Chapter 4.

Regulatory Changes In National Policies.

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4.1 INTRODUCTION.


The Patent Act 1970 was designed to address health needs of our country to provide cheap medicines to mass population. It stimulated growth of domestic pharmaceutical industry by reverse engineering patented and off-patented medicines. As a result of this India becomes one of the leading player in production of bulk drugs and formulations in world. Due to protection under this act medicine produce in India not only fulfilled domestic demand of cheap medicines but, today it becomes leading player in supply of generics to developed world and Indian medicines are becoming quality supply of life saving medicaments in combating HIV epidemic in Africa and even control of Anthrax in U.S.A.

Year 1995, started sphere heading reforms regarding protection that patent law granted to domestic firms regarding process patent in chemicals and agrochemicals. Since India is signatory to WTO, there was not any alternative regarding implementing product patent régime in chemicals including drugs by amending its patent legislation to make it complaint with TRIPS.


\textsuperscript{22}Patents, Businessworld, 4-04-2005(24).
Two successive central governments in India (National Democratic Alliance and United Progressive Alliance) have successfully navigated through this turmoil by amending patent act in year 2005. It successfully protected interests of domestic pharmaceutical industry regarding varies issues like immunity for generic manufacturing, exports of generic pharmaceutical products, opposition to grant of patents, terms of patents and compulsory licensing. It is expected that these amendments reasonably meet local as well as export demands of domestic pharmaceutical companies. These amendments in final draft are result of extensive guidance from left political parties regarding availability of low cost drugs for domestic market.

Although there are some issues not sorted out yet and they are referred to expert committee, such as definition and patentability of new chemical entity (NCE) and microorganisms.

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22 Patents: Frontline, 22-04-05(28-32).
23 Patents: Businessworld, 17-01-05(22-26).
27 Collein Chien; Cheap drugs at what price to innovation: Does the compulsory licensing of Pharmaceuticals hurt innovation, Berkeley School of Law, University of California, 2003.
Research and development is one crucial point that Indian pharmaceutical industry has to tackle in coming decade, if it wants to survive in International market. Leading domestic firms like Ranbaxy and Dr Reddy's Laboratories has acquired some success in this regard. Several other emerging areas like Knowledge Process Outsourcing (KPO), contract manufacturing, organic synthesis, clinical trials, convergence of pharmaceutical and biotech sector, vaccine production are going to shape Indian pharmaceutical industry in coming decade. With available trained human force and world class manufacturing facilities as largest number of U.S.F.D.A. approved outside U.S.A. India can play pivotal role in global pharmaceutical industry in some areas like generics and biogenerics, bulk drug and formulations supply, herbal /Ayurvedic drugs; vaccines are areas where India can excel in coming decade. Research and development is one critical issue and even though in last decade we seen number patents filled in India are increasing, we can not predict any concrete outcome for coming decade because of uncertainty involve in pharmaceutical and biotech research in short span of ten years.

Patents, as globally accepted is revenue generating tool for inventor. Last decade witness debate about price of medicine and affordability of medicines. Since India grants protection to drugs invented prior to year 2005 and most of patented drugs are going off patent by year 2007, we foresee, not significant change in cost of essential drugs in India. Market size affected (importance) and patents (predictability) are other factors, which determines cost of drugs (differential pricing) in domestic market. Doha Declaration on Public Health and Drug Price Control Order (DPCO) under National Pharmaceutical Pricing Authority (NPPA) and future amendments in Drugs and Cosmetic Act 1940 are critical factors regarding availability of quality essential medicines in India in coming decade. This point is more elaboratory discussed in Chapter Research and Development.

Due to success on coping with domestic and global demand regarding availability of drugs, Indian government has confidentially consolidated its stand on international trade platforms like WTO and WIPO. Although pro-patent stand of India as seen in recent WIPO meeting held on 15-16th February
2005 in Casablanca, Morocco\(^{31}\). Main agenda of this WIPO meet was upward harmonization of patent regime by TRIPS-plus measures in Substantive Patents Law Treaty (SPLIT). Dr. R. Mashelkar, Director, Council For Scientific And Industrial Research (CSIR) chaired this meet. This may prove as a turning point and may open further debate on issues of patentability related with inventions related with industrial applications. Many developing countries including G-20 group and IBSA (India, Brazil, South Africa) initiative, of which India is leading player, may oppose views of India on IP issues.

