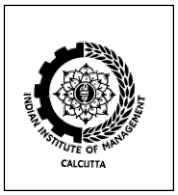

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Impact of Product Patents on Pharmaceutical Market Structure and Prices in India

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Impact of Product Patents on Pharmaceutical Market Structure and Prices in India

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ABSTRACT

Re-introduction of product patent protection in pharmaceuticals in India in line with TRIPS has led to a controversy about the impact on prices of patented medicines. Using a comprehensive database covering all the products in the market, we find that the pharmaceutical market is increasingly becoming monopolized and in the markets with limited competition, manufacturers have started charging very high prices at levels unheard of in the pre-TRIPS period. On the basis of a sample of products, the study also compares the market structure and prices of the patented products with that of not patented products and patent rejected products. The exercise throws interesting light on the impact of TRIPS in the pharmaceutical industry in India.

KEY WORDS: TRIPS, product patents, pharmaceuticals; monopolies, prices, biologics.

1. INTRODUCTION

To comply with the Agreement on the Trade Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organization (WTO), India has re-introduced product patent protection in pharmaceuticals from 1 January, 2005. Earlier, in 1972, India abolished such patent protection and this was one of the major factors behind the rise and growth of the pharmaceutical industry in India. And India began to be known as a source for supply of affordable high quality drugs for the entire world. Thanks to such supplies, millions of people in middle and low income countries get treatment for diseases such as HIV/AIDS. As India re-introduced product patent protection in pharmaceuticals, concerns have been expressed in different circles that patented medicines will become unaffordable.

Considering the controversy that TRIPS has generated, and the important role that India played in the debate, the absence of systematic empirical studies on the impact of TRIPS on market structure and prices is surprising. Most of the notable earlier studies are simulation exercises to find out the likely effects of product patent protection on drug prices and welfare loses (for

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example, Challu, 1991; Nogues, 1993; Fink, 2000; Watal, 2000; Chaudhuri, Goldberg, & Jia, 2003). The study by Chaudhuri, Goldberg, & Jia (2003) is the most comprehensive and for a sub-segment of the antibiotics market, it concludes that the loss of consumer welfare resulting from product patent protection will be substantial.

The objective of this paper to see what has really happened in post-TRIPS pharmaceutical formulations market[1] in India using not simulated data but relying on the actual experience. TRIPS was introduced more than two decades back. So we have a long enough period to examine the issue. In this regard, an exception is the study by Duggan, Garthwaite & Goyal (2016). On the basis of an analysis covering the entire pharmaceutical industry in India, it has estimated that the average price increase is not more than about 5% after patents are granted (pp. 102-3) and has concluded that concerns that TRIPS would result in dramatic prices are unfounded (p. 132). This paper contests such conclusions.

The basic logic is that product patent leads to monopoly and hence prices are higher than what would have been the case if there were no patent barrier to entry of generics. But it has been argued that prices of patented products may not necessarily be high. Prices depend on how firms responds and also on the regulatory environment. Measures such as price control and compulsory licensing can keep prices of patented medicines under check. In fact the mere threat of compulsory licences can constrain excessive price rise (Duggan et al., 2016, p. 101). The monopolist itself may not charge a high price. Patents may not be enforced. Even when it is enforced, depending on demand conditions and availability of close substitutes, the profit maximizing price may not be high (Duggan et al. 2016, pp. 101, 103, 122). But to know whether in reality prices are high or not, a concrete analysis of the market structure and information on product level prices are required.

The paper is classified into the following sections. In Section 2, we provide an overview of the implementation of TRIPS in India. This is important to understand the specific pharmaceutical market structure in India. In Section 3 we describe the data sources and methodology. We present our results in Section 4. In the last section we recapitulate and summarize the main findings.

In the first part of Section 4, using a comprehensive database covering all the products in the market, we will see that overall the market is quite competitive. Monopoly products account for only 2.3% of the market in 2015-16. The market share of products with two sellers is only 4.2%. But we will argue that it will be misleading to conclude that the impact of TRIPS has not been significant. The overall point estimate hides the degree of monopolization that is taking over time and also the high monopoly shares in several therapeutic groups including those for critical diseases such as cancer. Further, overall low monopoly shares do not mean that prices of monopoly molecules are low. We will in fact see that manufacturers have started charging very high prices at levels unheard of in the pre-TRIPS period.

But relatively, how high are these prices? A convenient method is to estimate the rise in average prices after product patents are granted. But average prices grossly underestimate the impact prices of patented medicines when the overall share of the patented market is small, as in India (see Sections 2 and 4 below). Moreover, if TRIPS has made product patenting mandatory, then

the impact must be assessed in terms of how high are the prices of patented medicines. In countries such as the United States, a common method to find the impact of product patent protection on prices is to compare the prices before and after patent expiry. Price erosion after patent expiry signifies the extent to which prices were higher under patents. In India the product patents of molecules introduced after TRIPS have expired for only for a few products. For these products, we will find out the extent of price erosion (see Section 4 below). But for all the other products for which patents have not yet expired, how do we find out the extent of monopoly patent pricing? To demonstrate that the price rise (of about 5%) after TRIPS in India is not significant, Duggan et al. (2016, p. 102) refer to the situation in the US where patented products on an average are about three times more expensive than the generic versions. But in the US, as we have mentioned, such estimates are based on comparisons of prices of the same molecule before and after patent expiry. When product patent for a molecules has not yet expired, with what does one compare?

Comparing the prices before and after the grant of compulsory licences is another option. But in India, compulsory licence has been granted for only one molecule. Product patents for some of the molecules have been denied or rejected in India (see Section 2 below). Comparison of the prices before and after patent rejection could also throw some light on the pricing of patented products. But we do not have time series data to attempt this exercise. Another method is to compare the prices of products under patents in one country with those of the same products in another country where product patents are not recognized. This could be done before TRIPS when most countries recognized product patents in pharmaceuticals but some countries such as India did not. In fact excessive pricing of patented antiretroviral drugs were exposed by Indian generic companies when they started supplying these products at a fraction of the patented price. But with product patents being in force now in all WTO members countries, this is no longer possible.

The method that we employ in this paper is to compare the market structure and prices in the three categories: (i) patented products; (ii) patented rejected products and (iii) not patented products. The first two categories are post TRIPS phenomenon. For the third category we have not considered the large number of products introduced before TRIPS and which are obviously not patented. We focus on the products which have been introduced in the post TRIPS period but which are not patented due to the specific background and circumstances in India. As elaborated in Section 3, we started with a representative sample of potentially patentable products and identified 135 molecules, 26 of which were found to be patented, 43 patent rejected and 66 not patented. In terms of sales, these account for 12%, 56% and 32% respectively of the total sales of Rs 77026 million of the 135 molecules. We are unable to estimate the extent to which prices of patented are high. To do so we need to wait till the patents expire. But this comparative exercise in the second part of Section 4 throws interesting light on the post TRIPS market structure and pricing in India.

2. IMPLEMENTATION OF TRIPS IN INDIA

TRIPS came into force on 1 January 1995. It aims at establishing strong minimum standards for patents and other intellectual property rights such as copyrights and trademarks. Under TRIPS, patents are mandatory "for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application" and the term of protection must be a minimum of 20 years from the date of filing. Before TRIPS, India recognized process patents but not product patents in pharmaceuticals. Hence India had to introduce product patent protection for pharmaceutical products. Articles 65.2 and 65.4 of TRIPS however permitted developing countries such as India which did not provide product patent protection, a transition period of ten years to implement the provisions of TRIPS. India opted for this option and hence introduced product patents in pharmaceuticals from 1 January, 2005. But as required under TRIPS, India was required to introduce a facility ("mail box") from 1 January, 1995 to receive and hold pharmaceutical product patent applications. These applications however could be and in fact were processed for grant of patents not before 1 January, 2005.

In view of India's past patent regime, the flexibilities which TRIPS provide and the way product patent protection has been introduced in India, the post TRIPS market structure is quite different in India compared to countries such as the United States.

Under Article 70(3) of TRIPS, a WTO member country has no obligation to provide patent protection for any subject matter which has fallen into the ‘public domain’ before WTO came into being, i.e., before 1 January 1995. Thus any drug patented abroad or for which an application has been made before 1995 can continue to be manufactured and sold in India after 1994 by generic companies even though these may be under patent protection in other countries such as the US which recognized product patents even before TRIPS.

Under TRIPS, any product or process involving "new" and "inventive step" must be patentable. But it has not defined these terms. This provides some flexibility. Developed countries, for example, the US, follow very liberal patent standards. Product patents can be granted not only for a new chemical entity (NCE) or a new biologic entity (NBE). Secondary patents are also possible for new chemical derivatives and other new forms of exiting molecules.

The Patents Act, 1970, as amended in line with TRIPS, defines the terms "new" and "inventive step." To be eligible for grant of a patent, the invention must involve a technical advance that is "not obvious to a person skilled in the art" (Section 2(1)(ja). Further under Section 3(d), new forms of existing NCEs/NBEs such as new combinations or new derivatives such as salts, esters, polymorphs will not be as treated as "inventions" and hence not patentable "unless they differ significantly in properties with regard to efficacy". These can be manufactured and sold in India after 1995 by any firm even when it may not be possible in other countries. Secondary patent applications are typically made after the primary patent on the base compound. Thus in

countries where secondary patents are more liberally granted, the market dominance of the patentees continue for a much longer period.

What is also significant is that in India anyone can oppose a patent application at any time even before the grant of a patent. Any such opposition needs to be heard before the patent office can grant a patent. Because of the specific provisions in India's patent act and also because of active opposition by many civil society organizations and generic companies, a number of patent applications have been rejected or withdrawn in India primarily under Section 2(1)(ja) and Section 3(d). (Appendix 1 provides a list of products for which patents have been denied).

Another feature of the Indian patent system is Section 11A(7). The patent applications made and kept in the mailbox were taken up for processing after 2004, but if granted the term of patent were to start from the date of filing of the patent. Not knowing what is there in the mailbox if a non-patentee had started manufacturing and selling a product before 2005 for a patent obtained after 2004, then under Section 11A(7), it can continue to manufacture and sell even after 2004 on payment of "reasonable royalty". This too can explain why even when some products are patentd protected, multiple companies may sell the product.

The market structure of patented products is also influenced by the compulsory licensing regime. As permitted under TRIPS, India's Patent Act has elaborate provisions of compulsory licensing. One of the grounds under which a compulsory licence can be made obtained is that the product is not available at a "reasonably affordable price". But in India as of now, only one compulsory licence has been granted (for an anti-cancer drug, Sorafenib). Only two other applications were made (for Dasatinib (cancer) and Saxagliptin (diabetes)) and both were rejected by the patent office.

3. DATA SOURCES AND METHODOLOGY

(a) Sales and price data

For sales and price data, we have used the Sales Audit Data, PharmaTrac of AIOCD Pharmasofttech AWACS Pvt Ltd (henceforth AIOCD-AWACS). This is a pharmaceutical market research company formed by the All Indian Origin Chemists and Distributors Ltd (AIOCD Ltd) in a joint venture with Trikaal Mediinfotech Pvt Ltd. It is based on sales data (institutional plus retail) of stockists.

This is a comprehensive data base which provides sales data for all the molecules with details of the brand, the company, the therapeutic group, the drug type (tablet, capsule, injection etc), the drug strength (5 mg, 100 ml etc), whether sold as a single molecule ("plain") or as combinations of two or more molecules ("combinations"). The data base for the period, 2011-12 to 2015-16 covers 2947 products (of which 1577 are plain molecules), sold by 915 companies in 94562 different SKUs. (The same molecule sold in different forms - tablets,

syrups etc - and in different strength are considered as separate SKUs).[2] AIOCD-AWACS also provides information on the month and year in which the molecule was launched in the Indian market (except for a small number of molecules). We have used the same data base for information on prices. It provides the maximum retail prices (MRP) for each of the 94562 SKUs.

(b) Patent data:

No such comprehensive database exists for patent data. Finding out the product patent status of molecules marketed is a very difficult exercise because of the absence of any data base linking the patent status with the molecules approved for marketing in countries such as India (Sampath & Shadlen, 2015). The patent status needs to be investigated individually using various sources as explained below. To make it manageable, we have attempted to search the patent status for a representative sample as elaborated below.

To start with, we focused on the potentially patentable molecules:

1. Monopoly molecules introduced in India between 1 January 1995 and 31 March 2016: All molecules sold by a single company are considered as monopoly molecules. Product patent protection usually leads to monopolies and hence some of the monopoly molecules are likely to have received product patents in India.
2. Molecules approved for marketing by the US Food and Drug Administration (USFDA) between 1995 and 2015 and introduced in India between 1 January 2005 and 31 March 2016: Under TRIPS, any molecule patented before the beginning of TRIPS on 1 January, 1995 is not patentable. Again after a patent is applied (and granted), it takes approximately 10 years for a molecule to be developed for getting marketing approval from drug control administration. Thus some molecules approved for marketing post 1994 (but patented before 1995) are not patentable in India. But some, especially those introduced 2005 onwards (i.e., 10 years after the introduction of TRIPS) may be patented and hence can be a good starting point for finding out the patent status.

