Competition Law and the Pharmaceutical Sector in India

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Abstract

The Indian pharmaceutical industry is one of the largest in the world both in terms of volume and value. Given its critical importance, the sector has been subject to a series of regulatory interventions, which have altered the nature of the industry quite significantly. With enacting the Indian competition Act (2002), India has joined the list of countries that has a robust competition regime. The purpose of this chapter is to understand the pharmaceutical sector through the prism of competition law.

* Authors are listed in alphabetical order of their last name. This paper is intended as a chapter in the forthcoming book, "Competition Regulation and Policy: An Economic Approach," Payal Malik and Avirup Bose (eds.), Oxford University Press, India.

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1. Introduction

The Indian pharmaceuticals market is one of the largest in the world, both in terms of volume and value. The market in has also seen a significant growth rate over several decades. Moreover, it is also one of the critical sectors in determining public health. Therefore, no wonder, over a period of time this sector has seen several regulatory interventions that have altered the dynamics of this industry quite substantially. Even when compared to the other pharmaceutical regimes in the world, change in patenting regime (product patenting to process patenting to product patenting), unique nature of competition (for example, branded generics), etc. have made the Indian pharmaceutical market unique. With the enactment of the Indian Competition Act in 2002, India has become one of the newer countries that have a robust competition regulation. Given the unique nature of the pharmaceutical markets, it is important to understand how competition law applies to this sector. The purpose of this article is to fill this gap and discuss the pharmaceutical market through the prism of competition law. In this article, we discuss the evolution of this industry and compare it with the other competition law regimes in the world. We then expand to the other relevant issues like market definition, intellectual property regime, etc. which are crucial for understanding the overall law. Finally, we also discuss some of the other issues that need to be resolved.

More specifically, in the next section, we start by presenting a brief history of the pharmaceutical industry in India and discuss various important policy amendments that have altered the nature of competition in this market. Following that we discuss how the sector is unique, and present a broad overview of the regulatory framework in terms of drug approvals. This sector is crucial for all the countries in the world, and therefore, in Section 4, we discuss how this sector is regulated in other jurisdictions. This helps us understand how various jurisdictions treat this important segment, and what India can learn from their regulatory frameworks. Subsequently, in the next section, we discuss the role of the Competition Commission of India in regulating this sector. In any competition law framework, an important question to ask is definition of appropriate market, and how market power is measured once the market dimensions are established. Given the unique nature of pharmaceutical sector, traditional theories of market definition and market power are not directly adaptable. Therefore, in Section 6, we discuss how to measure market power in the pharmaceutical sector. We also discuss briefly

some of the recent cases related to competition law in this sector. An area that is directly related to competition law is intellectual property law. In Sector 7 we discuss the trade-off between the twin concerns of affordability and availability of innovative medicine and establish a relationship between competition law and intellectual property regime. Here, we argue that competition authorities should play greater role in intellectual property cases as well. We conclude in Section 8 by presenting some issues that need to be resolved in order to arrive at a more robust pharmaceutical market regulation in India.

2. Brief History of Pharmaceutical Industry in India

The history of the Indian pharmaceutical industry can be divided into three distinct phases. In the first phase, immediately after independence, the Indian pharmaceutical industry was dominated by global multinational manufacturers. The prevailing system was due to a law enacted in British India called Patents and Designs Act, 1911, which ensured strong product patent protection regime.[1] Entry into the Indian market was easy for the global manufacturers who had the technological capabilities to bring new medicines to the market, but at a very high cost for the existing population (in fact, average drug prices in India were among the highest in the world). There were very few indigenous manufacturers of consequence during this time, and eight of the top 10 pharmaceutical firms were subsidiaries of MNCs (Greene 2007). Most of the patents granted originated from foreign countries, a consequence of underdevelopment of India. More importantly, it appeared to commentators at the time that most of these patents were unused, and foreign patentees were more motivated by prevention of the use of patented inventions rather than selling their products in India. Thus, while price of products was very high, access to such products was not guaranteed even if someone was willing to pay such high prices.[2] In addition, at this time, India was severely dependent of import of pharmaceutical products. More importantly, lack of affordability, coupled with lack of domestic competition had led to a bad equilibrium in the Indian pharma market.

Concerned about such state of affairs, the Govt. of India formed a one-man committee of Justice N. Rajagopala Ayyangar in 1957 to revise laws of patents and design. The Committee

[1] "Competition Law and Indian Pharmaceutical industry," (2010), Center for Trade and Development (Centad), New Delhi.
[2] "Unused Patents," (1964) Weekly Notes, *Economic & Political Weekly*, Vol. 16(21), p. 42 accessed on Nov. 4, 2015 from http://www.epw.in/system/files/pdf/1964_16/21/unused_patents.pdf

came to the conclusion that the contemporary patent regime under the Patents and Design Act, 1911 did not serve national interest, and led to the situation with high pharmaceutical prices. The Committee recommended the adoption of a process patent regime that was prevalent in Germany at the time that conferred exclusive right to the inventor of a pharmaceutical product to manufacture and sell products according to a given process. In 1970, the Govt. of India adopted the recommendations of the Ayyangar Committee, and formulated the Patents Act, 1970, which allowed process patent protection for pharmaceutical products for a period of 7 years from the date of patent filing. The purpose of this act was, ostensibly, to create and encourage domestic manufacturing of essential drugs, and foster a vibrant competitive environment in the sector.

The Patents Act, 1970 can be considered a watershed moment in the evolution of pharmaceutical industry in India. It led to the development of the domestic pharmaceutical industry which now specialized in reverse engineering bulk drugs. Moreover, the Foreign Exchange Regulation Act (1973) limited foreign ownership of Indian companies to 40% except for some exceptional cases, and they were required to produce most of the bulk drugs (intermediate products) that go into formulations (products sold to retail customers) in India rather than importing them. In addition to this, price controls in the form of Drug Price Control Orders (DPCOs) under the framework of National Drug Policy, 1978 were introduced. These sets of events eliminated incentives of foreign multinationals to sell their products in India; and in their place, domestic pharmaceutical companies specializing in manufacturing generic versions of patented pharmaceutical drugs developed. The domestic companies were supported by research and development activities undertaken by Govt. of India. Two public sector companies, Hindustan Antibiotics Ltd. (HAL) and Indian Drugs and Pharmaceuticals Ltd. (IDPL) engaged in significant research and development, and their R&D efforts spilled over to the private sector through various means -- often through movement of scientists. In addition, research efforts of laboratories such as Central Drug Research Institute (CDRI), Indian Institute of Chemical Technology (IICT) and National Chemical Laboratory (NCL) provided various technical supports to the pharmaceutical industry (Joseph, 2011).

