PARLIAMENT OF INDIA RAJYA SABHA

DEPARTMENT RELATED PARLIAMENTARY STANDING COMMITTEE ON COMMERCE

EIGHTY EIGHTH REPORT

ON

PATENTS AND TRADE MARKS SYSTEMS IN INDIA

(PRESENTED TO THE RAJYA SABHA ON THE 24TH OCTOBER, 2008) (LAID ON THE TABLE OF THE LOK SABHA ON THE 24TH OCTOBER, 2008)

> RAJYA SABHA SECRETARIAT NEW DELHI

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CONTENTS

PAGES

- 1. COMPOSITION OF THE COMMITTEE
- 2. PREFACE
- 3. <u>REPORT</u>
 - Chapter I. Introduction Chapter II. Written and Oral Submissions: Central Ministries/Departments Chapter III. Written and Oral Submissions: Individuals/ Organisations Chapter IV. Study Visits Chapter V. Observations and Recommendations
- 4. OBSERVATIONS AND RECOMMENDATIONS AT A GLANCE
- 5. APPENDIX
- 6. <u>ANNEXURES</u>
 - (i) Note by Sh. B. K. Keayla of the Centre for Study of Global Trade System and Development
 - (ii) Note by Ms. Krishna Sarma, Managing Partner, Corporate Law Group
 - (III) Note by Lawyers Collective/HIV Aids
 - (iv) Note by Shri Gajanan Wakankar, Executive Director, Indian Drug Manufacturers Association (IDMA), Mumbai
 - (v) Note by Ms. Leena Menghaney, Campaign for Access to Essential Medicines
 - (VI) Note by Dr. S. Vedaraman, Controller General of Patents, Designs and Trade Marks (Retd.)
 - (VII) Note by National Law University, Jodhpur
 - (VIII) Note by MAKs on Improving the Patents Systems India
 - (ix) Note by Organisation of Pharmaceutical Producers of India (OPPI) Patentability
 - (X) Note by Justice V. K. Krishna Iyer (Former Judge, Supreme Court)
- 7. <u>MINUTES</u>

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** Nominated w.e.f 11th December, 2006

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- Shri Mohammed Amin
- Shri Y.P. Trivedi 9. Shri Parimal Nathwani
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- Shri Sarvananda Sonowal
 Shri Braja Kishore Tripathy
- 31. Shri Balashowry Vallabhaneni

SECRETARIAT

Shri Ravi Kant Chopra, JS & FA Shri Surinder Kumar Watts, Director Shri M.K. Khan, Deputy Director Smt. Indira Chaturvedi Vaidya, Committee Officer

PREFACE

I, the Chairman of the Department Related Parliamentary Standing Committee on Commerce, having been authorised by the Committee, present this Eightyeighth Report of the Committee on the Patents and Trade Marks Systems in India.

2. The Department Related Parliamentary Standing Committee on Commerce took up for an indepth study the subject of Patents and Trade Marks Systems in India on 12th June, 2006. The Committee held discussions with the Secretary, Department of Industrial Policy and Promotion (IPP). It also heard the views of the representatives of the various Ministries/Departments and Individuals/Organisations. It considered the information on the subject supplied by the Department of IPP, Ministry of Commerce and Industry, Ministry of Health and Family and Welfare, Ministry of Science and Technology besides the other papers/documents received during the course of deliberations on the subject. The Committee held a total number of nine sittings. The Committee visited Kolkata and Chennai from 8th to 11th July, 2006, Ahmedabad, and Mumbai from 6th to 13th November, 2006 and Intellectual Property Office, Dwarka, New Delhi on 6th June, 2007 for on-the-spot visits on the subject.

3. The Committee considered and adopted this report at its sitting held on 26th September, 2008.

NEW DELHI; September 26, 2008 DR.MURLI MANOHAR JOSHI, Chairman, Department Related Parliamentary Standing Committee on Commerce

CHAPTER-I

INTRODUCTION

**History of Patents and Trade Marks System in India

Patents Systems

1.1 The first legislation in India relating to patents was Act VI of 1856. The objective of this legislation was to encourage inventions of new and useful manufactures and to induce inventors to disclose secret of their inventions. The Act was subsequently repealed by Act IX of 1857, since it had been enacted without the approval of the British Crown. Fresh legislation for granting exclusive privileges was introduced in 1859, as Act XV of 1859. This Act was based on the United Kingdom Act of 1852, with certain departures, which included allowing assignees to make application in India and also taking prior public use or publication in India or United Kingdom for the purpose of ascertaining novelty.

The Act of 1859 was consolidated in 1872, to provide protection relating to designs. It was renamed as The 1.2 Patents and Designs Protection Act under Act XIII of 1872. The Act of 1872 was further amended in 1883 (XVI of 1883), to introduce a provision to protect novelty of an invention, which prior to making application for their protection were disclosed in the Exhibition of India. This Act remained in force for about 30 years, without any change, but in the year 1883, certain modifications in the patent law were made in United Kingdom and it was considered that those modifications should also incorporated in the Indian be

^{**} Source : Website of Department of Industrial Policy and Promotion

law. In 1888, an Act was introduced to consolidate and amend the law relating to invention and designs, in conformity with the amendments made in the U.K. law.

1.3 The Indian Patents and Designs Act, 1911, (Act II of 1911) replaced all the previous Acts. This Act brought patent administration under the management of Controller of Patents for the first time. This Act was further amended in 1920, to enter into reciprocal arrangements with UK and other countries, for securing priority. In 1930, further amendments were made to incorporate, *inter-alia*, provisions relating to grant of secret patents, patent of addition, use of invention by Government, powers of the Controller to rectify register of patent and increase in the term of the patent from 14 years to 16 years. In 1945, an amendment was made to provide for filing of provisional specification and submission of complete specification within nine months.

1.4 Another amendment was made in 1950(Act XXXII of 1950) in relation to working of inventions and compulsory licence/revocation. Other provisions were related to endorsement of the patent with the words 'licence of right' on an application by the Government, so that the Controller could grant compulsory licences. In 1952 (Act LXX of 1952), an amendment was made to provide compulsory licence in relation to patents in respect of food and medicines, insecticides, germicides or fungicides and a process for producing substance or any invention relating to surgical or curative devices. A new Act, viz., the Patents Act, 1970 was passed after in-depth consideration by Parliamentary Committee and extensive debate in both Houses of Parliament. This Act repealed and replaced the 1911 Act, so far as the patents law was concerned. However, the 1911 Act continued to be applicable to designs. Most of the provisions of the 1970 Act were brought into force on 20th April, 1972, with publication of the Patent Rules, 1972.

1.5 This Act remained in force for about 24 years, without any change, till December 1994. An ordinance effecting certain changes in the Act was issued on 31st December, 1994, to satisfy the transitional period requirements of TRIPS Agreement of WTO which ceased to operate after six months. Subsequently, another ordinance on the exact lines of December ordinance of 1994 was issued in 1999. This ordinance was subsequently replaced by the Patents (Amendment) Act, 1999, that was brought into force retrospectively from 1st January, 1995. The amended Act provided for filing of applications for product patents in the areas of drugs, pharmaceuticals and agro chemicals, though such patents were not allowed under Patents Act, 1970. However, such applications for grant or rejection of patents were to be examined only after 31st December, 2004. Meanwhile, the applicants could be allowed Exclusive Marketing Rights (EMR) for 5 years, to sell or distribute these products in India, subject to fulfillment of certain conditions specified in the Patents (Amendment) Act, 1999.

1.6 The second amendment to the 1970 Act was made through the Patents (Amendment) Act, 2002 (Act 38 0f 2002) after consideration and report by a Joint Parliamentary Committee. This Act came into force on the 20th May, 2003, with the introduction of new Patent Rules, 2003, by replacing the earlier Patent Rules, 1972

1.7 The third amendment to the Patents Act, 1970 was introduced through the Patents (Amendment) Ordinance,

2004, w.e.f. 1st January, 2005. This Ordinance was later replaced by the Patents (Amendment) Act 2005 (Act 15 of http://164.100.47.5/newcommittee/reports/EnglishCommittees/Committee%20on%20Commerce/88th%20Report.htm 5/92

2005) on 4th April, 2005, which was brought into force w.e.f 1st January, 2005. The relevant Bill was not referred to

any Parliamentary Committee.

Salient Features of the amended Patents Law

- 1.8 The salient features of the existing patents law are as under:
 - i) Product and process patent protection for all inventions, except those prohibited specifically.
 - ii) Term of patent to be 20 years from date of patent application.
 - iii) Rights of patentees include importation.
 - iv) Comprehensive provisions for working of Patents, Compulsory Licences and Revocation.
 - v) Mandatory publication of applications after 18 months of filing, with option for early publication, on request by applicant.
 - vi) Examination of application on request by applicant or third party.
 - vii) Provision of both pre-grant and post-grant opposition to grant of patents.
 - viii) Protection of bio-diversity and traditional knowledge.
 - ix) Provision for mandatory disclosure of source and geographical origin of the biological material in the application, when used in an invention.
 - x) Provision for establishment of Appellate Board for hearing appeals against the decisions of the Controller of Patents.
 - xi) Provision for compulsory licence for export of medicines to countries, having insufficient or no manufacturing capacity.

Safeguards in the Patents Law

1.9 The patents law balances and calibrates Intellectual Property (IP) protection, with public health, national security and public interest concerns. The salient safeguards are detailed below:

- Availability of products at reasonable price is ensured through the provision of compulsory licence (Section 84).
- ii) Compulsory licence can be issued to deal with circumstances of national emergency, extreme urgency or public non-commercial use (Section 92).
- iii) Parallel imports can be allowed to ensure availability of patented drugs at reasonable prices through parallel imports (Section 107 A). Parallel import need not be only from a person authorised by the patentee.
- iv) With a view to making available patented drugs through Government dispensaries, hospitals, etc., the Government can import patented drugs without the consent of the patent holder (Section 47).
- v) For public purpose the Government can compulsorily acquire patent rights. Compensation may be determined by mutual agreement between the Government and the patent holder, failing which by the High Court (Section 102).
- vi) Patent can be revoked on the ground of non-working or the patented invention not being available to the public at reasonably affordable price (Section 85).
- vii) Patent can be revoked by the Government in public interest, if it is prejudicial to the public or exercised in mischievous manner (Section 66).
- viii) No patent rights accrue to a patent holder for mailbox applications for the period prior to the date of grant of patent (Section 11 A).
- ix) Manufacturing of products by enterprises having made substantial investment to continue, on payment of reasonable royalty, even if patent is granted on a mailbox application (Section 11 A).
- x) Bolar Provision: Those interested in manufacturing generic version of a patented product on expiry of the patent can make necessary preparations for production even during the validity of the patent (Section 107). This provision facilitates availability of generic version of the patented product at competitive prices immediately on expiry of the patent.
- xi) No Evergreening: No patent is allowed for a new use of a known drug or substance (Section 3):
 - a. Mere discovery of a new form/ use/ property/ process, etc. of a known substance which does not result in enhanced efficacy is not patentable.
 - b. Salts, esters, ethers, polymorphs, etc., of known substance are to be considered to be the same substance until these differ significantly in properties with regard to efficacy.

xii) Patent can be revoked in the interest of security of India (Section 157 A).

Patents Rules

1.10 The Patent Rules, 1972 were comprehensively reviewed and replaced by a new set of rules, namely, the Patents Rules, 2003. These Rules were subsequently reviewed and amended in 2004 and again in 2006 - the latest amendment was issued on May 05, 2006. The Patents (Amendment) Rules, 2006 were finalized through a consultative process, involving Patent Attorneys, industry associations, Government Departments concerned and other stake-holders. The thrust of the Patents Rules was to introduce transparency, to decentralize the functioning of Patent Offices, to simplify the procedures and to make them user-friendly.

Administration of Patents Law in India

1.11 The patents law is administered through the Patent Offices under the charge of the Controller General of Patents, Designs & Trademarks. The Patent Offices are located at Kolkata, Mumbai, Chennai and Delhi. These offices receive and process applications, based on territorial jurisdiction.

1.12 Pursuant to the new legislative initiatives, the Government embarked upon a major modernisation programme 1 1.13 New integrated Intellectual Property Offices comprising Patents, Designs, Trademarks and Geographical Indications, having a built-up area of over 5,000 sq. mts. per location have been constructed at Delhi, Kolkata, Chennai and Mumbai. The location-wise area and cost of construction are as follows:

| City | Area | Cost |
|---------|-----------------|----------------|
| Delhi | 5765 sq. metres | Rs.12.37 Crore |
| Kolkata | 5113 sq. metres | Rs.11.61 Crore |
| Chennai | 5000 sq. metres | Rs.9.14 Crore |
| Mumbai | 5113 sq. metres | Rs.11.86 Crore |

1.14 Main features of the new IP buildings include:

- State-of- the-art land mark buildings of international standard.
- Corporate look.
- Functional efficiency.
- IT enabled friendly building.
- Uniformity in the façade of buildings at four locations.
- Public convenience and ease.
- Public facilitation.
- Modular/specially designed furniture.
- Uninterrupted electricity supply to enable efficient functioning.
- Semi-transparent poly carbonate dome at the central reception area to add grandeur to the building.
- Eco-friendly building taking full advantage of natural light
- User-friendly building with public areas and hearing rooms located on lower floors.

Website and Computerization

1.15 A website of Intellectual Property offices, namely, <u>www.ipindia.nic.in</u> has been launched. All laws, rules and forms are available on this site. Initial level of computerization, including provision of internet facility, has been completed. Comprehensive computerisation of operations, so as to facilitate on-line processing of applications, is under implementation.

Human Resource

1.16 213 additional posts of technical personnel were sanctioned to handle the existing as well as the emerging fields of technologies, such as bio-technology, information technology, bio-chemistry, etc. Newly recruited Examiners were trained at the Intellectual Property Training Institute (IPTI) at Nagpur.

Performance

1.17 The filing of patent applications increased from 4824 in the year 1999-2000 to 35,000 in 2007-2008. Year-wise statistics on patent applications filed, examined and granted during the period of the eight years is given below.

| Item | 1999- 2000 | 2001-02 | 2002-03 | 2003-04 | 2004-05 | 2005-06 | 2006-07 | 2007-08 |
|--------------------------|---------------|---------|---------|---------|---------|---------|---------|---------|
| Applications filed | 4824 | 10,592 | 11,466 | 12,613 | 17,466 | 24415 | 28, 882 | 35,000 |
| Applications Examined | 2824 | 5104 | 9538 | 10,709 | 14,813 | 11569 | 14,119 | 11, 751 |
| Patents Granted | 1881 | 1591 | 1379 | 2469 | 1911 | 4320 | 7359 | 15000 |

Training and Awareness

1.18 IP Offices are engaged in the promotion of a culture of innovation and creation of IP culture by disseminating the advantages and benefits of IPR protection, in association with various industry associations. Reaching out to Prospective IP users is being done by organising workshops on benefits of using IP to industry with local business associations, Chambers of Commerce, etc. and universities particularly IITs and technological training centres, and also by organising international symposium/seminars and national Symposium/seminars. An Information brochure on Patent law has also been prepared for the use of applicants, inventors, researchers, industry, etc.

International Cooperation

1.19 In its endeavour to modernize IP administration, the Government is actively seeking cooperation of international agencies and other IP offices, such as World Intellectual Property Organization.

Future Initiatives:

1.20 A proposal is under preparation for taking up further modernization of Patent Offices in the 11th Five Year plan.

The objectives of the next phase of modernization are:

- a. to make Indian Patent Office an International Search Authority (ISA) and International Preliminary Examining Authority (IPEA) under the Patent Cooperation Treaty (PCT);
- b. to build up the capabilities of the Indian Patent Offices for providing intellectual property services of global standard;
- c. to develop human resource capabilities to handle increasing number of patent applications in the product patent regime; and
- d. to undertake awareness generation and sensitization among professionals and general public about importance of Intellectual Property Rights for economic and trade development and also to develop the

culture of respect for IPRs.

1.21 This is proposed to be done by:

- a. Strengthening the databases of Patent Offices, in collaboration with other ISAs and IPEAs, namely, Australia, Canada, China, European Patent Office, Spain, Finland, Japan, Republic of Korea, Russia, Sweden and USA, and also with World Intellectual Property Organization (WIPO).
- b. Upgrading the Intellectual Property Training Institute, Nagpur into a National Institute for Intellectual Property Management, to provide training to both the personnel of the IP Offices and attorneys, academics, managers, etc. and also to serve as a think tank on intellectual property rights issues.
- c. Organizing country-wide awareness and sensitization programmes.
- d. Facilitating obtaining of patent rights by small inventors / individuals

TRADE MARKS

1.22 A trade mark is a distinctive sign, which identifies certain goods or services as those produced or provided by a specific person or enterprise. It can be words, letters, numerals, labels, pictures, shape of goods, colours, etc. The registration of trade mark in India is governed by the Trade Marks Act, 1999, which came into force on September 15, 2003. This Act has comprehensively revised the Trade and Merchandise Marks Act, 1958, taking into account the changing trading and commercial practices, increased globalization of trade and industry, with a view to encouraging investment flow and transfer of technology, to simplify and harmonise the trade mark management system, and to give effect to important judicial decisions over the last four decades.

1.23 The registration of a trade mark is not compulsory under the law. However, when registered, a trade mark gives to the registered proprietor the exclusive right to the use of the trade mark, in relation to the goods or services for which it is registered and obtain relief from courts for infringement of trade marks. The Act also provides for prevention of use of fraudulent marks through civil remedies and criminal penalties.

1.24 Some of the salient features of the Trade Marks Act, 1999, in comparison with the Trade and Merchandise Marks Act, 1958, are listed below:-

- Expanded the definition of a trade mark to include both goods and services.
- Prevents imitation of well-known trade marks.
- Protection for collective marks owned by Associations.
- Setting up of Intellectual Property Appellate Board for speedy disposal of registration disputes.
- Simplified licensing procedure of registered trade mark and enlarged scope of permitted use.
- Enhanced the terms of registration and renewal from seven to ten years.
- Enhanced punishment for trade mark offences, on par with Copyright Act 1957, to prevent sale of spurious goods.
- A grace period of six months for payment of renewal fees.

1.25 To implement the Trade Marks Act, 1999, the Trade Marks Rules, 2002 were notified, which contain simple and easy to follow procedures. Timelines have also been prescribed for various activities, with a view to expeditious disposal of applications. The procedure to secure registration of a trade mark now is as follows:

"An application has to be filed at the appropriate office in the prescribed form, alongwith the requisite fee. At the counter, the office issues a receipt alongwith one copy of the representation containing the trade mark as

acknowledgement, which also bears the application number that would become the registration number, when the trade mark is finally registered. Applications are then subjected to data entry, scanning and thereafter physical files are created. New applications are allocated to various Examiners, for substantive examination under the Act and Rules. The Examination Report is normally issued within 15 days of filing, alongwith a formality check report regarding deficiencies in the application, such as non-filing of Power of Attorney, wrong classification of goods or services, non-mention of period of use of mark, etc. In such cases, opportunity is given to the applicant/agent to comply with the requirements called for or file evidence by way of affidavit, to establish the use of the mark in India. If desired, a hearing is also offered to the applicant/agent. Applications may be accepted absolutely or subject to such amendments, modifications, conditions or limitations, as appropriate. If the application is accepted for registration, it is published in the Trade Marks Journal, inviting objections from any person within four months from the date of publication. If objections are received, a copy of the Notice of Opposition is served on the Applicant, who has two months to file a counter statement, failing which the application is treated as abandoned. Thereafter, the counter statement is served on the opponent who then has a maximum of three months to file evidence in support of opposition. On receipt of the opponent evidence, the Applicant is given three months to file evidence in support of the application. Subsequently, the opponent has one month's time to file rebuttal/rejoinder. On completion of evidence, the case becomes ripe for hearing, which is marked to a Hearing Officer for adjudication. In cases where no opposition has been filed, the application proceeds for registration and a certificate is issued by the office. A provision for Appeal to the Intellectual Property Appellate Board from the Orders and decisions of the Registrar is provided under the Act".

1.26 Currently, the Trade Marks Registry takes on an average 12 months to issue registration certificate, where no

opposition has been filed.

1.27 A Modernisation Project "Strengthening and Enhancing the Infrastructure of the Trade Marks Registry", with an

outlay of Rs 16 crore, is under implementation since 2002-03. The main components of the Project are as follows:

- a) Liquidation of backlog
- b) Strengthening the Infrastructure Support
- c) Public Utility Services
- d) Automation Support System

1.28 Salient achievements of the Modernisation Project are detailed below:

- Backlog of about 450,000 applications, pending at various stages, was liquidated at all stages except contest cases.
- Online linkage of all branch office had been established, and consequently branches are receiving applications and issuing allocation numbers on the same day. Earlier, it took upto three months, as the papers were to be physically sent to Head Office at Mumbai.
- Creation of physical files and data entry are normally being done by the end of the next working day, whereas earlier it took up to six to nine months.
- Examination of applications is now being done within two weeks of filing application. Earlier, it took three years.
- Pendency in publication of accepted trademarks applications in Trade Marks Journals has almost been liquidated. Earlier, it took two to three years to publish an accepted application
- Publication of trademark applications is being done in electronic form in Compact Discs (CDs). Paper publication of Trade Mark Journal has been discontinued since 2004.
- TM certificate is normally being issued within four weeks of its becoming due for issuance of certificate. Earlier, it took six months.
- Renewal of TM certificates is being done in clear cases on the very day of receipt of application. In other cases, renewal is being done within two months. Earlier, it took more than a year.
- Across-the-counter post-registration changes are being effected in clear cases.
- Computerized public search facility has been made functional since November, 2004 at all TMR branches.

- All functions prior to publication stage (receipt of application, creation of physical file, data entry, issue of allocation number, examination and clarification) have been decentralized. Branch Offices are carrying out these activities.
- Details of over 5,00,000 registered trademarks have been entered in the data base.
- Nearly 3,00,000 registration certification have been issued during the last three years
- Details of 1,50,000 trade mark records have been scanned in CDs

1.29 The following table presents the statistics of filing, examination and registration of trade marks during the last seven years.

| | 2001-02 | 2002-03 | 2003-04 | 2004-05 | 2005-06 | 2006-07 |
|------------|----------|----------|---------|---------|----------|----------|
| Filed | 90,236 | 94,120 | 92,251 | 78,996 | 85,605 | 98,782 |
| Examined | 1,59,735 | 2,49,003 | 89,958 | 72,091 | 79,200 | 79,021 |
| Registered | 6,204 | 11190 | 39,762 | 45,015 | 1,84,325 | 1,09,937 |

1.30 There has also been substantial increase in the revenue earned by the Trade Marks Registry during the last few years as may be seen from the following table:

| | | | | (INUPEES III GIOLES) |
|-------------------|---------|---------|---------|----------------------|
| Financial Year | 2003-04 | 2004-05 | 2005-06 | 2006-07 |
| Revenue generated | 27.06 | 37.94 | 49.75 | 55.79 |

1.31 The aforementioned achievements have created a positive impact amongst the public and trade mark users, who are able to secure registration of a mark within a year, compared to seven to eight years till recently. This success has been appreciated by WIPO and other International Bodies. As a result, India is now in a position to take advantage of International Treaties like the Madrid Protocol relating to International Registration of Trade Marks. Preparatory steps are being taken to accede to the Madrid Protocol in the near future.

1.32 The Modernization Project also envisages a Total IT Solution for the Trade Marks Registry. The salient features of this project are indicated below:

- Use of state-of-the art technology to establish a single window integrated services for trade mark.
- Establish web-enabled on-line services and create a paperless Trade Marks Office, as per international norms.
- All processes involved from the stage of filing of the trade mark application to the issuance of the registration certificate will be computer-based and the human interference would be significantly reduced.
- Establish automated system for on-line filing and processing of TM applications at all stages during the life cycle of the trade mark.
- Create an electronic record, leading to substantial savings in stationery, printing, publishing and keeping of records.
- · Re-engineered work processes, leading to transparency, speed and efficient delivery of services

1.33 The Project was being implemented on a turn-key basis by the National Informatics Centre (NIC), which was to

be completed by 31st March, 2007.

Future Initiatives

1.34 The following activities are proposed to be taken up during the 11th Five Year Plan:

(Puppes in crores)

- Possibilities of India acceding to the Madrid Protocol are being explored. This will facilitate trade marks owners of India, seeking protection of their trade marks in different countries, through a single application.
- Liquidation of backlog of contested cases
- Strengthening of Infrastructural Support (complete digitization of records, creation of digital library, creating requisite infrastructure to implement the Madrid Protocol).
- Organizing awareness seminars and workshops for disseminating the advantages and benefits of trade mark protection, in association with various industry associations.
- Re-engineering the work process, in tune with international norms by providing for timelines for processing of trade marks at every stage during its life cycle
- Further upgrade of the IT infrastructure of TMR
- Promotion of cooperation in the field of trade marks at regional and international level

CHAPTER II

Written and Oral Submissions: Central Ministries/Departments

2.1 The Committee considered the back ground note on the Patent and Trade Marks Systems in India, received from the Department of Industrial Policy and Promotion. Besides inviting written submissions on the subject, it heard the views of representatives of various and Ministries/Departments, which are summarized below:-

Department of Industrial Policy and Promotion

2.2 The Secretary, Department of Industrial Policy and Promotion deposed before the Committee and submitted that amendments to the Patents Act and notification of rules thereafter were made towards the end of 2005, and, since then the Government has taken a decision to accede to the Madrid Protocol on Trade Marks, of which 73 other countries are already Members.

2.3 The first phase of the modernization of all Patents & Trade Marks Offices was launched in 1999, with a total allocation of Rs. 153 crore, out of which Rs. 137 crore was allocated for patents and Rs. 16 crore for Trade Marks. The focus was on:-

- (i) creation of state-of-the art infrastructure;
- (ii) augmentation of human resources;
- (iii) computerization;
- (iv) awareness creation; and
- (v) training

2.4 An amount of Rs. 134.16 crore was spent on modernization of Patents Offices and Rs. 15.42 crore for modernization of Trade Marks Registry. Against a total allocation of Rs. 153 crore, an amount of Rs. 149.58 crore was spent.

2.5 In terms of infrastructure development four state of-the-art Intellectual Property offices were commissioned at Delhi, Kolkata, Chennai and Mumbai. On the Human Resources front, 213 additional posts for patent offices and 27 additional posts of Examiners of Trade Marks were sanctioned. An Intellectual Property Training Institute was established at Nagpur in 2001, to provide and to develop strategy for awareness creation. There had been a eightfold increase in patent applications, up from 4824 applications in 1999-2000 to 35000 applications in 2007-08. There has been a quantum jump in patents granted, up from 1381 in 2000-01 to 10650 (estimated) in 2007-08.

PARLIAMENT OF INDIA

Similarly, the Trade Marks Applications went up from 66378 in 1999-2000 to 98782 in 2006-07. The number of Trade Marks Registered went up from 8010 in 1999-2000 to 109000 in 2006-07. In the last three years, 3,38,000 trade marks were registered – more than those registered in the proceeding 50 years.

2.6 The Trade Marks Registry incurred an expenditure of Rs. 15.87 crore upto 2006-07, whereas it earned a Revenue of Rs. 163.67 crore. There had been a six times increase in filing of Patent applications and 2.5 times increase in filing of Trade Marks applications after the modernization. Similarly, the average time for examination of patents, after modernisaton, has been reduced from 4-5 years to 2-3 months. For Trade Marks, the average time for examination has been reduced from 2-3 years to 3-6 months.

2.7 A total of 1.5 lakh patent applications out of 2.1 lakh applications, have been digitalized after modernization. Similarly six lakh Trade Mark Applications, out of 12 lakh application, have been digitalized. Further, the processing of applications has become fully electronic after modernization. There had been a four-fold increase in recruitment of Patent Examiners and two times increase in Examiners of Trade marks since modernization.

2.8 The Department has built into the 11th Five Year Plan schemes for modernisaton of Intellectual Property Offices (IPOs) and Establishment of NIIPM. In this connection, a scheme for establishment of NIIPM at Rs. 25 crore has been already approved and construction was to commerce soon. A scheme for modernization and strengthening of IPOs, at a cost of Rs. 300 crore, had been recommended by Expenditure Finance Committee and approval of CCEA was being sought. The broad component of modernization and strengthening of IPOs under the new scheme include:-

(i) **Infrastructure:-** Construction of office Building viz. expansion of New Delhi office and for Trade Marks Registry and IP archives at Ahmedabad, for which the land is already available.

