes of this Act shall have the qualifications specified in sub-section (2).

(2) A person shall not be qualified for appointment as a Technical Member for the purposes of this Act unless he—

(a) has, at least five years, held the post of Controller under this Act or has exercised the functions of the Controller under this Act for at least five years; or

(b) has, for at least ten years, functioned as a Registered Patent Agent and possesses a degree in engineering or technology or a masters degree in science from any University established under law for the time being in force or equivalent; or

(c) has, for at least ten years, been an advocate of a proven specialised experience in practising law relating to patents and designs.

117. (1) The Central Government shall determine the nature and categories of the officers and other employees required to assist the Appellate Board in the discharge of its functions under this Act and provide the Appellate Board with such officers and other employees as it may think fit. Staff of Appellate Board.

(2) The salaries and allowances and conditions of service of the officers and other employees of the Appellate Board shall be such as may be prescribed.

(3) The officers and other employees of the Appellate Board shall discharge their functions under the general superintendence of the Chairman of the Appellate Board in the manner as may be prescribed.

117A. (1) Save as otherwise expressly provided in sub-section (2), no appeal shall lie from any decision, order or direction made or issued under this Act by the Central Government, or from any act or order of the Controller for the purpose of giving effect to any such decision, order or direction. Appeals to Appellate Board.

(2) An appeal shall lie to the Appellate Board from any decision, order or direction of the Controller or Central Government under section 15, section 16, section 17, section 18, section 19, section 20, section 25, section 27, section 28, section 51, section 54, section 57, section 60, section 61, section 63, section 66, sub-section (3) of section 69, section 78, sub-sections (1) to (5) of section 84, section 85, section 88, section 91, section 92 and section 94.

(3) Every appeal under this section shall be in the prescribed form and shall be verified in such manner as may be prescribed and shall be accompanied by a copy of the decision, order or direction appealed against and by such fees as may be prescribed.

(4) Every appeal shall be made within three months from the date of the decision, order or direction, as the case may be, of the Controller or the Central Government or within such further time as the Appellate Board may, in accordance with the rules made by it, allow.

47 of 1999. 117B. The provisions of sub-sections (2) to (6) of section 84, section 87, section 92, section 95 and section 96 of the Trade Marks Act, 1999 shall apply to the Appellate Board in the discharge of its functions under this Act as they apply to it in the discharge of its functions under the Trade Marks Act, 1999. Procedure and powers of Appellate Board.

Bar of jurisdiction of courts, etc.

117C. No court or other authority shall have or, be entitled to, exercise any jurisdiction, powers or authority in relation to the matters referred to in sub-section (2) of section 117A or section 117D.

Procedure for application for rectification, etc., before Appellate Board.

117D. (1) An application for rectification of the register made to the Appellate Board under section 71 shall be in such form as may be prescribed.

(2) A certified copy of every order or judgment of the Appellate Board relating to a patent under this Act shall be communicated to the Controller by the Board and the Controller shall give effect to the order of the Board and shall, when so directed, amend the entries in, or rectify, the register in accordance with such order.

Appearance of Controller in legal proceedings.

117E. (1) The Controller shall have the right to appear and be heard—

(a) in any legal proceedings before the Appellate Board in which the relief sought includes alteration or rectification of the register or in which any question relating to the practice of the patent office is raised;

(b) in any appeal to the Appellate Board from an order of the Controller on an application for grant of a patent—

(i) which is not opposed, and the application is either refused by the Controller or is accepted by him subject to any amendments, modifications, conditions or limitations, or

(ii) which has been opposed and the Controller considers that his appearance is necessary in the public interest,

and the Controller shall appear in any case if so directed by the Appellate Board.

(2) Unless the Appellate Board otherwise directs, the Controller may, in lieu of appearing, submit a statement in writing signed by him, giving such particulars as he thinks proper of the proceedings before him relating to the matter in issue or of the grounds of any decision given by him or of the practice of the patent office in like cases, or of other matters relevant to the issues and within his knowledge as the Controller may deem it necessary, and such statement shall be evidence in the proceeding.

Costs of Controller in proceedings before Appellate Board.

117F. In all proceedings under this Act before the Appellate Board, the costs of the Controller shall be in the discretion of the Board, but the Controller shall not be ordered to pay the costs of any of the parties.

Transfer of pending proceedings to Appellate Board.

