FICCI's POSITION ON SECTION 3(d) OF THE PATENTS ACT, 1970

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INTRODUCTION:

The introduction of the new Patent Act in 1970, provided for the process patents and led to the sharp rise of the generic pharma companies in India and their proliferation for the next two decades. The market share of the Indian pharma companies went upto 72.77% from a nil position. There were over 20,000 units, and they were meeting 95% of the country's pharmaceutical needs. The value of the then pharmaceutical industry was 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.

India's acceptance of TRIPS provisions led to the introduction of product patent regime. This also led to an intense debate amongst the stakeholders and parliamentarians if this will seriously effect the affordability and availability of medicines to the Indian public. It also raised issue of evergreening of patents. The Government introduced Section 3 (d) which intends to check ever greening of patents but does not aim to restrict patenting to new chemical entities only.

Section 3(d) of the Indian Patents Act, 1970 has drawn considerable attention of various Intellectual Property academics, attorneys and pharmaceutical firms ever since its implementation from 2005. The prolonged debate over its potential effect on the grant of pharma patents has also been going on for some time.

INNOVATION AND THE TRIPS AGREEMENT:

TRIPS agreement, which while on one side advocates that the member countries should provide patent protection to inventions but on the other side cautions the member states to implement enough safeguards in their respective country laws so as to strike a fair balance between the interest of the right holders and legitimate users of Intellectual Property.

It is worth quoting 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[1].

TRIPS Agreement provides certain flexibilities as to the method of implementing TRIPS obligations. These result from **Article 1.1** of the agreement, as per which, WTO members can exploit creative solutions to transpose into their national law and practice those concepts of TRIPS Agreement which have been mentioned but not defined. Thus, herein lies the genesis of Section 3(d) of Patents Act, 1970 which is nothing but an exercise of liberty given to all member states under TRIPS.

Further, **Article 27.1** of the TRIPS Agreement obliges WTO Members to make available patent protection to all inventions, in all fields of technology. The said article apart from spelling out the criterion of patent eligibility also offers some flexibility as it does not define the parameters of novelty, inventiveness and industrial applicability, thus giving WTO members the scope to determine the criteria of how these should be interpreted and applied.[2]

The types of innovations in the pharmaceutical sector may be classified as 'major' and 'minor'. New molecules are rare, yet thousands of pharmaceutical patents are granted each year which raises the number of concern as to the number of patents that may be granted for minor modifications.[3] As is evident, the bulk of such minor modifications would be based on merely new use of a known pharma product. The TRIPS agreement itself does not prevent countries from denying the patentability of new uses for lack of novelty, inventive step or industrial applicability.[4] In the case of new uses, countries are free to decide whether or not to allow their

[1] Correa, Carlos M., Public Health and Patent Legislation in Developing Countries, 3 TUL. J. TECJ & INTELL, p 1.49 (2001)
[2] Sisule F. Musungu and Cecilia Oh, Study on The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines? *Available at* http://www.who.int/intellectualproperty/studies/TRIPSFLEXI.pdf
[3] Id citing The National Institute of Health Care Management Research and Educational Foundation (NIHCM) showed that the 12 year period of 1988-2000, only 35% of the 1035 drugs approved by the FDA contained a new active ingredient (NIHCM 2002). Highly innovative drugs are increasingly rare.
[4] Id

patentability. The IPR Commission[5] in 2002 recommended that in order to promote access to medicines the developing countries should exclude diagnostic, therapeutic and surgical methods from patentability, including new uses of known products.

It is worth highlighting that, **Article 7** of the TRIPS agreement obliges member states to provide Intellectual Property protection in such a manner that it gives mutual advantage to the producers and users of the technological knowledge which is conducive to the social and economic welfare. It is equally important to mention here that **Article 8** of TRIPS Agreement which aims at cautioning member states, that while they formulate or amend their laws, adequate measures must be adopted necessary to protect public health and nutrition besides ensuring that the intellectual property rights are not abused by the right holders. WHO says the pharmaceuticals cost about 60% of the total cost of health care in India. India's healthcare initiatives should consider the interests of the 40% of the people who live below poverty line. The crux of the matter is that monopolies should not be extended to inventions which are not 'genuinely innovative enough' which otherwise if granted protection would hamper or prove to be highly deterrent to the social and economic welfare. As far as pharmaceuticals are concerned, the system should ensure timely access to essential medicines at affordable rates to the general public by preventing or checking the abuse of patent protection from extending of such monopolies to frivolous pharmaceutical inventions, leading to the welfare of public at large.