(ii) **HRD:-** (a) Augmentation of Human Resources, primarily Examiners, to effectively handle increased workload, as also to be in the tune with international standards.

(b) To bring the Patent Examination standards upto international norms, which is currently 214 applications/annum in India whereas the standard in European Patent Office (EPO) is 90, United States Patent Trade Office (USPTO) is 97 and 88 in China. The Department proposes to fix the norm at 100 applications per Examiner/annum.

2.9 By 2012, a total of 70,000 patent applications and 20,00,00 Trade Mark applications are expected to be filed annually and to meet this workload, 1380 posts are proposed to be created, including 617 Examiners, 157 posts of controller for Patents and Designs and 128 posts of Examiners and 53 posts of Registrar for Trademarks.

2.10 Out of Rs. 300 crore estimated to be spent in the second phase of modernization, Rs. 76.00 crore will be spent on infrastructure, Rs. 88.00 crore on computerization, Rs. 97.00 crore on Human Resource Development, Rs. 20.00 crore on sensitization and awareness creation and Rs. 19.00 crore on contingencies.

2.11 As far as the task of integrating the offices is concerned, earlier, most of the offices were in rented buildings, and they were separated. Even in a city, a Patent Office could be at more than one place. Trade Marks offices which were separate, have been unified at four metropolitan cities. With regard to the facilities, earlier everything used to be done manually. Computers have been installed and almost every Officer/Examiner has a computer.

PARLIAMENT OF INDIA

There is fair amount of hardware given. Earlier, faxing was not easily possible. Equipments for scanning, copiers, etc., have been given. All the four offices stand interlinked on computer through the NIC. In addition, records have been put in compactors. Earlier, it was difficult to trace a file of a patent. Now all the applications, which have been made till the grant of a patent, have been put in numbered files in compactors installed there and arranged serially. Library facilities, both in physical as well as digital form, have been created in the four offices. The patent offices in India can be linked to the large patent offices around the world like the European Patent Office, the Japanese Patent Office, and the Korean Patent Office. All of them have their own digital libraries.

2.12 In order to work on the competitive advantage of IT, the Department had initiated an exercise to become an International Search Authority and an International Preliminary Examination Authority under the PCT of WIPO. One set of experts has already come from WIPO who have advised as to what steps need to be taken before filing applications. It includes additional computerisation and staff. Linking with the international library comes in there, so that the search process becomes quicker.

2.13 With regard to online connection with other nations' patent offices, the Department had entered into an MoU with the European Patent Office on a system called EPOQUE.

2.14 With the 10th Five Year Plan ending, the posts which were on temporary basis, had to be discontinued, particularly for trademarks. The Department had been able to get approval from the Ministry of Finance that all the Examiners can be treated under the Flexible Complementary Scheme for promotion and appointment as if they are scientific personnel. A fresh set of recruitment rules, which did not require that their recruitment be done by the UPSC, was prepared, which will make it possible to do that departmentally. A recruitment drive will now be started with all these things in position, to fill not only the vacant posts but also for 500 additional posts in the 11th Five Year Plan. It is proposed that five hundred posts of Examiners and 190 posts of Trademarks Examiners be sanctioned. These are against only 56 posts of Trademarks Examiners sanctioned at present. Forty-five of them have been filled and eleven posts are vacant. Permission has been sought from the Government that 190 more posts be filled, as the workload has increased.

2.15 Since the modernisation programme was started, the changes in the laws etc., which have come, the number of patent applications has already gone up six-fold. In 2000, there were 4008 applications; last year the number was 20,000. At that time, the number of patents granted was 1800, now it is 7,600. The capacity to deal with the applications, etc., has increased *pari pasu*. The Department has been able to remove the backlog of trademarks of 4.5 lakh applications which were pending with the Department earlier. A backlog of 70,000 trademark applications and about 20,000 patent applications were pending. This was largely because of the shifting of these offices. There was a temporary dislocation. But shortage of staff has become an issue once again and the issue needs to be attended so that the pendency does not build up.

2.16 The average time taken to process the application, the minimum is 54 months and the maximum is 108 months. Now, with the new rules put in position, it is possible to have the fastest application process in seven to

PARLIAMENT OF INDIA

eight month time, and over all in about four years time, from nine years.

2.17 On the issue whether the litigation in the trademark regime had reduced or had gone up, including challenging of the trademarks, duplication of trademarks, etc, it was informed that the total challenges were about 8000, out of seven or 7.5 lakh granted, which meant it was 11 to 12 per cent of that. The process of going online would make it a little less challengeable because as soon as a trademark application is available, within five minutes it is put on the net and the person can see whether application which made for certain trademark has been given to another person or not. Further, the idea of becoming an International Search Authority and an International Preliminary Examination Authority was to cash in on our large manpower skills. Twelve such international offices are recognised and India has become the 13th under the international scheme.

2.18 Regarding the fate of Mashelkar Report, it was submitted that the Report signed by all the members was received by the Department some time ago. The Report was put on the Ministry's website so that people could comment on it. However, after receiving the Report, the Department was informed by Dr. Mashelkar in February that he wished to take back the Report and sought time to rewrite it to remove certain technical inaccuracies. The Department agreed and told that he may remove these inaccuracies and resubmit the Report. Dr. Mashelkar followed up within a month by saying that he was resigning from the Chairmanship and the Department may instead find new Chairman, who may rewrite the Report. But the Department had not acceded to that request and told him that since the Report was in public domain and also put it on the Ministry's website and the Parliament had been informed, his suggestion of removing technical inaccuracies was acceptable but his suggestion of finding some other Chairman and re-writing of the Report was not acceptable to the Department.

2.19 Regarding 'evergreening' and whether it is permissible under our patents law, it was informed that the reference to Mashelkar Committee was with regard to two points -- not insisting on new chemical entities only is TRIPS compatible or not, and secondly, whether micro organisms being excluded would be TRIPS compatible or not. On both these issues the Report said that what the Department had done under the law was correct on both the issues.

2.20 However, the Committee felt that the veracity of the report had been put in doubt, whether it is accepted or rejected. Further, in the academic and scientific world, the report had lost its meaning.

2.21 With regard to pre-grant opposition, it was informed that it has been explicitly provided in the law that after the application has been published, before it is taken up for examination, anybody aggrieved can object and could approach court of law. Ever since this provision came into force in January, 2005, less than 200 pre-grant oppositions had been received, against a total of 50,000 new applications. In fact, the Department is ensuring that the post-grant opposition becomes less and this process becomes quicker, rather than people having to go to courts of law.

Intellectual Property Training Institute, Nagpur

PARLIAMENT OF INDIA

2.22 The representative of IPTI informed the Committee that the Government of India set up the Intellectual Property Training Institute (IPTI) at Nagpur on 16th August, 2002, for providing training to the Examiners and Controllers of Patents & Designs and Trade Marks. The Institute is provided with modern amenities, such as a training hall (30-35 capacity), computer-aided training hall, internet with LAN-WAN and other IT-enabled services.

2.23 IPTI is organizing foundational training courses for the newly recruited Examiners. Besides training new Examiners of Patents and Designs, it has organised refresher course for Examiners of Patents and Designs. Appropriate study material for different courses was prepared by IPTI, for dissemination among participants. About 30-35 Controllers of Patents & Designs and about 5-6 Officers of Trade Marks Registry function as faculty members at the IPTI, in addition to their regular work of handling patent/trade mark matters. Besides, IP-Professionals are regularly invited as visiting faculty at the IPTI for various training programmes, especially for programmes of more than three days duration and for the Refreshers Courses to give presentations on practical aspects on IP-litigations, drafting of specifications, etc. By the end of 2011-12, it is estimated that the number of patent applications filed annually would reach about 70,000. Similarly, there is expected to be considerable increase in the number of applications for Trade Mark filed also. In order to cope up with the resultant increase in the work involved in examination and processing of the Patent and Trade Mark applications, it is estimated that about 1380 Examiners of Patents and Designs and 617 Examiners of Trade Mark procedures and related aspects, to maintain high standards of examination and Patent/Trade Mark granted. This would require upgradation of the existing training facilities at the IPTI.

Department of Scientific and Industrial Research

2.24 The Secretary, Department of Scientific and Industrial Relations and DG, CSIR informed the Committee that the cost of filing patents in the United States is fairly high and most of our public funded institutions in the university sector do not have such resources. The Department was trying to help by not only paying for resources but also providing help to write the patents. The Ministry of Science and Technology was running a training course for patent writing and drafting. A proposal was made by the Ministry of Science and Technology to establish on institution for Intellectual Property management capacity building. Even ASEAN countries wanted to join hands with India, to establish a regional centre. Another important area brought to the notice of the Committee was the national system of innovation, which offered immense possibilities, not only to public and private sector, but also for the informal sector. The total number of grassroot innovation practices was 35000 in the year 2006-07 under this system, which could go to 5,000 in one year's time. The Ministry has set up a mechanism of protecting the IPRS. What was basically required was a strong licensing system, for ensuring business development. In order to ensure that the so called out-sourcing of R and D within the country does not lead to IP going elsewhere by de fault, thereby creating wealth in third party nation, the R and D investments needed to be enhanced significantly.

Department of AYUSH, Ministry of Health and Family Welfare

2.25 In the interaction of the Committee with the Secretary, Department of AYUSH on 14th September, 2007, it was informed that at the international level, an interesting debate regarding mutual incompatibility between Convention on Biological Diversity (CBD) and the TRIPS Agreement. In this regard, may countries including India, have been advocating that the TRIPS agreement should incorporate same of the basic elements of CBD, as a condition of patentability such as identification of source of genetic material and associated traditional knowledge, evidence of fair and equitable beneficiating and evidence of prior informed concert from the Government etc. The Committee are of the view that India is a repository of traditional knowledge and is one of the biggest biodiversity region of the worked thereby making it more imperative on the part of Government to take proactive stand that facets of CBD should be made a part of the TRIPS agreement as it world protect the biodiversity of the country from being usurped. An example in this regard is that due to lack of clarity in this matter quite a large number of germplasms which may need to be used in preparation of traditional formulations may have been taken away by other countries of the developed world. The Committee, therefore, recommend that the Government should set up an inter-Ministerial Task Force Comprising of the Ministry of Health, Ministry of Science and Technology and Ministry of Agriculture whose Terms of Reference should be collection, collation, publication and publicity of all the traditional knowledge of the country so that the same are not usurped by developed countries. There should also be a authority say traditional knowledge intelligence on the lines of commercial intelligence which could keep an eye on the protection of traditional knowledge of the country. Efforts should also be made in the direction to encourage research in the field of traditional knowledge as a fool proof way of protecting traditional knowledge is to encourage research in traditional resources. This would not only protect the traditional wealth of the country but also provide opportunities for million of people involved in our country in the use of traditional wealth for health care but are not able to disperse their knowledge due to lack of support form the Government to help them in their research. The Government should make efforts to integrate the traditional systems to the Health Care System of the country so that the existing load an Allopathic System of Heath Care is reduced.

2.26 The **Council of Scientific and Industrial Research(CSIR)** informed that Patent Facilitating Center (PFC) of Technology Information Forecasting and Assessment Council (TIFAC) under Department of Science & Technology (DST) provide financial assistance for filing patent applications in India and abroad to the researchers in the academic institutions, and also help them in preparing their patent applications. PFC is also conducting a number of workshops and training programmes in various universities all over the country. The Department of Information Technology (DIT) is initiating a scheme to provide partial financial assistance to SMEs for filing their patent applications in India and abroad. Similar initiatives may follow from other departments also.

2.27 Individual inventors could seek assistance for patent filing and development work under the Technopreneur Promotion Programme (TePP) scheme, jointly operated by Department of Scientific & Industrial Research (DSIR), Technology Information Forecasting and Assessment Council (TIFAC) and Department of Science & Technology (DST). TIFAC is enlarging the scope of its IPR training under Woman Scientists Scheme to about 400 women i.e.

PARLIAMENT OF INDIA

10 times of the present intake. Under the Scheme, the women scientists are trained for about 4-5 weeks on various aspects of IP management and, therefore, they are placed as interns in various Government departments and patent attorney firms for a period of one year for the purpose of on the job training. CSIR also provides training to half a dozen Research Interns in the field of IPR management for a period of two years.

2.28 Indira Gandhi National Open University is providing one year's Post Graduate Diploma in Intellectual Property Rights. During the last four years, they had enrolled about 1000 students for this programme. IGNOU is also starting a six months' Certificate Programme, with focus on patent drafting, with the assistance of Intellectual Property Management Division (IPMD), Council of Scientific and Industrial Research (CSIR). Several other academic institutes like NALSAR, IITs, IIMs and ILI have started different courses on IPR. The Department of Science & Technology (DST) has promoted a special scheme called "Innovation in Science Pursuit for Inspired Research".

2.29 The Government is bringing the Public Funded R & D Projects (Protection of Intellectual Property) Bill, 2007 before the Parliament. The proposed Bill would help in capturing the IP generated from publicly-funded research, especially from academic institutions. This would also help providing incentives to the inventors and help promoting inventive activity in the country. As a result, a lot of valuable R&D work which gets published, without generating any wealth for the nation, would get protected and would help in realizing value from the Indian R&D efforts, nationally and internationally. These efforts may also foster global R&D partnerships and have a multiplier effect.

2.30 India and Heads of science and technology agencies of the ASEAN countries have agreed for the establishment of an India-Asian Institute for Intellectual Property Management, for building human resource capacities and for training, to serve the ASEAN region. It was also resolved that India-ASEAN partnership will encourage academic exchange and collaboration amongst the members of the scientific community in the region.

2.31 CSIR would make an effort to launch a Pilot Project for imparting IPR training to interested school and collegegoing students, depending upon the availability of resources at the lab/IPMD. The Pilot Project would be implemented by the Intellectual Property Management Division, CSIR with the network of IP Cells in CSIR labs.

CHAPTER III

Written and Oral Submissions: Individuals/Organisations

3.1 The Committee considered the written submissions (Annexure I to X) as well as oral evidence of the following individuals/organizations:-

- i) Sh. B. K. Keayla of the Centre for Study of Global Trade System and Development;
- ii) Ms. Krishna Sarma, Managing Partner, Corporate Law Group;
- iii) Lawyers Collective/HIV Aids;
- iv) Sh. Gajanan Wakankar, Indian Drug Manufacturers Association(IDMA);
- v) Ms. Leena Menghaney, Campaign for Access to Essential Medicines;
- vi) Dr. S. Vedarman, Controller General of Patents, Designs and Trade Marks (Retd.);
- vii) National Law University, Jodhpur;

viii) MAKs Submissions on Improving the Patents Systems India;

- ix) Organisation of Pharmaceutical Producers of India (OPPI);and
- x) Justice V. K. Krishna Iyer (Former Judge, Supreme Court)

3.2 The individuals/organizations at SI. No. (i) to (v) also appeared before the Committee for oral evidence. Oral evidence of the above-said witnesses are summarized below: -

Sh. B. K. Keayla of the Centre for Study of Global Trade System and Development

3.3 Shri Keayla, while deposing before the Committee, stated that it was felt that the new Product Patent regime will soon have impact on prices and availability of pharmaceutical products. If the flexibilities available under the TRIPS Agreement and which have been clarified in the Doha Declaration on TRIPS Agreement and Public Health, are not implemented, the role of the domestic enterprises would be seriously affected. The Indian patients are under tremendous burden of high excise duty of 16% with 2% surcharge on medicines. In addition to these duties the pharmaceutical products are sold with VAT and Sales tax of 4 to 10% and Octroi and turnover tax of 3% to 5%. Service tax of 12% is another burden which also indirectly affected the prices of medicines. All these issues also need to be looked into in the new product patent scenario. Indian industry, as compared to the industry in foreign countries, has also to bear the impact of poor infrastructure, non availability of adequate power, water and transport facilities. These facts are being indicated, keeping in view the impact of TRIPS Agreement and non-implementation of flexibilities available would have serious impact, alongwith the impact of high duties on prices and role of domestic industry, which, in the coming future, needs to be strengthened to effectively face the global competition.

3.4 Another issue which the TEG Group was examining was whether it would be TRIPS compatible to exclude micro-organisms from patenting. The Committee was informed that the provisions about patenting of micro-organisms should be kept in abeyance till a final verdict on the issue comes out in the WTO, particularly in the Doha Work Programme where it is under consideration.

3.5 Another important provision which has arrested the attention of the Committee is a particular provision in TRIPS namely Article 31 (b). A contingency in the said Article provides that if any enterprise wants to exploit a patent, it has to approach the patent holder with reasonable terms and conditions and wait for a reasonable period. If there is no response, the enterprises can approach the Patent Controller for patent rights. This provision has still not been implemented in India.

3.6 A vital issue emerging out of the debate is. The TRIPS agreement has not defined the issue of the payment of royalty. The Principal Act (Patents Act, 1970) had a ceiling of 4% royalty that was applicable for process patent. In the prevailing product patent system, it is a natural collolary that a ceiling should be provided. The Committee was informed that a ceiling of 5% to 6% could be provided, as keeping the issue hanging in abeyance could lead to dispute between patent holder and the compulsory licence holder.

3.7 On Mail Box Applications, TRIPS agreement (viz Article 70.3) says that there is no need to give any patent to any Mail box product which has fallen into public domain as on 1st January, 2005. This provision has been ignored

in the Patents Act which says that protection will be given for the remaining period of 20 years, counting from the date of filing and those who are producing will have to pay royalty.

3.8 The Committee was informed that the Doha Declaration on Public Health was issued in November, 2005 which recognized the gravity of Public Health Problems afflicting many developing and the least developed countries, especially those resulting from HIV/AIDS, T.B, malaria, etc. Post this declaration every country has the right to determine measures necessary for public health and every country has a right to determine what should be the grounds for giving compulsory licences. However, this freedom conferred by Doha Declaration has not been fully used, particularly in regard to compulsory licensing.

3.9 On data exclusivity, it was informed that the provision was rejected by the multilateral forum of Uruguay Round. However, the issue has been brought to the fore ground by certain Multinational corporations. Conceding to this demand would mean that one is going beyond what is mandated by the TRIPS agreement. It would mean implementation of TRIPS-plus. This is nothing but getting exclusivity for marketing.

3.10 Regarding implementation of Article 22 of the TRIPS Agreement. This relates to Geographical Indications (GIs), it was informed that according to TRIPS Agreement, Geographical Indications (GIs) are available only to wines and spirits of France. It was agreed through Doha Declaration that it would be reviewed for other countries also. There are several Geographical Indications in our country which need to be protected. India has enacted a law, but that law cannot be used till we have a multilateral facility available. Approval of WTO forum on such products, so that no one would be able to use these indications, would help a lot of our traditional Geographical Indications (GIs) from being usurped by others.

3.11 Regarding Convention on Biodiversity and the relationship between TRIPS and the former, India has made provision in the Patents Act that if a biodiversity material is used for producing a new product, the producer will have to disclose what biodiversity material one is going to use as also whether consent of the person who provided the knowledge was taken. But unfortunately, the TRIPS Agreement has not provided for it. Concerns about this issue have been made at the Hong Kong Declaration but progress was very slow.

Ms. Krishna Sarma, Managing Partner, Corporate Law Group

3.12 The witness submitted that though the Trademarks Law was a good one, there was a need to make trademark prosecution more efficient. The time-frame for registration was exceptionally lengthy in comparison to other countries. Further, there was a delay in procurement of search reports despite the statutory time-limit. There was no adherence to the rules regarding expediting screening/examination of applications for trademarks.

3.13 A major drawback in the working of Patent Offices was that at present the backlog of applications is about 22000. The Examiners and controllers are required to determine patent applications in multiple disciplines, which may affect the quality of processing, viz. a Controller/Examiner with mechanical engineering background is examining a bio-tech patent. Unlike USPTO and JPO, India has four patent offices as per original jurisdiction, more or less independently. There has been a lack of synergy between the four offices viz:-

- (i) Filing is independent;
- (i) Processing is independent; and
- (i) Grant is independent.

3.14 The only aspect where there is synchronization is in issuing patent numbers after grant. This left scope for difference in interpreting and implementing the law by different offices, in the absence of a Central guiding parameter. Such variation in interpretation becomes apparent in cases where language of statute is open-ended thus, leaving room for subjective enquiry. Nowhere is it more palpable than in the case of interpretation and application of Section 3(d) of the Patents Act. Various decisions emanating from the four offices regarding interpretation of Section 3(d) have resulted in a wide latitude in its application. The following suggestions would help streamline the Patents system in India:-

- (i) The term "efficacy" needs to be defined in the explanation to Section 3(d) and guidelines should be set out for examining "inventive step";
- (ii) The Patents Act needs to be modified to make provisions clear and transparent, so that there is no unnecessary litigation for our already over-burdened judiciary;
- (iii) There is a pressing need for introduction of patents for "new use of a known substance", so as to encourage research for new use of Ayurvedic medicines and to find new cures to address our unmet medical needs;
- (iv) The lack of definition of the term efficacy may result in a lot of scientific waste. Further, genuine R and D may not be rewarded, discouraging innovation by the industrial and scientific community;
- (v) Protection of incremental innovation and allowing second use patent will encourage innovation in India and will reflect current capabilities in R and D. The need of the hour is a transport legislation which would be beneficial both to the consumer and the industry. There was a need for better training for patent Examiners and more patent Examiners are also required.

Lawyers Collective/HIV Aids

3.15 The main contention of the Forum was Section 3(d), 8 and 10 of the Patents Act. Their main suggestions were:-

- (i) Duty to disclose all relevant material prior art;
- (ii) Duty to disclose international non-proprietary name for pharmaceutical patent application with continuing obligation; and
- (iii) Duty to disclose whether an application relates to a disease of public health priority, as determined from time to time by Ministry of Commerce, after consultation with Ministry of Health. Failure to comply should be a ground for opposition and/ or revocation of patent.
- 3.16 On compulsory licensing the India Law provides:-
 - (i) Failure to satisfy reasonable requirements of the public;
 - (ii) Unavailability of patented product at reasonably affordable prices and
 - (iii) Non-working of patent in India.

3.17 The witness submitted that unreasonable refusal to issue license on reasonable terms as a ground for issuance of compulsory license be included as a ground. Further, the Act should adopt clear and predictable remuneration guidelines in the Act or Rules and deemed refusal to license in accordance with these guidelines

should constitute prima facie case of refusal to license. The bottom line was that the compulsory licensing was needed to be simplified.

3.18 There was a need to simplify access to information and opposition proceedings. There should also be an effort to limit injunctive relieves. Any attempt to introduce data exclusivity should be opposed. Any amendment that diluted Section 3(d) should be opposed. Lastly, there was a strong need to strengthen and overhaul the patent examination system.

Indian Drug Manufacturers Association (IDMA)

3.19 The representative of IDMA submitted before the Committee that Patent harmonization, which provides for uniform law on Patents for all the countries of the world, was nothing but a ploy by the United States to substitute the law of that country on all countries of the world. In a world where every country had different Constitution, different commercial laws, different economic laws, it was downright not possible to provide for a uniform patent law for the entire world.

3.20 Regarding the amended Patent Act of 2005, it was informed that the law should be observed for a period of five years and in case there are any deficiencies, the same may be rectified in 2010. At present, it was felt that there was a need to remove all 'qualifying phrases' from the Patents Act and to bring in all flexibilities available under the TRIPS Agreement.

3.21 The pre-grant opposition provision was a positive step which would help the developing countries, but pregrant opposition provision had not been fully incorporated, thereby weakening it. The provision for an Opposition Board had not been accepted as in the case of post-grant opposition. Further, an appeal to the Controllers orders has not been accepted and the Controllers Orders are final. It was felt that such a step was a half hearted relief and could not prevent 'ever greening' attempts by multi-national corporations.

3.22 Another provision on which objection was raised was on 'Right of Patent applicants after publication', i.e., Section 11(A) (7) which states that "on and from the date of publication of the application for patent and until the date of grant of a patent in respect of such application, the applicant shall have the like privileges and rights as if a Patent for the invention has been granted on the date of publication of the application". such a provision was not required by TRIPS and benefits only the multi-national corporations. Therefore, this provision should be removed.

3.23 The Compulsory Licence Procedure was too lengthy and complicated and was totally in favour of the Patent holders, who are mostly multinational corporations (MNCs). The resultant effect was that the chances of getting a Compulsory Licence were very low, because of a protracted and expensive legal battle.

Campaign for Access to Essential Medicines

3.24 India has, through its laws and policies, limited patent monopolies for the past three decades and promoted competition in the form of generic production, with a view to bringing down the prices of drugs. This policy has not only made essential drugs much more affordable to its people (as compared to patented drugs), but also has, in the

long run, been instrumental in making India self sufficient in the production of drugs. As a result, India plays a crucial role in supplying low cost essential medicines to other developing countries. Aptly named the 'pharmacy of the developing world', it supplies formulations and active pharmaceutical ingredients (raw material) to a large number of countries in Asia, Africa and South America.

3.25 In HIV/AIDS treatment, due to competition among Indian generic manufacturers, it was possible to disallow patent monopolies and strongly encourage generic production. The price of first-line antiretroviral drug regimens has fallen from an average of US \$10,439 to the current price of US \$ 99 per patient, per year.

3.26 However, with the implementation of its new patent regime for medicines, India is already drying up as a source of affordable versions of newer medicines. The Indian patent office has since April 2005 started to publish and examine thousands of pending patent applications, many of which relate to essential medicines such as antiretroviral used in the treatment of AIDS. These newer drugs are under patent or pending patent grant in other key countries with generic production capacity, such as Brazil and Thailand, which keeps prices high and availability low. If patents are granted too easily on these essential medicines in India, India's role as the "pharmacy of the developing world" may end.

3.27 It is important that the patentability standard, as introduced by the Patent (Amendments) Act, 2005 – novelty, non-obviousness and section 3(d) – which has the potential of addressing a proliferation of patent applications filed in the Indian Patent Office that claim protection for minor, and in some cases of obvious, variants of existing drugs, is strictly implemented, to ensure the widest possible access to affordable life-saving medicines in developing countries.

CHAPTER IV

STUDY VISITS

4.1 The Committee visited the Patents Offices at Kolkata, Chennai, Ahmedabad, Mumbai and Delhi to study the Patents and Trademarks System in India and held discussions with the Officials, Patents Attorneys, etc. During the visit the following important issues were raised:

4.2. Kolkata and Chennai: -

i) The quality of professional training needs to be vastly upgraded and there is an urgent need to increase the number of Examiners. More number of Examiners are required to be recruited and should be trained, to reduce the pending patent applications. Non-granting of Patent due to slow speed, which could be directly related to the shortage of Examiners, could lead to the Patent being granted to somebody else, who could translate the same into a business opportunity. This could lead to loss of investment on the basis of the Patent which could have been registered in India. Steps should be taken to recruit more Examiners who are Post Graduates in chemistry or Graduates in Engineering, which should be basic qualification for recruitment of Examiners.

Design Patent would become a very important area in the future, as apart from actual technology inventions.
 Design part of the invention is an emerging area, for which the Intellectual Property administration should gear up.

iii) Digitalization of Traditional Knowledge is very important. The Department should depute their personnels to get in touch with institutions, which have already digitalized their records.

iv) Due to incorrect interpretation of the provisions made under the Patents Act and Rules by the Department, the applicants face inconvenience in the processing of their applications. Judicial interference is required in proper redressal of the issue and in most of the cases the Patent Office has issued an administrative instruction in view of such Court Order.

v) Proper data base is not available for novelty search and for getting any information about patent applications. Also, the number of patents granted so far should be digitized completely, for the purpose of search

vi) There are plenty of mistakes in the title of the registration certificates being issued by the Trade Marks Registry. There is delay in issuance of Registration Certificates by the Trade Mark Registry. The software technology must be upgraded, to reconstruct old files of the Trademark Registry in the software version.

vii) The proposal for handling files by Patent Attorneys should be resolved by Patent Attorneys at the earliest. Rectifications should only be filed before the Appellate Board and not before the Registrar or Court.

viii) At present the Appellate board did not have disciplinary jurisdiction and it could not punish officers. The Appellate authority ought to be vested with disciplinary jurisdiction. Another basic lacunae in the Patent System was that a Patent would be granted for something which is tangible i.e., which you can hold in one's hand. It was felt that the Parliament could include software, which was not a tangible item, by putting software in the definition of tangible items, as long as it satisfied other norms such as it must have an industrial application.

ix) There is a provision for advertising a mark before acceptance. Such a provision is absolutely unnecessary, whether it is advertised before acceptance or after acceptance. This needs to be abolished. As in Germany, all the applications should be treated as registered, and when there is an opposition, that particular application would be decided after full-fledged opposition proceeding. Such a provision could be considered here too, in view of the tremendous volume of Trade mark applications. Further, under section 57 of the Trade Marks Act, a rectification could be filed either before Registrar or before the High Court. The rectification was something like a revision or appeal. So, it would be more appropriate if the rectification was given only to the Appellate Board.

x) Earlier one month's time was granted to pay fees for filing patents. Presently this is not being done. It is, therefore, imperative that the system should be restored, as it would be useful for the clients.

xi) At present all Trade Marks offices in India are computer linked with the Head Registry at Mumbai, and are updated. However, there should be decentralization of each branch office of the Trade Marks Registry in India, and each branch should be in a position to furnish information that is necessary.