Initially, the domestic companies were confined to simply producing for the domestic market, but later they developed capabilities to produce generic versions of branded drugs for the world market that were off-patent. They also specialized in production of bulk drugs that

formulation-producing MNCs outsourced to India, and thus generated exports. However, in most cases the domestic pharmaceutical companies did not develop the technological capability, nor did invest enough in research and development to be pioneers in producing new and innovative therapeutic solutions and new drugs. In any case, they did not have the incentives to do so under the existing patent regime, which only offered process patents for a period of seven years. The cost of drug discovery (which we discuss later) could also have been a significant deterrent as well. While the industry grew during this period, it was not a sufficiently important industry during this period to have an independent assessment during the Annual Economic Surveys of the country until about 2004-05, and was occasionally mentioned as part of chemical industry. However, by 2004-05, Indian pharmaceutical industry had USD 4 billion in domestic sales, and USD 3 billion in exports.[3] One could summarize this as the period which has seen the emergence of a very potent generic industry, which catered to the needs of not just the Indian market, but also to markets across the globe. However, the presence of the Indian pharmaceutical companies in the new molecules space is virtually non-existent.

The next epoch in the Indian pharmaceutical industry began when India became a signatory to the World Trade Organization (WTO) in 1995. As part of it, India was required to offer a product patent regime, which was extended to the pharmaceutical companies as well. Thus, the Indian Patent Act was amended in 2005 to allow for the WTO regulations. An immediate artifact of this is that the previous strength of the Indian pharmaceutical industry, i.e., reverse engineering a patented drug and producing it through a different process to sell in countries that allowed it was rendered moot, and the industry had to look for a different competitive strategy (Greene, 2007). It was hoped that the introduction of product patent will encourage both domestic and foreign firms to engage more in research and development activities (R&D) in India. While that didn't necessarily happen, the domestic industry found another source of growth: a large number of drugs coming off patent protection in the United States that permitted the Indian companies to sell generic drugs in the US provided they were able to obtain regulatory approval. The industry continued to grow, mostly fueled by exports of global generics. For instance, in 2000 – 01, Dr. Reddy's Laboratories, one of the leading pharmaceutical companies in Indian, had roughly equal shares of sales of global generics (50%)

[3] Economic Survey of India, 2004 – 05

and active pharmaceutical ingredients (44%).[4] As per the latest report available, for the year 2014 – 15, the sale of global generics was nearly 4 to 5 times that of APIs for Dr. Reddy's Laboratories.[5] For the same company, domestic revenue was approximately 13% of its overall sales in 2014 – 15, whereas, in 2000 – 01, domestic revenue was 54% of the total sales. For the current market leader, Sun Pharmaceutical Industries Ltd., APIs constituted almost 35% of the revenues earned in 1999-2000,[6] whereas in 2014 – 15, the APIs constitute less than 4% by revenue.[7] By 2009 – 10, Indian pharmaceutical industry became the third largest in the world by volume of production having 10 percent of the global share and 14th by value having 1.4 percent of global share (Economic Survey of India, 2009 – 10).

The expectation that the companies would invest heavily in research and development was not met, and this is especially true of multinational corporations operating in India (Chaudhuri, 2014). The Indian companies on the other hand, have stagnated in R&D spend as a percentage of total sales immediately at the start of the new patent regime (Joseph, 2011), perhaps daunted by some high profile failures. Two drugs by Dr. Reddy's, balaglitazar and ragaglitazar were licensed to Novo Nordisk, but were abandoned due to side effects or lack of effectiveness in clinical trials (Singh and Datta, 2006). Only a handful of Indian companies spend more than 10% of their revenue on R & D.

Firms that derive a lot of their sales revenue from bulk drugs are mostly small and medium enterprises that are perhaps new entrants. India currently imports close to 80% of its bulk drug requirements from China.[8] Thus, Indian firms now face significant competition from Chinese firms in the bulk drugs segment, which poses significant threat to small and medium scale enterprises in this segment that derive a higher percentage of their revenue from the APIs. The Katoch Committee was set up to "…formulate a long term policy and strategy for promoting domestic manufacture of APIs/Bulk Drugs in the country…" It recommended providing appropriate infrastructure, creation of manufacturing clusters, revival of public sector units and providing economic incentives to the players in this field.

[4] Annual Report, Dr. Reddy's Laboratories, 2001 – 02. The APIs, generics and formulations are reported as separate strategic business units in 2001 – 02.
[5] Annual Report, Dr. Reddy's Laboratories, 2014 – 15. The API is reported under PSAI (Pharmaceutical Services and Active Ingredients) in 2014 – 15.
[6] Annual Report, Sun Pharmaceuticals Ltd., 1999 – 2000.
[7] Annual Report, Sun Pharmaceuticals Ltd., 2014 – 15.
[8] Press Trust of India, 2015, www.businessstandard.com/article/printerfriendlyversion?article_id=115022500808_1.

Thus, the Indian companies that exist today are a combination of many different types of enterprises that specializes in different aspects of the pharmaceutical industry.

3. Uniqueness of the Pharmaceutical Industry

The most important aspect of the pharmaceutical industry is that it affects every human's life and well-being, and therefore ensuring access to end-users is of critical importance. For most other products and services that consumers buy in a marketplace, a consumer might choose to not use a product or service that is beyond their means. In many instances, a pharmaceutical product beyond the means of a particular consumer might result in adverse consequences including death. This results in highly inelastic demand for certain life-saving pharmaceutical products, and left entirely to market forces, might result in prices for a product that will be inaccessible to a large number of consumers. Thus, in most jurisdictions, the pharmaceutical industry is heavily controlled with an aim to ensure access of live-saving drugs to a wide segment of the population.

However, the pharmaceutical industry also relies on large costs of research and development for development of a successful product, and oftentimes the success rate for any given R & D project is rather low. It is estimated that out of 10,000 molecules that pass the stage of basic research and are patented, only about 1 is marketed successfully, and the current cost of bringing in a successful product to the market is estimated at more than USD 2.5 billion.[9] In the absence of any protection, an intellectual property, once developed is available to all for commercial production. Given the costs and risks involved, and the fact that the risk of R&D is borne almost entirely by the pharmaceutical company that develops it, sufficient incentive needs to be provided to the manufacturer to engage in the R&D activity in the first place. Thus, original inventions are rewarded in the form of product patents, which allows a manufacturer/inventor to enjoy monopoly profits on a product for a certain period of time. However, once a successful drug is approved to be sold in the market (it is successful), the production costs of such drugs are relatively low.