For identifying the monopoly molecules, we have relied on the AIOCD-AWACS data base mentioned above. For molecules approved by USFDA for the years 1999 to 2015, we have accessed the year-wise lists of "New Molecular Entity (NME) Drug and New Biologic Approvals" available from the USFDFA website.[3] For New Molecular Entities approved by the USFDA between 1995 and 1998, we have relied on Chaudhuri, Park & Gopakumar (2010, Table 7 (pp. 160-70).[4]

The number of molecules common between the two groups is 350. This is too large a number for the painstaking exercise that needs to be followed for identifying the actual patent status. Hence we focus on a sample of 123 molecules.[5] For the monopoly molecules we have selected (i) the top 50 molecules (in terms of sales) out of the 265 post 1994 monopoly molecules sold whether by MNCs or others accounting for 93.8% of the total sales in 2015-16 and (ii) the top 50 molecules (in terms of sales) out of the 72 post 1994 monopoly molecules sold by MNCs

accounting for 99.3 % of the total sales in 2015-16. For the USFDA approved molecules, we have selected (i) all the 49 monopoly brands and (ii) the top 50 molecules out of the 135 post 2004 accounting for 92.3% of the total sales in 2015-16. Excluding the molecules common among these groups, the sample of 123 molecules account for 94.9% of the total sales of Rs 42904.70 of the 350 molecules in 2015-16.

(i) Patent search

Patent applications for a molecule are typically made in different countries. These are considered to be parts of the same family of patents. Locating any of these patent of the family in one country helps to find out the patents in other countries. We first try to identify the patent corresponding to a molecule in another country and then find the Indian equivalent. We narrow down the patent search to focus on product patents. Our objective is to find out whether there is a product patent - a patent on the product which prevents others from manufacturing and selling it. In this paper, we are not considering other types of patents, for example on process of manufacture or on particular types of formulations (for example sustained release tablets) which as such do not prevent the entry of any competing firm.

This requires expertise of both pharmaceutical science and patent law. Hence we hired the services of a registered patent agent with a post graduate degree in pharmacy. He was assisted by two other experts with background in pharmacy and law. They tried to find out the patent status of the 123 molecules following broadly the procedure that Sampath and Shadlen (2015) used (though the details of specific sources vary).

In USA, when seeking marketing approval for a drug, applicants are required to list the product patents relevant for that drug. The information is listed in "Approved Drug Products with Therapeutic Equivalence Evaluations" commonly known as the "Orange Book". For new chemical molecules for which patents have not yet expired, Orange Book information was used to locate foreign compound patents. For chemical compounds for which patents have expired and for biologic patents, for which information is not available in the Orange Book, a number of sources were used to locate the foreign patent or to find the oldest reference. The sources included DrugLead, DrugFuture, SciFinder, Newport and general and patent google search. Once the foreign patent was located, databases such as Newport, SciFinder, Orbit and Patseer were used to identify the Indian equivalent. The fact that India is a member of the Patent Cooperation Treaty (PCT), facilitates the task of locating the Indian equivalent of a foreign patent. Through PCT, single applications can be made in multiple countries. The information was filtered to focus on product patents and not on process patents. Once Indian equivalents were located, their legal status was determined by using the Indian Patent Advanced Search System (InPASS) of the Indian Patent Office (http://ipindiaservices.gov.in/publicsearch/). The claims of Indian patent applications were further checked from InPASS to identify the product patent.

We then added 36 molecules with sales of Rs 40532.34 million in 2015-16 which are not in the above sample of 123 molecules but which have been involved in patent disputes leading to the patent applications being rejected or revoked or abandoned or withdrawn. Some of these

disputes are yet to be resolved as the contending parties have approached appellate authorities and higher courts including the Supreme Court of India. The list of these patent rejected[6] molecules has been obtained from different sources including, India's Patent Office decisions listed in www.patentoppositions.org (accessed on 23 June, 2016); those summarized in Abrol, Dhulap, Aisola and Singh (2016); Nair, Fernandes and Nair (2014); Arora and Chaturvedi, (2016) and particularly for Section 3(d) cases, the supplementary materials provided by Sampath, Shadlen and Amin (2012).[7]

Thus the total number of molecules considered by us for patent analysis is 159 molecules with sales of Rs 81240 million. The results of the patent search are summarized in Table 1. Out of the 159 molecules, patent applications were found to have been rejected for 43 molecules. Product patents were granted for 20 molecules (designated in the table as "Patented-1"). For 6 molecules no Indian equivalent were located but the priority date of the foreign patents located are post 1994 and hence are considered as patented in India ("Patented-2"). We consider as Patented both "Patented-1" and "Patented-2". For 75 molecules, no Indian equivalent were located but the priority date of the foreign patents located are pre 1995. And hence these are considered as not patented in India. No patent could be located for 15 molecules. These however account for only 5.2% of the total sales of Rs 81240 million.

Thus we were able to locate whether there are products patents or not for 144 out of the 159 molecules accounting for about 95% of the total sales of our sample. However 9 of these were not sold in 2015-16, the reference year for analysing the patent status and price relationship in Section 4 and hence are not further considered. Finally therefore we will focus on 135 molecules, 26 of which were found to be patented, 43 patent rejected and 66 not patented. In terms of sales, these account for 12%, 56% and 32% respectively of the total sales of Rs 77026 million of the 135 molecules.

The 135 molecules are listed in Appendix 1. Apart from the patent status, the Appendix 1 also provides information on the market size (total sales in 2015-16), the number of brands (in 2015-16), the therapeutic group and the launch date. Appendix 2 provides for these 135 molecules the prices in March 2016 based on information obtained from the AIOCD-AWACS database as mentioned above. The brands refer to the names used by companies to market their products. To give an example, Bortezomib, an anti cancer drug, was sold in 2015-16 in 14 brands by different companies – as Velcade by Janssen, Proteoz by Zydus Cadila, Veltip by Pfizer, Bortenat by Natco Pharma and so on. MNC brands refer to the names used by MNCs to market their products, for example in this example, Velcade by Janssen and Veltip by Pfizer. In case of molecules sold in different types and strength, we have considered the type and the strength with the highest price (in 2015-16). In case of molecules sold by several companies, we have considered, the maximum price, the minimum price and also the median price.

4. RESULTS

(a) Monopoly and Market structure

(i) Overall

India is one of the major players in the global pharmaceutical industry. It is ranked 3rd by volume and 14th by value in the world (OPPI, 2016). It has emerged as a very important source of medicines for both developed and developing countries. Here we focus on the domestic pharmaceutical formulations market. During 2015-16, medicines worth Rs 984144 million were sold in 2947 molecules. Excluding one group of "unclassified molecules" and 181 molecules (1.6% of the total market in 2015-16) for which no information is available on the year of introduction), the total pharmaceutical market in 2015-16 was Rs 967159 million (2765 molecules). Out of these 2765 molecules, 696 are pre-TRIPS, i.e., introduced before 1995 (40 %of sales in 2015-16) and 2069 (60%) are post-TRIPS, i.e., introduced after 1994 (Table 2).

In Table 3, we compare the market structure of the molecules introduced before TRIPS with those after TRIPS. Not unexpectedly the market structure is very competitive for the pre-TRIPS molecules. Monopoly molecules (i.e., molecules with only one seller) account for only 0.2% of the total sales of all pre-1995 molecules in 2015-16. But even if we focus on the molecules introduced after 1994, the market is quite competitive. The market share of monopoly molecules is only 2.3% of the total market of Rs 580039 million of post 1994 molecules in 2015-16. The market share of molecules with two sellers is only 4.2%. The market share of molecules with more than 5 sellers is 88%, those with more than 10 sellers (79 %), more than 50 sellers (42.5 %) and more than 100 sellers (27.2 %) (Table 3).

BMI Research (2018, p. 25) has estimated that the sales of patented products accounted for 9.9% of the total sales in 2016. It is not clear how the figure of 9.9% has been arrived at. This seems to be an over estimate. Of course patented molecules may not necessarily be sold by a single seller. We will provide evidence below of patented products being licenced out to Indian generic companies for marketing. But these are typically done to one company for a particular molecule. If we consider the molecules with one or two molecules, the market share increase to only 4.2% (Table 3). Further as we will see below, some monopoly products are actually not patented. Hence even if we consider the figure of 4.2%, it over estimates the degree of patented molecules in India. Our estimates of molecules with limited competition are more in tune with the findings of Chaudhuri (2012) and Abrol, Dhulap, Aisola & Singh (2016). On the basis of information available from the websites of USFDA and India's Central Drugs Standard Control Organization (CDSCO) and using sales data from AIOCD-AWACS, Chaudhuri (2012) estimated the share of patented molecules to be 1.2% in 2010. Using a similar methodology, Abrol et al. (2016) estimated the percentage of patented molecules in total sales in 2015 to be 3.3%.[8]

It might be tempting to conclude on the basis of low market shares of molecules with limited competition as indicated in Table 3, that the impact of TRIPS has not been significant. But it would be misleading to do so. First, the overall point estimates hide the degree of monopolization that is taking over time and also the high monopoly shares in several therapeutic groups including those for critical diseases such as cancer. Second, overall low monopoly shares do not mean that prices of monopoly molecules are low. As we have pointed out in the context of the study by Duggan et al. (2016), even excessive prices of patented medicines may not be reflected in aggregate figures. Let us elaborate.

(ii) Year-wise monopoly and market structure

If we take not the aggregate figures for the entire post 1994 period, but the more recent years, we see that the proportion of monopoly brands is much higher (Table 4). The share of sales of monopoly brands among the plain and combination molecules introduced during 1995 to 1999 was only 0.4% and for those introduced during 2000 to 2004, only 1.88%. But sharp increases are observed since 2010. The monopoly share rose to 5.78% during 2010 to 2012 and to 25% during 2013 to 2015. Thus compared to less than 1% in the earlier years of TRIPS, about a fourth of the molecules introduced in later years of TRIPS are monopolized. As we have noted, several patented molecules are licensed out to other firms for marketing purposes. If we consider the molecules with two brands, the degree of monopolization is even higher at 36.8% during 2013 to 2015. A similar picture emerges if as in Table 5, we focus only on the plain molecules.

Cancer is currently the second most common cause of deaths in India (after cardiovascular disease) (http://cancerindia.org.in/cancer-factsheet/). A competitive market structure and affordable prices are extremely important for the treatment of this critical disease. But as Table 6 shows the market for anti-neoplastics (anti-cancer) drugs has become highly monopolized after TRIPS in India. None of the cancer drugs introduced during 1995 to 1990 were monopoly molecules. But the proportion of monopoly molecules has increased from 6.4% during 2000 to 2004 to 18.8% during 2010 to 2012 and to 59.5% during 2013 to 2015. The molecules with two brands account for about two-thirds of the market during 2013 to 2015.

The low monopoly share in the earlier years of TRIPS is a reflection of the patent regime that existed in India before the introduction of TRIPS in 1995. And the higher monopoly share in later years of TRIPS is the result of TRIPS. There is a gap between the time a molecule is patented and when it is introduced in the market after developing the product and after getting regulatory approved. Molecules patented anywhere in the world and hence in public domain before 1995 were not eligible for product patents in India and hence there were no legal barrier to entry of generics in India. For example a molecule patented in the US in 1986 and introduced in the US market in 1996 would enjoy monopoly status there till the expiry of the patent (say in 2006). Not so in India. But 1995 onwards, molecules are eligible for patenting and hence when ready for the market after a gap, generic entry could be prevented. The trend toward monopolization as indicated in Tables 4 to 6 is likely to intensify in future. Quite naturally, with the passage of time, the impact of the pre TRIPS regime is expected to be weaker and more and more new molecules introduced would be those which are protected by product patents.

(iii) Therapeutic group wise monopoly and market structure

The degree of monopolization in currently high not only in the anti-neoplastics market, but also in several other therapeutic groups.

Medicines are classified into different broad therapeutic groups (referred to as "super groups" in the AIOCD-AWACS darabase), such as nti-diabetic, cardiac, anti-neoplastics (anti-cancer), neuro/CNS, gastro intestinal, respiratory, anti-infectives, pain/analgesics, blood related and so on. Each of these super groups is further classified into finer "groups". For example cardiac medicines are further classified into beta blockers, fibrates, heparins, statins, anti-arrhythmics, calcium antagonists and so on.

The 223 post 1994 monopoly molecules worth Rs 9860 million of sales in 2015-16 can be classified into 132 therapeutic groups. The sales of 38 of these groups are negligible. We focus in Table 7 on the 94 groups, each with sales of monopoly brands of more than Rs 100,000 accounting for about 99.9% of the total sales of the 132 groups. In 12 groups, monopoly molecules account for 100% of the entire group's sales. This includes groups such as Insulin analogues premix (anti-diabetic), Anti-TNF products (anti-neoplastics), Trichomonacides (anti-infectives), Lung surfactants (respiratory). For 6 groups, the share of monopoly molecules is between 50% and 100%, for example, Non-steroidal respiratory anti-inflammatories (respiratory). For another 5 groups the share of monopoly groups is between 25% and 50%, for example, Cystostatic hormones (anti-neoplastics). It is less than 10% for 66 groups. But these account for only 21.5% of the total sales of these monopoly molecules. The monopoly molecules with share of 50% or more account for 34.9% of the total sales (Table 7).

(iv) Prices of monopoly products

We focus here on 119 monopoly brands with sales of Rs 9579.36 million accounting for about 95% of all the monopoly brands introduced after 1994.[9]

As can be seen from Table 8, one product, Cabazitaxel is priced at Rs 3,30,000. Two other products (Trabectedin and Cetuximab) are priced above Rs1,00,000. Fifteen products are priced above Rs 10,000 accounting for 13% of sales of the monopoly molecules. Thirty nine products are priced above Rs 1,000 accounting for 34.6% of sales of the monopoly molecules.

