COMMENTARY ON INDIA'S ECONOMY AND SOCIETY SERIES - 10

ARE MEDICINE PRICES HIGH AND UNAFFORDABLE AFTER TRIPS? EVIDENCE FROM PHARMACEUTICAL INDUSTRY IN INDIA

Sudip Chaudhuri

CENTRE FOR DEVELOPMENT STUDIES

(Under the aegis of Govt. of Kerala & Indian Council of Social Science Research)

Thiruvananthapuram, Kerala, India

December 2019

ABSTRACT

The TRIPS agreement has been one of the most contentious agreements of WTO. The pharmaceutical industry has been central to this debate, especially the case of India, which did not recognize product patents in pharmaceuticals before TRIPS and evolved as a major pharmaceuticals manufacturer and exporter. During the AIDS pandemic when patented products were exorbitantly priced, supply of these drugs from India dramatically made medicines affordable and accessible. After the re-introduction of product patent protection in pharmaceuticals in India in line with the TRIPS agreement, considerable speculation and controversy have surrounded the potential impact. Rather than speculation, this paper examines a comprehensive database covering all the products in the market. We contest the claims that there would be, and there has been little negative impact of TRIPs. Our study shows that firms have started selling products at high and unaffordable prices particularly in some therapeutic groups such as cancer. Cancer is not yet a pandemic like AIDS but it is now recognized as one of the greatest public health challenges globally. Our study highlights the gravity of the situation with several cancer medicines much more expensive than the annual cost of US$ 10,000 per person for HIV/AIDs medicines which led to an international outcry in the early 2000s. Another important finding is that prices are high not only because of legal patent barriers to entry of generics but also because of manufacturing and regulatory barriers especially in biologic products. This has implications for policy intervention to make medicines more affordable for universal healthcare. What is important is not only that flexibilities such as compulsory licensing and price control which TRIPS permits are utilized but also that regulatory barriers are simplified as in the case of biologics.

Keywords: TRIPS, patents, pharmaceuticals, monopolies, prices, biologics.
JEL classification: E64, F13, L43, L81, O34.

Are Medicine Prices High and Unaffordable after TRIPS?

Evidence from Pharmaceutical Industry in India

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. India began to be known as a source of supply of affordable good quality drugs for the entire world. Thanks to such supplies, the annual cost of an effective three drug combination used for HIV/AIDS reduced from US$ 10,000 per person to less than US$ 100, leading to considerable scaling up of treatment in low and middle-income countries. As India re-introduced product patent protection in pharmaceuticals, concerns have been expressed in different circles that patented medicines will become unaffordable. Médecins Sans Frontières (MSF), which received the 1999 Nobel Peace prize for pioneering humanitarian work in different countries, for example issued a Briefing paper on India with the title, "Will the lifeline of affordable medicines for poor countries be cut?", drawing attention to the adverse effect that introduction of product patents in India might have on prices of drugs(MSF, 2005).

The link between product patents and prices in the context of TRIPS which civil society organizations such as MSF and others, for example, Commission on Intellectual Property Rights (2002), Correa (2002) and Abbott (2002) have highlighted, however, has remained controversial and often contradictory views are expressed on the issue. While some consider it obvious that product patenting will lead to higher prices, others have argued that prices of patented products may not necessarily be high. Prices depend on how firms fix prices and also on the regulatory environment. Measures such as price control and compulsory licensing which TRIPS permits can keep the prices under check. Patents may not be enforced. Even when patents are enforced, depending on demand conditions, availability of close substitutes and other factors, the profit maximizing prices may not be high (Duggan, Garthwaite & Goyal, 2016, pp. 101, 103, 122).

That prices may not be high is a theoretical possibility, yet what matters is what is happening in reality. In view of the controversy that TRIPS has generated particularly in relation to prices of

pharmaceutical products, paucity of systematic empirical work is surprising either supporting the hypothesis that the impact is marginal or confirming the apprehensions about high and unaffordable prices. The high cost of patented ARVs (in the early 2000s) and some simulation exercises (for example, Fink, 2000; Watal, 2000 and Chaudhuri, Goldberg, & Jia, 2006)have mainly been used as evidence. In this regard, Kyle & Qian (2014) and particularly Duggan (et al., 2016) are notable exceptions. The latter specifically focusses on India. On the basis of an analysis of the pharmaceutical industry in India for the period, 2003 to 2012, Duggan et al. (2016) have estimated that the average price increase is not more than about 5% after patents are granted (pp. 102-3) and have concluded that concerns that TRIPS would result in dramatic rise in prices are unfounded (p. 132). What the paper demonstrates is that on the average people are not paying significantly more for medicine purchase during a period of about 10 years after TRIPS. This is an important conclusion but only partially deals with the post-TRIPS situation. TRIPS makes no difference to the market structure and prices of generics. The generic drugs can be sold as before and may be reasonably priced depending on the number of sellers. What TRIPS has done is to introduce product patent protection in pharmaceuticals. Hence unlike in the past, firms can apply for patents and if successful, can prevent the entry of generics in these new products. A proper assessment of the impact of TRIPS on prices must consider not only the rise in the average price level comprising of all drug products after patents are granted as Duggan et al. (2016) have done. The focus must also be to investigate whether there are products with high and unaffordable prices in the post TRIPS market and if so, how significant are these. This is what we have attempted in this paper by examining prices at the detailed product level. And contrary to the conclusion of Duggan et al. (2016), we find that as apprehended during the TRIPS debate, medicines are indeed becoming unaffordable particularly in some therapeutic groups especially in the life-threatening disease of cancer. The situation is actually worse than what was witnessed during the AIDs pandemic with the annual cost of treatment per person of several medicines exceeding US$ 10,000.

We focus on India. A major manufacturer and exporter of pharmaceuticals, India has attracted international attention in the TRIPS debate and we have mentioned above, supplies from India made ARVs affordable. In fact, India is considered as one of the main reasons why multinational corporations (MNCs) wanted TRIPS to be created (Roemer-Mahler, 2013; Horner, 2013). Not surprisingly most of the significant studies analysing the impact of TRIPS on pharmaceutical prices, for example, Watal, 2000; Chaudhuri, Goldberg, & Jia, 2006 and Duggan et al.,2016 have taken India as the country of reference. This paper is another addition to the literature. Like these studies, a major concern of the paper is to analyse the implications of product patent protection on prices. But unlike these studies, we will study the non-patent factors as well which may be responsible for high prices. As Kyle & Qian (2014)have shown, the impact of patent protection on prices in a country is influenced by the status of the generic sector. India has a large and strong generic sector. The phase of globalization and liberalization from the 1990s, in fact, has provided new opportunities and the generic firms have

employed different strategies to gain from it (see for example Chaudhuri (2005); Gehl Sampath (2006); Athreye, Kale & Ramani (2009); Horner (2014) and Joseph (2016)). Our study also covers a longer period (till March 2019). An updated analysis of the Indian situation can also help other developing countries to understand the post TRIPS pharmaceutical market much better.

The paper is classified into five sections. In Section 2, we will provide an overview of the implementation of TRIPS in India. This is important to understand the specific post-TRIPS pharmaceutical market structure in India. In Section 3 we will describe the data sources and methodology. We will present our results in Section 4.

The results of this paper in Section 4 are presented in two parts. In Section 4.1.1 on "Prices, Cost of Treatment and Affordability," we focus on product level drug prices based on an examination of all the 74900 products sold in India during 2018-19. But what matters is not only the prices but also how much it costs to carry out the treatment and whether this is affordable. For a sample of anti-cancer medicines, we first estimate the cost of treatment per person (Section 4.1.2) and then take up the issue of affordability (Section 4.1.3).

In the second sub-section of Section 4 on "Market Structure, Product Patent Status and Prices", we have attempted an analysis of the factors responsible for the high and unaffordable prices. Absence of competition enables firms to charge higher prices. We first examine the market structure and find that the level of market concentration has increased in the pharmaceutical market in India in the post TRIPS period particularly in recent years (Section 4.2.1). Market concentration may be due to product patenting. But there can be other non-patent factors as well. On the basis of primarily a sample, we discuss the market structure and pricing of patented products in Section 4.2.2 and then the non-patent barriers in Section 4.2.3.

The basic economic rationale of product patenting is that it will stimulate R&D for innovation. A trade-off is involved between the potential positive effect (on R&D) and the likely negative effect (on prices) and the net benefits of the patent system have remained controversial. It may be clarified that our concern in this paper is on pricing and affordability of medicines. Our intention is not to provide an overall assessment of TRIPS. The latter must also consider the impact on R&D and innovation (and also on other aspects such as foreign direct investment, technology transfer and introduction of new medicines). It may, however, be pointed out that though proponents of TRIPs largely in the global North argued that developing countries will benefit technologically from stronger patent protection (for example Ryan, 1998 and Maskus, 2000), recent cross country studies on innovation by Sweet and Maggio (2015) and Gamba (2017) find that developing countries have not benefitted much from patent protection. Even in the developed country context, providing incentives in the form of patent protection to stimulate innovation is increasingly being questioned. Baker, Jayadev and Stiglitz (2007), for example, discuss some of the alternative financing and incentive mechanisms.

2. Implementation of TRIPS in India

TRIPS came into force on 1 January, 1995 and India was required to start accepting product patent applications from this date. But taking advantage of the transition period permitted under TRIPS, India started examining and granting product patents in pharmaceuticals not before 1 January, 2005. The applications made between 1995 and 2004 were kept in a "mailbox." The rights of a patentee accrued only from the date of grant of the patent after processing of applications started from 2005.

Article 70(3) of TRIPS and Section 3(d) of India's Patent Act are important to understand some of the distinguishing features of the post TRIPS pharmaceutical market structure in India. 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 (Chaudhuri, 2005). Thus, any drug patented abroad or for which a patent application has been filed with priority date (year of first global filing) before 1 January, 1995 could not be patented in India after TRIPS. Moreover, while amending the patent law in line with TRIPS, under Section 3(d), India has disallowed patents for new forms of existing molecules such as new combinations or new derivatives such as salts, esters, polymorphs "unless they differ significantly in properties with regard to efficacy".

The implication of Article 70(3) and Section 3(d) is that some drug products which are under patent protection in other countries, for example in the US, need not be so in India. After a patent is applied (and granted) for a new molecule, usually it takes approximately 10 years for the product to be developed for getting marketing approval from drug control administration. Thus, in the US, a new molecule with a patent granted before 1995, say in 1990 and introduced in the market as a new drug say in 2000 (10 years from 1990) would enjoy patent protection there till the patent expired in 2010 (with a patent term of 20 years). But in India, such a pre-1995 molecule will not be eligible for a patent, and hence generic firms can manufacture and sell these new products without any legal barrier even when introduced after TRIPS.

Again, in the US for example, a patent can be applied for and obtained 1995 onwards for a new form of a pre-1995 molecule and can enjoy market exclusivity. But in India in the absence of therapeutic efficacy, such patents can be denied under Section 3(d). For example, though Imatinib mesylate was patented in the US, it was denied in India and in 2018-19, there were 16 sellers in the market.

Another important aspect is that India's patent law provides for not only post-grant opposition and revocation proceedings before the Indian Patent Office, but also for pre-grant opposition. India is among the few countries which permit pre-grant opposition. Because of this provision and also because of active opposition by some civil society organisations and some generic companies, a number of patent applications have been rejected or withdrawn in India leading to a more competitive market for these products.

3. Data Sources and Methodology

3.1. Sales and Price Data

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, etc. In this paper, we focus on the final formulations market, henceforth referred to as the pharmaceutical market. For sales data in the formulations market, we have used the Sales Audit Data, PharmaTrac of AIOCD Pharmasofttech AWACS Pvt Ltd (henceforth AIOCD-AWACS). It is based on sales data (sold to both institutions such as hospitals and in the retail market) of a sample of 8000 stockists. This is a comprehensive data base which provides sales data for all the molecules marketed in India with details of the brand, the company, the therapeutic group, the drug type (tablet, capsule, injection etc) and the drug strength (5mg, 100ml etc). 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). The maximum retail price (MRP) for each product is also available from this database. For our analysis of prices in Section 4.1, we have used annual sales data for 2018-19 for all the 1453 molecules sold by 915 companies as single molecules ("plain") or as combinations of two or more molecules ("combinations") in 74900 different SKUs (stock-keeping units). (The same molecule sold in different forms such as tablets, syrups and in different strength such as 5 mg, 10 mg and by different firms are considered as separate SKUs). We have considered prices as on March 2019.

The other major data base widely used, for example by Duggan et. al (2016) is provided by IMS (now rechristened as IQVIA). This is also based on sales data collected from stockists. The version used by Duggan, et al. (2016) used data from 5100 stockists. Depending on the sampling and statistical techniques used, results may vary for particular products and firms, but both data bases are considered to be reliable and are used as alternatives by pharmaceutical firms, the main users of these databases. It may be noted that the price data provided by AIOCD-AWACS is not survey based but actual prices charged by the firms.