This tension between the two concerns is what is called the dynamic efficiency of the pharmaceutical industry. Most competition jurisdictions must find a balance between the need to provide cheap access to medicines to the population at large, and also incentivizing innovating

[9] (UNCTAD, 2015), See http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014..pdf

pharmaceutical companies to continue to invest in high risk research and development so that better quality drugs and drugs for treatment of hitherto untreated diseases could be developed. This trade-off between the current and the future market conditions is what governs the structure of competition policy for the pharmaceutical industry.

Another important aspect that differentiates the pharmaceutical industry from the other industries is that the end-users don't exercise any choice in the medicines they purchase. Except for the over-the-counter (OTC) segment, the choice is made by physicians, which potentially creates an agency problem in the sense that the physicians may not be motivated by the best interests of their patients when prescribing pharmaceutical drugs. Significant efforts are expended by the pharmaceutical companies to generate awareness of their products among the physicians through maintenance of a sales force. We discuss in detail the implications for competition of this aspect later.

3.1 Process of Bringing a Drug to the Market and the Regulatory Framework

The process of manufacturing and bringing a new pharmaceutical product to the market is complex and is subject to regulation by multiple authorities in most jurisdictions. In addition, the nature of the market also varies because of different institutional features. In most cases, a molecule is first patented by a pharmaceutical company, and in most jurisdictions, the patent enjoys a protection for a period of 20 years. In India, the patent granting authority is the Office of the Controller General of Patents Designs and Trademark in the Department of Industrial Policy and Promotion (DIPP), Ministry of Commerce and Industry. The Indian Patent Act (1970), along with the amendments is the corresponding legislation.

Next, the molecule undergoes various phases of pre-clinical testing and clinical trials conducted on human subjects that attempt to prove the efficacy and safety of the drug above and beyond the existing cures for the particular therapeutic segment for which the drug is intended. These phases include pre-clinical trials (usually involving non-humans) that test for acute toxicity or short term adverse effects, pharmacology or drug action and chronic toxicity or long term adverse effects, and three phases of clinical trials involving human subjects to evaluate the efficacy of the intervention and the effects of dosages. The clinical trials have to be registered in Clinical Trials Registry – India according to an order by the Central Drug Standard Control Organization (CDSCO), which falls under the Ministry of Health and Family Welfare. After

being satisfied of the efficacy of the new drug in treating the particular disease, the appropriate authority (in India, the Central Drug Controller) then approves the drug for the particular indication, and the company gains exclusive marketing rights for this product until the exclusivity period expires (i.e., normally 20 years from the date of filing of patent). This is governed under the Drug and Cosmetics Act, 1940 ("DCA") that regulates the import, manufacture, sales and distribution of a drug in India. For bringing new drugs to the market that have already been granted marketing approval in certain developed countries, the DCA does not make it mandatory that local clinical trial is always necessary except for a bridging Phase III clinical trial involving 100 patients. Additionally, the Clause 122-A(2) of Schedule Y of DCA mandates that in "public interest," the licensing authority (i.e., Drugs Controller General of India) may rely on data available from other countries to grant permissions for their manufacturing, distribution and sale in India.

In many countries, an additional form of protection is available to pharmaceutical companies called "data exclusivity." The patent for a product offers a protection for the product until loss of exclusivity. In addition, data exclusivity offers an incremental layer of protection. Under this, the proprietary test data by originator companies that demonstrate efficacy of a pharmaceutical product are protected from use by later generic companies. While this does not preclude a generic company from generating its own data to show efficacy of the generic version of a particular drug it intends to sell, it certainly adds to cost of production, results in delays to generic entry (and thus enhancing profits of the originator), and results in potentially socially wasteful duplicative expenditure (Sharma, 2007). The purpose of this is of course preventing generic companies from free-riding on costly data generated by originator companies. As of now, India does not provide this protection.

In most jurisdictions in developed countries, usually strict price controls are absent, although the extent of price controls are higher in the European Union than in the USA. This is usually because the populations in these countries have higher purchasing power, and additionally are covered by employer provided or privately bought health insurance or the government. provided healthcare services as part of social security net. The physicians are encouraged or required to write prescriptions with the generic names of medicines that are not under patent protection, so pharmacies may steer the consumers towards low-priced options.

Because the insurance companies and the formularies have direct incentives to keep their payments low, they hunt for low-priced drugs in a particular therapeutic category, and thus there is a lesser need to keep prices in check through direct price controls.

In many developing countries including India, many drugs are subject to pricing controls. The universal health coverage by the government or a high level of insurance coverage usually does not exist, resulting in large out-of-pocket expenses by the patients. In India, the regulatory authority for pricing decisions falls under the Drug Price Control Order (DPCO) of 1995 (subsequently DPCO 2013). The National Pharmaceutical Pricing Authority (NPPA) is empowered to set prices of medicines covered under the National List of Essential Medicines (NLEM), although that leaves out a large number of drugs outside of the purview of price controls.

Beyond price controls, there are also numerous issues that arise in competition, such as trade practices, marketing practices, mergers and acquisitions by companies and the Competition Commission of India (CCI) is the appropriate regulatory authority for those industry related matters. Thus, the pharmaceutical industry is a highly regulated market, with different regulatory authorities controlling different aspects that arise in the context of this industry.

3.2 Pharmaceutical Industry and the Nature of its Market in India

As mentioned before, the pharmaceutical industry is one of the most important industries in India, and these days quite a few Indian firms have become large global players in the generic formulations market. The size of the pharmaceutical market in India is estimated to be USD 34 billion as of 2013 – 14, including exports.[10] As can be expected, the Indian market is dominated by generics with 72 percent market share in terms of revenues. Patented drugs cover only 9 percent of the overall market supplied almost entirely by MNCs, whereas over-the-counter market is 19 percent. India also is the largest exporter of generic drugs in the world, accounting for 20 percent of the worldwide exports by volume (IBEF, 2015). As of 2013, the total exports by India stood at USD 10.1 billion. Indian firms provided 95% of India's medical needs as of 2009 (Gouri, 2009).