All the 5 most costly medicines - Cabazitaxel, Trabectedin, Cetuximab, Ixabepilone and Nimotuzumab - are anti-neoplastics. For the monopoly molecules priced more than Rs 1000, anti-neoplastics account for 31.3%. These prices are for a single unit – single injection/tablet/capsule. The cost of treatment for many of these molecules is much more. For example the price of a 40 Mg tablet of Regorafenib is Rs 1,311.80 (Table 8). This medicine used for the treatment of colorectal cancer needs to be taken for several cycles of 21 days each. At this price, the first cycle costs about Rs 82000 and each subsequent cycle every 28 days Rs 1,10,000.[10] If this is the cost of treatment of a drug with unit price of around Rs 1,000, the cost of treatment of those with much higher prices can be well imagined.

Among the other high priced products are Alteplase, Rs 49,899 (Blood related); Abatacept, Rs 30,000 (pain – treatment of rheumatoid arthritis); Porractant Alfa, Rs 19395.55 (respiratory), Posaconazole, Rs 17,440 (anti infective); Resburicase, Rs 14,423.07 (detoxifying agents for anti-neoplastics treatment).

Such high prices and high cost of treatment were unheard of in the pre TRIPS period. A new era of monopoly markets and high prices has started and the products are becoming unaffordable. The number of monopoly molecules is still not very high. But as argued above, as degree of monopolization intensifies, more high priced products in all probability would be coming to the market. But beneficiaries of new products introduced in the market are limited. The sales volume of most of the high priced products are relatively low, for example Trabectedin (sales of Rs 2.62 million in 2015-16); Ixabepilone (Rs 1.59 million); Tocilizunab (Rs 0.55 million); Abatacept (Rs 5.38 million). Among the few products with significant sales but excessive prices are Alteplase (Rs 435.36 million); Bevacizumab (Rs 509.75 million); Liraglutide (Rs 363.38 million) and Micafungin (Rs 122.70 million) (Table 8). If the products were priced at lower levels, potentially more people in India who finance medicine purchase out of own pocket, would be able to afford these products.

(v) High prices of multi brand products

It may not be irrelevant here to point out that high prices are not restricted to only monopoly molecules. Some of the multiple brand products, particularly biologic products are also priced very high. In Table 9, we have listed 15 biologics priced above Rs 10,000 per injection in 2015-16.

Unlike chemically synthesized small molecule traditional medicines, biological medicines are large complex molecules typically derived from living organisms using biotechnology (for example recombinant DNA technology). The latter are more difficult and costlier to manufacture. But biologics also face regulatory barriers. As product patents expire, other firms can enter the market. But the entry of generic products is more difficult in biologics compared to traditional chemical products. The differences between biologics and conventional drugs have influenced regulatory agencies to follow different regulatory processes for granting approval of generic versions. For getting regulatory approval for chemical products, it is considered adequate for generic companies to demonstrate pharmaceutical equivalence and bioequivalence between the generic and innovator products. Pre-clinical and clinical data are not required to establish the safety and efficacy of the product. But in the case of generic versions of original biologics (commonly referred to as biosimilars), regulatory authorities in different countries including India subject biosimilars to additional pre-clinical and clinical testing to demonstrate similar structural characteristics and safety and efficacy. What justifies such a stricter requirement for biosimilars is the view often propounded and supported by innovator biotechnology firms such as Amgen (2017) is that because of the complexity of manufacturing processes and reliance on living cells, no two products can be considered as identical unless clinical trials are done.

But here too the virtues of competition is evident. As can be seen from Table 9, some of the injectable biologics available in the Indian market are priced exorbitantly high. But with passage of time as more firms enter the market, cheaper substitutes are available. For example the prices of a single injection varies between Rs 79,992 and Rs 37,500 for Rituximab; between Rs 75,000 and Rs 52,154.19 for Trastuzumab; between Rs 60,360 and Rs 12,500 for

Bortezomib; between Rs 28,333.32 and 16,350 for Reteplase; between Rs 10147.50 and Rs 1469.52 for Epoetin Alfa.

Trastuzumab is a good example of the barriers which generic manufacturers face and also how prices fall when competition intensifies. Roche introduced the product in the Indian market in 2002 with a price tag of Rs 1,25,000 for a single vial. As the campaign for more affordable Trastuzumab gained momentum, Roche reduced the price to Rs 75,000. In 2013 Roche withdrew its patent application in India. But it continued to enjoy the monopoly status until Biocon and Mylan developed a biosmilar in 2014. But Roche filed a suit against the Indian drug regulator for granting marketing approval of the biosimilar. The Delhi High Court delivered a judgment against Roche in 2017 and upheld the licence granted by the regulator. Significantly, in the same year, in response to a complaint filed by Biocon and Mylan, the Competition Commission of India ordered a detailed probe against Roche noting that prima facie Roche seems to have indulged in anti-competitive practices (Rajagopal, 2017). After the favourable court ruling, another firm has entered the market and the 440 mg injection is available at a price of Rs 38690.47 from August 2017.

Justifiably the impact of product patent protection on prices of medicines has received world-wide attention. But simplifying regulatory barriers to entry of generics in biologics is also very important considering the rising importance of biologics in critical illness such as cancer.

The regulatory environment which biologics face today in the US and elsewhere is not basically different from what chemical products faced in the US before the Hatch-Waxman Act of 1984. It was felt necessary that generic companies must repeat the costly clinical trials to establish the safety and efficacy of generic products. That made generic entry difficult. In fact the USFDA estimated that by 1984 there were no generic equivalents for about 150 drugs whose patents have expired (Federal Trade Commission, 2002, pp. 3-4). The rise of generics is attributed to the revolutionary change that the Hatch-Waxman Act brought about by exempting generic companies from repeating costly clinical trials. A similar revolutionary change is required in the regulatory environment for biosimilars.

(b) Product Patents and Market structure

To find out how high or low patented prices are, prices can be compared before and after patent expiry. Let us do so for the three molecules for which product patents have expired in India – Cabazitaxel, Micafungin and Luliconazole.

In March 2016, the costliest medicine in India was Cabazitexal. It was protected at that time by a patent and Emcure - in terms of a marketing arrangement with Sanofi – was the sole seller, charging a price of Rs 3,30,000 for a 60 Mg, 1 Ml injection. With the entry of the first generic product in June 2016, the price reduced to Rs 32359.46. Thereafter with the entry of additional generic companies in the market, the price fell to Rs 32359.46 in October 2016, Rs 19947.5 in March 2017 and then to Rs 18947.87 in August 2017. The enormity of excessive

pricing under patents is demonstrated by the fact that after generic entry, the price erosion that has taken place is about 94% (Table 10).

Similarly the price erosion that has taken place in Luliconazole after patent expiry is about 33%. Ranbaxy introduced the patented medicine, Luliconazole in India in January 2010 under licence from a Japanese firm, Summit.[11] In March 2016, it was the sole supplier and charged a price of Rs 299 for 20 GM cream. After patent expiry, by June 2018 there were 39 other sellers and it is available at Rs 199.

Much smaller price erosion of about 9% is observed for Micafungin. GSK introduced it in May 2010 and charged a price of Rs 5911 for 50 MG injection, 1 Ml. By June 2018, three other sellers were there in the market. GSK reduced its price to Rs 5602.85 and it is available from a generic company at Rs 5389.03.[12]

The above exercise naturally cannot be done for the products for which patents are yet to expire. We have reported above high absolute levels of prices of monopoly products. But we could not compare these with the thousands of molecules sold by multiple sellers. As explained in the Introduction, we focus on a sample of 135 molecules, 26 of which were found to be patented, 43 patent rejected and 66 not patented. We analyse the market structure and pricing of these three categories of products to see what light it throws on the impact of TRIPS in the pharmaceutical industry in India.

(i) Market competition

Out of the 26 patented products in our sample, 20 are monopoly brands (76.9%) (Table 11). There can be multiple sellers for patented products in case of voluntary licensing or compulsory licensing. As part of formal marketing arrangements, Dr Reddys, for example sells Astraeneca's product, Saxagliptin; Lupin sells Boehringer Ingelheim's, Linagliptin; Sun Pharmaceuticals sells AstraZeneca's products, Ticagrelor and Merck's (MSD)'s product Sitagliptin.[13] The share of molecules with one or two sellers is 88.4% (Table 11).

Presence of multiple sellers for patented products can also be due to Section 11A(7). Under this Section, for products marketed before 2005 but patent obtained after 2004, non-patentees can continue to sell these products (on payment of royalty) (see Section 2 above).

For the 43 patent rejected products, the presence of multiple sellers is over whelming. But even here there are 4 products sold by a single seller. This might reflect the hesitancy on the part of the generic companies to enter the market till the legal proceedings are fully over. Patents rejected by the patent office and lower courts are often challenged at higher courts including in the Supreme Court of India.

But what is surprising is that 33 out of the 66 not patented products (50%) are sold by a single seller. As can be seen from Appendix 1, for most of these products, MNCs are the sole sellers. Even after product patents expire, because of various other barriers including, manufacturing and regulatory, generic companies may be unwilling or unable to enter the market. Hence MNCs can continue to dominate the markets. Examples of innovator companies continuing to

dominate the market even after patent expiry include Janssen for Trabectedin; Roche for Tocilizunab; BMS for Abatacept; Pfizer for Idarubicin and Novartis for Aliskiren.

Apart from the entry barriers that may exist, it may also reflect the lack of interest of other firms to enter due to small size and poor profit prospects. It is significant that whereas 50% of the not patented products have only one seller, their proportion in sales is only 7.2%. For about 90% of the market, there are 5 or more sellers in the case of not patented products.

(i) Prices

If we compare the prices of monopoly products in Table 8 with the prices of patented products in Appendix 2, we find that not surprisingly, many products are common and are highly priced including, Cabazitaxel (Rs 3.30,000), Cetuximab (Rs 1,01,110), Ixabepilone (Rs 71,175), Bevacizumab (Rs 41,250).

The same Appendix also shows that some of the not patented molecules are also highly priced. A single injection, for example costs Rs 1,21,485.68 for Trabectedin; Rs 73660 for Pemetrexed; Rs 60360, for Bortezomib; Rs 51,241.92 for Nimotuzumab; Rs 40,600 for Tocilizunab; Rs 30,000 for Abatacept. Some of the patent rejected products too are highly priced, for example, Teriparatide (Rs 23,462) and Paclitaxel (Rs 19,825.57). Some of these high priced not patented products are biologics, for example Bortezomib, Nimotuzimab, Tocilizumab and Abatacept. We have discussed above that in biologics, even in the absence of patent protection, because of manufacturing and regulatory barriers, prices can be high.

But overall, as Tables 12 and 13 show, both in terms of number and sales, the proportion of higher priced products is higher in the patented category compared to the patent rejected category. Between the patented and not patented categories too the proportion is higher for the former but the difference is much smaller.

There are no patent rejected molecules costing more than Rs 25,000. Four out of 26 patented molecules are priced above Rs 10,000, compared to 2 out of 43 patent rejected molecules and 9 out of 66 not patented molecules. Considering price per unit of Rs 1000 as a bench mark, we find that there are 40 products priced more than Rs 1000 and out of these:

- Patented products are 11 in number (42.3% of the 26 patented molecules) with sales of Rs 1743.77 million (18.6% of total sales of patented molecules of Rs 9380.05 million)
- Patent rejected products are 7 in number (16.3% of the 43 patented rejected molecules) with sales of Rs 4236.55 million (9.9% of total sales of patent rejected molecules of Rs 42805.68 million)
- Not patented products are 22 in number (33.3% of the 66 not patented molecules) with sales of Rs 4092.22 million (16.5% of total sales of not patented molecules of Rs 24840.37 million).

Probing further the data provided in Appendix 1 and 2, several insights can be obtained about the market structure and prices in post TRIPS India.

The prices that we have considered above are the highest prices for the molecule concerned. Unlike in the case of monopoly patented products, cheaper substitutes are available for many of the high priced patent rejected and not patented molecules. For example whereas the maximum price for Pemetrexed, a not patented product is Rs 73,660, it is also available at Rs 4,500. The price of not patented, Bortezomib varies between Rs 60,360 and Rs 12,500. The prices of patent rejected molecules molecules, Teriparatide and Paclitaxel vary between Rs 23,462 and Rs 6,900 and between Rs 19, 825.57 and Rs 7,380.95 respectively.

The high priced patented products (for example those priced higher than Rs 1000) are sold by MNCs directly with the exception of the costliest drug, Cabazitaxel. It is sold by an Indian company, Emcure under a licence from the patentee, Sanofi. Several Indian companies are involved in marketing of patented products including larger ones such as Sun, Dr Reddys, Lupin. The prices of the 8 patented products sold by Indian companies are relatively very low: 6 of these vary between Rs 25.90 and Rs 51.00; and 2 products between Rs 155.00 and Rs 740.00. What is striking is not only that the prices are low. There is practically no difference between the MNC and Indian prices where both are involved in marketing.

Most of the high priced products whether patented or not are medicines used for critical diseases such as cancer. All the nine products costing more than Rs 40,000 are anti-neoplastics. Out of the 20 products priced above Rs 5000, 15 are anti neo-plastics. Among the remaining five are a product (Abatacept) used for pain for treatment of rheumatoid arthritis and a hormone (Teriparatide) used for the treatment of osteoporosis.

All the 20 products each with sales of more than 1% of the total sales of the 135 molecules are relatively low priced (less than Rs 622) except two products, Pacilitaxel and Sofosbuvir, both patent rejected with prices of Rs 19,825.57 and Rs 1990 (Appendix 1 and 2). But for both these products, cheaper substitutes with prices of Rs 7380.95 and Rs 661.90 respectively are available. The 15 products priced more than Rs 10,000 constitute only 5.59.1% of total sales and 40 products with prices more than Rs 1000, 13.1% of total sales. Apart from Pacilitaxel (sales of Rs 1531.51 million in 2015-16) and Sofosbuvir (Rs 1252.40 million), other higher priced products with substantial sales include Caspofungin Acetate (Rs 749.79 million), Teriparatide (Rs 723.18 million), Tigecycline (Rs 665.32 million), Bevacizumab, (Rs 509.75 million), Fondaparinux (Rs 414.98 million) etc.