4.3 Ahmedabad and Mumbai: -

(i) Include the definition of Micro-organism in the Patents Act, as microorganisms, per se, has not been defined under the Patent Act.

(ii) Scope for patent protection for living forms such as cells, tissues, which are higher than the microorganisms, biological material, such as cell lines, enzymes, plasmids, cosmids and genes with human intervention being involved. Also, there is no scope of patentability or protection of living forms such as cells, tissues, which are higher than the micro-organisms.

(iii) Guidelines should be given by IPO to what extent inventions involving elements of human origin should be patentable. The Patents Act does not permit patentability of biological material such as cell lines, enzymes, plasmids, cosmids and genes, in spite of the human intervention being involved. Therefore, it will not be possible to seek protection on the cell biology research and for cell- based and tissue- based products, unless micro-organisms *per se* is defined under the Act.

iv) Full-fledged Intellectual Property Office at Ahmedabad, consisting of Patents, Designs and GI be set - up. This will help in faster disposal of applications, as it will provide easy access to data and officials. The building will act as a meeting place for the industry and the practitioners, which will help in faster movement of applications and also remove roadblocks, if any. Granting powers would not only cut down on delay, but will also increase the efficiency. Moreover, it will also have an effect over the revenue as the pre and post registration fees would then be paid at the respective branches itself.

v) As in Passport Office, TMR should get rid of Trade Marks Agents who are mere touts indulging in malpractices.

vi) Trade Marks Records are not properly maintained and are in a complete mess. The files and records must be regularized and kept in such a way, to get the same as and when required by the authority.

vii) Courier system is not satisfactory. Many TM applications were abandoned without giving the chance of hearing. The courier system should be held responsible for many mistakes in the past.

viii) Litigation volume has increased tremendously. The litigation cases should be disposed off within the time-limit fixed i.e. two to three years. The files must be transferred to the Registration section if the application is entitled for registration. The files are not transferred even after a year.

ix) Inexperienced contract Examiners have messed up an already difficult situation, which TMR is struggling to cope with. Also, the computer system is experiencing technical problems. The computer system should be made 100% reliable. There must be complete co-ordination between various sections. The contract people must be properly trained to deliver the desired results. They should be properly paid. A little more staff should be employed to meet the ever increasing volumes of work.

x) The Central Government should sanction more funds to the Registry of Trademarks, to enable them to overcome administrative problems.

xi) The Registry of Trademarks should evolve a system to acknowledge and give reply to the letters written by the Advocates or public at large. There must be periodical meetings between the Registry, The Intellectual Property Owners' Association and the Advocates'/Agents' Association to sort out the problems and to bring the solutions.

xii) Issue Examination Report via email and hearing be held by telephone.

PARLIAMENT OF INDIA

xiii) The quality of trade marks published in TM Journal is not upto international norms. Some examples provided include **Khadder** for 'clothing, garments', for '**Asal**'(genuine in English) for utensils, '**Kabaj**' (constipation) for medicine, '**Classic'** for oil for machines, lubrication; '**Scientific'** for computers, etc. Extension for request to file opposition in form TM-44 should be reckoned from date of availability of TM Journal, and not date of publication of Journal

xiv) It has come to notice that registration certificates are being sent to the applicants, instead of to the Advocate/Agent on record, and applicant is ignorant of timely renewal requirement.

xv) Notice of hearing should be put on Notice Board and in cases of show cause notice, the name of applicant should be mentioned for ready recollection. When a Hearing Officer is on leave, this should be communicated to Advocate in advance, to avoid inconvenience. Judgments should be delivered on time by Hearing Officers.

4.4 Comments of the Department of Industrial Policy and Promotion on the above-mentioned issues:-

i) Microbiology and biotechnology are fast developing fields. Inclusion of a definition of 'micro-organism' will unnecessarily limit the interpretation of the term based on the state of technology prevailing at any given point of time.

ii) Cell-lines and Natural Gene / protein sequences are not patentable. Enzymes, plasmids, cosmids and recombinant DNA are patentable under the Patents Act, if they meet patentability criteria.

iii) Patent protection to higher life forms (plants and animals) is not provided under the Patents Act. Protection to plant varieties is provided under the Protection of Plant Varieties and Farmers' Rights Protection Act, 2001.

iv) At present there is no proposal to open more IP Offices in the country. E-filing and E-payment at IPO is under implementation, which will avoid visit to IP Offices.

v) It is hoped that with the implementation of the Total IT solution, the services will be further improved. The agent's role so far has been only to facilitate small traders in securing registration. They are enrolled as agents as per the provisions of the Trade Marks Act. With the rise in awareness in the general public, their role will diminish in due course of time.

vi) Due to shortage of space to store, physical records/files could not be arranged serially and properly. To some extent, with the setting of new IP buildings and installation of compactors at all the TMR branches, the problem has been tackled. The Second phase of Modernization Project during the 11th Plan, envisages setting up of a centralized IP warehouse to store IP records. Additional space will enable proper maintenance and retrieval of records.

vii) Contract Examiners had to be appointed to dispose huge backlog of TM applications. Errors constituted less than 2% of the total applications examined and it was mainly due to work pressure. Most of complaints have since been rectified. A new application software is currently under development by NIC and would be operational soon.

PARLIAMENT OF INDIA

viii) An Examination Manual is under preparation for guidance of Examiners, to improve the quality of examination. A National Training Institute (NIIPM) is being set up under 11th Plan, which will meet the training needs of the Examiners and other officers of TMR. The Modernization Plan to be implemented during the 11th Plan envisages recruitment of additional officers at all levels, on regular basis.

ix) With implementation of the second phase of the modernization project to be undertaken during the 11th Plan period, services by TMR are expected to improve further.

x) On-line issuance of examination report is envisaged under IT solution presently under development.

xi) Proposed Examination Manual under preparation would include a chapter on sound and shape trademarks for guidance of Examiners and Hearing Officers.

xii) It is proposed to give refresher training to all the Examiners as well Assistant Registrars/Deputy Registrars at

the proposed Training Institute at Nagpur to be constructed under the 11th Five Year Plan Scheme.

xiii) Cases like publishing of identical or obviously similar marks in Trade Marks Journal are being dealt with in accordance with the provisions of Section 12 and Section 19 of the Trade Marks Act, 1999.

xiv) The issue regarding extension to filing of opposition in form TM-44 from the date of availability in the Trade Marks Journal is already in place.

xv) Presently, TMR is providing details of opposition matters fixed for hearing on the Notice Board. Attorney/agents are also expected to keep track of their cases.

xvi) Presently, registration certificates and all correspondence are sent to the address for service mentioned in the TM applications.

xvii) Due to acute shortage of manpower, the name of the applicant is not being mentioned while displaying the notice of hearing on the Notice Board. There is acute shortage of staff in the Trade Marks Registry. Also, this is not a usual practice before any court or tribunal. The delay is due to acute shortage of Hearing Officers. Additional staff is proposed in the second phase of modernization project.

4.5 Delhi:-

- i) There is need to establish a separate Archive Office for storing and digitalization of all records.
- ii) There is need to set up one inter ministerial Committee with the Department of Industrial Policy and Promotion as the nodal agency, to bring under one umbrella all Intellectual Rights such as copy rights, which was under the administrative control of Ministry of Human Resource Development and the Patents, Designs, Trade Marks and Geo-graphical Indicators which was under the control of Department of Industrial Policy and Promotion.
- iii) MOUs have been signed with patent offices of US and UK for absorption of latest technology.

CHAPTER V

OBSERVATIONS AND RECOMMENDATIONS

5.1 The patent law in India is administered through the Patent Offices, under the charge of the Controller General of Patents, Designs & Trademarks, located at Kolkata, Mumbai, Chennai and Delhi. All these four offices stand interlinked on computer, through the NIC. The facilities for processing the application, including payment of fee for

all the services in patent offices are available online.

5.2 The Department of Industrial Policy and Promotion had initiated an exercise to become an International Search Authority and an International Preliminary Examination Authority under the Patent Cooperation Treaty (PCT) of World Intellectual Property Organisation (WIPO).

5.3 The Committee recommend that the Department should make all out efforts at capacity building of the Indian Patent Offices, so as to provide intellectual property services of global standards. Efforts should also be made to make the Indian Patent Office an International Search Authority(ISA) and International Preliminary Examining Authority(IPEA) under the Patent Cooperation Treaty(PCT). The Department should undertake an exercise aimed at awareness generation and sensitization among professionals as well as general public, about the importance of Intellectual Property Rights for economic and trade development, and also to develop in the country a culture of respect for IPRs.

Publication of Patent information and a Searchable Public Patent Database

5.4 Currently, Section 145 of the Patents Act provides that 'the Controller shall publish periodically an official journal, which shall contain such information as may be required to be published by or under the provisions of this Act or any rule made thereunder'. Rule 27 of the Patents Rules, 2006, read with Section 153 allows any person, after publication and upon written request, the right to inspect the complete and provisional specification or drawings of an application, on payment of a fee.

5.5 The Committee feel that most significant constraint of the current patent publication system in India is the lack of a searchable patents database, that can provide all requisite information on an updated basis. Though the Patent Amendment Act, 2005 had been passed, yet electronic searchable patent database is not available. The current PDF file format is not suitable for searching all the journal publications at once. The fallout of the absence of a public searchable patent database is that the inventors, commercial competitors, academic researchers and a host of public interest groups are not able to effectively search patents. This is a significant problem, as these groups need to know what patents exist in India, so they can determine any legal risks or the validity of the patents being filed and granted. The current system is thus cumbersome and time-consuming and places a heavy resource burden on the information seeker. Lack of readily available information does not help create a transparent patent system.

5.6 The Committee, therefore, recommend that an electronic searchable patent database should be made public at the earliest. In order to legally provide such a database, it may perhaps be necessary to amend the provisions governing the patent information, namely Sections 145 & 153, and Rules 27 & 134.

5.7 Regarding access to Examination Reports, the Committee was informed that currently Section 144 of the Patents Act states that reports of the Examiners to the Controller shall not be open to public inspection, or be published by the Controller. The Committee feel that the lack of transparency with regard to the process of examination of applications not only tends to weaken the patent system, it makes the Patent Office non-

participative and unaccountable for its decisions. Moreover, for a pre- and post-grant opposition system that India has, it is all the more important that opponents can track the work of Examiners, so that they can decide whether to file an opposition based on prior/art evidence, an Examiner may have missed. Transparency would help strengthen the patent system and also assist the Examiners constructively in their work.

5.8 The European Patent Office (EPO) and U.S Patent and Trademarks Office (USPTO), amongst others, offer free access to all examination reports of pending applications. In the EPO's case the access remains free, even after the patent has been granted.

5.9 The Committee recommend that section 144 of the Patents Act should be repealed and a transparent examination system should be made available, for all to view. The public should be permitted access to all the examination reports, preferably via an online searchable database. The system should also provide information on any amendments an applicant may make during prosecution of an application, such information being critical in determining the rights claimed.

5.10 With regard to access to decisions of the Patent Office relating to Oppositions, the Committee was informed that the Patent Office does not make available on website the decisions on pre-grant and post-grant oppositions or the decisions of the Opposition Board and the Appellate Board. The inability to access such decisions only serves to retard the development and understanding of case law amongst Examiners in other branches of the Indian Patent Office, patent attorneys and lawyers, future students of the patent profession, inventors, researchers and the public at large. Indeed, the lack of access to decisions prejudices applicants and opponents, who may wish to rely on a decision as being a precedent.

5.11 The Committee recommend that the Patent Office decisions on the pre- and post-grant oppositions should be made available on the patent office website.

Pre-Grant Opposition

5.12 The pre-grant opposition provision is a positive step, particularly in the developing countries. A view in favour of pre-grant opposition is that, in a way, it forces the patent office to do better analysis of patent applications. It also forces compulsory licensing for drugs, when a patent is granted. A view has been expressed that the pre-grant opposition provision has not been fully incorporated, thereby weakening it; for example, the provision for an Opposition Board had not been accepted, as is the case of post-grant opposition; an appeal against the Controller's Orders has not been accepted and the Controller's Orders are final. It is felt that a half-hearted pre-grant opposition provision could not prevent 'evergreening' attempts by Multinational Corporations.

5.13 The Committee was informed that the rules for filing a representation for opposition before the grant of a patent under section 25(1) are not being applied in a consistent fashion by the patent offices. For example, the Chennai Patent Office reportedly issued a patent, without providing a hearing to the opponent, despite the fact that the latter had requested for one.

5.14 The Committee observes that Rule 129 provides that before using any discretionary powers under the Act or Rules, which is likely to adversely affect an applicant or a party to the proceedings, the Controller shall give hearing to the applicant/party where either party requests for a hearing. It is difficult to see why the party should not be heard, even if the Controller is inclined to grant the patent.

5.15 The Committee, therefore, recommend that rules for pre-grant opposition should not be applied in such a way as to make them resemble an *ex parte* procedure. Government should endeavour to remove the weaknesses of the provisions relating to pre-grant opposition, which have the potential of keeping a Patent Office alert and make it to analyse a patent application more thoroughly, before granting the patent. It would also give *locus standi* to the affected public, who should be able to point out if a patent was being mistakenly granted.

Patent Manual

5.16 The Committee was informed that the Department of Industrial Policy and Promotion has, through the website of the Patent Office, put up a Draft Manual of Patent Practice and Procedure for implementing the Patents Act. The principal Act of 1970 has been drastically revised to comply with TRIPS Agreement and the Paris Convention. The Patent law, as amended in 2005, has been in operation for nearly three years, and the Patent Office Procedure under the new law is still evolving.

5.17 The Committee was further informed that neither the Controller nor the Central Government has any authority or sanction of law to publish a manual of the kind put on the website. The patent office, in the document itself, has inserted language, which recognizes the absence of any legality for the document and disowns any authoritative nature of contents of the document. Containing as it does interpretation of various provisions of law by the patent office, which is the function of judiciary, the official manual, if implemented, would provide a fertile ground for litigation and controversy in interpretation of the legal aspects (vis-à-vis the Act/Rules and the manual), tending to tilt the balance of convenience in favour of MNCs, who have the resources to litigate. The document has no legal basis and cannot be relied upon in respect of any proceedings under the Act and Rules for its authority.

5.18 There was a suggestion that if at all it is necessary to publish a manual, it should be modeled on what the Patent Office has been doing for over a century, by publishing a 'Patent Office Hand Book', updated through revised editions from time to time. The present draft manual should be wholly scrapped, and in its place a new edition of Patent Office Hand Book may be brought, if it is considered necessary. It has been pleaded that the absence of a manual or a Patent Office Hand Book will not do any harm, but a manual of this nature will do more harm than good. 5.19 The Dictionary meaning of "manual" is "a book of instructions, especially for operating a machine or learning a subject" and includes a "handbook". The Committee are of the opinion that the apparent motive of the Department in bringing out a Manual must be to make available in simple and lucid language the procedures for processing the applications and grant of patents. Such a publication would enable Examiners to smoothly process the applications and also ensure uniformity of examination in all Patent

Offices throughout the country. The Committee, however, feel that in order to allay the apprehensions of the public, due care should be taken to draft the Manual or Hand book, by whatever name it is called, in such a manner so that the same is not open to varying or conflicting interpretations.

Human Resource

5.20 The Committee was informed that by 2012, a total of 70,000 patent applications and 20,00,00 Trade Mark applications were expected to be filed annually. To meet this workload, 1380 posts were proposed to be created, including 617 Examiners, 157 posts of Controller for Patents and Designs, 128 posts of Examiners and 53 posts of Registrar of Trade Marks.

5.21 The Committee feel that the number of posts sanctioned was less than that required and the time taken for recruitment was very long. The Committee, therefore, recommend that in view of the huge number of patent applications expected in the near future, it is imperative that the Government increases the number of posts sanctioned, in order to ensure efficient and timely examination of the patent applications. The Government should also strive to reduce the recruitment time for inducting the Examiners.

5.22 The Committee feel that one of the basic lacunae hampering the process of modernization of Patents and Trade Marks Offices is the migration of staff to greener pastures viz. private sector, once they grasp the know-how in the Intellectual Property offices, as the salary structure/incentives are better there.

5.23 The Department should explore the possibility of upgrading the staff in the Patents and Trade Marks Offices, on the lines of scientific cadres, with impressive salary/remuneration/incentive packages so as to check migration and enhance job satisfaction. In order to attract people to the field of Intellectual Property Rights, the Government may consider introducing a scheme, whereby these people are treated as scientific personnel. This could help in attracting and retaining people in the Patent Offices. The help of Ministry of Health & Family Welfare, Ministry of Human Resource Development and Ministry of Science and Technology could also be elicited in engaging intellectuals and scientists, especially in the field of biotechnology, for examination of patent applications.

5.24 The Department of Scientific and Industrial Relations and DG, CSIR informed the Committee that the cost of filing patents in the United States was fairly high and most of our public funded institutions in the University sector did not have the required resources. The Department was trying to help by not only paying for resources, but also by providing help to write the patents. The Ministry of Science and Technology was running a training course for patent writing and drafting. The IPR Section and other Departments of the Ministry should come together and strive to create a system capable of generating a self-sustaining pool of patent Examiners of international standards.

5.25 There was a proposal by the Ministry of Science and Technology to establish an institution for capacity-building in Intellectual Property Management. In fact, the ASEAN countries want to join hands with India, to establish a regional centre in this regard. **The Government should exploit this opportunity to setup an IP Management**

Centre; in collaboration with ASEAN countries, which could help the country imbibe the best practices in the domain of Intellectual Property Rights and Intellectual Property Management.

5.26 The Department of Industrial Policy and Promotion was proposing to convert the Intellectual Property Training Institute (IPTI Nagpur) into a National Institute. However, the number of staff being trained vis-à-vis the actual staff needed, has not been upto the mark. Help from the outside Consultants or Institutions, who could guide on how the Institute could cater to the demand of manpower required, was also not being taken.

5.27 The Committee feel that there is a huge gap between the demand and supply of specialized manpower in the field of IP management. The set-ups like Intellectual Property Management Division, CSIR, TIFAC and NRDC should be provided necessary infrastructure and support, to enable them to become "Centers of Excellence", in providing specialized IPR training to members of the scientific community. CSIR could also launch a Pilot Project, for imparting IPR training to the interested school and college-going students, depending upon the availability of resources at the lab/IPMD. This Pilot Project could be implemented by the Intellectual Property Management Division, CSIR, with the network of IP Cells in CSIR labs. On another plane, the Government should encourage Universities to introduce short-term and medium-term programmes of instruction/training in IPR, including in the fields of bioscience and biotechnology.

5.28 In order to ensure that the so called out-sourcing of R and D within the country does not lead to IP going elsewhere by default, thereby creating wealth of talent in third party nations, the R and D investments need to be enhanced significantly. The Government should allocate sufficient funds for R and D investments, so as to retain the IP wealth within the country. For a better coordination on this front, an Inter-Ministerial group should be set up by the Department of Industrial Policy and Promotion with members *inter-alia* from the Ministry of Human Resource Development and Ministry of Science and Technology.

Technical Expert Group (TEG)

5.29 The Committee was informed that a Technical Expert Group (TEG) under the Chairmanship of Dr. R.A. Mashelkar, Director General, CSIR, was set up on 5th April, 2005. The terms of reference of the group were as under:

- Whether it would be TRIPS compatible to limit the grant of patent for pharmaceutical substance to new chemical entity or to new medical entity involving one or more inventive steps; and
- Whether it would be TRIPS compatible to exclude micro-organisms from patenting.

5.30 The Group held six meetings and submitted its report to the Government on 29th December, 2006. The Chairman of the group requested the Government for approval to "withdraw the Report, re-examine it and resubmit a Report which meets with the requirements of the highest standards". The Government had agreed to allow the TEG to remove the "technical inaccuracies" in the Report. The final report of the Group is awaited.

5.31 The Department of Industrial Policy and Promotion informed that communications had been addressed to Dr. Mashelkar on 7th & 15th March, 1st May, 9th July, 24th August, 10th October, 19th October, and 25th October, 2007 for expediting the report. The question of submission of TEG report came up for discussion in this Committee's meetings held on 18th December, 2007, 11th January, 2008 and 25th March, 2008. The Committee during the course of its meeting on 18th December, 2008 directed the Department to indicate a clear deadline by which the report would be submitted. The Department responded that the report would be received within two months. In February, 2008, the Department shifted the deadline to the month of March, 2008, and in the Committee's meeting held on 25th March, 2008, Secretary, Department of Industrial Policy and Promotion stated that the report was expected by 8th April, 2008 but, till date, the report has not been received.

5.32 The Committee note regretfully that the TEG appointed by the Government to suggest amendments to the Patents Act has not submitted its final report, despite lapse of a period of more than three years. Though the Department gave assurances to the Committee from time to time that the said report would be made available by a particular date, yet it failed to fulfil all such assurances. So much so that the Committee delayed its report on the Patents and Trade Marks Systems so as to be able to take into account the TEG's recommendations.

5.33 The Committee are, therefore, of the opinion that the resultant delays in such a vital matter as to the definition of patentability will lead to serious setbacks in the protection of Intellectual Property Resources of our country. Such slackness/dilly-dallying on the part of the Department would tend to seriously affect the Pharmaceutical Industry in India, which is unit-based, unlike in developed countries, where multinational companies control the pharmaceutical trade.

5.34 Regarding the other issue being examined by the Technical Expert Group i.e. whether it would be TRIPS compatible to exclude micro-organisms from patenting, there is a provision for patentability of micro-organisms in the Patents Act, 1970. Micro-organisms as such occur in nature, and should be considered as discoveries and not inventions. Genetically modified micro-organisms perform certain activities. The viable proposition would be to patent only specific activity under process patent. It may be equally important to define "micro-organisms is a subject of mandated review by the Scope of their patentability. The issue of patenting of micro-organisms is a subject of mandated review by the WTO. WTO has been examining this issue since 1999, but they have not come to any conclusion. The Committee are of the view that the Government should take an early and unequivocal decision with regard to patentability of micro-organisms per se or their specific activities. If needed, necessary amendments should be expeditiously carried out in the Patents Act.

5.35 Another issue which came up during deliberations with various experts involved in the field was the inadequacy in the definition of the term "invention". It was submitted that Section 3(d) of the Patents Acts provides that any new forms of known substances should not be patented, unless there is significant difference in the levels of efficacy and that patents should be restricted to basic inventions only. Certain common law countries like USA,

PARLIAMENT OF INDIA

Canada and England follow classical criteria with regard to the definition of the term "invention". What India had done was that it had adopted a part of that criteria and put a rider, which is Section 3(d). However, even Section 3(d) is not free from ambiguities. The Government should clarify the usage of terms 'significantly' and 'efficacy', which form part of Section 3(d), to clear the ambiguities involved in the interpretation of the said section. It needs to be ensured that the laws are not TRIPS-plus but just TRIPS compliant.

5.36 The Committee was informed that presently, as per Section 3(k) of the Patents Act, computer programmes *per se* are not patentable. Section 3(k) of the Patents Act, 1970 provides that 'a mathematical or business method or computer programme *per se* or algorithms' are not patentable. The Committee feel that the domain of "*per se*" in the definition needs to be clearly defined.

Royalty Payment

5.37 Article 31 (h) of TRIPS Agreement provides for adequate remuneration, based on economic value of the authorization, to be paid by the compulsory licence holder, i.e. the domestic enterprise, for use of the patent. The original Patents Act, 1970 provided for a ceiling on royalty of 4% payable to the patent holders. The practice followed by several countries about payment of royalty is between 1% and 5%. The Committee was informed that a ceiling of 5% to 6% could be provided, as holding the issue in abeyance could lead to dispute between patent holder and the compulsory licence holder. In order to avoid disputes, it is important that royalty ceiling payable is stipulated at least in the Patent Rules. The Committee recommend that the Department should provide for a royalty ceiling payable by the compulsory licence holder, to the patent holder. This could be done by suitably amending the Patent Rules. If need be, the system of royalty prevailing in different countries could be taken into consideration, for arriving at a reasonable and practicable ceiling.

5.38 The Committee was informed that the system of relief by way of injunction by the courts was leading to a situation whereby, consequent to the injunction being granted, the public interest is bypassed, which results in rise in the prices of drugs, making them unaffordable. Instead of the injunction, payment of royalty should be the norm, at the interim as well as at the final stages. The Committee, therefore, urge the Government to introduce payment of Royalty, both at the interim and at the final stage, and even in revocation proceedings, which would provide revenue to the patent holder and access to medicines under the Public Health System. This would also keep the prices of drugs under control.

5.39 Article 70.3 of TRIPS Agreement provides that there shall be no obligation to restore protection to the subject matter which, on the date of application (i.e. 1st January, 2005 of TRIPS Agreement) for the Member in question has fallen into public domain. There are reportedly 36 products, with a turnover of over Rs. 3000 crore, which the domestic enterprises were producing as on 1st January, 2005, for which mailbox applications were filed by the applicants. Instead of implementing this provision, the amended Patents Act stipulates that those enterprises which have been producing mailbox products on 1st January, 2005, will have to pay royalty to the patent holder during the

remaining period of the patent, and this amount of royalty works out to more than Rs. 150 crore annually to MNCs, even if paid @ 5%.

5.40 The Committee express surprise that the Department allowed a loss of valuable foreign exchange due to this provision, which could have been avoided, had the Department made use of Article 70.3 of TRIPS Agreement in the amended Patents Act. The Department should have taken advantage of this flexibility, to safeguard public interest in respect of availability of medicines at competitive prices through the domestic enterprises. The Committee, therefore, recommend that the Department should consider to implement this provision in future, by way of amendment to the Patents Act.

5.41 In the Ministerial Conference of WTO held at Doha in November, 2001, a special declaration, known as declaration on TRIPS Agreement and Public Health, was issued. The declaration recognized the gravity of Public Health Problems afflicting many developing and the least developed countries, especially those resulting from HIV/AIDS, T.B., malaria, etc. Post this declaration, every country has the right to determine measures necessary for public health as well as to determine what should be the grounds for giving compulsory licences. However, these flexibilities, which have been clarified in the declaration with regard to compulsory licensing, have not been used while amending our Patents law. There is no denying the fact that India has a large number of HIV/AIDS patients. Our compulsory licensing system is quite weak and there are impediments for the domestic enterprises to play

substantive role in meeting the demand of the country in respect of patented products. The Committee, therefore, feel that a stage has come for taking urgent steps, to determine what constitutes national emergency or the circumstances of extreme emergency, and allow domestic enterprises to take compulsory licences and produce products, for mitigating the sufferings of the people afflicted with such diseases, not only in the country, but also in other developing countries.

Compulsory License

5.42 The Committee was informed that the scope of Compulsory Licensing has been broadened to include affordability, non-working of patent, etc. The Patent holder will be entitled for compensation from the licensee. Compulsory Licensing will be available for export to any country, having insufficient or no manufacturing capacity, to address public health needs. However, Compulsory Licensing procedure U/S 87 is too lengthy and complicated. It is totally in favour of the Patent holders, who are mostly MNCs. For example, the Right of Opposition granted to the Patent holder against the applicant of Compulsory Licensing, absence of any time limit, not fixing the royalty rate, etc., are all tilted in their favour. The result is that the chances of success in getting a compulsory licence are very low, because of a protracted and expensive procedures.