Supply of essential medicines to develop and developing economies by India, litigations related with patents are going to shape developments in Indian pharmaceutical industry in coming decade.

Developments in Indian IP sector, which are going to give directions to future outcome of above, mentioned points are discussed this chapter.

4.2

**LAWS PERTAINING TO MANUFACTURE, DISTRIBUTION AND SALE OF DRUGS.**

This segment deals with provisions in various regulatory affairs, which are going to affect future developments in the field of pharmaceutical industry. Emergence of knowledge-based society and its implication on legal framework of Nation has created turmoil in Industry. Since pharmaceuticals is the knowledge based industry, which works on pool of best scientific know-how from all across the globe, is the most affected sector of Indian industries due to globalization.

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\(^{31}\)The New Battle Ground; Businessworld, 11-04-05(42-49)
The property in the form of Intellectual Property, which is the result of human intelligence, has come to play very vital role in lives of human beings and world economy at large. It is a category of intangible rights protecting commercially valuable products of the human intellect. This new protection is going to alter shape of drug research industry. Discussed herewith some of the provisions from various legislation's, which are already passed by Central government of India or in the process of implementation.

Interestingly some of the provisions in the new legislation are started being criticized from professional not only from India but also on global platforms. Such reviews on provisions on various Acts, which are relevant to pharmaceutical industry, are also referred while preparing this article.34,35,36,37

1. The Copyright Act, 1957.

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34The Drugs and Cosmetic Act 1940: Bare Act, Law Publishers (India) Pvt Ltd, Delhi.
36The Geographical indications of Goods (Registration And Protection) Act 1999, Law Publisher (India) Pvt Ltd, Delhi.
3. The Trade and Merchandise Marks Act, 1958
   The Trade and Merchandise Marks Act, (Amendment) 1999.
   At present there are several act relating to manufacture, distribution, sale and other related aspects of Drugs in India. There are also rules framed under the provisions of these laws, which govern the production and sale.
   a. The Drugs and Cosmetic Act of 1940 as amendment by the Drugs (Amendment) Act, 1955.
      The Drugs and Cosmetic (Amendment) Act 1960
      The Drugs and Cosmetic (Amendment) Act 1962
      The Drugs and Cosmetic (Amendment) Act 1964
      The Drugs and Cosmetic (Amendment) Act 1972
      The Drugs and Cosmetic (Amendment) Act 1982
      The Drugs and Cosmetic (Amendment) Act 1986.
   b. The Drugs and Cosmetic Rules of 1945.
      The Drugs and Cosmetics (Amendment) Act of 1964
      The Drugs and Cosmetics (Amendment) Act of 1972
      The Drugs and Cosmetics (Amendment) Act of 1982
      The Drugs and Cosmetics (Amendment) Act of 1986

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c. The Pharmacy Act of 1948.
d. The Drugs and Magic Remedies (Objectionable Advertisement) Act of 1954
e. The Narcotic Drugs and Psychotropic Substances Act, 1985.
f. The Poisons Act of 1919
g. The Medicinal and Toilet Preparations (Excise Duties) Act of 1956.
h. The Drugs (Control) Act 1930.
i. The Industries (Development and Regulation) Act of 1951.

4.3
POLICY DOCUMENTS OF GOVERNMENT OF INDIA RELATED WITH PHARMACEUTICAL INDUSTRIES.
a. The Drugs (Prices Control Order,) 1995
c. New Drug Policy, 2002
d. New Health Policy, 2002
e. EXIM Policy, 2002

4.4
INDIA’S JOURNEY TO INTELLECTUAL PROPERTY RIGHTS PROTECTION.

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1994</td>
<td>The Uruguay Round Negotiations Are Ratified.</td>
</tr>
<tr>
<td>1994</td>
<td>India Accepts WTO Membership.</td>
</tr>
<tr>
<td>1994</td>
<td>Ordinance To Amend Patent Laws Is Promulgated.</td>
</tr>
<tr>
<td>1995</td>
<td>The Uruguay Round Agreements Come Into Force.</td>
</tr>
<tr>
<td>1995</td>
<td>The Patents (Amendment) Ordinance Lapses.</td>
</tr>
<tr>
<td>1995</td>
<td>The Patents (Amendment) Bill Is Introduced In The Lok Sabha.</td>
</tr>
</tbody>
</table>