3.2. Product Patent Status

Finding out the product patent status 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. The patent status needs to be investigated individually using various sources. To do so for all the products introduced in the post-TRIPS period is too demanding an exercise. This perhaps explains why there are so few systematic studies on product patent status of post TRIPS molecules. Sampat & Shadlen (2015) is one of the exceptions but they primarily deal with Section 3(d) cases of secondary patenting.

To make the task manageable, we have considered a sample. First, we considered the patent status of molecules from publicly available sources. We used the Medicines Patents and Licences database, MedsPal of the Medicines Patents Pool which provide information on patent status of selected essential medicines in low and middle-income countries including India (www.medspal.org).[1] Then we traced the outcome of pre-grant opposition to patent applications from miscellaneous sources. This yielded a list of 45 molecules with information on patent status - granted, rejected, withdrawn etc.[2]

Thereafter, we considered another 123 molecules. Though the number of 123 may appear to be small, these are 123 top selling molecules accounting for 95% of the total sales of Rs 42905 million of the potentially patentable molecules of 350 in 2015-16.[3]This exercise was done in 2016 and hence sales data for the latest year, i.e., 2015-16 was used.

Finally, 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 a procedure broadly similar to that used by Sampat & Shadlen (2015). Where no direct information was available on patent status, the priority date of the foreign patents was used to classify between patented (post 1994) and not patented (pre 1995).

Excluding the molecules which were not sold in 2015-16 and those for which the patent status could not be identified, we ultimately obtained a list of 138 molecules comprising of 27 patented molecules, 46 patent rejected and 65 not patented molecules (Table 1). The details of the patent status of the 138 molecules as well as the sales and prices are provided in the Appendix. The elaborate patent search exercise done in 2016 could not be extended to cover the molecules launched since 2015-16. But we have used in Section 4.2.2, some additional information that came to light regarding the patent status of molecules launched since then.

---

1 https://www.medspal.org/?country_name%5B%5D=India&page=1, accessed on 3 October, 2019.

2 The list of these 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 & Singh (2016); Nair, Fernandes & Nair (2014); Arora & Chaturvedi, (2016) and particularly for Section 3(d) cases, the supplementary materials provided by Sampath, Shadlen & Amin (2012).

3 Monopoly molecules introduced in India between 1 January 1995 and 31 March 2016 and all the 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 have been considered as potentially patentable molecules. Combining these and avoiding duplication, the number is 350 molecules.

Table 1: Patent status of sample of 138 molecules

Molecules	Single seller	Multiple sellers	Total
Patented			
Number	19	8	27
Sales, 2015-16 in Rs million	3056.52	7023.94	10080.45
Percent of total sales*	54.9	9.7	12.9
Patent rejected			
Number	5	41	46
Sales, 2015-16 in Rs million	728.61	42249.15	42977.75
Percent of total sales*	13.1	58.4	55.2
Not Patented			
Number	32	33	65
Sales, 2015-16 in Rs million	1784.54	23055.82	24840.37
Percent of total sales*	32.0	31.9	31.9
Total			
Number	56	82	138
Sales, 2015-16 in Rs million	5569.67	72328.91	77898.57
Percent of total sales*	100.0	100.0	100.0

Source: Sales data from AIOCD-AWACS database.
Note: The details of molecule wise patent status, number of sellers, sales (2015-16) and prices (March, 2016) are provided in the Appendix.
*: percentages of total sales of patented, patented rejected and not patented molecules with single sellers in col 2 and with multiple sellers in col 3.

4. Results

4.1 Prices, Cost of Treatment and Affordability

4.1.1 Prices

The sales value of all the 1453 molecules available in the pharmaceutical market in India amounted to Rs 1305064 million in 2018-19. What are sold in the market are not molecules as such but different products of the molecules in different forms such as tablets, syrups and in different strength such as 5 mg, 10 mg. In Table 2 we have shown the price structure of all the 74900 products (SKUs[4]) sold as on March 2019. To make the figures internationally comparable, we have also indicated the price ranges in US$ using the purchasing power parity (PPP).

4 As we have mentioned above in Section 3, the databases used by us refers to molecules sold in different forms and in different strength and by different firms as different SKUs.

Table 2: Price structure of pharmaceutical products in India, March 2019

Price range in Rs	Price range in US$ PPP	No of SKUs*	Sales of SKUs in col 3 as % of total sales in 2018-19
> 200,000	> 11,033	4	0.0028
> 150,000	> 8,275	7	0.0035
> 100,000	> 5,516	12	0.0050
> 50,000	> 2,758	39	0.28
> 25,000	> 1,379	117	0.58
> 15,000	> 827	239	0.92
> 10,000	> 552	373	1.15
> 5,000	> 276	656	1.60
> 1,000	> 55	2175	5.69
> 500	> 28	3577	9.57
> 100	> 6	13984	26.31
< or = Rs 100	< or = 6	60916	73.69
Total number of SKUs		74900	
Total sales in 2018-19 in Rs million			1305064
Total sales in 2018-19 in US $ PPP			71993

Sources: Sales and price data from AIOCD-AWACS database; US$ PPP rate for 2018 from OECD, "Purchasing Power Parities" (https://data.oecd.org/conversion/purchasing-power-parities-ppp.htm), accessed on 25 September, 2019.
Note: * SKU: stock keeping unit - see text; US$ PPP rate was Rs 18.12759 in 2018.

As can be seen from Table 2, on the whole, the prices are quite low. In 60916 out of the 74900 SKUs, unit prices, i.e., prices per tablet, per injection etc. are equal to or less than Rs 100. And these products account for about three-fourths of the total market. The number of SKUs priced above Rs 1000 (US$ 55) is 2175 accounting for only 5.69% of the total sales. If we consider products in higher price ranges, the proportion is even lower - 373 products with prices above Rs 10,000 (US$ 552) accounted for only 1.15% of sales in 2018-19. It would be misleading to conclude on the basis of such low shares that the impact of TRIPS has been marginal. These proportions are low because of the preponderance of low-priced generics in the market, given India's history of absence of product patent protection and the way TRIPS has been implemented in India (Section 2). The focus of this paper is not on the competitive generic sector unaffected by TRIPS. As we have mentioned in Section 1, the focus is on whether in the post TRIPS pharmaceutical market in India, there are high priced products and if so, how significant are these. We find that in March 2019, while the number of

products in the price range more than Rs 100,000 (US$ 5500) is very small (12), those priced more than Rs 1000[5] are not negligible (2175). In fact, the number of products with prices more than Rs 1000 has increased by about 50% from 1468 in March 2013. As we have mentioned, the same molecule is sold in different SKUs. The number of molecules involved in these 2175 SKUs is 276. If we explore the structure of these 2175 products priced above Rs 1000, we see that these are mainly concentrated in a few therapeutic groups. Nine therapeutic groups accounted for 2040 out of the 2175 products (94%) (Table 3). Among these nine groups again, the incidence of high-priced products is particularly high in vaccines, anti-neoplastics, blood-related and hormones groups. In the price range more than Rs 1000 (US$ 55), in vaccines 215 SKUs (32 molecules) account for 76.4% of sales, in anti-neoplastics 666 SKUs (79 molecules) account for 54.6% of sales and in blood-related group 171 SKUs (17 molecules) account for 35.9% of sales (Table 3).

Table 3: Price structure of pharmaceutical products in selected therapeutic groups in India, March 2019

Therapeutic group	No of SKUs with prices > Rs 1,000 (US$ PPP 55)	Sales of SKUs in col 2 as % of total sales of the group in 2018-19	No of SKUs with prices > Rs 5,000 (US$ PPP 276)	Sales of SKUs in col 4 as % of total sales of the group in 2018-19	No of SKUs with prices > Rs 10,000 (US$ PPP 552)	Sales of SKUs in col 6 as % of total sales of the group in 2018-19
Vaccines	215	76.4	24	5.0	14	2.5
Anti-neoplastics	666	54.6	339	38.4	217	32.0
Blood related	171	35.9	27	6.6	10	2.1
Hormones	120	15.9	52	7.9	31	3.7
Gynaecological	150	8.6	28	1.2	13	0.7
Anti-infectives	298	4.9	45	0.5	19	0.2
Pain/analgesics	102	3.1	42	1.8	32	1.6
Derma	201	1.9	33	0.08	5	0.02
Gastro Intestinal	117	1.2	1	0.06	1	0.10
Total	2040					

Sources and Notes: Same as in Table 2.

5 Unit price of Rs 1000 is considered as a benchmark for prices in this paper. In an economy where the monthly average income is Rs 12,000 (Table 7), Rs 1000 for one tablet or injection is actually quite a high figure. As we will see from our discussion below, a unit price of Rs 1000 can lead to substantial cost of treatment.

Even if we consider higher price ranges of more than Rs 5000 or more than Rs 10,000, there are vaccines and blood-related products. But relatively the number and sales proportions are small (Table 3). But the anti-neoplastics group stands out. Even in higher price ranges, the sales of anti-neoplastics SKUs continue to be significant. 217 SKUs priced above Rs 10,000 (41 molecules) contribute to one third of total sales and 142 SKUs priced above Rs 15,000 (37 molecules) about a fourth. Even in the price ranges of more than Rs 25,000 or Rs 50,000, anti-neoplastics SKUs are sold with substantial sales share of 18.7% (78 SKUs, 25 molecules) and 11.5% (31 SKUs, 16 molecules) respectively (Table 4).

Table 4: Price structure of anti-neoplastics (cancer) products in India, March 2019

Price range in Rs	Price range in US$ PPP	No of SKUs	Sales of SKUs in col 3 as % of total sales in 2018-19
> 200,000	> 11033	4	0.13
> 150,000	> 8275	5	0.15
> 100,000	> 5516	9	0.19
> 50,000	> 2758	31	11.5
> 25,000	> 1379	78	18.7
> 15,000	> 827	142	25.5
> 10,000	> 552	217	32.0
> 5,000	> 276	339	38.4
> 1,000	> 55	666	54.6
> 500	> 28	780	59.3
> 1,00	> 6	1040	79.7
< or = 1,00	< or = 6	509	20.3
Total		1549	

Sources and notes: Same as in Table 2

The presence of high-priced products particularly in some therapeutic groups is a significant development in the post TRIPS pharmaceutical market in India. This is in sharp contrast to the situation before TRIPS when drug prices in India were very competitively priced (Chaudhuri, 2005, pp. 53-58). Aggregate or the average figures hide the existence of such high-priced products. Identification of these products in this paper followed the product level and therapeutic group-wise level examination of all the products in the market.

4.1.2 Cost of Treatment

What we have considered in the previous section are unit prices. Depending on the indications for which medicines are used, these may be required to be taken or administered only once, few times

or for extended periods. Therefore, what matters is not only the prices but also what the total cost is and whether these are affordable.

In this section, we consider the cost of treatment and in Section 4.1.3, affordability.

In view of the high incidence of high prices in anti-neoplastics (anti-cancer) and also because these medicines need to be taken for extended periods, we have focussed on anti-neoplastics products for calculation of cost of treatment. In cancer, the 666 SKUs priced more than Rs 1000 involved 79 molecules. For cost calculation we have considered a sample of 30 molecules which account for about 52% of the total sales of these 79 molecules in 2018-19. These 30 molecules are from different price ranges (see Table 5).

Table 5: Prices and monthly cost of treatment per person of selected anti-cancer medicines

Molecule	No of sellers	Unit for price	Price, March 2019, Rs	Dosage frequency	Monthly cost of treatment, Rs
Afatinib	1	40 mg tablet	1975.08	Once a day	59,252
Axitinib	1	5 mg tablet	2981.21	Twice a day	1,78,873
Bevacizumab*[1]	11	400 mg injection	72144	14 days in 21 days	1,18,193
Bortezomib*[2]	15	2 mg injection	11300	4 times in 21 days	52,884
Cabazitaxel*[2]	6	60 mg injection 1.5 ml	18947.9	Once in 21 days	11,369
Carmustine	1	100 mg injection	5180	Twice every 6 weeks	13,986
Cetuximab	1	100 mg infusion 20 ml	20222	Once in 7 days	3,63,996
Cladribine	2	10 mg injection	13400	For 5 days	70,350
Crizotinib	1	250 mg capsule	1771.17	Twice a day	1,06,270
Daratumumab*[3]	1	400 mg injection 20 ml	75500	Once in 28 days	2,26,500
Dasatinib	1	50 mg tablet	3287.3	Once a day	2,76,133
Denosumab	3	120 mg injection	27416.2	Once in 28 days	27,416
Erlotinib	14	150 mg tablet	311.77	Once a day	9,353
Fludarabine	4	10 mg tablet	1527.32	5 days in 28 days	54,983
Golimumab	1	50 mg injection 0.5 ml	128000	Once every month	1,28,000
Ibrutinib	1	140 mg capsule	3644.44	Once a day	3,28,000
Idarubicin*[2]	1	5 mg injection 5 ml	8192.91	Once	70,787
Imatinib Mesylate	20	400 mg tablet	202.7	Once a day	6,081
Nilotinib	1	200 mg tablet	1747.5	Twice a day	1,57,275
Pemetrexed*[2]	21	500 mg injection	27500	Once in 21 days	49,500

Cont'd.....

