Pharmaceuticals, Product Patent and TRIPS Implementation

Dinesh Abrol
Sivakami Dhulap
Malini Aisola
Nidhi Singh

Working Paper 191

March 2016

ISID
Institute for Studies in Industrial Development
New Delhi

ISID
Working Paper
191

Pharmaceuticals, Product Patent and TRIPS Implementation

Dinesh Abrol
Sivakami Dhulap
Malini Aisola
Nidhi Singh

ISID
Institute for Studies in Industrial Development
4, Institutional Area, Vasant Kunj Phase II, New Delhi - 110 070
Phone: +91 11 2676 4600 / 2689 1111*; Fax:* +91 11 2612 2448
E-mail: info@isid.org.in; *Website:* http://isid.org.in

March 2016

ISID Working Papers are meant to disseminate the tentative results and findings obtained from the ongoing research activities at the Institute and to attract comments and suggestions which may kindly be addressed to the author(s).

CONTENTS

Abstract 1

Introduction 1
Analytical framework 5
Method 7
Results and Analysis 8
Emerging Pattern of Sales of Newer Drugs 8
Rise in the Sales of Post-1995 Compounds in Retail Market 9
Emergence of Greater Market Concentration 9
Declining Contribution of Delayed TRIPS Implementation 10
Evidence of the Rise of Foreign Firms 13
Product Patents and Newer Compounds 17
Patent Opposition and Market Power 19
Delayed TRIPS Implementation, Market Leadership and Foreign Firms 22
Conclusion 31
References 34

List of Table(s)

Table 1 Share of post-1995 USFDA New Drugs Approved by DCGI for Introduction in the Retail Pharmaceutical Market as on January 2015 9
Table 2 Sales of Pre-1995, Post 1995 and Patent Expired Compounds in 2015 9
Table 3 Sales of Pre-1995, Post 1995 and Patent Expired Compounds in 2010 and 2015 10
Table 4 Number of Compounds in which Companies and Sales have Increased from 2010 to 2015 10
Table 5 Number of Compounds (268) with Number of Companies 11
Table 6 Single Monopoly Compounds 11
Table 7.1 Therapeutic segment wise sales of Pre-1995, Post-1995 and Expired Molecules 12
Table 7.2 Therapeutic segment wise sales of Pre-1995, Post-1995 and Expired Molecules 12
Table 8 Post 1995 Patented Compounds 13

Table 9	Compounds Introduced during 2010-2015	14
Table 10	Foreign Firms' Sales of 262 NMEs as a Share of Total Annual Sales	15
Table 11	Foreign and Domestic firms' Sales and Shares of Post-1995 262 NMEs of Annual Sales of 2015	16
Table 12	New Chemical Entities by Foreign Firms	17
Table-13	New Chemical Entities Targeted Specific Therapeutic Areas	18
Table 14	TRIPS Flexibilities, Patent oppositions and Post-1995 compounds	20
Table 15	TRIPS Flexibilities, Patent Oppositions and Market Structure	21
Table 16	Pattern of Emergence of Foreign and Domestic Firms as Market Leaders	23
Table 17	Pattern of Emergence of Foreign and Domestic Firms as Market Leaders	23
Table 18	Monopolies, Market Leadership, Domestic and Foreign Firms	23
Table 19	Market Leader and Sales of 91 compounds out of 268 compounds with Patent Status	23
Table 20	Post-1995 Patented Compounds and Foreign firms as Market Leaders	30

Pharmaceuticals, Product Patent and TRIPS Implementation

Dinesh Abrol, Sivakami Dhulap, Malini Aisola, and Nidhi Singh[*]

[***Abstract**: In this article the authors examine the impact of delayed product patent implementation on the introduction of new drugs by domestic and foreign firms in India. Examination focuses on how much the foreign and domestic firms succeeded in using the freedom to operate obtained through delayed TRIPS implementation in the domestic pharmaceutical market. Two distinct data sets have been created, one that relates to the priority year of primary patent of active pharmaceutical ingredient for the new drugs introduced after 1995 and the other that relates to the ability of foreign and domestic firms to compete in the domestic market in the case of new drugs. Evidence of the ability of domestic firms to compete with the "multinational originator companies" is analysed. Analysis confirms that in the case of more recently approved drugs the market power of foreign firms is on the rise, and the share of patented compounds is fast increasing in the case of anti-cancer, cardiovascular, central nervous system, diabetes, urology and few more groups involving therapies for acute and chronic conditions. However, it also suggests that the market power of "multinational originator companies" would have been even greater if India had opted for early TRIPS implementation like many of the countries in Latin America did. Finally it suggests that since the patented monopolies are on the rise in products where the market demand is growing and the newer drugs are fast becoming unaffordable in the case of chronic and acute conditions related therapies there is an urgent need to implement the provisions of compulsory licensing and introduce public procurement and price control to allow the interested firms to participate in the introduction of patented compounds through local production to ensure affordable access.]*

Introduction

In 1995 the Trade Related Intellectual Property Rights (TRIPS) Agreement that India signed to become a member of the World Trade Organization (WTO) required the Government of India to grant product patents for pharmaceutical products. The TRIPS Agreement was accepted by India as a part of the larger final trade package which established the WTO. However, in India at home the opposition to product patent for pharmaceutical products was widespread on account of the experience with the colonial patent law wherein the British government was enforcing pharmaceutical product patents without working them. Consequently India had experienced high prices for antibiotics during the decade of sixties.

[*] Dinesh Abrol, Professor ISID, E-mail: dinesh.abrol@gmail.com; Sivakami Dhulap, Research Scientist, URDIP (CSIR), Pune; Malini Aisola, Independent Researcher and Nidhi Singh, Research Associate, ISID.

India was characterized by imports of formulations and active pharmaceutical ingredients. Foreign firms dominated the pharmaceutical industrial landscape. The first amendment to Patent Act, 1970 took place only after India lost the WTO dispute. The enactment of first amendment to the Patent Act, 1970 that permitted the government to establish a mail box to receive the patent applications on new pharmaceutical products was itself delayed for close to a period of two years (AV Ganesan, 2015, Dinesh Abrol, 2010, Shamnad Basheer, 2005 and Shukla SP, 1994).

In the case of delayed TRIPS implementation by India there is an important counterfactual natural experiment available to be assessed for the actual impact of stronger intellectual property rights (IPRs) system on pharmaceutical innovation and access. In Latin America, the governments opted for early TRIPS implementation. The governments of most Latin American countries chose to grant product patents for pharmaceuticals well before the expiry of the transitional period. There was no delay in the implementation of TRIPS. Argentina, for instance, changed its patent law in 1995 after a turbulent legislative process, and granted pharmaceutical product patents as of October 2000[1]. Uruguay started to grant patents for pharmaceutical products as of 1 November 2001. Brazil went even further in adopting the 'pipeline' mechanism actively promoted by US industry and government, which permitted the retroactive recognition of the till-then-prohibited pharmaceutical product and process patents based on applications made before its entry into force, provided that the covered inventions had not previously been commercialized in any market, nor serious preparation for the exploitation of the invention been made in Brazil.

India exhibited public resistance to the early introduction of pharmaceutical product patent on account of the efforts put in by the larger democratic movement against TRIPS which the National Working Group on Patent Laws (NWPGL) helped coordinate by bringing in the support of generic pharmaceutical industry for delayed TRIPS implementation. While the Indian TRIPS debate too experienced the narratives of coercion, bargain, ignorance and self-interest, but the public interest narrative prevailed. This effort successfully determined the ultimate outcome in favour of delayed product patent implementation. The approach to patent law amendments was formulated with the understanding that India should make

[1] As developing countries, Argentina, Brazil, India and Mexico, had the option to use the TRIPS flexibility available under Article 65 of the TRIPS Agreement. Not all the governments chose to use the option of the transition periods in full and delayed the implementation of product patent for pharmaceuticals. For those developing countries that had exceptions to patentability enshrined in their statues, Article 65.2 of TRIPS provided the flexibility to delay the TRIPS implementation for a period of five years till 2000. Article 65.4 provided the flexibility to delay the implementation of product patent protection for a period of another five years till 2005 to India and many other countries in Latin America if not providing for product patent at the time of entry into WTO. Articles 70.8 and 70.9 of TRIPS put a limitation on the transitional periods allowed under Articles 65. The limitation was that if a developing country chooses to exploit the transitional periods in full, then the country would also introduce the provisions of "mail box" and "exclusive marketing rights" to become effective from 1 January 1995.

full use of the TRIPS flexibilities and of the transitional period of ten years available up to 2005 to the developing world. India was dragged by the developed world governments to the WTO Dispute Settlement Body (DSB). But the UF Government held on firmly. It was able to delay the implementation of TRIPS provisions of exclusive marketing rights (EMR) and product patent on pharmaceuticals[2].

Decision making involved not only resistance and controversy but also uncertainty existing over the scale and scope of patenting of new drugs that the foreign firms would be able to seek monopolies on through the post-TRIPS patent law in India. Recently the literature has started suggesting that India consciously used the TRIPS flexibilities to fashion for itself a law which suited Indian sensibilities, especially those of its pharmaceutical sector (Prashant Reddy, 2014). This view tends to ignore the challenge of decision making faced by the policymaking world in 1995. To what extent foreign firms would be able to secure product patent rights in actual practice during the transition period of 1995-2005 was far less clear and involved more theoretical and political debate (Dinesh Abrol, 2010). Neither the opponents nor the advocates of early TRIPS implementation had the required information in India at the time when the country had to take the decision on TRIPS implementation.

Lack of sufficient information on the type of patent claims that could be filed by the multinational originator companies for the newer drugs with the priority year of their primary or basic patents being of post-1995 period was a critical information gap. The knowledge base of the policymaking community was rather weak. It was not easy for the apparatus to make an assessment of the ability of product patent to act as an entry barrier in the case of newer drugs that the industry could be expected to introduce in the future in the Indian market. In the pharmaceutical industry patents on new chemical entities (NCEs) are usually filed early during the research phase to secure monopoly rights on a possible new drug. Since foreign firms had a large number of new chemical entities (NCEs) and new biological entities (NBEs) to patent they were also the strongest advocates of early TRIPS implementation in India.

The Organization of Pharmaceutical Producers of India (OPPI) tried its best to get the government to pave way for the early TRIPS implementation. Argument of the Organization of Pharmaceutical Producers of India (OPPI), which represents the interests of multinational corporations, was that India should reject the option of delayed TRIPS implementation since India needs 'high quality' foreign direct investment (FDI), foreign technology transfer (FTT) and overseas R&D (ORD) investments to upgrade the domestic pharmaceutical industry. The option of delayed TRIPS implementation would end up delaying the introduction of new medicines. Foreign firms would not take interest to

[2] This pressure worked because the United Front (UF) government was in power from 1995 to 1998 with the help of the left parties. The Government had Mr. S. P. Shukla, the former GATT ambassador as member planning commission who had led from the front the battle against TRIPS Agreement in the Uruguay Round of GATT Negotiations.

introduce these medicines through local production. Foreign firms should be encouraged by undertaking early TRIPS implementation. Doubts were cast on the ability of domestic firms to introduce newer medicines into market in time. Details of how the controversy unfolded and progressed over the TRIPS implementation have been analysed (Dinesh Abrol, 2010).

Furthermore in the case of pharmaceutical industry India also took to the implementation of a neo-liberal path to industrial development and innovation after 2002. As the ability of domestic firms to gain from the decision taken was posited to be adversely impacted this could have also influenced the ultimate outcome. Evidence is available of adverse impacts experienced not only in respect of the system of innovation but also for the system of local production of pharmaceuticals in India (Dinesh Abrol, 2010 and 2013).Today an influential section is once again active to dilute the amended Indian patent law. The political and bureaucratic apparatus is under pressure from United States, European Union and Japan to accept TRIPS plus provisions. If these provisions are implemented, then the government would be made to enforce patents for new uses of older molecules, data exclusivity and patent linkage. As the law on patentability can also change due to the clamour for the new regional agreements for trade and investment it is important to analyse the contribution of product patent or TRIPS based patent amendments to induce foreign firms to prioritise and invest in India[3].