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1997 The US Complains To The WTO That India Is Violating The TRIPS Agreement.
1997 EU Files Complaint With The WTO On The Failure To Set Up Mailbox Facilities
1997 The WTO’s Dispute Settlement Body (DSB) Rules Against India.
1997 India Appeals Against The DSB Ruling.
1997 The WTO’s Appellate Body Rejects India’s Appeal.
1998 The WTO Formally Ask India To Amend Her Patent Laws.
1998 India Agrees To 15 Month Implementation Period.
1998 India Decides To Accede To The Paris Convention.
1998 The DSB Rules Against India in EU Complain.
1999 Deadline For Complying With The Recommendations Of The DSB.
2002 Doha Declaration On TRIPS Agreement And Public Health.
            New Drug Policy 2002 And Drugs (Price Control) Order 2002 Published. (Presently Under Litigation In Supreme Court)
### TABLE No 4.1
#### INDIAN POSSESSION ON PATENTS ISSUES.

<table>
<thead>
<tr>
<th>WTO Requirement</th>
<th>Present Law</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>3. There should be no discrimination between domestic and imported products.</td>
<td>The Indian Patents (Amendment) Act. 2005. and Drugs and Cosmetic Act 1940.</td>
<td>Complied.</td>
</tr>
<tr>
<td>4. Microorganisms, non biological and microbiological processes must be patented</td>
<td>The Indian Patents (Amendment) Act. 2005.</td>
<td>Referred to expert committee.</td>
</tr>
<tr>
<td>5. Plant varieties must be protected through either patents or <em>sui generis</em> system</td>
<td>Not protected. some protection under Plants Varieties and Farmers Right Act 2001.</td>
<td>The draft of The Plants varieties and Breeders Rights Bill is circulated amongst the ministries.</td>
</tr>
</tbody>
</table>

As on April 2005.

### TABLE 4.2
#### INDIA'S POSITION ON INTELLECTUAL PROPERTY RIGHTS.

<table>
<thead>
<tr>
<th>Area</th>
<th>WTO Requirements</th>
<th>Current Law</th>
<th>Transition Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Copyrights</td>
<td>Protection must be Extended to literary, scientific and artistic work</td>
<td>After 1994 amendment in Copyrights Act 1957 and Rules 1958 and International Copyright Order 1999, copyright Act provides for both economic and non-market rights.</td>
<td>Legislation more than meets WTO requirements. But Enforcement is weak.</td>
</tr>
<tr>
<td>Trademarks</td>
<td>Minimum registration period of 7 years. Service marks should be allowed</td>
<td>Trade and Merchandise Marks Act 1999 and Rules 2002 specify registration period 7 years. No service marks</td>
<td>Complied.</td>
</tr>
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<td>-------------------------</td>
<td>-----------------------------------------------------------------</td>
<td>-----------------------------------------------------------------</td>
<td>-----------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Industrial Designs</strong></td>
<td>Industrial designs that are new or original must be protected</td>
<td>The Indian Designs Registration Act, 2000 and Rules 2004, provides</td>
<td>Legislation meets WTO requirements although protection period needs to</td>
</tr>
<tr>
<td></td>
<td>for 10 years</td>
<td>protection period to industrial designs.</td>
<td>be extended.</td>
</tr>
<tr>
<td><strong>Geographical</strong></td>
<td>Must be protected, no specific legislation is required</td>
<td>Geographical Indication of Goods (Registration and Protection) Act</td>
<td>Complied.</td>
</tr>
<tr>
<td><strong>Integrated Circuits</strong></td>
<td>Must be protected for 10 years although no specific legislation</td>
<td>Protection For Layouts For Integrated Circuits Act 2000.</td>
<td>Complied.</td>
</tr>
<tr>
<td></td>
<td>is required</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Trade Secrets</strong></td>
<td>Undisclosed information should be treated as a form of property</td>
<td>No specific statues exist.</td>
<td>National Official Secrets Act (NOS), Indian Contracts Act and Indian Partnership Act offer minor protection. Data protection is proposed through the Amendments in Drugs and Cosmetic Act 1940. Rules 122 A, B and introduction of new section 18 A. Section 9 and amendment in Form 318</td>
</tr>
</tbody>
</table>