Molecule	No of sellers	Unit for price	Price, March 2019, Rs	Dosage frequency	Monthly cost of treatment, Rs
Pertuzumab*[4]	1	420 mg injection 14 ml	246799	Once in 21 days	3,21,018
Pomalidomide*[2]	8	2 mg capsule	476.19	21 days in 4 weeks	20,000
Ramucirumab	1	500 mg injection 50 ml	257532	Once in 2 weeks	6,18,077
Regorafenib	1	40 mg tablet	1506.95	21 days in 28 days	1,26,584
Rituximab*[3]	12	500 mg injection	30285.6	Cycle 28 days	70,414
Sorafenib	3	200 mg tablet	74	2 times a day	8,880
Sunitinib	1	50 mg capsule	8714.78	28 days in 42 days	2,44,014
Tocilizunab	1	400 mg injection	40545	Every 4 weeks	65,683
Trabectedin	2	1 mg injection	28600	Every 3 weeks	77,220
Trastuzumab	11	440 mg injection	58820	Once in 21 days	80,209

Sources: Price data have been obtained from AIOCD-AWACS database – see text. Prices are MRP (maximum retail price). Following WHO (2018, p. 78), information on dosage used for treatment for anti-cancer medicines has been obtained mainly from eviQ, the Australian Government online resource of cancer treatment protocols (https://www.eviq.org.au). We also used the print edition of the *British National Formulary*, No 69 (March 2015 to September 2015), British Medical Association and Royal Pharmaceutical Society. These were accessed in the first week of October, 2019. For products where dosage depends on body weight or Body Surface Area (BSA), we have considered the average weight of 75 kgs and Average Body Surface Area of 1.8m^2, as in inter-country cost calculations by WHO (2018, p. 78). Monthly dosage in mg has been multiplied by the price per mg for estimating the monthly cost of treatment. The cost is only for the cancer medicines. It does not include other costs, for example on other medicines, diagnostics, hospitalization.

Notes: For each molecule, we have considered all the SKUs and selected for the March 2019 price, the SKU with highest sales in 2018-19, not the highest priced SKU. In products with multiple sellers, some products are sold often at a much higher price compared to the prices mentioned in the table. In such cases, the cost of treatment is higher than what is shown in the table for example for Rituximab, Bortezomib and Erlotinib.

*[1]: The cost of treatment for Bevacizumab includes the cost of Capecitabine which needs to be administered with the former.

*[2]: For these drugs, actual cost of treatment is higher since these need to be taken with some other cancer drug(s).

*[3]: For, Rituximab, the monthly dosage is the average of 6 cycles; for Daratumumab, it is from cycle 7 – initial dosage and hence cost is higher.

*[4]: The cost for Pertuzumab includes that for Trastuzumab and Docetaxel which need to be administered together with Pertuzumab

Out of the 30 anti-cancer molecules, the monthly cost of treatment per person is above Rs 100,000 for 13 molecules, between Rs 50,000 and Rs 100,000 for nine molecules; between Rs 10,000 and Rs 50,000 for five molecules and between Rs 6,000 and Rs 10,000 for three molecules (Table 5). The monthly cost of treatment of Ramucirumab, currently the costliest drug with unit price of Rs 257532 is Rs 6,18,077. Other high-cost anti-cancer drugs include, Cetuximab with a monthly cost of treatment of Rs 3,63,996, Daratumumab (Rs 226500) and Nilotinib (Rs 157275) (Table 5).

To put it in international and comparative perspective, let us recall that the annual cost of ARVs per person in the early 2000s was US$ 10,000 and this was considered to be exorbitant and led to an international outcry. In 20 out of the 30 anti-cancer molecules, the annual cost is actually more than US$ 10,000 (Table 6). In fact, in four products it is more than US$ 50,000 and in eight products between US$ 20,000 and 50,000. If we consider US$ values not at market exchange rates but at purchasing power parity (PPP) which is perhaps more appropriate, we see that 25 molecules have annual costs exceeding US$ 10,000 (Table 6). We have considered in our sample of 30 molecules, some but not all high-priced medicine. In all probability, the number of exorbitantly priced anti-cancer medicines is more than what Table 6 suggests. Unlike AIDS, cancer is not yet a pandemic. But cancer is now recognised as one of the greatest public health challenges globally. With an estimated 18.1 million new cancer cases and 9.6 million cancer deaths in 2018, it has emerged as the single most important barrier to increasing life expectancy in every country of the world in the 21st century (Bray et al., 2018). Thus, in a market of critical importance, the situation after TRIPS is far worse than what was experienced during the HIV/AIDS pandemic.

Table 6: Annual cost of treatment per person of selected anti-cancer medicines

Molecule	Annual cost of treatment, 2019, US$ PPP*	Annual cost of treatment, 2019, US$**
Ramucirumab	409152	108451
Cetuximab	240960	63869
Ibrutinib	217128	57553
Pertuzumab	212508	56328
Dasatinib	182796	48452
Sunitinib	161532	42816
Daratumumab	149940	39743
Axitinib	118404	31386
Nilotinib	104112	27596
Golimumab	84732	22460
Regorafenib	83796	22211
Bevacizumab	78240	20739
Crizotinib	70344	18647

Cont'd.....

Molecule	Annual cost of treatment, 2019, US$ PPP*	Annual cost of treatment, 2019, US$**
Trastuzumab	53100	14074
Trabectedin	51120	13549
Idarubicin	46860	12421
Rituximab	46608	12355
Cladribine	46572	12344
Tocilizunab	43476	11525
Afatinib	39228	10397
Fludarabine	36396	9648
Bortezomib	35004	9279
Pemetrexed	32772	8686
Denosumab	18144	4811
Pomalidomide	13236	3509
Carmustine	9264	2454
Cabazitaxel	7524	1995
Erlotinib	6192	1641
Sorafenib	5880	1558
Imatinib Mesylate	4020	1067

Sources and notes: Same as in Table 5 for cost of treatment in rupees using March 2019 prices.

* For calculating the cost in US$ PPP, the PPP rate has been taken to be Rs 18.12759 from OECD, "Purchasing Power Parities" (https://data.oecd.org/conversion/purchasing-power-parities-ppp.htm), accessed on 25 September, 2019.

** For calculating the cost in US$, we have taken the market exchange rate of Rs 68.3896 per $ (the average exchange rate during 2018-19) from www.rbi.org.in.

4.1.3 Affordability

A common method to find out the affordability of a medicine is to calculate how long a person needs to work to pay for a course of treatment. In developing countries such as India where out of pocket spending is predominant, this actually estimates the financial burden of medicine purchase. WHO and Health Action International have used the indicator of number of days an unskilled government worker needs to work to pay for a month's treatment cost (Mendis et al., 2007; Niëns et al., 2012). A medicine is considered as unaffordable if more than a few days of work are required to buy the monthly medicine requirement (Mendis et al., 2007, p. 284). Another method is to use the average income of the country (GDP per capita or GNI per capita) (Love, 2012; Goldstein et al., 2017); These methods were used by the Patent Office in India while granting a compulsory licence in

2012 to a generic firm, Natco to manufacture and sell Sorafenib, a drug for liver and kidney cancer patented by Bayer.[6] The Patent Office did not find the monthly cost of Rs 280428 of Bayer's brand to be a "reasonably affordable price." The judgement noted that a lowest paid government worker would have to work for three and a half years to afford the monthly cost. And a person earning the average income (GNI per capita) will have to work for four and a half years.

We use both these indicators to find out the affordability of medicines. We consider the monthly GNI per capita in India in 2018-19 (Rs 12035) (US$ PPP 660) and the monthly salary of the lowest paid central government employee in March 2019 (Rs 20160) (US$ PPP 1100) for the purpose of examining affordability (see Notes to Table 7).

Cancer medicines are typically administered in cycles of once in two weeks, five days in four weeks, 28 days in 42 days and so on. And these cycles need to be repeated until "disease progression or unacceptable toxicity." Hence for the purpose of estimating the cost and affordability of anti-cancer drugs, WHO (2018, p. 78) considered the annual cost of treatment. Similarly, for the anti-cancer drugs listed in Table 6, we estimate how many months/years it will take to pay for the annual cost of treatment using both government salary and GNI per capita as income indicators. This is shown in Table 7.

Table 7: Affordability of selected anti-cancer products

Anti-neoplastics molecule	Annual cost of treatment, 2019, Rs	Affordability: govt salary*	Affordability: GNI per capita**
Afatinib	711028	2.94	4.92
Axitinib	2146474	8.87	14.86
Bevacizumab	1418311	5.86	9.82
Bortezomib	634608	2.62	4.39
Cabazitaxel	136425	0.56	0.94
Carmustine	167832	0.69	1.16
Cetuximab	4367952	18.06	30.24
Cladribine	844200	3.49	5.85
Crizotinib	1275243	5.27	8.83
Daratumumab	2718000	11.24	18.82
Dasatinib	3313600	13.70	22.94
Denosumab	328994	1.36	2.28
Erlotinib	112239	0.46	0.78
Fludarabine	659801	2.73	4.57
Golimumab	1536000	6.35	10.64

Cont'd.....

6 The text of the judgment is available at http://www.gnaipr.com/CaseLaws/Controller%20Order%20-%2012032012.pdf.

Anti-neoplastics molecule	Annual cost of treatment, 2019, Rs	Affordability: govt salary*	Affordability: GNI per capita**
Ibrutinib	3936000	16.27	27.25
Idarubicin	849441	3.51	5.88
Imatinib mesylate	72972	0.30	0.51
Nilotinib	1887300	7.80	13.07
Pemetrexed	594000	2.46	4.11
Pertuzumab	3852217	15.92	26.67
Pomalidomide	240000	0.99	1.66
Ramucirumab	7416922	30.66	51.36
Regorafenib	1519005	6.28	10.52
Rituximab	844968	3.49	5.85
Sorafenib	106560	0.44	0.74
Sunitinib	2928165	12.10	20.28
Tocilizunab	788195	3.26	5.46
Trabectedin	926640	3.83	6.42
Trastuzumab	962509	3.98	6.66

Sources and Notes: Annual cost of treatment is derived from Table 5. GNI per capita has been calculated from Tables A1 and A 38 of *Economic Survey, 2018-19* (https://www.indiabudget.gov.in/economicsurvey/). The monthly GNI per capita was Rs 12035 in 2018-19. For the lowest paid government employee, we have taken the basic salary and dearness allowance of a central government employee. In March 2019 it was Rs 20160.

*: Number of years the lowest paid government employee will have to work to fund the annual cost in Col 2.

**: Number of years a person earning an income equivalent to GNI per capita will have to work to fund the annual cost in Col 2.

Out of the 30 anti-cancer drugs, the lowest paid government employee will have to work for more than 10 years to afford the annual cost of treatment for seven drugs, between five and 10 years for six drugs, between 1 and five years for 11 drugs and less than a year for the remaining six drugs (Table 7). For these six drugs requiring work for less than a year, in none of the drugs is it less than a month. If we take the average Indian salary (GNI per capita), one needs to work for a longer period to fund the cost of treatment as col 4 of Table 7 shows.

If a person is required to use the entire income to fund the medicine cost and that too for months and years, then the conclusion is inescapable that these are unaffordable for most Indians who do not earn more than the average national income of GNI per capita or even less. With much larger annual costs for several cancer medicines, the situation is worse than what was witnessed during the AIDs pandemic when the exorbitant cost made the drugs beyond the reach of most people in developing countries.

For calculating the cost of treatment, we have considered the MRP (maximum retail price) data available from the database used by us. But particularly for medicines which are high priced and need to be taken for a considerable period of time as in the case of cancer, products are available at a discount. If these discounted prices are considered, then obviously the cost of treatment will be less. But the magnitude of the cost as discussed above is such that it hardly makes a difference from the point of view of affordability. Thus rather than the MRP, if we consider the Price to Retailer (PTR) (which does not include any retail margin), the annual cost for Ramucirumab, for example, will be Rs 5562691 (rather than Rs 7416922), for Cetuximab, Rs 3249964 (Rs 4367952), for Ibrutinib, Rs 2951999 (Rs 3936000), for Dasatinib, Rs 2650880 (Rs 3313600), for Sunitinib, Rs 2230982 (Rs 2928165) and for Daratumumab, Rs 2038509 (2718000). The number of years of work that the government employee needs to do to afford this reduced cost for these medicines is at least 8 years thereby still making these unaffordable.

