Patent Protection and Innovation

Section 3(d) of the Patents Act and Indian Pharmaceutical Industry

T C James

Director, National Intellectual Property Organization, New Delhi
and
Former Director, Intellectual Property Rights (IPRs) Division
Ministry of Commerce & Industry
Government of India.

Printed by :
Indian Pharmaceutical Alliance
C/o. Vision Consulting Group
201, Darvesh Chambers
743 P D Hinduja Road, Khar
Mumbai 400 052
India.
E-mail : dgshah@vision-india.com

November 2009

अजय शंकर
AJAY SHANKAR
सचिव भारत सरकार
Secretary to Government of India

औद्योगिक नीति और संवर्धन विभाग
वाणिज्य एवं उद्योग मंत्रालय
उद्योग भवन, नई दिल्ली-110011
Deptt. of Industrial Policy and Promotion
Ministry of Commerce & Industry
Udyog Bhawan, New Delhi-110011
Tel. : 23061815, 23061667 Fax : 23061598
e-mail : a.shankar@nic.in

3rd November 2009

FOREWORD

I am pleased to note that Mr. T.C. James who has worked in the area of Intellectual Property Rights in the Department of Industrial Policy and Promotion in the Government of India for many years has used his vast experience and knowledge and brought out a well researched paper "Patent Protection and Innovation".

The study carried out by Mr. James is a welcome and timely addition to the existing literature on the scope of patentability as dealt under the Indian Patents Act, 1970. This would be of considerable value in the ongoing discourse on this important issue.

I compliment Mr. James on his effort and wish him all the best in his future research endeavours in the important area of Intellectual Property.

(Ajay Shankar)

Contents

Executive Summary

The report of the US-India Business Council entitled *The Value of Incremental Innovation: Benefits for Indian Patients and Indian Business* makes a strong plea for abolition of section 3(d) of the Indian Patents Act so that incremental innovations in the pharmaceutical sector can get patented in India. According to the report, this is beneficial to patients and also the domestic pharmaceutical industry since they are good at such incremental innovations.

India has a history of patent law going back to the 19th century and the early legislations were mostly adaptations of the British law. However, the colonial period resulted in a tottering pharmaceutical industry and one of the poorest healthcare systems in the world. The Patents Act, 1970 facilitated the growth of a strong domestic pharma industry and India became a major exporter of generics.

When India moved to product patent regime in pharmaceuticals in 2005, it introduced certain modifications in section 3(d) to guard against ever greening of patents. This was done while withstanding pressure from many to restrict patenting of drugs to new chemical entities (NCEs), since the government felt that, that would not be TRIPS compatible. The section only sets a standard for inventiveness and does not debar incremental innovations which meet the criteria for patentability. Experience with section 3(d) during the last four years shows that the section has not stood in the way of patenting of incremental innovations. In the number of patent applications and grants in India, there has been perceptible growth during the last few years and non-residents have been major beneficiaries.

Government of India, however, appointed a committee under the chairmanship of Dr. Mashelkar to examine whether it would be TRIPS compatible to restrict patents to NCEs. This Committee has answered the question in the negative. Since the Patents Act has not restricted patents to NCEs, it does not require any amendment on the basis of the Committee's recommendations.

The argument that patenting of all incremental innovations is beneficial to generic companies is facetious. It is likely to delay launching of generics. Further, the evidence that patent protection is essential for innovation is not conclusive. Public funded research has been behind most pharmaceutical breakthroughs.

Marketing strategies of companies dictate seeking extension of market exclusivity for their products through various means. Patenting becomes one such strategy and many companies seek to increase number of patents on a single product as part of this strategy, mainly to keep off competition. Even without intellectual property protection, originator companies have an advantage over the generic pharma companies as they can bring their products to the market much before the latter and that gives them strong market presence by the time others enter. Generics serve a major public health cause by introducing cheaper drugs compared to the patented ones. Removal of section 3 (d) will result in ever greening and delay in the entry of generics thereby adversely affecting public health.

In the US too perceptions about standards of patentability for incremental innovations are undergoing change. Policy briefs and judiciary are raising questions about the advisability of continuing the present practice of granting patents to minor modifications.

Innovations by Indian companies are influenced by the market abroad and the local laws in each country dictate their patenting and marketing strategies in that country. In any case, patenting by them is insignificant compared to that by applicants from developed countries.

The criticism that Section 3 (d) is not compatible with TRIPS Agreement is not correct. It has stood the test of time and does not introduce any unreasonable restrictions on patenting. It is a major public health safeguard as it blocks extension of patent period through additional patents on insignificant improvements, thus paving way for introduction of generics on expiry of the original patent.

Pharma companies need to be given incentives for undertaking more research and development, but removing section 3(d) will be counter productive. A good marketing strategy for the companies would be to concentrate on R & D in diseases which are endemic to countries like Brazil, China and India which are fast emerging as major economies.

Introduction

Section 3(d)[1] of the Indian Patents Act, 1970 has drawn considerable attention of Intellectual Property (IP) academics, attorneys and pharmaceutical firms ever since 2005. The latest in the series of studies that have been done on this subject is the report of the United States — India Business Council (USIBC) entitled ***The Value of Incremental Innovation: Benefits for Indian Patients and Indian Business*** that came out in June 2009[2]. The Report purports to present the various advantages that would accrue to India in industrial investment as well as in health care in supporting a patent regime that grants patents to incremental innovations and makes a fervent plea for abolition of section 3 (d) of the Indian Patents Act. The Report is divided in to four sections, in addition to an Introduction and a Conclusion, namely, the Nature of Incremental Innovation, the Benefits of Incremental Pharmaceutical Innovation for India and the Need for Adequate Incentives, Incremental Pharmaceutical Innovation under section 3(d) of the Indian Patents Act, and Performing the Patents Act to Realise the Benefits of Incremental Pharmaceutical Innovation.

The important points made in the Report are the following:

- Most inventions are incremental innovations rather than big breakthroughs
- Incremental innovations contribute to availability of multiple better drugs suiting local conditions and reduction of prices and health care costs through competition
- The strength of Indian pharma companies is in incremental innovations and Indian companies are increasingly filing applications abroad for incremental innovations
- Section 3(d) is a bar to incremental innovations and is not TRIPS (Agreement on Trade Related Aspects of Intellectual Property Rights) compatible
- Even after incremental innovations are patented, others can manufacture and use the original patented product after expiry of its patent.

I gratefully acknowledge that I have benefited immensely from discussions on the topic with Dr. N.S. Gopalakrishnan, MHRD IPR Chair Professor, Cochin University of Science and Technology, Kochi, Mr. D.G. Shah, Secretary General, Indian Pharmaceutical Alliance, Mumbai, and Mr. Raghu Cidambi of Dr. Reddy's Laboratories Ltd.

Patent Law and Pharmaceutical Industry of India

India is not a newcomer to patent protection. The discussion on having a law to protect inventions goes back to as early as 1832.[3] After a number of failed attempts, the first Patents Act of India was enacted finally in 1856. This was really a copy of the British patent law of 1852. This was soon replaced with Act No. XV of 1859. Then followed a series of laws in 1872 and 1883 and finally they were all consolidated in the Inventions and Designs Act of 1888[4]. Consequent on major changes in British law, a new Patents & Designs Act was enacted in 1911, again adapting the British law. This, with minor amendments from time to time, remained the patent law of India until 1970.

The ostensible purpose of any patent system is to motivate an innovative culture, but as brought out by the Patent Enquiry Committee, in 1950,

> *the Indian patent system (of the pre-Independence period) has failed in its main purpose, namely, to stimulate invention among Indians and to encourage development and exploitation of new inventions for industrial purpose in the country, so as to secure the benefits thereof to the largest section of the public.*[5]

The long period of more than 110 years of patent protection as per the norms of an industrialised country resulted in a tottering pharmaceutical industry and one of the poorest medical care systems in the world. These have been amply brought out in the seminal Report on the Revision of the Patents Law by Justice N. Rajagopala Ayyangar Committee in September 1959, who had studied the Indian patents system and the pharmaceutical industry for well over three years. It was the diagnosis of the problems of the Indian pharma industry by this Committee as well as its recommendations that paved way for the Patents Act of 1970. This Committee rightly observed, after studying the growth of Indian pharmaceutical industry under the colonial period and post colonial period but under a colonial Patent law, that India was not in a position to afford product patents in the field of drugs, chemicals and food items.

The uninterrupted working of the new regime for almost a quarter century[6] till 1995, saw the emergence of India as the generic factory of the world. During this period, while the number of patents granted by the Patent Office annually declined from 4951 in 1969 to 1759 in 1994-95[7], the total domestic production of pharma products increased so substantially that India became a net exporter in 1988-89, a position that it has been maintaining ever since, thanks to the domestic generic companies[8]. The number of pharmaceutical companies also increased from 2237 in 1969-70 to an estimated 16,000 in 1992-93.[9] So far as domestic market share is concerned, that of transnational corporations declined from 80 % in 1970 to 50 % in 1982 and to 39% in 1993[10]. The Federation of Indian Chambers of Commerce & Industry (FICCI), in a report prepared for the National Manufacturing Competitiveness Council (NMCC) in March, 2005, assessed the market share of Indian companies, in 2003 as 72.77 per cent and observed the Indian pharmaceutical industry, with over 20,000 units, was meeting 95 % of the country's pharmaceutical needs.[11] This report estimated the value of the then pharmaceutical industry at approximately US $ 8.00 billion which made it the 13th largest industry globally, though by sheer volume it was 4th in the world. Exports constituted more than 40 per cent of the total production[12], which it would be right to estimate as almost entirely from the domestic sector.

It was to this scenario of dominance of the Indian drug market by the Indian pharma companies that the changes obligated by the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) were introduced in the Patents Act, 1970. A series of three amendments were brought in from 1999 onwards. The final one was in 2005 when section 5 of the Patents Act, which prevented product patents in the fields of drugs, chemicals and food items, was deleted, thus paving way for product patents in all fields of technology. The impact of the expansion of the scope of product patent regime on public health, however, became a matter of serious concern of the parliamentarians. They felt that the new patent laws should not facilitate a marketing strategy which many innovator pharma companies had been practising. This strategy is commonly referred to as 'ever greening' of patents. It is the practice of obtaining new patents for minor improvements on a product towards the end of the patent period of the original product whereby the patent protection for the product gets extended. Some of the members of the parliament were of the view that an invention in order to get protection should be genuinely new in every respect, which would mean it should be a new chemical entity and not any derivatives. The government felt that it would not be TRIPS compatible to restrict the patentability criteria thus, though it promised to set up an Expert Group to study the issue in-depth. Thus the Mashelkar Committee was set up. The government, however, introduced certain additions to Section 3 (d) which it felt were necessary to prevent bad patenting and the phenomenon of ever greening.