5.43 The Committee are concerned that the Compulsory Licence regime was introduced to keep the prices of drugs in control, by allowing production of patented drugs in circumstance necessitating the need for their availability, but getting a compulsory licence is a long drawn process, involving protracted legal battle, which is an expensive proposition. Even the TRIPS agreement does not impose such conditions for issue

of Compulsory Licence, as have been incorporated in the Patents Act. The Committee, therefore, urge the Government to revisit this provision, and make the process of Compulsory Licensing simpler and conducive of public interest.

5.44 The Committee is also of the view that it is in the interest of the country to have a Patent Law which has correlation with our Health Policy and is also pro-generic industry. On its part, the pharmaceutical industry in the country should also shun profit-centric approach, and look at the problem from a human angle. The guiding principles for the Patent regime as well as the Industry should be affordability, safety, accessibility and availability of a pharmaceutical system, which provides a coherent, cogent and people-centric health system in the country.

5.45 Article 31 (b) of TRIPS Agreement provides that if any enterprise wants to exploit a patent, it has to approach the patent holder, with an offer of reasonable commercial terms and conditions, and wait for response from the patent holder, for a reasonable period of time. If there is no response, the enterprises can approach the Patent Controller for grant of Compulsory License. A number of countries like China, Brazil, Argentina, U.K., etc., have made provision implementing this Article in their patent laws. This provision has still not been implemented in India. The Committee feel that the provision of compulsory licencing contained in Article 31(b) of the TRIPS Agreement is extremely important to ensure effective role of the domestic industry to meet the demand for patented products in the country. Implementation of this provision would also open avenues for exports The Department should, therefore, make provision for implementing TRIPS 31(b) Article in our Patents Law at the earliest.

Exclusive Marketing Rights

5.46 The concept of Exclusive Marketing Rights had resulted in prohibiting the local producers of life saving drugs, to the advantage of the multinationals, who had obtained Exclusive Marketing Rights. This had led to a situation where the prices of life saving drugs had gone through the roof, thereby affecting the vital Public Health System in the country, where such drugs had become unaffordable. The right to public health is a fundamental right of the citizens of the country. The Committee express anguish that the Exclusive Marketing Rights Regime was allowed to prevail over the basic Public Health System. The Government should, therefore, take immediate steps to align the balance of convenience, as per the Indian patentability criteria laid down in the Act of 2005 so that the Public Health System does not suffer due to the Exclusive Marketing Rights Regime (EMRs).

Data Exclusivity

5.47 As a condition for registering pharmaceutical and agro-chemical products, National authorities normally require the applicant to submit data relating to quality, safety and efficacy of the product. The Committee were informed that the MNCs are demanding 'Data Exclusivity' on their data, so that its use could be prevented for allowing generic

manufacturers to take marketing approval. The Committee is aware of the fact that there is considerable pressure on the Government to accede to this demand. The Committee feel that conceding to demand for Data Exclusivity would amount to agreeing to TRIPS plus provisions. Once such a demand is agreed at bilateral forum, there will be additional demands, which may relate to higher level of intellectual property right, such as extension of patent period, restriction on compulsory licences, restriction on parallel imports, and may be on R&D activity on patented subject matter. Data Exclusivity may result in delay in ensuring role of domestic enterprises through compulsory licensing system, and in preventing other parties from developing similar data.

5.48 Since the consequences of Data Exclusivity are quite serious, the Committee strongly recommend that the Government should not fall prey to such demands of MNCs. The Government must thwart such attempts, being made at the behest of certain vested interests. It should also guard against moves to enter into FTA with USA, as the developed countries, particularly the USA, are trying to bring in certain TRIPS Plus measures through Bilateral and Regional Agreements.

Protection of Geographical Indications

5.49 Geographical Indications (GIs) are intellectual property rights, which identify a product's geographic origin. Article 22 of TRIPS Agreement deals with establishment of a multilateral system of notification and registration of geographical indications of products, other than wines and spirits, in other countries. The protection of Geographical Indication is supposed to extend to agriculture, natural goods, manufactured goods or any goods of handicraft or goods of industry or food stuff. India has enacted Geographical Indications of Goods (Registration and Protection) Act, 1999. In order that this Act becomes truly operational, the provisions of Article 24 of TRIPS Agreement should be extended to all products, other than wines and spirits in other countries. There is no decision yet in WTO on this issue.

5.50 For operationalisation of Article 22 and extension of Article 24 to Article 22 of TRIPS Agreement, the Government should actively co-ordinate with like-minded countries, to push the WTO to take a decision in this regard, so that the Domestic Law in the domain of Geographical Indications is effectively operationalised.

5.51 There are Several Geographical Indications Viz. Muga Silk (Assam); Kanjeevaram (Tamil Nadu); Mysore Silk (Karnataka); Kangra Tea (Himachal Pradesh); Darjeeling Tea (West Bengal), etc., in our country, which need to be protected. India has enacted a law, but that law cannot be used till we have a multilateral facility available. Approval of WTO forum on such products, so that no one would be able to use these indications, would help a lot of our traditional Geographical Indications from being usurped by other countries. The Committee are of the view that this system of origin-labelling and Quality-certification is supportive of rural development, related to agricultural products, especially in marginalized areas. Products using Geographical Indications, that indicate specific characteristics and homogeneity, command a premium price. The Committee, therefore,

impress upon the Government to take measures on a war footing to ensure recognition of Geographical

indications originating from our country at the WTO.

Review of TRIPS

5.52 Article 71 of the TRIPS Agreement stipulates review of the Agreement by the TRIPS Council, in the light of

new developments, which may warrant modification or amendment of the TRIPS Agreement. The following

problematic issues, which require consideration by the TRIPS Council, were highlighted before the Committee:-

- Patent holder enjoys similar patent rights on his import or locally produced patented products. Providing similar patent right for imported patented product may be relevant for small countries, but not for a big country like India;
- (ii) The patent holder should have the obligation of either producing the patented product in the country himself, or licence producing of patented product to domestic enterprises, as the demand of large country like India can be satisfied only through such stipulations;
- (iii) Article 31(h) of TRIPS provides that the right holder shall be paid adequate remuneration, taking into account the economic value of the authorization. This provision is not explicit in the sense that neither there is a fixed royalty nor there is a ceiling on royalty. It would be appropriate if specific provision is made in regard to royalty payment in the TRIPS Agreement, to avoid disputes; and
- (iv) Articles 27 of TRIPS stipulates that patent shall be available for any inventions, whether products or process. The terminology of patentable invention needs to be defined, so that frivolous claims are not filed. It would be appropriate to define the invention as 'patentable basic invention'. Similarly, the patentable pharmaceutical product should be restricted only to 'new drug molecules'.

5.53 The Committee feel that a thorough review of the TRIPS Agreement has become a sine qua non, as the interests of developing countries were given a short shrift in the original TRIPS Agreement, which was heavily loaded in the interest of developed countries. The Government should postulate its position on the need for this review and whether a patent holder can bring imports and enjoy the same rights as domestic production.

5.54 The Committee was informed that the issue of Patent Harmonization, which provides for uniform law on Patents for all countries of the world, was nothing but a ploy by the United States to substitute the law of that country on all the countries of the world. In a world where every country had different Constitution, different commercial laws, different economic laws, and different stages of development, it was downright not possible to provide for a uniform patent law for the entire world. The Committee feel that the issue regarding Patent Harmonization should be opposed tooth and nail by India and other developing countries. The Government should make serious efforts to see that Patent Harmonization does not see the light of the day, as it would have repercussions against the interests of the developing countries.

Convention on Bio-Diversity (CBD)

5.55 Another important issue is the Convention on Biodiversity(CBD) and its relationship with TRIPS Agreement. Article 15 of CBD provides that each party shall take legislative, administrative or policy measures, as appropriate, with the aim of sharing, in a fair and equitable way, the results of research and development, and the benefits arising from the commercial and other utilization of generic resources, with the contracting parties. The sharing has

to be upon mutually agreed terms. It is also important that the patent applicant must disclose the source of biological material and related knowledge. They have also to indicate about the consent of knowledge provider.

5.56 In this connection, the country has enacted Bio-diversity Act, 2002. Suitable provision has also been made in the Patents Act, 1970. Unless the issues involved are recognised at multilateral fora, issues involved cannot be applied at multilateral level. This issue is important and there is hardly any progress at the WTO forum.

5.57 At the international level, an interesting debate regarding mutual incompatibility between Convention on Biological Diversity (CBD) and the TRIPS Agreement is going on. In this regard, many countries, including India, have been advocating that the TRIPS Agreement should incorporate some of the basic elements of CBD, as a condition of patentability, such as identification of source of genetic material and associated traditional knowledge, evidence of fair and equitable benefit sharing, the evidence of prior-informed consent from the Government, etc.

5.58 The Committee recommend that the Department should take necessary steps to get recognition to all the issues involved between TRIPS Agreement and the CBD at multilateral forum of WTO as, unless these issues are recognised, they cannot be applied at multilateral level.

5.59 India is a repository of traditional knowledge and is one of the biggest biodiversity regions of the world, which makes it more imperative on the part of Government to take proactive stand that facets of CBD should be made a part of the TRIPS Agreement as it would protect the biodiversity of the country from being usurped. For example, due to lack of clarity in this matter, guite a large number of germplasms, which may need to be used in preparation of traditional formulations, may have been taken away by the countries of the developed world. The Government should, therefore, set up an inter-Ministerial Task Force, Comprising the Ministry of Health & Family Welfare, Ministry of Science and Technology and Ministry of Agriculture, whose Terms of Reference should be collection, collation, publication and publicity of all the traditional knowledge of the country, so that the same is not usurped by the developed countries. There should also be an Authority for the Protection of Traditional Knowledge which could keep an eye on the protection and preservation of traditional knowledge of the country. Efforts should also be made to encourage research in the field of traditional knowledge, as a fool proof way of protecting it. This would not only protect the traditional intellectual wealth of the country, but also provide opportunities for millions of its people involved in the use of traditional methods of health care. Government support in their research would help them to being forth their knowledge in the public domain. The Government should make efforts to integrate the traditional systems to the Health Care System of the country, so that the undue load on the Allopathic System is reduced.

Design Patenting

5.60 Regarding the design patenting, the Committee voiced the concern that the country does not seem to have applied legal and technical mind to study the implications of Design Patenting in relation to a manufacturing plant, which could be an important component of a pharmaceutical company. It could lead to a situation where designs are

patented and even a small change in design is also accepted as a new design, which could lead to loss of money. The Committee feel that the issue of design patent needs serious Government attention, both at the legal and technical levels, otherwise it could lead to serious implications, whereby small changes in designs could lead to financial loss to the existing patent holder of designs.

5.61 Regarding the present amended Patent Act of 2005, the Committee was informed that the law should be observed for a period of five years. In case there are any deficiencies, the same may be rectified in 2010. At present, there was a need to remove all the 'qualifying phrases' from the Patents Act and to bring in all flexibilities available under the TRIPS Agreement.

5.62 The Committee feel that in the fast changing Intellectual Property Regime (IPR), the Patent Law needs revision. However, the larger issue would be that any revision to be effective must be based on mandated review of TRIPS Agreement, which is still pending. The Government should, therefore, direct its energies at building pressure for a mandated review of the TRIPS Agreement.

TRADE MARKS

5.63 The Trade Marks law in India is administered through the Trade Mark Offices, under the charge of the Controller General of Patents, Designs & Trade Marks, located at Kolkata, Mumbai, Chennai, Delhi and Ahmedabad. The facilities for processing the applications, including payment of fee for all the services in Trade Mark offices are available online.

5.64 The Committee, during its visit to the Trade Marks Registry at Ahmedabad, was informed that at present the Registry has approximately 2500 sq. feet of space. There was no room for hearing room, library room, parking, canteen, etc. Looking at the growth of development in trade, industry and commerce and corresponding requirement of additional staff for the Intellectual Property Service, there is a felt need for additional space.

5.65 This lack of space is a major hindrance which prohibits efficient functioning of the system. Further, poor storage facilities make it difficult to access records when required, thus making registration of Trade Mark applications a cumbersome and time-consuming process. It often leads to problems because filing is not done on time due to non-availability of documents. The Department informed that a new building for accommodating the existing Trade Marks Registry Office at Ahmedabad has been projected in the 11th Five Year Plan 'Modernization Project' which will take care of the constraints of space.

5.66 The Committee recommend that the Government should ensure that the modernization Project of Trade Mark Registry at Ahmedabad is completed within the Plan period itself. The Committee feel that infrastructure-related problems need prompt solutions. The Department should, therefore, take necessary steps to remove infrastructural constraints hampering the efficient functioning of the Trade Marks Registry at Ahmedabad. If need be, some additional space may be rented, till completion of the new Trade Marks Registry building.

7/20/2018

PARLIAMENT OF INDIA

5.67 It was submitted before the Committee that the time-frame for registration of a trademark is exceptionally lengthy, in comparison to that in other countries. There is also a delay in procurement of search reports, despite the statutory time-limit. Further, the rules to expedite screening/examination of applications for trademarks are not adhered to. The Committee, therefore, recommend that there should be strict adherence to the statutory time-limits for trademark search and examination/screening of applications. There should be proper channels of supervision and accountability. The Trade Marks Registry should be fully computerized to reduce paper work and to increase efficiency, and for quick disposal of applications. A provision for trademarks search through Trade Marks Official website, to check the registrability, should be put in place.

5.68 Though the Trade Mark Registry is not a revenue earning office, it earned a Revenue of Rs. 163.67 crore in 2006-07 by way of fees collected for its services, and incurred an expenditure of Rs. 15.87 crore leaving a substantial surplus revenue. It is a fundamental principle that the fees collected from the public should match the service rendered. However, there seems to be a big gap in this respect in the TMR. This shortfall is attributable to the increased volume of work and the lack of infrastructure in the TMR, which needs to be augmented immediately. **The Committee recommend that the Department should examine whether at least a part of the revenue being earned by the Trade Marks Registry can be ploughed back in a way as the Japanese and the Koreans are doing. The additional allocation could be used for the training of scientific cadres, for creating upgraded infrastructure, more staff and more equipment.**

5.69 The achievements of Trade Marks office have created a positive impact among the public and trade marks users, who are able to secure registration of a mark within a year, compared to seven to eight years, till recently. This success has been appreciated by WIPO and other International Bodies. As a result, India is now in a position to take advantage of International Treaties like the Madrid Protocol relating to International Registration of Trade Marks. Preparatory steps are being taken to accede to the Madrid Protocol in the near future.

5.70 The Committee in its 84th Report on the Trade Marks (Amendment) Bill, 2007 had recommended that the proposed amendment to Section 23 of the Trade Marks Act should not come into force till the Trade Marks Registry is sufficiently and adequately equipped to dispose of both the domestic and the international applications within the stipulated period of 18 months from the filing of such applications.

5.71 The Committee reiterate their said recommendation, that the Government should not accede to the Madrid Protocol, till the Trade Marks Registry is equipped with adequate, skilled manpower and requisite infrastructure and enabled to handle the pressure of dealing with trade mark applications, both domestic and international, within a period of eighteen months.

5.72 The Committee was informed that there is a continuing increase in the filing of applications for registration of trade marks. The development of trade and commerce and the promulgation of the Trade Marks Act, 1999, providing for registration of trade marks for 'services', has given additional responsibility to the TMR. There is no corresponding increase in the examining and supporting staff, to efficiently manage the growing volume of work.

7/20/2018

PARLIAMENT OF INDIA

Apart from the growing number of applications for trade marks registration, the requests from public for prior official search, as provided under the law on Form TM-54 (which involves no less than 50% effort towards examination of trade mark applications), have also registered a steep increase. The existing level of manpower strength at the TMR, which was assessed by the Work Study Unit in 1992, was based on the volume of work during the period prior to 1992. Since then, the work in the TMR has increased manifold in every area of trade mark administration - the number of applications having risen from about 30,000 to more than 90,000 and the requests for searches having registered a phenomenal increase, viz. from 38,000 to over two lakh. It would be unrealistic to expect this huge volume to be handled by the very same staff provided in the early nineties. Taking into account the huge increase in backlog of work, the increasing volume of work and the shortage of manpower at the TMR, very few posts of Contract Examiners were sanctioned by Government, with · no corresponding increase at the supervisory and supporting staff levels. Thus, it has helped in a limited way, only one part of the work, viz. examination of backlog of trademark applications. It has not led to final disposal of the cases, as the post examination work on those cases has piled up, in the absence of required manpower.

5.73 The Committee feel that on account of the increasing number of trade- mark applications and huge increase in the requests for official searches, the backlog of unexamined applications has been escalating. The pressure of work on the limited number of Examiners is having an adverse effect on the quality of examination and other follow up procedures. The exercise connected with backlog clearance involves a chain of activities and is a multi functional process. By just taking up one part of the activity through appointment of contract Examiners, the TMR is merely shifting the backlog from one level of operation to another, with practically little effect on the overall "backlog clearance" drive. The Committee, therefore, recommend that the Government should quickly organize a work study about the requirements of TMR and strengthen the administration, to enable it to perform its duties efficiently, instead of ad hoc management of work through contract Examiners. The system of appointment of contract Examiners may prove to be undesirable on a long-term basis, as such appointees, whose tenure is uncertain, are susceptible to be used by the Trade Marks Attorneys/Agents as their representatives inside the TMR office. The rigours of Conduct Rules for Government servants will have no effect on such temporary appointees.

5.74 The modernization of trademarks administration by computerization has, no doubt, modernized the performance of the TMR, but its impact will be felt by the end users of the system, only if sufficient man power is put in place, to efficiently manage the system. The Committee, therefore, recommend that staff should be suitably augmented, to efficiently manage the system, and to also ensure that the benefits of computerization of Trade Marks offices reach the end user.

5.75 The inadequate office space at the Head Office in Mumbai and in the branch offices, for proper upkeep of the growing volume of records, was seriously affecting the overall efficiency of the trade marks administration. The TMR is an office of record of the ownership of trade marks of the business community, both in India and abroad and,

therefore, record management should receive adequate attention of Government. Unlike other Government departments, files in the TMR do not remain in one section. They keep moving between sections and branch offices, and are made available for public inspection, as provided in the Act. They are also requisitioned by Courts and Appellate Board, in connection with legal proceedings. File tracking has been one of the major problems of the Registry, resulting in untraced or lost files, necessitating reconstruction or creation of duplicate files. Therefore, apart from warehousing facility for upkeep of records, bar-coding system for file tracking needs to be considered. **The Committee recommend that the Department should provide storage facilities for proper upkeep of the growing volume of records at TMR offices. Apart from this, the Department should also consider bar-coding system, for keeping track of the files.**

5.76 The Committee was informed that no provisions for Smell Marks, Taste Marks or Sound Marks as trademarks, was given anywhere in the Act. These concepts have not at all been incorporated, and the definition of a mark or trade mark revolves around the concept of visual representation. But where a smell of a perfume or a taste of a fruit juice or sound of a particular toy can represent a product's source and is capable of distinguishing the goods or services of the proprietor of such products from that of others, they can be considered to be trade marks. **The Committee is, therefore, of the opinion, that Government should examine the need to provide for inclusion of Smell Marks, Taste Marks and sound Marks in the definition of trade marks.**

5.77 The enactment of the Trade Marks Act, 1999 was hailed as a progressive measure, in tune with the modern day requirements of the commercial community. The one change, which was thought would help the trade mark owners, was the establishment of an Appellate Board. Unfortunately, it seems to have failed. The Board has not been functioning properly in the absence of a technical member in the Board. The quality of decisions of the Board is also far from satisfactory, because of appointment of inexperienced persons, not familiar with this branch of law. Most of the decisions are either taken on further appeal to Higher Courts by way of writs, and if not, such wrong decisions become a fait accompli, and continue to prevail. The Committee recommend that more technical and experienced persons, familiar with the Intellectual Property Law, may be appointed on the Intellectual Property Appellate Board (IPAB), in order to improve its functioning.

5.78 Trade Marks offences are cognizable under section 115(3), which means any police officer can take cognizance of an offence committed under the Act, in terms of the provisions of Cr. P. C. But the effect of this important change in law has been completely washed out by the proviso to sub-section (4), which mandates that the police officer should obtain the opinion of the Registrar. The Committee feel that on the one hand the law declares the offence to be cognizable, and on the other' hand it deprives the police officer to take cognizance of the offence, and forces him to refer the case to the Registrar of Trade Marks for his opinion, and to abide by the same. The Committee, therefore, recommend that the proviso to section 115(4) should be dropped, to give the law its intended effect, obviating the need for the police officer to obtain opinion of the Registrar, to proceed with cognizance of cognizable offences.

OBSERVATIONS AND RECOMMENDATIONS AT A GLANCE

- 1. The Committee recommend that the Department should make all out efforts at capacity building of the Indian Patent Offices, so as to provide intellectual property services of global standards. Efforts should also be made to make the Indian Patent Office an International Search Authority(ISA) and International Preliminary Examining Authority(IPEA) under the Patent Cooperation Treaty(PCT). The Department should undertake an exercise aimed at awareness generation and sensitization among professionals as well as general public, about the importance of Intellectual Property Rights for economic and trade development, and also to develop in the country a culture of respect for IPRs. (Para 5.3)
- 2. The Committee feel that most significant constraint of the current patent publication system in India is the lack of a searchable patents database, that can provide all requisite information on an updated basis. Though the Patent Amendment Act, 2005 had been passed, yet electronic searchable patent database is not available. The current PDF file format is not suitable for searching all the journal publications at once. The fallout of the absence of a public searchable patent database is that the inventors, commercial competitors, academic researchers and a host of public interest groups are not able to effectively search patents. This is a significant problem, as these groups need to know what patents exist in India, so they can determine any legal risks or the validity of the patents being filed and granted. The current system is thus cumbersome and time-consuming and places a heavy resource burden on the information seeker. Lack of readily available information does not help create a transparent patent system. (Para 5.5)
- 3. The Committee, therefore, recommend that an electronic searchable patent database should be made public at the earliest. In order to legally provide such a database, it may perhaps be necessary to amend the provisions governing the patent information, namely Sections 145 & 153, and Rules 27 & 134. (Para 5.6)
- 4. The Committee feel that the lack of transparency with regard to the process of examination of applications not only tends to weaken the patent system, it makes the Patent Office non-participative and unaccountable for its decisions. Moreover, for a pre- and post-grant opposition system that India has, it is all the more important that opponents can track the work of Examiners, so that they can decide whether to file an opposition based on prior/art evidence, an Examiner may have missed. Transparency would help strengthen the patent system and also assist the Examiners constructively in their work. (Para 5.7)
- 5. The Committee recommend that section 144 of the Patents Act should be repealed and a transparent examination system should be made available, for all to view. The public should be permitted access to all the examination reports, preferably via an online searchable database. The system should also provide information on any amendments an applicant may make during prosecution of an application, such information being critical in determining the rights claimed. (Para 5.9)
- 6. The Committee recommend that the Patent Office decisions on the pre- and post-grant oppositions should be made available on the patent office website. (Para 5.11)
- 7. The Committee, therefore, recommend that rules for pre-grant opposition should not be applied in such a way as to make them resemble an *ex parte* procedure. Government should endeavour to remove the weaknesses of the provisions relating to pre-grant opposition, which have the potential of keeping a Patent Office alert and make it to analyse a patent application more thoroughly, before granting the patent. It would also give *locus standi* to the affected public, who should be able to point out if a patent was being mistakenly granted. (Para 5.15)

7/20/2018

- 8. The Dictionary meaning of "manual" is "a book of instructions, especially for operating a machine or learning a subject" and includes a "handbook". The Committee are of the opinion that the apparent motive of the Department in bringing out a Manual must be to make available in simple and lucid language the procedures for processing the applications and grant of patents. Such a publication would enable Examiners to smoothly process the applications and also ensure uniformity of examination in all Patent Offices throughout the country. The Committee, however, feel that in order to allay the apprehensions of the public, due care should be taken to draft the Manual or Hand book, by whatever name it is called, in such a manner so that the same is not open to varying or conflicting interpretations. (Para 5.19)
- 9. The Committee, therefore, recommend that in view of the huge number of patent applications expected in the near future, it is imperative that the Government increases the number of posts sanctioned, in order to ensure efficient and timely examination of the patent applications. The Government should also strive to reduce the recruitment time for inducting the Examiners. (Para 5.21)
- 10. The Department should explore the possibility of upgrading the staff in the Patents and Trade Marks Offices, on the lines of scientific cadres, with impressive salary/remuneration/incentive packages so as to check migration and enhance job satisfaction. In order to attract people to the field of Intellectual Property Rights, the Government may consider introducing a scheme, whereby these people are treated as scientific personnel. This could help in attracting and retaining people in the Patent Offices. The help of Ministry of Health & Family Welfare, Ministry of Human Resource Development and Ministry of Science and Technology could also be elicited in engaging intellectuals and scientists, especially in the field of bio-technology, for examination of patent applications. (Para 5.23)
- 11. The IPR Section and other Departments of the Ministry should come together and strive to create a system capable of generating a self-sustaining pool of patent Examiners of international standards. (Para 5.24)
- 12. The Government should exploit this opportunity to setup an IP Management Centre; in collaboration with ASEAN countries, which could help the country imbibe the best practices in the domain of Intellectual Property Rights and Intellectual Property Management. (Para 5.25)
- 13. The Committee feel that there is a huge gap between the demand and supply of specialized manpower in the field of IP management. The set-ups like Intellectual Property Management Division, CSIR, TIFAC and NRDC should be provided necessary infrastructure and support, to enable them to become "Centers of Excellence", in providing specialized IPR training to members of the scientific community. CSIR could also launch a Pilot Project, for imparting IPR training to the interested school and college-going students, depending upon the availability of resources at the lab/IPMD. This Pilot Project could be implemented by the Intellectual Property Management Division, CSIR, with the network of IP Cells in CSIR labs. On another plane, the Government should encourage Universities to introduce short-term and medium-term programmes of instruction/training in IPR, including in the fields of bioscience and biotechnology. (Para 5.27)
- 14. In order to ensure that the so called out-sourcing of R and D within the country does not lead to IP going elsewhere by default, thereby creating wealth of talent in third party nations, the R and D investments need to be enhanced significantly. The Government should allocate sufficient funds for R and D investments, so as to retain the IP wealth within the country. For a better coordination on this front, an Inter-Ministerial group should be set up by the Department of Industrial Policy and Promotion with members *inter-alia* from the Ministry of Human Resource Development and Ministry of Science and Technology. (Para 5.28)
- 15. The Committee are, therefore, of the opinion that the resultant delays in such a vital matter as to the definition of patentability will lead to serious setbacks in the protection of Intellectual Property Resources of our country. Such slackness/dilly-dallying on the part of the Department would tend to seriously affect the Pharmaceutical Industry in India, which is unit-based, unlike in developed countries, where multinational companies control the pharmaceutical trade. (Para 5.33)
- 16. The Committee are of the view that the Government should take an early and unequivocal decision with regard to patentability of micro-organisms per se or their specific activities. If needed, necessary amendments should be expeditiously carried out in the Patents Act. (Para 5.34)