This analysis is also important because scholars from many disciplines are continuing to take a far more positive view of the TRIPS implementation on the aspect of the performance of domestic pharmaceutical firms (Athreye Suma, et al., 2009 and J Mueller, 2007). The National Pharmaceutical Policy of 2002 and all the complementary innovation policy measures which have embedded the development of pharmaceutical industry into a neo-liberal path of innovation making and industrial development are an important area of academic debate (Dinesh Abrol, 2004, 2006, 2010, 2013)[4]. Finally the government has been dithering to take effective steps with regard to price control, public procurement and compulsory licensing[5]. Assessment of the actual outcome of delayed TRIPS implementation will help the public debate to be conducted in an informed way on the interventions that the government is required to make vis-à-vis price control, public procurement and compulsory licensing.

This article examines the impact of the decision to delay the implementation of TRIPS Agreement on the ability of foreign and domestic firms to compete in the retail

---

[3] See Dinesh Abrol (2016), "The wrong incentive: The National Intellectual Property Rights Policy Must Be Opposed, http://www.epw.in/journal/2016/24/commentary/wrong-incentive.html# sthash.jjXZ35zC.dpuf and Dinesh Abrol (2016), "Who gains from National IPR Policy?" ISID Policy Brief, July 2016.

[4] The important exception to the neo-liberal path was the enactment of third amendment to the patent act which the parliament adopted under pressure from the left MPs.

[5] The important exception to the neo-liberal path was the enactment of third amendment to the patent act which the parliament adopted under pressure from the left MPs.

pharmaceutical market in respect of the introduction of new drugs during the period of last two decades in actual practice in India. Evidence building has involved the creation of two distinct data sets, one relating to the priority year of primary patent of the active pharmaceutical ingredient and the other relating to the changing nature of market structure. Evidence of the ability of domestic firms to compete with the "multinational originator companies" in respect of the two hundred sixty eight (268) new drugs introduced since 1995 in the retail market is analysed. The market power of foreign firms is on the rise in the case of newer, more recently approved drugs. Analysis brings out that the share of patented compounds is fast increasing in therapeutic groups such as anti-cancer, cardiovascular, central nervous system, diabetes, urology and few more groups involving therapies for acute and chronic conditions.

Analysis confirms that the market power of "multinational originator companies" would have been even greater if India had opted for early TRIPS implementation like many of the countries in Latin America did. It concludes that since the patented monopolies are on the rise in products where the market demand is growing rapidly the policymakers need to take the following steps: 1) implement the compulsory licensing provision provided for commercial use in the patent act of 2005, 2) introduce public procurement and price control of medicines involving compounds having effective product patents and 3) invoke the provision of compulsory licensing for government use and collaborate with the domestic firms that are interested to participate in the introduction of patented compounds in the market to ensure affordable access.

Analytical Framework

Available studies by Bhaven N Sampat and Tahir Amin (2010) and Sudip Chaudhuri (2011)explored in the past the impact of Indian patent law on the patent status of new drugs from USFDA till 2010on the basis of information collated by them from USFDA orange book. Sudip Chaudhuri (2011) specifically considers the impact of the introduction of product patent on the rise of multinationals and monopolies in the pharmaceutical industry after the implementation of TRIPS. Analysis of the pattern of sales and market structure obtaining in 2010 suggests that the sale of the post-1995 basket of 180 new drugs was about 9.1 per cent of the total pharmaceutical market in 2010. Impact is emphasized in respect of high prices of patented medicines. It is suggested that the worse is yet to come. Patented drugs would become a bigger problem in the near future on account of the faster increase of patenting of new compounds by the multinationals in India is predicted. Recently Bhuven Sampat (2014) hypothesized that the share of post-1995 patented products would now increase more rapidly in the case of Indian pharmaceuticals. Argument emphasizes that the importance of Section 3 (d) would decline. Predictably one should therefore expect the market share of patented drugs to rise in the case of more recently approved drugs in 2015.

Past assessments of the impact on market power of foreign firms by the option of delayed TRIPS implantation were debated by both the sides only in theory. Argument from the anti-early TRIPS implementation side was apparently sound to the extent that India would experience a positive impact on the entry of domestic firms for all those drugs where the basic (primary) patents on active pharmaceutical ingredients were of pre-1995 origin and hence not patentable in India. But uncertainty existed due to the lack of data on existence of actual types and numbers of new chemical entities (NCEs) or new biological entities (NBEs) in the pipeline. It was not clear how many and in which therapeutic groups product patents would be received on them in the mail box by India. It was not therefore possible for either side to argue how far the ability of foreign and domestic firms would be impacted with some certainty. Contribution of the decline of R&D productivity to the actual impact of the option of delayed TRIPS implementation in actual practice during the post-TRIPS regime could not be anticipated in advance which has also resulted in a positive outcome to some extent.

In theory, incentives exist for both foreign as well as domestic firms to make their due contribution to the introduction of new drugs in India. The ability of foreign firms to use product patent as an entry barrier was discussed by the side opposing the early TRIPS implementation on the basis of scanty evidence available at that time on the experience of Western Europe in theory (Dinesh Abrol, 1994). Several scholars discussed the issue of how India would be impacted in theory. India was considered to be better placed to benefit from stronger patent protection in theory. Several scholars have been reviewed elsewhere in detail (Dinesh Abrol, 2004, 2010).

Arvind Subramanian who happens to be the chief economic advisor to the Modi government was one who thought India should be careful with regard to the TRIPS flexibilities implementation. Argument was that the effects of patent protection are sensitive to assumptions about market size and structure (Arvind Subramanian, 1995, 1999, 2004). Argument is based on the theory of divergence in the impacts of stronger patent system on access and innovation. In policymaking terms, this argument meant that India is likely to gain more than other developing countries from early TRIPS implementation because of the size of its market. Thus the advice from him has been that the government should not be rushing to implement compulsory licensing in the case of pharmaceuticals.

Decision making continues to face this challenge of theoretical and empirical nature in actual practice. It has not been possible for the either side to state with much certainly that for how long the competitive advantage of domestic firms is going to persist in practice. India is continuing to embark on its journey towards progressive external liberalisation demanded by the developed world countries. Investment behaviour of the domestic firms has been changing via the marketing arrangements that foreign firms are in position to offer to domestic firms. Impact of the policy changes on the manufacturing capability is also not fully clear as yet. It is not only possible to go beyond the broad conjectures and the thumb rules of how competition would be influenced. Numerous imponderables continue to exist with regard to the ongoing theoretical discourse. Empirical analysis can help better

with the analysis of the ability of foreign and domestic pharmaceutical firms to introduce newer drugs on the basis of local production.

Method

Information on the new drugs approved by the Drug Controller General of India (DCGI) is taken from the data base available with CDSCO and USFDA. We have had to live with the information gaps that continue to exist in respect of many of the NCEs and NBEs on account of their patents being of recent vintage. These NCEs and NBEs are still under clinical trials. Some of these NCEs and NBEs will hit the domestic market very soon. However the accumulated evidence is certainly enough to create stylized facts on the impacts of the decision to delay the introduction of product patent on the Indian pharmaceutical industry for a period of over last twenty years.

Evidence building on the use of primary patents was challenging from the data gathering point of view. Linking patents to active ingredients is undoubtedly an important challenge on account of no explicit mention in the patent claims of the active ingredient contained by a drug. Primary patents refer to patents on active pharmaceutical ingredient (API). The primary patent is filed to protect potential API that forms the basis of the new drug. In later phases of the drug development, secondary patents are filed on other aspects of active ingredients such as different dosage forms, formulations and production methods. Secondary patents emerge from changes to formulations and dosages or new uses, discovered during clinical trials.

Investigations were restricted to studying the role played by primary patent because of its ability to provide foreign firms the necessary monopoly power and use patent as an effective barrier to entry of the domestic firms in the retail pharmaceutical market. We relied on the U.S Food and Drug Administration (USFDA) to identify the post-1995 approved drugs. The Drug General Controller of India (DCGI) approved the identified two-hundred sixty two drugs for introduction in the domestic market over the period of last twenty years. The Orange book of the USFDA has been used to identify US patents on the compounds registered by the DCGI in India. Further we have also found out about the priority year of basic patent (primary patent on active ingredient). Because companies can obtain competitive advantage also through brand building, we have matched the patentable product data with all the pharmaceutical products on sales in the pharmaceutical retail market in India using the AIOCD-AWACS database called Pharmatrac for the period from 2011 to 2015.

Empirical information is not provided by the Indian patent office in a manner that allows the primary patent priority year status to be checked for the patents granted to the multinational originator company for active pharmaceutical ingredient (API) contained in the products on market. Data set was built from the information collected with the help of CSIR Unit for Research and Development on Information Products (URDIP) from the relevant proprietary data bases. Analysis of the data obtaining on the priority year in the

case of primary patent on API granted in India was undertaken. We have been able to construct a data set that contains information for two-hundred sixty new drugs introduced after TRIPS and on market in India on the aspects such as active ingredient contained, date of USFDA drug approval, primary patent applicant, priority year of primary patent, patent assignee, FDA expiry date, corresponding Indian patent and type of patent claim (NCE or Composition of Matter). Based on this dataset our study contributes not only to the sparse empirical literature but also offers up to date empirical evidence on the use of product patent for all the new drugs introduced in India after TRIPS.

Results on the type of exclusivity that the patent owner can be expected to enjoy in India have been obtained and studied in detail molecule wise on the introduction of new drugs introduced since 1995 in the light of the data generated on market structure. Information was generated on the annual sales of plain and combination products containing the relevant patented API in the case of every therapeutic group for the past 1995 USFDA approved drugs. We had to link the API to the products contained in respect of market information available from Pharmatrac to build the analysis of the contribution of patented drugs in the market sales of foreign and domestic firms for the products on sale in the retail pharmaceutical market in India.

Results and Analysis

Analysis in this investigation is based on the impact of the option of delayed TRIPS implementation on the introduction of products containing newly approved medicines till the year of 2015. Results span the evidence of changes observed in the market sales, market structure and competition till 2015 taking both plain products and combinations involving the new compounds. Analysis is made on the basis of the information available as on January 2015 from the AIOCD data on the sales of foreign and domestic companies selling the products containing two hundred sixty eight (268) new compounds in the retail market.

Emerging Pattern of Sales of Newer Drugs

Results indicate that the share of two hundred sixty eight (268) compounds in total retail sales as on January 2015 is now twenty six point one (26.1) per cent. See *Table 1* for the details of therapeutic group wise sales of new drugs as on 2015. This basket of 180 drugs included also some biologics. These were left out from our own analysis of the retail market in 2015. Our own analysis is confined to new chemical drugs approved after 1995. A threefold rise in the sales of products based on new drugs introduced up to 2015 totalling 268 merely within a period of five years is a significant rise. Up to the year of 2010 the share of products based on 180 new drugs introduced was 9.1 per cent (Sudip Chaudhuri, 2011).

A comparative picture of therapeutic group wise sales of new drugs based products of 268 new compounds introduced up to 2015 in the Indian pharmaceutical retail market indicates that there has been a steep rise in the sales of post-1995 compounds after 2010. See *Table 2*

for the details of sales of products based on pre-1995, post-1995 and patent-expired compounds totalling in 2015 as 268 compounds. The share of post-1995 compounds is 12.56 per cent of the total sales in 2015. Analysis shows that there is twelvefold increase in the share of the sales of post-1995 compounds in 2015 compared with 2010 figures. In 2010 the share of post-1995 patented drugs was 1.2 per cent (Sudip Chaudhuri, 2011).