> Section 3.-- **What are not inventions**.—
> The following are not inventions within the meaning of this Act,—… … … … … …(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 or the mere discovery of any new property or new use for a known substance or the mere use of a known process, machine or 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 duffer significantly in properties with regard to efficacy.

The focussed media attention on section 3(d) has created an impression among the general public that section 3(d) is an entirely new provision targeted only on pharmaceutical patents. In fact, section 3(d) was a pre-2005 existent provision. What the amendment in 2005 did was to add to that list of inventions not patentable, the category of "mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance" and the Explanation. The word used is 'discovery' which means finding an existing substance or use and not 'invention' which means creating something new. It is an accepted fact that a patent is for an invention and not for merely unravelling an existing fact or technology.

Mashelkar Committee Recommendations

The Mashelkar Committee was, *inter alia*, asked to study "whether it would be TRIPS compatible to limit the grant of patent for pharmaceutical substance to new chemical entity (NCE) or to new medical entity involving one or more inventive steps." The Patents Act had not restricted patents to NCEs. Therefore, if the Mashelkar Committee had answered the question in the affirmative, then there would have been pressure on the government to amend the Patents Act to provide for more restrictive definition of patentable subject matter. However, as it happened, the Committee observed that it would not be TRIPS compatible to limit the grant of patent for pharmaceuticals to NCEs alone, thereby indirectly supporting the argument for section 3 (d).[13]

The Committee further observed that "every effort must be made to prevent the grant of frivolous patents and 'ever greening'". This is the real function of section 3(d). It is not a section which is against innovation, rather it is supportive of innovations which "result in the enhancement of the known efficacy" of a substance. The Mashelkar Committee, in fact, also adds the criterion 'safety' factor when it observes in para. 4.4 of the report, "'incremental innovations' involving new forms, analogs, etc. but which have significantly better safety and efficacy standards, need to be encouraged."[14]

An impression has been created by a section of the pharmaceutical industry that because of section 3(d) any kind of incremental innovations will not get patents in India. This notion got strengthened on account of the challenges to section 3(d) by Novartis, a pharma major. The issue was agitated before the Madras High Court on the grounds of constitutionality by Novartis, pleading that it is against the fundamental right of equality as 'efficacy' has not been defined in the Act leaving it to the discretion of the Patent Controller. The court, however, was not impressed by the arguments on this ground and observed that efficacy is defined in the medical dictionaries. While Novartis did not appeal against the decision of the High Court, it argued its case against the rejection of its patent application for Glivec by the Patent Office, before the Intellectual Property Appellate Board (IPAB). What was material in the case was whether the beta form which Novartis claimed as an invention was a substantial improvement over its alpha form which was already prior art in India, so as to meet the criterion of patentability. The IPAB did not uphold the Novartis' logic. Novartis has since filed a Special Leave Petition in the Supreme Court of India against the orders of the IPAB[15]. It throws up a great opportunity for elucidation of the scope of section 3(d) of the Patents Act by the highest court in the country.

Section 3(d) and Patenting of Pharmaceutical Products

Despite the Novartis application for Glivec, which was rejected by the Patent Office on the grounds of lack of substantial improvement in efficacy, anticipation by prior art and non-fulfilment of the criterion of inventiveness, the fact remains that section 3 (d) had not come in the way of patenting incremental inventions which meet the criteria of patentability. This is evident from the statistics. There was steep increase in overall grant of patents between 2004-05, the year in which product patent for pharma products was introduced along with the restrictive clause of section 3(d), and 2008-09, from 1911 to 18,230[16]. Further, the number of pharma patents also recorded a rise from 765 to 2373 during the same period.[17] An interesting feature of the statistics is that the share of non-resident (foreign) applicants in Indian patents kept on steadily increasing since 2005, the year in which product patents for pharmaceutical products were introduced, as could be seen from tables 1 and 2.

Table 1

Applications filed by residents and non-residents

Applicants	2004-05		2005-06		2006-07		2007-08	
	Number	%	Number	%	Number	%	Number	%
Residents	3630	20	4521	18	5314	18	6040	17
Non-residents	13836	80	19984	82	23626	82	29178	83
Total	17466	100	24505	100	28940	100	35218	100

Table 2

Patents granted to residents and non-residents

Applicant	2004-2005		2005-2006		2006-2007		2007-2008	
	Number	%	Number	%	Number	%	Number	%
Residents	764	40	1396	32	1907	25	3173	21
Non-residents	1147	60	2924	68	5632	75	12088	79
Total	1911	100	4320	100	7539	100	15261	100

Both in applications and grants, the growth of the foreign constituency is remarkable. This steady increase in the patenting activity by the non-residents is indicative of the fact that the Patents Act, as it exists today, accommodates incremental innovations, since the patents granted are not only for new molecules but also for new processes as well as new uses, combinations and dosage forms.[18] During the last three years alone, the Indian Patent Office has granted 3506 patents relating to pharmaceutical innovations[19]. Therefore, on the basis of experience of the last four years it cannot be argued that section 3(d) was against incremental innovations.

It is also worth noting that a limited study by the Indian Pharmaceutical Alliance has come out with a list of 86 patents granted for pharmaceutical products by India after 2005 which inventions are not breakthrough drugs but only minor variations of existing pharmaceutical products.(see Tables 3 and 4).

Table-3

Illustrative List of Patents for New Form of a Known Substance

Sr. No.	Dt of Appin	Dt of Grant	Patent No.	Title	INN Name of the Drug	Year of First Patent #	Applicant
1	08.01.2002	24.06.2008	221507	Pharmaceutical Composition containing Fenofibrate and Method for the Preparation Thereof	Fenofibrate	1973	Laboratories Des Produits Ethiques Ethypharm
2	18.01.2002	17.12.2007	212945	A Pharmaceutical Composition	Reboxetine	1979	Pharmacia & Upjohn Company
3	02.08.2000	05.07.2007	208002	Pharmaceutical Composition comprising a Combination of Metformin and Fibrate, and its use for the preparation of Medicines intended to reduce Hyperglycaemia	Metformin+fenofibrate	1956 + 1973	Merck Paent GmbH
4	27.03.2001	03.10.2006	202371	A Sustained Release Oral Pharmaceutical Composition containing Rivastigmine	Rivastigmine	1990	Novartis AG
5	03.07.2002	20.12.2007	213140	A Pharmaceutical Composition Comprising A Serotonin Reuptake Inhibitor, and Deramciclane	Deramciclane+sertindole	1982 + 1985	H. Lundbeck A/S
6	15.07.2002	20.11.2006	203539	An Inject able Formulation Comprising NK 1 Receptor Antagonist and Magnesium Compound	_	-	M/s F Hoffmann-La Roche
7	04.10.2002	12.12.2007	212743	Pharmaceutical Composition Comprising (R)-(-)-2-[5-(4-Fluoropheny)-3-Pyridylmethylaminomethyl]-Chromane	-	-	Merck Patent GmbH
8	14.01.1998	11.08.2008	222441	An Immediate-Release Fenofibrate Composition	- Fenofibrate	- 1975	Laboratoires Fournier S.A.
9	28.08.1998	30.08.2007	209456	A Pharmaceutical Composition and Kit Comprising the Same	Ramipril + atorvastatin	1994 + 1993	Pfizer Inc
10	27.05.2003	28.03.2008	217702	Novel Crystal Forms of Atorvastatin Hemi-Calcium and Processes for their Preparation as well as Novel Processes for Preparing Other Forms	Atorvastatin	1993	Teva Pharmaceutical Industries Ltd
11	17.11.2004	09.09.2008	223313	A Pharmaceutical Composition Comprising Valsartan, Amlodipine, Hydrochlothiazide	Valsartain+amlodipine+hydrochlorthiazide	1991 + 1983 + 1962	Novartis AG
12	16.06.2003	09.11.2007	211807	Pharmaceutical Composition Comprising Benazepril and Amlodipine	Benazepril + amlodipine	1983 + 1983	Novartis AG
13	14.03.2002	05.09.2007	209548	A Pharmaceutical Composition for Treatment of Diabetes	Nateglinide + gltitazone	1995 + 1989	Novartis AG
14	18.04.1995	13.02.2008	214653	An Azithromycin Composition	Azithromycin	1982	Pfizer Inc
15	28.10.2003	22.08.2007	209165	Crystalline Azithromycin Sesquihydrate	Azithromycin	1982	Pfizer Products Inc
16	08.10.2002	23.06.2008	221437	Pharmaceutical Composition	Fluvastatin + hydroxypropyl methyl cellulose	1984	Novartis AG