117G. All cases of appeals against any order or decision of the Controller and all cases pertaining to rectification of register, pending before any High Court, shall be transferred to the Appellate Board from such date as may be notified by the Central Government in the Official Gazette and the Appellate Board may proceed with the matter either *de novo* or from the stage it was so transferred.

Power of Appellate Board to make rules.

117H. The Appellate Board may make rules consistent with this Act as to the conduct and procedure in respect of all proceedings before it under this Act.

Amendment of section 118.

48. In section 118 of the principal Act, after the words and figures "under section 35", the words and figures "or makes or causes to be made an application for the grant of a patent in contravention of section 39" shall be inserted.

Amendment of section 120.

49. In section 120 of the principal Act, for the words "five hundred rupees", the words "ten thousand rupees" shall be substituted.

Amendment of section 122.

50. In section 122 of the principal Act, in sub-section (1), for the words "one thousand rupees", the words "twenty thousand rupees" shall be substituted.

51. In section 123 of the principal Act,—
- Amendment
of section
123.
- (a) for the words "five hundred rupees", the words "ten thousand rupees" shall be substituted;
- (b) for the words "two thousand rupees", the words "forty thousand rupees" shall be substituted.
52. For section 125 of the principal Act, the following section shall be substituted, namely:—
- Substitution
of new
section for
section 125.
- "125. (1) The Controller shall maintain a register to be called the register of patent agents in which shall be entered the names, addresses and other relevant particulars, as may be prescribed, of all persons qualified to have their names so entered under section 126.
- Register of
patent agents.
- (2) Notwithstanding anything contained in sub-section (1), it shall be lawful for the Controller to keep the register of patent agents in computer floppies, diskettes or any other electronic form subject to such safeguards as may be prescribed."
53. In section 126 of the principal Act,—
- Amendment
of section
126.
- (a) in sub-section (1),—
- (i) in clause (c),—
- (A) for the words "degree from any University", the words "degree in science, engineering or technology from any University established under law for the time being in force" shall be substituted;
- (B) in sub-clause (ii), the word "or" shall be inserted at the end;
- (ii) after sub-clause (ii), the following sub-clause shall be inserted, namely:—
- "(iii) has, for a total period of not less than ten years, functioned either as an examiner or discharged the functions of the Controller under section 73 or both, but ceased to hold any such capacity at the time of making the application for registration;"
- (b) for sub-section (2), the following sub-section shall be substituted, namely:—
- "(2) Notwithstanding anything contained in sub-section (1), a person who has been registered as a patent agent before the commencement of the Patents (Amendment) Act, 2002 shall be entitled to continue to be, or when required to be re-registered, as a patent agent, on payment of the fees as may be prescribed."
54. In section 128 of the principal Act,—
- Amendment
of section
128.
- (a) in sub-section (1), the words "Subject to the provisions contained in sub-section (2) and to any rules made under this Act," shall be omitted;
- (b) sub-section (2) shall be omitted.
55. In section 130 of the principal Act,—
- Amendment
of section
130.
- (a) for the words "Central Government" wherever they occur, the word "Controller" shall be substituted;
- (b) in sub-section (1), for the word "it" at both the places where it occurs, the word "he" shall be substituted.
56. In section 132 of the principal Act,—
- Amendment
of section
132.

(a) in clause (a), the words "or any person, not being a patent agent, who is duly authorised by the applicant" shall be omitted;

(b) in clause (b), for the words "proceedings under this Act, otherwise than by way of drafting any specification", the words "hearing before the Controller on behalf of a party who is taking part in any proceeding under this Act" shall be substituted.

Amendment
of section
133.

57. In section 133 of the principal Act, the following *Explanation* shall be inserted at the end, namely:—

Explanation.—For the purposes of this Chapter "country" includes a group or union of countries or Inter-governmental organisation.

Amendment
of section
138.

58. In section 138 of the principal Act,—

(a) in sub-section (1), after the words "shall furnish," the words "when required by the Controller," shall be inserted;

(b) in sub-section (2), for the words "annexed to the specification or document", the words "furnished when required by the Controller" shall be substituted;

(c) after sub-section (3), the following sub-sections shall be inserted, namely:—

"(4) An international application filed under the Patent Cooperation Treaty designating India shall have effect of filing an application for patent under section 7, section 54 and section 135, as the case may be, and the title, description, claim and abstract and drawings, if any, filed in the international application shall be taken as complete specification for the purposes of this Act.