Table 1: Share of Post-1995 USFDA New Drugs Approved by DCGI for Introduction in the Retail Pharmaceutical Market as on January 2015

Therapeutic group	*Market size (MAT Jan 2015)*	*Market value of 262 NMEs (crores)*	*Share of 262 NMEs (%) based on MAT Jan 2015*
ANTI DIABETIC	6406	4882	76.2
ANTI MALARIALS	606	98	16.1
ANTI-INFECTIVES	13394	1448	10.8
ANTI-NEOPLASTICS	1380	546	39.6
BLOOD RELATED	943	10	1.1
CARDIAC	10485	5550	51.6
DERMA	4843	155	3.2
GASTRO INTESTINAL	9652	2752	28.5
GYNAECOLOGICAL	4237	465	11.0
HORMONES	1414	17	1.2
NEURO / CNS	5107	2090	40.9
OPHTHAL / OTOLOGICALS	1543	482	31.2
OTHERS	929	92	10.3
PAIN / ANALGESICS	5973	683	11.4
RESPIRATORY	6561	1899	28.9
SEX STIMULANTS / REJUVENATORS	466	391	83.8
STOMATOLOGICALS	366	0	0.0
UROLOGY	896	491	54.8
VACCINES	1181	0	0.0
VITAMINS / MINERALS / NUTRIENTS	7635	0	0.0
Total	84018	**22049**	**26.1**

Source: Authors prepared dataset from Pharmatrac data of AIOCD

Table 2: Sales of Pre-1995, Post 1995 and Patent Expired Compounds in 2015 (Denominator 268 Compounds)

Categories	*No. of Compounds*	*Total Sales in 2015 in %*
Pre 1995	66	16.45
Post 1995	60	12.56
Patent Expired	142	70.98
Total	**268**	

Source: Authors prepared datasets on AIOCD market data and Status of Primary Patents

Rise in the Sales of Post-1995 Compounds in Retail Market

The seriousness of ominous trends with regard to the rising share of post-1995 compounds as compared to the compounds whose patents have expired is also confirmed through our own analysis. Analysis suggests the following changes: 1) the sales of patent expired compounds numbering ninety (90) decreased from 70.61 per cent of total sales in 2010 to 45.81 per cent of total sales in 2015, 2) the sales of pre-1995 compounds numbering forty two (42) rose from 16.97 per cent of total sales in 2010 to 32.46 per cent of total sales in 2015 and 3) the sales of post-1995 compounds numbering thirty eight (38) rose from 12.42 per cent of total sales in 2010 to 21.73 per cent of total sales in 2015. See *Table 3* for the sales of pre-1995, post-1995 and patent expired compounds in 2010 and 2015.

Table 3: Sales of Pre-1995, Post 1995 and Patent Expired Compounds in 2010 and 2015 (Denominator 170 Compounds)

Categories	*No. of Compounds*	*Total Sales in 2010 in %*	*Total Sales in 2015 in %*
Pre 1995	42	16.97	32.46
Post 1995	38	12.42	21.73
Patent Expired	90	70.61	45.81
Total	**170**		

Source: Authors prepared dataset on AIOCD market data and Status of Primary Patents

Emergence of Greater Market Concentration

The rise of oligopolistic competition is evident in a larger number of compounds in 2015. The share of products where there is only one company active is itself now 2.5 per cent. See *Table 4* for the number of compounds in which the number of companies and sales have increased from 2010 to 2015 in the case of 170 compounds. Comparative analysis of the market of products based on APIs introduced till 2010 indicates that more companies have entered in the sales of products based on these compounds in 2015. The number of companies increased for the products based on seventy three (73) compounds out of ninety (90) patent expired compounds. The number of companies increased by 2015for the products based on the pre-1995 forty one (41) compounds out of forty two (42). The number of companies increased by 2015 for the products based on the post-1995 thirty six (36) compounds out of thirty eight (38) compounds.

Table 4: Number of Compounds in which Companies and Sales have Increased from 2010 to 2015 (Denominator 170 Compounds)

Categories	*No. of compounds in which companies have increased*	*No. of compounds in which companies have decreased*	*No. of compounds in which sales have increased*	*No. of compounds in which sales have decreased*
Pre 1995	41	1	33	9
Post 1995	36	2	35	3
Patent Expired	73	17	74	16

Source: Authors prepared dataset on AIOCD market data and Status of Primary Patents

Emergence of the monopolies in the case of thirty one (31) out of sixty (60) compounds accounting for 50 per cent of the post 1995 compounds is certainly an ominous development. As on January 2015 the share of post-1995 patented compounds where there are maximum up to five players active is itself now 4.662 per cent. This is a four time increase in the sales of compounds experiencing oligopolistic market competition. All of these are ominous developments that policymakers cannot ignore. Evidence obtaining clearly confirms the claim that patent monopolies will grow faster after 2005 in the pharmaceutical industry. See *Table 5 & 6* for the details.

Table 5: Number of Compounds (268) with Number of Companies

Categories	*One Company*	*Two companies*	*Three companies*	*Four companies*	*Five companies*	*More than five companies*	*Total*
Pre 1995	8	8	1	6	4	39	**66**
Post1995	31	6	3	2	3	17	**62**
Patent Expired	12	8	8	8	8	96	**140**
Total	**51**	**22**	**12**	**16**	**15**	**152**	**268**

Source: Authors prepared dataset on AIOCD market data and Status of Primary Patents

Table 6: Single Monopoly Compounds

Categories	*No. of Compounds*	*Market Sales 2015 in %*
Pre-1995	8	0.127
Post-1995	31	2.265
Patent Expired	12	0.483
Total	**51/268**	**2.875**

Source: Authors prepared dataset on AIOCD market data and Status of Primary Patents

Declining Contribution of Delayed TRIPS Implementation

Decline in the contribution of delayed TRIPS implementation to the rise of the sales of foreign firms for the compounds approved after 1995 is far more visible in the concentration of patented compounds in the case of selected therapeutic groups. See *Table 7.1 & 7.2* for the pattern of sales of pre-1995, post-1995 and patent expired compounds therapeutic group wise as on January 2015. Although we can also expect the barriers to entry for new companies on account of the increased secondary patenting all the products based on post-1995 APIs nut we have not investigated into this issue as yet. Due to the rapid growth in secondary patenting foreign firms can be still expected to emerge in a greater number as market leaders in the pharmaceutical retail market. Exporting domestic firms can also expect hurdles to emerge in the regulated markets of the US and EU for these compounds.

Table 7.1: Therapeutic Segment wise Sales of Pre-1995, Post-1995 and Expired Molecules

Therapeutic Areas (Number of Compounds)	*Pre-1995 (No. and % share of total sales*	*Post-1995 (No. and % share of total sales*	*Expired (No. and % share of total sales*	*Total (No. and % share of total sales*
Respiratory Disease (10)	4.00 (2.97)	2.00 (0.002)	4.00 (0.60)	10 (3.57)
Diabetes (34)	8.00 (0.68)	6.00 (3.64)	20.00 (23.21)	34 (27.53)
Cancer (34)	7.00 (0.49)	13.00 (0.61)	14.00 (0.81)	34 (1.91)
Blood related diseases (9)	2.00 (0.01)	5.00 (0.32)	2.00 (2.35)	9 (2.68)
Cardiovascular diseases (20)	5.00 (0.27)	4.00 (5.54)	11.00 (12.34)	20 (18.15)
CNS (48)	13.00 (4.34)	5.00 (0.96)	30.00 (2.01)	48 (7.31)
Skin Diseases (11)	1.00 (0.01)	1.00 (0.007)	9.00 (0.53)	11 (0.54)
Infections (39)	8.00 (1.34)	7.00 (0.29)	24.00 (3.82)	39 (5.45)
Genito urinary system and sex hormone (11)	2.00 (1.58)	2.00 (0.31)	7.00 (4.18)	11 (6.07)
Bone and Muscular diseases (14)	6.00 (0.08)	1.00 (0.033)	7.00 (0.40)	14 (0.51)
Diseases related to Sensory Organs (15)	5.00 (1.17)	2.00 (0.23)	8.00 (0.65)	15 (2.05)
Hormonal disorder (2)	1.00 (0.02)	-	1.00 (0.0003)	2 (0.023)
Drugs related to various diseases (5)	-	2.00 (0.03)	3.00 (0.11)	5 (0.14)

Source: Authors prepared dataset on AIOCD market data and Status of Primary Patents

Table 7.2: Therapeutic Segment wise Sales of Pre-1995, Post-1995 and Expired Molecules

Therapeutic Areas with Total no. of Molecules	*Sales of pre-1995 molecules 2015*	*Sales of post-1995 molecules 2015*	*Sales of Patent Expired molecule 2015*
Respiratory Disease (10)	4 (7338860437)	2 (6766279.9)	4 (1477120398)
Diabetes (34)	8 (1675405192)	6 (9001363860)	20 (57255991439)
Cancer (34)	7 (1205485828)	13 (1527884322)	14 (2009185160)
Blood related diseases (9)	2 (15475097.34)	5 (790463786.7)	2 (5787048132)
Cardiovascular diseases (20)	5 (655592050.3)	4 (13672968287)	11 (30453702621)
CNS (48)	13 (10711560300)	5 (2388576024)	30 (4953780874)
Skin Diseases(11)	1 (24054486.06)	1 (17427225.88)	9 (1312433791)
Infections(39)	8 (3296242015)	7 (720761200.4)	24 (9416307447)
Genito urinary system and sex hormone (11)	2 (3905787148)	2 (774318079)	7 (10313604283)
Bone and Muscular diseases (14)	6 (197996029.5)	1 (83278761.87)	7 (981939080.9)
Diseases related to Sensory Organs (15)	5 (2882470121)	2 (586311266.5)	8 (1591344191)
Hormonal disorder(2)	1(39064994.08)	-	1 (772727.17)
Drugs related to various diseases (5)	-	2 (66461992.28)	3 (263985033.2)

Source: Authors prepared dataset on AIOCD market data and Status of Primary Patents

Evidence of the Rise of Foreign Firms

Analysis brings out the therapy wise differences in the ability of foreign or domestic firm to use the patent as an instrument of market control for the establishment of market monopoly, market duopoly and market leader in the case of the post-1995 USFDA approved compounds by the DCGI and introduced in the retail pharmaceutical market by foreign and domestic firms. See *Table 8* for the details of compounds with foreign firms emerging as monopoly producers and the total number of companies active with regard to post-1995 compounds. See *Table 9* for the compounds introduced after 2010 which shows that twelve (12) out of twenty (20) compounds are single monopoly compounds with foreign firms controlling the market.