17	20.12.2000	13.03.2007	204983	Extended Release Oral Dosage Composition	Pseudoephed nine + desloratadine	1937 +1987	Schering Corporation
18	20.12.2000	09.11.2007	211749	Bilayer Sustained Release Oral Dosage Composition Comprising Desloratadine and a Nasal Decongestant	Pseudoephed rine + desloratadine	Old molecule +1987	Schering Corporation
19	01.11.2004	16.05.2008	220159	A Pharmaceutical Composition Comprising Ibandronate Formulation and Process for Preparing the same	Ibandronic acid	1990	F Hoffmann-La Roche AG et al
20	11.06.2003	05.09.2007	209657	Process for Preparation of Donepezil Hydrochloride Crystalline Polymorphs	Donepezil	1990	Hetero Drugs Limited
21	15.01.2004	26.03.2008	217464	Methyl-Thieno Benzodiazepine Lyophilized Formulation	Olanzapine	1993	Eli Lilly and Company
22	19.09.1997	28.11.2007	212288	A Pharmaceutical Composition Consisting of Olanzapine and Fluoxetine for the Treatment of Pyschoses	Olanzapine +fluoxetine	1993 + 1982	Eli Lilly and Company
23	26.03.2001	21.05.2008	220287	An Olanzapine Pamoate Salt Land Pharmaceutically Acceptable Folvate Thereof	Olanzapine	1993	Eli Lilly and Company
24	31.03.2004	26.03.2008	217469	Pharmaceutical Composition Comprising Gabapentin or an Analogue thereof and an (Alfa)-Aminoamide and its Analgesic Use	Gabapentin + pregabalin/ tiagabine	1990 + 1996 (pregaba line_/1991 (tiagabine)	Newron Pharmaceuti-cals Spa
25	24.04.2001	07.11.2007	211681	A Stabilized Solid Composition	Gabapentin	1977	Warner-Lambert Co.
26	22.05.2000	05.11.2007	211539	A Pharmaceutical Formulation	Tolterodine	1995	Pfizer Health AB
27	06.02.2002	26.09.2007	210300	Composition Comprising A Tramadol Material and an Anticonvulsant Drug	Tramadol + anticonvuls ant**	1965	Ortho McNeil Pharmaceuti cal Inc
28	19.03.2003	30.08.2007	209411	Ana Orally Administrable Tablet	(+) Tramadol	1965	Penwest Pharmaceuti cals Company
29	16.08.2002	26.06.2008	221597	Pharmaceutical Composition Comprising 5-[4-[2-(N-Methyl -N-(2-Pyridyl)Amino Ethoxy] Benzyl] Thiazolidine-2, 4-Dione and Metformin or Metformin Hydrochloride Suitable for the Treatment of Diabetes	Rosiglitazone + metformin	1991 + 1956	SmithKline Beecham Plc
30	02.08.2000	05.07.2007	208002	Pharmaceutical Composition Comprising a Combination of Metformin and Fibrate, and its use for the preparation of Medicines intended to reduce Hyperglycaemia	Fenofibrate + metformin	1975 + 1956	Merck Patent GmbH
31	08.04.2004	30.04.2008	219317	Medicinal Compositions for Nasal Absorption	**	**	Daiichi Suntory Pharma Co. Ltd
32	08.04.2004	13.06.2008	221054	Crystalline Sodium Salt of 4' [2-N-Propyl-4-Methyl-6-(1-Methylbenzimidazol-2YL) Benzimidazol-1-YLMethyl] Biphenyl-2-Carboxylic Acid of Formula A	Telmisartan	1992	Boehringer Ingelheim Pharma GmbH & Co. KG
33	24.05.2005	16.04.2008	218978	Piperazinyl and Diazapanyl Benzamides and Benzthioamides	**	**	Janssen Pharmaceuti-cal N.V.
34	04.12.2003	23.09.2008	223793	Controlled Release Composition and Method of Producing the Same	**	*8	Takeda Pharma-ceutial Co. Ltd.

35	20.10.2004	29.08.2008	222978	Process for Producing Enantiomer of Amlodipine in High Optical Purity	Amlodipine	1986	Emcure Pharmaceuti-cals Limited
36	31.10.2005	18.06.2008	221186	Oral Pharmaceutical Preparation for Proton Pump Antagonists	Proton pump antagonist	**	Altana Pharma AG
37	24.02.1995	19.07.2007	208191	A Pharmaceutical Composition	**	**	1. Janssen Pharmaceutical N.V. & 2. Alketmes Controlled Therapeutics Inc.,II
38	28.09.2004	22.10.2008	224805	Pharmaceutical Compositions	Risperdione	1989	Boehringer Ingelheim Pharma GmbH & Co KG
39	29.10.2004	03.09.2008	223014	Pharmaceutical Composition for Oral Administration Comprising a Tablet Core, containing Flibanserin Polymorph A	**		Boehringer Ingelheim Pharma GmbH & Co KG
40	02.06.2003	12.01.2006	198121	A Novel Cristeline Form of Cefdinir	Cefdinir	1985	Aurobindo Pharma Ltd.
41	17.10.2005	27.06.2008	221624	A Crystal of 1-(2-Methoxy-ethyl)-2-Methyl-4, 9-Dioxo-3 -(Pyrazin-2-YLMethyl)-4, 9-Dihydro-1 H-Naphtho [2,3-D] Imidazol-3- Ium Bromide	**		Astellas Pharma Inc
42	05.07.2005	24.03.2008	217098	A Pharmaceutical Composition Containing Eplerenone Crystalline Form	Eplerenone	1985	Pharmacia Corporation
43	10.07.1995	07.11.2007	211714	Aqueous Risperidone Formulations	Risperidone	1990	Janssen Pharma ceutical N.V.
44	07.04.2004	31.03.2008	218219	Introrally Disintecrating Valdecoxib Compositions Prepared by Spray Drying Process	Valdecoxib	1999	Pharmacia Corporation
45	05.01.2001	28.02.2008	215599	A Pharmaceutical Composition for the Treatment of Depression	Pramipexole + sertraline	1989 + 1981	Boehringer Ingelheim Pharma GmbH & Co KG
46	11.05.2001	07.05.2008	219478	Combination of a-Tocopherol and of Riluzone or of a Pharmaceutically acceptable Salt thereof	Tocopherol +riluzole	1963	Aventis Pharma S.A. et al
47	15.05.2001	22.08.2007	209167	A Controlled Release Formulation containing Galantamine as the Active Ingredient	Galantamine	1952	Janssen Pharmaceutical N.V.
48	05.09.2001	08.01.2008	213532	A Method of preparing Form H Crystalline Eplerenone	Eplerenone	1985	Pharmacia Corporation
49	01.10.2001	06.11.2007	211647	Modified Release Pharma-ceutical Formulation	Amoxicillin + clavulanic acid	1965 + 1979	Beecham Pharmaceuti cals (Pte) Ltd.
50	28.01.2004	27.02.2008	215514	An Antineoplastic Composition	**		Wyeth
51	09.04.2003	26.09.2007	210283	Adjuvant Composition comprising an Immunosti-mulatory Oligonucleotide and a Tocol	**		Glaxo SmithKline Biological S.A.

52	14.09.1998	23.08.2007	209250	Pharmaceutical Combinations comprising Nonsedating Antihistamines and A-Adrenergig Drug for the Topical Treatment of Rhinitis/Conjunctivitis and Cold, Cold-like and/or Flu Symptoms	**		Asta Medical Aktiengese lischaft
53	20.01.2003	22.08.2007	209185	A Pharmaceutical Composition Comprising 5-HT2c Receptor Agonist and 5-HT6 Receptor Antogonist	**		M/s Biovitrum AB
54	04.02.2000	13.11.2007	212024	A Pharmaceutical Combina-tion Comprising the HMG CO A Reductase Inhibitor and the All Antagonist Candesartan	Statin + candesartan	<1993 + 1993	AstraZeneca UK Limited
55	04.02.2000	30.11.2007	212310	A Non-Interacting Drug-Combination for Treating Hyperlipidaemia in Mammals	**		1) Syngenta Limited 2) Shionogi & Co Ltd., et al
56	24.07.2003	16.05.2007	207006	Composition Comprising Sterol Absorption Inhibitor(s) with Blood Modifier(s) for Treating Vascular Conditions	**		Schering Corporation
57	24.07.2003	16.05.2007	207007	A Composition of Sterol Absorption Inhibitor(s) with Cardiovascular Agent	**		Schering Corporation
58	25.08.2003	19.12.2007	213069	Combination Comprising A Signal Transduction Inhibitor and an Epothilone Derivative	**		Novartis AG
59	15.06.2004	16.04.2008	218814	Pyarrolidine and Piperidine Derivtives of General formula I	**		Schering Corporation
60	22.01.2003	16.05.2007	206969	A Pharmaceutical Composition Comprising Lipase Inhibitor and Bile Acid Sequestrant	**		M/s F Hoffmann-La Roche AG
61	23.02.1995	22.10.2008	224747	A Pharmaceutical Composition Comprising Raloxifene, A Surfactant and a Watersoluble Diluent	Raloxifene	1983	Eli Lilly and Company
62	17.11.2004	09.09.2008	223313	A Pharmaceutical Composition Comprising Valsartan, Amlodipine, Hydrochlothiazide	Valsartan + amlodipine + hydrochlorot hizide	1995 + 1986	Novartis AG
63	24.11.2004	01.12.2008	225905	A Combination Comprising A DPP-IV Inhibitor	**		Novartis AG
64	11.03.2004	13.11.2007	211844	A Combination Comprising 4-Pyridylmethyl-Phthalazine Antiangiogenic Agent and Platinum Compound	**		Novartis AG
65	25.04.2005	16.04.2008	218826	Combination Drug	**		Eisai R&D Management Co Ltd
66	19.04.2004	24.10.2008	224913	Composition Comprising Bisphosphonate, Cox-2 Inhibitor and Taxotere for Growth Inhibition of Cancer Cells	Zoledronic acid + COX II inhibitor+ taxol**	1988	Novartis AG et al
67	16.06.2003	09.11.2007	211807	Pharmaceutical Composition Comprising Benazepril and Amlodipine	Amlodipine + benazepril	1986 + 1983	Novartis AG

** indicates that either the abstract does not give clear idea or the drug is not identifiable or a new chemical entity

# indicates that the year of grant is based on the specific product patent granted; based on the Merck index data or IMS Patent database

TABLE –4

Illustrative List of Patents for Combinations

Sr. No.	Dt of Appin	Dt of Grant	Patent No.	Title	INN Name of the Drug	Year of First Patent #	Applicant
1	22.04.2004	31.03.2008	218083	Succinaate Salt of E-2-Methoxy -N-[3-[4-[3-Methyl-Pyridin-3-Yloxyl]-Phenylamino]-Quinazolin-6-YL]-Allyl]-Acetamide and Preparation Thereof	———	———	Pfizer Products Inc
2	23.04.2004	31.03.2008	218212	Crystalline 3-{(3R,4R)-4-Methyl-3-[Methyl-[7H-Pyrrolo [2,3-D]Pyrimidin-4-YL)-Amino] -Piperidin-L-YL}-3-Oxo-Propinitrile Mono Citrate Salt and Its Method of Preparation	———	———	Pfizer Products Inc
3	05.05.1997	04.12.2007	212536	Mesylate Dihydrate Salts of 5 -(2-(4-(1,2-Benzisothiazol-3-YL)-1-Piperazinyl)-Ethyl)-6-Chloro-1,3-Dihydro-2H-Indol-2-One	Ziprasidone	1989	Pfizer Inc
4	28.10.2003	22.08.2007	209165	Crystalline Azithromycin Sesquihydrate	Azithromycin	1985	Pfizer Products Inc
5	25.05.2004	31.03.2008	218230	The Citrate Salt of 4-(3,4-Dichlorophenyl)-2[2-4(4-Methylpiperazin-l-yl)-Benzylidene]-Thiomorpholin-3-one (I) and Pharmaceutical Compositions thereof	Elzasonan	———	Pfizer Products Inc
6	17.11.2004	09.09.2008	223313	A Pharmaceutical Composition Comprising Valsartan, Amlodipine, Hydrochlothiazide	Valsartan, Amlodipine, Hydrochlo-thiazide	1995+ 1986	Novartis AG
7	16.06.2003	09.11.2007	211807	Pharmaceutical Composition Comprising Benazepril and Amlodipine	Benazepril + Amlodipine	1983 + 1986	Novartis AG
8	20.08.2001	31.10.2006	202350	A Medicament containing Formoterol and Momentasone Furoate	Formoterolol + Mometa-sone Furoate	1976+ 1984	Novartis AG
9	14.03.2002	05.09.2007	209548	A Pharmaceutical Composition for Treatment of Diabetes	Nateglinide + Glitazone	1995	Novartis AG
10	08.12.2000	05.02.2008	214152	Pharmaceutical Combinations for treating Gasstro-Intestinal Disorders	———	———	Novartis AG
11	27.05.2003	28.03.2008	217702	Novel Crystal Forms of Atorvastatin Hemi-Calcium and Processes for their preparation as well as Novel Processes for preparing other forms	Atorvastatin	1993	Teva Pharmaceuti-cal Industries Ltd
12	14.09.1995	09.08.2007	208799	Improved Non-solvated Crystalline Raloxifene	Raloxifene	1983	Eli Lilly and Company