*As in year 2005*

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<table>
<thead>
<tr>
<th>No</th>
<th>Legislation Enacted</th>
<th>Compliance Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The Geographical Indications of Goods (Registration and Protection) Act 1999.</td>
<td>Complied</td>
</tr>
<tr>
<td>2</td>
<td>Protection of Plant variety and Farmers Rights Act 2001 (PPVFR 2001).</td>
<td>Complied</td>
</tr>
<tr>
<td>4</td>
<td>Plant Breeders Rights Bill.</td>
<td>At consultative committee of Parliament.</td>
</tr>
<tr>
<td>5</td>
<td>Data Protection</td>
<td>Article 39.3 of TRIPS requirement National Official Secrets Act to be referred.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Harmonization of patent term to 20 years.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Amendment in section 3, dealing with inventions that are not patentable.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Amendment in section 5, defines chemical, process including biochemical, biotechnological and microbiological process</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Amendment in section 10 to include</td>
</tr>
</tbody>
</table>
| ‘Biological materials’ | • Setting of ‘Appellate Board’ for Grounds of Oppositions.  
| | • ‘Ground of Revocations for inclusions of geographical origin, indigenous community knowledge.  
| | • Section 83 dealing with working of patents expanded  
| | • Section 84 gives more grounds for ‘Compulsory license’  
| | • Section 90 deals with ‘Fair Returns’ of patents  
| | • Special provisions (national emergency) in section 92(1)(ii) for compulsory license.  
| | • Section 100 deals with compensation to patentee in case of compulsory license.  

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**4.5**  

Third Amendment requires amendments in following sections of act to make it compliant with TRIPS obligations.\(^3\)

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TRIPS Articles.
27, 29(b), 31(b), 73.
27. Patentable Subject Matter.
29. Condition on Patent applications
31. Other Use without Authorization of Right Holder.
73. Security Exceptions.
Sections Amended.
2(1)(a), 3(d), 7, 8, 9, 10, 11(a)(b), 12, 13, 16, 17, 18, 19, 87, 90, 100, 105, 107(a),
113, 116, 117(a)(d)(g), 120, 122, 123, 126, 135, 138, 142, 143, 159.
New Sections Inserted.
14, 15, 21, 25, 26, 39, 43, 58, 65, 68, 92(a), 133.
Omission of Sections.
5, 22, 23, 24, 151, 152, 163.
Issues not sorted
Definition of patentability of new chemical entity (NCE) and microorganisms.

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<th>Section of Patent Act</th>
<th>Particulars</th>
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<td>2(1)(a)</td>
<td>Budapest Treaty (Amended)</td>
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<tr>
<td>2(1)(j)</td>
<td>Inventions And Inventive Steps.</td>
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<tr>
<td>3&amp;11</td>
<td>Standards And Exclusions For Patentability.</td>
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<tr>
<td>3(c)</td>
<td>Discovery Of Scientific Principles.</td>
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<tr>
<td>3(d)</td>
<td>Discovery Of New Properties (Substituted)</td>
</tr>
<tr>
<td>3(f)</td>
<td>Duplication Of Known Device.</td>
</tr>
<tr>
<td>3(e)</td>
<td>Admixtures.</td>
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<tr>
<td>3(k)</td>
<td>Mathematical And Business Models.</td>
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<td>6&amp;27</td>
<td>Inventions Not Patentable (Deleted)</td>
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<tr>
<td>7(1)(b)</td>
<td>Filling Date Of Application (Amended)</td>
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<tr>
<td>10(4)(b)</td>
<td>Contents Of Specifications (Substituted)</td>
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<td>11(a)(b)</td>
<td>Publication And Examinations Of Applications (Amended)</td>
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<td>14&amp;15</td>
<td>Consideration Of Report Of Examiners By Controller.</td>
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<td>Power Of Controller To Refuse Or Require Amendment</td>
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<td>Application In Certain Cases. (Amended)</td>
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<td>25&amp;26</td>
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<td>Relevance Of Patents For Defense Purpose (Substituted).</td>
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<td>47</td>
<td>Definition Of Drug/Medicine. (Amended)</td>
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<td>48</td>
<td>Products Whereof Do Not Qualify For Protection. (Amended)</td>
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</tbody>
</table>
Section 25.

Ground for Opposition of Patent.