- 17. However, even Section 3(d) is not free from ambiguities. The Government should clarify the usage of terms 'significantly' and 'efficacy', which form part of Section 3(d), to clear the ambiguities involved in the interpretation of the said section. It needs to be ensured that the laws are not TRIPS-plus but just TRIPS compliant. (Para 5.35)
- 18. The Committee was informed that presently, as per Section 3(k) of the Patents Act, computer programmes *per se* are not patentable. Section 3(k) of the Patents Act, 1970 provides that 'a mathematical or business method or computer programme *per se* or algorithms' are not patentable. The Committee feel that the domain of "*per se*" in the definition needs to be clearly defined. (Para 5.36)
- 19. The Committee recommend that the Department should provide for a royalty ceiling payable by the compulsory licence holder, to the patent holder. This could be done by suitably amending the Patent Rules. If need be, the system of royalty prevailing in different countries could be taken into consideration, for arriving at a reasonable and practicable ceiling. (Para 5.37)
- 20. The Committee, therefore, urge the Government to introduce payment of Royalty, both at the interim and at the final stage, and even in revocation proceedings, which would provide revenue to the patent holder and access to medicines under the Public Health System. This would also keep the prices of drugs under control. (Para 5.38)
- 21. The Committee express surprise that the Department allowed a loss of valuable foreign exchange due to this provision, which could have been avoided, had the Department made use of Article 70.3 of TRIPS Agreement in the amended Patents Act. The Department should have taken advantage of this flexibility, to safeguard public interest in respect of availability of medicines at competitive prices through the domestic enterprises. The Committee, therefore, recommend that the Department should consider to implement this provision in future, by way of amendment to the Patents Act. (Para 5.40)
- 22. The Committee, therefore, feel that a stage has come for taking urgent steps, to determine what constitutes national emergency or the circumstances of extreme emergency, and allow domestic enterprises to take compulsory licences and produce products, for mitigating the sufferings of the people afflicted with such diseases, not only in the country, but also in other developing countries. (Para 5.41)
- 23. The Committee are concerned that the Compulsory Licence regime was introduced to keep the prices of drugs in control, by allowing production of patented drugs in circumstance necessitating the need for their availability, but getting a compulsory licence is a long drawn process, involving protracted legal battle, which is an expensive proposition. Even the TRIPS agreement does not impose such conditions for issue of Compulsory Licence, as have been incorporated in the Patents Act. The Committee, therefore, urge the Government to revisit this provision, and make the process of Compulsory Licensing simpler and conducive of public interest. (Para 5.43)
- 24. The Committee is also of the view that it is in the interest of the country to have a Patent Law which has correlation with our Health Policy and is also pro-generic industry. On its part, the pharmaceutical industry in the country should also shun profit-centric approach, and look at the problem from a human angle. The guiding principles for the Patent regime as well as the Industry should be affordability, safety, accessibility and availability of a pharmaceutical system, which provides a coherent, cogent and people-centric health system in the country. (Para 5.44)
- 25. The Committee feel that the provision of compulsory licencing contained in Article 31(b) of the TRIPS Agreement is extremely important to ensure effective role of the domestic industry to meet the demand for patented products in the country. Implementation of this provision would also open avenues for exports The Department should, therefore, make provision for implementing TRIPS 31(b) Article in our Patents Law at the earliest. (Para 5.45)

- 26. The right to public health is a fundamental right of the citizens of the country. The Committee express anguish that the Exclusive Marketing Rights Regime was allowed to prevail over the basic Public Health System. The Government should, therefore, take immediate steps to align the balance of convenience, as per the Indian patentability criteria laid down in the Act of 2005 so that the Public Health System does not suffer due to the Exclusive Marketing Rights Regime (EMRs). (Para 5.46)
- 27. Since the consequences of Data Exclusivity are quite serious, the Committee strongly recommend that the Government should not fall prey to such demands of MNCs. The Government must thwart such attempts, being made at the behest of certain vested interests. It should also guard against moves to enter into FTA with USA, as the developed countries, particularly the USA, are trying to bring in certain TRIPS Plus measures through Bilateral and Regional Agreements. (Para 5.48)
- 28. For operationalisation of Article 22 and extension of Article 24 to Article 22 of TRIPS Agreement, the Government should actively co-ordinate with like-minded countries, to push the WTO to take a decision in this regard, so that the Domestic Law in the domain of Geographical Indications is effectively operationalised. (Para 5.50)
- 29. The Committee are of the view that this system of origin-labelling and Quality-certification is supportive of rural development, related to agricultural products, especially in marginalized areas. Products using Geographical Indications, that indicate specific characteristics and homogeneity, command a premium price. The Committee, therefore, impress upon the Government to take measures on a war footing to ensure recognition of Geographical indications originating from our country at the WTO. (Para 5.51)
- 30. The Committee feel that a thorough review of the TRIPS Agreement has become a sine qua non, as the interests of developing countries were given a short shrift in the original TRIPS Agreement, which was heavily loaded in the interest of developed countries. The Government should postulate its position on the need for this review and whether a patent holder can bring imports and enjoy the same rights as domestic production. (Para 5.53)
- 31. The Committee feel that the issue regarding Patent Harmonization should be opposed tooth and nail by India and other developing countries. The Government should make serious efforts to see that Patent Harmonization does not see the light of the day, as it would have repercussions against the interests of the developing countries. (Para 5.54)
- 32. The Committee recommend that the Department should take necessary steps to get recognition to all the issues involved between TRIPS Agreement and the CBD at multilateral forum of WTO as, unless these issues are recognised, they cannot be applied at multilateral level. (Para 5.58)
- 33. The Government should, therefore, set up an inter-Ministerial Task Force, Comprising the Ministry of Health & Family Welfare, Ministry of Science and Technology and Ministry of Agriculture, whose Terms of Reference should be collection, collation, publication and publicity of all the traditional knowledge of the country, so that the same is not usurped by the developed countries. There should also be an Authority for the Protection of Traditional Knowledge which could keep an eye on the protection and preservation of traditional knowledge of the country. Efforts should also be made to encourage research in the field of traditional knowledge, as a fool proof way of protecting it. This would not only protect the traditional intellectual wealth of the country, but also provide opportunities for millions of its people involved in the use of traditional methods of health care. Government support in their research would help them to being forth their knowledge in the public domain. The Government should make efforts to integrate the traditional systems to the Health Care System of the country, so that the undue load on the Allopathic System is reduced. (Para 5.59)
- 34. The Committee feel that the issue of design patent needs serious Government attention, both at the legal and technical levels, otherwise it could lead to serious implications, whereby small changes in designs could lead to financial loss to the existing patent holder of designs. (Para 5.60)

- 35. The Committee feel that in the fast changing Intellectual Property Regime (IPR), the Patent Law needs revision. However, the larger issue would be that any revision to be effective must be based on mandated review of TRIPS Agreement, which is still pending. The Government should, therefore, direct its energies at building pressure for a mandated review of the TRIPS Agreement. (Para 5.62)
- 36. The Committee recommend that the Government should ensure that the modernization Project of Trade Mark Registry at Ahmedabad is completed within the Plan period itself. The Committee feel that infrastructure-related problems need prompt solutions. The Department should, therefore, take necessary steps to remove infrastructural constraints hampering the efficient functioning of the Trade Marks Registry at Ahmedabad. If need be, some additional space may be rented, till completion of the new Trade Marks Registry building. (Para 5.66)
- 37. The Committee, therefore, recommend that there should be strict adherence to the statutory time-limits for trademark search and examination/screening of applications. There should be proper channels of supervision and accountability. The Trade Marks Registry should be fully computerized to reduce paper work and to increase efficiency, and for quick disposal of applications. A provision for trademarks search through Trade Marks Official website, to check the registrability, should be put in place. (Para 5.67)
- 38. The Committee recommend that the Department should examine whether at least a part of the revenue being earned by the Trade Marks Registry can be ploughed back in a way as the Japanese and the Koreans are doing. The additional allocation could be used for the training of scientific cadres, for creating upgraded infrastructure, more staff and more equipment. (Para 5.68)
- 39. The Committee in its 84th Report on the Trade Marks (Amendment) Bill, 2007 had recommended that the proposed amendment to Section 23 of the Trade Marks Act should not come into force till the Trade Marks Registry is sufficiently and adequately equipped to dispose of both the domestic and the international applications within the stipulated period of 18 months from the filing of such applications. (Para 5.70)
- 40. The Committee reiterate their said recommendation, that the Government should not accede to the Madrid Protocol, till the Trade Marks Registry is equipped with adequate, skilled manpower and requisite infrastructure and enabled to handle the pressure of dealing with trade mark applications, both domestic and international, within a period of eighteen months. (Para 5.71)
- 41. The Committee, therefore, recommend that the Government should quickly organize a work study about the requirements of TMR and strengthen the administration, to enable it to perform its duties efficiently, instead of ad hoc management of work through contract Examiners. The system of appointment of contract Examiners may prove to be undesirable on a long-term basis, as such appointees, whose tenure is uncertain, are susceptible to be used by the Trade Marks Attorneys/Agents as their representatives inside the TMR office. The rigours of Conduct Rules for Government servants will have no effect on such temporary appointees. (Para 5.73)
- 42. The Committee, therefore, recommend that staff should be suitably augmented, to efficiently manage the system, and to also ensure that the benefits of computerization of Trade Marks offices reach the end user. (Para 5.74)
- 43. The Committee recommend that the Department should provide storage facilities for proper upkeep of the growing volume of records at TMR offices. Apart from this, the Department should also consider bar-coding system, for keeping track of the files. (Para 5.75)
- 44. The Committee is, therefore, of the opinion, that Government should examine the need to provide for inclusion of Smell Marks, Taste Marks and sound Marks in the definition of trade marks. (Para 5.76)
- 45. The Committee recommend that more technical and experienced persons, familiar with the Intellectual Property Law, may be appointed on the Intellectual Property Appellate Board (IPAB), in order to improve its functioning. (Para 5.77)
- 46. The Committee, therefore, recommend that the proviso to section 115(4) should be dropped, to give the law its intended effect, obviating the need for the police officer to obtain opinion of the Registrar,

to proceed with cognizance of cognizable offences. (Para 5.78)

APPENDIX

The Committee considered the written submission as well as oral evidence of the following individuals/organizations given below:-

- i) Sh. B. K. Keayla of the Centre for Study of Global Trade System and Development;
- ii) Ms. Krishna Sarma, Managing Partner, Corporate Law Group;
- iii) Lawyers Collective/HIV Aids;
- iv) Sh. Gajanan Warkankar, Indian Drug Manufacturers Association(IDMA);
- v) Ms. Leena Menghaney, Campaign for Access to Essential Medicines;
- vi) Dr. S. Vedarman, Controller General of Patents, Designs and Trade Marks (Retd.);
- vii) National Law University, Jodhpur;
- viii) MAKs Submissions on Improving the Patents Systems India;
- ix) Organisation of Pharmaceutical Producers of India (OPPI);and
- x) Justice V. K. Krishna Iyer (Former Judge, Supreme Court)

ANNEXURE-I

Note by Sh. B. K. Keayla of the Centre for Study of Global Trade System and Development

As member of the WTO, the country is under an obligation to implement the TRIPS Agreement provisions in our Patents and Trade Marks System. The Patents Act 1970 was amended through three amending legislations in 1999, 2002 and 2005. Similarly Trade Marks Act 1999 was enacted to comply with our obligations. There are several issues which need to be presented to the Hon'ble Committee for their consideration.

The important issues are:-

- a. Flexibilities under TRIPS Agreement implementation in our Patent Law;
- Flexibilities clarified in Doha Declaration on TRIPS Agreement and Public Health application in our Patents Act 1970;
- c. Data Protection/Date exclusivity submitted for making approval of new products;
- d. Free Trade Agreements by USA with other countries implication for India; and
- e. TRIPS Issues in the Doha Work Programme

I. Flexibilities under TRIPS Agreement – implementation in our Patent Law

There are a number of flexibilities available in the TRIPS Agreement which have been confirmed by various international studies. The important flexibility issues are:-

(i) Scope of Patentability

There is an alarming situation which has developed in the world arising out of the patent system being practiced by the developed countries. The data of the <u>active patents</u> during 2004 in the developed countries is as follows:-

| USA | 16,31,977 |
|---------------|-----------|
| Japan | 11,04,640 |
| Great Britain | 4,73,904 |
| Germany | 4,11,671 |

The volume of patent applications being filed in these countries annually is also alarming. In USA, during 2004, 3,56,943 patent applications were filed. In China also, there are similar situations. Upto December 31, 2003, the accumulated number of patent applications was 19,31,118 and, during 2003 ,China received 3,08,487 patent applications. There are reports about the subsequent years and it is understood that the number is now crossing 4 lakhs every year. This data has been compiled from WIPO website. In USA, there are about 3,700 Examiners to examine the patent applications whereas it is understood that China has more than 4000 Examiners. Compared to these India has only about 225 Examiners. It is import and to quote this data so that our country also does not face similar situation. IPR Commission of U.K. has clarified in their Report that the member countries of WTO have the right to define 'patentable invention' and other 'patent terminologies'. They have also recommended that developing countries should aim limiting the scope of subject matter that can be patented. Even the WHO Commission on Public Health, Innovation and Intellectual Property Rights have commented in the same manner. Quoting from WHO Commission report as: "Thus developing countries may determine in their own ways the definition of an invention, the criteria for judging patentability, the rights conferred on patent owners and what exceptions to patentability are permitted, provided these are consistent with the relevant articles of TRIPS (for WTO Members)". This report also states: "As also recognised in the Doha Declaration (Members) may on various grounds provide for measures such as parallel imports, government use and compulsory licensing". The issue of scope of patentability is before the Dr. Mashelkar Committee. It is important that we should restrict the scope of patentability only to the basic inventions and new drug molecules only in the case of pharmaceutical sector. This will help us in limiting the patentable subject matter. If the issue is left as it is, there will be flood of patent applications in our country. There will be chaos in handling high volume of applications. Due to large volume of active patents, there will be unimaginable level of inflation. TRIPS does not define patentable invention and we are free to define and we must define as suggested. The point was made before Dr. Mashelkar Committee.

Patenting of Micro-organisms

The issue patentability of micro-organisms has been provided in the Patents Act 1970. The issue of patenting of micro-organisms is a subject of mandated review by the WTO who has been examining this issue since 1999 but they have not come to any conclusion. Since this provision has already been in the amended Patents Act 1970

about the patenting of micro-organism, the best course available is to notify the WTO that this provision would be implemented only after the WTO has taken a decision on this issue.

(ii) Role of domestic enterprises

Article 31 (b) of TRIPS Agreement provides that if any enterprise is interested to work the patent, they have to approach the patent holder with offer of reasonable commercial terms and conditions and wait for response from the patent holder for a reasonable period of time. If there is no response, the concerned enterprise can approach the patent authority for grant of compulsory licence.

Unfortunately, this provision has not been implemented. A number of other countries like China, Brazil, Argentina, U.K, etc have made provision implementing this article in their patent laws. This provision is extremely important for effective role by the domestic industry in meeting the demands of the patented product in the country. It is not understood as to why the government has ignored this stipulation in the TRIPS Agreement.

(iii) Export of patented products

Article 31 (f) provides for grant of compulsory licences 'predominantly' for supply of domestic market. Since the word 'predominantly' has been used, it should have been possible for the government to freely allow our domestic enterprise who are given compulsory licence to produce the patented product both for domestic and export markets. The procedure prescribed by the WTO for exports of pharmaceutical products is impossible to work.

(iv) Royalty payment

Article 31 (h) provides for adequate remuneration based on economic value of the authorization to be paid by the compulsory licence holder i.e. the domestic enterprise for use of the patent. The original Patents Act 1970 provided for a ceiling on royalty of 4% payable to the patent holders. The practice followed by several countries about the payment or royalty is from 1% and 5%. In order to avoid disputes, it is important that royalty ceiling payable is stipulated atleast in the Patent Rules.

(v) Transfer of technology

Article 7 of the TRIPS Agreement clearly provides for transfer and dissemination of technology as an objective of TRIPS Agreement. This provision should have been implemented.

(vi) Protection of Patented products in public domain on 1.1.2005

Article 70.3 of TRIPS Agreement provides that there shall be no obligation to restore protection to subject matter which on the date of application (i.e. 1.1.2005) of TRIPS Agreement for the member in question has fallen into public domain. There are 36 products with a turnover of over Rs. 3000 crores which the domestic enterprises were producing as on 1.1.2005 for which Mail Box applications were filed by the applicants. Instead of implementing this provision, the amended Patents Act stipulates that those enterprises who are producing Mail Box products on 1.1.2005 will have to pay royalty to the patent holder during the remaining period of patent and this amount of

royalty works out to more than Rs. 150 crores annually even if the royalty of 5% is paid. This flexibility should have been taken advantage, but unfortunately this have not been done.

II. Flexibilities clarified in Doha Declaration on TRIPS Agreement and Public Health

In the Ministerial Conference of WTO held at Doha in November, 2001, Indian delegation led by the then Commerce Minister played an important role on the most crucial issue relating to Public Health under TRIPS Agreement. A special Declaration was issued in this respect known as Declaration on TRIPS Agreement and Public Health. This Declaration specifically deals with certain important issues. These issues are crucial for effective role of domestic enterprises about the availability of medicines. They are:-

- (i) The Declaration recognises the <u>gravity</u> of Public Health problems afflicting many developing and least developed countries especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics;
- (ii) The declaration stipulates that TRIPS Agreement does not and should not prevent Members from <u>taking</u> <u>measures</u> to protect public health; and
- (iii) The Declaration recognises the following flexibilities:-
 - (a) TRIPS Agreement should be read in the light of the object and purpose of the Agreement as expressed, in particular, in its <u>objectives</u> and <u>principles</u>. (as stated in Articles 7 and 8). The objectives are related: to conducive to social and economic welfare, and balance of rights of obligations. The principles provide for: to present the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology;
 - (b) Each Member has the right to <u>grant compulsory licences</u> and have freedom to determine the grounds upon which such licences can be granted; and
 - (c) Member have the right to determine what <u>constitutes</u> a national emergency or other circumstances of extreme urgency, it being understood that public health crises including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent national emergency or other circumstances of extreme urgency.

These are extremely important flexibilities which have been clarified in the declaration, but unfortunately none of those flexibilities have been used in the amending process of the Patents Act. The compulsory licensing system is quite weak and there are impediments for the domestic enterprise to play substantive role in meeting the demands of the country of patented product.

The country recognised the gravity of situation about HIV/AIDS, tuberculosis, malaria and other epidemics as they are covered in our National Health Programme. Neither circumstances of extreme urgency nor has national emergency been declared to meet these diseases. It is not clear as to why the Ministry of Health or the Ministry of Commerce and Industry were not acting on these crucial issues.

The country has now the highest number of HIV/AID cases. Even then the provisions of the Patents Act 1970 are not being used to declare circumstances of extreme urgency. There are a number of new drugs required for treatment of HIV/AID cases. Patent applications filed are pending for these drugs. If circumstances of extreme urgency are declared, the pharmaceutical industry can get compulsory licences and play effective role. Some of the patent applications do not adequately satisfy the criteria for grant of patent.

III. Data Protection/Data Exclusivity submitted for marketing approval of products

- (i) As a condition for registering pharmaceutical and agro-chemical products National authorities normally required applicant to submit data relating to quality, safety and efficacy of the product. The issue being raised is whether directly or in-directly the test data should be used for subsequent registration of products similar to those originally registered. The MNCs are demanding 'data exclusivity' on the data so that its use could be prevented for allowing generic manufacture to take marketing approval;
- (ii) The TRIPS Agreement in Article 39.3 stipulates as follows:-

"Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products while utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use."

- (iii) The issues are:-
 - (a) The stipulation in Article 39.3 is restricted to marketing of pharmaceutical or agricultural chemical products which utilise <u>new chemical entities</u>. There is no clear definition of new chemical entity. This matter is being looked into by Dr. Mashelkar Committee. A clarity is needed on this aspect; and
 - (b) The other point is that the data should be protected against unfair commercial use. This would mean that data could be used for fair commercial use on payment of compensation.
- (iv) Arguments against 'data exclusivity'
 - (a) Article 39.3 was settled during the Uruguay Round of GATT negotiations. During negotiations the developed countries particularly the USA demanded for providing data exclusivity on data submitted for marketing approval to the concerned authority. This demand was rejected at the multilateral forum and as such there should be no question of agreeing to bilateral demand of MNCs. The implications are as follows:-
 - (b) Conceding to demand would mean agreeing to TRIPS plus provision. One such a demand is agreed at bilateral forum there will be additional demands which may relate to higher level of intellectual property right such as extension of patent period, restriction on compulsory licences, restriction on parallel imports and may be also on R&D activity on patented subject matter;
 - (c) Data exclusivity may result in delay in ensuring role of domestic enterprises through compulsory licensing system; and
 - (d) Data exclusivity will result in preventing other parties from developing similar data.

Keeping the above in view it may be concluded that the game plan of MNCs is for market exclusivity for a

period. There can be demand for extension of such exclusivity for some reasons or the other for further period.

(v) It is understood that Ministry of Health and Ministry of Commerce are not supporting grant of data exclusivity, whereas Ministry of Chemical and Petro-chemical and Ministry of Agriculture and supporting the demand for data exclusivity. Since the consequences are quite serious Committee may look to this issue and impress upon the government not to concede to data exclusivity as demanded.

(IV) Implication of US Free Trade Agreement with number of countries.

- a. The new phenomena created by the free trade agreements entered into by USA with a number of countries needs to be carefully studied and taken note of the TRIPS Agreement mandated the introduction of protection of intellectual property rights, notably patents for pharmaceutical products. While the implications for the access to medicines have raised significant concerns all over the world, a recent new wave of free trade agreements (FTAs) entered into by USA with a number of countries outside the WTO, requires higher levels of intellectual property protection for medicines.
- b. The measures involved in these FTAs include:
 - i. extension of the patent term beyond 20 years;
 - ii. limitations to the grounds for granting compulsory licences;
 - iii. restrictions on parallel imports; and
 - iv. prohibition on use to test data on drug efficacy and safety for certain periods for the approval of generic products.

- c. The higher level of intellectual property rights as stated has implication for the country's industry for free trade in these countries. Since 2001 USA has initiated 11 bilateral and regional free trade agreements with 24 countries. In this respect, agreements with Chile, Jordan, Morocco, Singapore, the countries of Central America have been ratified by the US Congress. Six free trade agreements with 13 additional countries have also been initiated and are under negotiation. In additional there are other FTAs which have been signed by or are under negotiation between developing countries and the EU. Thus the dimensions of these agreements is wide spread and would significant implication for free trade with these countries.
- d. With some of these countries we are also trying to have bilateral free trade agreements. With the higher level of intellectual property, free trade with these countries will be only one sided as goods from our country would not have easy entry.
- e. This phenomena of free trade agreements is virtually making the multilateral system weak if not in fructuous.

(V) TRIPS Related Issues in the Doha Work Programme

- 1. Ministerial Conference held in November, 2001 issued Ministerial Declaration which <u>inter alia</u> dealt with Doha Work Programme. TRIPS issues incorporated in this Work Programme are as follows:-
 - (i) Implementation of Article 23.4: establishment of a multilateral system of notification and registration of geographical indications for products other than wines and spirits in other countries.
 - (ii) Review of Article 27.3 (b) relating to micro-organism and non-biological and micro-biological processes.
 - (iii) Examination <u>inter alia</u> of the relationship between TRIPS Agreement and Convention on Biological Diversity and protection of traditional knowledge and folklore.
 - (iv) Review and amendment of TRIPS Agreement under Article 71.1.
 - (v) Examination of relationship between Trade and Transfer of Technology.
- 2. The Ministerial Declaration also stipulated that in undertaking the Work Programme mentioned, the TRIPS Council shall be guided by the objectives set out under Articles 7 and 8 of the TRIPS Agreement and shall take into account also the development dimensions.

The Declaration also provided that these matters should be addressed on priority basis and reported by the end of 2002.

3. The progress in regard to the negotiations on these issues has been rather slow or incomplete. These issues are important for the developing countries whereas developed countries are least interested in their conclusion. The relevant aspects in the various issues are as follows:-

(a) Protection of geographical Indications:-

The protection is supposed to extend to agriculture, natural goods, manufactured goods or any goods of handicraft or goods of industry or food stuff. We have several products which need to be protected through geographical indications, they are Darjeeling tea, Basmati rice and Alfanzo mango etc. India has enacted Geographical Indications of Goods (Registration and Protection) Act 1999. In order to operationalise the Act the provisions of Article 23 (4) of TRIPS have to be extended to all other relevant products in other countries as stated. There is no decision yet in WTO on this issue.

(b) Patenting of Micro-organism and Non-biological and Micro-biological Processes:-

Articles 27.3 (b) of TRIPS provides for a mandated review which started in WTO in 1999 and so far there is no decision.

Micro-organisms as such occur in nature and should be considered as discoveries and not inventions. Genetically modified micro-organisms perform certain activities. The viable proposition would be to patent only specific activity under process patent. It is also important to define micro-organism so that there is no confusion about the scope of their patentability.

We have amended our Patents Act 1970 and provided patenting of micro-organisms. This issue is before the Dr. Mashelkar Committee and their report is awaited about the scope of patenting of this subject matter.

Till the mandated review in WTO is not concludes this provision should not be operationalised in our Patent Act. The specific notification can be issued in this respect.

(c) Relationship between TRIPS Agreement and CBD:-

Article 15 of CBD provides that each party shall take legislative, administrative or policy measures, as appropriate, with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of generic resources with the contracting parties.

The sharing has to be upon mutually agreed terms. it is also important that the patent applicant must disclose the source of biological material and related knowledge. They have also to indicate about the consent of knowledge provider.

In this connected, the country has enacted Bio-diversity Act 2002. Suitable provision has also been made in the Patents Act 1970. Unless the issues involved are recognised at multilateral forum, issues involved cannot be applied at multilateral level. This issue is important and there is hardly any progress at the WTO forum.

(d) The review of TRIPS under Article 70.1:-

Article 70.1 stipulates review of TRIPS Agreement by the TRIPS Council in the light of new developments which may warrant modification or amendment of the TRIPS Agreement.

There are several problematic issues which require consideration by the TRIPS Council. There are:-

- Patent holders enjoy similar patent rights on their import or locally produced patented products. Providing similar patent right for imported patented product to domestic enterprises as the demand of large country like India can be satisfied only through such stipulations;
- (ii) The patent holder should have the obligation of either producing the patented product in the country himself or licence producing of their patented product to domestic enterprises as the demand of large country like India can be satisfied only through such stipulations;
- (iii) Article 31(h) of TRIPS provides that the right holder shall be paid adequate remuneration taking into account the economic value of the authorization. This provision is not explicit in the sense that neither there is a fixed royalty nor there is a ceiling of royalty. It would be appropriate if specific provision is made in regard to royalty payment in the TRIPS Agreement to avoid disputes; and
- (iv) Articles 27 of TRIPS stipulates that patent shall be available for any inventions, whether products or process. The terminology of patentable invention needs to be defined so that frivolous claims are not filed. it would be appropriate to define the invention as 'patentable basic invention'. Similarly the patentable pharmaceutical product should be restricted only to 'new drug molecules'.

(e) Trade and transfer of technology:-

This issue should be settled on the basis of stipulation under Article 7 of TRIPS Agreement on objectives which provides that:-

"the protection and enforcement of intellectual property rights should 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".

To sum up, it is evident that almost all TRIPS related issues of Doha Work Programme are important for the

developing countries. The need is to take pro-active approach by the government otherwise <u>fait accompali</u> suits the developed countries.

VI. Trade Mark Issues

There are no problems in the Trade Marks Act, 1999. The issue which is being raised is use of well-known International Trade Marks. The demand is that these trade marks should not be used for any product in any country. Unless such trade marks are registered under our Act, it would be difficult to meet the demand raised.

"To conclude:-

7/20/2018

PARLIAMENT OF INDIA

The new Product Patent regime will soon have impact on prices and availability of pharmaceuticals products. If the flexibilities which are available under the TRIPS Agreement and which have been clarified in the Doha Declaration on TRIPS Agreement and Public Health are not implemented, the role of the domestic enterprises would be seriously affected. Already, the Indian patents are under tremendous burden on medicines of high exercise duty of 16% with 2% surcharge. In addition to these duties, the pharmaceutical products are sold with a VAT and Sales tax of 4 to 10% and Octroi and turnover tax of 3 to 5%. Service tax of 12% is another burden which also in-directly affected the prices of medicines. All these issues also needs to be looked into in the new product patent scenario. Indian industry, as compared to industry in foreign countries, has also to bear the impact of poor infrastructure, non availability of adequate power, water and transport facilities. These facts are being indicated keeping in view the impact of TRIPS Agreement and non-implementation of flexibilities available would have serious impact along with the impact of high duties on prices and role of domestic industry which in the coming future needs to be strengthened to effectively face the global competition.

The Committee was apprised that a situation was fast developing whereby India could face an acute shortage of patent Examiners in view of the ever growing number of patent applications being filed. Patent examination, it was felt, was a very delicate and sensitive matter which had serious economic consequences in the sense that shortage of staff could lead to depletion of quality of examination which could lead to spurious/fraudulent patents being granted due to more number of patent applications being allocated per person.