13	14.09.1998	23.08.2007	209250	Pharmaceutical Combinations Comprising Nonsedating Antihistamines and A-Adrenergig Drug for the Topical treatment of Rhinitis/Conjnuct-ivitis and Cold, Cold-Like and/or Flu Symptoms	———	———	Asta Medical Aktiengese-lischaft
14	30.08.1995	16.05.2007	206898	Crystalline Form of Dihydro-2, 3-Benzodiazodiazepine Derivative	Talampanel	———	Eli Lilly and Company
15	30.08.1995	19.03.2008	216867	A Form III of (R)-7-Acetyl-5-(4-Aminophenyl)-8,9-Dihydro-8 Methyl-7H-1, 3-Dioxolo [4,5-H] [2,3]-Benzodiazepine and Process for preparation thereof	Talampanel	———	Eli Lilly and Company
16	19.09.1997	28.11.2007	212288	A Pharmaceutical Composition Consisting of Olanzapine and Fluoxetine for the Treatment of Pyschoses	Olanzapine + Fluoxetine	1993+ 1982	Eli Lilly and Company
17	16.04.2003	05.11.2008	225209	A Crystalline Non-solvated Anhydrous Form of 6-Hydroxy -3-(4-[2-(Piperidin- 11-1-YL) Ethoxy] Phenoxy)-2-(4-Mthoxyphenyl) Benzo [B] Thiophene Hydrochloride	Arzoxifene	1998	Eli Lilly and Company
18	24.03.1999	21.05.2008	220287	An Olanzapine Pamoate Salt Land Pharmaceutically Acceptable Folvate Thereof	Olanzapine	1993	Eli Lilly and Company
19	06.10.1998	13.10.2006	202128	Crystalline Antifungal Polymorph	Posaconazole	1997	Schering Corporation

——— indicates data not available from abstract

# indicates that the year of grant is based on the specific product patent granted; based on the IMS Patent database

The argument that patenting of all incremental innovations is beneficial to generic companies is facetious. For one, it is voiced not by the supposed beneficiary party but its competitor. For another, it ignores the fact that it delays the launch of the generic drugs by two decades, at least, if not more.[20] Further, the industry sections representing large pharmas have been arguing even at the time of the drafting of the Patents (Amendment) Bill 2005 too that Indian pharmaceutical industry is good at minor innovations and, therefore, section 3(d) should not be strengthened in their interest! Even after four years, the same argument is brought out in the USIBC Report. To buttress its argument, it has been stated that Indian drug companies have been filing patents for minor innovations abroad.

Patenting of minor innovations by Indian companies in some developed countries cannot be a justification for extension of those regimes to India[21]. Patent laws, like other intellectual property rights, are territorial in nature and differ from country to country.[22] Every company has to abide by the laws of the country in which it is operating and play by the market rules. If a company can get market monopoly over certain products or processes in a country through patents by virtue of the laws of that country, market strategy dictates that course of action for that company.[23] Further, those Indian companies who have been filing patent applications abroad also generally file applications for the same products and processes in India too.

Indian pharmaceutical firms have been filing patent applications abroad prior to 2005 too. Since 1999 they have been showing a steady increase in the number of applications from just 33 in 1999 to 492 in 2005.[24] A reason for this development possibly could be the increased industrial activity thanks to the liberalised economic environment in India. At the same time, it has to be remembered that the number of patent applications by Indian firms is insignificant compared to those from developed countries, particularly from the US. Table-5 gives a comparative picture of PCT (Patent Cooperation Treaty) filings by US and India.

Table-5					
PCT Filings					
Country	**2004**	**2005**	**2006**	**2007**	**2008**
USA	43,350	46,803	50,941	54,086	53,521
India	724	679	831	901	753
All countries	122,610	136,688	149,156	159,886	163,60

We could also draw conclusions as to the impact of section 3(d) on the sector by looking at the growth figures of the Indian pharma industry. The exports alone, which constitute a substantial part of the total production of pharmaceuticals in India, grew from Rs. 6256.06 crore in the year 1998-99 to Rs. 17,857.80 crore in the year 2004-05 and to Rs. 21,578.96 crore in the year 2005-06.[25] This seems to have gone upto Rs. 31,317 crore by 2008-09.[26] The total revenue of the pharma companies, as per a compilation by the Indian Pharmaceutical Alliance on the basis of published annual reports, grew from Rs. 43,986 crore in the year 2004-05 to Rs. 80,336 (provisional) in the year 2008-09. What these figures bring out clearly is that the pharma sector in India has not suffered any serious adverse effect on its growth on account of the 2005 amendments to the Patents Act including the provision of section 3(d). Any change in the law will have serious impact on the export front.

The focus of the USIBC Report on Indian generic companies ignores the fact that the law cannot and does not make any distinction between domestic and foreign companies or between generics and 'originator' companies. It is even to all. The basic purpose of the Patents Act is to lay down the fundamental concepts of patentability, keeping in view India's international obligations and maintaining a balance between the need for an intellectual property regime which provides enough incentive to innovation while protecting public interest, particularly public health, concerns.

Rationale of Section 3(d)

It is quite educating to look into the rationale given by the government for introducing the existing provision in section 3(d). In his reply to the debate in the Lok Sabha on the Patents (Amendment) Bill, 2005, the Minister of Commerce and Industry stated, after quoting the proposed provision of section 3(d), "there is no question of ever greening."[27] This clearly brought out the intention of the government in introducing the particular provision in the Patents Act. Further, it was stated in unambiguous terms by the government in a press release that "in order to prevent 'ever greening' 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 ambiguities as to the scope of patentability."[28] This could be considered as a pro-domestic industry measure since big pharmas tend to patent minor/ insignificant improvements[29]. This makes it clear that the provision is there to counter the unethical practices of many drug firms to extend their patents by obtaining patents on minor/insignificant improvements. The Madras High Court which considered the pleas of Novartis challenging the constitutionality of the provision, accepted the object of section 3(d) as preventing ever greening.

Madras High Court on the issue of discretion in section 3(d)

We reiterate here at this stage that the amended section with its Explanation is capable of being understood and worked out in a normal manner not only by the patent applicant but also by the Patent Controller. In other words, the Patent Controller would be guided by various relevant details which every patent applicant is expected to produce before him showing that the new discovery had resulted in the enhancement of the known efficacy; the derivatives differ significantly in properties with regard to efficacy and therefore it cannot be said that the Patent Controller had an uncanalised power to exercise, leading to arbitrariness. The argument that the amended section must be held to be bad in Law since for want of guidelines it gives scope to the Statutory Authority to exercise its power arbitrarily, has to be necessarily rejected since, we find that there are in-built materials in the amended section and the Explanation itself, which would control/ guide the discretion to be exercised by the Statutory Authority. In other words, the Statutory Authority would be definitely guided by materials to be placed before it for arriving at a decision.[30]

Any new product or process involving an inventive step and capable of industrial application can get a patent as per the Patents Act[31]. Inventive step is defined as a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art[32]. The level of technical advance required for an invention to qualify for a patent has not been elaborated. However, section 3(d) sets certain standards in this regard which help the patent examiner to decide the issue of patentability as well as in preventing grant of frivolous patents leading to ever greening of patents. To that extent it is a clarificatory provision. And that appears to be the real object of it. In fact, most of the criticism against the provision harps on the fact that it is not clarificatory enough and leaves a lot to the discretion of the controller of patents.

Innovation and Patent Protection in Pharmaceutical Industry

The main issues worth considering are the following:

(i) Is innovation dependent on patent protection?
(ii) Do incremental innovations deserve patent protection?
(iii) Does section 3(d) stand in the way of significant incremental innovation?

It is true that technological progress is a step-by-step one. Most new developments are based on an earlier stage of development. This applies to all fields of technology, particularly pharmaceuticals. At times, substantial improvements are made on an existing product which significantly improves its utility and effectiveness. Besides, as a matter of routine, companies make minor improvements on the products which make them more attractive and user friendly. The issue is whether all kinds of improvements need to be protected through patent law. What is the threshold level for patenting? While the broad criteria of novelty, inventiveness and utility remain common to all patent regimes, the details vary from country to country.

Intellectual Property and Innovation

The argument that Intellectual Property (IP) protection is essential for innovation is not substantiated by empirical evidence. Countries like Japan and Switzerland had not extended product patent for pharmaceuticals in the early years of industrialization. Yet, innovation flourished in those countries. Even the United States, in the first forty-seven years of its existence, provided strong patent protection to its residents only and denied patents to foreigners[33]. Socio-economic milieu of a country has a major role in promotion of innovative culture.[34] Perhaps, the most crucial element is competition. Any economy that incentivises competition is likely to see a blooming of innovations.