4.2 Market Structure, Product Patent Status and Prices

4.2.1 Market Structure

Absence of competition enables firms dominating the market for a particular drug (molecule) to fix prices at higher levels. To understand the price structure, we first analyse the level of market concentration, i.e. the extent to which the market is dominated by few firms. But market concentration may be high, as we will see below not only because of the legal patent barrier to entry of generics but also because of manufacturing and regulatory barriers.

Two common methods to measure market concentration are CR4 and Herfindahl-Hirschman Index (HHI). CR4 is the market share of the top 4 firms in the market. HHI is the sum of squares of the market shares of all the firms in the market. When a single firm has 100% market share, the HHI is ten thousand (square of 100).

Medicines are classified into broad therapeutic groups such as anti-neoplastics, anti-diabetic, cardiac, neuro/CNS, and so on. And within each of these groups, there are several molecules, for example, Cetuximab, Dasatinib, Erlotinib, and Trastuzumab for the anti-neoplastics group. We consider market at the molecule level for finding out market concentration. This is the relevant market in the case of product patent protection since it prevents other firms from selling this molecule and not the other molecules in that therapeutic group. In fact, in this paper by monopoly we mean monopoly at molecule level, not at therapeutic group level or at the industry level.

The database used by us provides information on sales of all the firms in all the markets. Thus, it is possible to find out the degree of market concentration. As Table 8 shows, the CR4 ratio was quite low for the molecules introduced before 2005 (less than 5%). But since then it has started rising from 20.5% for molecules introduced during 2005 to 2009 to 46.5% during 2016 to 2018. In fact, for the molecules introduced in 2018, CR4 is 100%. We have also tried to find out using HHI, the proportion

of monopoly molecules, i.e., where HHI is 10000. We find a similar trend of increasing market concentration. From insignificant monopoly share before 2005, it has increased substantially from 7.8% during 2005 to 2009 to 30.6% during 2016 to 2018. In the last three years, it has increased from 24.5% in 2016 to 30.9% in 2017 and to 77.7% in 2018.

Table 8: Concentration in pharmaceutical market in India

Year of introduction of molecules	No of molecules	Sales, 2018-19 in Rs million	Market share of monopoly molecules (HHI: 10000)*	Market share of top 4 firms of molecules (CR4)**
Before 1995	367	241239	0.1	2.3
1995 to 2004	513	291535	1.6	4.8
2005 to 2009	135	61819	7.8	20.5
2010 to 2012	92	26560	2.4	30.7
2013 to 2015	58	20230	9.6	44.6
2016 to 2018	68	6048	30.6	46.5
Total	1233	647433		

Source: Calculated from AIOCD-AWACS database.

Notes: Considered in the table only plain molecules sold in 2018-19. Excluded unclassified molecules and also all molecules launched in 2007. This is because the molecules for which year of introduction is not known, has been designated by default in the AIOCD-AWACS database as introduced in April, 2007, i.e., the year the database was launched.

* Sales of monopoly molecules as % of total sales in col 3.

** Sales of top 4 firms of molecules as % of total sales in col 3.

For the anti-neoplastics group, market concentration is even higher. From low market concentration before 2005, CR4 has gone up from 21.4% during 2010 to 2012 to 70.9% during 2016 to 2018 and monopoly share from 4.9% to 39.5% respectively during these periods (Table 9). Out of the 17 molecules introduced during 2016 to 2018, 11 are monopoly molecules and the monopoly share has increased from 22.4% in 2016 to 89.8% in 2018. The CR4 ratio is 100% for 2016 and 2018 and 46.5% for 2017.

Thus, we see that the level of market concentration is increasing over time in the post TRIPS period. We also found evidence of high product level prices and high cost of treatment. (Tables 2 to 5). Both these findings are based on an examination of the entire pharmaceutical market and are major contributions of the paper.

As can be seen from Table 5, some of the high cost molecules are monopoly molecules, for example Ramucirumab, Cetuximab, Ibrutinib, Pertuzumab and Dasatinib. One reason for the monopoly status of course could be that these are patented. But there can be factors other than patent protection explaining the high market concentration and high prices. There are also high cost molecules sold by

multiple firms, for example, Bevacizumab and Trastuzumab. To explore these aspects, we need information on the patent status of molecules. But as discussed in Section 3, it is difficult to get such information. Hence, we have considered a sample. Our sample comprises of 138 molecules - 27 are patented, 46 are patent rejected and 65 not patented molecules (Table 1). Price information in Section 4.1.1 is based on all the products in the market. Based as it is on a sample, the discussion on market structure and pricing below covers only a part of the market. For patented molecules the sample may appear to be small. But we are able to provide some evidence of analytical significance and offer some explanations for some interesting developments in the post TRIPS patented and generics markets in India.

4.2.2. Market Structure and Pricing of Patented Products

Market Structure. Out of the 27 patented molecules in our sample, 19 are monopoly molecules. But the remaining eight are not (Table 1). The later might appear surprising but this is possible in the case of compulsory licensing. The compulsory licence granted for Sorafenib, a patented drug in India has permitted generic entry. This is also possible when a patentee provides a voluntary licence to others to manufacture and sell, as in the case of Sofosbuvir. But what is noteworthy is that a new development that is witnessed in post TRIPS India is that MNCs have started entering into formal marketing arrangements with Indian generic firms also to sell patented products. Dr Reddy's, for example, sells AstraZeneca's product, Saxagliptin; Lupin sells Boehringer Ingelheim's, Linagliptin; Sun Pharmaceuticals sells AstraZeneca's product, Ticagrelor and Merck's (MSD)'s product Sitagliptin.[7] Presence of multiple sellers for patented products also could be due to Section 11A(7). Patent applications made between 1995 and 2004 were kept in a mailbox and processed only after 2004 (Section 2). Not knowing what is there in the mailbox if a non-patentee which have made "significant investment" 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 is an interesting feature of India's Patent Act but not much is known about the extent to which this provision has actually been used.

Pricing of Patented Products. It is often argued, for example by the International Federation of Pharmaceutical Manufacturers Associations, whose members dominate the patented medicine markets worldwide, that competition of new patented medicines with other products in the same therapeutic group keeps prices low (IFPMA, 1997). This indeed appears to be the case among several molecules out of the 27 patented molecules in our sample. In fact, 17 out of the 27 patented drugs have unit prices Rs 1000 or less and 10 drugs have unit prices of Rs 100 or less (Table 10).[8] In some cases, prices

---

7 "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" (http://www.thehindubusinessline.com, 2 June, 2015); "Sun, Merck team up to market diabetes drugs" (http://timesofindia.indiatimes.com, 26 April, 2011)..

8 Even a patented molecule with a single seller can be and often is sold in different SKUs, for example in different strengths. We have considered the price of the highest sold SKU rather than highest priced SKU.

Table 9: Concentration in market for cancer medicines in India

Year of introduction of molecules	No of molecules	Sales, 2018-19 in Rs million	Market share of monopoly molecules (HHI: 10000)*	Market share of top 4 firms of molecules (CR4)**
Before 1995	15	1699	4.2	6.8
1995 to 2004	44	14505	0.1	3.5
2005 to 2009	10	1067	0.03	34.6
2010 to 2012	8	3725	4.9	21.4
2013 to 2015	12	2033	19.9	50.5
2016 to 2018	17	1019	39.5	70.9
	106	24048		

Source and Notes: Same as in Table 8.
* Sales of monopoly molecules as % of total sales in col 3.
** Sales of top 4 firms of molecules as % of total sales in col 3.

are relatively low in India because of compulsory and voluntary licensing as in the case of Sorafenib (Rs 74 for 200 mg tablets) and Sofosbuvir (Rs 536 for 400 mg tablet) respectively.

But what is significant is that despite therapeutic competition, all patented molecules are not reasonably priced. The prices of the oral diabetic drugs, Saxagliptin and Sitagliptin are Rs 43 (5 mg tablet) and Rs 45 (100 mg tablet) respectively. There is a large number of low-priced products available in the market with only three oral diabetic drugs (tablets/capsules) priced above Rs 100. Thus, it is not unexpected that pricing has been done for these two products at competitive levels. The problem is

Table 10: Price structure of sample of 138 molecules

Prices of highest sold SKU	Number of patented molecules	Col 2 as % of total number of patented molecules	Number of patent rejected molecules	Col 4 as % of total number of patented rejected molecules	Number of not patented molecules	Col 6 as % of total number of not patented molecules
> Rs 25,000	2	7.4	2	4.3	5	7.7
> Rs 10,000	3	11.1	4	8.7	9	13.8
> Rs 1000	12	44.4	6	13.0	21	32.3
> Rs 100	17	63.0	23	50.0	39	60.0
< = Rs 100	10	37.0	23	50.0	26	40.0
Total	27	100.0	46	100.0	65	100.0

Source: Price data from AIOCD-AWACS database.
Note: Same as in Table 1.

with patented drugs which involve major improvements and are more effective than competing products as in the case of some of the anti-cancer drugs. Prices in such cases can be very high as the same sample shows (Table 10). Table 5 shows the high prices and costs of treatment of some of these patented drugs, for example, Cetuximab (monthly cost of Rs 3,63,996; US$ (PPP) 20080; Dasatinib (Rs 276133; US$ (PPP) 15233; Axitinib (Rs 178873; US$ (PPP) 9867).

The number of patented medicines is more than what Table 10 based on our sample shows. The elaborate patent search exercise was done in 2016 (see Section 3 above). Market concentration has intensified since then (Tables 8 and 9). An examination of the recently launched monopoly molecules shows that some of these, for example, Afatinib, Daratumumab, Golimumab, Ibrutinib, Nilotinib, Pertuzumab, Ramucirumab, Osimertinib and Palbociclib are in fact patented (Table 11). As can be seen from Table 11, unit prices of five of these exceed Rs 100,000. One of these is priced at Rs 75,000 and another at Rs 20,000. The remaining seven molecules are priced less than Rs 5,000. Some of these are included in Table 5 and as can be seen from the table, the costs of treatment are very high for these medicines, for example, Ramucirumab (monthly cost of Rs 6,18,077; US$ (PPP) 34096), Golimumab (monthly cost of Rs 1,28,000; US$ (PPP) 7061); Daratumumab (monthly cost of Rs 226500; US$ (PPP) 12495), Ibrutinib (monthly cost of Rs 328000; US$ (PPP) 18094), Nilotinib (monthly cost of Rs 157275; US$ (PPP) 8676).

The issue is not only about the absolute level of prices. The concern is whether prices are higher than what would have been the case if there were no patent barrier to entry of generics. But new patented molecules are new products which did not exist before. With what does one compare to measure how high these prices are? In countries such as the United States, the prices of patented monopoly medicines are considered to be very high. To find this out, the standard practice is to compare the prices before and after patent expiry. Price erosion after patent expiry is used as a proxy for the extent to which prices were high under patents. In these countries, product patents have been in force for a long time and every year several molecules become off-patent and price erosion can be measured for each of these. In India where pharmaceutical product patent protection has been introduced only recently, product patents have expired till date for only four molecules. We will compare the prices before and after patent expiry for these molecules to find out what light it throws on pricing of patented products in India. But for other products for which patents are yet to expire, how does one find out the impact of product patenting on prices? Even when patents have not expired, if the patented drugs are exposed to competition, as in the case of compulsory licensing, then the resultant price differential, if any can also be treated as indicators of higher pricing of patented drugs. Another method is comparison of prices in different countries with different patent regimes. On the basis of whatever evidence is available, we try to use these methods below to get an idea about the pricing in a product patent regime.