5. RECIPITULATION AND SUMMARY

Using a comprehensive database covering all the products in the market, we found that the market structure in post-TRIPS pharmaceutical market in India on the whole is quite competitive. The monopoly molecules account for only 2.3% of the total sales of Rs 580039 million in 2015-16 of the molecules introduced in 1995 or later. The market share of molecules with two sellers is only 4.2%.

It would be misleading, however to conclude on the basis of such low market shares of molecules with limited competition that the impact of TRIPS has not been significant. These are overall point estimates and hide the degree of monopolization that is taking place over time. Compared to less than 1% in the earlier years of TRIPS, about a fourth of the molecules introduced in later years of TRIPS are monopolized. If we focus on the anti-neoplastics drugs used for the life threatening disease, cancer, we find that the increase in the degree of monopolization is even sharper. The share of monopoly molecules among the molecules introduced during 2013 to 2015 is more half and the share of molecules with two sellers about two-third. For some finer therapeutic groups, we found that the entire group sales are monopolized by a single seller, for example in renin inhibitor (cardiac), anti-TNF (cancer), lung surfactants (respiratory).

The low monopoly share in the earlier years of TRIPS is a reflection of the patent regime that existed in India before the introduction of TRIPS in 1995. Molecules patented anywhere in the world and hence in public domain before 1995 were not eligible for product patents in India even if introduced after 1994. Hence there were no legal barrier to entry of generics in India. But 1995 onwards, molecules are eligible for patenting and hence when these ready for the market, generic entry could be prevented. The higher monopoly share in later years of TRIPS is the result of TRIPS. Quite naturally, with the passage of time, with the impact of the pre TRIPS regime weakening that of TRIPS becoming stronger, the trend toward monopolization as expected to further intensify in future.

Linked to the monopolization of the market, we observe exorbitant prices of some of the monopoly molecules. Thirty products are priced more than Rs 1,000/- accounting for about one-third of the total sales of the monopoly molecules. Fifteen products are priced more than Rs 10,000/-; 5 products more than Rs 50,000/-; three products more than Rs1,00,00/- and even one more than Rs 3,00,000/-. All these are unit prices. Depending on the duration of the treatment, the cost of treatment is much more.

Such high absolute levels of prices and high cost of treatment were unheard of in the pre TRIPS period. The number of monopoly molecules is still not very high. But with the increase in monopolization that is expected in future, more high priced products in all probability would be coming to the market. This is a matter of serious concern.

But relatively, how high are these prices? For Cabazitaxel, which was the costliest product in March, 2016 (Rs 3,30,000 for a single injection), the product patent has since expired. The enormity of excessive pricing is demonstrated by the fact that after patent expiry and entry of generics, the price has eroded by about 94% by June, 2018. But this method cannot be applied for all the other products except the other two drugs for which product patents have expired (for these too price erosion has taken place though not by the same degree). Hence we cannot estimate the precise extent to which patented prices are high. To do so we will have to wait till the patents expire. And as in the case of Cabazitaxel, it is possible that for other patented monopoly products too, sharp price erosion will be observed.

But as a second best solution, what we have done is to compare the prices of patented products with those of others. We considered a sample of post TRIPS potentially patentable molecules and compared the market structure and prices of products where patents were granted with those where patents could not be obtained or where patents were rejected.

Overall, both in terms of number and sales, the proportion of higher priced products is higher in the patented category compared to the patent rejected category. Between the patented and not patented categories too the proportion is higher for the former but the difference is much smaller.

The analysis of prices throw some interesting light on the post-TRIPS pharmaceutical market in India. The innovator MNCs dominate not only patented markets. In several molecules, they continue to be the monopoly seller even the expiry of product patents. High prices are observed not only for some patented products but also for some not patented and patent rejected products. But a crucial difference is that unlike in the case of patented products, for the other two categories some cheaper substitutes are available. Most of the high priced products are in the critical diseases areas such as cancer. Again most of the high priced products have relatively lower volume of sales. If the products were priced at lower levels, potentially more people in India who finance medicine purchase out of own pocket, perhaps would be able to afford these products.

To ensure that new medicines are affordable, it is important to utilize all the flexibilities that TRIPS permit. Section 3(d) has been used in India to deny some product patents, most famously in the case of the anti-cancer drug Imatinib mesylate (sold by Novartis as Glivac in India). The benefit in this case is clear: there are 15 sellers of the product in India and the lowest price at which it is available in the market is Rs 74 for a 400 mg tablet. But new drugs which are currently under patents, for example those listed in Appendix 1 or those which will be patented in future will continue to be under monopoly till the patents expire. The more powerful flexibility that TRIPS permit is compulsory licensing. The high prices of patented medicines are a good enough reason to grant compulsory licences for more products. But compulsory licence has been granted in India for only one molecule – Sorafinib, permitting generic entry and availability of the product at Rs 70.48 for a 200 mg tablet compared to the patentee's price of Rs 2437.21 in March 2016.

Another flexibility which India can utilize is to control the price of patented drugs. Price control is not forbidden under TRIPS or any other agreement of the WTO. India has an elaborate drug price control system. But it is applied only to generic products. The government has not yet introduced any price control schemes for patented products. But the difference between price control measures and compulsory licensing must be noted. If the price is controlled, the MNCs holding the patent may discontinue to sell the product in India. In the case of compulsory licensing, generic entry can reduce the price independent of how the patentees react.

But patent is not the only barrier which generic companies face. They also face manufacturing and regulatory barriers especially for biologic products. In India the prices of several biologics

are very high despite the absence of product patents. A major factor is the stricter regulatory process applicable to biologics. Unlike in the case of chemically synthesized small molecule traditional medicines, for getting regulatory approval for generic versions of original biologics (biosimilars), clinical testing needs to be repeated to establish the safety and efficacy of the product. Justifiably the impact of product patent protection on prices of medicines has received world-wide attention. But simplifying regulatory barriers to facilitate the entry of generics in biologics is also very important considering the rising importance of biologics in critical areas such as cancer treatment.

Table 1: Patent search results

	No of molecules	Sales 2015-16, Rs million	Sales %
Patent rejected*	43	42805.68	52.7
Patented-1	20	8408.76	10.4
Patented-2	6	971.29	1.2
Not patented- pre 1995	75	24840.37	30.6
No patent located	15	4213.85	5.2
Total	159	81239.95	100.0

Sources and Notes: See text. Patented-1 includes patents for three products which have expired in 2016. *: "Patent rejected" includes those abandoned, revoked or withdrawn.

Table 2: Pharmaceutical formulations market in India, 2015-16

	Total number of molecules	Sales 2015-16, Rs million
1) Total molecules	2947	984144
2) Molecules with year of introduction data available	2765	967159
3) Pre 1995 molecules out of 2)	696	387120
4) Post 1994 molecules out of 2)	2069	580039
5) Plain molecules out of 2)	1467	537941
6) Pre 1995 plain molecules out of 5)	440	231899
7) Post 1995 plain molecules out of 5)	1027	306042

Source: Calculated from the AIOCD-AWACS data base (see text).

Table 3: Competition in pharmaceutical formulations market in India, 2015-16: Pre and Post-TRIPS (plain and combination molecules)

No of brands	Total number of molecules pre 1995	Total number of molecules post 1994	Pre 1995 Sales 2015-16 Rs million	Pre 1995 Sales 2015-16 (% of total)	Post 1994 Sales 2015-16 Rs million	Post 1994 Sales 2015-16 (% of total)
1	43	482	925	0.2	13595	2.3
2	44	272	1989	0.5	11308	1.9
3	33	169	2058	0.5	10387	1.8
4	45	122	4056	1.0	20968	3.6
5	27	93	2371	0.6	13155	2.3
6 to 10	110	340	19251	5.0	52439	9.0
11 to 20	143	267	43466	11.2	72597	12.5
21 to 50	145	216	83951	21.7	139251	24.0
51 to 100	52	68	58822	15.2	88828	15.3
> 100	54	40	170231	44.0	157511	27.2
TOTAL	696	2069	387120	100.0	580039	100.0

Source: Calculated from the AIOCD-AWACS data base (see text).

Note: The tables considers both plain and combination molecules. As explained in text, we have not taken in this table one group of "unclassified molecules" and 181 molecules for which no information is available on the year of introduction.

Table 4: Competition in pharmaceutical formulations market in India, 1995 to 2015 (plain and combination molecules)

Year(s) of introduction of molecules	Total number of molecules	Sales, 2015-16, Rs million	Share of monopoly brand in total sales	Share of molecules with two brands in total sales
Before 1990	450	270378	0.33	0.82
1990 to 1994	246	116742	0.03	0.59
1995 to 1999	388	177824	0.40	1.18
2000 to 2004	725	235199	1.88	2.84
2005 to 2009 exc 2007	379	100560	3.07	4.65
2010 to 2012	305	41132	5.78	15.98
2013 to 2015	169	11133	25.00	36.85
1995	62	29065	0.08	0.13
1996	61	23831	0.08	1.53
1997	86	25804	0.66	1.42
1998	104	67768	0.61	1.41
1999	75	31356	0.30	1.20
2000	186	68250	1.96	2.89
2001	127	43555	1.18	1.90
2002	162	51723	0.10	0.73
2003	124	39018	5.97	6.82
2004	126	32653	0.57	2.55
2005	105	32455	0.30	1.18
2006	96	27109	9.58	10.12
2008	89	22032	0.83	4.17
2009	89	18963	1.12	3.34
2010	124	21804	4.43	10.46
2011	104	8318	6.16	14.42
2012	77	11010	8.14	28.09
2013	53	4076	34.01	37.76
2014	74	3733	20.14	47.04
2015	42	3324	19.41	24.31

Source: Calculated from the AIOCD-AWACS data base (see text).

Note: The table considers both plain and combination molecules. We have not considered, one group of unclassified molecules. In the database that we have used, the molecules for which no information on year of introduction is available have been shown as introduced in April 2007 (i.e., when the database started). We have not considered the molecules introduced in the year 2007.

Table 5: Competition in pharmaceutical formulations market in India, 1995 to 2015 (plain molecules)

Year(s) of introduction of molecules	Total number of molecules	Sales, 2015-16 in Rs million	Share of monopoly brand in total sales	Share of molecules with two brands in total sales
Before 1995	440	231899	0.05	0.85
1995 to 1999	230	125208	0.30	0.67
2000 to 2004	382	110434	2.78	4.02
2005 to 2009 exc 2007	169	42658	6.29	7.85
2010 to 2012	112	11894	14.09	40.15
2013 to 2015	68	5860	31.80	36.69
1995	38	20955	0.00	0.00
1996	38	16553	0.12	0.36
1997	49	18377	0.05	0.66
1998	59	49534	0.50	0.57
1999	46	19790	0.48	1.88
2000	103	26447	0.37	2.28
2001	74	33378	1.53	2.33
2002	87	19069	0.17	0.99
2003	63	24192	9.53	10.37
2004	55	7348	1.62	4.97
2005	44	15840	0.24	0.96
2006	37	11789	20.35	20.74
2008	42	11006	1.12	3.85
2009	46	4023	3.00	8.17
2010	47	5271	15.43	32.54
2011	36	2410	6.14	13.71
2012	29	4213	16.96	64.81
2013	25	2022	60.15	60.15
2014	24	878	9.68	41.26
2015	19	2960	19.01	19.32

Source: Calculated from the AIOCD-AWACS data base (see text).

Note: The table considers only plain molecules. We have not considered the molecules introduced in the year, 2007 - see Notes to Table 7).

Table 6: Competition in anti-neoplastics market in India, 1995 to 2015 (plain molecules)

	No of molecules	Sales 2015-16, Rs million	Share of monopoly brands in total sales	Sales of molecules with 2 brands in total sales
Before 1994	15	1464.65	0.0	7.2
1995 to 1999	9	2334.72	0.0	0.0
2000 to 2004	37	8011.23	6.4	7.3
2005 to 2009	29	2210.71	7.9	7.9
2010 to 2012	12	1038.28	18.8	18.8
2013 to 2015	10	557.94	59.4	65.3
1995	0	0.00	0.00	0.00
1996	2	6.56	0.0	0.1
1997	2	539.28	0.0	0.0
1998	3	1712.42	0.0	0.0
1999	2	76.46	1.2	1.2
2000	11	1617.81	0.0	0.0
2001	7	2017.49	25.3	25.7
2002	8	2070.86	0.0	0.0
2003	5	1269.96	0.0	4.0
2004	6	1035.12	0.0	1.9
2005	1	97.17	0.0	0.0
2006	3	251.86	6.3	6.3
2007	15	1749.06	5.1	5.1
2008	5	45.57	91.3	91.3
2009	5	67.05	41.6	41.6
2010	5	895.66	10.5	10.5
2011	5	49.45	16.0	16.0
2012	2	93.18	100.0	100.0
2013	4	452.27	57.3	57.3
2014	3	54.49	39.1	100.0
2015	3	51.18	100.0	100.0

Source: Calculated from the AIOCD-AWACS data base (see text).