Many a time, minor innovations and improvements over an existing invention can lead to major leaps cumulatively. To that extent, they need to be encouraged through incentives, including IP protection. However, in the area of pharmaceuticals, this has another dimension. In the case of an electrical or mechanical product, usually the consumer takes the decision keeping in view his requirements and affordability and features of the product. For example, if one cannot afford a four leaf fan which is costing Rs. 2000 one may opt for a three leaf one costing Rs. 1200. However, in the case of medicines, the decision is taken not by the ultimate consumer, but by a third party, that is the medical practitioner who does the prescription. From the doctor's angle what is important is not the price of the product, but the perceived better effectiveness and a defence, in case of a future possible allegation of criminal neglect, that he had prescribed the latest drug available in the market. Even, the patient also will be willing to pay a price beyond his affordability, since he looks upon the issue as one of life and death. This leads to great advantages for the new products claiming improvements over the existing products, howsoever minor they are. Patenting of minor improvements thus lead to 'ever greening' of the patent, as it effectively shuts out competition, unlike the case in other fields. The net result is that even a fairly effective or equally effective old drug loses the market when there is a new product claiming better effectiveness, even when the claims have not been proved. This adversely affects public health in developing countries.

An aspect that has not been much stated by the pharma industry is their real contribution to innovation. One often hears so much about cost of innovation and that it is incremental innovations which lead the growth of technology. But, particularly in the case of drugs and pharmaceuticals, the fact remains that most of the path breaking inventions are the result of public funded research. In the book, ***The Truth About the Drug Companies***', Marcia Angell, former editor in chief of the *New England Journal of Medicin*e, states, "the few innovative drugs that do come to market nearly always stem from publicly supported research."[35] She has substantiated the same through a number of examples.[36]

Similar is the case in Europe too where the rationale of patent as essential for research and development is increasingly being questioned. The issue of intellectual property protection has even led to the establishment of a new political party in Sweden demanding a more balanced approach to copyright and patent protection which takes care of the needs of access and research and development. A recent report in ***The Economic Times*** says,

> *They* (The Pirate Party of Sweden) *also say that pharmaceutical patents are a bad way to fund global research, because any way in Europe it is the governments who end up paying Big Pharma, they could just put that money into researchers and universities, instead, and do the whole world a big favour.*

It further observes that the movement initiated by the Pirate Party "seems to be snowballing, with similar organization in over 20 countries," and opines that "it may still be small change, but it is a significant breakout in western attitudes to intellectual property rights."[37] Countries like India need to take note of these developments while drawing up their policies, so that innovation thrives but public funds do end up in creating private monopolies over knowledge.

Intellectual Property and Market

A second aspect is that, even without IP protection the originator companies are better positioned in competition compared to their generic counterparts. Because of their experience and expertise in the manufacture of that drug, they have the advantage of lead time in coming out with the 'improved' versions, than the generic firms, despite the Bolar provisions. They can also launch the improved versions even before expiry of the patented period of the original product, since they are the patent holders, while the generics have to wait the expiry of the patent period. Market studies have shown that the first innovator gets major presence in the market. A recent study on pharma sector commissioned by the European Union has found that "on average the launch (of the new product by the originator company) took place one year and five months before loss of exclusivity of the first generation product."[38]It is not really patent protection for the new version which gives the company the material advantages, but the early market presence, though patent protection adds to that advantage by enabling them to keep others away from the market.[39]

The issue needs to be viewed from the prevailing market strategies of pharma companies. Each group of companies follow practices that give them maximum advantage. For example, it is a fact that firms withdraw not only the original version of a drug but also either do not renew or withdraw the registration for marketing the same when they launch a new version of that drug thus making it difficult for the drug controller to approve the generic version.[40]

Another strategy being followed by big pharmas is that of filing a large number of patent applications for the same drug, thus creating a cluster of patents for one medicinal product, which is usually done towards the expiry period of the original patent. This helps those companies to delay the market entry of generics. The study by the European Union showed that "individual blockbuster medicines are protected by up to 1,300 patents and/or pending patent applications EU-wide"[41] and most of these applications are made towards the end of the life of the original patent thus effectively delaying the entry of generics. This market strategy is not dictated by need for protecting innovativeness but is focussed only on excluding competition.[42] In the US, it is a documented fact that innovator companies delay entry of generics by obtaining add-on patents on the original product. The patenting history of Paroxetine by Smith Kleine is one example[43]. Another case is that of paclitaxel by Bristol-Myers Squibb.[44]

Additional patenting on the same drug is again a market strategy followed by all pharmaceutical firms, but, as Mueller points out, Multi National Companies are well versed in developing new dosage forms, searching for alternative uses of established drugs, and obtaining U.S. patent protection on the results.[45]"

Intellectual Property and Development

Patent protection is perhaps the strongest intellectual property; it gives a virtual monopoly for a period of 20 years. During this period no competition, including independent invention, is allowed. Therefore, extension of such a monopoly needs to be viewed seriously, particularly where it affects public interest such as public health. In the matter of intellectual property laws one size fits all approach is neither right nor in the interest of humanity. Stage of development of a country has to be borne in mind while prescribing patent standards.

The United Kingdom Commission on Intellectual Property Rights (CIPR), which looked into the issue of integrating development objectives into the making of policy on intellectual property rights world-wide, also felt that "developing countries should not feel compelled or indeed be compelled, to adopt developed country standards for IPR regimes."[46] The recommendations of CIPR in this regard deserve special consideration in this context:

> *The underlying principle should be to aim for strict standards of patentability and narrow scope of allowed claims, with the objective of:*
>
> - *limiting the scope of subject matter that can be patented*
> - *applying standards such that only patents which meet strict requirements for patentability are granted and that the breadth of each patent is commensurate with the inventive contribution and the disclosure made*
> - *facilitating competition by restricting the ability of the patentee to prohibit others from building on or designing around patented inventions*
> - *providing extensive safeguards to ensure that patent rights are not exploited inappropriately.*[47]

It is not clear whether in drafting the new amendments to section 3(d) in 2005, Government of India had drawn inspiration from the CIPR Report, but, the section is an example of how rational limitation of the scope of patent can be achieved. It applies standards which ensure "that only patents which meet strict requirements for patentability are granted." One can, of course, argue that this section does not go the extent of the CIPR position that developing countries should strictly exclude new uses of known products from patentability.[48] It is, however, in the spirit of the recommendation of the Commission on Intellectual Property Rights: "The objective of any standard should be to ensure that routine increments to knowledge, involving minimal creative input, should not generally be patentable."[49]

It seems over the years, many have found section 3(d) as an effective tool for limiting ever greening tactics. Philippines have since incorporated similar provisions in their IP Code as section 22.1.[50] Thus section 3(d) could be considered a path breaking one which has given a lead to other countries on measures to prevent the unhealthy practice of extending patents by frivolous or insignificant additions.

It should also be remembered that period of patent protection earlier was 14 years. This has already been extended to 20 years, which has been considered by the international community as sufficient for recouping the investment and making good profit in the pharma industry; enough incentive for investment in research and development for innovation. Furthering this period by round about ways can adversely affect development.

One important aspect that the USIBC report has ignored is that while the intellectual property laws are still territorial, the market is global. That means even domestic companies when they come of age produce for the world market and not merely for their domestic consumers. The export figures of the Indian pharma companies already cited prove this. Therefore, the regimes in the developed countries are more likely to influence many of their investment and marketing decisions. As Chaudhuri has argued, "since developed country markets are much larger and more lucrative than the Indian market, Indian companies would have the incentive to do New Chemical Entity R & D for such pharmaceutical products even in the absence of TRIPS."[51]

Section 3 (d) and Public Health

One of the concerns of public interest groups has been that the Patents (Amendment) Act, 2005 by introducing product patent for pharmaceuticals would adversely affect public health. On the other hand, the big pharmas keep on repeating *ad nausseum* that section 3(d) stands in the way of innovations which would be beneficial to the patients in India. The experience with the new law during the last more than four years, however, does not substantiate both the arguments. No major public health crisis has occurred in India during this period which can be attributed to the grant of product patents for pharmaceuticals. Similarly, as already brought out above, section 3(d) has not come in the way of patenting incremental innovations. In fact, as Basheer observes,

> *By making derivatives with enhanced efficacy patentable, section 3(d) encourages the sequential development of existing products or technologies to help bring in improved products that address unmet public health needs.*[52]

Those who argue, as in the Report under discussion, that section 3(d) is to prevent patenting of genuine improvements in the pharma sector, keep a studied silence over section 54 of the Patents Act which provides for patent of addition, which is adding on new uses and improvements to the original patented invention. The reason for this quietness is obvious: patent of addition under section 54 expires along with the main patent and will not help those who are trying for ever greening. Hence their effort to get section 3(d) scrapped so that they can move for fresh patents for minor improvements and not patent of addition, which will keep the product out of competition by generics.

While it is true that world over, during the last more than two decades, patenting activity, particularly in the pharmaceutical sector, has increased many fold, the substantial impact of it on health care may not be commensurate. An assessment of new drugs introduced between 1981 and 2000 done by Prescrire International, quoted by the Society for Economic and Social Studies, brings out that 63.23 per cent or such new drugs are superfluous and do not add to the clinical possibilities offered by previous products[53]

A major issue affecting public health is the price of drugs. The real contribution of Indian generic companies is in this vital area. *The Guardian*, London, observed in 2006 itself:

Exports of Indian companies helped to cut off the price of anti-retroviral treatment from $ 15,000 (£ 8,000) per patient per year a decade ago to $200. Indian companies now provide two-thirds of the world's cheap Aids' therapies.[54]

Ever greening will adversely affect public health as it would delay the entry of cheap generics. Section 3(d) remains a pro-public health regulation in that it seeks to prevent extension of exclusivity of drugs beyond the twenty year period of the original patent. Even with all such provisions, the average time gap between the date of loss of exclusivity and the date of entry of the first generic is about seven months.[55]

Changing US Law

It must be noted that even in the US, the attitude towards patenting is changing. Susan S. DeSanthi, FTC Deputy General Counsel for Policy Studies, in a statement before the Antitrust Modernization Commission (AMC) hearing on Patent Law Reform had stated in November, 2005, "the prevalence of poor quality patents is an impediment to competition, and it is an impediment that, by definition, is governmentally created and, like private business restraints, harms consumer welfare" and, accordingly urged the AMC to consider patent law reform from this angle.[56] [57]

The special report on Reforming U.S Patent Policy got prepared by Council on Foreign Relations in November, 2006, has categorically observed that "more rigorous standards for determining whether an invention is obvious or novel be applied to patent applications."[58] Subsequently, in the KSR International v. Telefex case (2007), the US Supreme Court observed:

granting patent protection to advances that would occur in the ordinary course without real innovation retards progress and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility.[59]

The new standards of obviousness raise the bar on patentability in the U.S.

US Supreme Court on innovation and patent laws in KSR International Co. v. Teleflex Inc.