Table 8: Post 1995 Patented Compounds

Generic Name	*Applicant*	*FDA Approval Date*	*Number of Companies*	*Market Sales 2015 in %*
Abiraterone Acetate	Centocor Ortho Biotech Inc	28-Apr-11	8	0.036
Anidulafungin	Vicuron	17-Feb-06	1	0.025
Aprepitant	Merck	27-Mar-03	9	0.017
Arsenic Trioxide	Cell Therapeutics	25-Sep-00	2	0.008
Atazanavir	Bristol-Myers Squibb	20-Jun-03	5	0.077
Bortezomib	Millennium Pharms	13-May-03	14	0.196
Celecoxib	Gd Searle	31-Dec-98	12	0.033
Cetrorelix Acetate	Serono	11-Aug-00	12	0.054
Crizotinib	Pfizer Inc	26-Aug-11	1	0.023
DabigatranEtexilateMesylate	BoehringerIngelheim Pharmaceuticals Inc	19-Oct-10	1	0.102
Dasatinib	Bristol-Myers Squibb	28-Jun-06	1	0.003
Deferasirox	Novartis	02-Nov-05	2	0.008
EltrombopagOlamine	Glaxosmithkline	20-Nov-08	1	0.014
Eptifibatide	Schering	18-May-98	11	0.037
Erlotinib Hydrochloride	Osi Pharms	18-Nov-04	9	0.110
Fondaparinux Sodium	Fonda Bv	07-Dec-01	4	0.140
Gabapentin Enacarbil	Glaxo Group Ltd DbaGlaxosmithkline	06-Apr-11	73	0.740
Gefitinib	Astrazeneca	05-May-03	24	0.113
Indacaterol Maleate Inhalation Powder	Novartis Pharmaceuticals Corp	01-Jul-11	1	0.000
Insulin Aspart Recombinant	Novo Nordisk	07-Jun-00	1	0.764
Insulin Glulisine Recombinant	Aventis Pharms	16-Apr-04	1	0.044
Ixabepilone	Bristol-Myers Squibb	16-Oct-07	1	0.005
Lacosamide	Schwarz Biosciences	28-Oct-08	10	0.055
Lanthanum Carbonate	Shire Pharm	26-Oct-04	5	0.018
Lapatinib	Glaxosmithkline	13-Mar-07	1	0.010

Generic Name	*Applicant*	*FDA Approval Date*	*Number of Companies*	*Market Sales 2015 in %*
Lenalidomide	Celgene	27-Dec-05	8	0.039
Linagliptin	BoehringerIngelheim Pharmaceuticals Inc	02-May-11	1	0.332
Liraglutide	Novo Nordisk Inc	25-Jan-10	1	0.080
Lopinavir; Ritonavir (New Drug-Lopinavir)	Abbott Labs	15-Sep-00	7	0.020
Micafungin Sodium	Fujisawa	16-Mar-05	1	0.055
OlmesartanMedoxomil	Sankyo	25-Apr-02	37	2.259
Oseltamivir Phosphate	Hoffmann-La Roche	27-Oct-99	4	0.006
Pazopanib Tablet	Glaxosmithkline	19-Oct-09	1	0.009
Poractant Alfa	Dey Labs	18-Nov-99	1	0.002
Posaconazole	Schering	15-Sep-06	1	0.063
Raltegravir Potassium	Merck	12-Oct-07	2	0.016
Ramelteon	Takeda Global	22-Jul-05	1	0.009
Ranolazine	Cv Therapeutics	27-Jan-06	16	0.259
Retapamulin	Glaxosmithkline	12-Apr-07	2	0.007
Rivaroxaban	Johnson And Johnson Pharmaceutical Research And Development Llc	01-Jul-11	1	0.000
Rosuvastatin Calcium	IrpAstrazenca	12-Aug-03	58	2.730
Saxagliptin	Bristol Myers Squibb Co	31-Jul-09	1	0.361
Silodosin	Watson Labs	08-Oct-08	8	0.202
Sitagliptin Phosphate	Merck	16-Oct-06	3	2.002
Solifenacin Succinate	Yamanouchi	19-Nov-04	5	0.101
SorafenibTosylate	Bayer	20-Dec-05	3	0.017
Sunitinib Malate	Pfizer	26-Jan-06	1	0.030
Tapentadol	Ortho Mcneiljanssen	20-Nov-08	20	0.105
Ticagrelor	AstrazenecaLp	20-Jul-11	1	0.118
Tolvaptan	Otsuka America Pharmaceutical Inc	19-May-09	6	0.097
Travoprost	Alcon Universal	16-Mar-01	10	0.093
Varenicline	Pfizer	10-May-06	1	0.025

Source: Authors prepared dataset on AIOCD market data and Status of Primary Patents

Table 9: Compounds Introduced during 2010-2015

Generic Name	*Applicant*	*FDA Approval Date*	*Market Sales 2015 in %*	*Number of Companies*
Abiraterone Acetate	Centocor Ortho Biotech Inc	28-Apr-11	0.036	8
Cabazitaxel	Sanofi Aventis Us Inc	17-Jun-10	0.039	1
Clobazam	LundbeckInc	21-Oct-11	0.522	26
Crizotinib	Pfizer Inc	26-Aug-11	0.023	1
DabigatranEtexilateMesylate	BoehringerIngelheim Pharmaceuticals Inc	19-Oct-10	0.102	1
Eslicarbazepine Acetate	Sunovion Pharms Inc	08-Nov-13	0.021	6

Generic Name	*Applicant*	*FDA Approval Date*	*Market Sales 2015 in %*	*Number of Companies*
Gabapentin Enacarbil	Glaxo Group Ltd DbaGlaxosmithkline	06-Apr-11	0.740	73
Indacaterol Maleate Inhalation Powder	Novartis Pharmaceuticals Corp	01-Jul-11	0.000	1
Ivabradine Hydrochloride	Amgen Inc	15-Apr-15	0.203	11
Linagliptin	BoehringerIngelheim Pharmaceuticals Inc	02-May-11	0.332	1
Liraglutide	Novo Nordisk Inc	25-Jan-10	0.080	1
Luliconazole	Medicis	14-Nov-13	0.059	1
Pirfenidone	IntermuneInc	15-Oct-14	0.057	2
Polidocanol	ChemischeFabrikKreussler And Co Gmbh	30-Mar-10	0.001	2
Rivaroxaban	Johnson and Johnson	01-Jul-11	0.000	1
Roflumilast	Forest Research Institute Inc	28-Feb-11	0.001	1
Sodium Picosulfate	Ferring Pharmaceuticals As	16-Jul-12	0.126	19
Ticagrelor	AstrazenecaLp	20-Jul-11	0.118	1
Tocilizumab	Genentech	21-Oct-13	0.000	1
Tocilizumab	Genentech, Inc.	08-Jan-10	0.000	1

Source: Authors prepared dataset on AIOCD market data and Status of Primary Patents

Analysis indicates that foreign firms have a significant percentage of market share in the case of products that are connected with therapies for diabetes, cancer, cardiac, urology, central nervous system and rejuvenation which fall in the category of acute and chronic conditions. Their sales are growing rapidly. Further see *Table 10* for the pattern of foreign firms' sales of 262 compounds as a percentage share of total sales in different therapeutic groups. See also *Table 11* which shows the sales and share of Indian and foreign firms in the case of post-1995 compounds in these therapeutic groups. as on January 2015 even today within the basket of sales of post-1995 patented compounds based on products of 262 new compounds domestic firms retain a share close to two third of sales. Foreign firms have a share of one fourth only in overall terms.

Table 10: Foreign Firms' Sales of 262 NMEs as a Share of Total Annual Sales (%)

	Feb10-Jan11	*Feb11-Jan12*	*Feb12-Jan13*	*Feb13-Jan14*	*Feb14-Jan15*
ANTI DIABETIC	23.1	25.4	26.4	25.1	25.8
ANTI MALARIALS	0.8	1.3	0.9	0.8	0.7
ANTI-INFECTIVES	2.1	2.4	2.9	2.7	2.6
ANTI-NEOPLASTICS	9.7	10.7	10.3	9.3	9.1
BLOOD RELATED	0.0	0.0	0.1	0.5	0.8
CARDIAC	6.9	7.2	7.2	6.8	7.6
DERMA	0.6	0.6	0.6	0.6	0.7
GASTRO INTESTINAL	2.1	2.1	2.0	1.7	1.8
GYNAECOLOGICAL	0.0	0.1	0.1	0.1	0.1

	Feb10-Jan11	*Feb11-Jan12*	*Feb12-Jan13*	*Feb13-Jan14*	*Feb14-Jan15*
HORMONES	0.1	0.0	0.1	0.1	0.0
NEURO / CNS	6.0	6.4	6.5	6.9	7.4
OPHTHAL / OTOLOGICALS	8.8	10.3	10.7	11.0	11.9
OTHERS	0.1	0.2	0.2	0.2	0.3
PAIN / ANALGESICS	3.2	4.0	4.3	4.7	4.6
RESPIRATORY	4.8	4.8	5.3	4.8	5.0
SEX STIMULANTS / REJUVENATORS	13.1	12.6	10.8	11.0	11.6
UROLOGY	10.0	11.5	11.1	10.7	12.0
Grand Total (includes all combinations and analogues of the 262 compounds)	**4.2**	**4.7**	**5.0**	**4.9**	**5.3**

Source: Authors prepared dataset on AIOCD market data and Status of Primary Patents

Table 11: Foreign and Domestic Firms' Sales and Shares of Post-1995 262 NMEs of Annual Sales of 2015

Therapeutic Groups	*Market size (MAT Jan 2015)*	*Market value and share of 262 NMEs based on MAT Jan 2015 (crores)*	*Sales and share of Indian firms in post-1995 NMEs (crores)*	*Sales and of foreign firms in post-1995 NMEs (crores)*
ANTI DIABETIC	6406	4882(76.2%)	3226(50.4%)	1656(25.8%)
ANTI MALARIALS	606	98(16.1%)	93(15.4%)	4(0.7%)
ANTI-INFECTIVES	13394	1448(10.8%)	1104(8.2%)	344(2.6%)
ANTI-NEOPLASTICS	1380	546(39.6%)	421(30.5%)	125(9.1%)
BLOOD RELATED	943	10(1.1%)	2(0.2%)	8(0.8%)
CARDIAC	10485	5550(51.6%)	4753(45.3%)	797(7.6%)
DERMA	4843	155(3.2%)	121(2.5%)	34(0.7%)
GASTRO INTESTINAL	9652	2752(28.5%)	2581(26.7%)	171(1.8%)
GYNAECOLOGICAL	4237	465(11.0%)	461(10.9%)	4(0.1%)
HORMONES	1414	17(1.2%)	17(1.2%)	1(0.0%)
NEURO / CNS	5107	2090(40.9%)	1713(33.5%)	377(7.4%)
OPHTHAL / OTOLOGICALS	1543	482(31.2%)	299(19.4%)	183(11.9%)
OTHERS	929	92(10.3%)	89(9.6%)	3(0.3%)
PAIN / ANALGESICS	5973	683(11.4%)	410(6.9%)	273(4.6%)
RESPIRATORY	6561	1899(28.9%)	1570(23.9%)	329(5.0%)
SEX STIMULANTS / REJUVENATORS	466	391(83.8%)	337(72.2%)	54(11.6%)
STOMATOLOGICALS	366	0	0	00.0
UROLOGY	896	491(54.8%)	384(42.8%)	108(12.0%)
VACCINES	1181	0	0	00.0
VITAMINS / MINERALS / NUTRIENTS	7635	0	0	00.0
	84018	**22049(26.1%)**	17581(**20.9%)**	4468(**5.3%)**

Source: Authors prepared dataset on AIOCD market data and Status of Primary Patents

Product Patents and Newer Compounds

There are eight hundred seventy seven (877) new chemical entities (NCEs) wherein foreign firms are not just dominating the emerging landscape of patented compounds in pipeline but also the pattern of concentration of ownership is a cause for worry. See *Table 12* for the emerging pattern of distribution of patents granted for NCEs to Novartis (84), Roche (76), Sanofi-aventis (73), Astrazeneca (62), Bayer (58), Pfizer (53), Boehringer Ingelheim (46), Smithkline Beecham (48), Aventis (44) and Janssen (39). Similarly it is also evident from the analysis of Table that the patents granted on NCEs. Table shows the pattern of indications targeted by the patentees in the case of patented granted NCEs during the period of 1995-2015. A large number of NCEs have been patented for the compounds targeting Anti-inflammation, Heart Diseases, Anti-Depressants, Cancer and Respiratory Diseases. See *Table 12 & 13* for the product patents granted on NCEs to the foreign firms in all the therapeutic groups in India. There is clear evidence from the emerging pattern of ownership of new chemical entities and their therapeutic groups that there is the need to keep a close watch on the pipeline in the light of the growing share of patented new chemical entities (NCEs) in the light of their importance for the changing domestic retail market for the consumption of new medicines in the case of non-communicable diseases.