Prices before and after Patent Expiry. The four molecules where product patents have expired in India are Cabazitaxel, Micafungin, Dabigatran and Luliconazole. In March 2016, the costliest medicine

Table 11: Patented medicines launched in India, 2016-18

Molecules	Unit for price	Therapeutic group	Company	Price, Rs	Date of launch
Afatinib	40 mg tablet	Anti-Neoplastics	Boehringer Ingelheim	1975.08	Jun-18
Daratumumab	400 mg injection 20 ml	Anti-Neoplastics	Johnson & Johnson	75500.00	Mar-18
Golimumab	50 mg injection 0.5 ml	Anti-Neoplastics	Johnson & Johnson	128000.00	Apr-16
Ibrutinib	140 mg capsule	Anti-Neoplastics	Johnson & Johnson	3644.44	May-18
Idarucizumab	50 mg injection 1 ml	Others	Boehringer Ingelheim	152852.81	Mar-18
Imiglucerase	injection 10 ml	Gastro Intestinal	Sanofi	116718.75	Oct-18
Lixisenatide	10 mcg penfill	Anti Diabetic	Sanofi	4114.00	Apr-16
Nilotinib	200 mg tablet	Anti-Neoplastics	Novartis	1747.50	Aug-16
Nintedanib	150 mg capsule	Respiratory	Boehringer Ingelheim	2436.11	Dec-17
Osimertinib	80mmg tablet	Anti-Neoplastics	Astra Zeneca Pharma	20443.58	Aug-17
Palbociclib	125 mg capsule	Anti-Neoplastics	Pfizer	4523.81	Dec-16
Pertuzumab	420 mg injection 14 ml	Anti-Neoplastics	Roche	246798.75	Aug-17
Ramucirumab	500 mg injection 50 ml	Anti-Neoplastics	Eli Lilly	257532.00	May-18
Ruxolitinib	20 mg tablet	Anti-Neoplastics	Novartis	4251.45	May-16

Source: Price information from AIOCD-AWACS database. For patent status information for Afatinib and Nilotinib from https://www.medspal.org. No direct information is available whether the other drugs are patented in India or not. But the priority dates for foreign patents for these are post-2005 and these are only sold by the originator companies in India (https://www.drugpatentwatch.com and https://www.pharmacompass.com). These are accordingly considered as patented in India.

in India was Cabazitaxel with a price of Rs 3,30,000 (US$ PPP 18,000) for one injection. With the entry of the first generic product in June 2016, the price reduced to Rs 32359, i.e. the price eroded by 90%. Thereafter, with the entry of additional generic companies in the market, further price erosions have taken place. The enormity of excessive pricing under patents is demonstrated by the fact that by August, 2017, price erosion amounted to 94%. This is not quite different from the US situation where price erosion of more than 90% following patent expiry is not unusual (Abbott, 2016, p. 316).

Similarly, comparing the price in March 2016 when the product was under patent protection with that after patent expiry, the price erosion that has taken place for Luliconazole by March, 2019 is 78% and for Dabigatran, 74%. Only for Micafungin, the price erosion is low (9%).

Compulsory Licensing. Only one compulsory licence has been granted for the drug, Sorafenib. The patentee (Bayer) charged a high price resulting in a monthly cost of treatment of about Indian 280,000 (US$ (PPP) 15400), as we have mentioned above. But after getting the compulsory licence, an Indian generic company (Natco) is supplying the same drug at a monthly cost of Rs 8880 resulting in a saving of about 97%. The contrast with Dasatinib for which an application for compulsory

licensing was rejected by the patent office is striking. This monopoly patented product is sold at Rs 3288 for one 50 mg tablet and the monthly cost of treatment is Rs 276133 (US$ (PPP) 15200) (Table 5).

Inter country Patent Status and Prices. Before TRIPS when most countries recognized product patents in pharmaceuticals but some countries such as India did not, excessive pricing of patented antiretroviral drugs, for example, was exposed by Indian generic companies charging much lower prices. Now Bangladesh is the only country with substantial pharmaceutical manufacturing capacity where product patent protection is not in force. As a Least Developed Country (LDC), it is permitted to delay the introduction of such patent protection.

The progress that Bangladesh has made is mainly in the formulations sector. For the APIs, the country mainly relies on imports, the major sources being China and India. Bangladesh has started manufacturing and selling some medicines patented in other countries. But manufacturing of patented medicines is challenging because the APIs of patented products cannot be imported from China and India where product patent protection is in force. We are able to identify six molecules which are patented in India and also manufactured and sold in Bangladesh (Table 12). To compare the prices, we have converted the prices in local currencies to US$ using the PPP rates. In all the six products the prices in India are higher than those in Bangladesh. For the costliest drug in the group (Pertuzumab), whereas the price in India is US$ (PPP) 13635, it is only 2187 in Bangladesh, i.e., the former is higher by 523%. For the other five drugs, the extent to which Indian prices are higher varies between 43% (for Cetuximab) and 7129% (for Osimertinib) (col 5). In four out of the six products, there are multiple sellers in Bangladesh and prices vary depending on the firm. If we take the lowest price in Bangladesh the price variation would be even higher as col 6 of Table 12 shows. These cheaper products from Bangladesh cannot legally enter the Indian market since these are patented in India. But such is the extent of price differential that smuggling of such drugs has started into India from Bangladesh and the Organization of Pharmaceutical Producers of India representing the MNCs in India have taken up the issue with the government (Mukherjee 2019).

Product patent protection has started only recently in India and patents for only four products have expired. But the case studies discussed above provide some indications of the extent to which patented products are higher priced due to lack of generic competition.

4.2.3 Market Structure and Pricing of Not Patented products

Absence of patents has, as expected led to, in general, a less concentrated market structure and lower prices. Out of the 46 patented rejected molecules in our sample, 41 are sold by multiple sellers and out of the 65 not patented molecules, 33 have multiple sellers (Table 1). Again, out of the 46 patent rejected molecules, 40 are priced Rs 1000 or less. In fact, 23 molecules are priced less than Rs 100. Among the not patented molecules, 44 out of 65 are priced below Rs 1000 and 26 below Rs 100 (Table 10).

Table 12: Price differentials of selected molecules in Bangladesh and India,

Molecule	Unit for price	Price in India, US$ PPP	Highest price in Bangladesh, US$ PPP	Lowest price in Bangladesh, US$ PPP	Price differential* (%)	Price differential** (%)
Cetuximab	100 mg infusion 20 ml	1117.24	781.25	781.25	43	43
Dasatinib	50 mg tablet	181.62	6.25	4.38	2806	4051
Eltrombopag	50 mg tablet	119.92	28.41	28.13	322	326
Pertuzumab	420 mg injection 14 ml	13635.29	2187.50	2187.50	523	523
Osimertinib	80 mg tablet	1129.48	15.63	9.06	7129	12363
Ibrutinib	140 mg capsule	201.35	18.75	15.63	974	1189

Sources: For prices in India, AIOCD-AWACS database (prices as on March 2019). For Prices in Bangladesh, website of the Directorate General of Drug Administration, https://dgda.gov.bd, accessed 30 August, 2019.

Notes:

1 US $ PPP = BDT 32 (https://knoema.com/atlas/Bangladesh/topics/Economy/Inflation-and-Prices/Purchasing-power-parity), accessed 30 August, 2019.

1 US $ PPP = INR 18.1 (https://knoema.com/atlas/India/topics/Economy/Inflation-and-Prices/Purchasing-power-parity), accessed 30 August, 2019

A number of other patented products, for example, Crizotinib, Nintedanib and Afatinib have been registered with DGDA, Bangladesh. But price data are not available on the website.

*: Extent to which prices in India are higher than the highest price in Bangladesh (col 4).

**: Extent to which prices in India are higher than the lowest price in Bangladesh (col 5).

But several products which are patent rejected and not patented are also high priced. There are six patent rejected products costing more than Rs 1000 including Sunitinib with price of Rs 8715 (50 mg capsule) and monthly cost of Rs 244014. There are also 21 not patented molecules costing more than Rs 1000 including Trabectedin with price Rs 28200 (1 mg injection) and monthly cost of Rs 77220 (see Tables 5 and 10).

These findings do not imply that product patents do not play a role. Medicines are typically patented and introduced in the market by the MNCs. When patents expire or when the products are not patented in a country, generic products may enter the market. But generic entry is not automatic. In the absence of generics, the originator companies can continue to dominate the market and charge high prices as we see happening in India. Examples of originator companies continuing to dominate the

market even in the absence of product patents include Janssen for Trabectedin; Roche for Tocilizumab; BMS for Abatacept; Pfizer for Idarubicin and Novartis for Aliskiren.

Absence of generic sellers in patent rejected molecules may appear surprising. But 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. It also takes time for generic companies to develop the product for marketing it. While Bevacizumab, a patent rejected molecule was sold by only one firm in 2015-16, there are 11 firms in the market in 2018-19. Another example is Trastuzumab. Roche withdrew the patent but initially, its product was the only one in the market. It took time for the generics to enter the market. In 2015-16, there were three sellers. By 2018-19, eight more firms have started selling it.

MNCs have the advantage that they dominate the market during the life of the patent. Despite being the sole seller, they promote the products through branding and by the time the patents expire, their products are well entrenched in the market. This gives them a marketing advantage. Generic firms may not find it worthwhile to undertake the investments to develop the product and market it, particularly when revenue and profit expectations are not large. Most of the not patented monopoly molecules are actually small in terms of market size. Not patented monopoly products account for about 50% of all the not patented products in terms of numbers but only 7.2% in terms of sales in 2015-16. Most of the high volume not patented products are sold by multiple sellers.

Even when generic firms are willing, they may not be able to enter not necessarily because of the legal barrier of product patents but also because of manufacturing and regulatory barriers. This is particularly true for biologic products which are increasingly becoming important in critical diseases such as cancer (WHO, 2018, p. 29). In Table 13, we have listed 31 biologic products sold in India in 346 SKUs. As can be seen from the table, the anti-cancer (anti-neoplastics) group alone accounts for about 50% of the products both in terms of numbers and sales. The prices are in general very high. Out of the 31 products, 24 are priced above Rs 10,000 per unit accounting for about 96% of the total sales of all the biologics and 10 are priced more than Rs 50,000 accounting for about 41% of the sales.[9] Some of these biologics including Ramucirumab, Pertuzumab, Golimumab, Daratumumab and Cetuximab are patented monopoly products and we have discussed above the high prices and costs of treatment (Table 5). But Table 13 also shows that some of the products sold by multiple firms and which are not patented are also highly priced. For example, the highest price for Rituximab with 22 sellers is Rs 79732 (500 mg infusion 50 ml); that for Bevacizumab with 14 sellers, Rs 116000 (400 Mg Injection 16 Ml) and for Trastuzumab with 12 sellers, Rs 210440 (160 Mg Injection). The costs of treatment for these molecules are also high (Table 5).

9 For each molecule here we have considered the highest priced SKU. But as Table 13 shows, even if we take the highest sold SKUs, similar conclusions can be derived.

Table 13: Prices of selected biologic products in India, March, 2019

Biologic Product	No of sellers	Sales, 2018-19, Rs million	Therapeutic Group	Unit for Highest Priced SKU	Price of Highest Priced SKU, Rs	Unit of Highest Sold SKU	Price of Highest Sold SKU, Rs	Price of Lowest Priced SKU, Rs*
Abciximab	4	5.37	Cardiac	10 mg injection 5 ml	9300.00	10 mg injection 5 ml	6750.00	6750.00
Adalimumab	11	613.76	Pain / Analgesics	Prefilled syringe	27475.00	40 mg prefilled syringe	25000.00	25000.00
Aflibercept	1	389.48	Ophthal / Otologicals	40 mg injection 1 ml	56693.00	40 mg injection 1 ml	56693.00	56693.00
Alteplase	1	183.17	Blood Related	50 mg injection 1	41688.87	50 mg injection	41688.87	41688.87
Asparaginase	8	80.10	Anti-Neoplastics	10 k injection	1582.08	10 k injection	1582.08	1582.08
Becaplermin	1	19.06	Derma	0.01 % gel 15 gm	1930.68	0.01 % gel 15 gm	1930.68	1930.68
Bevacizumab	14	1202.80	Anti-Neoplastics	400 mg injection 16 ml	116000.00	400 mg injection	72144	36250.00
Cetuximab	1	231.17	Anti-Neoplastics	100 mg infusion 20 ml	20222.00	100 mg infusion 20 ml	20222.00	20222.00
Daratumumab	1	105.00	Anti-Neoplastics	400 mg injection 20 ml	75500.00	400 mg injection 20 ml	75500.00	75500.00
Darbepoetin Alfa	20	989.54	Blood Related	200 mcg injection	11200.00	40 mcg prefilled syringe	2276.50	2276.50
Denosumab	4	83.00	Anti-Neoplastics	120 mg injection	27416.20	120 mg injection	27416.20	27416.20
Dulaglutide	3	352.39	Anti Diabetic	Prefilled 0.75 mg pen 0.5 ml	4998.00	Prefilled 0.75 mg pen 0.5 ml	4998.00	4998.00
Epoetin Alfa	35	2909.86	Blood Related	40000 IU injection	12332.00	4000 IU injection 6 ml	1263.85	1263.85
Etanercept	3	218.94	Pain / Analgesics	50 mg injection 10 ml	17170.00	50 mg injection 10 ml	17170.00	17170.00
Filgrastim	25	774.00	Anti-Neoplastics	6 mg prefilled syringe 0.6 ml	10990.00	300 mcg prefilled syringe 1 ml	1442.50	1120.93
Golimumab	1	2.37	Anti-Neoplastics	50 mg injection 0.5 ml	128000.00	50 mg injection 0.5 ml	128000.00	128000.00
Infliximab	2	128.82	Pain / Analgesics	100 mg injection 10 ml	41039.00	100 mg injection 10 ml	41039.00	41039.00
Interferon Alpha 2B	7	6.98	Anti-Neoplastics	5 MIU injection	964.00	3 MIUu injection	706.00	400.00
Interferons, Beta	3	339.01	Anti-Neoplastics	0.25 mg injection	69557.50	0.25 mg injection	69557.50	69557.50
Omalizumab	1	32.14	Respiratory	150 mg injection	10500.00	150 mg injection	10500.00	10500.00
Pegfilgrastim	11	463.17	Anti-Neoplastics	6 mg injection	18530.00	6 mg prefilled syringe 0.06 ml	12078.00	12078.00

Cont'd.....