We build and create by bringing to the tangible and palpable reality around us new works based on instinct, simple logic, ordinary references, extraordinary ideas, and sometimes even genius. These advances, once part of our shared knowledge, define a new threshold from which innovation starts once more. And as progress beginning from higher levels of achievement is expected in the normal course, the results of ordinary innovation are not the subject of exclusive rights under the patent laws. Were it otherwise patents might stifle, rather than promote, the progress of useful arts.

A view that has emerged following the Supreme Court decision is that "practitioners can expect that improvement or 'optimization' claims for pharmaceuticals with different salt forms, different excipients, adjusted dosages, release rates or formulations of known active ingredients, or optimized variables for known combinations, are very vulnerable to invalidation or rejection for obviousness, even when supported by unexpected results."[60] It is ironical that when the US itself is having doubts about their prevailing system of granting patents for anything and everything, industry inspired papers are emerging out of that country arguing for liberal patenting.

Section 3(d) and TRIPS

It is one of the often repeated arguments of big pharma firms that section 3(d) is not compatible with the TRIPS Agreement. The USIBC Report also echoes the same view. There have been enough papers on the issue explaining the wider scope of TRIPS flexibilities. One need not repeat all of them. Enough to quote Correa who says,

> *While TRIPS requires member states to protect products and processes, it does not specifically refer to the protection of new uses, thus leaving member countries free to choose whether or not to protect them. In principle, a country that broadly excludes methods of medical treatment could also broadly exclude new therapeutic uses for old products.*[61]

The TRIPS Agreement, while setting out the general norms of patentability, provides enough flexibility in the finer details. Patent laws, therefore, differ in those matters. In certain countries, published document is required to prove the existence of prior art. Thus, a matter of traditional knowledge such as the wound healing properties of turmeric could qualify for a patent in the US whereas the Indian law specifically prohibits traditional knowledge from being patented since it is prior art. The threshold level for inventiveness is another matter which differ from country to country. Patentability of new uses is, again, an area where there are differing perceptions.[62]

One of the arguments for introduction of product patent regime in pharmaceuticals was that it would incentivize local companies to put resources in developing drugs needed by developing countries. The experience of the last few years has not substantiated this.[63] The beneficiaries of the system have been transnational pharma companies. The present argument also appears in tune with the previous one, which ostensibly appears favourable to Indian firms, but may actually be more favourable to the larger multi national companies than the Indian generic drug manufacturers.

Those who claim that section 3(d) is not in compliance with TRIPS ignore the negotiating history of that agreement. Jayashree Watal, who had represented India in the TRIPS negotiations, has pointed out that at the time of the negotiations, “the patent laws of several developed and developing countries excluded from patentability any new use for known substances.”[64] Given this background, the Agreement did not define inventiveness and left much to the discretion of the domestic legislations. The shrill cry that section 3(d) is not in conformity with the TRIPS Agreement can only be presumed as an attempt to coax the country to adopt certain new norms which have since become prevalent in some of the developed countries, but the academia in those countries already have serious doubts about the positive impact of those norms on innovation.

Conclusion

What emerges from this discussion is that there is no clinching evidence to show that without a strong patent protection regime innovations cannot occur, that minor incremental innovations in the pharmaceutical sector do not require patent protection and that section 3(d) of the Patents Act is not a bar for patenting of significant incremental innovations.

What is required is more genuine innovations leading to development of drugs for diseases which still pose a challenge to humanity and not minor cosmetic modifications on existing drugs. It is necessary to provide attractive incentives to Indian pharma industry to get into genuine R&D. While having a conducive intellectual property regime is one of the components of such an incentive package, removal of section 3(d) thereby paving way for ever greening of existing patents in pharmaceuticals will be counter productive. With the risk of a large number of pharma products either already expired or getting expired soon[65] (see Annexure) and very few new blockbuster drugs being invented, many large pharmaceutical firms are exploring strategies to extend their hold on the market, including through obtaining patents on minor improvements on existing drugs. The efforts to get section 3(d) scrapped have to be understood as part of this strategy and not motivated by the needs or strength of Indian pharma companies, nor really based on a sound market strategy. The report of the USIBC becomes a tool in these efforts. Instead, a better market strategy for both big pharmas and the generics would be that of devoting more resources for research into new medicines for diseases which are endemic in emerging economies like India, China, Brazil, etc. As the capacity of the people of these countries to pay for higher health care increases, the market for the new drugs would expand, thereby making it a profitable investment.

Annexure*

Patent Expiry Dates of Some Drugs

Chemical ingredient	Category	Manufacturer/Marketer	US patent expiry date dd.mm.yyyy
Abciximab	Biopharmaceutical	Centocor Inc.	23.06.2015
Alandronate	Hormone Sodium	Merck & Co.	04.08.2007
Almotriptan	Diabetes	Pharmacia	15.10.2013
Corporation m® Alosetron HCI	Gastrointestinal	Glaxo Wellcome	02.02.2010
Amprenavir	HIV/AIDS	Vertex	17.12.2013
Atorvastatin	Cardiovascular calcium	Warner-Lambert	28.12.2010
Caspofungin	Antibiotics & Antifungals	Merck & Co.	16.03.2013
Cerivastatin	Cardiovascular	Bayer Group	17.01.2009
Cetirizine	Respiratory	Pfizer Inc.	25.06.2007
Ciclesonide	Respiratory	Altana/Aventis	09.01.2013
Cilomilast	Respiratory	GlaxoSmithKline	03.09.2013
Colesevelam	Cardiovascular	Galtex	02.12.2014
Cusapride	Gastrointestinal	Johnson & Johnson	09.10.2007
Dacliximab	Biopharmaceutical	Protein Design	25.06.2013
Docefaxel	Cancer/Oncology	Aventis	14.05.2010
Dofetilide	Cardiovascular	Pfizer Inc.	25.09.2007
Efavirenz	HIV/AIDS	DuPont	21.05.2013
Eletriptan	Diabetes	Pfizer Inc.	13.08.2013
Eprosartan	Cardiovascular	Merck &Co	09.02.2010
Ertapenem	Antibiotics & Antifungals	Merck & Co.	02.02.2013
Erythropoietin	Biopharmaceutical	Amgen Inc.	03.12.2013
Esomeprazole	Gastrointestinal	AstraSeneca	19.05.2014
Ezetimibe	Cardiovascular	Schering-Plough	16.06.2015
Fleroxacin	Antibiotic	Kyorin	21.02.2009
Flunisolide	Respiratory	Forest Laboratories	12.06.2007
Frovatriptan	CNS	GlaxoSmithKline	07.12.2012
Gatifloxacin	Antibiotics & Antifungals	Bristol-Meyers	25.12.2007
Gemifloxacin	Antibiotics & Antifungals	GlaxoSmithKline	15.06.2015

Chemical ingredient	Category	Manufacturer/Marketer	US patent expiry date dd.mm.yyyy
Granisetron	Gastrointestinal	GlaxoSmithKline	29.12.2007
Grepafloxacin	Antibiotic	GlaxoSmithKline	08.10.2013
Hepatis A vaccine	Vaccine	GlaxoSmithKline	22.02.2010
Ibadronate sodium	Hormone	Boehringer Ingelheim	09.07.2007
Indinavir	HIV/AIDS	Merck & Co	09.05.2012
Insulin aspart	Diabetes	Novo Nordisk	28.09.2013
Insulin glargine	Diabetes	Aventis Pharma	25.04.2014
Insulin lispro	Diabetes	Eli Lilly	07.05.2013
Interferon beta-1b	Biopharmaceutical	Berlex Labs	07.07.2007
Ipratropium bromide & salbutamol	Respiratory	Boehringer Ingelheim	09.06.2015
Irbesartan	Cardiovascular	Sanofi	20.03.2011
Ironotecan HC1	Cancer/Oncology	Aventis Pharma	20.08.2007
Lamivudien	HIV/AIDS	Glaxo Wellcome	17.11.2009
Lansoprazole	Gastrointestinal	Takeda	10.05.2009
Levofloxacin	Antibiotic	Johnson & Johnson	01.10.2008
Linezolid	Antibiotic & Antifungal	Pharmacia	18.11.2014
Erythropoietin	Biopharmaceutical	Amgen Inc.	20.08.2013
Lopinavir+	HIV/AIDS	Abbot Laboratories	13.12.2015
Losartan	Cardiovascular	Merck & Co.	11.08.2009
Montelukast sodium	Respiratory	Merck & Co	15.10.2013
Naritiptan	Diabetes	Glaxo SmithKline	12.08.2008
Nelfinavir	HIV/AIDS	Agouron Pharma	07.10.2013
Nevirapine	HIV/AIDS	Boehringer Ingelheim	22.11.2011
Olanzapine	CNS	Eli Lily & Co.	23.04.2011
Omalizumab	Respiratory	Roche/Genetech	03.02.2015
Omapatrilat	Cardiovascular	Bristol-Meyers	15.06.2015
Paclitaxel	Cancer/Oncology	Bristol-Meyers Squibb	03.08.2012
Palivizumab	Biopharmaceutical	Medimmune Inc.	17.12.2013
Paroxetine	CNS	GlaxoSmithKline	24.09.2008
Pitavastatin	Cardiovascular	Nissan Chemical	05.01.2016
Posaconazole	Antibiotics & Antifungals	Schering-Plough	26.08.2014

Chemical ingredient	Category	Manufacturer/Marketer	US patent expiry date dd.mm.yyyy
Rabeprazole	Gastrointestinal	Eisai/J&J	03.09.2008
Risedronate	Hormone	Proctor & Gamble	10.12.2013
Sodium Risperidone	CNS	Johnson & Johnson	29.12.2007
Ritonavir	HIV/AIDS	Abbot Laboratories	30.07.2013
Rituximab	Biopharmaceutical	Genentech Inc	19.03.2013
Rizatriptan	CNS	Merck & Co.	28.01.2013
Roflumilast	Respiratory	Altana/Byk Gulden	27.10.2015
Rosiglitazone	Diabetes	Glaxo SmithKline	30.08.2008
Rosuvastatin	Cardiovascular	AstraZeneca	12.06.2012
Salmeterol xinofoate	Respiratory	Claxo Wellcome	12.02.2008
Saquinavir	HIV/AIDS	Roche	19.11.2010
Stavudin	HIV/AIDS	Bristol-Meyers Squibb	24.06.2008
Sumatriptan	CNS	Glaxo Wellcome	06.08.2008
Tegaserod	Gastrointestinal	Novartis	23.04.2013
Telethromycin	Antibiotics & Antifungals	Aventis	21.04.2015
Telmisartan	Cardiovascular	Boehringer Ingelheim	07.01.2014
Teriparatide	Hormone	Eli Lilly & Co.	27.07.2013
Tirofiban hydrochloride	Cardiovascular	Merck & Co.	08.03.2012
Tirofiban	Cardiovascular	Merck & Co.	08.03.2011
Transtuzumab	Biopharmaceutical	Genentech Inc.	14.10.2014
Troglitazone	Diabetes	Warner- Lambert	09.11.2008
Trovafloxacin	Antibiotic	Pfizer Inc.	17.11.2009
Valproate semisodium	Diabetes	Abbot Laboratories	29.01.2008
Valsartan	Cardiovascular	Novartis Group	21.03.2012
Venlafexine	CNS	American Home Products	13.12.2007
Voriconazole	Antibiotics & Antifungals	Pfizer Inc.	22.10.2013
Zafirlukast	Respiratory	AstraZeneca	26.09.2010
Zalcitabine	HIV/AIDS	Roche	02.07.2008
Zileuton	Respiratory	Abbot Laboratories	09.12.2010
Zolmitraiptan	CNS	AstraZeneca	14.11.2012
Zopolrestat	Diabetes	Pfizer Inc	03.07.2007

*This Annexure is taken from the document *Public Health Safeguards in the Indian Patents Act and Review of Mailbox Applications* pages 121-124. Please see bibliography.