Table 12: New Chemical Entities by Foreign Firms

Firms	*No of NCEs*	*NCE targeting for specific therapeutic area*	*NCEs not targeting specific therapeutic area*
Abbott	15	4	10
Allergan	8	3	4
Astrazeneca	62	36	28
Aventis	44	9	34
Bayer	58	5	38
Boehringeringelheim	46	14	32
Bristol- mayerssquibb	27	18	9
Eli lilly and company	34	9	29
Roche	76	45	33
Glaxo smith kline/glaxo group	35	11	24
H. Lundbeck	16	5	11
Janssen	39	17	24
Merck	13	7	6
Novartis	84	29	52
Novo nordisk		6	16
Pfizer	53	29	25
Sanofi-aventis	73	10	62
Altanapharma	18	8	7
Ortho mcneil	20	4	16
N.v. organon	22	5	17
Novozymes	17	2	15
Schering corporation	33	25	9

Firms	*No of NCEs*	*NCE targeting for specific therapeutic area*	*NCEs not targeting specific therapeutic area*
Smithklinebeecham	48	18	31
Solvay	22	10	12
Wyeth	14	6	8
Total	**877**	**335**	**552**

Source: Authors prepared dataset from AIOCD data and Status of Patents

Table-13: New Chemical Entities Targeted Specific Therapeutic Areas

	Antifungal/ Antibacterial/Antiviral	*Anti depressant*	*Anti-inflammation*	*HIV*	*Cancer*	*Diabetes*	*Heart Disease*	*Blood related disorders*	*Neurological disorder*	*Respiratory Diseases*	*Antilipemic/cytostatic/vasotropic/anorectic/Tranquilizer/contraception/migrane/modulator*	*Total*
Abbott	1	1	1		1							4
Allergan			1				2					3
Astrazeneca		2	15			3	8	2			6	36
Aventis	1		4		4							9
Bayer	1	1			3							5
Boehringer Ingelheim	4	1	6		1	1	1					14
Bristol- Mayers Squibb	1		8		1	2	3		2		1	18
Eli Lilly And Company	1	1	3		2		1	1				9
Roche		12	11		7	6	3				6	45
Glaxo Smith Kline/Glaxo Group		1	4		1		3			2		11
H. Lundbeck		3		1							1	5
Janssen	4	2	9		1						1	17
Merck		2	2				2				1	7
Novartis		2	13		3	1	7		1		2	29
Novo Nordisk			2			2					2	6
Pfizer	3	4	6		4	4	1				7	29
Sanofi-Aventis	1	1			1	1	5	1				10
Altana Pharma			1				7					8
Ortho Mcneil			2				1			1		4
N.V. Organon		2			1						2	5
Novozymes	2											2
Schering Corporation	1	4	10	2	2		3				3	25
Smithkline Beecham	8		1			5	4					18
Solvay		7					2				1	10
Wyeth		2	2								2	6
Total	**28**	**48**	**101**	**3**	**32**	**25**	**53**	**4**	**3**	**3**	**35**	**335**

Source: Authors prepared dataset from AIOCD data and Status of Patents

Patent Opposition and Market Power

Evidence also suggests that not just the rejection of product patent through the implementation of Section 3(d) has had a positive impact on access to medicines (Gleevac case is well known where the level of competition being provided by the domestic companies was sought to be resisted by Novratis, but also there are also other kind of patent oppositions that have played a positive role in the reduction of market power that foreign firms can obtain through the patents on products. Sudip Chaudhuri (2011) gives the well-known examples of two important post-1995 products, Novartis' anti-cancer drug, imatinibmesylate and Gilead's anti-HIV/AIDS drug, tenofovirdisoproxilfumarate to underline the role of patent opposition[6]. There are many more examples of successful patent oppositions using various sections whose details are available in *Table 14*.

In the case of Darunavir the positive role has been played by the successful opposition mounted to the method for the synthesis of an intermediate of darunavir (prezista). It was rejected under the sections (u/s) 25(1)e, (f), section 3(d). Rejection was mounted in the case of Gefitinib u/s 25(1)e, 3(d), 2(1)(j). In the case of Adefovir Diivoxil rejection came u/s 25(1)e, 3(d), 2(1)(j). Patent on lopinavir + ritonavir deemed was abandoned under Section 15 when Applicant's agent did not appear for hearing. More examples are available namely Oxcarbazepine, Oseltamivir Phosphate, Abacavir Sulfate, Nevirapine, Valsartan, Glatiramer Acetate, Glimepride + thiazolidinedione, Atorvastatin Calcium, Zidovudine / Iamivudine, Valagancyclovir, S-Omeprazole trihydrate, Salmeterol Xinafoate, Teriparatide, Tetrahydrolipistatin, Ascomycin and Benzoquinolizines.

The impact of patent oppositions mounted is evident from *Table 15*. Domestic firms have been able to emerge as market leaders in the case of many important molecules. Cipla Ltd. is a leader in Daraunavir, Sorafenib Tosylate, Adefovir Dipivoxil, Tenofovir Disoproxilfumarate, Lopinavir in combination with Ritonavir, Abacavir Sulfate and Nevirapine. Natco Pharma Ltd is a market leader in the cases of Erlotinib Hydrochloride, Gefitinib, Imatinib Mesylate and Glatiramer Acetate. Zydus Cadila is a market leader in the case of Atrovastatin Calcium. Usv Ltd is a market leader in the case of Glimepiride. Torrent is a market leader in the case of Valsartan. Shares of originator companies are smaller in all

[6] Product patents are in force in the United States for these products. But for both these products the original compound – imatinib and tenofovir - were disclosed before 1995. What actually have been patented are a particular (beta crystalline) form (mesylate) and a particular salt (disoproxilfumarate). Hence these are not patentable in India subject to the enhanced efficacy clause of Section 3(d). Patent Office/High Courts have rejected these patent applications. The matter is currently with the Supreme Court.In the absence of any legal barrier to enter these markets a number of Indian generic companies are manufacturing and selling these products in the market. There are 14 companies selling imatinibmesylate and 6 companies selling tenofovirdisoproxilfumarate. Another product where the MNC product patent has been contested relates to the anti-cancer drug, erlotinib. This is manufactured by 6 Indian companies.

these cases. Calculations show close to four (4) per cent of the total sales of 2015 can be attributed solely to the positive impact of patent oppositions on access to medicine in India.

Domestic firms will certainly see more of their competitive advantage eroding for those compounds where many of the patented NCEs are already under clinical trials in phase III in India.

Table 14: TRIPS Flexibilities, Patent Oppositions and Post-1995 Compounds

Generic Name	*Flexibilities - Successful Opposition, Cl Etc.*
Darunavir	Method for the synthesis of an intermediate of darunavir (prezista) rejected u/s 25 (1)(e), (f), section 3(d); darunavir Rejected u/s 25(1)(e), (f), (g), 3(d)
SorafenibTosylate	CL
Erlotinib Hydrochloride	Patent was granted with amended claims (Need details on both patents). Subsequently, the patent was upheld against infringement by Cipla; Roche settled patent dispute with Glenmark in January 2016
Gefitinib	Patent rejected u/s 25(1)(e), 3(d), 2(1)(j)
AdefovirDipivoxil	adefovirdipivoxil Rejected u/s 25(1)(e),2(1) j, 25(1)(f), 3(d)
TenofovirDisoproxilFumarate	Patent for tenofovir (TD) rejected u/s 25(1)(e), (f), (g), 3(d); Patent for tenofovirdisoproxilfumarate (TDF) rejected u/s 25 (1)(b), (e), (f), 3(d); Patent for tenofovirdisoproxilfumarate + emtricitabine rejected u/s 25 (1)(e), (f), 3(d), 3(e), 2(1)(ja)
ImatinibMesylate	Patent for imatinibmesylate rejected u/s 25(1)(e), (f), 3(d), 25(1)(g)
LOPINAVIR In Combination With Ritonavir	Patent on lopinavir + ritonavir deemed abandoned; Patent for lopinavir rejected section 15 (Applicant's agent did not appear for hearing)
Oxcarbazepine	Rejected u/s 25(1)(d), (e)
Oseltamivir Phosphate	oseltamivir Rejected u/s 25(1)(e), (g), 3(d)
Tolterodine Tartrate	patent granted after amended claims.[Need to explore why no monopoly]
AbacavirSulfate	patent withdrawn due to pre grant opposition
Cefepime Hydrochloride	Cefepime/ amikacin - Applicant ordered to narrow down claims to only that which is supported by example & test data. Who had filed for patent (venus?)
Nevirapine	nevirapine hemihydrate pre grant, 25(1)(e), 3(d), 3(e)
Valsartan	amlodipine + valsartan rejected u/s 25(1)(e) ; valsartan Rejected u/s 25 (1)(b), (c), (d),(e), (f), (g), (h) (or u/s 15??)
Glatiramer Acetate	Rejected u/s 25(1)(e), 2(1)(j), 3(d)
Atorvastatin Calcium	Rejected u/s 2(1)(g), 3(d); Amlodipine + atorvastatin rejected u/s 25(1)(e), 3(d), 3(e), 25(1)(g)
Glimepiride	Glimepiride+thiazolidinedione rejected u/s 25(1)(e), 3(e). What about patent on Glimepiride?
Zidovudine/ Iamivudine	Opposition filed on u/s 3(d); Patent Application withdrawn
Valgancyclovir	Granted but revoked later on the grounds of obviousness & section 3(d)

Generic Name	*Flexibilities - Successful Opposition, Cl Etc.*
Omeprazole	Rejected u/s 25(1)(e), 2(1)(j), 3(d)' S-omeprazole trihydrate rejected u/s 25(1)(e), 2(1)(j)(a), 3(d)
SalmeterolXinafoate	Rejected u/s 25(1)(e), 2(1) j, 25(1)(f), 3(d),25(1) (g)
Teriparatide	Rejected u/s 3(d) & 3(e)
Tetrahydrolipstatin	Rejected u/s 25(1)(e)
Ascomycin	Rejected u/s 25(1)(e), 2(1)(ja), 3(d)
Benzoquinolizines	Rejected u/s 3(d), 2(1)(j), 25(1)(d)
Ascomycin	Rejected u/s 25(1)(e), 2(1)(ja), 3(d)
Benzoquinolizines	Rejected u/s 3(d), 2(1)(j), 25(1)(d)

Source: Authors prepared dataset on the basis of information provided by Feroz Ali on patent oppositions

Table 15: TRIPS Flexibilities, Patent Oppositions and Market Structure

Generic Name	*DCGI Earliest Approval Date*	*Originator Marketing In India*	*Market Leader*	*Share of Market Leader (%)*	*Share of Originator (%)*	*Market Sales 2015 Crores*
Darunavir	19-Mar-09	Tibotec	Cipla Ltd. (Indian)	56.7%	none	3.3
SorafenibTosylate	31-Jul-07	Bayer	Cipla Ltd. (Indian)	56.80%	43.10%	4.3
Erlotinib Hydrochloride	13-Jul-05	Hoffmann-La Roche	NatcoPharma Ltd (Indian)	80.40%	3.80%	28.2
Gefitinib	17-Feb-04	AstraZeneca	NatcoPharma Ltd (Indian)	46.30%	15.90%	28.8
AdefovirDipivoxil	03-Apr-04	Gilead Sciences	Cipla Ltd. (Indian)	43.70%	none	2.5
TenofovirDisoproxil Fumarate	17-Aug-05	Gilead Sciences	Cipla Ltd. (Indian)	48.20%	none	98.1
ImatinibMesylate	09-Dec-01	Novartis	NatcoPharma Ltd (Indian)	28%	0.20%	36.4
LOPINAVIR In Combination With Ritonavir	18-Jan-01	Abbott	Cipla Ltd. (Indian)	56.70%	5.90%	5.0
Oxcarbazepine	30-Oct-01	Novartis	Sun Pharma Laboratories Ltd. (Indian)	38.30%	12.80%	159.7
Oseltamivir Phosphate	25-Oct-05	Hoffmann-La Roche	Cipla Ltd. (Indian)	64.50%	none	1.6
Tolterodine Tartrate	13-Sep-01	PFIZER	RANBAXY LABORATORIES LTD (Foreign)	49.40%	2.70%	34.7
AbacavirSulfate	22-Mar-02	VIIV HLTHCARE	Cipla Ltd. (Indian)	97.80%	none	1.6
Cefepime Hydrochloride	30-Oct-02	HOSPIRA INC/ BMS?	Venus Remedies Ltd (Indian)	100%	none	2.3
Nevirapine	06-Mar-00	BOEHRINGER INGELHEIM	Cipla Ltd. (Indian)	42.20%	none	28.3