While it is common to speak of a pharmaceutical industry, it is somewhat naïve to speak of a pharmaceutical market. Because a specific drug belonging to the pharmaceutical industry

[10] Annual Report, OPPI, 2013 – 14

cannot be a substitute of another drug unless it is in the same therapeutic class, markets need to be defined in terms of therapeutic categories. Thus, there are many different fragmented markets in the pharmaceutical industry. Moreover, because of patent protection, a firm bringing a new drug to the market will have very few or no substitutes. Thus, for patented drugs, markets will be highly concentrated and prices tend to be very high. For formulations without any patent protection, much cheaper generic substitutes exist, and competition among the generic producers generally ensures a very low and affordable price. Given that generics constitute the majority of the market in India along with over-the-counters, drug prices in India are among the cheapest in the world.

Price Competition: Price competition among generics is an important feature of Indian pharmaceutical industry. While generally this leads to low prices, instances of high prices and high dispersion of prices for a particular molecule may exist even when the number of suppliers of the same drug is high. As we discuss later, a specific feature of the Indian market is prevalence of *branded* generics, which is not found in most developed markets. Thus, there is inter-brand competition at the intra-molecule level. This sometimes creates artificial differentiation, and firms spend advertising and marketing resources to increase expenditure on their products (Bhattacharjea & Sindhwani, 2014), and are thus able to charge high prices for their products even when they have high market shares.

Price competition coexists with price controls. Since 1970, the pharmaceutical prices have been controlled through the DPCO under the Essential Commodities Act, 1955. While initially, prices of a large number of drugs were controlled (370 through the DPCO 1979), this was brought down systematically to 74 to DPCO 1995. However, the DPCO 2013 brought a large number (348) of domestic generic formulations under the ambit of price regulation from an erstwhile 74 molecules under DPCO 1995, covering an estimated 30 percent of the overall domestic market (Yes Bank - Assocham, 2015). Thus, a significant portion of the market is now regulated through direct pricing rather than competition policies. The DPCO 2013 (paragraph 19) was also interpreted by NPPA in May 2014 to allow them to bring a large number of drugs outside of National List of Essential Medicines (NLEM) under price control for reasons of "extraordinary circumstances" or "public interest," and in implementing so, the NPPA brought

108 formulations under price control in July 2014. Due to opposition from pharmaceutical companies, this order was withdrawn in September 2014 and while it was conceded that such order won't be in effect going forward, the pricing of the formulations brought under control was not changed (Moneycontrol, 2014). This mostly affected the MNCs operating in India, as a large number of these medicines were marketed by such companies. It is somewhat common wisdom that pricing is the driver of revenue for the foreign companies, whereas volume is the larger driver of revenue for domestic companies in India, who also increasingly rely on the export market for their growth. Currently, there are more than 500 drugs under pricing control by the NPPA (BS Reporter, 2015).

There has been a change in policy of pricing of pharmaceutical drugs by the NPPA. Earlier, the prices used to be computed according to a cost-plus formula that allowed companies a fixed margin above various costs. From 2013 onwards, the NPPA has decided on a pricing formula that calculates the simple average of market prices of different products with more than 1 percent market share in the same therapeutic category (available from IMS Health, a private data vendor that collects information on pharmaceutical prices), and adds a 16 percent margin to arrive at retail prices (DPCO 2013).

Price competition can also theoretically take place at the point of sale, where pharmacists and retailers may compete for consumers buying medicines. This price competition from retailers may lead to price competition among pharmaceutical firms trying to sell their own products in a particular therapeutic category. Because of trade associations, it is generally understood that such form of competition has not happened all that much in India. However, recently a few state governments have taken initiatives for sourcing the drugs: (i) procure drugs for sale in government hospitals and primary health care centers through centralized tendering (e.g., Tamil Nadu through Tamil Nadu Medical Services Corporation Ltd), or (ii) opening Fair Price Medicine Shops in the public private partnership (PPP) mode facilitating purchase of drugs through the hospital and other government outlets in West Bengal. In addition, the Central Govt. of India has also created Jan Aushadhi Schemes that intend to make generic medicines affordable through special outlets. All these are likely to have a bearing on price competition even for branded companies.

Cost Advantages: One of the primary advantages enjoyed by the Indian producers is low-cost but quality manufacturing of drugs. According to Greene (2007), the cost advantages stem from lower labour costs (approximately one-seventh of that in the US), lower infrastructure costs and fixed costs compared to the USA and Western Europe, large number of FDA-approved plants and availability of technical personnel. While some bulk drug producers have been able to maintain cost advantage and thrive with process innovations that usher in greater efficiency[11], Indian bulk drug manufacturers are increasingly facing competition in this segment from the Chinese producers of bulk drugs, who have greater cost efficiency in production of bulk drugs. While most of the established Indian pharmaceutical companies have moved away from bulk drug productions to formulations, where the pharmaceutical companies enjoy higher profit margins, other bulk drug producers have targeted regulated markets where the margins are somewhat protected.[12] However, Indian firms continue to enjoy cost advantages in formulations, and thus are able to sell a lot of off-patent generic drugs. Other areas where firms operating in India potentially enjoy cost advantages are contract research and clinical trials. Thus, there exist incentives for many domestic firms to partner with multinational firms for the conduct of clinical trials, which would lead to reduction in costs in clinical trials.

Product Innovation: Indian firms have historically specialized in process innovation, and not necessarily product innovations.[13] This is due to the fact that the Indian pharmaceutical industry developed in a protected environment where product patent was not recognized from a period of 1970 to 2005. It is usually claimed that out of 5,000 to 10,000 molecules that receive a product patent, only about one is successfully marketed. This makes the pharmaceutical industry a high technology and a high fixed cost industry with very high entry barriers for firms in new product development. Indian firms' capability of development of new drugs is limited by the R&D budget. Usually, it is believed that for developing a new drug, an investment in excess of USD 1 billion probably over a period of 15 years is needed. The largest R & D spend by an Indian firm is the newly merged Sun Pharma (thus it includes Ranbaxy Laboratories) in 2015, which is 20

[11] See, for instance, "Some Indian bulk drug makers are becoming world leaders in niche areas" E. Kumar Sharma, Business Today, September 18, 2014.
[12] "From bulk drugs to formulations," P. Vikram Reddy, The Hindu, Jan 19, 2004, and "API Market loses out to formulations," Sushmi Dey, Business Standard, August 27, 2012.
[13] This segment borrows heavily from Joseph (2011).

billion Indian rupees, which falls far short of the annual expenditure by global new drug developing companies. In addition, India lacks the infrastructure and the technical skills in chemistry and biology to sustain an environment of R&D excellence.