Table 7: Therapeutic group wise monopoly brands

Group	Super group	Sales of monopoly brands in Rs million	Total sales of the groups in Rs million	Monopoly brand sales as % of total group sales
Allergens	Others	19.27	19.27	100.00
Anti-TNF products	Anti-neoplastics	21.29	21.29	100.00
Direct factor Xa inhibitors	Blood related	112.85	112.85	100.00
Fat emulsions, including total parenteral nutrition products	Blood related	4.56	4.56	100.00
Insulin analogues premix	Anti diabetic	1759.17	1759.17	100.00
Lung surfactants	Respiratory	8.33	8.33	100.00
MRI agents	Others	1.71	1.71	100.00
Other antithrombotic agents	Blood related	62.09	62.09	100.00
Renin inhibitor	Cardiac	2.59	2.59	100.00
Skin / dermal / epidermal preparations	Derma	19.34	19.34	100.00
Systemic dermatological antifungals	Anti-infectives	16.31	16.31	100.00
Trichomonacides	Anti-infectives	44.77	44.77	100.00
Ocular anti-allergics, decongestants, antiseptics	Ophthal / otologicals	0.15	0.15	99.67
Non-steroidal respiratory anti-inflammatories	Respiratory	37.20	41.57	89.48
Standard solutions (<100ml)	Blood related	26.71	32.59	81.95
Insulin analogues rapid	Anti diabetic	884.27	1090.88	81.06
All other cholesterol / triglyceride regulators	Cardiac	304.79	448.92	67.89
Low osmolar angio-urography	Others	118.96	226.68	52.48
Cytostatic hormones	Anti-neoplastics	91.33	214.88	42.50
Other antithrombotic agents	Cardiac	480.90	1157.46	41.55
Ion-exchange resin	Cardiac	7.58	23.40	32.38
Cardiac stimulants excluding cardiac glycosides	Cardiac	93.46	326.99	28.58
Fibrinolytics	Blood related	435.36	1686.18	25.82
All other antineoplastics	Anti-neoplastics	912.90	4940.29	18.48
Hormonal contraceptives, systemic	Gynaecological	1646.97	10326.93	15.95
Insulin analogues Basal	Anti diabetic	535.88	4048.02	13.24
Anti-smoking products	Neuro / cns	78.15	729.03	10.72
Other laxatives	Gastro intestinal	15.75	155.21	10.15

Table 7 (Contd)

Detoxifying agents for antineoplastic treatment	Others	5.07	76.93	6.59
Conventional antipsychotics	Neuro / cns	19.89	418.25	4.75
Topical dermatological antifungals	Derma	250.50	5656.49	4.43
Antimetabolites	Anti-neoplastics	76.06	1753.27	4.34
Anti-migraine preparations	Neuro / cns	22.21	535.83	4.15
Oral antidiabetics	Anti diabetic	837.85	20595.50	4.07
Anti-arrhythmics	Cardiac	22.66	592.40	3.82
Vinca alkaloids and other plant products	Anti-neoplastics	81.58	2152.76	3.79
All other non-therapeutic products	Others	5.48	144.86	3.78
Anti-thyroid preparation	Hormones	31.62	853.02	3.71
Plain antispasmodics and anticholinergics	Gastro intestinal	53.52	1498.38	3.57
Interferons	Anti-neoplastics	16.85	512.91	3.28
Systemic agents for fungal infections	Anti-infectives	184.30	6817.66	2.70
Antifibrinolytics	Blood related	50.32	1889.60	2.66
Iron-chelating agents	Blood related	0.75	31.23	2.41
Ophthalmological anti-infectives	Ophthal	30.28	1485.56	2.04
Antitubercular products	Anti-infectives	18.98	1492.55	1.27
Other drugs used in diabetes	Anti diabetic	0.90	71.95	1.26
Systemic antihistamines	Respiratory	79.22	6963.03	1.14
Oral anti-acne preparations	Derma	8.49	791.50	1.07
Hypnotics/sedatives	Neuro / cns	15.61	1584.39	0.99
Cerebral and peripheral vasotherapeutics	Cardiac	1.87	199.25	0.94
Sweetener	Others	10.46	1157.46	0.90
Miotics and antiglaucoma preparations	Ophthal	19.16	2321.18	0.83
Alkylating agents	Anti-neoplastics	4.47	550.48	0.81
Eye/ear anti-infectives	Ophthal / otologicals	7.22	894.54	0.81
Tetracyclines and combinations	Anti-infectives	9.50	1221.42	0.78
Specific immunoglobulins - antiviral	Vaccines	13.82	1990.46	0.69
Anti-alzheimer products	Neuro / cns	15.64	2277.33	0.69
Antiobesity preparations, excluding dietetics	Others	6.70	994.28	0.67

Table 7 (Contd)

Anti-parkinson drugs	Neuro / cns	9.25	1379.62	0.67
Muscle relaxants, centrally acting	Pain / analgesics	12.12	1939.48	0.62
Other dermatological preparations	Derma	8.22	1378.45	0.60
Other cough & cold preparations	Respiratory	2.01	344.20	0.59
Antitoxic sera	Vaccines	3.37	652.60	0.52
Products for treatment of rheumatoid arthritis	Pain / analgesics	5.38	1046.47	0.51
Varicose therapy, systemic	Others	1.53	318.85	0.48
Intestinal anti-infective antidiarrhoeals	Gastro intestinal	20.37	4541.44	0.45
Artificial tears and ocular lubricants	Ophthal	17.47	4118.12	0.42
HIV antivirals	Anti-infectives	5.59	1351.74	0.41
Specific anti-rheumatic agents - systemic	Pain / analgesics	1.48	366.05	0.41
Plain topical corticosteroids	Derma	15.34	4054.36	0.38
Immunostimulating agents excluding interferons	Anti-neoplastics	6.77	1937.65	0.35
Inhaler device	Others	1.79	554.14	0.32
Erectile dysfunction products	Sex stimulants / rejuvenators	12.38	4174.05	0.30
Topical nasal preparations - non steroidal	Respiratory	4.89	1817.48	0.27
Respiratory stimulants	Respiratory	0.53	239.31	0.22
Ocular anti-allergics, decongestants, antiseptics	Ophthal	1.30	623.93	0.21
Atypical antipsychotics	Neuro / cns	8.46	4075.91	0.21
Ace inhibitors, plain	Cardiac	6.68	3293.75	0.20
Antineoplastic antibiotics	Anti-neoplastics	0.91	504.30	0.18
Anabolic hormones, systemic	Hormones	1.40	806.46	0.17
Anti-rheumatics, non-steroidal - systemic	Pain / analgesics	17.30	11698.48	0.15
Systemic corticosteroids, plain	Hormones	9.81	6875.34	0.14
Pure vaccines	Vaccines	11.61	8768.51	0.13
Anti-ulcerants acid pump inhibitors	Gastro intestinal	16.13	15218.55	0.11
Muscle relaxants, peripherally acting	Pain / analgesics	0.28	304.90	0.09
Vitamin k antagonists	Blood related	0.61	731.95	0.08

Table 7 (Contd)

Topical nasal preparations - steroidal	Respiratory	0.92	1115.62	0.08
Anti-malarials	Anti malarials	2.87	4672.47	0.06
Other nutrients	Vitamins / minerals / nutrients	2.20	3789.69	0.06
Topical anti-rheumatic, non-steroidal	Pain / analgesics	1.60	5380.92	0.03
Heparins	Cardiac	1.78	6366.72	0.03
Statins	Cardiac	3.25	14978.39	0.02
Topical antibiotics and / or sulphonamids	Derma	0.48	2753.50	0.02
Androgens excluding G3E & G3F	Gynaecological	0.11	1129.78	0.01

Source: Calculated from the AIOCD-AWACS data base (see text).

Table 8: Prices of monopoly molecules

Molecule	Unit for price	Maximum price, Rs	Therapeutic group	Sales, 2015-16, Rs million
Cabazitaxel	60 Mg Injection 1 Ml	3,30,000.00	Anti-Neoplastics	81.58
Trabectedin	1 Mg Injection	1,21,485.68	Anti-Neoplastics	2.62
Cetuximab	500 Mg Infusion 50 Ml	1,01,110.00	Anti-Neoplastics	15.88
Ixabepilone	45 Mg Injection	71,175.00	Anti-Neoplastics	1.59
Nimotuzumab	50 Mg Injection 10 Ml	51,241.92	Anti-Neoplastics	82.23
Alteplase	50 Mg Injection 1	49,899.00	Blood Related	435.36
Bevacizumab	100 Mg Injection	41,250.00	Anti-Neoplastics	509.75
Tocilizunab	400 Mg Injection	40,600.00	Anti-Neoplastics	0.55
Botulism Sera	500 IU Injection 1	31,500.00	Vaccines	3.37
Abatacept	250 Mg Injection	30,000.00	Pain / Analgesics	5.38
Poractant Alfa	240 Mg Injection	19,396.55	Respiratory	6.20
Posaconazole	40 Mg Oral Suspension 105 Ml	17,440.00	Anti-Infectives	61.59
Rasburicase	1.5 Mg Injection	14,423.07	Anti-Neoplastics (Detoxifying agents)	5.07
Cladribine	10 Mg Injection	13,400.00	Anti-Neoplastics	22.95
Interferons, Alfa	100 Mcg Injection	10,793.65	Anti-Neoplastics	10.87
Sunitinib	50 Mg Capsule	8714.78	Anti-Neoplastics	65.94
Itolizumab	25 Mg Injection 5 Ml	8,229.76	Anti-Neoplastics	6.94
Micafungin	50 Mg Injection 1 Ml	5,911.00	Anti-Infectives	122.70
Idarubicin	5 Mg Injection 5 Ml	5,889.52	Anti-Neoplastics	0.91
Colfoscaril Palmitate	108 Mg Injection 10 Ml	5,790.00	Respiratory	2.13
Axitinib	5 Mg Tablet	5678.50	Anti-Neoplastics	24.10
Interferons, Beta	30 Mg Prefilled Syringe	5,623.57	Anti-Neoplastics	5.98
Liraglutide	6 Mg Injection 3 Ml	4840.00	Anti Diabetic	363.38

Table 8 (Contd)

Carmustine	100 Mg Injection	3,497.95	Anti-Neoplastics	1.85
Dasatinib	50 Mg Tablet	3287.30	Anti-Neoplastics	11.04
Growth Hormones	12/4 IU Injection 1	3,260.00	Hormones	0.05
Sargramostim	500 Mcg Injection	3,077.00	Anti-Neoplastics	6.77
Endokine	300 Mcg Prefilled Syringe	2,431.58	Anti-Neoplastics	14.35
Nartograstim	300 Mcg Injection 1 Ml	2,031.25	Others	19.27
Eltrombopag	50 Mg Tablet	1931.97	Blood Related	50.32
Becaplermin	0.01 % Gel 15 Gm	1,930.68	Derma	19.34
Carmofur	1000 Mg Injection 10 Ml	1,925.00	Anti-Neoplastics	7.94
Degludec	100 IU Disposable Pen 3 Ml	1800.00	Anti Diabetic	424.05
Iopromide	370 Mg Infusion 100 Ml	1,757.86	Others	36.09
Regular Aspart	100 IU Injection 10 Ml	1,750.00	Anti Diabetic	637.69
Gadopentetic	I.V. 469 Mg Injection 10 Ml	1,655.95	Others	1.71
Crizotinib	200 Mg Capsule	1553.71	Anti-Neoplastics	139.39
Iopamidol	370 Solution 100 Ml	1,500.00	Others	82.86
Regorafenib	40 Mg Tablet	1,311.80	Anti-Neoplastics	24.45
Determir	100 IU Flexpen 3 Ml	998.00	Anti Diabetic	111.84
Biphasic Lispro	100 IU Disposable Pen 3 Ml	640.00	Anti Diabetic	622.45
Biphasic Aspart	50/50 100 IU Flexpen 3 Ml	616.00	Anti Diabetic	1136.72
Bemiparin	Hibor 5000 IU Injection 0.2 Ml	602.86	Cardiac	0.18
Lispro	100 IU Disposable Pen 3 Ml	582.00	Anti Diabetic	246.58
Udenafil	100 Mg Tablet	575.00	Sex Stimulants / Rejuvenators	12.38
Pazopanib	400 Mg Tablet	460.32	Anti-Neoplastics	37.98
Zuclopenthixol	200 Mg Injection 1 Ml	406.85	Neuro / CNS	19.89
Zolmitriptan	5 Mg Nasal Spray	404.00	Neuro / CNS	11.09

Table 8 (Contd)

Parnaparin	3200 IU Injection 0.3 Ml	399.05	Cardiac	0.03
Rabies Immunoglobulin	Injection	350.55	Vaccines	13.82
Cholera Vaccine	Oral Drops 1.5 Ml	324.00	Vaccines	11.61
Lapatinib	250 Mg Tablet	254.29	Anti-Neoplastics	39.45
Xylitol Solutions <100ml	48 Mg Lotion 75 Ml	245.00	Blood Related	25.46
Ardeparin	3500 IU Injection 0.4 Ml	185.00	Cardiac	0.01
Phosphoric Acid	24.417/5.439 Gm Solution 45 Ml	161.00	Gastro Intestinal	15.75
Luliconazole	Cream 10 Gm	155.00	Derma	189.44
Denatonium Benzoate	Lotion 9 Ml	155.00	Others	20.41
Apixaban	5 Mg Tablet	145.00	Blood Related	112.85
Tegafur	100/224 Mg Capsule	141.60	Anti-Neoplastics	3.34
Besifloxacin	0.60 % Eye Drops 5 Ml	140.00	Ophthal	26.12
Levobunolol Eye Drops	0.5 % Eye Drops 5 Ml	135.52	Ophthal	19.16
Doxapram	20 Mg Injection 5 Ml	126.00	Respiratory	0.53
Methdilazine	8 Mg Expectorant 450 Ml	113.00	Respiratory	72.51
Eberconazole	1 % Cream 10 Gm	94.50	Derma	61.06
Dexpanthenol	5 % Ointment 5 Gm	93.00	Ophthal	17.47
Trypan Blue	0.06 % Injection 1 Ml	82.91	Others	3.84
Sodium Tetradecyl	3 % Injection 2 Ml	78.75	Others	1.53
Dabigatran	60/75 Mg Capsule	71.80	Cardiac	480.90
Eletriptan	40 Mg Tablet	70.50	Neuro / CNS	6.86
Varenicline	1 Mg Tablet	60.71	Neuro / CNS	78.15
Aliskiren	300 Mg Tablet	58.36	Cardiac	2.59
Pentosan Polysulphate Sodium	100 Mg Tablet	54.75	Blood Related	62.09
Terizidone	250 Mg Tablet	49.43	Anti-Infectives	18.98
Empagliflozin	25 Mg Tablet	48.00	Anti Diabetic	125.15