Biologic Product	No of sellers	Sales, 2018-19, Rs million	Therapeutic Group	Unit for Highest Priced SKU	Price of Highest Priced SKU, Rs	Unit of Highest Sold SKU	Price of Highest Sold SKU, Rs	Price of Lowest Priced SKU, Rs*
Pertuzumab	1	18.56	Anti-Neoplastics	420 mg injection 14 ml	246798.75	420 mg injection 14 ml	246798.75	246798.75
Ramucirumab	1	2.90	Anti-Neoplastics	500 mg injection 50 ml	257532.00	500 mg injection 50 ml	257532.00	257532.00
Ranibizumab	2	61.23	Ophthal / Otologicals	0.5 mg injection 0.05 ml	75000.00	10 mg injection	17000.00	17000.00
Rasburicase	4	19.39	Others	1.5 mg infusion	9592.00	1.5 mg injection 1 ml	8800.00	8800.00
Reteplase	7	507.08	Cardiac	18 mg kit	35915.00	18 mg kit	17968.65	17968.65
Rituximab	22	1142.04	Anti-Neoplastics	500 mg infusion 50 ml	79732.50	500 mg injection	30285.60	30285.60
Sargramostim	1	13.57	Anti-Neoplastics	500 mcg injection	3077.00	500 mcg injection	3077.00	3077.00
Tenecteplase	4	398.13	Cardiac	40 mg injection	48120.00	40 mg injection	43900.00	43900.00
Tocilizunab	1	7.70	Anti-Neoplastics	400 mg injection	40545.00	400 mg injection	40545.00	40545.00
Trastuzumab	12	2450.58	Anti-Neoplastics	160 mg injection	210440.47	440 mg injection	58820.00	35714.28

Sources: For sales and price data, AIOCD-AWACS database. For identification of biologic products, "Purple Book" listing of products approved by the Center for Drug Evaluation and Research (CDER) from USFDA website, https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/therapeuticbiologicapplications/biosimilars/ucm411418.htm, accessed 30 August, 2018.

Notes: *: Among the SKUs with the same unit as in col 5.

Unlike chemically synthesized small molecule traditional medicines, biologic medicines are large complex molecules typically derived from living organisms using biotechnology. The latter are more difficult and costlier to manufacture. This explains why prices are high in general even with multiple sellers. But biologics also face regulatory barriers. 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 originator biotechnology firms such as Amgen (2017) that because of the complexity of manufacturing processes and reliance on living cells, no two products can be considered as similar unless clinical trials are done. This makes the development of biosimilars costlier and time consuming. The necessity of such an elaborate procedure, however, is being questioned. A group of eight scientists from different parts of the world, for example, have asked for a revision of regulatory guidelines taking into account the technological advances and the scientific evidence available.[10]

Even though prices, in general, are higher in biologics, here too virtues of competition are evident. With the passage of time as more firms enter the market, cheaper substitutes become available. Hence it is important to stimulated generic competition as the US President's Cancer Panel (2018, p. 21) has stressed. As can be seen from Table 13, there is a significant variation between the prices charged by different sellers. For example, for Rituximab, whereas the price of the costliest product is Rs 79732, it is also available at less than half that price. For Bevacizumab, whereas the costliest product is priced at Rs 116000, the price of the highest sold product is Rs 72144 and it is also available at Rs 36250.00. For Trastuzumab the prices vary between Rs 210440 and Rs 35714.

5. Discussion and Conclusions

In contrast to claims that there would be, and there has been little negative impact of TRIPs, this paper demonstrates that firms have started charging very high prices in some products after TRIPS. The proportion of high-priced products in the overall market is low. And hence the impact of TRIPS might appear to be small. These proportions, however, are low because of the preponderance of low-priced generic products given India's history of the absence of product patent protection before TRIPS. Market concentration has gone up after TRIPS. The number of high-priced products is increasing. The proportion of high-priced products is high in several therapeutic groups, particularly in cancer. Cancer is not yet a pandemic like HIV/AIDS. But cancer is now recognised as one of the greatest public health challenges globally and several cancer medicines are much more expensive than the ARV cost of US$ 10,000 per person per year in the 2000s which led to an international outcry. In developing countries such as India where out of pocket spending is predominant, most of the people

10. The text of the Statement is reproduced in, https://www.twn.my/title2/health.info/Article/Memo% 20on% 20WHO%20Guidelines%20on%20SBPs.pdf

will have to work for years to be able to fund the cost of treatment and that makes these drugs simply unaffordable.

Product patent protection is one of the factors explaining the high prices and costs. Our study also provides some estimates of the extent to which the products are higher priced because of lack of generic competition. But product patents are not the only reason for high prices and costs. Medicines are typically patented and introduced in the market by the originator companies. When product patents expire or when the products are not patented in a country, generic products may enter the market. But the entry of generics may not be immediate and automatic. In the absence of generics, the originator companies can continue to dominate the market and charge high prices as we find in the paper. Generic entry may be discouraged or delayed not only due to legal patent barrier but due to manufacturing and regulatory barriers. This is particularly true in biologics, which are large complex molecules typically derived from living organisms using biotechnology and unlike chemically synthesized small molecule traditional medicines, are more difficult and costlier to manufacture. Our study finds that the prices and costs are high for several not patented biologic products.

About 400 million people in the world lack healthcare including access to medicines (UN High Level Panel on Access to Medicines, 2016, p. 15). Ensuring adequate access to medicines is a basic development goal. Price of medicine is of course not the only barrier to access. Factors such as sustainable financing and reliable health and supply systems are also important. In this paper, we have focussed on prices.

That depending on the behaviour of firms and market structure, prices can be high and unaffordable, is recognised as a possible outcome and the paper shows that prices indeed can be high. But in such cases what is also widely advocated is that government can and must intervene. A detailed treatment of the subject is beyond the scope of the paper but it might be useful to refer to some of the policy options available and the current status.

Countries will have to operate under the constraints imposed by TRIPS. But protection of the rights of patentees is not the sole concern of TRIPS. TRIPS provides for flexibilities for governments to fine-tune the protection to ensure that social and economic goals are also taken into account.

India did make some innovative attempts to use TRIPS flexibilities, as in the case of Section 3(d) of India's amended Patents Act. But as Sampat & Shadlen (2017) show, attempts to prevent secondary patenting has not been very successful in general in developing countries including in India. Section 3(d) actually deals with only a part of the problem. At best it can prevent patents for new forms of pre-1995 molecules under certain conditions. Section 3(d) cannot be used to deny patents for post-1994 molecules and with the passage of time, more and more such products are entering and likely to enter the market.

The more potent policy option is compulsory licensing. But till date, compulsory license has been granted for only one medicine - Sorafenib. The reason is not that there are no grounds for applying and getting such licences. Several medicines have costs higher than what was found to be affordable by the Patent office in the case of Sorafenib. Getting a compulsory licensing is a long drawn and costly process and invariably the MNC patentees oppose these legally and otherwise. Unless there is strategic intervention on the part of national governments to support generic firms and use the compulsory licensing provisions, collaborating with MNCs appears to be a more attractive option for generic firms rather than getting involved in disputes with them. The paper provides some evidence of such collaboration. But as the UN High Level Panel on Access to Medicines (2016, p. 25) has observed, developing countries have also been subjected to undue political and economic pressure to forego the use of TRIPS flexibilities. Developing countries seem to be unable to act to take advantage of TRIPS flexibilities.

In view of the strong opposition to use of compulsory licensing by developed country governments and MNCs, an alternative that is often suggested is that voluntary licensing and differential pricing must be encouraged. There are examples of such initiatives in developing countries (Watal & Dai, 2019). Kyle & Qian (2014) in fact have reported that the extent of differential pricing has gone up in the post TRIPS period. These make the products relatively more affordable. But the outcome essentially depends on what the MNCs decide rather than what developing countries require or what can be achieved through competitive markets. In any case, these initiatives have not prevented price fixation at high levels as reported in this paper.

Another flexibility which developing countries can utilize is to control the prices 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 it seems has decided not to introduce any price control schemes for patented products.[11]

Justifiably the impact of product patent protection on prices of medicines has received world-wide attention. But in biologic products, prices have been found to be high even in the absence of product patents. Simplifying regulatory barriers to facilitate greater and faster entry of generics in biologics is also another issue of critical importance.

11 Vinod K Paul, Member (Health) of Niti Aayog (which replaced India's Planning Commission) and head of the Expert Committee on pharmaceutical pricing has been reported to have said that "the prices of patented drugs cannot be curbed and should not be curbed" and that government has no proposal to reduce the prices of patented cancer medicines (Chandna, 2019).

Acknowledgements

A part of the paper is based on the Working Paper No 813/September, 2018 of the Indian Institute of Management Calcutta. Most of the work has been done after I joined the Centre for Development Studies, Trivandrum. Some of the findings were presented in seminars in Bangalore, Manchester and New Delhi. I would like to thank particularly Rory Horner and also Bhaven N. Sampat and Kenneth C. Shadlen for detailed comments and suggestions. I would also like to thank Judit R Sanjuan, Leslie Ong and Sunil Mani for useful discussions and Chidambaran G Iyer, Ritika Jain, Sunandan Ghosh and Thiagu Ranganathan for helpful comments. Usual disclaimers apply.

Sudip Chaudhuri *is a Visiting Professor at the Centre for Development Studies, Trivandrum. His main areas of research interest include intellectual property rights regime and pharmaceutical industry, industrialization and economic development in developing countries and role of state in economic change.*

Email contact: *sudip@cds.edu*
sudip@iimcal.ac.in

Appendix

The analysis on product patent status, market structure and prices in the paper is based on 138 molecules. Section 3.2 of the paper has discussed the methodology for finding out the patent status and how the sample of 138 molecules was selected. Patent rejected includes those which were revoked or withdrawn. The following data are based on the AIOCD-AWACS data base. For prices, we have considered the plain molecules, not the combination ones. The same molecule sold in different forms such as tablets, syrups and in different strength such as 5 mg, 10 mg and by different firms are considered as separate SKUs. For molecules with a single seller, we have considered the SKU with the highest sales in 2015-16. For molecules sold by multiple firms, we have similarly considered the SKU with the highest sales in 2015-16 and then also considered the lowest price for this particular SKU.

Molecule	Patent status	No of sellers	Therapeutic group	Sales, 2015-16, Rs million	Unit for Price	Price of the highest sold SKU, March 2016	Price of lowest priced SKU, March, 2016
Abacavir	Patent rejected	2	Anti-Infectives	8.40	300 mg tablet	51.08	48.15
Abatacept	Not Patented	1	Pain / Analgesics	5.38	250 mg injection	30000.00	-
Abiraterone Acetate	Not Patented	11	Anti-Neoplastics	193.33	250 mg tablet	1250.00	230.83
Adefovir	Patented Rejected	3	Anti-Infectives	16.38	10 mg tablet	27.00	22.45
Aliskiren	Not Patented	1	Cardiac	2.59	150 mg tablet	48.96	-
Ambrisentan	Not Patented	4	Cardiac	212.36	5 mg tablet	145.00	36.19
Apixaban	Patented	1	Blood Related	112.85	5 mg tablet	145.00	-
Ardeparin	Not Patented	1	Cardiac	0.01	3500 IU injection 0.4 ml	185.00	-
Atazanavir	Patented Rejected	1	Anti-Infectives	35.32	300 mg capsule	75.10	-
Atorvastatin	Patented Rejected	116	Cardiac	8633.49	20 mg tablet	23.96	1.25
Axitinib	Patented	1	Anti-Neoplastics	24.10	5 mg tablet	5678.50	-
Benazepril	Not Patented	1	Cardiac	6.68	5 mg tablet	8.57	-
Bendamustine	Patent Rejected	6	Anti-Neoplastics	39.17	100 mg injection	7830.00	5952.38
Benzonatate	Not Patented	1	Respiratory	61.43	100 mg capsule	6.71	-
Besifloxacin	Not Patented	1	Ophthal	26.12	0.60 % eye drops 5 ml	140.00	-
Bevacizumab	Patent Rejected	1	Anti-Neoplastics	509.75	100 mg injection	41250.00	-
Biphasic Lispro	Not Patented	1	Anti Diabetic	622.45	100 IU disposable pen 3 ml	640.00	-
Bortezomib	Not Patented	14	Anti-Neoplastics	291.01	2 mg injection	15864.75	3847.62
Brinzolamide	Not Patented	5	Ophthal	137.82	1 % eye drops 5 ml	460.00	290.00
Cabazitaxel	Patented	1	Anti-Neoplastics	81.58	60 mg injection 1 ml	330000.00	-
Canagliflozin	Patented	3	Anti Diabetic	253.50	100 mg tablet	51.00	51.00
Carmofur	Not Patented	1	Anti-Neoplastics	7.94	1000 mg injection 10 ml	1925.00	-

Cont'd.....