(5) The filing date of an application for patent and its complete specification processed by the patent office as designated office shall be the international filing date accorded under the Patent Cooperation Treaty.

(6) Amendment, if any, proposed by the applicant for an international application designating India or designating and electing India before international searching authority or preliminary examination authority shall, if the applicant so desires, be taken as an amendment made before the patent office."

Amendment
of section
140.

59. In section 140 of the principal Act,—

(a) in sub-section (1), in clause (iii), after sub-clause (c), the following sub-clause shall be inserted, namely:—

"(d) to provide exclusive grant back, prevention to challenges to validity of patent and coercive package licensing,";

(b) sub-section (5) shall be omitted.

Amendment
of section
141.

60. In section 141 of the principal Act, in sub-section (1), the words, "whether made before or after the commencement of this Act," shall be omitted.

Amendment
of section
142.

61. In section 142 of the principal Act,—

(a) for sub-section (3), the following sub-section shall be substituted, namely:—

"(3) Where a fee is payable in respect of the filing of a document at the patent office, the fee shall be paid along with the document or within the prescribed time and the document shall be deemed not to have been filed at the office if the fee has not been paid within such time,";

(b) in sub-section (4), the words "or within the extended period not later than nine months from the date of recording" shall be inserted at the end.

62. In section 143 of the principal Act, for the words "or be open to public inspection at any time before the date of advertisement of acceptance of the application", the words "before eighteen months from the date of application or the priority date of the application or before the same is open to public inspection" shall be substituted.

Amendment of section 143.

63. For section 157A of the principal Act, the following section shall be substituted, namely:—

Substitution of new section for section 157A.

'157A. Notwithstanding anything contained in this Act, the Central Government shall—

Protection of security of India.

(a) not disclose any information relating to any patentable invention or any application relating to the grant of patent under this Act, which it considers prejudicial to the interest of the security of India;

(b) take any action including the revocation of any patent which it considers necessary in the interest of the security of India by issue of a notification in the Official Gazette to that effect.

Explanation.—For the purposes of this section, the expression "security of India" includes any action necessary for the security of India which—

(i) relates to fissionable materials or the materials from which they are derived; or

(ii) relates to the traffic in arms, ammunition and implements of war and to such traffic in other goods and materials as is carried on directly or indirectly for the purpose of supplying a military establishment; or

(iii) is taken in time of war or other emergency in international relations.'

64. In section 159 of the principal Act, in sub-section (2),—

Amendment of section 159.

(a) after clause (i), the following clauses shall be inserted, namely:—

"(ia) the details to be furnished by the applicant under sub-section (2) of section 8;

(ib) the manner of making the request for examination of an application for patent under sub-sections (1), (2) and (3) of section 11B;"

(b) in clause (iii), after the word "manner", the words "and time" shall be inserted;

(c) in clause (ix), after the word "patents", the words "and the safeguards to be observed in the maintenance of such register in computer floppies, diskettes or any other electronic form" shall be inserted;

(d) after clause (xii), the following clauses shall be inserted, namely:—

"(xiiia) the salaries and allowances and other conditions of service of the officers and other employees of the Appellate Board under sub-section (2), and the manner in which the officers and other employees of the Appellate Board shall discharge their functions under sub-section (3), of section 117;

(xiiib) the form of making an appeal, the manner of verification and the fees payable under sub-section (3) of section 117A;

(xiiic) the form in which, and the particulars to be included in, the application to the Appellate Board under sub-section (1) of section 117D;"

(e) in clause (xiv), after the word "maintained", the words, brackets and figures "under sub-section (1) of section 125 and the safeguards to be observed in the

maintenance of such register of patent agents on computer floppies, diskettes or any other electronic form under sub-section (2) of that section" shall be inserted

Omission of
section 161.

65. Section 161 of the principal Act shall be omitted.

Amendment
of section
162.

66. In section 162 of the principal Act, sub-sections (2) and (3) shall be omitted.

SUBHASH C. JAIN,
Secy. to the Govt. of India.

Hiermit erkläre ich an Eides statt, die Arbeit selbständig verfasst und keine anderen als die angegebenen Hilfsmittel verwendet zu haben.

Viraj Mehta