Table 8 (Contd)

Chlorbutanol Eye Drops	10 Ml	47.90	Ophthal / Otologicals	0.15
Dydrogesterone	10 Mg Tablet	46.00	Gynaecological	1646.97
Feracrylum	Gel 30 Gm	44.58	Others	0.00
Dapagliflozin	10 Mg Tablet	43.21	Anti Diabetic	349.16
Doxifluridine	200 Mg Capsule	42.28	Anti-Neoplastics	2.17
Cholestyramine	5 Mg Sachet 5 Gm	39.50	Cardiac	7.58
Naratriptan	2.5 Mg Tablet	37.50	Neuro / CNS	4.26
Fluvastatin	80 Mg Tablet Xl	33.82	Cardiac	3.25
Lymecycline	408 Mg Capsule	33.30	Anti-Infectives	9.50
Tioguanine	40 Mg Tablet	30.00	Anti-Neoplastics	0.22
Saroglitazar	4 Mg Tablet	25.90	Cardiac	304.79
Galantamine	8 Mg Tablet	25.20	Neuro / CNS	15.64
D-Chiroinositol	150 Mg Tablet	22.60	Vitamins / Minerals / Nutrients	2.20
Tetryzoline	0.05 % Eye Drops 10 Ml	21.50	Ophthal	0.44
Flecainide	100 Mg Tablet	21.00	Cardiac	11.63
Kionutrime CS	500 Mg Tablet	20.00	Others	6.70
Propafenone	150 Mg Tablet	19.72	Cardiac	11.03
Dexlansoprazole	60 Mg Tablet	19.50	Gastro Intestinal	16.13
Papaverine	60 Mg Injection 2 Ml	18.75	Gastro Intestinal	0.06
Berberine	500 Mg Tablet	14.90	Anti Diabetic	0.90
Tolbutamide	500 Mg Tablet	14.44	Anti Diabetic	0.17
Soya Isoflavones	Capsule	14.27	Gynaecological	0.03
Benazepril	10 Mg Tablet	13.69	Cardiac	6.68
Pipercuronium Bromide	50 Mg Tablet	12.81	Pain / Analgesics	0.28

Table 8 (Contd)

Camostat	100 Mg Tablet	12.19	Gastro Intestinal	0.00
Cimetropium Bromide	50 Mg Tablet	11.89	Gastro Intestinal	53.52
Piperaquine	Capsule	11.70	Anti Malarials	2.53
Ramelteon	8 Mg Tablet	10.90	Neuro / CNS	15.61
Fructooligosaccharides	Capsule	10.00	Others	10.46
Nimorazole	500 Mg Tablet	9.85	Anti-Infectives	23.38
Tolfenamic Acid	200 Mg Capsule	9.60	Pain / Analgesics	17.30
Sulphasalazine	Tablet	8.80	Pain / Analgesics	1.48
Tiapride	100 Mg Tablet	8.20	Neuro / CNS	8.07
Tiagabine	12 Mg Tablet	7.98	Neuro / CNS	0.00
Deferiprone	500 Mg Capsule	7.94	Blood Related	0.75
Etidronate	200 Mg Tablet	7.92	Pain / Analgesics	0.06
Proguanil	100 Mg Tablet	7.00	Anti Malarials	0.03
Primidone	250 Mg Tablet	6.85	Neuro / CNS	21.80
Benzonatate	100 Mg Capsule	6.71	Respiratory	61.43
Acrivastine	363 Mg Tablet	6.49	Respiratory	6.71
Noscapine	25 Mg Tablet	6.48	Respiratory	0.78
Busulfan	2 Mg Tablet	6.10	Anti-Neoplastics	0.00
Propylthiouracil	50 Mg Tablet	4.08	Hormones	31.62
Ethylestrenol	5 Mg Tablet	3.81	Hormones	1.40
Alizapride	DSR Capsule	1.94	Gastro Intestinal	0.05
TOTAL				9579.36

Source: Calculated from the AIOCD-AWACS data base (see text).

Table 9: Prices of multi-brand biologic products

Molecule	No of brands	Therapeutic group	Unit for price	Max price	Min price	Median price	Sales 2015-16, Rs million
Rituximab	6	Anti-Neoplastics	500 Mg Infusion 50 Ml	79,992.00	37,500.00	58,746.00	932.38
Trastuzumab	3	Anti-Neoplastics	440 Mg Injection	75,000.00	52,154.19	56,689.01	675.81
Ranibizumab	2	Ophthal	See Note	75,000.00	17,000.00	46,000.00	55.59
Interferon Alpha 2B	4	Anti-Neoplastics	See Note	69,557.50	14,017.13	41787.32	25.54
Bortezomib	14	Anti-Neoplastics	3.5 Mg Injection	60360.00	12,500.00	36430.00	291.01
Tenecteplase	2	Cardiac	40 Mg Injection	43,889.00	41,668.00	42778.5	495.83
Infliximab	2	Pain / Analgesics	See Note	41,039.00	30,476.80	35,757.90	106.40
Reteplase	4	Cardiac	18 Mg Injection	28,333.32	16,350.00	21,931.25	390.30
Pegfilgrastim	9	Anti-Neoplastics	6 Mg Injection	27,099.53	9,030.00	10,906.25	624.60
Adalimumab	2	Pain / Analgesics	See Note	23,809.50	20,000.00	21,904.75	172.17
Abciximab	3	Cardiac	10 Mg Injection 5 Ml	21,552.00	6,750.00	8,857.13	28.74
Etanercept	3	Pain / Analgesics	See Note	17,170.00	9,523.81	13,346.91	135.19
Pegylated Interferon Alpha 2B	5	Anti-Neoplastics	80 Mcg Injection	15,093.32	4,285.71	9,689.52	368.65
Pegylated Interferon Alpha 2A	2	Anti-Neoplastics	See Note	10,495.75	9,175.00	9,835.38	97.17
Epoetin Alfa	20	Blood Related	40000 IU Injection 1 Ml	10,147.50	1,469.52	9,980.00	3114.11

Source: Calculated from the AIOCD-AWACS data base (see text).

Notes:

(i) Number of brands and prices among those sold in 2015-16.
(ii) Ranibizumab - Unit For Max Price: 0.5 Mg Injection 0.05 Ml; Unit For Min Price:- 2.3 Mg Injection 0.23 Ml.
(iii) Interferon Alpha 2B - Unit For Max Price: 0.25 Mg Injection; Unit For Min Price: 18 Miu Penfill.

Table 9 Notes (Contd)

(iv) Infliximab - Unit For Max Price:100 Mg Injection 10 Ml ; Unit For Min Price: Injection 1 Ml.
(v) Adalimumab - Unit For Max Price: Prefilled Syringe ; Unit For Min Price: 40 Mg Prefilled Syringe.
(vi) Etanercept - Unit For Max Price: 50 Mg Injection 10 Ml ; Unit For Min Price: 50 Mg Injection 1 Ml.
(vii) Pegylated Interferon Alpha 2A - Unit For Max Price: 100 Mcg Injection; Unit For Min Price: 180 Mg Injection 0.5 Ml.

Table 10: Price erosion in Cabazitaxel after product patent expiry in India

Company	Unit for price	Date of launch	Price, Rs, June 2018	Price erosion (the reduction in price as % of patented price)
Sanofi (Emcure)	60 MG, 1 Ml injection	Jan-13	330000.00	0.0
Intas Pharmaceuticals	60 MG, 1.5 Ml injection	Jun-16	32359.46	90.2
Dr. Reddys Laboratories	60 MG, 1.5 Ml injection	Oct-16	24053.27	92.7
Panacea Biotec	60 MG, 1.5 Ml injection	Mar-17	19947.50	94.0
Natco Pharma	60 MG, 1.5 Ml injection	Aug-17	18947.87	94.3

Source: Compiled from AOIOCD-AWACS database (see Section 3)

Table 11: Market structure of patented, patent rejected and not patented molecules

	Number	Number (%)	Number	Number (%)	Number	Number (%)	Number	Number (%)
No of brands	Patented	Patented	Patented rejected	Patented rejected	Not Patented	Not Patented	Total	Total
1	20	76.9	4	9.3	33	50.0	57	42.2
2	3	11.5	4	9.3	1	1.5	8	5.9
3	1	3.8	5	11.6	2	3.0	8	5.9
4	1	3.8	1	2.3	1	1.5	3	2.2
5	0	0.0	2	4.7	4	6.1	6	4.4
6 to 10	1	3.8	8	18.6	8	12.1	17	12.6
> 10	0	0.0	19	44.2	17	25.8	36	26.7
Total	26	100.0	43	100.0	66	100.0	135	100.0

Source: Computed from Appendix 1 and 2.

Table 12: Prices of patented, patent rejected and not patented molecules (Numbers)

	No	No %	No	No %	No	No %	No	No %
Max price	Patented molecules	Patented molecules	Patent rejected molecules	Patent rejected molecules	Non-Patented molecules	Non-Patented molecules	Total	Total
> 3,00,000	1	3.8	0	0.0	0	0.0	1	0.7
> 1,00,000	2	7.7	0	0.0	1	1.5	3	2.2
> 50,000	3	11.5	0	0.0	4	6.1	7	5.2
> 25,000	4	15.4	0	0.0	6	9.1	10	7.4
> 15,000	4	15.4	2	4.7	7	10.6	13	9.6
> 10,000	4	15.4	2	4.7	9	13.6	15	11.1
> 5,000	6	23.1	3	7.0	11	16.7	20	14.8
> 2,500	8	30.8	5	11.6	14	21.2	27	20.0
> 1000	11	42.3	7	16.3	22	33.3	40	29.6
> 500	13	50.0	10	23.3	28	42.4	51	37.8
> 100	16	61.5	20	46.5	41	62.1	77	57.0
> 50	19	73.1	25	58.1	45	68.2	89	65.9
> 10	26	100.0	41	95.3	62	93.9	129	95.6
< 10	0	0.0	2	4.7	4	6.1	6	4.4
Total	26	100.0	43	100.0	66	100.0	135	100.0

Source: Computed from Appendix 1 and 2.

Table 13: Prices of patented, patent rejected and not patented molecules (Sales)

	Sales, 2015-16, Rs million	Sales, 2015-16 (%)	Sales, 2015-16, Rs million	Sales, 2015-16 (%)	Sales, 2015-16, Rs million	Sales, 2015-16 (%)	Sales, 2015-16, Rs million	Sales, 2015-16 (%)
Max price	Patented molecules	Patented molecules	Patent rejected molecules	Patent rejected molecules	Non-Patented molecules	Non-Patented molecules	Total	Total
> 3,00,000	81.58	0.9	0.00	0.0	0.00	0.0	81.58	0.1
> 1,00,000	97.45	1.0	0.00	0.0	2.62	0.0	100.08	0.1
> 50,000	99.05	1.1	0.00	0.0	602.02	2.4	701.07	0.9
> 25,000	608.80	6.5	0.00	0.0	607.95	2.4	1216.75	1.6
> 15,000	608.80	6.5	2254.69	5.3	669.55	2.7	3533.03	4.6
> 10,000	608.80	6.5	2254.69	5.3	1442.29	5.8	4305.78	5.6
> 5,000	755.60	8.1	2320.62	5.4	1534.52	6.2	4610.75	6.0
> 2,500	1130.02	12.0	2710.47	6.3	2776.02	11.2	6616.51	8.6
> 1000	1743.77	18.6	4236.55	9.9	4092.22	16.5	10072.54	13.1
> 500	2125.33	22.7	7636.33	17.8	9215.56	37.1	18977.22	24.6
> 100	2465.61	26.3	11945.62	27.9	11269.22	45.4	25680.45	33.3
> 50	4033.47	43.0	12950.22	30.3	11401.82	45.9	28385.52	36.9
> 10	9380.05	100.0	42054.44	98.2	24733.76	99.6	76168.26	98.9
< 10	0.00	0.0	751.24	1.8	106.61	0.4	857.84	1.1
Total	9380.05	100.0	42805.68	100.0	24840.37	100.0	77026.10	100.0

Source: Computed from Appendix 1 and 2.