It is also a fact that when the last amendment to the Patents Act was passed in April, 2005, the Minister gave an assurance that a Committee would be set up that will look into the aspects on what is the scope of patentable pharmaceutical products. The Committee was informed that a Committee headed by Dr. Mashelkar is examining as to what are the subject matters which should be patented. The Committee in its 86th Report on Demands for Grants (2008-09) pertaining to the Department of Industrial Policy and Promotion had observed that the TEG (Committee headed by Dr. Mashelkar) had not discharged its functions expeditiously and consequently the prices of life saving drugs have been going up, which is a cause for serious concern. As a result, the necessary amendments to the Patents Act, which could control prices has been held up. The Committee had, therefore, conveyed its serious displeasures and directed that the report be finalized without further delay.

Another issue, which the TEG Group was examining, was whether it would be TRIPS compatible to exclude micro-organisms from patenting. The Committee had been informed that the provisions about patenting of micro-organisms should be kept in abeyance till a final verdict on the issue comes out in the WTO particularly in the Doha Work Programme where it is under consideration. Another provision, which has arrested the attention of the Committee, is a particular provision in TRIPS namely Article 31 (b). A contingency in the said Article provides that, if any, enterprise wants to exploit a patent, it has to approach the patent holder with reasonable terms and conditions and wait for a reasonable period. If there is no response, then the enterprises can approach the Patent Controller for patent rights. This provision has still not been implemented in India.

A vital issue emerging out of the debate is the payment of royalty. The TRIPS agreement has not defined the issue. The Principal Act (Patents Act, 1970) had a ceiling of 4% royalty that was applicable for process patent. In the prevailing product patent system, it is a natural corollary that a ceiling should be provided. The Committee was informed that a ceiling of 5% to 6% could be provided as keeping the issue hanging in abeyance could lead to dispute between patent holder and the compulsory licence holder.

A serious matter meriting attention is the issue of Mail Box Applications. TRIPS agreement (viz Article 70.3) says that there is no need to give any patent to any Mail box product which has fallen into public domain as on 1st January, 2005.

This provision has been ignored in the Patents Act which says that protection will be given for the remaining period of 20 years counting from the date of filing and those who are producing will have to pay royalty. The Committee expresses surprise at the ignorance of the Department which overlooked such a serious issue thereby allowing loss of valuable foreign exchange of the provision which could have been totally avoidable had the Department worked in this Particular Article into the amended Patents Act

The Doha Declaration on Public Health was issued in November, 2005 which recognized the gravity of Public Health Problems afflicting many developing and least developed countries especially those resulting from HIV/AIDS, T.B, malaria etc. Post this declaration, every country has the right to determine measures necessary for public health and every country has a right to determine what should be the grounds for giving compulsory licences. However, this freedom conferred by Doha Declaration has not been fully used, particularly in regard to compulsory licensing.

Another issue meriting serious debate is the issue of data exclusivity. The provision was rejected by the multilateral forum of Uruguay Round. However, the issue has been brought to the fore ground by certain Multinational corporations. Conceding to this demand would mean that one is going beyond what is mandated by going the TRIPS agreement. It would mean implementation of TRIPS-plus. This is nothing but getting exclusivity for marketing.

The Government should also look at the aspect whereby consequent upon failure of concerned Ministerial countries like USA, EU have been entering into bilateral agreements/Free Trade Agreements (FTA) to include the extension of patent term beyond 20 years and similarly grant of data exclusivity say for 5 to 10 years.

Another important issue is that of implementation of Article 23.4 of the TRIPS Agreement. This relates to Geographical Indications (GIs). According to TRIPS Agreement, GIs are available only to wines and spirits of France. It was agreed through Doha Declaration that it would be reviewed for another countries also. There are Several Geographical Indications in our country which need to be protected. India has enacted a law, but that law cannot be used till we have a multilateral facility available. Approval of WTO forum on such products, so that no one would be able to use these indications, would help a lot of our traditional GIs from being usurped by others.

Then, there is the issue regarding convention on Biodiversity and the relationship between TRIPS and the former. India has made provision in the Patents Act that if a biodiversity material is used for producing a new product, the producer will have to disclose what biodiversity material one is going to use and whether consent of the person who provided the knowledge was taken. But, unfortunately the TRIPS Agreement has not provided for it. Concerns about this issue have been made at the Hong Kong Declaration but progress was very slow.

ANNEXURE -II

Note by Ms. Krishna Sarma, Managing Partner, Corporate Law Group

Though the Trademark Law was a good one, there was a need to make trademark prosecution more efficient. The time frame for registration was exceptionally lengthy in comparison to other country. Further, there was a delay in procurement of search reports despite the statutory time limit. Further, there was no adherence with the rules regarding expediting screening/examination of applications for trademarks.

Further, the witness informed Geographical Indications (GIs) that indicate specific characteristics and high quality assurance and homogeneity command a premium price. It was felt that there should be a human dimension to goods and should not focus primarily on mass production. The witness informed that Government should aid in research in product improvement and portfolio to achieve economics of scale and expand sales.

On the working of Patent Offices, the witness informed that a major drawback was that at present the backlog of application is about 22000. The Examiners and controllers are required to determine patent application in multiple disciplines, which may effect the quality of prosecution viz. a Controller/Examiner with mechanical engineering background is examining a bio tech patent. Unlike USPTO and JPO, India has four patent offices as per original jurisdiction, more or less independently. There has been a lack of synergy between four offices viz:-

- (i) Filing is independent;
- (ii) Prosecution is independent; and
- (iii) Grant is independent.

The only aspect where there is synchronization is in issuing patent numbers after grant. This left scope for difference in interpreting and implementing the law by different offices in the absence of a Central guiding parameter. Such variation in interpretation becomes apparent in cases where language of statute is open ended, thus, leaving room for subjective enquiry. Nowhere is it more palpable than in the case of interpretation and application of Section 3(d) of the Patents Act. Various decisions emanating from the four offices regarding interpretation of Section 3(d) have resulted in a wide latitude in its application. The witness then suggested certain recommendations which would help streamline the Patents system in India:-

- The term "efficacy" needs to be defined in the explanation to Section 3(d) and guidelines should be set out for examining "inventive step";
- (ii) The Patents Act need to be modified to make provisions clear and transparent so that there is no unnecessary litigation for our already over burdened judiciary;
- (iii) There is a pressing need for introduction of patents for "new use of a known substance" so as to encourage research for new use of Ayurvedic medicines and to find new cures to address our un-met medical needs;

- (iv) The lack of definition of the term efficacy may result in a lot of scientific waste. Further Genuine R & D may not be rewarded, discouraging innovation by the industrial and scientific community;
- (v) Protection of incremental innovation and allowing second use patent will encourage innovation in India and will reflect current capabilities in R & D. The need of the hour is a transparent legislation which would be beneficial to the consumer and industry both. There was a need for better training for patent Examiners and also more patent Examiners are required.

Moreover, patent Examiners and controllers should be better paid and a system of bonuses and other incentives created both for talent retention and encouraging better performance. There was also a need to make Patent Offices more autonomous as the office earned over Rs. 150 crores a year. Detailed guidelines should be put in place to encourage transparency and clarity.

ANNEXURE-III

Note by Lawyers Collective/HIV Aids

The main contention of the Forum was Section 3(d), 8 and 10 of the Patents Act. The main recommendations suggested were:-

- (i) Duty to disclose all relevant material prior art;
- (ii) Duty to disclose international non-proprietary name for pharmaceutical patent application with continuing obligation;
- (iii) Duty to disclose whether an application relates to a disease of public health priority, as determined from time to time by Ministry of Commerce after consultation with Ministry of Health; and
- (iv) Failure to comply should be a ground for opposition and/ or revocation of patent.

On compulsory licensing, the Indian Law provides:-

- (i) Failure to satisfy reasonable requirements of the public;
- (ii) Unavailability of patented product at reasonably affordable prices; and
- (iii) Non-working of patent in India.

Unreasonable refusal to issue license on reasonable terms as a ground for issuance of compulsory license be included as a ground. Further, the Act should adopt clear and predictable remuneration guidelines in the Act or Rules and deem refusal to license in accordance with these guidelines should constitute prima facie case of refusal to license. The bottom line was that the compulsory licensing was needed to be simplified. There was a need to simplify access to information and opposition proceedings. There should also be a effort to limit injunctive relief. Any attempt to introduce data exclusivity should be opposed. Any amendment that diluted Section 3(d) should be opposed. Lastly there was a strong need to strengthen and overhaul the patent examination system.

ANNEXURE-IV

Note by Shri Gajanan Wakankar, Executive Director, Indian Drug Manufacturers Association (IDMA), Mumbai

Patent Harmonization which provides for uniform law on Patents for all countries of the world was nothing but a ploy by the United States to substitute the law of that country on all countries of the world. In a world, where every country had different Constitution, different commercial laws, different economic laws, it was downright not possible to provide for a uniform patent law for the entire world.

Regarding the present amended Patent Act of 2005, the Committee was informed that the law should be observed for a period of 5 years and, in case, there are any deficiencies, the same may be rectified in 2010. At present, it was felt that there was a need to remove all 'qualifying phrases' from the Patent Act and to bring in all flexibilities available under the TRIPS Agreement.

The Committee was further informed that the pre grant opposition provision was a positive step which would help the developing countries but pre- grant opposition provision had not been fully incorporated thereby weakening it. The provision for an Opposition Board had not been accepted as it is in the case of post grant opposition. Further, an appeal to the Controller's Orders has not been accepted and the Controller's Orders are final. It was felt that such a step was a half hearted relief and could not prevent 'ever greening' attempts by Multi-National Corporations.

Another provision on which objection was raised was on 'Right of Patent applicants after publication', i.e., Section 11(A) (7) which states that "on and from the date of publication of the application for patent and until the date of grant of a patent in respect of such application, the applicant shall have the like privileges and rights as if a Patent for the invention has been granted on the date of publication of the application". The Committee was informed that such a provision was not required by TRIPS and benefited only the Multi-National Corporations. The Committee was, therefore, requested to remove this provision.

Another matter on which the assistance of the Committee was sought was that the Compulsory Licence Procedure was too lengthy and complicated. It was felt that it was totally in favour of the Patent Holder who are mostly Multinational Corporations (MNCs). For example, the Right of opposition was granted to the Patent Holder against the applicant of Compulsory Licence, there was absence of time lines, the rates of royalty had not been fixed which was loaded in favour of patent holder who were mostly MNCs. The resultant effect was that the chances of getting a Compulsory Licence was very low because of a protracted and expensive legal battle.

The witness also informed the Committee that in the interest of the country, what was needed was a Patent Law which is pro-people, which in turn, required a pro-generic industry.

ANNEXURE-V

Note by Ms. Leena Menghaney, Campaign for Access to Essential Medicines

The Campaign for Access to Essential Medicines submitted the following points for consideration of the Committee on India's effort to prevent "evergreening": Section 3(d).

Each WTO Member has to make a decision about how to operate the balances of the patent system with the need to make drugs affordable and accessible. In developed countries, access problems flowing from the high cost of patented medicines may be offset by mechanisms such as health insurance or national universal healthcare programmes. Countries like India, where these latter mechanisms do not cover the majority of the population, quite simply cannot afford a patent system where exclusive rights are granted more extensively than required by

international obligations. A patent system in India that is not oriented towards public health needs can have huge repercussions for the availability of affordable essential medicines in the developing world. Therefore, when the India parliament designed its patent law, an effort was made to find a balance between stimulating and rewarding real innovation from pharmaceutical companies and the need to make drugs affordable to the majority of the population. The new law contains several crucial features to prevent patents from being granted too easily, such as provisions that specifically prohibit patenting of known compounds, and the possibility for anyone to object to a patent before it is granted.

Concerns about "evergreening" patent applications

At the time of amending the Patents Act, 1970, the Indian parliament was aware of concerns about the patenting of substances/compounds that are not new. After applying for a patent for a promising compound, manufacturers file new patent applications on variations of it in order to extend their monopolies for as long as possible. Also called "evergreening," this practice keeps medicines buried under successive patents and delays the introduction of generic competition that could lead to lower prices.

As a result, the overwhelming majority of pharmaceutical patents granted across the world cover minor modifications of older existing compounds. An increasing number of studies are showing that while patent protection has increased in the last 15 years, the innovation rate has been falling, with an increase in the number of 'me-too' drugs that have little or no therapeutic gain. According to a report of the National Institute for Health Care Management (2002) in the US, in the 12-year period between 1989 and 2000, just 153 (15%) of all new drug approvals were medicines providing significant clinical improvements. A survey published in April 2005 by La Revue Prescrire concluded that 68% of the 3,096 new products approved in France between 1981 and 2004, brought "nothing new" over previously available preparations. Similarly, the British Medical Journal published a study rating barely 5% of all newly patented drugs in Canada as "breakthrough".

To prevent this practice, Indian lawmakers included a provision in the Patent (Amendment) Act 2005 that stipulates that patents should only be granted on medicines that are truly novel and inventive. This means that companies should not be able to obtain patents in India for medicines that are not actual inventions, such as drug combinations or slightly improved formulations of existing medicines. Thus, S. 3(d) stipulates that the following shall not be treated as an invention within the meaning of the Act:

"the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine of apparatus unless such known process results in a new product or employs at least one new reactant."

Explanation. – For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

7/20/2018

PARLIAMENT OF INDIA

The law [section 3(d)] was specifically targeted at combating the practice of "evergreening" and preventing drug companies from obtaining additional patents on insignificant improvements of drugs in India that unnecessarily restrict access to medicines. According to a Press Release from the Ministry of Commerce (4 April,2005) referring to the amendments to the patent legislation, "...in order to prevent "evergreening" of patents for pharmaceutical substances, provisions listing out exceptions to patentability (or what cannot be patented) have been suitably amended so as to remove all ambiguity as to the scope of patentability".

S.3(d) has been used by patients groups over the past three years to oppose drug patent applications that claim new forms or new uses or other changes of existing compounds and which if granted could block generic competition. This provision came into play in the case of the blood cancer drug *imatinib mesylate* that Swiss multinational pharmaceutical company, Novartis was claiming as a patentable invention. As a result of oppositions filed by the Cancer Patients Aid Association (which has been fighting for generic versions of this drug since before 2005) and generic manufacturers, Novartis' application was rejected in January 2006 on the grounds that it was simply a new form of an old substance and not patentable under Indian law. The invention claimed has also already been disclosed by Novartis itself before 1995. As a result of the patent rejection by the Chennai Patent Office, generic production was revived and reinstated by India pharmaceutical companies. The price therefore of *imatinib mesylate* is significantly less in India as compared to other countries where the drug is patented. In India the drug is available at \$200 for a month's treatment (per patient). In comparison in Brazil where a patent monopoly on the same drug has been granted, Novartis sells *imatinib mesylate* for \$5000 per patient per month. Novartis challenged the rejection in the Madras High Court. As part of its challenge, Novarits took the Indian Government, cancer patients and generic manufacturers to Court over the Constitutional validity of S.3(d). The company also claimed that the provision was in violation of WTO rules.

In August, 2007 the Madras High Court upheld the validity of section 3(d) of the Indian Patents Act, 1970 and dismissed the Novartis' challenge in *Novartis AG and another v. Union of India and others* [W.P. No.s 24759 and 24760 of 2006]. The court pronounced S. 3(d) to be constitutionally valid and affirmed the State's fundamental duty to ensure access to medicines for all and clearly stated that "*We have borne in mind the object which the Amending Act wanted to achieve, namely…to provide easy access to the citizens of this country to lifesaving drugs and to discharge their Constitutional obligation of providing good health care to its citizens".*

Section 3(d) and TRIPS

Although the TRIPS Agreement obliges all WTO countries to grant patents on medicines, there is no such obligation for WTO member countries to replicate patent systems of wealthy countries. TRIPS allows each country to define the meaning of "novelty", "inventiveness" and "industrial applicability", and does not prevent countries from including safeguards against the grant of patents for known substances. The Doha Declaration, signed by all WTO countries, states that " the [TRIPS] Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."

Developing countries therefore have the right to design their patent laws in a way that takes their public health http://164.100.47.5/newcommittee/reports/EnglishCommittees/Committee%20on%20Commerce/88th%20Report.htm 62/92

needs into account. An important flexibility in this respect is the right to define the patentability criteria in accordance with particular national priorities. This is precisely what India did through the Patents (Amendment) Act, 2005 while fulfilling its obligation to make patent protection available for pharmaceutical products. It is perhaps also worth recalling that the UK Commission on Intellectual Property Rights has recommended that developing countries avoid patenting of new uses of known products and "apply strict standards of novelty, inventive step and industrial applicability or utility (consider higher standards than currently applied in developed countries)". [See "Integrating Policy", CIPR, Intellectual Property Rights and Development 2001. 122. available page at http://www.iprocommission.org/graphic/documents/final_report.htm

Implementation of patentability criteria by the India patent offices

India's patent law lays down the following patentability criteria:

- 'invention' means a product or process should be new, not obvious to a person skilled in the art and capable of industrial application;
- S. 3 details products or processes that are not considered inventions such as new forms, new uses, combinations, admixtures and so on.

The provisions of S. 3(d), if applied strictly, have the potential of effectively addressing the threat posed by the multitude of patent applications claiming protection for variants of existing compounds. However, despite the provisions of the patent law, an examination of some of the patents granted by the Indian patent office reveals that there are increasing numbers of patents being granted for variations of existing compounds.

Although such patents may be weak or, if subject to strict scrutiny, likely to be invalidated, they can be effectively used in many cases to prevent generic competition thereby reducing access to medicines. Further the complexity and cost of overturning patent grant decisions generally pose insurmountable barriers to patients who are affected. This lack of competition on newer essential drugs today has had the result of prices for these medicines remaining much higher than those for older drugs, despite price reductions offered by originator companies.

On whether Indian Patent Offices can determine the threshold test of patentability

The determination of where the threshold tests (for example the meaning of 'mere' discovery, and the requirements for efficacy and inventive step) will be sent is for India to decide. If the threshold for the tests is set low, the bulk of pharmaceutical product patent applications will fall into the 'patentable' part of the list. If, by contrast, the threshold for the tests is set high, then many more of these patent claims will fall into the 'non-patentable' part of the list.

Inventive Step

Inventive step is a very important consideration, setting the threshold for what is to be regarded as obvious to the skilled person, and what is not. Inventive step will, for example, be relevant in considering the patentability of new forms of known substances. In general, if the bar is set too low, there is a danger that trivial inventions may be patented.

Patent examiners will, therefore, need to be trained according to Indian patentability criteria in order to apply each criterion separately and strictly. Examples of patents granted on polymorphs, which the Indian draft patent manual agrees are well known in the art, may be an indication of patent examiners not applying the inventive step test rigorously.

Capable of industrial application

One of the tests of patentability is that the invention claimed must be "capable of industrial application". In several jurisdictions, patent offices tend to apply a very low threshold for this patentability criterion; as in the case of Europe where this test is easily met, if, an invention can be made or used in any industry. The patent office should ensure that along with the other tests of patentability, this test too is applied strictly and not overlooked.

Efficacy

S. 3(d) excludes from patentability variants of existing products unless they differ significantly with regard to efficacy. With increasing reports of questionable patents being granted for essential medicines, it is not clear how the test of "enhancement of the known efficacy" is applied by the Indian patent office. The greater the degree of increase in efficacy required, the fewer "evergreening" patents should be expected to be granted.

In fact, this higher threshold of efficacy has already been established by the Madras High Court in the Novartis case which has ruled that efficacy means ' therapeutic efficacy.' (See Novartis AG and another v. Union of India and others W.P. Nos. 24759 and 24760 of 2006). It may, therefore, be important that the Patent office increases its cooperation with the Ministry of Health to determine whether a variant of an existing molecule does indeed possess significantly increased therapeutic efficacy.

As the threshold tests are raised, the logical end-point would be that patents would be granted for truly inventive medicines thus serving public health needs by fostering true innovation and ensuring that generic versions of drugs continue to be available.

Conclusions

India has, through its laws and policies, limited patent monopolies for the past three decades and promoted competition in the form of generic production with a view to bringing down the prices of drugs. This policy has not only made essential drugs much more affordable to its people (as compared to patented drugs), it has in the long run been instrumental in making India self sufficient in the production of drugs. As a result, India plays a crucial role in supplying low cost essential medicines to other developing countries. Aptly named the 'pharmacy of the developing world', it supplies formulations and active pharmaceutical ingredients (raw material) to a large number of countries in Asia, Africa and South America.

In HIV/AIDS treatment, thanks to competition among Indian generic manufacturers, which was possible because it did not allow patent monopolies and strongly encouraged generic production, the price of first-line antiretroviral drug regimens has fallen from an average of US \$10,439 to the current price of US \$ 99 per patient per year.

However, with the implementation of its new patent regime for medicines, India is already drying up as a source of affordable versions of newer medicines. The Indian patent office has since April 2005 started to publish and examine thousands of pending patent applications, many of which relate to essential medicines such as antiretroviral used in the treatment of AIDS. These newer drugs are under patent or pending patent grant in other key countries with generic production capacity, such as Brazil and Thailand, which keeps prices high and availability low. If patents are granted too easily on these essential medicines in India, India's role as the "pharmacy of the developing world" may end.

It is, therefore, important that the patentability standard as introduced by the Patent (Amendments) Act, 2005 – novelty, non-obviousness and section 3(d) – which has the potential of addressing a proliferation of patent applications filed in the Indian Patent Office that claim protection for minor, and in some cases of obvious, variants of existing drugs, is strictly implemented to ensure the widest possible access to affordable life-saving medicines in developing countries.

Currently, MSF is treating more than 100,000 PLHAs in thirty different countries including India. Most of the patients in MSF's treatment programs are receiving affordable generic medicines manufactured in India that allow us to treat the largest possible number of people. Access to affordable medicines is, therefore, key in making life-extending treatment available to more people who need it.

As a result of the TRIPS agreement, the 2005 Patents (amendment) Act provides for granting patents on pharmaceuticals, which may include essential drugs such as antiretroviral used in the treatment of AIDS. Many patent applications on antiretroviral and medicines for opportunistic infections are pending with the patent offices in India. This is causing concern about the future of millions of people living with HIV/AIDS dependent for treatment on affordable generic drugs from India.

Since March 2005, subsequent to the introduction of product patents on pharmaceuticals in India, MSF through its 'Campaign for Access to Essential Medicines' provided technical support to networks of people living with HIV/AIDS to oppose the grant of patent on essential drugs (pre-grant oppositions). If attention is brought to information that shows that the patent application is for a 'derivative' or a 'new use' of a known drug, and not a 'new chemical entity', the possibility of invalid patents being granted is reduced.

In this process of working in partnership with Indian organizations, we have observed (a) a number of shortcomings in the management of the patent system in India and (b) grant of invalid patents in India i.e. the incorrect implementation of Section 3(d) of the Patents Act 2005, which acts as a public health safeguard.

MSF is endeavouring towards making essential medicines accessible at affordable prices.

The Committee was informed of another disturbing feature viz the concept of Exclusive Marketing Rights. The concept of Exclusive Marketing Rights had resulted in prohibiting local producers of life saving drugs to the advantage of the Multinationals who had obtained Exclusive Marketing Rights. This had led to a situation where the

prices of life saving drugs had gone through the roof thereby affecting the vital Public Health System in the country where prices of such drugs have become unaffordable.

Another issue which came during deliberations with various experts involved in the field was the inability to define the term "invention". It was submitted that the term invention as Section 3(D) of the Patents Acts provided that all known substances, if there are new forms, should not be patented unless there is efficacy in certain countries like USA, Canada and England which are classical criteria available in common law. What India had done was that it had adopted a part of their criteria and put a rider which is Section 3(D).

A major lacuna in the Patent law of the country is that there should be obligation in the patent application to disclose the details of what the patent intends to do, which is presently not the case. Secondly, it should be online searchable. The said patent may be given a non-proprietary name if it is an application related to pharmaceutical. Thirdly, if the same is related to public health the same should be disclosed. If not, the same be made basis for revocation or non-grant of patent.

A major lacuna of the patent system is that in spite of norms for patentability being laid in Section 3(D) of the Act, all the four patent offices are following their own norms. There is a need to integrate the four offices to the usage of uniform norms for patentability so that a patent application rejected by one office is not accepted by the other office.

A view in favour of pre-grant opposition was that it was an extremely important safeguard as in a way it forced the patent office to do better analysis of patent application. It also forces compulsory licensing for drugs when a patent is granted.

ANNEXURE-VI

Note by Dr. S. Vedaraman, Controller General of Patents, Designs and Trade Marks (Retd.)

Regarding toning up of Trade Marks Administration, the following points were raised therein viz. as distinguished from 'patents or designs, the duration of statutory protection to trade marks is universally eternal, as registration can be renewed endlessly every 10 years.

Therefore, it is the responsibility of the Government to see that the Trade Marks Registry, established by law to carry out the functions and responsibilities for efficient administration and implementation of the Trade Marks Act, 1999, is well equipped in terms of manpower resource, financial support and automation.

Status of the TMR:

The repeated studies by the Work Study Unit of the Government of India and recommendations of national experts and the international experts commissioned by WIPO in the context of modernization of trade marks administration, highlight one common finding of fact, namely, that-

 There is continuing increase in the filing of applications for registration of trade marks. The number of applications filed during 2003-04 was 92,251 as against 30,266 filed during 1993-94, as per TMR Annual Report.

- The development of trade and commerce and the promulgation of the new Trade Marks Act, 1999, providing for registration of trade marks for 'services', has given additional responsibility to the TMR.
- There is no corresponding increase in the examining and supporting staff to efficiently manage the growing volume of work
- Apart from the growing number of applications for trade marks registration, the requests from public for prior official search as provided under the law on Form TM-54 (which involves no less than 50% effort towards examination of trade mark applications) have also registered a steep increase. As against 38,013 requests sfor searches filed in 1993-94, the number of requests steadily rose to a phenomenal height of 2,84,197, during 2003-04, as revealed by the TMR Annual Report.
- On account of increasing number of trade mark applications and huge increase in requests for official searches, the backlog of unexamined applications, has been escalating by more than 5000 cases each and every month. The pressure of work on the limited existing resource of examiners has an adverse effect on the quality of examination and other follow up procedures.
- Inadequate office space at the Head Office in Mumbai and in the branch offices, for proper upkeep of the growing volume of records, seriously affects the overall efficiency of the trade marks administration. The TMR is an office of record of the ownership of trade marks of the business community, both in India and abroad and, therefore, record management should receive adequate attention of Government. Warehousing facility for proper upkeep of records is, thus, an indispensable necessity.
- Unlike other Government departments, files in the TMR do not remain in one section. They keep moving between sections, between branch offices and are also made available for public inspection, as provided in the Act. They are also requisitioned by Courts and Appellate Board in connection with legal proceedings. File tracking has been one of the major problems of the Registry, resulting in untraced or loss of files, necessitating reconstruction or creation of duplicate files. Therefore, apart from warehousing facility for upkeep of records, bar coding system for file tracking needs to be seriously considered.
- The existing level of manpower strength at the TMR which was assessed by the Work Study Unit in 1992 was based on the volume of work during the period prior to 1992. Since then, the work in the TMR has increased manifold in every area of trade mark administration the number of applications having risen from about 30,000 to more than 90,000 and the requests for searches having registered a phenomenal increase, viz. from 38,000 to over 2 lakhs. It will be unrealistic to, expect this huge volume to be handled by the very same staff provided in the early nineties. The modernization of trade mark administration, by computerization, has no doubt modernized the performance of the TMR, but its impact will be felt by the end users of the system, only if sufficient man power is put in place to efficiently manage the system.
- Though the TMR is not a revenue earning office, by way of fees collected for its services, it has generated a revenue of Rs. 27.6 crores during 2003-04, as against an expenditure of just Rs. 4.49 crores, leaving a substantial surplus revenue. It is a fundamental principle that the fees collected from the public should match the service rendered. There seems to be a big gap in this respect in so far as the TMR is concerned. The shortfall in standard of service, as stated above, is attributable to the increased volume of work and lack of infrastructure in the TMR, which needs to be augmented immediately. The increased cost is justifiable in public interest and could easily be found from the overall earnings of the TMR.