Respecting the ethos of TRIPS, India implemented Section 3(d) which ensures that patent protection is accorded only to meritorious inventions and not some frivolous inventions thus preventive abuse of the patent regime.

Section 3(d) to the Patents Act, 1970, provides that mere discovery of a new form of a known substance which does not result in enhancement of the known efficacy of that substance or mere discovery of new property or new use for a known substance or of the mere use of a known process, etc., are not patentable.

[5] Id

ISSUES CONCERNING SECTION 3D – ROUNDTABLE DISCUSSION

The debate over Section 3(d) of the Patent Act however will be incomplete without the mentioning of the Novartis case and the court's interpretation of the section. In fact this was the case which started it all with Novartis challenging the constitutionality of the section and its compatibility with TRIPS after the rejection of its patent applications over its anticancer drug Glivec by the Patent Office.

In this backdrop, Federation of Indian Chambers of Commerce and Industry (FICCI) organized a Roundtable on **March 29th, 2010, at FICCI, New Delhi.** The objective of the Roundtable was to discuss the issue of Section 3(d) and whether it comes in the way of granting of meritorious inventions eligible of patent grant.

The Roundtable was attended by government officials, lawyers, pharma industry representatives academicians, NGOs, etc.

A report was also presented on this occasion by Mr. T C James titled 'Patent Protection and Innovation: Section 3(d) of the Patents Act and Indian Pharmaceutical Industry'.

The overall consensus of opinion that was arrived at this discussion are as follows:

1. **Report on Patent Protection and innovation: Its conclusions were:**

    a. <u>Section 3d has not come in way of grant of pharma patents:</u>

The overall opinion on section 3d that it should continue as it is not hampering the growth of the pharmaceutical industry. The above mentioned report revealed the statistics that the total number of pharma patents granted in 2004-05 were 765 and in 2008-09 it was 2373. Since the implementation of the new patent Act since 2005 a total of 3500 'product patents'[6] have been granted for pharmaceuticals which is a significant figure in light of the total product patents

[6]Patently Wrong, FINANCIAL EXPRESS August 23, 2010, *Available at* http://www.financialexpress.com/news/FE-Editorial---Patently-wrong/663548/

granted in India. This shows that that the filing of number of pharma patents has increased and section 3d has not really stood in the way of grant of pharmaceutical patents. It is also worth mentioning after 2005 that 86 patents have been granted for pharmaceutical products in India which at best can only be said as minor variations of existing pharmaceutical products and not breakthrough drugs[7] (Annexure I).

b. Section 3d has not stifled innovation:

The report also revealed that implementation of section 3d has not stifled innovation. The report revealed the statistics that in 2004-05, 1911 patents were granted and in 2008-09, 18230 patents were granted. Thus, there has been no reduction in the innovation activity due to new amendments in the law.

c. Foreign MNCs have been major beneficiaries:

The report also highlighted that major beneficiaries of product patent regime after the implementation of section 3d have been foreign multinationals. The growth in terms of applications filed and grant of patents the foreign applicants has been appreciable. The statistics revealed that in 2004-05, 20% of the patent applications were filed by residents and 80% by non-residents. . In 2007-08 residents were granted 21% of the patents and 79% to non residents. In 2007-08 alone 12088 patents were granted to foreign applicants amounting to 79% as against 3173 patents granted to residents amounting to 21%[8].In 2008-09, 17% of the applications were filed by residents and 83% by non-residents. In the matter of grants, 40% of the patents were granted to residents and 60% to non-residents

[7] Id at Pg 10
[8] For Details See Annexure 1 (Source: Patent Protection and Innovation, Section 3(d) of the Patents Act and Indian Pharmaceutical Industry by TC James; *Available at* http://www.nipoonline.org/Section-report.doc

2. Synopsis of the discussions:

a. MNCs confirmed there is no appeal pending against section 3d:

Also, one MNC clarified that no challenge is pending before the Supreme Court against section 3(d). The case pending before the Supreme Court is appeal against the decision of the Intellectual Property Appellate Board. The challenge is only with respect to applicability of the section 3(d) and not against 3d per se.

b. Section 3d aims to check evergreening:

In essence, section 3(d) aims to check ever-greening by providing that only those pharmaceutical derivatives that demonstrate significantly enhanced "efficacy" are patentable. Section 3(d) draws a line between ever-greening and incremental innovation. The mere reading of the said section clearly recites as to what is not patentable. In other words if the 'prospective patent' substance results in the enhancement of the known efficacy of the substance then it is patentable. The section only tries to filter out any frivolous inventions made in an attempt to ever-green patent incorporating trivial changes unless such changes result in significant improvement in the efficacy. It is worth mentioning that Section 3(d) was enacted by the legislature only with the intent of discouraging the abysmal practice of the pharmaceutical companies from ever greening of patents.

c. Section 54 of the Patents Act:

It was observed that under Section 54 of the Patent Act, patent of addition may also be granted for an improvement in or modification of an invention in respect of the main invention. (Though the life of such a patent granted for improvement is set to expire with that of the main invention). This should support the debate as far as any questions relating to the grant of patents for incremental inventions are concerned.

CONCLUSION:

In light of the above, It can be safely concluded that India should continue to maintain its present stance on Section 3(d) which is a statutory provision taking care of public interest and preventing ever-greening of patents.

The Mashelkar Committee, set up by the Government, 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). 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 of '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."

Annexure I

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

Table-3							
Illustrative List of Patents for New Form of a Known Substance							
Sr No	**Dt of Appln**	**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	1973	Laboratories Des Produits

				Fenofibrate and Method for the Preparation Thereof			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	_	-	M/s F Hoffmann -La Roche

				Receptor Antagonist and Magnesium Compound			
7	04.10.2002	12.12.2007	212743	Pharmaceutical Composition Comprising (R)-(-)-2-[5-(4-Fluoropheny)-3-Pyridylmethylamino methyl]-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,	Valsartain +amlodipine+hydrochlorthiaz	1991 + 1983 + 1962	Novartis AG

				Amlodipine, Hydrochlothiazide	ide		
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	Pseudoephedrine + desloratadine	1937 +1987	Schering Corporation
18	20.12.2000	09.11.2007	211749	Bilayer Sustained Release Oral Dosage Composition Comprising	Pseudoephedrine + desloratadine	Old molecule +1987	Schering Corporation

				Desloratadine and a Nasal Decongestant			
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	Olanzapine	1993	Eli Lilly and Company

				Thereof			
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 (pregabaline_ /1991 (tiagabine)	Newron Pharmaceuticals Spa
25	24.04.2001	07.11.2007	211681	A Stabilized Solid Composition	Gabapentin	1977	Warner-Lambert Company
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 +anticonvulsant**	1965	Ortho McNeil Pharmaceutical Inc
28	19.03.2003	30.08.2007	209411	Ana Orally Administrable Tablet	(+) Tramadol	1965	Penwest Pharmaceuticals Company
29	16.08.2002	26.06.2008	221597	Pharmaceutical Composition Comprising 5-[4-[2-(N-Methyl-N-(2-Pyridyl)Amino)Ethoxy]Benzyl]Thiazolidin	Rosiglitazone +metformin	1991 + 1956	SmithKline Beecham Plc

				e-2,4-Dione and Metformin or Metformin Hydrochloride Suitable for the Treatment of Diabetes			
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 Pharmaceutical N.V.
34	04.12.2003	23.09.2008	223793	Controlled Release Composition and Method of Producing the Same	**	*8	Takeda Pharmaceutical Company Limited
35	20.10.2004	29.08.2008	222978	Process for Producing Enantiomer of Amlodipine in High Optical Purity	Amlodipine	1986	Emcure Pharmaceuticals 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 Limited
41	17.10.2005	27.06.2008	221624	A Crystal of 1-(2-Methoxyethyl)-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 Pharmaceutical 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 Pharmaceutica 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 Pharmaceutical Formulation	Amoxicillin +clavulan	1965 + 1979	Beecham Pharmaceuticals

					ic acid		(Pte) Limited
50	28.01.2004	27.02.2008	215514	An Antineoplastic Composition	**		Wyeth
51	09.04.2003	26.09.2007	210283	Adjuvant Composition comprising an Immunostimulatory Oligonucleotide and a Tocol	**		GlaxoSmithKline 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 Aktiengeselischaft
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 Combination Comprising the HMG	Statin +candesartan	<1993 + 1993	AstraZeneca UK Limited

				COA Reductase Inhibitor and the All Antagonist Candesartan			
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 + hydrochlorothizide	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 Managem

							ent 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

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