Generic Name	*DCGI Earliest Approval Date*	*Originator Marketing In India*	*Market Leader*	*Share of Market Leader (%)*	*Share of Originator (%)*	*Market Sales 2015 Crores*
Valsartan	10-Dec-01	NOVARTIS	Torrent Pharmaceuticals Ltd. (Indian)	49.90%	18%	31.3
Glatiramer Acetate	21-Feb-07	TEVA PHARMS USA	NatcoPharma Ltd (Indian)	59.80%	none	1.1
Atorvastatin Calcium	17-Sep-99	PFIZER	ZydusCadila (Indian)	13.70%	8/12%	1274.4
Glimepiride	22-Jan-99	SANOFI AVENTIS US	Usv Ltd (Indian	17.40%	7.70%	2191.6

Source: Authors prepared dataset from the information provided by Feroz Ali, patent lawyerand author who has written on patent oppositions

Delayed TRIPS Implementation, Market Leadership and Foreign Firms

Although there are many sources of market power, but when the competitive advantage is due to the product patent it is reflected in the ability of the firm to raise and maintain price above the level that would prevail under competition. This is already happening at an alarming scale in the case of imported or voluntary licence based compound sales. Foreign firms prefer to import medicines whose product patents are strong and enforceable. Their sales still do not show their share in the retail sales. It is possible that the share of patented medicines is underestimated because the retail market does not show the sales of products containing these APIs. This means that the impact of patented medicines is more than the estimates of January 2015 AIOCD data of the retail market. This indicates the need for a continuous system of monitoring of pharmaceutical market by the government in India.

There exists in the retail market a high level of concentration due to the growth of monopolies created through the route of brand loyalty among the physicians and patients in case of several products. It is also however evident that the monopolies will grow more rapidly on account of the implementation of product patents in the near future itself. See *Table 16 & 17* for the pattern of emergence of foreign and domestic firms as market leaders. Lack of technological know-how for the manufacture of biopharmaceuticals is known to have emerged in the recent period as a formidable barrier to competition in the case of some products that this study could not explore.

Competitive advantage of the foreign firms vis-a-vis the domestic firms is on the rise in the Indian pharmaceutical market. Domestic companies happened to be market leaders in close to eighty four (84) per cent of the products approved before 2005. Foreign companies were market leaders in only sixteen (16) per cent of the products approved before 2005. Analysis shows that foreign firms have been able to strengthen their market domination after 2005. Foreign firms are market leaders in thirty eight (38) per cent of the products that

contain APIs approved after 2005. See *Table 18 & 19* on the sales of 91 compounds out of 268 compounds where the concentrated market structure has emerged. Analysis of *Table 20* shows the company wise information on how foreign firms are market leaders in twenty three (23) compounds out of 30 post-1995 compounds.

Table 16: Pattern of Emergence of Foreign and Domestic Firms as Market Leaders

	Indian	*Foreign*
Number of market leaders	77 (62%)	48 (38%)
Number of monopolies	13	27
Number of companies involved in production post-2005 approved compounds	139	30

Source: Authors prepared datasets

Table 17: Pattern of Emergence of Foreign and Domestic Firms as Market Leaders

	Indian	*Foreign*
Number of market leaders	115 (84%)	22 (16%)
Number of monopolies	4	3
Number of companies involved in production pre-2005 approved compounds	372	38

Source: Authors prepared dataset from AIOCD data and Status of Primary Patents

Table 18: Monopolies, Market Leadership, Domestic and Foreign Firms

Patent Status	*No. of Compounds*	*Market Leader*		*Market Sales 2015*	
		Indian Firm	*Foreign Firm*	*Indian Firm*	*Foreign Firm*
Pre-1995	22	15	7	441549264.61 (0.12%)	308433064.94 (0.17%)
Post- 1995	30	7	23	378489574.49 (0.15%)	10463135498.14 (4.27%)
Patent Expired	39	31	8	1252148209.10 (0.50%)	926565655.95 (0.37)
Total	**91/268**	**53**	**38**		

Source: Authors prepared dataset from AIOCD data and Status of Primary Patents

Table 19: Market Leader and Sales of 91 compounds out of 268 compounds with Patent Status

Generic name	*Applicant*	*FDA Approval date*	*Patent Status*	*Number of companies in 2015*	*Market sales 2015*	*Market leader*	*Foreign/ Indian marker leader*
Aliskiren	Novartis	05-Mar-07	Pre 1995	1	8053525.26	Novartis India Ltd	Foreign
Anidulafungin	Vicuron	17-Feb-06	Post 1995	1	62921201.28	Pfizer Ltd	Foreign
Azacitidine	Pharmion	19-May-04	Patent Expired	1	19695281.7	Intas Pharmaceuticals Ltd	Indian

Generic name	*Applicant*	*FDA Approval date*	*Patent Status*	*Number of companies in 2015*	*Market sales 2015*	*Market leader*	*Foreign/ Indian marker leader*
Cefepime Hydrochloride	HospiraInc	18-Jan-96	Patent Expired	5	22509074.32	Venus Remedies Ltd	Indian
Ceftibuten Dihydrate	PernixTherap	20-Dec-95	Pre 1995	1	0	Fulford (India) Ltd.	Foreign
Cerivastatin Sodium	Bayer Pharms	26-Jun-97	Expired	1	0	Bayer Pharmaceuticals Pvt. Ltd.	Foreign
Crizotinib	Pfizer Inc	26-Aug-11	Post 1995	1	58245054.64	Pfizer Ltd	Foreign
Dabigatran EtexilateMesylate	BoehringerIngelheim Pharmaceuticals Inc	19-Oct-10	Post 1995	1	261656432	BoehringerIngelheim	Foreign
Dasatinib	Bristol-Myers Squibb	28-Jun-06	Post 1995	1	7416152.56	Bms India Pvt. Ltd.	Foreign
Decitabine	MgiPharma	02-May-06	Patent Expired	1	15248679.84	Sun Pharma Laboratories Ltd.	Indian
Eletriptan Hydrobromide	Pfizer	26-Dec-02	Pre 1995	1	6538559.7	Intas Pharmaceuticals Ltd	Indian
EltrombopagOlamine	Glaxosmithkline	20-Nov-08	Post 1995	1	36502058.19	Glaxosmithkline Pharmaceuticals Ltd.	Foreign
Fosfomycin Tromethamine	Zambon Spa	19-Dec-96	Patent Expired	2	34045054.2	Modi Mundi Pharma Pvt Ltd	Foreign
GalantamineHydrobromide	Janssen Research	28-Feb-01	Patent Expired	1	14819234.46	Sun Pharma Laboratories Ltd.	Indian
Indacaterol Maleate Inhalation Powder	Novartis Pharmaceuticals Corp	01-Jul-11	Post 1995	1	468190.66	Cipla Ltd.	Indian
Insulin Aspart Recombinant	Novo Nordisk	07-Jun-00	Post 1995	1	1955072871	Novo Nordisk India Pvt Ltd	Foreign

Generic name	*Applicant*	*FDA Approval date*	*Patent Status*	*Number of companies in 2015*	*Market sales 2015*	*Market leader*	*Foreign/ Indian marker leader*
Insulin Detemir Recombinant	Novo Nordisk	16-Jun-05	Pre 1995	1	140298096.3	Novo Nordisk India Pvt Ltd	Foreign
Insulin Glulisine Recombinant	Aventis Pharms	16-Apr-04	Post 1995	1	111694461.8	Sanofi India Ltd.	Foreign
Insulin Lispro Recombinant	Lilly	14-Jun-96	Patent Expired	1	765578131.2	Eli Lilly And Company (India) Pvt. Ltd.	Foreign
Ixabepilone	Bristol-Myers Squibb	16-Oct-07	Post 1995	1	13038681.6	Bms India Pvt. Ltd.	Foreign
Lapatinib	Glaxosmithkline	13-Mar-07	Post 1995	1	24869901.52	Glaxosmithkline Pharmaceuticals Ltd.	Foreign
Linagliptin	BoehringerIngelheim Pharmaceuticals Inc	02-May-11	Post 1995	1	849152666.4	BoehringerIngelheim	Foreign
Liraglutide	Novo Nordisk Inc	25-Jan-10	Post 1995	1	204260889.8	Novo Nordisk India Pvt Ltd	Foreign
Luliconazole	Medicis	14-Nov-13	Pre 1995	1	151129306.6	Ranbaxy	Foreign
Micafungin Sodium	Fujisawa	16-Mar-05	Post 1995	1	141638832.2	Glaxosmithkline Pharmaceuticals Ltd.	Foreign
Naratriptan Hydrochloride	GlaxosmithklineLlc	10-Feb-98	Patent Expired	1	4694743.9	Sun Pharma Laboratories Ltd.	Indian
Nateglinide	Novartis Pharms	22-Dec-00	Patent Expired	3	14529062.07	Glenmark Pharmaceuticals Ltd.	Indian

Generic name	*Applicant*	*FDA Approval date*	*Patent Status*	*Number of companies in 2015*	*Market sales 2015*	*Market leader*	*Foreign/ Indian marker leader*
Pazopanib Tablet	Glaxosmithkline	19-Oct-09	Post 1995	1	22526665.46	Glaxosmithkline Pharmaceuticals Ltd.	Foreign
Pegaptanib Sodium	Eyetech Pharms	17-Dec-04	Pre 1995	1	1212342.76	Pfizer Ltd	Foreign
Pentosan Polysulfate Sodium	Janssen Pharms	26-Sep-96	Patent Expired	1	42597804.32	Ranbaxy Laboratories Ltd	Foreign
Pitavastatin	Kowa Research Institute Inc	03-Aug-09	Patent Expired	1	63175845.75	ZydusCadila	Indian
Poractant Alfa	Dey Labs	18-Nov-99	Post 1995	1	6298089.24	Abbott Healthcare Pvt. Ltd	Foreign
Posaconazole	Schering	15-Sep-06	Post 1995	1	160741526.9	Msd Pharmaceuticals Private Ltd.	Foreign
Ramelteon	Takeda Global	22-Jul-05	Post 1995	1	22392888.52	Ranbaxy Laboratories Ltd	Foreign
Repaglinide	Novo Nordisk Inc	22-Dec-97	Patent Expired	6	197349323.6	Torrent Pharmaceuticals Ltd.	Indian
Rivaroxaban	Johnson And Johnson Pharmaceutical Research And Development Llc	01-Jul-11	Post 1995	1	468190.66	Bayer Pharmaceuticals Pvt. Ltd.	Foreign
Roflumilast	Forest Research Institute Inc	28-Feb-11	Pre 1995	1	2596909.08	Intas Pharmaceuticals Ltd	Indian