Nevertheless, there have been some attempts by Indian firms to develop new drugs. In the 1990's, Dr. Reddy's Laboratory developed and out-licensed two molecules called balaglitazone and ragaglitazar to Novo Nordisk. Novo Nordisk has paid Dr. Reddy's paid a licensing fee for the rights of testing and if successful, marketing it. However, both these drugs could not be successfully brought to the market by Novo Nordisk, and for balaglitazone, by Rheoscience which conducted human clinical trials after 2005.[14] Ranbaxy Ltd., another pioneering pharmaceutical company from India, had a similar fate with a molecule it out-licensed to Schwarz Pharma in 2002, as its development was discontinued. However, Ranbaxy had a slightly better outcome. In 1999, Ranbaxy out-licensed once-a-day ciprofloxacin, an anti-anthrax compound to Bayer AG, Germany for marketing globally except in India and China. This was brought to the market by Bayer AG in 2003, for which Ranbaxy received royalty payments at different milestones. It is worth noting that none of these drugs fall under completely new class of drugs, but are new molecules belonging to an existing class of drugs, so these cannot be categorized in the class of "breakthrough" or "blockbuster" drugs. This category is generally classified as New Drug Delivery System (NDDS) rather than a new drug, which is a New Chemical Entity (NCE). Other companies that have had success in the NDDS category are Alembic Pharmaceuticals with UCB for Keppera and Dabur Pharma for Nanoxel in 2007. Ranbaxy would also later successfully develop[15] and market Synriam, a New Chemical Entity (NCE) that received approval for marketing in India and other African countries. In addition, Cadila discovered and developed Saroglitazar, which was marketed under the name Lipaglyn for treatment of diabetes in India in 2013 (The Hindu Business Line, 2013).

Due to perhaps the high risk of product development, comparatively low investment in R&D and somewhat uncertain regulatory environment that involves unethical practices, delays in approval and uncertainty regarding conduct of clinical trials, it has become challenging to

[14] "Dr. Reddy's Struggles for Homegrown Hits to Escape Rival Clones," Abhay Singh and Mrinalini Datta, December 5, 2006, Bloomberg.
[15] It is worth noting here that the drug in question is a fixed dose combination of two APIs. The success of Ranbaxy in his case stems from basic research funded by a non-profit organization called Medicines for Malaria Venture, which developed and owns the patent for one of the APIs called Arterolane, and gave Ranbaxy a worldwide royalty-free license for it. For Phase III clinical trials, Ranbaxy also received some money from the Indian Govt.

establish India as an innovation hub. Thus, Indian firms have looked at strategies that require them to only take up innovation partially. We have already discussed out-licensing by Indian firms, which develops the chemical compound up to a point, and leaves the late stage development and marketing of the drug in the hands of other firms in exchange for various payments and royalty. Some Indian companies are following a strategy of in-licensing products developed by other companies, which is the opposite of out-licensing in that Indian firms will fund the clinical trials and market the product and pay royalties to the out-licensing firm. There have been instances where a new drug developer like Merck has entered into an agreement with Sun Pharmaceuticals, giving the latter worldwide marketing rights for tildrakizumab in exchange for an upfront payment of USD 80 million and later royalty payments in case the product is successfully marketed (BS Reporter, 2014). This can be understood in the context of risk-sharing in an environment of increasing R&D costs and restricted budget for the Big Pharma (pharmaceutical companies whose business model center around bringing new, innovative "blockbuster" drugs to the market).

Indian pharmaceutical companies have also partnered with other multinational companies to undertake R&D activities under outsourcing arrangements such as Contract Research and Manufacturing Services (CRAMS), or Collaborative Research Projects (CRPs). CRAMS purports to take advantage of India's low cost manufacturing capabilities and large number of existing FDA-approved facilities, which will help MNCs bring down their drug development costs. The CRAMS market in India was USD 7.6 – 7.8 billion in 2013, and is expected to grow at a fast rate.[16] This partnership not only happens in the manufacturing activities but also in product development activities such as pre-clinical and clinical trials. However, these partnerships, especially for conducting clinical trials have recently come under the scanner of regulatory authorities. In 2013, The Supreme Court of India responded to a series of public interest litigations (PILs) alleging unethical practices – like lack of informed consent and payment of money to volunteers enrolled in clinical trials – by first putting all clinical trials on hold, and afterwards, by imposing a stringent three-tier control system. Subsequently, legislation was amended to improve regulatory oversight, but lack of clarity in policy and resulting delay in

[16] "Crams players set for $85 billion US drug bounty," DNA News, February 2, 2015.

registration and approval of clinical trials has resulted in a lot of companies moving clinical trials out of India.[17]

While there are procompetitive benefits to the partnerships in drug development between Indian and multinational companies, it does appear that R&D and product innovation in Indian companies are not up to the desired level, and the clinical trials that are taking place are not trying to innovate new drugs. More worrisome is the fact that the R&D efforts, even of domestic firms are geared towards diseases in developed countries and not necessarily towards diseases that mostly affect Indians. The reason for this could be the small size of any such market, as Indian consumers' purchasing power remains low.[18]

Marketing Practices: In India and in most parts of the world, most pharmaceutical products (except for the over-the-counter ones) cannot be directly advertised or sold by a pharmaceutical company to the end-user or the consumer. Rather, it is a physician who prescribes a particular drug to the consumer/patient, who buys it from a pharmacy. This phenomenon essentially makes the physician the agent of the consumer, and thus the advertising and marketing efforts of pharmaceutical companies target the physicians. According to a joint study by IMS Consulting Group and OPPI in 2011, most companies maintain a sales force that accounts for the highest share in promotional expenditure of the company, with the physician as the primary focus (Udeshi and Bahri, 2011).