1. Obtaining invention wrongfully.
2. Prior publication of complete specification before priority date of claim.
3. Filling Application patent in India, being claim of which the primary data is earlier than of Applicants claim.
4. Claim is publicly known of used before priority date of claim.
5. Claim is obvious and clearly does not involve any inventive step.
6. Claim is not inventive within means of this act or is not attestable under this act.
7. Claim does not clearly describe the invention or method by which it is to be performed.
8. Applicant fails to disclose to the controller the information required by Section 8.
9. Convention Application not made within 10 months.
10. Wrong mention of source or geographical origin of biological material use for invention.
11. Claim or specification is anticipated having regard to the knowledge, oral or otherwise available within any local or indigenous community in India or elsewhere.

Section 163 (Omitted).

Transitional Provisions.

1. EMRs will be deemed to be treated as request for specification for grant of patent under subsection (3) of section 11(b) of Principle Act.
2. Exclusive rights granted before 1-01-05 shall continue to be effective with same terms and conditions on which it was granted.
3. EMRs granted before 1-01-05 shall be examined for grant of patent immediately on the commencement of this Act.
4. All suits related with EMRs before 1-01-05 shall be dealt with same manner as if they were suits concerning infringement of patent under chapter XVIII of Principle Act.
5. No liability of EMRs by Central Government for grant of EMRs after 1-01-2005.

The Patents (Amendment) Act 2005; Salient Features.

Important section of amended act, which are significant as far as pharmaceutical industry are;

1. Scope of patentability.
   - Defines what is patentable, thus limiting patent protection to new entities and preventing pharmaceutical companies from filling patent applications for drugs that are not substantially different from the original products.
   - Software patents excluded.
   - Substituted ‘new use’ for ‘mere new use’ thus strengthening the provision that can be used to deny patents on the new use of known substance.
   - Refers the question of whether a pharmaceutical substance should be defined as ‘new entity involving one or more inventive steps’ or ‘a new chemical entity’ to expert committee.
To prevent frivolous claims, it clarifies that the ‘mere discovery of new form of known substance, which does not result in enhancement of known substances’ is not patentable.

Salts, esters, ethers, polymorphs, metabolites, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substances can not be patented, unless they ‘differ significantly’ in properties with regard to ‘efficacy’.

The applicant has to comply with and inventive step, which means that the invention has to involve technical advances as compare to existing knowledge or having economic significance or both.

2. Immunity for generic production.

Drugs that were being produced and marketed by Indian companies before 1-01-2005 can continue to produce them after paying reasonable royalty.  

3. Export of patented pharmaceutical products.

The requirement the country to which drugs were being exported needs to issue compulsory license has been removed.

4. Opposition to the grant of patent.

Pre-grant opposition restored.

The number of grounds on which patents can be opposed restored to 11.

Provision related to mandatory provision not restored. One has to pay fees to access this information.

Inventions either filled or claiming priority as of July 2003 are ‘deemed to be published’, without making physical publications available.

Businessworld

BusinessIndia
5. Terms of patent.
   - Twenty years from date of filling for all patents. The date patent comes in to force is calculated from the date of publication of the mailbox application.

6. Compulsory license.
   - 'Reasonable period' for grant of compulsory license has change to six months.
   - Company can apply for compulsory license only after three years after license is granted.

Ambiguity in certain issues.
1. Qualification regarding 'enhancement of known efficacy'.
2. Interpretation of term 'differ specifically in properties with regard to efficacy'
3. Reasonable royalty to be paid to inventor for drugs invented prior to 1-01-2005. Term 'reasonable royalty' has not been defined. (In most countries it is fixed at 4%).
4. Mechanism of issuing compulsory license to export drugs.
5. Access to information for claims filled or claimed as of July 2005.

4.6 THE PATENTS RULES 2005.


Ministry of Commerce and Industry (Department of Industrial Policy and Promotion) by notification in official gazette on 28th December, 2004 updated patents Rules, 2003 on the lines contained in amendment to The Patent Act 1970 under provision of subsection 3 of section 159 of The Patents Act 1970, central government dispenses these rules namely, The Patent Rules, 2005 w.e.f. January 1, 2005. Rules, which are particularly significant to pharmaceutical industry, are given below.