Appendix 1

Molecules	Patent status	Therapeutic group	Launch date in India	Sales, 2015-16, Rs million	Total No of Brands, 2015-16	No of MNC brand, 2015-16	MNC market share, 2015-16
Abacavir	Patented rejected	Anti-Infectives	Sep-03	8.40	2	0	0
Abatacept	Not patented	Pain / Analgesics	May-09	5.38	1	1	100
Abiraterone Acetate	Not patented	Anti-Neoplastics	Jul-13	193.33	11	1	6.7
Adefovir	Patented rejected	Anti-Infectives	Jan-04	16.38	3	0	0
Aliskiren	Not patented	Cardiac	Apr-07	2.59	1	1	100
Ambrisentan	Not patented	Cardiac	Feb-12	212.36	4	1	0.2
Apixaban	Patented	Blood Related	Nov-13	112.85	1	1	100
Ardeparin	Not patented	Cardiac	Sep-04	0.01	1	0	0
Atazanavir	Patented rejected	Anti-Infectives	May-06	35.32	1	0	0
Atorvastatin	Patented rejecte	Cardiac	Jun-99	8633.49	116	7	6.4
Axitinib	Patented	Anti-Neoplastics	May-15	24.10	1	1	100
Benazepril	Not patented	Cardiac	Aug-97	6.68	1	1	100
Benzonatate	Not patented	Respiratory	Apr-07	61.43	1	0	0
Besifloxacin	Not patented	Ophthal	Jan-12	26.12	1	0	0
Bevacizumab	Patented	Anti-Neoplastics	Dec-01	509.75	1	1	100
Biphasic Lispro	Not patented	Anti Diabetic	Apr-06	622.45	1	1	100
Bortezomib	Not patented	Anti-Neoplastics	Apr-07	291.01	14	2	6.1
Brinzolamide	Not patented	Ophthal	Nov-11	137.82	5	1	45.9
Cabazitaxel	Patented	Anti-Neoplastics	Jan-13	81.58	1	0	0
Canagliflozin	Patented	Anti Diabetic	Mar-15	253.50	3	2	76.9
Carmofur	Not patented	Anti-Neoplastics	Mar-11	7.94	1	1	100
Caspofungin Acetate	Not patented	Anti-Infectives	Nov-07	749.79	13	3	35.6
Cetrorelix	Not patented	Hormones	Apr-07	205.54	10	1	0.7
Cetuximab	Patented	Anti-Neoplastics	Jul-06	15.88	1	1	100
Cimetropium Bromide	Not patented	Gastro Intestinal	Jul-11	53.52	1	0	0
Cladribine	Not patented	Anti-Neoplastics	Jul-09	22.95	1	1	100

Appendix 1 (Contd)

Crizotinib	Patented	Anti-Neoplastics	Apr-13	139.39	1	1	100
Dabigatran	Patented	Cardiac	Apr-12	480.90	1	1	100
Dapagliflozin	Patented	Anti Diabetic	May-15	349.16	1	1	100
Darifenacin	Patented rejected	Urology	Apr-08	198.37	7	0	0
Darunavir	Patented rejected	Anti-Infectives	Aug-09	57.51	2	0	0
Dasatinib	Patented	Anti-Neoplastics	Oct-07	11.04	1	1	100
Degludec	Patented	Anti Diabetic	Oct-13	424.05	1	1	100
Denatonium Benzoate	Not patented	Others	Apr-07	20.41	1	0	0
Desvenlafaxine	Not patented	Neuro / CNS	Aug-09	378.11	26	4	36.6
Determir	Not patented	Anti Diabetic	Jan-06	111.84	1	1	100
Dienogest	Not patented	Gynaecological	Apr-14	128.95	7	0	0
Doripenem	Not patented	Anti-Infectives	Jun-09	319.08	14	2	3.8
Duloxetine	Patented rejected	Neuro / CNS	May-01	515.65	28	1	4.65
Eberconazole	Not patented	Derma	Aug-07	61.06	1	0	0
Efavirenz	Patented rejected	Anti-Infectives	Aug-01	39.95	5	1	1.35
Eletriptan	Not patented	Neuro / CNS	May-12	6.86	1	0	0
Eltrombopag	Patented	Blood Related	Mar-13	50.32	1	1	100
Empagliflozin	Patented	Anti Diabetic	Oct-15	125.15	1	1	100
Entecavir	Not patented	Anti-Infectives	Sep-07	695.54	10	1	28.7
Eplerenone	Not patented	Cardiac	Jun-05	359.46	6	0	0
Erlotinib	Patented rejected	Anti-Neoplastics	May-07	273.68	7	0	0
Ertapenem	Not patented	Anti-Infectives	May-07	257.10	5	1	80.4
Ezetimibe	Patented rejected	Cardiac	Sep-03	84.03	3	0	0
Febuxostat	Not patented	Pain / Analgesics	Dec-09	1251.78	47	4	16.7
Fluvastatin	Not patented	Cardiac	May-05	3.25	1	1	100
Fondaparinux	Not patented	Cardiac	Apr-07	414.98	5	2	40.1
Gefitinib	Patented rejected	Anti-Neoplastics	Jan-04	212.49	23	4	10.15

Appendix 1 (Contd)

Glargine	Not patented	Anti Diabetic	Dec-06	3512.13	5	1	77.7
Glulisine	Patented	Anti Diabetic	Sep-08	206.61	1	1	100
Ibandronate	Patented rejected	Hormones	Jan-06	177.36	8	0	0
Idarubicin	Not patented	Anti-Neoplastics	Apr-99	0.91	1	1	100
Imatinib Mesylate	Patented rejected	Anti-Neoplastics	Nov-02	425.13	19	1	3.77
Iopamidol	Not patented	Others	May-03	82.86	1	0	0
Iopromide	Not patented	Others	Aug-00	36.09	1	0	0
Ivabradine	Not patented	Cardiac	Apr-07	723.51	8	2	20.9
Ixabepilone	Patented	Anti-Neoplastics	Jul-09	1.59	1	1	100
Lacosamide	Not patented	Neuro / CNS	Jul-10	237.20	12	2	12.2
Lapatinib	Patented rejected	Anti-Neoplastics	Oct-08	39.45	1	1	100
Lenalidomide	Patented	Anti-Infectives	Apr-07	174.96	9	0	0
Letrozole	Patented rejected	Anti-Neoplastics	Jul-01	157.78	23	3	12.71
Levetiracetam	Not patented	Neuro / CNS	Jan-05	4346.25	41	9	15.6
Levobunolol Eye Drops / Ointment	Not patented	Ophthal	Nov-96	19.16	1	1	100
Linagliptin	Patented	Anti Diabetic	Jun-12	1166.02	2	1	95.9
Linezolid	Patented rejected	Anti-Infectives	Aug-01	1687.21	47	3	0.87
Liraglutide	Patented	Anti Diabetic	Jun-10	363.38	1	1	100
Lispro	Not patented	Anti Diabetic	Jun-98	246.58	1	1	100
Luliconazole	Patented	Derma	Jan-10	189.44	1	0	0
Methdilazine	Not patented	Respiratory	Aug-99	72.51	1	1	100
Micafungin	Patented	Anti-Infectives	May-10	122.70	1	1	100
Moxifloxacin	Patented rejected	Anti-Infectives	Oct-00	968.35	18	0	0
Naratriptan	Not patented	Neuro / CNS	Oct-09	4.26	1	0	0
Nepafenac	Not patented	Ophthal	Feb-09	453.29	25	1	36.3
Nevirapine	Patented rejected	Anti-Infectives	Jan-00	16.65	6	1	0.33
Nimorazole	Not patented	Anti-Infectives	Aug-13	23.38	1	0	0
Nimotuzumab	Not patented	Anti-Neoplastics	Jan-10	82.23	1	0	0
Olanzapine	Patented rejected	Neuro / CNS	Oct-99	750.79	61	3	4.26

Appendix 1 (Contd)

Olmesartan	Not patented	Cardiac	Jul-05	2432.51	43	5	7.3
Orlistat	Patented rejected	Others	Nov-96	562.57	27	1	0.08
Oseltamivir	Patented rejected	Anti-Infectives	Sep-09	49.32	3	0	0
Oxcarbazepine	Patented rejected	Neuro / CNS	Oct-01	1779.34	30	7	24.89
Paclitaxel	Patented rejected	Anti-Neoplastics	Sep-98	1531.51	32	3	23.05
Pantoprazole	Patented rejected	Gastro Intestinal	Dec-98	7547.65	265	6	2.6
Pazopanib	Patented	Anti-Neoplastics	Mar-13	37.98	1	1	100
Pemetrexed	Not patented	Anti-Neoplastics	Jul-06	226.15	16	2	24.4
Pentosan Polysulphate Sodium	Not patented	Cardiac	Aug-12	62.09	1	0	0
Pimecrolimus	Patented rejected	Derma	May-06	75.78	3	1	1.21
Pirfenidone	Not patented	Respiratory	Oct-10	238.78	3	0	0
Posaconazole	Not patented	Anti-Infectives	Mar-11	61.59	1	1	100
Pramipexole	Not patented	Neuro / CNS	May-05	350.01	8	0	0
Prasugrel	Not patented	Cardiac	Apr-10	372.85	13	0	0
Primidone	Not patented	Neuro / CNS	Apr-07	21.80	1	1	100
Rabeprazole	Patented rejected	Gastro Intestinal	Jan-00	3078.90	193	10	3.8
Raloxifene	Patented rejected	Gynaecological	May-01	12.95	5	0	0
Ramelteon	Patented	Neuro / CNS	Jan-11	15.61	1	1	100
Ranolazine	Not patented	Cardiac	Apr-07	782.32	19	1	1.5
Regorafenib	Not patented	Anti-Neoplastics	Oct-15	24.45	1	0	0
Repaglinide	Patented rejected	Anti Diabetic	Jan-00	230.30	2	1	19.7
Rifaximin	Not patented	Gastro Intestinal	Jun-08	1429.17	23	5	1.3
Risedronate	Patented rejected	Hormones	Mar-04	97.40	8	2	0.1
Ritonavir	Patented rejected	Anti-Infectives	Mar-03	12.13	3	0	0
Rosiglitazone	Patented rejected	Anti Diabetic	Feb-00	0.45	2	0	0
Rosuvastatin	Patented rejected	Cardiac	Jul-03	6118.15	93	6	6.8
Saroglitazar	Patented	Cardiac	Sep-13	304.79	1	0	0

Appendix 1 (Contd)

Saxagliptin	Patented	Anti Diabetic	Apr-10	591.94	2	1	99
Sevelamer	Not patented	Others	Mar-05	351.02	16	1	4.9
Sildenafil	Patented rejected	Sex Stimulants / Rejuvenators	Apr-00	3226.60	53	3	6.2
Silodosin	Not patented	Urology	Aug-11	472.12	9	1	0.5
Sirolimus	Patented rejected	Anti-Neoplastics	Jan-03	54.41	8	0	0
Sitagliptin	Patented	Anti Diabetic	Apr-08	2793.91	4	1	60.1
Sofosbuvir	Patented rejected	Anti-Infectives	Mar-15	1252.40	12	2	15.8
Sunitinib	Patented rejected	Anti-Neoplastics	Dec-07	65.94	1	1	100
Tadalafil	Patented rejected	Sex Stimulants / Rejuvenators	Nov-03	842.78	24	1	0.0001
Tenofovir	Patented rejected	Anti-Infectives	Jul-05	386.37	12	2	5.2
Teriparatide	Patented rejected	Hormones	Apr-07	723.18	13	2	1.6
Tiagabine	Not patented	Neuro / CNS	Apr-04	0.00	1	0	0
Ticagrelor	Patented	Cardiac	Oct-12	833.46	2	1	92.8
Tigecycline	Not patented	Anti-Infectives	May-07	665.32	25	3	32.1
Tiotropium	Patented rejected	Respiratory	Feb-03	456.62	7	0	0
Tocilizunab	Not patented	Anti-Neoplastics	Aug-10	0.55	1	1	100
Tolvaptan	Not patented	Cardiac	Oct-12	394.19	8	0	0
Trabectedin	Not patented	Anti-Neoplastics	Mar-15	2.62	1	1	100
Travoprost	Not patented	Ophthal	Feb-06	236.15	13	1	52
Triptorelin	Not patented	Anti-Neoplastics	Dec-12	91.33	2	1	3.4
Valganciclovir	Patented rejected	Anti-Infectives	Sep-08	76.47	8	0	0
Valsartan	Patented rejected	Cardiac	Sep-01	248.35	4	2	12.2
Varenicline	Patented rejected	Neuro / CNS	Feb-08	78.15	1	1	100
Zolmitriptan	Not patented	Neuro / CNS	Dec-07	11.09	1	0	0
Zonisamide	Not patented	Neuro / CNS	Mar-06	146.68	3	1	56.9
Zuclopenthixol	Not patented	Neuro / CNS	Sep-00	19.89	1	1	100

Source: See text.

Note: “Patent rejected” includes those abandoned, revoked or withdrawn.