Molecule	Patent status	No of sellers	Therapeutic group	Sales, 2015-16, Rs million	Unit for Price	Price of the highest sold SKU, March 2016	Price of lowest priced SKU, March, 2016
Caspofungin Acetate	Not Patented	13	Anti-Infectives	749.79	70 mg injection 10 ml	12857.13	10989.00
Cetrorelix	Not Patented	10	Hormones	205.54	0.25 mg injection	2184.61	618.75
Cetuximab	Patented	1	Anti-Neoplastics	15.88	100 mg infusion 50 ml	18036.53	-
Cimetropium Bromide	Not Patented	1	Gastro Intestinal	53.52	50 mg tablet	11.89	-
Cladribine	Not Patented	1	Anti-Neoplastics	22.95	10 mg injection	13400.00	-
Crizotinib	Patented	1	Anti-Neoplastics	139.39	200 mg capsule	1553.71	-
Dabigatran	Patented	1	Cardiac	480.90	60/75 mg capsule	71.80	-
Dapagliflozin	Patented	1	Anti Diabetic	349.16	10 mg tablet	43.21	-
Darifenacin	Patented Rejected	7	Urology	198.37	7.5 mg tablet	28.50	18.55
Darunavir	Patented Rejected	2	Anti-Infectives	57.51	600 mg tablet	183.10	3.05
Dasatinib	Patented	1	Anti-Neoplastics	11.04	50 mg tablet	3287.30	-
Degludec	Patented	1	Anti Diabetic	424.05	100 IU disposable pen 3 ml	1800.00	-
Denatonium Benzoate	Not Patented	1	Others	20.41	lotion 9 ml	155.00	-
Desvenlafaxine	Not Patented	26	Neuro / Cns	378.11	50 mg tablet	11.99	7.80
Determir	Not Patented	1	Anti Diabetic	111.84	100 IU flexpen 3 ml	998.00	-
Dienogest	Not Patented	7	Gynaecological	128.95	2 mg tablet	49.00	45.00
Doripenem	Not Patented	14	Anti-Infectives	319.08	500 mg injection	3514.28	1756.97
Duloxetine	Patented Rejected	28	Neuro / Cns	515.65	20 mg capsule	8.30	5.07
Eberconazole	Not Patented	1	Derma	61.06	1 % cream 10 gm	94.50	-
Efavirenz	Patented Rejected	5	Anti-Infectives	39.95	600 mg tablet	79.42	62.48
Eletriptan	Not Patented	1	Neuro / Cns	6.86	20 mg tablet	32.00	-
Eltrombopag	Patented	1	Blood Related	50.32	25 mg tablet	965.99	-
Empagliflozin	Patented	1	Anti Diabetic	125.15	10 mg tablet	43.20	-
Entecavir	Not Patented	10	Anti-Infectives	695.54	0.5 mg tablet	353.58	75.00
Eplerenone	Not Patented	6	Cardiac	359.46	25 mg tablet	29.02	11.64
Erlotinib	Patented Rejected	7	Anti-Neoplastics	273.68	150 mg tablet	1090.85	220.83
Ertapenem	Not Patented	5	Anti-Infectives	257.10	1 gm injection 20 ml	2616.00	2138.91
Ezetimibe	Patented Rejected	3	Cardiac	84.03	10 mg tablet	11.95	8.95
Febuxostat	Not Patented	47	Pain / Analgesics	1251.78	40 mg tablet	12.00	4.85
Fluvastatin	Not Patented	1	Cardiac	3.25	80 mg tablet	33.82	-
Fondaparinux	Not Patented	5	Cardiac	414.98	2.5 mg injection 0.5 ml	715.00	649.00
Gefitinib	Patented Rejected	23	Anti-Neoplastics	212.49	250 mg tablet	3388.81	80.51
Glargine	Not Patented	5	Anti Diabetic	3512.13	100 IU cartridge 3 ml	542.96	460.00

Cont'd.....

Molecule	Patent status	No of sellers	Therapeutic group	Sales, 2015-16, Rs million	Unit for Price	Price of the highest sold SKU, March 2016	Price of lowest priced SKU, March, 2016
Glulisine	Patented	1	Anti Diabetic	206.61	Cartridge 3 ml	473.00	-
Ibandronate	Patented Rejected	8	Hormones	177.36	150 mg tablet	252.00	150.00
Idarubicin	Not Patented	1	Anti-Neoplastics	0.91	5 mg injection 5 ml	5889.52	-
Imatinib Mesylate	Patented Rejected	19	Anti-Neoplastics	425.13	400 mg tablet	397.44	74.00
Iopamidol	Not Patented	1	Others	82.86	300 mg infusion 100 ml	1411.17	-
Iopromide	Not Patented	1	Others	36.09	370 mg infusion 100 ml	1757.86	-
Ivabradine	Not Patented	8	Cardiac	723.51	5 mg tablet	19.64	13.20
Ixabepilone	Patented	1	Anti-Neoplastics	1.59	45 mg injection	71175.00	-
Lacosamide	Not Patented	12	Neuro / Cns	237.20	100 mg tablet	22.86	8.60
Lapatinib	Patented Rejected	1	Anti-Neoplastics	39.45	250 mg tablet	254.29	-
Lenalidomide	Patented Rejected	9	Anti-Infectives	174.96	10 mg capsule	299.20	113.43
Letrozole	Patented Rejected	23	Anti-Neoplastics	157.78	2.5 mg tablet	225.00	4.38
Levetiracetam	Not Patented	41	Neuro / Cns	4346.25	500 mg tablet	15.98	7.33
Levobunolol Eye Drops / Ointment	Not Patented	1 -	Ophthal	19.16	0.5 % eye drops 5 ml	135.52	
Linagliptin	Patented	2	Anti Diabetic	1166.02	5 mg tablet	45.00	45.00
Linezolid	Patented Rejected	47	Anti-Infectives	1687.21	600 mg tablet	107.25	27.91
Liraglutide	Patented	1	Anti Diabetic	363.38	6 mg injection 3 ml	4840.00	-
Lispro	Not Patented	1	Anti Diabetic	246.58	100 IU cartridge 3 ml	510.00	-
Luliconazole	Patented	1	Derma	189.44	cream 10 gm	155.00	-
Methdilazine	Not Patented	1	Respiratory	72.51	4 mg syrup 100 ml	49.25	-
Micafungin	Patented	1	Anti-Infectives	122.70	50 mg injection 1 ml	5911.00	-
Moxifloxacin	Patented Rejected	18	Anti-Infectives	968.35	0.5 % eye drops 5 ml	250.00	54.00
Naratriptan	Not Patented	1	Neuro / Cns	4.26	2.5 mg tablet	37.50	-
Nepafenac	Not Patented	25	Ophthal	453.29	0.10 % eye drops 5 ml	245.00	245.00
Nevirapine	Patented Rejected	6	Anti-Infectives	16.65	200 mg tablet	17.00	13.68
Nimorazole	Not Patented	1	Anti-Infectives	23.38	500 mg tablet	9.85	-
Nimotuzumab	Not Patented	1	Anti-Neoplastics	82.23	50 mg injection 10 ml	51241.92	-
Olanzapine	Patented Rejected	61	Neuro / Cns	750.79	5 mg tablet	5.90	1.89
Olmesartan	Not Patented	43	Cardiac	2432.51	40 mg tablet	21.65	4.90
Orlistat	Patented Rejected	27	Others	562.57	120 mg capsule	54.60	5.46
Oseltamivir	Patented Rejected	3	Anti-Infectives	49.32	75 mg capsule	47.50	44.90
Oxcarbazepine	Patented Rejected	30	Neuro / Cns	1779.34	300 mg tablet	13.62	2.41

Cont'd.....

Molecule	Patent status	No of sellers	Therapeutic group	Sales, 2015-16, Rs million	Unit for Price	Price of the highest sold SKU, March 2016	Price of lowest priced SKU, March, 2016
Paclitaxel	Patented Rejected	32	Anti-Neoplastics	1531.51	100 mg injection	17226.19	3446.71
Pantoprazole	Patented Rejected	265	Gastro Intestinal	7547.65	40 mg tablet	11.00	0.80
Pazopanib	Patented	1	Anti-Neoplastics	37.98	400 mg tablet	460.32	-
Pemetrexed	Not Patented	16	Anti-Neoplastics	226.15	500 mg injection	73660.00	4500.00
Pentosan Polysulphate Sodium	Not Patented	1	Cardiac	62.09	100 mg tablet	54.75	-
Pimecrolimus	Patented Rejected	3	Derma	75.78	1 % cream 10 gm	450.00	400.00
Pirfenidone	Not Patented	3	Respiratory	238.78	200 mg tablet	18.50	16.00
Posaconazole	Not Patented	1	Anti-Infectives	61.59	40 mg oral suspension 105 ml	17440.00	-
Pramipexole	Not Patented	8	Neuro / Cns	350.01	0.5 mg tablet	10.50	8.75
Prasugrel	Not Patented	13	Cardiac	372.85	10 mg tablet	27.65	9.43
Primidone	Not Patented	1	Neuro / Cns	21.80	250 mg tablet	6.85	-
Rabeprazole	Patented Rejected	193	Gastro Intestinal	3078.90	20 mg tablet	17.43	1.13
Raloxifene	Patented Rejected	5	Gynaecological	12.95	60 mg tablet	12.32	10.62
Raltegravir	Patented (Who)	2	Anti-Infectives	46.66	400 mg tablet	159.25	159.25
Ramelteon	Patented	1	Neuro / Cns	15.61	8 mg tablet	10.90	-
Ranolazine	Not Patented	19	Cardiac	782.32	500 mg tablet	12.95	6.48
Regorafenib	Not Patented	1	Anti-Neoplastics	24.45	40 mg tablet	1311.80	-
Repaglinide	Patented Rejected	2	Anti Diabetic	230.30	12 mg tablet	10.99	10.33
Rifaximin	Not Patented	23	Gastro Intestinal	1429.17	400 mg tablet	25.80	20.50
Risedronate	Patented Rejected	8	Hormones	97.40	35 mg tablet	577.50	16.05
Ritonavir	Patented Rejected	3	Anti-Infectives	12.13	100 mg tablet	32.60	30.00
Rivaroxaban	Patented	2	Cardiac	86.05	10 mg tablet	145.00	138.09
Rosiglitazone	Patented Rejected	2	Anti Diabetic	0.45	4 mg tablet	9.27	9.27
Rosuvastatin	Patented Rejected	93	Cardiac	6118.15	10 mg tablet	26.77	2.80
Saroglitazar	Patented	1	Cardiac	304.79	4 mg tablet	25.90	-
Saxagliptin	Patented	2	Anti Diabetic	591.94	5 mg tablet	43.21	43.21
Sevelamer	Not Patented	16	Others	351.02	400 mg tablet	1087.50	6.80
Sildenafil	Patented Rejected	53	Sex Stimulants / Rejuvenators	3226.60	100 mg tablet	621.85	2.72
Silodosin	Not Patented	9	Urology	472.12	4 mg tablet	25.00	13.50
Sirolimus	Patented Rejected	8	Anti-Neoplastics	54.41	1 mg tablet	181.34	111.11
Sitagliptin	Patented	4	Anti Diabetic	2793.91	100 mg tablet	45.00	28.43
Sofosbuvir	Patented	12	Anti-Infectives	1252.40	400 mg tablet	1990.00	661.90

Cont'd.....