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<td>Specifications.</td>
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<td>Duly Authorization By Applicant.</td>
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<td>24: Publication Of Application.</td>
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<td>24(A): Request For Publication.</td>
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<td></td>
<td>24(B): Examination Of Application.</td>
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<td>27</td>
<td>Substituted</td>
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<td>27: Inspection And Supply Of Published Documents.</td>
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<td>OPPOSITION PROCEEDINGS.</td>
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<td>55-57</td>
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<td>55: Opposition By Representatives Against Grant Of Patents.</td>
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<td>56: Constitution Of Opposition Board And Its Proceedings.</td>
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<td>57: Filling Of Written Statements Of Opposition And Evidences.</td>
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<td>63</td>
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<td>63A: Request Made Under Section 26(1)</td>
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<td>69: Proceedings For Hearing Of Claims Of An Application Under Section 28</td>
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<td>71: Permission For Making Patent Application Outside India Under Section 39</td>
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<td>74</td>
<td>New Section Inserted</td>
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<td>74A: Inspection Of Documents Related With Grant Of Patents.</td>
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<td>78</td>
<td>Substituted</td>
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<td></td>
<td>78: Procedure For Hearing Proceedings Under Section 51.</td>
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<tr>
<td>85</td>
<td>Substituted</td>
</tr>
<tr>
<td></td>
<td>Opposition To Restoration Under Section 61.</td>
</tr>
</tbody>
</table>
4.7 IMPACT ON BUSINESS.

Adherence to TRIPS will transform the legal and business framework in India. It is also going to radically alter competitive equations. For starters, better intellectual property protection will facilitate the transfer of technology. That is vital for a country that is so dependent on technology imports that, according to a study by the PHD Chamber of Commerce and Industry, 95 percent of industrial production is based on imported technology. Second, better IPR protection will facilitate the transfer of better technology. Foreign firms are often accused of transferring second-best, outdated technologies to their Indian partners, but it is often forgotten that a lax IPR regime does not offer much incentive to do otherwise.

Cross-country analysis suggests that as the quality of intellectual property protection improves, expenditure on research and development by industry as a whole will climb. Specifically, the switch from process patents to product patents will transform the pharmaceuticals industry. And with the TRIPS agreement expanding the scope of patent protection to include all fields of technology, similar transformation could sweep the biotechnology industry and to a lesser extent, software.
PHARMACEUTICALS.

New drugs under development for treatment of diseases such as cancer, tuberculosis, and AIDS will be under patent and, hence, will be priced beyond the reach of all but a microscopic minority for 20 long years. Meanwhile, indigenous industry will be adversely affected. Already, many units have been forced to close down. Such scenarios are not surprising. After all, the rapid growth of the Indian pharmaceuticals industry owes much to a lax patent regime. In the 30 years since the Patents Act, 1970, came into being, the industry moved from trading in transnational brands to producing and exporting pharmaceutical substances and formulations. Since product patents were ruled out, Indian firms could freely reverse-engineer, the polite term for organized piracy. That made drugs available in India at a fraction of their price abroad for a fraction of investment. Naturally numbers mushroomed. There are over 24,000 pharmaceutical manufacturers in India. This multiplicity spends, on an average, 1.80 per cent of its total turnover on research and development. In the US, the comparable figure is 16 percent.

The introduction of product patents is bound to affect adversely the number of manufactures. For those that do survive, expenditure on research and development must grow exponentially. The basis for sustained competitive advantage in this industry will be research and development. Prices too are bound to rise, but the scope and extent of price-rise is exaggerated. Patents worldwide cover less than 10 per cent of India’s list of essential drugs. Moreover, prices of essential drugs are low not because of process patents, but because of Drug Price Control Order (DPCO). Nothing in the TRIPS agreement requires such price-controls to be revoked.

Even if the DPCO is relaxed, prices of patented drugs will not skyrocket. Sure, a patent by definition confers a limited monopoly. But most new drugs are substitutes for existing drugs. Their therapeutic properties and side effects may differ slightly, thus making it difficult for the monopolist to extract full monopoly prices. Even a monopolist can charge only what the market can bear. The assumption that drugs will retail here at international prices is a mistaken. The Indian consumer is used to cheap drugs, and will not prefer 10-12 times more for a basic drug.
4.8

THE STRATEGIC IMPACT

The scope of patent protection is constantly widening not only because the laws are changing, but also because discovery has become an inherently competitive process. Competitors will have to spend enormous amounts on researching innovations, which will circumvent of patents. Add the considerable costs of litigation and the possible compensation to be paid in case patent violation is proved, and the costs can be prohibitive. These aspects are discussed in topic "Research and Development"

Effect Of Change In Patent Regime.