Appendix 2

Molecules	Patent status	Unit for price	Max price, March 2016	Min price, March 2016	Median price, March 2016
Abacavir	Patented rejected	300 mg tablet	51.08	48.15	49.61
Abatacept	Not patented	250 mg injection	30,000.00	30,000.00	30,000.00
Abiraterone Acetate	Not patented	250 mg tablet	1250.00	230.83	785.71
Adefovir	Patented rejected	10 mg tablet	27.00	22.45	23.88
Aliskiren	Not patented	300 mg tablet	58.36	58.36	58.36
Ambrisentan	Not patented	5 mg tablet	145.00	36.19	90.60
Apixaban	Patented	5 mg tablet	145.00	145.00	145.00
Ardeparin	Not patented	3500 iu injection 0.4 ml	185.00	185.00	185.00
Atazanavir	Patented rejected	300 mg capsule	75.10	75.10	75.10
Atorvastatin	Patented rejected	80 mg tablet	44.62	6.37	30.05
Axitinib	Patented	5 mg tablet	5678.5	5678.5	5678.5
Benazepril	Not patented	10 mg tablet	13.69	13.69	13.69
Benzonatate	Not patented	100 mg capsule	6.71	6.71	6.71
Besifloxacin	Not patented	0.60 % eye drops 5 ml	140.00	140.00	140.00
Bevacizumab	Patented	100 mg injection	41,250.00	41,250.00	41,250.00
Biphasic Lispro	Not patented	100 iu disposable pen 3 ml	640.00	640.00	640.00
Bortezomib	Not patented	3.5 mg injection	60,360.00	12,500.00	36430.00
Brinzolamide	Not patented	1 % eye drops 5 ml	460.00	290.00	375.00
Cabazitaxel	Patented	60 mg injection 1 ml	3,30,000.00	3,30,000.00	3,30,000.00
Canagliflozin	Patented	100 mg tablet	51.00	51.00	51.00
Carmofur	Not patented	1000 mg injection 10 ml	1,925.00	1,925.00	1,925.00
Caspofungin Acetate	Not patented	70 mg injection 10 ml	12,857.13	10,989.00	11923.065
Cetrorelix	Not patented	0.25 mg injection	2,184.61	618.75	887.50
Cetuximab	Patented	500 mg infusion 50 ml	1,01,110.00	1,01,110.00	1,01,110.00
Cimetropium Bromide	Not patented	50 mg tablet	11.89	11.89	11.89
Cladribine	Not patented	10 mg injection	13,400.00	13,400.00	13,400.00
Crizotinib	Patented	200 mg capsule	1553.71	1553.71	1553.71
Dabigatran	Patented	60/75 mg capsule	71.80	71.80	71.80
Dapagliflozin	Patented	10 mg tablet	43.21	43.21	43.21
Darifenacin	Patented rejected	15 mg tablet	34.70	17.81	28.4
Darunavir	Patented rejected	300 mg tablet	152.38	76.19	87.92
Dasatinib	Patented	50 mg tablet	3287.3	3287.3	3287.3
Degludec	Patented	100 iu disposable pen 3 ml	1800.00	1800.00	1800.00

Appendix 2 (Contd)

Denatonium Benzoate	Not patented	Lotion 9 ml	155.00	155.00	155.00
Desvenlafaxine	Not patented	100 mg tablet	21.67	12.00	15.81
Determir	Not patented	100 iu flexpen 3 ml	998.00	998.00	998.00
Dienogest	Not patented	2 mg tablet	49.00	45.00	48.95
Doripenem	Not patented	500 mg injection	3,514.28	1,756.97	2926.005
Duloxetine	Patented rejected	30 mg capsule	15.80	7.17	10.50
Eberconazole	Not patented	1 % cream 10 gm	94.50	94.50	94.50
Efavirenz	Patented rejected	600 mg tablet	79.42	62.48	64.66
Eletriptan	Not patented	40 mg tablet	70.50	70.50	70.50
Eltrombopag	Patented	50 mg tablet	1931.97	1931.97	1931.97
Empagliflozin	Patented	25 mg tablet	48.00	48.00	48.00
Entecavir	Not patented	1 mg tablet	396.4	77.71	150.50
Eplerenone	Not patented	50 mg tablet	42.37	33.13	26.90
Erlotinib	Patented rejected	150 mg tablet	1,090.85	220.833	625.58
Ertapenem	Not patented	1 gm injection 20 ml	2,616.00	2,138.91	2,431.00
Ezetimibe	Patented rejected	10 mg tablet	11.95	8.95	11.1
Febuxostat	Not patented	80 mg tablet	19.29	8.11	13.85
Fluvastatin	Not patented	80 mg tablet xl	33.82	33.82	33.82
Fondaparinux	Not patented	7.5 mg injection 0.6 ml	1,445.00	1,320.00	1382.5
Gefitinib	Patented rejected	250 mg tablet	3388.81	80.507	295.13
Glargine	Not patented	100 iu cartridge 3 ml	542.96	460.00	468.50
Glulisine	Patented	100 iu injection 10 ml	952.97	952.97	952.97
Ibandronate	Patented rejected	6 mg injection	2,762.00	2,500.00	2,631.00
Idarubicin	Not patented	5 mg injection 5 ml	5,889.52	5,889.52	5,889.52
Imatinib Mesylate	Patented rejected	400 mg tablet	397.44	74.00	265.50
Iopamidol	Not patented	370 solution 100 ml	1,500.00	1,500.00	1,500.00
Iopromide	Not patented	370 mg infusion 100 ml	1,757.86	1,757.86	1,757.86
Ivabradine	Not patented	5 mg tablet	19.64	13.20	14.50
Ixabepilone	Patented	45 mg injection	71,175.00	71,175.00	71,175.00
Lacosamide	Not patented	200 mg tablet	45.73	14.68	15.30
Lapatinib	Patented rejected	250 mg tablet	254.29	254.29	254.29
Lenalidomide	Patented	25 mg capsule	740.00	559.04	574.18
Letrozole	Patented rejected	2.5 mg tablet	225	4.38	20.80
Levetiracetam	Not patented	1000 mg tablet	40.35	16.90	22.78
Levobunolol Eye Drops / Ointment	Not patented	0.5 % eye drops 5 ml	135.52	135.52	135.52
Linagliptin	Patented	5 mg tablet	45.00	45.00	45.00
Linezolid	Patented rejected	600 mg tablet	107.25	27.91	42.01
Liraglutide	Patented	6 mg injection 3 ml	4840	4840	4840

Appendix 2 (Contd)

Lispro	Not patented	100 iu disposable pen 3 ml	582.00	582.00	582.00
Luliconazole	Patented	Cream 10 gm	155.00	155.00	155.00
Methdilazine	Not patented	8 mg expectorant 450 ml	113.00	113.00	113.00
Micafungin	Patented	50 mg injection 1 ml	5,911.00	5,911.00	5,911.00
Moxifloxacin	Patented rejected	0.5 % eye drops 5 ml	250.00	54.00	92.40
Naratriptan	Not patented	2.5 mg tablet	37.50	37.50	37.50
Nepafenac	Not patented	0.10 % eye drops 5 ml	245.00	245.00	245
Nevirapine	Patented rejected	200 mg tablet	17.00	13.68	14.29
Nimorazole	Not patented	500 mg tablet	9.85	9.85	9.85
Nimotuzumab	Not patented	50 mg injection 10 ml	51,241.92	51,241.92	51,241.92
Olanzapine	Patented rejected	10 mg tablet	7.00	2.75	6.13
Olmesartan	Not patented	40 mg tablet	21.65	4.90	13.07
Orlistat	Patented rejected	60 mg capsule	28.30	12.00	21.90
Oseltamivir	Patented rejected	75 mg capsule	47.50	44.90	45.72
Oxcarbazepine	Patented rejected	600 mg tablet	27.35	7.25	14.75
Paclitaxel	Patented rejected	300 mg 50 ml injection	19,825.57	7,380.95	9,784.28
Pantoprazole	Patented rejected	40 mg tablet	11.00	0.80	5.83
Pazopanib	Patented	400 mg tablet	460.32	460.32	460.32
Pemetrexed	Not patented	500 mg injection	73,660.00	4,500.00	18,894.26
Pentosan Polysulphate Sodium	Not patented	100 mg tablet	54.75	54.75	54.75
Pimecrolimus	Patented rejected	10 mg cream 10 gm	999	790	894.5
Pirfenidone	Not patented	200 mg tablet	185.00	160.00	161.16
Posaconazole	Not patented	40 mg oral suspension 105 ml	17,440.00	17,440.00	17,440.00
Pramipexole	Not patented	1 mg tablet	15.00	14.10	14.60
Prasugrel	Not patented	10 mg tablet	27.65	9.43	17.70
Primidone	Not patented	250 mg tablet	6.85	6.85	6.85
Rabeprazole	Patented rejected	20 mg tablet	17.43	1.13	5.58
Raloxifene	Patented rejected	60 mg tablet	12.32	10.62	11.44
Ramelteon	Patented	8 mg tablet	10.90	10.90	10.90
Ranolazine	Not patented	500 mg tablet	12.95	6.476	9.32
Regorafenib	Not patented	40 mg tablet	1,311.80	1,311.80	1,311.80
Repaglinide	Patented rejected	2 mg tablet	17.50	15.17	16.33
Rifaximin	Not patented	550 mg tablet	33.10	28.50	30
Risedronate	Patented rejected	35 mg tablet	577.5	16.05	39.38
Ritonavir	Patented rejected	100 mg tablet	32.6	30	31.3
Rosiglitazone	Patented rejected	4 mg tablet	9.27	9.27	9.27
Rosuvastatin	Patented rejected	40 mg tablet	46.52	9.80	35.38

Appendix 2 (Contd)

Saroglitazar	Patented	4 mg tablet	25.90	25.90	25.9
Saxagliptin	Patented	5 mg tablet	43.21	43.21	43.21
Sevelamer	Not patented	800 mg tablet	1,260.00	12.70	36.7
Sildenafil	Patented rejected	100 mg tablet	621.85	2.72	32.87
Silodosin	Not patented	4 mg tablet	25.00	13.50	19.25
Sirolimus	Patented rejected	1 mg tablet	181.343	111.11	145.83
Sitagliptin	Patented	100 mg tablet	45.00	28.43	44.95
Sofosbuvir	Patented rejected	400 mg tablet	1,990.00	661.90	710.71
Sunitinib	Patented rejected	50 mg capsule	8714.78	8714.78	8714.78
Tadalafil	Patented rejected	20 mg tablet	79.88	4.69	37.50
Tenofovir	Patented rejected	300 mg tablet	150.00	36.67	47.62
Teriparatide	Patented rejected	750 mg injection 3 ml	23,462.00	6,900.00	12,000.00
Tiagabine	Not patented	12 mg tablet	7.98	7.98	7.98
Ticagrelor	Patented	90 mg tablet	50.00	50.00	50.00
Tigecycline	Not patented	50 mg injection	3,559.50	1,100.00	2,714.28
Tiotropium	Patented rejected	9 mcg inhaler	459.00	399.00	400.31
Tocilizunab	Not patented	400 mg injection	40,600.00	40,600.00	40,600.00
Tolvaptan	Not patented	30 mg tablet	800.00	720.00	756.00
Trabectedin	Not patented	1 mg injection	1,21,485.68	1,21,485.68	1,21,485.68
Travoprost	Not patented	0.4 % solution 2.5 ml	660.00	157.83	366.00
Triptorelin	Not patented	3.75 mg injection	7,750.00	7,117.50	7,433.75
Valganciclovir	Patented rejected	450 mg tablet	478.24	235.58	407.58
Valsartan	Patented rejected	160 mg tablet	28.60	22.50	25.55
Varenicline	Patented rejected	1 mg tablet	60.71	60.71	60.71
Zolmitriptan	Not patented	5 mg nasal spray 7 mdi	404.00	404.00	404.00
Zonisamide	Not patented	100 mg tablet	191.00	112.00	117.00
Zuclopenthixol	Not patented	200 mg injection 1 ml	406.85	406.85	406.85

Sources: See Text

Note: “Patent rejected” includes those abandoned, revoked or withdrawn.

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NOTES

[1] Henceforth referred to as just pharmaceutical market. Pharmaceutical manufacturing is broadly classified into (i) the production of active pharmaceutical ingredients (APIs) present in the drugs (also known as bulk drugs) and (ii) the production of formulations, i.e., processing of APIs into finished dosage forms such as tablets, capsules, ointments, etc. In this paper we focus only on the formulations market.

[2] The same molecule when used for different therapeutic purposes are considered as separate molecules, for example moxifloxacin (code J1G15 - anti-infectives); moxifloxacin (code S1A18 - ophtal); moxifloxacin (code S2A8 - ophthal/otologicals).

[3] From: https://wayback.archive-it.org/7993/20170404174205/https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/NDAandBLAApprovalReports/ucm373420.htm, accessed on 7 September, 2018.

[4] Thus we are unable to consider the new biologics approved during 1995 to 1999.

[5] We have considered all plain molecules including those for which information on the year of introduction is not available – see Table 2; (ii) Nine molecules which are very broad groups such as growth hormones, anti-smoking products etc have been excluded from the common group of 123 molecules.

[6] This includes those abandoned, revoked or withdrawn.

[7] See Table S1 accessed from http://science.sciencemag.org/content/suppl/2012/07/03/science.1224892.DC1), accessed 26 May, 2016).

[8] The estimate of 1.2% by Chaudhuri (2012) was based on patented molecules among the 180 new drugs introduced in India between 1995 and 2010. The 180 new drugs were identified as follows: first, the new drugs approved for marketing in USA were identified from the website of USFDA. Then the marketing status in India was ascertained from the website of the Central Drugs Standard Control Organization. This list does not include all the NBEs approved in USA. Another important limitation is that products approved for marketing in USA before 1995 but approved for marketing in India are not included. The patent status of these 180 drugs was found out indirectly using the information from the USFDA Orange Book, which is not a full proof way of finding out the patent status. In the present paper we have tried to find out the patent status in a more elaborate way - see the text on methodology above).

[9] We have not considered broad groups, for example "all tissue sealing preparations" and those which actually have multiple sellers but are monopoly brands for particular indications, e.g., Erythromycin and Stavudine.

[10] This as per the Guidelines of the National Comprehensive Cancer Network (https://www.onclive.com/web-exclusives/nccn-recommends-regorafenib-dose-escalation-in-metastatic-crc).

[11] "Ranbaxy launches anti-fungal chemical in India ", 4 January, 2010 (https://economictimes.indiatimes.com).

[12] Information for Luliconazole and Micafungin obtained form the AIOCD-AWACS data base

[13] "Dr Reddy's, AstraZeneca in pact for diabetes drug", https://www.thehindubusinessline.com, 29 May, 2015); "Lupin to market diabetes drug linagliptin for Boehringer in India", https://www.thehindubusinessline.com, 14 October 2015); "Sun Pharma to distribute AstraZeneca's cardio-drug in India", 2 June, 2015, http://www.thehindubusinessline.com; "Sun, Merck team up to market diabetes drugs", 26 April, 2011, http://timesofindia.indiatimes.com).