Molecule	Patent status	No of sellers	Therapeutic group	Sales, 2015-16, Rs million	Unit for Price	Price of the highest sold SKU, March 2016	Price of lowest priced SKU, March, 2016
Sunitinib	Patented Rejected	1	Anti-Neoplastics	65.94	50 mg capsule	8714.78	-
Tadalafil	Patented Rejected	24	Sex Stimulants / Rejuvenators	842.78	20 mg tablet	79.88	4.69
Tenofovir	Patented Rejected	12	Anti-Infectives	386.37	300 mg tablet	150.00	36.67
Teriparatide	Patented Rejected	13	Hormones	723.18	750 mg injection 3 ml	23462.00	6900.00
Ticagrelor	Patented	2	Cardiac	833.46	90 mg tablet	50.00	50.00
Tigecycline	Not Patented	25	Anti-Infectives	665.32	50 mg injection	3559.50	1100.00
Tiotropium	Patented Rejected	7	Respiratory	456.62	9 mcg inhaler	459.00	399.00
Tocilizunab	Not Patented	1	Anti-Neoplastics	0.55	400 mg injection	40600.00	-
Tolvaptan	Not Patented	8	Cardiac	394.19	15 mg tablet	396.00	35.00
Trabectedin	Not Patented	1	Anti-Neoplastics	2.62	1 mg injection	121485.68	-
Trastuzumab	Patented Rejected	3	Anti-Neoplastics	700.59	440 mg injection	75000.00	56689.01
Travoprost	Not Patented	13	Ophthal	236.15	0.004 % eye drops 3 ml	535.00	157.83
Triptorelin	Not Patented	2	Anti-Neoplastics	91.33	3.75 mg injection	7750.00	7117.50
Valganciclovir	Patented Rejected	8	Anti-Infectives	76.47	450 mg tablet	478.24	235.58
Valsartan	Patented Rejected	4	Cardiac	248.35	80 mg tablet	17.34	11.34
Varenicline	Patented Rejected	1	Neuro / Cns	78.15	1 mg tablet	60.71	-
Zolmitriptan	Not Patented	1	Neuro / Cns	11.09	5 mg nasal spray 7 mdi	404.00	-
Zonisamide	Not Patented	3	Neuro / Cns	146.68	100 mg tablet	191.00	112.00
Zuclopenthixol	Not Patented	1	Neuro / Cns	19.89	200 mg injection 1 ml	406.85	-

References

Abbott, F. M. 2002. 'WTO TRIPS Agreement and Its Implications for Access to Medicines in Developing Countries,' Study Paper 2a. London: Commission on Intellectual Property Rights.

Abbott, F. M. 2016. 'Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health,' *UC Irvine Law Review,* Volume 6, Issue 3.

Abrol, D., Dhulap, S., Aisola, M. & Singh, N. 2016. 'Pharmaceuticals, Product Patent and TRIPS Implementation,' Institute for Studies in Industrial Development, Working Paper 191, March.

Amgen. 2017. 'Biologics and Biosimilars: An Overview'. (accessed on 3 September, 2017 from www.amgenbiosimilars.com).

Arora, S. & Chaturvedi, R. 2016. 'Section 3(d): Implications and Key Concerns for Pharmaceutical Sector'. *Journal of Intellectual Property Rights,* Vol 21, January.

Athreye, S., Kale, D. &Ramani, S. V. 2009. 'Experimentation with Strategy and the Evolution of Dynamic Capability in the Indian Pharmaceutical Sector'. *Industrial and Corporate Change*, Volume 18, Number 4.

Baker, D, Jayadev, A. & Stiglitz, J. 2017. *Innovation Intellectual property and Development: A Better Set of Approaches for the 21st Century*. A joint publication of Azim Premji University (India), University of Cape Town Intellectual Property Unit (South Africa) and Oswaldo Cruz Foundation (Fiocruz) (Brazil), accessed on 27 January, 2019 from: https://www.accessibsa.org/media/2017/12/Innovation-Intellectual-Property-and-Development.pdf).

Bray, F., Ferlay J., Soerjomataram I., Siegel R. L., Torre L. A., &Jemal A. 2018. 'Global Cancer Statistics 2018: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries.' *CA: A Cancer Journal for Clinicians* (accessed from https://onlinelibrary.wiley.com/doi/full/10.3322/caac.21492 on 5 October, 2019)

Chandna, H. 2019. 'Modi Govt Slashed Prices of Cancer Drugs, Just Not for the Costly Ones', ThePrint (https://theprint.in/india/governance/modi-govt-slashed-prices-of-cancer-drugs-just-not-for-the-costly-ones/205115/).

Chaudhuri, S. 2005. *The WTO and India's Pharmaceuticals Industry: Patent Protection TRIPS and Developing Countries.* New Delhi: Oxford University Press.

Chaudhuri, S., Goldberg, P.K. & Jia, P. 2006. 'Estimating the Effects of Global Patent Protection in Pharmaceuticals: A Case Study of Quinolones in India'. *American Economic Review,*96 (5).

Commission on Intellectual Property Rights. 2002. *Integrating Intellectual Property Rights and Development Policy.* London: CIPR.

Correa, C. (2002). *Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options.* London: Zed Books and Penang: Third World network

Duggan, M., Garthwaite, C. & Goyal, A. 2016. 'The Market Impacts of Pharmaceutical Product Patents in Developing Countries: Evidence from India'. *American Economic Review, 106(1).*

Fink, C. 2000. 'How Stronger Patent Protection in India Might Affect the Behaviour of Transnational Pharmaceutical Industries.' *World Bank Policy Research Paper*, 2352, Washington DC: World Bank.

Gamba, S. 2017. 'The Effect of Intellectual Property Rights on Domestic Innovation in the Pharmaceutical Sector'.*World Development,* Vol. 99. (http://dx.doi.org/10.1016/j.worlddev.2017.06.003).

Gehl Sampath, P. 2006. 'Indian Pharma Within Global Reach?'. UNU-Merit Working Paper Series, No 2006-031.

Goldstein, D., Clark, J., Tu, Y., Zhang, J., Fang, F., Goldstein, R., Stemmer, S.M., &Rosenbaum, E. 2017. 'A Global Comparison of the Cost of patented cancer Drugs in Relation to Global Differences in Wealth'. *Oncotarget,* Vol. 8, No 42.

Horner. R. 2013. 'The Global Relevance of India's Pharmaceutical Patent Laws'. *Economic and Political Weekly*, August 3.

Horner, R. 2014. 'Strategic Decoupling, Recoupling and Global Production Networks: India's Pharmaceutical Industry.' *Journal of Economic Geography*, Volume 14, Issue 6.

IFPMA. 1997. *Intellectual Property: Patents and Pharmaceuticals*. Issue Paper, International Federation of Pharmaceutical Manufacturers Association, Geneva.

Joseph, R.K. 2016. *Pharmaceutical Industry and Public Policy in Post Reform India*. New Delhi: Routledge.

Kyle, M. & Qian, Y. 2014. 'Intellectual Property Rights and Access to Innovation: Evidence from TRIPS'. National Bureau of Economic Research, Working Paper 20799.

Love, J. 2012. Affidavit before the Controller of Patents, Delhi in the Compulsory Licensing Case Involving Bayer Patents on Cancer Drug Sorafenib (Nexavar) (accessed from https://www.keionline.org/21783 on 20 July, 2019.

Maskus, K. 2000. 'Intellectual Property Rights and Economic Development', *Case Western Reserve Journal of International Law,* Vol. 32.

Mendis, S., Fukino, K., Cameron, A., Laing, R., Filipe, A., Khatib, O., Leowski, J., &Ewen, M. 2007. 'The Availability and Affordability of Selected Essential Medicines for Chronic Diseases in Six low- and middle-income Countries.' *Bulletin of World Health Organization*. April, 85(4) (accessed from https://www.who.int/bulletin/volumes/85/4/06-033647.pdf?ua=1 on 17 July, 2019.

MSF. 2005. 'Will the Lifeline of Affordable Medicines for Poor Countries be cut?: Consequences of Medicines Patenting in India.' (accessed from https://www.msf.fr/sites/default/files/2005-02-01-msf.pdf on 5 October, 2019.

Mukherjee, R. 2019. 'Illegal Cancer Drugs from Bangladesh Flood Local Market.' *Times of India*, 18 November. (https://timesofindia.indiatimes.com/business/india-business/illegal-cancer-drugs-from-bdesh-flood-local-market/articleshow/72100024.cms).

Nair, G.G., Fernandes, A. & Nair, K. 2014. 'Landmark Pharma Patent Jurisprudence in India'. *Journal of Intellectual Property Rights,* Vol. 19, March.

Niëns, L.M., de Poel, E.V., Cameron, A., Ewen, M. Laing, R., & Brouwer, W.B.F. 2012. 'Practical Measurement of Affordability: an Application to Medicines.' *Bulletin of World Health Organization,* March, 90(3) (accessed from https://www.who.int/bulletin/volumes/90/3/10-084087.pdf on 8 October, 2019).

Roemer-Mahler. A. 2013. 'Business Conflict and Global Politics: The Pharmaceutical Industry and the Global Protection of Intellectual Property Rights', *Review of International Political Econ*omy, Vol. 20, No. 1.

Ryan, M. P. 1998. *Knowledge Diplomacy: Global Competition and the Politics of Intellectual Property.* Washington, DC: Brookings Institution Press.

Sampat, B.N. & Shadlen, K.C. 2015. 'TRIPS Implementation and Secondary Pharmaceutical Patenting in Brazil and India'. *Studies in Comparative International Development*. 50, 228–57.

Sampat, B.N. & Shadlen, K.C. 2017. 'Secondary Pharmaceutical Patenting: A Global Perspective.' *Research Policy*, Vol. 46.

Sampat, B.N., Shadlen, K.C. & Amin, T. 2012. 'Challenges to India's Pharmaceutical Patent Laws'. *Science,* Vol. 337, Issue 6093.

Sweet, C. D. M. & Maggio, D. S. E. 2015. 'Do Stronger Intellectual Property Rights Increase Innovation?.*World Development,* Vol. 66. (http://dx.doi.org/10.1016/j.worlddev.2014.08.025)

UN High Level Panel on Access to Medicines. 2016. *Report of the United Nations Secretary-General's High Level Panel on Access to Medicines: Promoting Innovation and Access to Health Technologies*. New York: United Nations Development Programme.

US President's Cancer Panel. 2018. *Promoting Value, Affordability, and Innovation in Cancer Drug Treatment*. (accessed from https://prescancerpanel.cancer.gov/report/drugvalue/pdf/PresCancerPanel_DrugValue_Mar2018.pdf on 5 October, 2019).

Watal, J. 2000. "Pharmaceutical Patents, Prices and Welfare Losses: Policy Options for India Under the WTO TRIPS Agreement." *The World Economy*, Vol. 23, No 5, May.

Watal, J. & Dai, R. 2019. 'Product Patents and Access to Innovative Medicines in a Post-TRIPS Era.' Staff Working Paper ERSD-2019-05, World Trade Organization, Economic Research and Statistics Division. (https://www.wto.org/english/res_e/reser_e/ersd201905_e.pdf).

WHO. 2018. *Pricing of Cancer Medicines and Its Impact.* Geneva: World Health Organization (accessed from https://apps.who.int/iris/handle/10665/277190 on 4 October, 2019).

PREVIOUS PAPERS IN THE SERIES

1. **Dimensions of India's Economy:** ***As seen through the Economic Survey 2017-18 and the Union Budget 2018-19.***
   Manmohan Agarwal, Sunandan Ghosh, M Parameswaran, Ritika Jain, P Seenath, Hrushikesh Mallick, Vinoj Abraham, Udaya S Mishra, Sunil Mani, P L Beena. March 2018.
2. **Dimensions of India's Intellectual Property Right System. How Many Patents are Commercially Exploited in India?**
   Sunil Mani. May 2018.
3. **An Uncertain Shift from 'Protectionism' to 'Empowerment'? Probing the Decision by NORKA to Recruit Women Domestic Workers for Kuwait**
   Praveena Kodoth, November 2018.
4. **Protectionism: US Tariff Policy and India's Response**
   Part I: Manmohan Agarwal, **Part II:** Sunandan Ghosh, December 2018.
5. **Industrial Investment Intention and Implementation in India: Broad Trends and Patterns at the State-level**
   Ritika Jain, March 2019.
6. **Monetary Policy Journey to Inflation Targeting**
   Manmohan Agarwal & Irfan Ahmed Shah, April 2019.
7. **Gender-Based Cyber Violence against Women in Kerala: Insights from Recent Research**
   J. Devika, May 2019.
8. **SWACHH BHARAT - 2019: Will Rural India be ODF/SWACHH?**
   G. Murugan, May 2019.
9. **Dimensions of Indian Economy** ***As seen through the Economic Survey 2018-19 and the Union Budget 2019-20***
   K. P. Kannan, P.L. Beena, M. Parameswaran, Vinoj Abraham, G. Murugan, Udaya Shankar Mishra, Hrushikesh Mallick, Sunil Mani**,** August 2019.