EFFECT ON TRANSNATIONALS.

- Investments will granted better IPR protection.
- Their R and D centers can be set up in India.
- Technology transfer to Indian joint ventures will be safer.
- Patents held by global parents will be recognized in India.

EFFECT ON CONSUMERS.

- Global products will become more easily available in India.
- Better products will be available to the consumer.
- More products will meet higher quality standards.
- Prices of some patented products will increase.

Businessworld, 2004(26-28).


EFFECT ON RESEARCH AND DEVELOPMENT.

- Research results must be patented before publication.
- Corporates and laboratories will collaborate on research and development.
- Commercialization of research will earn royalties to fund research and development.
- Technologies developed will be licensed out.

EFFECT ON THE GOVERNMENT.

- Policies for conforming to the new regime must be created.
- The process of granting patents must be speeded up.
- Patent application fees will become a source of revenue.
- Penalties for violation of patent laws will have to be hiked.

4.9.

REFORMS TAKEN BY INDIAN PATENTS OFFICE.

1. Modernisation and computerization of patent offices.
2. Initiatives for integrated IP offices in four metro cities.
3. Logo for IP administration has been designed and put in to use.
4. A website of IP office (http://www.ipindia.nic.in) has been launched.
5. 227 additional posts of patent examiners have been created.
6. A Intellectual Property Training Institute has been established at Nagpur for training of examiners.
7. Online search facilities have been established.

8. Work manual for IP office have been prepared
9. Patent (Amendment) Act, 2002 introduces examination on request system in place of examination of all application to reduce backlog of pending patent applications.
10. Digital database of over 1,00,000 patent records and 48,000 design records are prepared.

4.10.
RECOMMENDATIONS

While referring discussion papers by reputed trade organizations like Confederation Of Indian Chambers of Commerce And Industry (CII). Federation of Chambers of commerce And Industries (FICCI), Associated Chambers of Commerce (ASSOCHEM), we came across recommendations made by these Associations regarding administrative reforms in patent office. Some of the recommendations are as follows,

1. Training of patent examiners and attorneys.
2. Formation of Tribunal /Appellate board as soon as possible.
3. Electronic filling of patent application.
5. Appointment of permanent Controller General.
6. Digital bank for traditional drugs.
7. Development of database on lines of PCT gazette and USPTO.
8. Single set if serially allotted numbers, allotted both PCT and non-PCT applications.

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45 Interactive Session on amendment to The Patents Act 1970, Participated by, Department of Industrial Policy and Promotion, Government of India, CII, FICCI, ASSOCHAM.
SUMMARY.

By referring all above points, it seems that Indian Government has positively tackled issues related with intellectual property by making necessary amendments in patent act in following areas of IPRs.

1. Exclusion from patentability.
2. Protection of traditional knowledge.
3. Redrafting of compulsory license provisions.
4. Reintroduction of national security provisions.
6. Introduction of pregnant publication and deferred examination system.
7. Protection of bioavailability.

There is debate on interpretation of various clauses of Patents act and TRIPS articles. We hope in coming one or two years span we can successfully overcome this legal and procedural interpretation of some clauses and ambiguity related with it.

Issues, which are not sorted out like patentability of microorganisms and new chemical entity, are referred to expert committee, is to be viewed in total context of WIPO agreement. In coming years government is expected to take decisions base on national interests.

TRIPS –Plus an initiative seems to head start new debate in coming days regarding reinterpretation of term invention related with industrial applications. This may reduce flexibility available under present TRIPS agreement to address national issues related with health. In coming decade developments on various global platforms, which may affect health related issues, are,

   Harmonization of patent law.
   Development Agenda.
2. Free Trade Agreements (FTAs).
3. While pharmaceutical companies will find genetically engineered products being patented, seed makers will secure higher prices.
4. Companies will be able to use patent databases to track worldwide technology developments.
5. Marketing technology will become a viable business leading to the growth of research and development companies.
6. By establishing patents over their exclusive products, Corporate will be able to eliminate competition.