End Notes

[1] Section 3 of the Indian Patents Act, 1970 lists products or processes which are not inventions within the meaning of the Act. Sub-section (d) of this section reads:

> "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 the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant."

This is accompanied by the following 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 duffer significantly in properties with regard to efficacy."

Prior to 2005, the sub-section read:

> "the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant."

[2] Available at http://www.ahealthyindia.org/portal/chi/default.

[3] *Report of the Patent Enquiry Committee* (1948-50), p.11.

[4] *Patent Law* by P.Narayanan, p.6.

[5] *Ibid*, p.2.

[6] The 1970 Act was brought into force only on 20 April 1972. Therefore, while the law was there for 25 years, its actual implementation till the first amendment was for 23 years only. However, it is fair to presume that the generic pharma industry might have started to gear up for the new regime soon after the new law was passed by the parliament.

[7] The figures of patents granted are from the annual reports of the Patent Office. Up to the year 1972, figures were on calendar year basis and thereafter financial year (from 1 April of one calendar year to 31 March of next calendar year) basis. The number of patents granted in the year 1972 was 3923.

[8] See Mueller, Janice M., *The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation* in the University of Pittsburgh Law Review vol 68:491.

[9] Fink, Carsten, *How Stronger Patent Protection in India Might Affect the Behaviour of Transnational Pharmaceutical Industries*, World Bank, p.28. As per the cover story titled, 'Small and Smart: Pharma SMEs' Plans for 2005 and Beyond', by Gina Singh & T. Surendar in the *Business World* of 20 October,2003, the number of pharma companies in India at that time was estimated as "over 20,000", see p. 44 of the issue.

[10] Sankaranarayanan, S. and Pradeep, V. 'Trade Related Intellectual Property Rights (TRIPs): Impact and Implications for India with Reference to Indian Pharmaceutical Industry, chapter 28 of *WTO and India* ed by Anil Kumar Thakur and Nageshwar Sharma, p.546, quoting source as Redwood, H., 'New Horizons in India', *The Consequences of Pharmaceuticals Patent Protection,* Oldwick Press, 1994.

[11] FICCI, *Competitiveness of the Indian Pharmaceutical Industry in the New Product Patent Regime*, p.2.

[12] Exports of drugs, pharmaceuticals and fine chemicals grew from Rs. 7230.16 crore ($1.60 bn) in 1999-2000 to Rs.14100.00cr ($3.13 bn.) in 2003-04, *ibid*.

[13] The Report of the Technical Expert Group (commonly referred to as Mashelkar Committee Report, after the chairman of the Group) was finally presented to the Government of India on 13 March, 2009 and is available at the website of Department of Industrial Policy & Promotion at www.nic.in The terms of reference of the Technical Expert Group did not include TRIPS compatibility of section 3(d).

[14] The wording of the Explanation below section 3(d) is drawn from the following sentence in Article 10(2)(b) of Directive 2004/27/EC of the European Union: "The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in proportion with regard to safety and/or efficiency." This is in the context of drug marketing approval. However, the word 'safety' is not used in the Indian Act by the legislators.

[15] *The Times of India*, New Delhi dated 29 August, 2009.

[16] Reply to Lok Sabha Unstarred Question No. 2173 dated 20 July 2009.

[17] *Ibid*.

[18] See Annexure-IV of *Public Health Safeguards in the Indian Patents Act and Review of Mailbox Applications*, pp.160-171.

[19] Reply to Lok Sabha Starred Question No. 436 dated 3 August 2009.

[20] Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover, to the UN General Assembly, 2009. UN document No. A/HRC/11/12 dated 31 March 2009, p. 13.

[21] Rate and quantum of filing of patents abroad differ from company to company. A study by Evaluserve titled *Patenting Trends in India: Facts and Figures* has brought out that while Dr Reddy's Laboratories, Orchid Chemicals & Pharmaceuticals, Cadila Healthcare, Cipla and Sun Pharmaceutical Industries file majority of their applications in India, Ranbaxy Laboratories file a large proportion of their applications abroad. It is also interesting to note the observation by Prabodh Malhotra in an article titled, 'The Impact of TRIPS on innovation and exports: a case study of the pharmaceutical industry in India' in the *Indian Journal of Medical Ethics* vol. V No. 2, April-June 2008:

> *Indian institutions, notably the CSIR, are responsible for most of the increase in patent filings in the US as well as in India in the key sectors mentioned (which include chemicals, pharmaceuticals, etc.). It is also clear that the primary focus of India's research is on serving the lucrative markets of the rich nations rather than meeting the needs of developing countries.*

[22] This is the reason for the efforts at the World Intellectual Property Organisation (WIPO) to have a Substantive Patent Law Treaty aimed at upward harmonisation of patent laws of the member countries of WIPO.

[23] Chaudhuri, S., *Is Product Patent Protection Necessary in Developing Countries for Innovation? R&D by Indian Pharmaceutical Companies after TRIPS*, Indian Institute of Management, Calcutta Working Paper series No. 614/September 2007.

[24] *Product Patents and effect on Pharmaceutical Sector, Healthcare Services* by Biswajit Dhar and K M Gopakumar, p.82, Table 16.

[25] Planning Commission, *Report of the Working Group on Drugs and Pharmaceuticals for the Eleventh Five Year Plan (2007-2012*), p. 24.

[26] As per the research report, *Booming Pharma Sector in India*, by RNCOS, an industry research firm, in 2008, India has emerged as one of the world's most potential destinations for pharmaceutical exports, with the country exporting drugs worth US$ 7.2 Billion in 2007-08. According to this report, the US and Europe remain the biggest export destinations for Indian generics. As per Indian Pharmaceutical Alliance, North America and Western Europe accounted for more than 40 % of the total exports in the year 2004-05. (See, Dilip G.Shah, 'Generic to Innovative' in *Pharma Focus AsiA*, Issue – 5 2007.*)* The RNCOS Report predicted an export growth at a CAGR of 18.5% and the much bigger domestic market at a CAGR of nearly 16 % till 2011-12. The size of the markets and the potential of the Indian generic firms throw up critical challenges to pharma majors.

[27] Debate in the Lok Sabha dated 22 March, 2005.

[28] Press Release by Ministry of Commerce & Industry dated 4 April 2005.

[29] Mueller, Janice M., see note 8, p. 551 *ibid*: "MNCs are well versed in developing new dosage forms, searching for alternative uses of established drugs, and obtaining U.S. patent protection on the results."

[30] W.P. Nos. 24759 and 24760 of 2006 decided on 6 August 2007, para 16.

[31] Section 2(1)(j) read with (m) of the Patents Act.

[32] Section 2(1)(j) of the Patents Act.

[33] F.M. Scherer in an article entitled, 'The Political Economy of Patent Policy Reform in the United States' (September 2007), p. 40.

[34] Mark F. Schultz and David B. Walker argue in the article, 'The New International Intellectual Property Agenda' that while intellectual property laws may be necessary, they are "not sufficient to spur economic growth and innovation in developing countries." *Are Intellectual Property Rights Human Rights*, p.11.

[35] *The Truth About the Drug Companies*, p. 56

[36] Marcia Angell says, "most of Novartis' R&D investments in Gleevec was made several years *after* there was good scientific evidence to suggest that the drug would be useful." *Ibid* p. 64.

[37] *The Economic Times*, Chennai/Kochi, 7 September, 2009. column 'Letter from London'. The Pirate Party was founded in Sweden on1 January, 2006 which received 7.13 % of the total Swedish votes in the 2009 European Parliament elections. As per the Party's Declaration of Principles,

> *Patents are officially sanctioned monopolies on ideas. Large corporations diligently race to hold patents they can use against smaller competitors to prevent them from competing on equal terms. A monopolistic goal is not to adjust prices and terms to what the market will bear, but rather use their ill gotten rights as a lever to raise prices and set lopsided terms on usage and licensing.*

See http://docs.piratpartiet.se/Principles%203.2.pdf

[38] EU, Pharma Sector Inquiry Preliminary Report para 2.6, p.12. The study's findings are also that "for 40 % of the medicines in the sample selected for in-depth investigation, which had lost exclusivity between 2000 and 2007, originator companies launched so called second generation/follow-on medicines." *Ibid*.

[39] F.M. Scherer in an article entitled, 'The Political Economy of Patent Policy Reform in the United States" (September 2007) , quoting a Yale Group study says, "Having patent protection was found on an average to be relatively unimportant compared to three other ways of gaining first mover advantages. For new and improved processes, it was even less important on average, while, not surprisingly, secrecy was ranked more highly than either of the patent measures." The two patenting measures are patents to prevent duplication and patents to secure royalty income.

[40] EU Pharma Sector Inquiry Report, p. 12.

[41] EU Pharma Sector Inquiry Report, p. 9.

[42] The Pharmaceutical Sector Inquiry Preliminary Report Fact Sheet states that the originator companies name it 'defensive patent strategy."