This can potentially lead to subversion of competition. The doctors may (and is usually alleged, do) prescribe a branded medicine that has no or inconsequential therapeutic benefit over other brands selling the same compound but carries a higher price in exchange for inducements. This is a scenario that is peculiar to India because of existence of branded generics, as we discussed before. In the USA and the UK, the doctors are encouraged to prescribe only the name of the molecule for a generic drug, and not the brand name; pharmacists are also incentivized to steer the consumers to the cheapest available option.[19] However, strict quality controls are in place to ensure that all the drugs sold by different companies meet the required quality standards, which make these restricted markets. Insurance coverage of medicines and inclusion of

[17] "Clinical Research: Regulatory Uncertainty hits drug trials in India," The Pharmaceutical Journal, 14 March 2015, Vol 294, No 7853, online | DOI:10.1211/PJ.2015.20068063.
[18] "India: A Powerhouse of Innovation for Neglected Diseases?" David de Ferranti, The Huffington Post, 29/08/2012.
[19] For repercussions of such practice in the Indian context, please see Chatterjee, Kubo and Pingali (2013).

medicines in formularies then ensures that the incentives of the patients and insurance companies are aligned to keep the medicine prices down because the insurance companies insist on the lowest priced generic available, and thus, patients in these jurisdictions receive low cost generic medicines. In India, public provisioning and insurance coverage of healthcare is very low, and in most cases, insurance coverage is limited to inpatient care, leaving medicines purchased for outpatient care out of the purview of insurance. In fact, the out-of-pocket expenditure for health in India is rather high: more than 60% of all expenditure on health in India as of 2011 is out-of-pocket (Bhattacharjea & Sindhwani, 2014), and expenditure on medicine constitutes 72% of the out-of-pocket expenditure, among the highest in the world.[20] In such a scenario, the likelihood of a family falling into poverty due to high medical expenses is rather high, and the role of the physician assumes importance.

There is some evidence that the doctor's don't necessarily prescribe medicine that will be the cheapest for the patient without compromising on quality. A study by Nguyen (2011) finds evidence of higher prescription drug incidence by private providers compared to public providers for similar illness and patient profile in Vietnam. In India, such studies are hard to come by, but studies by CUTS in 1995 and 2010 have found evidence of a tendency for irrational prescription involving unnecessary medicines, and that only 20 percent of patients visiting public hospitals were prescribed medicines that they could obtain from the hospitals they visited for free, while the rest were prescribed medicines by companies that could be obtained from pharmacies close to the hospital. The study also showed that in contravention of Medical Council of India's guidelines, the acceptance of gifts in cash and kind by Indian doctors from pharmaceutical firms is rampant.[21]

In many states, the government regulations require doctors working in Govt. hospitals to prescribe only the generic name of the drug in their prescriptions, and the Govt. dispensaries in the hospitals provide the drugs free of cost, which is likely to alleviate the situation. It can be argued that a similar stipulation be enforced on private physicians as well. However, in the current scenario, there is a serious possibility that this may not have the desired effect, and may in fact exacerbate matters. Firstly, in the absence of a strong quality control regime, spurious drugs of low quality may be sold to the patients. Secondly, without a serious prescription audit

[20] "A bitter pill for Doctors, Pharma Companies," Pradeep S Mehta, The Asian Age, Jan 6, 2015.
[21] See, for instance (CUTS, 2014).

system in place, such a requirement may not have any bite, and doctors could simply go on as usual ignoring the stipulation. Thirdly, the agency will merely shift from doctors to the pharmacists, and the sales force of companies will try to influence the sale of their brand by targeting the pharmacist rather than (or in addition to) the doctor. The key is to ensure common application of Good Manufacturing Practices (GMP) and strict control of drug quality, and growth of a strong public provisioning and private health insurance system that will also cover medicine purchases. This will align the interest of the end user with that of the insurer or formulary. Additionally, growth of retail pharmacy chains might also help with price reduction: at least theoretically, pharmacy chains are likely to put pressure on the drug companies to be able to stock medicines at a cheaper cost, and this will result in price competition among companies that will reduce prices.

This year, the Government of India had asked for voluntary compliance of pharmaceutical companies and physicians with Uniform Code of Pharmaceutical Marketing Practices (UCPMP). In the UPCMP, Section 7 deals with "Relationship with Healthcare Professionals," which prohibits companies to extend travel facilities (usually in the guise of foreign travel for conferences), hospitality and cash or monetary grants to physicians or their families. It was to be reviewed after a period 6 months, and if compliance was found to be unsatisfactory, it would be made a statutory law. So far, the Govt. is still reviewing compliance and has extended the period of voluntary compliance to 12 months. Anecdotal evidence suggests that the voluntary uptake of this is not forthcoming from the pharmaceutical companies, and the Govt. may look to enforce this legally.[22]

Distribution Channel: In India, medicines are distributed through retail pharmacies to patients upon production of a prescription from a doctor for any other type of medicine other than the OTCs. However, the medicines would first need to be taken from their place of production (plants and pharmaceutical companies) to the place where they could be sold (retail pharmacies). As described in Jeffrey (2007), due to peculiarities in Indian tax system where inter-state sale of goods are taxed by Central Govt. but inter-state movement of goods are not, Indian pharmaceutical companies maintain Carrying (or Clearing) and Forwarding Agents (CFAs) to

[22] "UCPMP: 'Code' word for Pharma Industry," Sachin Jagdale, Financial Express, June 9, 2015.

maintain stocks of their products in every state they intend to sell. This replaced an earlier arrangement prior to mid-nineties where companies themselves maintained depots and warehouses in each state. The CFA earns a percentage margin of total revenue.

The stockists or wholesalers are next in the supply chain, and they procure medicines of pharmaceutical companies from the CFAs. A pharmaceutical company may have relationship with multiple stockists, and a stockist might in turn maintain stocks of medicines produced by many pharmaceutical companies. Once again, a stockist earns a margin on the maximum retail price (MRP) of the product, which is typically a discount. Estimates on these discounts range from 2 to 10 percent for CFAs on the turnover, and the margin obtained by wholesalers is close to 8% for price-controlled drugs and around 16% for other drugs. Stockists may pass along some of the discount they get (either in the form of formal discounts or free packs) to the retailers, the next in the supply chain.

The final point of contact between the pharmaceutical companies and the end-users are the retail pharmacists, or any other entity that is authorized the sell drugs such as hospitals or dispensaries. As mentioned before, they make money through discounts that they obtain from the wholesalers.

The wholesalers/stockists and retailers/pharmacists are organized through a trade association called All Indian Organization of Chemists and Druggists (AIOCD). AIOCD has state chapters, as well as associations at district levels which are affiliated to AIOCD. The AIOCD strictly controls the entry of wholesalers and pharmacists, and used to lay down strict rules for a pharmaceutical company to avail of the services of a stockist/retailer through grant of No Objection Certificates (NOCs) and Letter of Consent/Cooperation (LOC). AIOCD used to mandate that any new drug being sold to any state needs to be approved by it before they can be stocked by any wholesaler or sold by a retailer. They also used to charge Product Information Services (PIS) charges to pharmaceutical companies for each new drug launched for every state. They also had a practice of fixing margins for uncontrolled drugs through a memorandum of understanding (MoU) with IDMA and OPPI, two associations representing drug manufacturers in India. And in case any pharmaceutical company did not comply with these directives, AIOCD would boycott those pharmaceutical companies. Thus, AIOCD was (and probably still is) a very powerful association that restricted trade in a significant way until its practices were repeatedly

found unlawful in a series of cases by the Competition Commission of India, as we discuss later. A Cease and Desist (C&D) order and a Public Notice was passed by the CCI to ensure that all parties understood the anti-competitive nature of these issues.