Generic name	*Applicant*	*FDA Approval date*	*Patent Status*	*Number of companies in 2015*	*Market sales 2015*	*Market leader*	*Foreign/ Indian marker leader*
Saxagliptin	Bristol Myers Squibb Co	31-Jul-09	Post 1995	1	922659448.8	AstrazenecaPharma India Ltd	Foreign
Sunitinib Malate	Pfizer	26-Jan-06	Post 1995	1	75614380.63	Pfizer Ltd	Foreign
Temsirolimus	Wyeth	30-May-07	Pre 1995	1	5280274.02	Pfizer Ltd	Foreign
Ticagrelor	AstrazenecaLp	20-Jul-11	Post 1995	1	300627757.8	AstrazenecaPharma India Ltd	Foreign
Varenicline	Pfizer	10-May-06	Post 1995	1	63319220.28	Pfizer Ltd	Foreign
Zafirlukast	Astrazeneca	26-Sep-96	Patent Expired	1	6727.5	Dr.Reddys Laboratories Ltd	Indian
Zaleplon	Wyeth-Ayerst	13-Aug-99	Patent Expired	6	3963.36	Cipla Ltd.	Indian
Zanamivir	GlaxoWellcome	26-Jul-99	Patent Expired	1	336537.65	Cipla Ltd.	Indian
Zileuton	Cornerstone Therap	09-Dec-96	Patent Expired	1	697613.08	ZydusCadila	Indian
Zolmitriptan	Ipr	25-Nov-97	Patent Expired	2	8500821.48	Cipla Ltd.	Indian
AbacavirSulfate	ViivHlthcare	17-Dec-98	Pre 1995	5	15522711.39	Cipla Ltd.	Indian
Almotriptan Malate	Pharmacia & Upjohn	07-May-01	Pre 1995	2	8935733.52	Lupin Ltd	Indian
Amifostine	Medimmune	08-Dec-95	Patent Expired	5	7969512.48	Fulford (India) Ltd.	Foreign
Amlexanox	Uluru	17-Dec-96	Patent Expired	2	8031211.14	Zuventus Healthcare Ltd	Indian
Arsenic Trioxide	Cell Therapeutics	25-Sep-00	Post 1995	2	20747540.7	Intas Pharmaceuticals Ltd	Indian
Balsalazide Disodium	Salix Pharm	18-Jul-00	Pre 1995	5	26240724.88	Torrent Pharmaceuticals Ltd.	Indian
Cinacalcet Hydrochloride	Amgen	08-Mar-04	Pre 1995	4	2242617.19	Panacea Biotec Ltd	Indian

Generic name	*Applicant*	*FDA Approval date*	*Patent Status*	*Number of companies in 2015*	*Market sales 2015*	*Market leader*	*Foreign/ Indian marker leader*
Conivaptan Hydrochloride	Astellas	29-Dec-05	Pre 1995	2	9229875.62	ZydusCadila	Indian
Darunavir	Tibotec	23-Jun-06	Pre 1995	2	32990641.42	Cipla Ltd.	Indian
Deferasirox	Novartis	02-Nov-05	Post 1995	2	21268857.87	Cipla Ltd.	Indian
DronedaroneHcl	Sanofi Aventis Us Llc	01-Jul-09	Pre 1995	2	2459520	Sanofi India Ltd.	Foreign
Exenatide	Amylin	28-Apr-05	Pre 1995	3	8664377.17	Sun Pharma Laboratories Ltd.	Indian
Ganirelix Acetate	Organon	29-Jul-99	Patent Expired	2	772727.17	Sun Pharma Laboratories Ltd.	Indian
Imiquimod	Medicis	27-Feb-97	Pre 1995	4	24054486.06	Glenmark Pharmaceuticals Ltd.	Indian
IndinavirSulfate	Merck Sharp Dohme	13-Mar-96	Patent Expired	5	3899806.57	Cipla Ltd.	Indian
Lubiprostone	Sucampo	31-Jan-06	Pre 1995	2	26822213.02	Sun Pharma Laboratories Ltd.	Indian
Nelfinavir Mesylate	Agouron	14-Mar-97	Patent Expired	2	388560.48	Cipla Ltd.	Indian
Oseltamivir Phosphate	Hoffman-La Roche	27-Oct-99	Post 1995	4	15553812.72	Cipla Ltd.	Indian
Pirfenidone	InterMuneInc	15-Oct-14	Pre 1995	2	145457004.6	Cipla Ltd.	Indian
Polidocanol	ChemischeFabrik Kreussler And Co Gmbh	30-Mar-10	Patent Expired	2	1472622.47	Samarth Pharma Pvt Ltd	Indian
Raltegravir Potassium	Merck	12-Oct-07	Post 1995	2	41545696.53	Msd Pharmaceuticals Private Ltd.	Foreign
Rasagiline Mesylate	Teva	16-May-06	Pre 1995	4	84994459.31	Sun Pharma Laboratories Ltd.	Indian

Generic name	*Applicant*	*FDA Approval date*	*Patent Status*	*Number of companies in 2015*	*Market sales 2015*	*Market leader*	*Foreign/ Indian marker leader*
Retapamulin	Glaxosmithkline	12-Apr-07	Post 1995	2	17427225.88	Ajanta Pharma Ltd	Indian
Tazarotene	Allergan	13-Jun-97	Patent Expired	6	13082296.04	Glenmark Pharmaceuticals Ltd.	Indian
Tegaserod Maleate	Novartis Pharms	24-Jul-02	Patent Expired	9	20733	Torrent Pharmaceuticals Ltd.	Indian
Tetrabenazine	Prestwick	15-Aug-08	Patent Expired	2	277898133.9	Sun Pharma Laboratories Ltd.	Indian
Topotecan Hydrochloride	Glaxosmithkline	28-May-96	Patent Expired	4	5652624.93	Fresenius Kabi India Pvt Ltd	Foreign
Triptorelin Pamoate	DebioRecherche	15-Jun-00	Pre 1995	2	39064994.08	Dr.Reddys Laboratories Ltd	Indian
Acamprosate Calcium	Lipha	29-Jul-04	Patent Expired	4	64298791.36	Sun Pharma Laboratories Ltd.	Indian
AdefovirDipivoxil	Gilead Sciences	20-Sep-02	Patent Expired	3	24742174.1	Cipla Ltd.	Indian
Bosentan	Actelion	20-Nov-01	Patent Expired	3	128343996	Cipla Ltd.	Indian
Candesartan Cilexetil	Astrazeneca	04-Jun-98	Patent Expired	5	2178933.45	MedichemPharmceuticals Ltd	Indian
Entacapone	Orion	19-Oct-99	Patent Expired	4	92932816.09	Sun Pharma Laboratories Ltd.	Indian
Eszopiclone	Sepracor	15-Dec-04	Pre 1995	4	8193957.61	Sun Pharma Laboratories Ltd.	Indian
Exemestane	Pharmacia & Upjohn	21-Oct-99	Patent Expired	4	36946319.82	Pfizer Ltd	Foreign
Fosphenytoin Sodium	Parke Davis	05-Aug-96	Patent Expired	4	114888180.3	ZydusCadila	Indian
Fulvestrant	Astrazeneca	25-Apr-02	Patent Expired	3	33776208.98	AstrazenecaPharma India Ltd	Foreign

Generic name	*Applicant*	*FDA Approval date*	*Patent Status*	*Number of companies in 2015*	*Market sales 2015*	*Market leader*	*Foreign/ Indian marker leader*
Irbesartan	Sanofi Aventis Us	30-Sep-97	Patent Expired	3	59441345.43	Sun Pharma Laboratories Ltd.	Indian
Lanthanum Carbonate	Shire Pharm	26-Oct-04	Post 1995	5	45193134.41	Panacea Biotec Ltd	Indian
Pimecrolimus	Novartis Pharms	13-Dec-01	Patent Expired	3	73236082	Ajanta Pharma Ltd	Indian
Sitagliptin Phosphate	Merck	16-Oct-06	Post 1995	3	5120472430	Msd Pharmaceuticals Private Ltd.	Foreign
Solifenacin Succinate	Yamanouchi	19-Nov-04	Post 1995	5	257830812.3	Cipla Ltd.	Indian
Valdecoxib	Searle Pharms	16-Nov-01	Patent Expired	34	185967.13	Glenmark Pharmaceuticals Ltd.	Indian
Ziprasidone Hydrochloride	Pfizer	05-Feb-01	Patent Expired	3	24766923.78	Sun Pharma Laboratories Ltd.	Indian

Source: Authors prepared dataset from AIOCD data and Status of Primary Patents

Table 20: Post-1995 Patented Compounds and Foreign firms as Market Leaders

Active Ingredient	*Applicant*	*FDA Approval Date*	*Priority Date*	*Number of companies in 2015*	*Market sales 2015*	*Market leader*
Anidulafungin	Vicuron	Feb 17, 2006	24-05-1995	1	62921201.28	Pfizer Ltd
Crizotinib	Pf Prism Cv	Aug 26, 2011	26-02-2004	1	58245054.64	Pfizer Ltd
DabigatranEtexilateMesylate	BoehringerIngelheim	Oct 19, 2010	24-11-1997	1	261656432	BoehringerIngelheim
Dasatinib	Bristol Myers Squibb	Jun 28, 2006	13-04-2000	1	7416152.56	Bms India Pvt. Ltd.
EltrombopagOlamine	Novartis Pharms Corp	Nov 20, 2008	31-10-1997	1	36502058.19	Glaxosmithkline Pharmaceuticals Ltd.
Insulin Aspart Recombinant	Novo Nordisk Inc	Jun 7, 2000	20-06-1996	1	1955072871	Novo Nordisk India Pvt Ltd
Insulin Glulisine Recombinant	Sanofi Aventis Ussanofi Aventis Us	Apr 16, 2004	20-06-1997	1	111694461.8	Sanofi India Ltd.

Active Ingredient	*Applicant*	*FDA Approval Date*	*Priority Date*	*Number of companies in 2015*	*Market sales 2015*	*Market leader*
Ixabepilone	R-Pharm Us Llc	16-Oct-07	04-12-1997	1	13038681.6	Bms India Pvt. Ltd.
Lapatinib	Novartis Pharms Corp	Mar 13, 2007	07-12-1996	1	24869901.52	Glaxosmithkline Pharmaceuticals Ltd.
Linagliptin	BoehringerIngelheim	May 2, 2011	21-08-2002	1	849152666.4	BoehringerIngelheim
Liraglutide Recombinant	Novo Nordisk Inc	Jan 25, 2010	26-02-1999	1	204260889.8	Novo Nordisk India Pvt Ltd
Micafungin Sodium	Astellas	Mar 16, 2005	07-10-1994	1	141638832.2	Glaxosmithkline Pharmaceuticals Ltd.
Pazopanib Tablet	Novartis Pharms Corp	19-Oct-09	21-12-2000	1	22526665.46	Glaxosmithkline Pharmaceuticals Ltd.
Poractant Alfa	ChiesiUsaInc	Nov 18, 1999	08-04-1987	1	6298089.24	Abbott Healthcare Pvt. Ltd
Posaconazole	Schering	Sep 15, 2006	02-06-1995	1	160741526.9	Msd Pharmaceuticals
Raltegravir Potassium	Merck Sharp Dohme	12-Oct-07	19-12-2006	2	41545696.53	Msd Pharmaceuticals Private Ltd.
Ramelteon	Takeda Pharms Usa	Jul 22, 2005	12-07-1996	1	22392888.52	Ranbaxy Laboratories Ltd
Rivaroxaban	Janssen Pharms	01-Jul-11	24-12-1999	1	468190.66	Bayer Pharmaceuticals Pvt. Ltd.
Saxagliptin	Astrazeneca Ab	31-07-2009	01-12-2011	1	922659448.8	AstrazenecaPharma India Ltd
Sitagliptin Phosphate	Merck Sharp Dohme	Oct 16, 2006	05-07-2002	3	5120472430	Msd Pharmaceuticals Private Ltd.
Sunitinib Malate	CppiCv	Jan 26, 2006	15-02-2001	1	75614380.63	Pfizer Ltd
Ticagrelor	Astrazeneca Lp	Jul 20, 2011	22-07-1997	1	300627757.8	AstrazenecaPharma India Ltd
Varenicline	Pfizer Inc	May 10, 2006	13-11-1998	1	63319220.28	Pfizer Ltd

Source: Authors prepared dataset from AIOCD data and Status of Primary Patents

Conclusion

Evidence on the nature of adverse impacts that the country can experience due to the introduction of product patent is building up slowly. It is even today inadequately incomplete. This will remain the case. There is the absence of regular monitoring of the

impact of patents on pharmaceutical market structure, production, prices, access and innovation. Earlier theoretical discussion took place in the absence of full information on the pros and cons of early and delayed implementation of TRIPS Agreement. Even today the actual impact of the introduction of product patent is being made by the government on the basis of inadequate information because information is not being collected by the government.