Action taken by Government:

Taking into account the huge increase in backlog of work, on account of the increasing volume of work and shortage of manpower at the TMR, twenty (20) posts of Contract Examiners were sanctioned by Government, with no corresponding increase at the supervisory and supporting staff level. Thus, it has helped in a limited way only one part of the work, viz. examination of backlog of trademark applications. It has not led to final disposal of the cases, as the post examination work on those cases has piled up, in the absence of required manpower.

The exercise connected with backlog clearance involves a chain of activity, namely -

- Examination of trade mark application;
- Issuance of examination report, involving either acceptance, objections or other requirements;
- Where there are objections or other requirements, examination of the responses from the applicants, including evaluation of evidence, if any, filed by the applicants;

- Offer of hearings, wherever required, at the appropriate office. Adequate number of hearing officers is a must to enhance the quality of work and issuance of reasoned decisions to stand the test of appeal;
- If the application is acceptable in the light of evidence or compliance with official requirements, communication of acceptance orders. Lack of adequate manpower delays disposal of this part of the work;
- Preparing the cases class-wise for publication in the official journal and eventual publication,' ensuring the accuracy of the contents pertaining to each mark. The one area of strong public grievance is the inaccuracy of information published' in the Trade Marks Journal, leading to chain of mistakes in the consequential procedures of trade marks administration, e.g wrong advertisement, either mistaken opposition or failure to file opposition, wrong registration and, issue of mistaken certificates, causing great inconvenience to the members of public and trade mark owners, and finally to the Trade Marks Registry itself;
- Wherever notice of opposition is filed, taking prompt action on those is a must in accordance with the
 procedure prescribed by law, including quasi judicial hearing and issuing decisions. There is a big time
 lag between filing of oppositions and taking further action on those cases. Sometimes, it may result in
 wrongful registration during pendency of opposition, causing embarrassment to the parties and the TMR
 when notices are to be issued for cancellation of such wrongful registrations; and
- Where there is no opposition, or opposition is decided in favour of the applicant, the mark will proceed to
 registration, with all the required entries being made and certificate of registration being issued to the
 applicant, after due compliance with any further official requirements.

Backlog clearance is, thus, a multi functional process. By just taking up one part of the activity through appointment of contract examiners, the TMR is merely shifting the backlog from one level to another level of operation, with practically little effect on the overall "backlog clearance" drive.

When the increase in the work load is so apparent from the statistics, the Government should quickly organize a work study of the requirements of TMR and strengthen the administration to perform its duties efficiently, instead of ad hoc management of work through contract examiners.

The system of appointment of contract examiners is highly undesirable, as such appointees whose tenure is uncertain, are susceptible to be used by the Trade Marks Attorneys Agents as their representatives inside the TMR office. The rigors of Conduct Rules for Govt. servants will have no effect on such temporary appointees.

Review of TM Act, 1999:

The enactment of the TM Act, 1999 was hailed as a progressive measure in tune with modern requirements of the commercial community.

Appellate Board:

The one change, which was thought would help the trade mark owners, was the establishment of an Appellate Board. Unfortunately, it seems to have failed. The Board had been non-functional for a long time, in the absence of a technical member in trademarks. Now even the post of Chairman has been vacant for some time after the retirement of the incumbent.

The quality of decisions of the Board is also far from satisfactory, because of appointment of inexperienced persons, and not familiar with this branch of law. Most of the decisions are either taken on further appeal to Higher Courts by way of writs; and if not, such wrong decisions, become a fait accompli and continue to prevail. The following is one such example of wrong decision.

Section 47(1)(b) provides for removal of a trade mark from register on the ground of non use and states expressly the ground as - "that a continuous period of five years from the date on which the trade mark is actually entered in the register or longer had elapsed during which the trade mark was registered and during which there was no bona fide use thereof in relation to those goods or services by any proprietor thereof for the time being". In P. M. Diesel Pvt. Ltd. V. Thukra Mechanical Works [2005 - 30 PTC 77], the IPAD took the view that "any proprietor thereof for the time" occurring in section 46(1)(b) refers only to the proprietor of the trade mark at the time of filing the rectification petition." It was held that "in the absence of any provision in the Act to tag on the period of non use by the present proprietor of the trade mark, the tagging cannot be done. The stipulated period of non use would refer to each proprietor".

It is to be noted that it is a total distortion of the law as intended by the legislature. It has always been the law that the period of non use of the trade mark is reckoned continuously from the date of its registration. In American Home Products Corporation v. Mac Laboratories Pvt. Ltd. AIR 1986 SC 137, the Supreme Court has held that "the person seeking to have the trade mark removed from the register has only to prove such continuous non-user."

If the law were to be as interpreted by IP AD, any registered proprietor could easily defeat an application for removal of mark on ground of non use by merely assigning the mark to some other person to have a fresh period of 5 years non-use from the date of assignment. As stated in the notes on clause appended to the Bill "A trade mark which is not used within 5 years of its registration, becomes liable for removal either completely or in respect of those goods or services for which the mark has not been used". Such a clear and simple proposition has been twisted out of shape by the IP AB.

There are quite a number of such wrong decisions. The remedy lies in either scrapping the IP AD altogether and restore the earlier law providing for appeals to the High Court direct or to keep the IP AD as a lower tier of appeal, so that in the normal course an appeal can be filed to the High Court instead of by way of writ. The former course would be better, more effective and in overall terms less expensive to the litigants.

Section 115 - cognizance of offences:

Trade Mark offences are made cognizable under section 115(3), which means any police officer can take cognizance of an offence committed under the Act, in terms of the provisions of Cr. P. C. But the effect of this important change in law has been completely washed out by the proviso to sub-section (4) which mandates that the police officer should obtain the opinion of the Registrar. While on one hand the law declares the offence as cognizable, on the other hand it deprives the police officer to take cognizance of the offence, and forces him to refer the case to the Registrar of Trade Marks for his opinion and to abide by the same. As a result, even where the Magistrate takes cognizance of the offence and orders for police enquiry, the police officer rushes to the Registrar of Trade Marks to get his opinion. This is certainly not the intention of the legislature. The proviso to section 115(4) should, therefore, be dropped to give the law the intended effect, and make such offences really cognizable, as is being demanded by the owners of trademarks.

The following were the comments of the Department of Industrial Policy and Promotion on the issues raised in the representation of Dr. S. Vedaraman regarding toning up of Trade Marks administration.

On the Status of TMR, the Department stated that there has been a steady growth in the number of applications for registration of trade marks over the period of time. However, to handle the additional workload, in addition to the regular examiners, 30 contract examiners were appointed in 2003-04 to ensure speedy disposal of examination of trade mark applications. During the 2nd Phase of modernization of the Trade Marks Office under the XIth Plan, provisions are being made to increase the number of Examiners and supporting staff proportionate to the volume of filing trends. The Government is already seized of the urgency to upgrade the manpower strength of TMR and necessary steps are being initiated.

Further, to ensure timely examination of applications and avoid backlog, detailed proposals are being worked out in the 2nd phase of modernization under the XIth Plan to provide for additional Examiners and supporting staff which is expected to improve the quality of services provided by TMR. The 2nd phase of modernization also envisages capacity building and strengthening the infrastructure of the Trade Marks Registry which will create the right climate to ensure quality services to customers.

As a part of upgradation of the infrastructure of the Trade Marks offices in the country, provisions are being made for acquisition of additional space to store and maintain the physical records of the office. The records of the Trade Marks Registry have been serialized in sequential order to facilitate easy retrieval. Measures are proposed in the second phase of modernization to arrange the complete records of the Registry in compactors. In this connection, the proposal for bar coding of physical files is a good suggestion and would be considered as a part of infrastructural improvement which includes updation of information contained in the physical record.

Work Study of the integrated Intellectual Property Office (IPO), which includes Trade Marks Registry is being undertaken by Internal Work Study Unit (IWSU) of Department of Expenditure to assess the requirement of manpower. At the same time, most of the activities relating to processing of TMR applications have been computerized on decentralized basis by Trade Marks Registry Offices. A proposal to augment the additional manpower requirement of TMR is also being included in the 2nd phase of modernization project under the XIth Plan.

Infrastructure is being further augmented by making substantial investment. During the 10th Five Year Plan, total allocation towards Modernization of TMR has been increased to Rs. 16.00 crore. A comprehensive proposal to further upgrade the infrastructure of the Trade Marks Registry is envisaged in the 2nd phase of modernization. It is, therefore, expected that the quality of services provided by TMR will improve.

On the manpower front, the Department is fully conscious of the manpower requirement at all stages in TMR. Accordingly, sufficient provisions are being made in the 2nd Phase of modernization under the XIth Plan to improve the quality of services. The proposal to invite the Work Study Unit to assess the requirement of TMR is already being processed. A total IT solution to augment the IT infrastructure is currently under implementation. Further, it is

proposed to augment the manpower strength at TMR as part of the 2nd phase of modernization which will contribute to the efficient working of the Trade Marks Registry.

On the issue of Appellate Board the Intellectual Property Appellate Board (IPAB) is functional. The Chairman, Vice-Chairman and two Members are in position. Department is neither competent nor it is advisable to comment on the functioning of IPAB as it is a quasi-judicial body and is functioning as per the Law.

On the issue of Cognizance of Offences under Section 115 of Cr. PC, the Registrar is the custodian of the Register of Trade Marks. In the event of any stated cognizance, it becomes necessary to ascertain/verify the factual position with regard to rights of the complainant/petitioner. Without this safeguard, there is a likelihood of misuse of power. The question whether two trade marks are same or similar in respect of identical or similar goods involves a process of reasoning familiar to an expert on the subject . A Police Officer is not expected to have the required level of proficiency or expertise in coming to a conclusion whether the mark complained against is conflicting with registered trade mark on the record. The proviso to Section 115(4) is the safeguard measure included in the statute book to ensure that innocent traders and businessmen are not subjected to harassment by the Police. It is for this reason also that only a DSP level police official has been authorized to initiate enforcement of the cognizable offences mentioned in section 113, 114 and 115 of the Trade Marks Act, 1999. Suitable guidelines have been issued to the designated officers in the manner of providing the required opinion on a time bound basis.

ANNEXURE-VII

Note by National Law University, Jodhpur

Suggestions on the Patents Act, 1970

- 1. In Patent Act a provision related to time extension of patent should be added. Time extension of patent term should be allowed in the case where the exploitation of patent has not been fully done due to requirements of market approval. Time extension should be limited to 1 or 2 years.
- 2. In Patent Act extent of efficacy should be defined.
- 3. New and ambiguous definition of 'new invention' (as defined under sec 2 (1) (a) need clarification. It is submitted that this definition is not at all required because the definition as defined under section 2 (1) (j) defines an "invention" as "a new product or process involving an inventive stop and capable of industrial application." This includes all the requirements of patentability.
- 4. As per section 2 (1) (ja) in order to be patentable, the invention must be (1) non-obvious to a person skilled in the art, but in addition, it must also (2) " involve technical advance as compared to the existing knowledge or have economic significance or both....." By engrafting new "technical advance" and "economic significance" criteria onto the standard non-obviousness requirement, the Patents Act has broadened the meaning of non-obviousness.
- 5. If we look into section 3 (d) of the Patents Act, it reads "... (d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance..." If we analyze the definition, the extent of a claimed derivative's efficacy" will be the pivotal question raised by section 3(d) exclusion from patentability. The first paragraph of section 3 (d) permits the patenting of a derivative that provides an "enhancement of the known efficacy" of a "known substance," the second paragraph's "Explanation" further raises the bar by requiring that the derivative and the known substance "differ significantly in properties with regard to efficacy." Section 3 (d) thus raises both qualitative and quantitative questions-i.e., what kind of data will be required to establish "efficacy" and how great an improvement over the efficacy of the

prior art invention will be required to obtain a patent. This position (ambiguity of language) needs to be clarified by adding a proviso to the Explanation.

- 6. Further, for the purposes of section 3 (j) where it seems that micro organisms are patentable in nature, it is required that the proper scope and definition of the term 'micro organism' may be determined.
- 7. In section 3 (k), it is mandated that the computer programs are 'per se' not patentable. Now what does this 'per se' means? Do we have to go by meanings of dictionaries or other lexicons? Or the rulings of ECJ or US courts. It requires that the domain of per se be clearly defined.
- 8. If we look into the section 25 (both pre and post grant opposition) carefully, it can seen that the Act does not place any estoppel limitations on a party who previously filed a pre-grant opposition and later attempts to challenge the patent's validity in a court proceeding.
- 9. Another question that may be deliberated upon is that: Whether the provision of pre-grant opposition be removed from the Act? Since anyway if anyone has to oppose the grant of patent he can do so in post-grant opposition. This will in turn save the time of patent prosecution and grant of patent would not be lengthened.
- 10. The Patents Act 1970 makes the status of the Controller of the Patents and the High Courts equal when it comes to Revocation of Patents. If we look into the section 64 it provides for any person interested may petition before the High Court for revocation of Patent granted at the same time under Section 25 (2) also when it comes to post-grant opposition the patent may be revoked and this time by the Controller himself. This position may not acceptable and needs amendments.
- 11. The enforcement procedure and infringement of the patents needs to be checked by the Police and other enforcing agencies. Special wing for Patent protection may be created having specialized Engineers and other technical persons in the department.
- 12. The ascertainment of the damages of patent infringement etc., needs to be properly made out. The techniques of I.P. Valuation and other accounting and financial management techniques may be utilized for damages ascertainment. This is in fact the need of hour that in case of unliqudated damages the proper calculation may be made out. Consequently, a proper amendment in section 107 is warranted.
- 13. Like TRIPS, India's Patents Act does not further define nor elaborate on the nature of the anticompetitive practices. Consequently, required amendments in section 84 may be made in Patents Act 1970.
- 14. Testing Parameters for Software Patentability: There should be a proper explanation or clarity regarding the Patentability of Computer Software under section 3 (k) of the Patents Act, 1970. The term per se requires proper illustration.
- 15. Business Method patents: Although Business Methods are new and useful, but then also they do not qualify patentability criteria, as it is expressly barred under section 3 (k) of the Patents Act, 1970. But, if we see the trend in United States, the USPTO is readily giving Patent on those business methods which are qualifying the three requirements of Patentability viz. Novelty, Non-obviousness and Utility.
- 16. Compulsory Licensing should be given only in case of national emergencies. The Controller grants compulsory licenses of patents when the patent rights have not been commercially exploited by the patentee or available to the public in India at a reasonable price. The object of compulsory licensing is to ensure that the inventions are worked in India on a commercial scale for the benefit of the public. However, the requirement of a reasonable price puts the value of all patents in the hands of the Controller. (Ref. to section 84 of the Patents Act, 1970).
- 17. A proper clause suggesting the valuation mechanism of a Patent, is absent in the Patent Act, 1970. But there are few Valuation Techniques prevailing in the industry. If those can be incorporated then it would be helpful, for the Patentee as well as the Controller, in case of infringement and damages.
- 18. Under the Patents Act of 1970 any "new" and "useful" invention, qualifies for a patent, provided the claims and the specifications can be read in that light. But the terms "new" and "useful" were not statutorily defined.
- 19. The definition of Patents Act in Sec 2 (m) as modified by 2005 Amendment Act has been given as "a patent for any invention granted under this Act". This might have serious consequences if a patent granted in violation of the provisions of the act, say for example, there is a case of anticipation but the PTO grants a patent. In that case, HC can revoke it stating that the patent has not been granted under the provisions of Act as it is not a patent under the provisions of Patents Act & in turn, not being a patent under Sec 2 (m). But under normal circumstance HC can't revoke that patent. It can only ask Controller to revoke a patent. So, there comes contraction. So, the definition must be changed as it is giving overriding effect to the powers of controller.
- 20. Further the definition of pharmaceutical substance is given in Sec 2 (ta) of the 2005 Amendment Act, which talks about " any new entity involving one or more inventive steps". Here, it is stated that this term

pharmaceutical substance is nowhere used in the whole Act and should not be a part of definition clause. Secondly, it speaks about any new entity, which widens the scope of subject matter. It should be limited to chemical substances and, therefore, if the term is to be kept in here, definition should be amended to that effect.

- 21. There is another definition under Sec 2 (1) in the Patents Act 1970 which talks about the term New Invention. Here, it is stated that the term Invention defined in Sec 2 (j) explains the term which involves an inventive step and capable of industrial application. There is no further need to explain what New Invention is. The concept explained under Sec 2 (I) is the "concept of Novelty", but the termed used in it is "New Invention". So, necessary amendment of replacing new invention with novelty should be made, so as to avoid ambiguity between the two concepts of invention and novelty.
- 22. There happens very frequently evergreening of patents because of some concepts like data exclusivity and trade secrets. This can be controlled by Sec 3 (d) of the Patents Act. So, Sec 3 (d) should have some more limitations to take care of this aspect of Patents.
- 23. Sec 2 (ja) broadens the existing provision to the benefit of patent holders and is ambiguous to the extent that it allows for two criteria for meeting an inventive step. The patentee will either have to show that the invention includes a technical advance or has economic significance or both.
- 24. This provision should make it mandatory to comply with both the requirements because the requirements of technical advance can be compromised and a patent can be granted on economic significance alone. Economic significance alone cannot determine the inventive step of a patentable invention.
- 25. Determination of economic significance not dealt-Moreover no mentions to the determination of economic significance has been mentioned under the act. Under what circumstances or criteria can a patent be considered as one having economic significance over the prior patent.
- 26. Quick Examination-The examination procedure has been covered under the rules, which now provides for a period of one month for the examination report to be issued but previously was 18 months. This is likely to create immense pressure on the Indian Patent Office as there will not be enough examiners to deal thoroughly with the application thus resulting in improperly examined and legally invalid patents.

Sections on the Trade Marks Act, 1999

- 1. In Trademark Act, a provision related to domain name should be added.
- 2. In Trademark Act, a provision related to trade dress should be added.
- 3. The definition of "Trademark" under section 2 (zb) does not cover Domain Name, expressly. Now, if we see the recent trend, the Trademark owners are interested in getting their Trademark, registered as their Domain Name. Therefore, this issue needs to be considered.
- 4. A proper valuation scheme has to be adopted for the Trademarks because in due course, these marks attain a value which might be comparable or higher then the net Tangible asset of the Company. Therefore, it is required to be valued properly for sale and tax purpose.
- 5. No provisions for Smell marks, Taste Marks or Sound Marks as trademarks given anywhere in the Act-These concept have not at all been incorporated and the definition of a mark or trademarks includes the concept of visual representation. But, where a smell of a perfume or a taste of a fruit juice or Sound of a particular toy can represent a product's source and is capable of distinguish the goods or services of the proprietor of such products for that of others, they can be considered to be trademarks, which has been nowhere defined in the Act.
- 6. No definitions are given for defining house/family mark & property mark-this should be inserted in the Act to give a specific meaning to these concepts which are used frequently in practical sense, but creates confusion and ambiguity for want of definition.
- 7. Clarity as to situations where giving protection to commonly used names or surnames as trademarks can be justified-Under Sec 14 registration of names and representations of living persons and recently dead persons have been given. But there is nowhere given in the act that whether a commonly used name, title/surname or caste name can be used as a trademark or not. The conditions and situations should be strictly defined under the Act.
- 8. Domain Names Provisions & Provisions for trade dress must be included as this is not at all covered in anyways under the Act, although covered under the law of trademarks by various judicial pronouncements.
- 9. Clarification as to the concept of brand and brand equity-the term "Brand" has been given a very narrow meaning under Sec 2 (m) of the Act, defining the term Mark. But the term "brand" obviously has a much wider

meaning than that. It covers a very broad area when taken under brand equity concept as a part of financial management. Trademark is a subset of "brand" when taken in this light, which seems missing in the act. This is required to be dealt within the Act.

ANNEXURE-VIII

Note by MAKs on Improving the Patents Systems India

1. Publication of Patent Information and Searchable Public Patent Database.

It is well known that the key philosophies behind the origins of the modern patent system in order to encourage

innovation were.

- that for period of exclusivity, an inventor would agree to fully disclose his/her invention in a manner that would allow others to learns, conduct further research from and practice the invention once the patent on the said invention expired;
- (b) that inventions be published in full and made available to all so that other inventors and the public at large could see the type of inventions for which patents were being granted and how improvements could be made without risking a possible infringement action; and
- (c) that a granted patent is a contract between the government (on behalf of the public) and the inventor.

Currently, section 145 of the Patents Act provides that 'the Controller shall publish periodically an official journal which shall contain such information as may be required to be published by or under the provisions of this Act or any rule made thereunder'.

Rule 27 of the Patents Rules 2006 (read with s153) allows any person, after publication and upon written request, the right to inspect the complete and provisional specification or drawings of an application on payment of a fee. Rule 134 (read with s153) then lists the type of information that is admissible upon request.

Rule 74 allows a person upon written request to inspect, after date of publication of the granting of a patent, the complete/provisional specification and drawings, if any, and other documents relating thereto.

While the above statutory provisions and rules aim to provide access to patent information, they are far too restrictive or inefficient to users seeking information on patent applications and granted patents. Ultimately, India's current system of providing access to patent information fails to meet the reasons why the patent system exists, namely to fully disclose, and make freely and easily accessible all patent information. Rather, the cost of accessing patent information under the current system is placed on those requesting or using the information, albeit the difference in official fees for individuals and entities.

Presently, because of the particular wording of section 145 ('such information as may be required to be published'), the patent office only publishes a limited amount of information in its Journal. This information consists of the Title, Abstract, Applicant, Inventors, Convention Priority Data and Classification. Very often the publications in the Journals are missing key information such as priority data, from which at least users can establish what the corresponding patent is in another country. The current system also places a heavy resource burden on the

7/20/2018

PARLIAMENT OF INDIA

information seeker. As our experience of obtaining patent information has shown, in particular specifications and status reports of applications, the current system is cumbersome and inefficient financially and time wise.

The same problem exists in relation to granted patents. Although the patent office journals list the granted patents, the full and final specification as granted is only available if one follows the procedure under Rule 74. Once again, this is a resource constraint on users of the patent system. It also goes against the philosophy that once a patent is granted it should be made free public information.

The most significant constraint of the current patent publication system in India, is the lack of a searchable patents database that provides all the above information on an updated basis. Two years have passed since the 2005 Patent Amendments Act, yet an electronic searchable patent database is not available. The current PDF file format is not suitable for searching all the journal publications at once. It has taken the intervention of a third party, Big Patents India (http:// India.bigpatents.org//), to create one form of a searchable database. However, because the patent office does not publish the full specifications either at application or at the granted stage, databases such as Big Patents are not able to provide the full information without having to expand huge resources making written requests for specifications and the status of applications.

The fallout from not having a public searchable patent database is that inventors, commercial competitors, academic researchers and a variety public interest groups are not able to effectively search for patents. This can be a significant problem, as these groups need to know what patents exist in India so they can determine any legal risks or the validity of the patents being filed and granted. Unless one is to request all the information and pay all the required fees on an ongoing basis, as currently required, the information is not easily accessible and, therefore often remains with the patent office, the applicant or an opponent. This lack of readily available information does not help create transparent patent system, in particular one that will ensure only quality patent rights are made available.

2. Access to Examination Reports

Currently section 144 of the Patents Act states that reports of the examiners to the Controller shall not be open to public inspection or be published by the Controller.

The lack of transparency in how the patent office is examining applications only serves to make for a weaker patent system. This is because the patent office becomes less accountable for its decisions and it also prevents the public form being able to monitor and even engage in how patents are granted. After all, it is the public, as consumer of many patented goods, who are required to pay higher prices that often result from patent monopolies that may not be legally valid. Moreover, for a pre and post grant opposition system that India has, it makes it all the more important that opponents can track the work of examiners so that they can decide whether to file an opposition based on prior/art evidence an examiner may have missed. Such transparency helps to strengthen the patent system and also assist examiners in their work.

In view of this, the public should be permitted access to all examination reports via an online searchable database. The European Patent Office (EPO) and U.S Patent and Trademarks Office (USPTO), among other, offer free access to all examination reports of pending applications (in the EPO's case the access remains free even after the patent has been granted).

3. Access to Patent Office Decisions relating to Oppositions

In relation to the point made above, the patent office does not make available copies of decisions from pregrant oppositions, the Opposition Board hearing post-grant oppositions or the Appellate Board.

The inability to access such decisions only serves to retard the development and understanding of case law among examiners in other branches of the Indian Patent Office, patent attorneys and lawyers, future students of the patent professions, inventors, researches and the public at large. Indeed, the lack of access to decisions prejudices applications and opponents who may wish to rely on a decision as being a precedent. This is particularly so with a new model provision like s3(d) of the Patents Act, which requires full transparency in how it is being interpreted and applied. No legal system, which the patent office is supposed to implement, can function effectively without its case law and decisions being open to review and scrutiny.

4. Re-writing or Clarifying the Pre-Grant Opposition Rules and Procedure

It appears that the rules for filing a representation of opposition before the granting of a patent section 25(1) are not being applied in a consistent fashion by the patent office.

Recently, the Chennai Patent Office issued a patent for application number 959/MAS/1995 without providing a hearing to the Opponent, despite the fact that the Opponent requested one.

This is not the first time that the rules for pre-grant opposition have been applied inconsistently between the four patent offices. In the matter concerning the opposition against application numbers 896/DEL/2002 and 963/DEL/2002, the Delhi Patent Office refused to provide the opponents with applicant's response to the opposition. It was only after the matter was taken to the High Court in Delhi that the Delhi Patent Office agreed to provide applicant's response. In another matter concerning patent application number 2485/DEL/1998, the same office (Delhi) provided the applicant's response. In the well documented Gleevec patent opposition, the Chennai patent office applied the post-grant opposition rules whereby the opponent received Novartis's response to the opposition from the Chennai Patent Office and the procedure/hearing was conducted *inter parties*. The Mumbai patent office has been known to adopt the practice of not passing on the applicant's response to an opponent in a pre-grant opposition and deciding matters on the papers in front of it.

The problem appears to lie in the wording of Rule 55 and the lack of guidelines for examiners. Based on the wording of Rules 55 (3) and 55(5), which state that 'on consideration of the representation of opposition or response of the applicant, the Controller can either refuse to grant a patent for the application or request amendment', it would seem that bar a hearing requested by either party, technically the representation of opposition or the

7/20/2018

PARLIAMENT OF INDIA

application could be dismissed at either of these points of the procedure by the Controller based on the merits of the opposition/response of the applicant. It would appear this can happen without any further exchanges between the opponent, application and the patent office.

But where either party has requested a hearing, then it is difficult to see why the party should not be heard, even if the Controller is leaning towards granting the patent. Otherwise what is the point of providing the right to a hearing in s25(1)? Also, if a hearing is requested, then surely the opponent should be entitled to see the response of the applicant – else what is the opponent going to address at the hearing, his/her own opposition?

It is also worth noting Rule 129, which says that before using any discretionary powers under the Act or Rules, which is likely to adversely affect an applicant or a party to the proceeding, the Controller shall give the applicant/part a right to a hearing. The question here though is whether an opponent to a pre-grant opposition is a 'party' to proceedings?

It appears the rules for pre-grant opposition were drafted in a way to make them different from the rules for post-grant oppositions – and possibly to resemble an ex parte/observation procedure (but with a hearing – which is a strange format in itself). But the different patent offices are applying a mixture of the pre and post grant opposition rules, which is resulting in a dysfunctional pre-grant opposition system.

5. 'Any Person Interested' – Section 25(2)

Section 25 (2) of the Patents Act provides that 'any person interested' may oppose an application after grant but within one year of the date of publication of grant. Section 2(1)(t) describes a 'person interested' as including a person engaged in, or in promoting, research in the same field as to which the invention relates. Section 25(1) of the Act on the other hand uses the broader term 'any person'.

It is noticeable that the term 'any person interested' is a remnant from the old Patents Act as taken from s14(1) of the now repealed UK Patents Act 1949 and is being interpreted by some to have a narrower scope than 'any person', namely only being limited to persons or bodies engaged in research or with commercial interests. Although the patent office has yet to rule on the meaning of the term, we believe it serves little purpose to have a distinction between the *locus standi* available for pre-grant and post-grant oppositions. This is because a narrow interpretation of the term, as being pushed by patentees, could potentially prevent a number of people from being able to oppose a poor quality patent after it has been granted. While we accept that the pre-grant opposition takes care of this problem to some degree, it has to be noted that new evidence may subsequently come to light and so any person should be able to file an opposition as a result.