Needless to say, this has been the most publicly visible and noted aspect of competition regulation in India by CCI in the pharmaceutical sector. However, as we discuss in detail later, there has been some curious interpretation of the competition aspects of these cases, particularly when it came to analyze the nature of agreement between the associations such as AIOCD, IDMA and OPPI.

4. Comparison of Competition Authorities around the World

In this section, we compare a few regulatory authorities around the world with a view to provide perspectives on regulatory issues that have concerned different jurisdictions. Our choice of jurisdictions reflects several types of economies and geographies (advanced countries, emerging markets, different continents etc.), and this will provide us a benchmark against which to discuss the efforts of regulatory authorities in India, including the Competition Commission of India.

European Union: The EU has quite a few countries that house some of the largest innovating drug manufacturers in the world. The European Commission is the relevant competition authority. Among the competition concerns that have been noted by the EC is the tendency of the branded manufacturers to delay generic entry for drugs through different life-cycle management strategies. Such strategies include pay-for-delay settlements, evergreening, product-hopping and abuse of data exclusivity, which allow companies to protect data on pre-clinical and clinical trials for a period of up to 10 years from being referenced in applications for introduction of generic products. Essentially, this reduces the scope for free-riding on data produced by originator companies by the generic companies, but may also result in delay of introduction of generics after patent exclusivity lapses. In terms of regulatory activities, European Commission has fined companies (e.g., Sanofi Aventis for allegedly misinforming physicians and pharmacists regarding the safety and efficacy of generic version of clopidogrel, its blockbuster drug; AstraZeneca for allegedly misleading representations to patent offices and requests for deregistration of marketing authorization of Losec capsules prior to introduction of Losec

tablets) for engaging in anticompetitive conduct, Lundbeck for reverse payment settlement and Schering-Plough for excessive discounts to block generic entry in France. In Italy, competition authorities fined Pfizer for engaging in a number of anticompetitive activities with a view to blocking generic entry that was considered abuse of dominant position (UNCTAD, 2015). In terms of pricing, individual countries within the EU have responsibilities to come up with pricing policies, and thus, there are variations in pricing policies pursued. It appears that 5 of the 30 countries in the EU have free pricing for the generic products, whereas the rest have a regulated price system. Within the regulated system, price regulation of generic medicines can be based on external reference pricing (based on prices on other EU countries), or a price ceiling that is a certain fraction of the original price of the originator company. There is also the reference pricing system, most notably in Germany, where the regulator would establish a reimbursement level for a group of medicines that are considered interchangeable. In general, countries that have more free pricing system tend to have higher medicine prices on average coexisting with higher generic penetration (Dylst & Simeons, 2010).

USA: The USA combines patent protection with affordability through IPR protection, simple rules for introduction of generic medicine once the patent protection expires through the Hatch – Waxman Act of 1984, and legally allowing pharmacists to fill a prescription for a branded medicine with its generic equivalent. Regular FDA inspections of pharmaceutical plants worldwide ensure that the medicines produced by generics are of high quality and can be substituted for branded medicines once patent protection expires. However, the brand – generic competition may be subverted through collusion between originator and generic companies through a tactic called "pay-for-delay." An incumbent originator company, facing loss of exclusivity over its branded drug might bring a lawsuit against a generic entrant. This usually results in a settlement, with the originator company paying the generic entrant who agrees to delay the entrance of the generic product. While the US Federal Trade Commission (FTC) has pursued several cases that challenged such exclusion payments, they have met with limited success. However, in 2013 the Supreme Court ruled that such settlements can violate antitrust rules (Dwyer, 2013). The generic – generic competition, which is crucial to lowering of prices, is another area where FTC targets anti-competitive behavior. There have been instances where

companies have entered into agreements to supply the same drug of different dosages to the market, each covering a different dosage exclusively (UNCTAD, 2015). Another concern is "product hopping" where branded firms introduce a new formulation without significant therapeutic benefit over the old formulation (e.g. a capsule is introduced in the place of a tablet) as the patent is about to expire, and then recall all versions of the earlier formulation (tablet) from the market to switch consumers and physicians to a new formulation before generic entry. This sometimes creates problems for pharmacists to substitute the generic product for the chemical as this is now available in the form of capsule from the branded manufacturer, and the generic is available only in the old formulation for which the physician may not write a prescription. Recently, in the New York vs Actavis case, the United States Court of Appeals for the Second Circuit has held that coercively switching consumers from one formulation to the other is anti-competitive (DavisPolk, 2015). In the merger and acquisition space, the FTC has sought to encourage aggressive price competition, and has challenged certain M&A activities that has often resulted in divestitures of certain products from the merging companies. But efficient mergers and acquisitions are viewed pro-competitive by the US FTC.

Canada: In Canada, drug prices for prescription medicines under patent protection are controlled through the Federal Govt. through the Patented Medicine Price Review Board (PMPRB) as well as the provincial governments when the drugs are listed in the formularies. The PMPRB does not set a price, but decrees that the price of a drug cannot increase by more than the CPI, and the prices of new innovative drugs cannot be more than the highest in a particular therapeutic category. For breakthrough drugs, PMPRB uses reference prices from various EU countries and the USA (Menon, 2001). Usually, negotiations with Provincial governments result in firstly, a decision whether a medicine is listed in the Provincial Formulary, and secondly a price that the province will reimburse to patients. The Provincial Formulary price then determines the open market prices, both for the innovator drugs as well as the generic substitute drugs. Off-patent drugs have their prices fixed in the open market (Vanveen, 2009). It is usually believed that this does not result in lower drug prices in Canada relative to the US, and significantly, the generic prices are much higher in Canada than in the USA. One reason for this is that there is very little incentive for the branded drugs to lower their prices once they are off-patent as the PMPRB uses

the price of existing drugs in a therapeutic category to determine price of a new medicine being marketed. Further, because the generic competitors reference their prices to branded drugs, the generic prices also remain high (Skinner, 2005). Thus, the Canadian competition authorities have attempted to relook at price controls. Recent concerns of the Canadian authorities include product hopping. The Competition authorities in Canada also intervene in court cases to bring in competition perspectives.