We do not have yet the relevant information required on the patents granted for the NCEs. Many of these NCEs will find their way into the market. Similarly though the patents filed in the mail box have been examined and granted but we do not have the required information. It is not therefore possible to assess how the granted NCE patents would impact in the near future on the pharmaceutical market and on the pharmaceutical innovation and access. We have been able to assess the therapeutic groups that are likely to be impacted on account of the patents granted on NCEs in an indicative way for the time being. Since the Indian patent office has also granted patent rights to a wide range of secondary patents on NCEs and NBEs all of these patents also need a separate impact evaluation.

Analysis shows that the favourable impact of delayed TRIPS implementation is largely on account of the successful public opposition put up to the early introduction of pharmaceutical product patent in India. The Department of Pharmaceuticals (DOP) does not have a ready list of patented drugs. The committee set up by the DOP started its work in 2006. But it has also not been able to suggest how which drug under product patent should be invoking what type of price control mechanism. A similar fate awaits the recommendations made by a committee on the Ministry of Health and Family Welfare on compulsory licensing. The committee set up for the establishment of legally valid evidence for the issue of compulsory licenses on the patented compounds is defunct.

Policymakers need to use the policy space earned and the safeguards introduced in the form of compulsory licensing provisions for full working of pharmaceutical product patents to provide remedial measures. Although domestic companies still have a good presence on account of the efforts made with regard to the use of delayed TRIPS implementation and patent oppositions, there is an urgent need to revitalise the policy capable of tackling industrial development, access and innovation in the light of the challenge arising out of the introduction of product patent on pharmaceutical compounds.

As far as the policy on the administration and enforcement of product patent is concerned, India needs to use the standards of full disclosure (enablement), novelty, inventive step and industrial application to keep out the trivial inventions from being patented in India. India also needs to use the CL provisions for commercial use, public interest and government use. This will help bring down the share of emerging product monopolies. India needs to keep a close watch on the prices of patented medicines. The MNCs have started marketing new patented drugs at exorbitant prices particularly for life-threatening diseases such as cancer, cardiac, CNS, Diabetes and Hepatitis through the marketing

arrangements being established with the help of new and old domestic pharmaceutical companies.

India needs to take the domestic firms out of the relations of dependence that domestic firms have become involved with through strategic alliances and collaborations with foreign firms for the introduction of new compounds and the development of new products. The Government of India should gear up the public sector research system to help the domestic firms in the busting of patents of new pharmaceutical products and the intermediates involved in their production. India should resist further strengthening of product patent monopoly. The model of patent based incentives for the development of innovators from among the domestic companies for the priority needs is also required to be revisited.

References

Arvind Subramanian (1995): 'Putting some numbers on the TRIPS pharmaceutical debate', DOI: http://dx.doi.org/10.1504/IJTM.1995.025626

Arvind Subramanian (1999): 'Intellectual Property Post-Seattle: Challenges for India as User and Creator', Paper presented at the Workshop on South Asia and the WTO, New Delhi, December 20-21, 1999

Arvind Subramanian (2004): Medicines, Patents, and TRIPS: Has the intellectual property pact opened a Pandora's Box for pharmaceuticals? In Health and Development, International Monetary Fund, Published December 2004, ISBN 1-58906-341-4

Athreye, S., Kale, D. and Ramani, S.V. (2009) "Experimentation with Strategy and the Evolution of Dynamic Capability in the Indian Pharmaceutical Sector", Industrial and Corporate Change, 18(4): 729-759.

Dinesh Abrol (2016): "The wrong incentive: The National Intellectual Property Rights Policy Must Be Opposed, http://www.epw.in/journal/2016/24/commentary/wrong-incentive.html#sthash.jjXZ35zC.dpuf

Dinesh Abrol (2016):"Who gains from National IPR Policy?" ISID Policy Brief, Institute for Studies in Industrial Development, New Delhi, July 2016, pp. 1-5

Dinesh Abrol, Pramod Prajapati and Nidhi Singh (2013): Innovation patterns, limits to learning and the pathway of neoliberal globalisation: evidence from Indian pharmaceutical multinationals, in Int. J. Technological Learning, Innovation and Development, Vol. 6, Nos. 1/2, 2013, pp. 102-135

Dinesh Abrol, Pramod Prajapati and Nidhi Singh (2011): Globalization of the Indian Pharmaceutical Industry: Implications for innovation, in International Journal of Institutions and Economies, Vol. 3, No. 2, July 2011, pp. 327-365

Abrol Dinesh (2004): "Post-TRIPs Technological Behaviour of the Pharmaceutical Industry in Dinesh India", Science, Technology & Society, 9(2): 243-271.

Chaudhuri Sudip (2011): "Multinationals and Monopolies: Pharmaceutical Industry in India after TRIPS", Working Paper Series Number 685, Indian Institute of Management Calcutta, http://facultylive.iimcal.ac.in/sites/facultyliveiimcal.ac.in/files/WPS%20685_0.pdf)

DIPP (2010): "Discussion Paper: Compulsory Licensing" (New Delhi: Department of Industrial Promotion and Policy, Government of India)

Frederick M. Abbott (2007): "The Problems of Intellectual Property in Latin America and How to Address Them", United Nations and ECLAC and GTZ, UNDP Panama City, June 20-21, 2007

Janice M. Mueller (2007): The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Industry Innovation -In Depth Analysis of Indian Patents Law, University of Pittsburgh Law Review68 U. Pitt. L. Rev. 491, spring, 2007

Basheer, Shamnad (2005): 'India's tryst with TRIPs: The Patent (Amendment)Act, 2005', in the Indian Journal of Law and Technology, 1: 15–46.

Amin Tahir(2011): "Re-visiting the patents and access to medicines dichotomy: an evaluation of TRIPs implementation and public health safeguards in developing countries, Electronic copy available at: http://ssrn.com/abstract=1573723

Jayashree Watal (2016): Patents: An Indian perspective, in the Making of the TRIPS Agreement Personal Insights from the Uruguay Round Negotiations,http://www.wto.ru/wp-content/uploads/2016/02/history_of_trips_nego_e.pdf#page=320

A.V. Ganesan (2016): Negotiating for India, in the Making of the TRIPS Agreement Personal Insights from the Uruguay Round Negotiations by Jayashree Watal and Antony Taubman (eds), 211- 240

Prashant Reddy (2014): TRIPS and TRIPS-Plus Development in India, in Intellectual Property, Trade and Development: Strategies to Optimize Economic Development in a TRIPS-Plus Era, Edited by Daniel J Geravis, Osxford University Press, 2014.

List of ISID Working Papers

190 FDI, Technology Transfer and Payments for Know-How: A Case Study of Automobile Sector, *Swati Verma & K.V.K. Ranganathan*, March 2016

189 Pharmaceutical Innovation and Contribution of In-house R&D of Domestic Firms after TRIPS in India, *Dinesh Abrol & Nidhi Singh*, March 2016

188 Impact of Mergers on Competition in the Indian Manufacturing: An Assessment, *Beena Saraswathy*, March 2016

187 Trends in Foreign Investment in Healthcare Sector of India, *Reji K. Joseph & K.V.K. Ranganathan*, February 2016

186 Industrial Finance in the Era of Financial Liberalization in India: Exploring Some Structural Issues, *Santosh Kumar Das*, December 2015

185 Private Sector in Healthcare Delivery Market in India: Structure, Growth and Implications, *Shailender Kumar*, December 2015

184 Growth and Distribution: Understanding Developmental Regimes in Indian States, *Kalaiyarasan A.*, October 2015

183 Foreign Exchange Use Pattern of Manufacturing Foreign Affiliates in the Post-Reform India: Issues and Concerns, *Swati Verma*, August 2015

182 India's Manufacturing Sector Export Performance: A Focus on Missing Domestic Inter-sectoral Linkages, *Smitha Francis,* May 2015

181 Foreign Investment in Hospital Sector in India: Trends, Pattern and Issues, *Shailender Kumar Hooda*, April 2015

180 India: Trade in Healthcare Services, *T.P. Bhat*, March 2015

179 Clinical trials industry in India: A Systematic Review, *Swadhin Mondal & Dinesh Abrol*, March 2015

178 Seaports, Dry ports, Development Corridors: Implications for Regional Development in Globalizing India, *Atiya Habeeb Kidwai & Gloria Kuzur*, February 2015

177 Determinants of Public Expenditure on Health in India: The Panel Data Estimates, *Shailender Kumar Hooda*, January 2015

176 Manufacturing Strategy in a Changing Context, *Nilmadhab Mohanty*, December 2014

175 Freight logistics & Intermodal Transport: Implications for Competitiveness, *Arvind Kumar*, December 2014

174 Industrial Policy: Its Relevance and Currency, *Biswajit Dhar*, December 2014

173 INDIA: Structural Changes in the Manufacturing Sector and Growth Prospect, *T.P. Bhat*, December 2014

172 Post-Fordism, Global Production Networks and Implications for Labour: Some Case Studies from National Capital Region, India, *Praveen Jha and Amit Chakraborty*, November 2014

---

* Most of the working papers are downloadable from the institute's website: http://isidev.nic.in/ or http://isid.org.in/

About the Institute

The Institute for Studies in Industrial Development (ISID), successor to the Corporate Studies Group (CSG), is a national-level policy research organization in the public domain and is affiliated to the Indian Council of Social Science Research (ICSSR). Developing on the initial strength of studying India's industrial regulations, ISID has gained varied expertise in the analysis of the issues thrown up by the changing policy environment. The Institute's research and academic activities are organized under the following broad thematic areas:

Industrialization: Land acquisition, special economic zones, encroachment of agricultural land, manufacturing sector, changing organized-unorganised sector relationship, rise of service economy in India, training and skill formation etc.;

Corporate Sector: With special emphasis on liberalization-induced changes in the structures of the sector, corporate governance, individual firms/groups, emerging patterns of internationalization, and of business-state interaction;

Trade, Investment and Technology: Trends and patterns of cross-border capital flows of goods and services, mergers & acquisitions, inward and outward FDI etc. and their implications for India's position in the international division of labour;

Regulatory Mechanism: Study of regulatory authorities in the light of India's own and international experience, competition issues;

Employment: Trends and patterns in employment growth, non-farm employment, distributional issues, problems of migrant labour and the changes in workforce induced by economic and technological changes;

Public Health: Issues relating to healthcare financing, structure of health expenditure across states, corporatisation of health services, pharmaceutical industry, occupational health, environment, health communication;

Media Studies: Use of modern multimedia techniques for effective, wider and focused dissemination of social science research to promote public debates;

Other Issues: Educational policy and planning, role of civil societies in development processes etc.

ISID has developed databases on various aspects of the Indian economy, particularly concerning industry and the corporate sector. It has created On-line Indexes of 230 Indian Social Science Journals (OLI) and 18 daily English Newspapers. More than one million scanned images of Press Clippings on diverse social science subjects are available online to scholars and researchers. These databases have been widely acclaimed as valuable sources of information for researchers studying India's socio-economic development.

ISID

Institute for Studies in Industrial Development
4, Institutional Area Phase II, Vasant Kunj, New Delhi - 110 070
Phone: +91 11 2676 4600 / 2689 1111; Fax: +91 11 2612 2448
E-mail: info@isid.org.in; Website: http://isid.org.in