[43] Paroxetine is an anti depressant compound. A Danish company, A/S Ferrosan, had UK and US patents with priority dates in1973. In May 1984, a licensing agreement was signed between Ferrosan and SmithKleine Beecham (SKB). From 1985 to 1998, SKB applied for patents for various salts, methods of production, uses, etc. of paroxetiune. After narrating the history of patenting of this product from 1973 to 1998, World Health Organisation observes: "this case illustrates how it may be possible to extend the patent protection for an active ingredient, through processes for producing salts that add little or nothing in terms of innovation, occasionally resorting to well-known techniques." *S*ee World Health Organization, *Trends in Drug Patenting – Case Studies*, 2001, available at http://apps.who.int/medicinedocs/en/d/Js4915e/2.1.html

[44] The drug paclitaxel was developed by the National Cancer Institute and placed on public domain. Bristol-Myers Squibb (BMS) obtained FDA (US drug regulator) approval in 1992 and got market exclusivity for a period of 5 years. However, before expiry of that period BMS sought patents on paclitaxel for methods of administering it as an anti-tumour agent. It then took legal measures to prevent the entry of generics. Although BMS finally lost the legal battle, it could delay the entry of generics till 2000.

[45] Mueller, Janice, *The Tiger Awakens*. p.61

[46] *Integrating Intellectual Property Rights and Development Policy*, p.49.

[47] *Ibid.*

[48] *Ibid*., p.50.

[49] *Integrating Intellectual Property Rights and Development Policy*, p. 116.

[50] "SECTION 22. Non-Patentable Inventions. — The following shall be excluded from patent protection:

22.1. Discoveries, scientific theories and mathematical methods, and in case of drugs and medicines, the mere discovery of a new form or new property 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 the mere use of a known process unless such known process results in a new product that employs at least one new reactant.

For purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations, and other derivatives of a known substance, unless they differ significantly in properties with regard to efficacy;"

[51] See note 12 *supra*, p. 5. The R & D spend of Indian pharmaceutical industry has grown at constant dollar from 31.1 in 1995 to 411.6 in2005. (see D G Shah cited at endnote 26 *supra*.)

[52] Basheer, S and Reddy, Prashant, *Ducking TRIPS in India: A Saga Involving Nature and Legality of Section 3(d),* SSRN 1329201, p. 136.

[53] The study report *Public Health Safeguards in the Indian Patents Act and Review of Mailbox Applications*, quotes the following table from the source *Prescrire International* on p. 28:

Assessment of New Drug Introduced Between 1981 and 2000		
Category	**Number**	**Percent**
Major therapeutic innovation in an area where previously no treatment was available	7	0.31
Product is an important therapeutic innovation but has certain limitations	67	2.96
Product has some value but does not fundamentally change the present therapeutic practice	192	8.51
Product has minimal additional value and should not change prescribing habits except in rare circumstances	397	17.59
Product may be a new molecule but is superfluous because it does not add to the clinical possibilities offered by previous products available. Inmost cases it concerns a me-too product	1427	63.23
Product without evident benefit but with potential or real disadvantages Editors postpone their judgements until better data and a more though	58	2.57
evaluation of the drug is available	109	4.83

[54] *The Guardian,* 11 May 2006, report entitled 'Drug firms seek to stop Generic HIV treatment' by Randeep Ramesh.

[55] EU, Pharmaceutical Sector Inquiry, Final Report, p.9

[56] Remarks of Susan S. DeSanti, FTC Deputy General Counsel for Policy Studies Before the Antitrust Modernization Commission Hearing on Patent Law Reform, November 8,2005 available at http:// www.docstoc.com/docs/5730413/Remarks-of-Susan-S-DeSanti-FTC-Deputy-General-Counsel

[57] Harvard Business Review in its November 2004 issue highlighted the deleterious impact of recent patent policies and practices on US innovation system. Its two observations are very valid:

> "For the better part of two centuries, the US patent system has driven America's extraordinary innovativeness. In the last two decades, however, the system of laws that for so long fueled the innovation engine has become sand in its gears."
> "Two apparently mundane changes in law and policy have transformed the patent system. The results? Weakened examination standards, a runaway increase in marginal patent applications, and indiscriminate filing of patent infringement suits as a generic competitive weapon."

[58] Maskus, Keith E., *Reforming U.S Patent Policy Getting the Incentives Rights,* p.33.

[59] 550 U.S 398 (2007)

[60] Steinhauer, Esther H (2007), 'Pharmaceutical Patents after KSR: Withstanding the Obviousness Challenge'.

[61] Correa, Carlos M., *Public Health and Patent Legislation in Developing Countries*, 3 TUL.J.TECH & INTELL, p.1.49 (2001)

[62] Correa, Carlos M and Yusuf, Abdulqawi A., *Intellectual Property and International Trade: The TRIPS Agreement*, p.238

[63] Chaudhuri, Sudip, *Is Product Patent Protection Necessary in Developing Countries for Innovation? R & D by Indian Pharmaceutical Companies after TRIPS,* Indian Institute of Management, Calcutta Working Paper Series No. 614/September 2007.

[64] Watal, Jayashree, *Intellectual Property Rights in the WTO and Developing Countries*, p. 105.

[65] EU, Pharmaceutical Sector Inquiry, Final Report, p.4

> "The pharmaceutical industry is undergoing significant changes. Several "blockbuster" medicines (i.e. medicines whose annual global turnover exceeds US$ 1 billion), which account for a substantial part of the sales and profits of large originator companies, have lost patent protection in recent years and more will do so in the coming years. At the same time, in spite of increasing investments in R&D, it appears to be a challenge for originator companies to refill the product pipeline and the number of novel medicines reaching the market has been decreasing. Combined with other factors, this makes originator companies increasingly dependent on the revenues from their existing best-selling products and they inevitably wish to maintain these for as long as possible."

Select Bibliography

Angell, Marcia, M.D., *The Truth About the Drug Companies: How They Deceive Us and What to Do About it.*, Random House Trade Paperbacks, New York, 2005.

Arcuri, Alessandra and Castro, Rosa. *How Innovative is Innovative Enough? Reflections on the Interpretation of Article 27TRIPS from Novartis v.Union of India*, Society of International Economic Law, Inaugural Conference, July 15-17, 2008, Geneva, Working Paper No. 52/08.

Basheer, Shamnad. *India's Tryst With TRIPS: The Patents (Amendment) Act 2005*, The Indian Journal of Law and Technology, vol. 1, 2005. 15-46. SSRN-id764066basheer2.pdf.

Basheer, Shamnad and Reddy, Prashant. *"Ducking" TRIPS in India: A Saga involving Novartis and the Legality of Section 3(d)*, SSRN-id1329201.pdf.

Basheer, Shamnad, and Reddy, Prashant. *The "Efficacy" of Indian Patent Law: Ironing Out the Creases of Section 3(d*), SSRN-id1086254basheer.pdf.

Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy*, London, available at http://www.iprcommission.org

Correa, Carlos M and Yusuf, Abdulqawi A (eds), *Intellectual Property and International Trade: The TRIPS Agreement*, second edition, Wolters Kluwer, 2008.

Dhar, Biswajit & Gopakumar, K.M. *Product Patents and effect on Pharmaceutical Sectors, Healthcare Services*, EU-India Trade and Investment Development Programme, New Delhi.

European Union, *The Pharmaceutical Sector Inquiry Report*, Preliminary and Final, 2008 available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry

Federation of Indian Chambers of Commerce & Industry, *Competitiveness of the Indian Pharmaceutical Industry in the New Product Patent Regime,* FICCI Report for National Manufacturing Competitiveness Council, March 2005, available at www.ficci.com/studies/**pharma**.pdf.

Fink, Carsten, *How Stronger Patent Protection in India Might Affect the Behaviour of Transnational Pharmaceutical Industries,* SSRN-id63072carstenfink.pdf.

Garrison, Christopher. *Exceptions to Patent Rights in Developing Countries*, International Centre for Trade and Sustainable Development, Issue Paper No. 17.

Gopalakrishnan, N.S., *Intellectual Property Laws,* LXIII, *Annual Survey of Indian Law*, Indian Law Institute, New Delhi (2007)

Gopalakrishnan, N.S. & Agitha, T.G., *Principles of Intellectual Property,* Eastern Book Company, Lucknow, 2009. ISBN – 978-81-7012-157-2

Government of India, Ministry of Industry and Supply, *Report of the Patents Enquiry Committee (1948-50).*

Government of India, Ministry of Industry, *Report on the Revision of the Patent Law*, 1959.

Mashelkar, R.A. Report of the Technical Expert Group on Patent Law Issues, Revised Report, March, 2009, available at http://dipp.nic.in

Maskus, Keith E., Reforming U.S. Patent Policy: Getting the Incentives Right, The Bernard and Irene Schwartz Series on American Competitiveness, CSR No. 19, November 2006, Council on Foreign Relations.

Mueller, Janice M., *The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of India's Pharmaceutical Innovation,* SSRN-id923538Mueller.pdf

Narayanan, P., *Patent Law*, Eastern Law House, 2006

Raju, KD, *WTO-TRIPs Obligations and Patent Amendments in India: A Critical Stock taking,* SSRN – id813387raju2.pdf.

Raju, KD, *The Debacle of Novartis Patent Case in India: Strict Interpretation of Patentability Criteria under Article 27of the TRIPS Agreement,* SSRN – id103096raju3.pdf.

Rangnekar, Dwijen, *No Pills for Poor People? Understanding the Disembowelment of India's Patent Regime*, Centre for Study of Globalization and Regionalization, University of Warwick, Working Paper No. 176/05, 2005.

Society for Economic and Social Studies, New Delhi, *Public Health Safeguards in the Indian Patents Act and Review of Mailbox Applications*, September 2007. This document was brought out in collaboration with WTO Cell, Ministry of Health and Family Welfare, Government of India and WHO Country Office for India.

Thakur, Anilkumar and Sharma, Nageswar, ed. *WTO and India*, Deep & Deep Publications Pvt Ltd., New Delhi, 2007.

The Federalist Society for Law & Public Policy Studies, Washington, *Are Intellectual Property Rights Human Rights?*

US-India Business Council and Coalition for Healthy India, *The Value of Incremental Pharmaceutical innovation: Benefits for Indian Patients and Indian Business*, A Report prepared for the US-India Business Council by White & Case LLP and Dua Consulting, June 2009, available at http://www.ahealthyindia.org/portal/chi/default

Watal Jayashree, *Intellectual Property Rights in the WTO and Developing Countries*, Oxford University Press, 2001.