Interestingly, it is worth noting that Article 99 of European Patent Convention (which governs the EPO postgrant opposition practice) and s72(1) of the UK Patents Act 1977 (Amended) in relation to revocation proceedings (akin to post-grant opposition proceedings) use the term 'any person'. Therefore, there is no restriction on who can oppose or revoke a patent once granted.

6. Telephone Access of Examiners

Our experience to date shows that there is a lack of direct telephone access to examiners and other officials of the office holding patent status information. The inability to be able to speak directly with a relevant examiner to obtain immediate information can be frustrating and time consuming to one involved in running a legal service for clients.

7. Manual of Patent Practice and Procedure

Despite the deadline for comments on the draft Manual of Patent Practice passing in August 2005, the final version of the Manual is still not available. Every functional patent office should have a public Patent Practice Manual which users can refer to ensure they follow correct procedure or understand how the patent office guidelines for examination of patents. The lack of a Practice Manual reduces the transparency in how the patent system is making decisions and developing its practice. It also prejudices applicants, opponents and any other person interested in engaging in the patent system.

ANNEXURE-IX

Note by Organisation of Pharmaceutical Producers of India (OPPI) Patentability

Indian Parliament passed the Patents Act 2005 on 23rd March, 2005, reestablishing product patent protection in all fields, including food, agrochemicals and pharmaceuticals for a period of twenty years.

Presently, the Indian Patents Act allows only New Chemical Entities (NCEs) to be patentable. Other forms such as polymorphs, metabolites, Novel Drug Delivery Systems (NDDS), etc. should show significant efficacy over the NCE Section 3 (d) to be patentable. The Government had appointed a Committee under the Chairmanship of Dr. R. A. Mashelkar, then Director General, Council of Scientific & Industrial Research (CSIR) to examine whether this stand is Trade Related Aspects of Intellectual Property Rights (TRIPS) complaint. However, this report has been withdrawn due to certain charges of technical inaccuracies in the report. We request the Government to accept the part of the report which recommends extending patentability to polymorphs, NDDS, etc.

OPPI believes that apart from NCE's all other forms should be patentable provided they meet the criteria of novelty, non-obviousness and commercial applicability.

Pre & Post Grant Opposition

Both pre and post grant opposition is introduced in the Act allowing oral hearings. Opposition can be filed any time after the date of publication of the patent application to the date of grant. This has resulted in large number of pre-grant oppositions being filed resulting in delaying of patent granting process. Also 'serial' pre-grant oppositions are made which causes further delay. OPPI does not approve pre-grant opposition. Post Grant opposition is an internationally accepted practice.

Compulsory Licensing (CL)

Scope of CL has been broadened to include affordability, non-working of patent, etc. The patent holder will be entitled for compensation from the licensee. CL will be available for export to any country having insufficient or no manufacturing capacity to address public health needs. While OPPI has no objection to granting of CL in national emergency or extreme urgency, it feels that broadening the scope for affordability, etc. will result in abuse of this provision.

Data Protection (DP)

DP is an integral part of IPR. Lack of DP provision will be disincentive to R&D based companies and innovators.

M/s. Satwant Reddy Committee Report on Data Protection was recently submitted (May 2007). The Report, while accepting the importance of Data Protection does not provide proper guidelines for its implementation and recommends calibrated approach.

OPPI believes that for public health reasons, every applicant for a marketing approval, whether the first or subsequent applicant, must generate their own data. It is important that the regulator should not be permitted to rely upon the data generated by another applicant, as any lacuna in such applicants' data will merely be repeated/endorsed in the case of subsequent applicants. In short, it is not sufficient to merely not disclose regulatory data submitted for seeking regulatory approval, there must be non-reliance on another applicant's data as well. It is therefore important that all applicants, must generate their own data for seeking marketing approval of a new drug.

Data Protection and Patents, as rightly mentioned in the Report, are two distinct Intellectual Property Rights; the former protects <u>data/information</u> generated by an applicant which is required to be submitted to Regulatory Authorities for seeking Marketing approval, whereas the latter protects the **innovation** itself. These separate forms of Intellectual Property Rights ought not to be linked and should be dealt with separately.

Many of our members have plans to make substantial investments in R&D, clinical trials, etc. in India. Lack of provision for Data Protection will be seen as inadequate protection of Intellectual Property resulting in reduced FDI flow since such investment will be diverted to countries with a friendlier Intellectual Property regime and also slow down early launch of some of the new drugs.

According to a recent report dated 27th August, 2007 by Mr. Andrew Jack, Financial Times, London – "China has overtaken India as one of the fastest growing locations for Drug Trials, in a fresh sign of the importance of world's most populous country to the Pharma Industry". Six years of Data Protection provided by China may have helped them.

Data Protection should not be limited only to data generated in respect of NCEs but also extended to any other data submitted to the Regulatory authority for seeking marketing approval. To illustrate, the Government of India is planning to invest Rs. 1000 crores for developing Nanotechnology. In the context of Pharmaceuticals,

Nanotechnology will help in developing new drug delivery systems which will have considerable positive impact on public health. Data generated from such technology in the context of pharmaceuticals will have to be submitted to the Regulatory authorities for seeking marketing approvals. Without the benefit of Data Protection, the Government's own data into the generation of which, the Government has invested several hundred crores, could be unprotected and relied upon by any party without the need for investing any amounts for generating such data. OPPI requests Data Protection for minimum 5 years after grant of marketing approval in India.

Calibrated Approach

India already had 10 years of transition period from 1995 to 2005 to comply with WTO commitment on product patents. We believe that there is no need to further transition period through "calibrated approach" for grant of Data Protection.

ANNEXURE-X

Note by Justice V. K. Krishna lyer (Former Judge, Supreme Court)

The former Justice has stated that the Department of Industrial Policy and Promotion has through the website of the Patent Office, put up a Draft Manual of 2008 practice and procedure for implementing the Patents Act, 2005. He has informed that the principal Act of 1970 has been drastically revised to comply with TRIPS agreement and Paris Convention. Thus, the new law of 2005 has been in operation for just a little over 2 years and the Patent Office Procedure, under the new law, is still to evolve. In any case the practice has to be within the frame-work of statute law and all questions which arise there-under are solely within the purview of and regulated by the provisions contained in the Act and Rules. Secondly, the Powers of Controller are clearly defined in the Act and neither the Controller nor the Central Government has any authority or sanction of law to publish a manual of the kind put on the website. The patent office in the document itself has inserted language which recognizes the absence of any legality for the document and disowns any authoritative nature of contents of the Document. Containing as it does interpretation of various provisions of law by the patent office which is the function of judiciary, the official manual if implemented would provide a fertile ground for litigation and controversy in inter-pretation of the legal aspects (vis-à-vis the Act/Rules and the manual), tending to tilt the balance of convenience in favour of MNCs, who have the resource to litigate. Admittedly, the document has no legal basis and cannot be relied only any one in respect of any processings under the Act and Rules for its authority. He has instead suggested that if at all it is necessary to publish a manual, it should be modeled on what the Patent Office has been doing for over a century by publish a 'Patent Office Hand Book', updated through revised editions from time to time. He has, therefore, urged that the present draft manual should be wholly scrapped and in its place a new edition of Patent Office Hand Book may be brought, if it is considered necessary. The absence of a manual or a Patent Office Hand Book will not do any harm, but a manual of this nature will do more harm than good.

MINUTES

*XI ELEVENTH MEETING

The Department Related Parliamentary Standing Committee on Commerce meet at 11.00 A.M. on Friday, the 12th June, 2006, in Room No. '63', First Floor, Parliament House, New Delhi.

PRESENT

1. Dr. Murli Manohar Joshi — Chairman

RAJYA SABHA

- 2. Shri Thennala G. Balakrishna Pillai
- 3. Shri Abu Asim Azmi
- 4. Shri Robert Kharshiing

LOK SABHA

- 5. Shri K. Francis George
- 6. Shri Shankhlal Majhi
- 7. Shri Ram Chandra Paswan
- 8. Shri Jivabhai A. Patel
- 9. Shri Haribhau Rathod
- 10. Shri S.P.Y. Reddy
- 11. Shri Sarbananda Sonowal
- 12. Shri C.H. Vijayashankar

WITNESS

Shri B.K.Keayla, Managing Trustee, Centre for Study of Global Trade System and Development, Delhi.

SECRETARIAT

Shri Ravi Kant Chopra, JS & FA Shri Surinder Kumar Watts, Director Shri D.K.Mishra, Committee Officer

2. The Chairman drew attention of members to the Committee's deliberations on the subject of *** some experts in connection with the problems which the country may come across on account of amendments to the Patents Act, 1970, with a view to find out what could have been possible within the framework of our * 1st to 10th

Meeting of the Committee pertains to other subject matter.

*** pertains to other subject.

international commitments under the TRIPS Agreement. Further, in the era of globalisation and lliberalization of the Indian economy, the Government of India has been taking various initiatives to modernize and streamline the intellectual property administration in the country. The Patent office and the Trademarks Registry are the revenue

generating offices under the intellectual property administration. The laws on Patents, Designs, Trademarks and Geographical indications have been amended/enacted and updated. Government have also taken up modernization of intellectual property offices in the country. Considering the importance assumed by intellectual property administration in the country, he had, therefore, selected the subjects of Patent and Trademarks Systems in India for examination by the Committee. Shri B.K.Keayla, Managing Trustee, Centre for Study of Global Trade System and Development, Delhi had been invited to present his views on the subjects before the Committee.

3. The Committee then heard the views of Shri B.K.Keayla on the subject of Patents and Trade Marks Systems in India. Members sought some clarifications, which were provided by the witness.

4. A verbatim record of the proceedings of the meeting was kept.

5. *** The Members were of the view that it would be better if on-the-spot visits to ***, Patents Offices and Trademarks Registry at Kolkata, Chennai and Mumbai are undertaken. Accordingly, the Committee decided to visit the ***, Patents Offices and Trademarks Registry at Kolkata, Chennai and Mumbai tentatively on or after 5th of July, 2006. It authorized the Chairman to finalise the programme and details of the visit and approach Hon'ble Chairman, Rajya Sabha, to obtain permission for the visit of the Committee.

6. The Committee adjourned at 12.50 A.M.

*** pertains to other subject.

*III THIRD MEETING

The Department Related Parliamentary Standing Committee on Commerce met at 3.00 P.M. on Tuesday, the 26th September, 2006, in Room No. '63', First Floor, Parliament House, New Delhi.

PRESENT

1. Dr. Murli Manohar Joshi — Chairman

Rajya Sabha

- 2. Shri Thennala G. Balakrishna Pillai
- 3. Shri Banwari Lal Kanchhal
- 4. Shri Moinul Hassan
- 5. Shri Dinesh Trivedi
- 6. Shri Robert Kharshiing

LOK SABHA

- 7. Shri C.K. Chandrappan
- 8. Shri D.V. Sadananda Gowda
- 9. Shri Jivabhai A. Patel
- 10. Shri Virchandra Paswan
- 11. Shri Shisupal N. Patle
- 12. Shri E. Ponnuswamy
- 13. Shri Kashiram Rana
- 14. Shri Haribhau Rathod
- 15. Shri S.P.Y Reddy
- 16. Shri Bharatsinh Madhavsinh Solanki
- 17. Shri Sarvananda Sonowal
- 18. Shri Manjunath Kunnur

- 19. Shri Amitava Nandy
- 20. Shri Braja Kishore Tripathy

SECRETARIAT

Shri Ravi Kant Chopra, JS & FA Shri M.K. Khan, Under Secretary Shri D.K.Mishra, Committee Officer

2. *

<u>* 1st & 2nd Meetina</u>

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| | of the Committee pertains to other subject matter. |
| | *** pertains to other subject. |
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5. The Committee also decided to further examine the subject of '*** and 'Patents and Trademarks System in India' by making on-the-spot visit to Kandla and Surat SEZs, as well as Patents and Trademarks office at Mumbai and Trademarks Registry at Ahmedabad. Accordingly, the Committee decided to visit the *** and Patents and Trademarks office at Mumbai and Trademarks Registry at Ahmedabad from 15th to 20th October, 2006. The Committee authorized the Chairman to finalise the programme as well as details of the visit and to approach Hon'ble Chairman, Rajya Sabha, to obtain permission for the visit of the Committee.

- 6. The Committee decided to meet again on 14th October, 2006 at 3.00 P.M. in Delhi.
- 7. The Committee adjourned at 4.20 p.m.
- *** pertains to other subject.

*XVII SEVENTEENTH MEETING

The Department Related Parliamentary Standing Committee on Commerce met at 11:00 A.M. on Thursday, the 07th June, 2007, in Committee Room 'C', Ground Floor, Parliament House Annexe, New Delhi.

PRESENT

1. Dr. Murli Manohar Joshi — Chairman

Rajya Sabha

- 2. Shri Thennala G. Balakrishna Pillai
- 3. Shri Banwari Lal Kanchhal
- 4. Shri Dinesh Trivedi

LOK SABHA

5. Shri C.K.Chandrappan

- 6. Shri D.V. Sadananda Gowda
- 7. Shri Radhey Shyam Kori
- 8. Shri N. N. Krishnadas
- 9. Shri E. Ponnuswamy
- 10. Shri Haribhau Rathod
- 11. Shri S. P.Y. Reddy
- 12. Shri Nikhilananda Sar
- 13. Shri Sarbananda Sonowal
- 14. Shri Manjunath Kunnur
- 15. Shri Braja Kishore Tripathy
- 16. Shri Sippiparai Ravichandran

WITNESSES

Representatives of the Department of Industrial Policy and Promotion

Dr. Ajay Dua, Secretary Shri N. N. Prasad, Joint Secretary Shri Gopal Krishna, Joint Secretary Mrs. Gauri Singh, Director Mrs. Rugmini Parmar, Director Shri M.S. Dhakad, Director Shri T.C. James, Director Shri V. Ravi, CGPDTM Shri N.K. Seth, Deputy Controller, Patents Shri D.P.S. Parmar, Deputy Controller, Patents

* 4th to 16th Meeting of the Committee pertains to other subject matter.

SECRETARIAT

Shri Ravi Kant Chopra, JS & FA Shri Surinder Kumar Watts, Director Shri M.K. Khan, Under Secretary

2. The Committee heard the views of the Secretary, Department of Industrial Policy and Promotion on the subjects of i) 'Patents and Trademarks Systems of India' and ii) '***. Members sought some clarifications, which were replied to by the witnesses. The Chairman directed the witnesses to send their written replies in response to the queries, for which information was not readily available.

A verbatim record of the evidence was kept.

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4. The Committee adjourned at 2.30 p.m.

^{***} pertains to other subject.

The Department Related Parliamentary Standing Committee on Commerce met at 4.00 P.M. on Thursday, the 13th September, 2007, in Committee Room 'A', Ground Floor, Parliament House Annexe, New Delhi.

PRESENT

1. Dr. Murli Manohar Joshi — Chairman

Rajya Sabha

- 2. Shri Jai Parkash Aggarwal
- 3. Shri Banwari Lal Kanchhal
- 4. Shri Mohammed Amin
- 5. Shri Dinesh Trivedi

LOK SABHA

- 6. Shri C. K. Chandrappan
- 7. Shri Kashiram Rana
- 8. Shri Haribhau Rathod
- 9. Shri S.P.Y. Reddy
- 10. Shri Nikhilananda Sar
- 11. Shri Sarvananda Sonowal
- 12. Shri Braja Kishore Tripathy

WITNESSES

Representatives of Corporate Law Group

Ms. Krishna Sarma, Managing Partner Ms. L. Balasubrahmanyam, Partner Mr. Bhaskar Bhattacharya, Sr. Associate

SECRETARIAT

Shri Surinder Kumar Watts, Director Shri M.K. Khan, Deputy Director Smt. Indira C. Vaidya, Committee Officer

* 1st Meeting of the Committee pertains to other subject matter.

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3. The Committee then heard the views of representatives of Corporate Law Group, New Delhi on Patents and Trademarks System in India. Members sought some clarifications, which were replied to by the witnesses. The Chairman directed the witnesses to send their written replies in response to the queries, for which information was not readily available.

A verbatim record of the evidence was kept.

4. The meeting adjourned at 4.35 p.m.

*** pertains to other subject.

III

THIRD MEETING

The Department Related Parliamentary Standing Committee on Commerce met at 4.00 P.M. on Friday, the 14th September, 2007, in Committee Room 'A', Ground Floor, Parliament House Annexe, New Delhi.

PRESENT

1. Dr. Murli Manohar Joshi — Chairman

Rajya Sabha

- 2. Shri Banwari Lal Kanchhal
- 3. Shri Mohammed Amin

LOK SABHA

- 4. Shri C. K. Chandrappan
- 5. Shri Radhey Shyam Kori
- 6. Shri Amitava Nandy
- 7. Shri Virchandra Paswan
- 8. Shri Shishupal N. Patle
- 9. Shri Kashiram Rana
- 10. Shri Haribhau Rathod
- 11. Shri Nikhilananda Sar
- 12. Shri Braja Kishore Tripathy

WITNESSES

Department of Industrial Policy & Promotion

Dr. W. M. Dhumane, Incharge, Intellectual Property Training Institute, Nagpur Shri T. C. James, Director

Representatives of Ministry of Health and Family Welfare, (Department of AYUSH)

Smt. Anita Das, Secretary (AYUSH) Shri Shiv Basant, Joint Secretary Shri S.K. Chadha, Director Shri V.K. Gupta, Head IT. (CSIR) Dr. Bala Subramaniam, Scientist 'F' (CSIR) Mrs. Alpana Jain, IT Expert (CSIR) Dr. Jaya Saklani, Ayush Expert (CSIR) Dr. Ehsan Ahmed, Unani Expert (CSIR) Dr. Sugandha Sivakumar, Siddha Expert (CSIR)

Representatives of Council for Scientific and Industrial Research (CSIR)

Dr. T. Ramasami, Secretary, DSIR and DG, CSIR Shri Nikhilesh Jha, Joint Secretary (Admn.) DSIR/CSIR Ms. Sheila Sangwan, FA, DSIR/CSIR Dr. Naresh Kumar, Head RDPD, CSIR Dr. D. Yogeshwar Rao, Head TNBD, CSIR Shri V. K. Gupta, Head, IT & TKDL, CSIR Shri R.K. Gupta, Head, IPMD, CSIR Dr. A. V. Gomkale, Scientist, IPMD, CSIR Shri A. Wahid, Scientist, CSIR

SECRETARIAT

Shri Ravi Kant Chopra, JS & FA Shri Surinder Kumar Watts, Director Shri M.K. Khan, Deputy Director Smt. Indira C. Vaidya, Committee Officer

2. The Committee heard the views of representatives of Department of Industrial Policy & Promotion, Ministry of Health and Family Welfare, (Department of AYUSH) and Council for Scientific and Industrial Research (CSIR) on Patents and Trademarks System in India. Members sought some clarifications, which were replied to by the witnesses. The Chairman directed the witnesses to send their written replies in response to the queries, for which information was not readily available.

A verbatim record of the evidence was kept.

- 3.
- 4. The meeting adjourned at 6.20 p.m.

*V FIFTH MEETING

The Department Related Parliamentary Standing Committee on Commerce met at 11.00 A.M. on Wednesday, the 10th October, 2007, in Committee Room 'A', Ground Floor, Parliament House Annexe, New Delhi.

PRESENT

1. Dr. Murli Manohar Joshi — Chairman

Rajya Sabha

- 2. Shri Thennala G. Balakrishna Pillai
- 3. Shri Jai Parkash Aggarwal
- 4. Dr. K. Keshava Rao
- 5. Shri Mohammed Amin
- 6. Shri Dinesh Trivedi

LOK SABHA

- 7. Shri Radhey Shyam Kori
- 8. Shri Manjunath Kunnur
- 9. Shri Jivabhai A. Patel
- 10. Shri Shishupal N. Patle
- 11. Shri E. Ponnuswamy

^{***} pertains to other subject.

- 12. Shri Kashiram Rana
- 13. Shri Haribhau Rathod
- 14. Shri Braja Kishore Tripathy

WITNESSES

Indian Drug Manufacturers Association, Mumbai

Shri Gajanan Wakankar, ED Shri S. K. Arya, Joint Director

SECRETARIAT

Shri Ravi Kant Chopra, JS & FA Shri Surinder Kumar Watts, Director Shri M.K. Khan, Deputy Director Smt. Indira C. Vaidya, Committee Officer

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* 4th Meeting of the Committee pertains to other subject matter.

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*** pertains to other subject

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6. The Committee thereafter heard the views of representatives of Indian Drug Manufacturers Association on the subject of Patents and Trademarks Systems in India. Members sought some clarifications, which were replied to by the witnesses. The Chairman directed the witnesses to send their written replies in response to the queries, for which information was not readily available.

7. With this, the Committee decided to close the evidence on the subject of Patents and Trademarks Systems in India. However, it decided to hear the concluding evidence of the Secretary, Department of Industrial Policy and Promotion on the subject, in its next meeting.

A verbatim record of the evidence was kept.

8. The Committee adjourned at 12.45 p.m.

VI SIXTH MEETING

The Department Related Parliamentary Standing Committee on Commerce met at 11.00 A.M. on Tuesday, the 18th December, 2007, in Room No. '63', First Floor, Parliament House, New Delhi.

http://164.100.47.5/newcommittee/reports/EnglishCommittees/Committee%20on%20Commerce/88th%20Report.htm

^{***} pertains to other subject.

PRESENT

1. Dr. Murli Manohar Joshi — Chairman

Rajya Sabha

- 2. Shri Mohammed Amin
- 3. Shri Rajkumar Dhoot
- 4. Shri Dinesh Trivedi
- 5. Shri Robert Kharshiing

LOK SABHA

- 6. Shri Omar Abdullah
- 7. Shri C.K. Chandrappan
- 8. Shri Radhey Shyam Kori
- 9. Shri N.N. Krishnadas
- 10. Shri Manjunath Kunnur
- 11. Shri Virchandra Paswan
- 12. Shri Shishupal N. Patle
- 13. Shri E. Ponnuswamy
- 14. Shri Kashiram Rana
- 15. Shri Haribhau Rathod
- 16. Shri Nikhilananda Sar
- 17. Shri Braja Kishore Tripathy
- 18. Shri T.K. Hamza

WITNESSES

REPRESENTATIVE OF LAWYERS COLLECTIVE HIV/AIDS UNIT

Mr. Anand Grover, Project Director

REPRESENTATIVE OF CAMPAIGN FOR ACCESS TO ESSENTIAL MEDICINES, NEW DELHI.

Ms. Leena Menghaney, Project Manager

REPRESENTATIVES OF DEPARTMENT OF INDUSTRIAL POLICY AND PROMOTION

<u>Shri Ajay Shankar, Secretary</u> <u>Shri N.N. Prasad, Joint Secretary</u> <u>Shri M.S. Dhakad, Director</u> <u>Shri T.C. James, Director</u> <u>Shri V. Ravi, CGPDTM</u>

MINISTRY OF LAW & JUSTICE

Dr. B. A. Agrawal, Additional Secretary Shri N.K. Ambastha, Consultant Smt. Sudha Rani, Deputy Legislative Counsel Shri K. Sreemannaranayan, Assistant Legislative Counsel

SECRETARIAT

Shri V.K. Agnihotri, Secretary General Shri Ravi Kant Chopra, JS & FA Shri Surinder Kumar Watts, Director Shri M.K. Khan, Deputy Director Smt. Indira C. Vaidya, Committee Officer

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4. The Committee heard the views of representatives of Lawyers Collective HIV/AIDS Unit and Campaign for Access to Essential Medicines on Patents and Trademarks Systems in India. Members sought some clarifications, which were replied to by the witnesses. The Chairman directed the witnesses to send their written replies in response to the queries, for which information was not readily available.

5.

6. The Committee then heard the concluding evidence of the Secretary, Department of Industrial Policy & Promotion on the Patents and Trademarks Systems in India which, however, remained inconclusive.

7.

A verbatim record of the evidence was kept.

8. The Committee adjourned at 3.15 p.m.

*** pertains to other subject.

*IX NINTH MEETING

The Department Related Parliamentary Standing Committee on Commerce met at 11.00 A.M. on Friday, the 11th January, 2008, in Room No. '63', First Floor, Parliament House, New Delhi.

PRESENT

1. Dr. Murli Manohar Joshi — Chairman

Rajya Sabha

- 2. Shri Jai Parkash Aggarwal
- 3. Dr. K. Keshava Rao
- 4. Shri Banwari Lal Kanchhal
- 5. Shri Dinesh Trivedi
- 6. Shri Robert Kharshiing

LOK SABHA

- 7. Shri Omar Abdullah
- 8. Shri Radhey Shyam Kori
- 9. Shri N. N. Krishnadas
- 10. Shri Virchandra Paswan
- 11. Shri E. Ponnuswamy
- 12. Shri Kashiram Rana
- 13. Shri Nikhilananda Sar
- 14. Shri Braja Kishore Tripathy
- 15. Shri T. K. Hamza

WITNESSES REPRESENTATIVES OF DEPARTMENT OF INDUSTRIAL POLICY AND PROMOTION

<u>Shri Ajay Shankar, Secretary</u> <u>Shri N.N. Prasad, Joint Secretary</u> <u>Shri M.S. Dhakad, Director</u> <u>Shri T.C. James, Director</u>

SECRETARIAT

Shri Ravi Kant Chopra, JS & FA Shri Surinder Kumar Watts, Director Shri M.K. Khan, Deputy Director Smt. Indira C. Vaidya, Committee Officer

* 7th & 8th Meeting of the Committee pertains to other subject matter.

2. The Committee resumed hearing the concluding evidence of the Secretary, Department of Industrial Policy and Promotion on Patents and Trademarks Systems in India. Members sought some clarifications, which were replied to by the witnesses. The Chairman directed the witnesses to send written replies to the queries, for which information was not readily available.

A verbatim record of the evidence was kept.

- 3. The Committee adjourned at 1.00 p.m.
- *** pertains to other subject.

*III THIRD MEETING

The Department Related Parliamentary Standing Committee on Commerce met at 3.00 P.M. on Friday, the 26th September, 2008, in Committee Room 'A', Ground Floor, Parliament House Annexe, New Delhi.

PRESENT

1. Dr. Murli Manohar Joshi — Chairman

Rajya Sabha

- 2. Shri Thennala G. Balakrishna Pillai
- 3. Dr. K. Keshava Rao
- 4. Shri Banwari Lal Kanchhal
- 5. Shri Mohammed Amin
- 6. Shri Parimal Nathwani

LOK SABHA

7. Shri Omar Abdullah

- 8. Shri C.K. Chandrappan
- 9. Shri D. V. Sadananda Gowda
- 10. Shri Radhey Shyam Kori
- 11. Shri Manjunath Kunnur
- 12. Shri Amitava Nandi
- 13. Shri Virchandra Paswan
- 14. Shri Shishupal N. Patle
- 15. Shri E. Ponnuswamy
- 16. Shri Gingee N. Ramachandran
- 17. Shri Kashiram Rana
- 18. Shri Sippiparai Ravichandran
- 19. Shri Nikhilananda Sar
- 20. Shri Bharatsinh Madhavsinh Solanki
- 21. Shri Braja Kishore Tripathy
- 22. Shri Balashowry Vallabhaneni

WITNESSES

Shri S.C. Sethi, President, The Federation of Publishers & Booksellers Associations in India (FPBAI) Shri Vijay Prakash Jain, General Secretary, Bharitya Udyog Vyapar Mandal Shri K. K. Mittal, Delhi Shri N. C. Joshi, Delhi Shri Himanshu Goel, Dehradun

* 1st & 2nd Meeting of the Committee pertains to other subject matter.

SECRETARIAT

Shri Ravi Kant Chopra, JS & FA Shri Surinder Kumar Watts, Director Shri M.K. Khan, Deputy Director Smt. Indira C. Vaidya, Committee Officer

2. *

3. The Committee then took up for consideration the draft Report on the Patents and Trade Marks Systems in India. The Committee adopted the Report, and authorized the Chairman to effect changes therein, necessitated by the views expressed by the Members in the meeting or otherwise, before presenting/laying the Report in both the Houses.

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4. *

5. A verbatim record of the proceedings of the meeting was kept.

6. The Committee adjourned at 5.30 p.m.

*** pertains to other subject.