Japan: Generic usage in Japan is relatively low, at around 17 percent of total pharmaceutical expenses as of 2009, although this figure is comparable to jurisdictions in the EU (OECD, 2009). Thus, competition authorities in Japan have looked at policies that can increase the usage of generic drugs to bring down costs of healthcare provision. Among the factors under consideration that inhibit generic usage are innovator pharmaceutical companies engaging in negative campaigning against the competitor generic products, and generic producers not engaging in enough information sharing on their products which results in adverse opinion of generic drugs among the public and the distributors. Prices of pharmaceutical products in Japan are regulated (JPMA, 2014) via National Health Insurance price list, and pharmaceutical products are made available through health insurance programs. Thus, there seems to be little price competition by generics, as its prices are tied to brand it is identical to.

UK: In the UK, generic penetration was between 20 to 40 percent as of 2009 (OECD, 2009). The major competition issues faced by the UK regulatory authorities is the lifecycle management strategies by pharmaceuticals such as evergreening, patent-pooling and product-hopping strategies by innovator companies that tries to stave off generic competition, and supply chain related vertical agreements. In the UK, for the state-run National Health Services (NHS), there is a voluntary agreement involving the Department of Health and the Association of the British Pharmaceutical Industry regarding pricing of pharmaceutical products called Pharmaceutical Price Regulation Scheme (PPRS). The PPRS allows for a profit cap and a range of price controls that involves some restriction on pricing and price increases (but not on initial price setting for a new active substance). Other relevant issues of concern to the authorities in the UK are that of evergreening, charging high prices for the private sector for the branded product but predatory

prices for the public sector, and tendency of general physicians to prescribe branded drugs when cheaper generic alternatives exist. The regulatory authorities in the UK recently fined Reckitt-Beckinser for trying to product-hop a branded drug called Gaviscon with the specific purpose to block generic entry (UNCTAD, 2015).

Other Emerging Markets: In other emerging markets, we consider other members of the BRICS countries. In almost all these countries, price controls of different types exist. In **South Africa**, the practices of parallel importing (that can result in importation of a drug under patent protection by the country's authorities from places where it carries a lower price) and compulsory licensing (whereby a product of an innovator company can be produced by the generic producers upon payment of a royalty) have been used to make necessary medicines accessible to HIV/AIDS patients. Legal avenues exist to promote generic substitution at the point of sale for a particular branded drug. Authorities also resort to price control mechanisms such as single exit price (SEP) to prevent instances of excessive rebates to hospitals by manufacturers. It has also dealt with cases where companies were alleged to charge excessive prices for medicines and cases of mergers and acquisitions. **Russian Federation** has imposed quite a bit of price control over pharmaceutical companies, but it has been noted that this has resulted in many medications vanishing from pharmacies. Moreover, inefficiency also exists in drug procurement which results in higher prices for medicines.[23] **Brazil** has dealt with issues that are somewhat similar in nature to India in that there have been cases of subversion of competition at the retail level. The Administrative Council for Economic Defence of Brazil (CADE) imposed sanctions on a drugstore cartel where competitors decided on specific days of the week to offer discounts. It has also made use of compulsory licenses since 2007, and was one of the first countries to make use of it (Smith, 2013). **China** has dealt with cases of vertical agreements in supply chain. Two pharmaceutical distribution companies, Shuntong and Huaxin entered into agreements with suppliers (there are only two of those) of promethazine hydrochloride, ingredients for production of hypertension medicine "compound reserpine tablets" that prohibited the manufacturers from supplying to manufacturers of compound reserpine tablet without approval from the aforementioned pharmaceutical companies (UNCTAD, 2015). These companies then increased

[23] (Federal Antimonopoly Service of Russia, 2013).

price of both the upstream and the downstream product which led to reduced supply of the downstream product in the market. The companies were found to have violated antimonopoly laws and were fined.[24] China's competition authorities have also fined GlaxoSmithKline for bribes paid to hospitals and doctors. In attempting to control prices of pharmaceutical drugs, China used to employ a policy of establishing maximum resale price maintenance.[25] However, China now has decided to abolish this practice and promote competitive forces to take care of prices. Among other developing countries, **Mexico** has dealt with situations of bid rigging in public procurement, which has resulted in significant drop in prices (UNCTAD, 2015).

Our review of different jurisdictions indicates that different countries face different challenges and have different priorities when it comes to regulating the pharmaceutical industry. Developed nations are more concerned about achieving the right balance of dynamic efficiency to incentivize new drug production, and reducing price through enhancing price competition by generic entry. Affordability is ensured through state provision of healthcare benefits or developed insurance markets. In developing world, in the absence of sufficient budgetary provisions for public health and lack of developed insurance markets the concerns shift more towards ensuring access and affordability through price controls and other mechanisms such as parallel imports and compulsory licensing that introduce medicines to its population at an affordable price. In the process, these countries may lose out on the most advanced medicines of the world that carry patent protection, as innovator drug companies do not have much incentives to introduce their drugs in these countries.

5. Competition Commission and the Pharmaceutical Industry

In this section, we review the regulatory efforts in India in recent times in terms of competition laws, and how the CCI attempts to fulfil its mandate with respect to competition issues in the pharmaceutical sector in India.

The Competition Commission of India was set up in 2003 subsequent to the passage of the Competition Act of 2002, which was amended further in 2007 and 2012. Among the CCI's

[24] http://www.chinalawinsight.com/2011/12/articles/corporate/antitrust-competition/ndrc-fined-two-pharmaceutical-companies-for-abusive-conducts/.
[25] Resale price maintenance are agreements between manufacturers and distributors that set the retail price of the product by the distributors. See, for instance (Elzinga & Mills, 2009).

mandates are to "…eliminate practices having adverse effect on competition, promote and sustain competition, protect interests of consumers and ensure freedom of trade in the markets of India."[26] In addition, CCI is also "… required to give opinion on competition issues on a reference received from a statutory authority established under any law and to undertake competition advocacy, create public awareness and impart training on competition issues."

The CCI consists of a Chairperson and between 2 to 6 full-time members at all time, who are appointed by the Central Govt. The CCI is served by a Director General (DG) who conducts "…inquiry into contravention of any of the provisions of (the Competition) Act…"[27] While the strength of the personnel to assist the DG in his/her investigations is unknown, the Competition Act provides for engagement of experts and professionals as is deemed necessary to assist the Commission in the discharge of its functions.

The CCI is empowered to conduct inquiry either "on its own motion" or receipt of information by any interested/affected party or any reference made to it by Central or State governments, or any other statutory bodies. Upon receipt of information, the CCI may either decide that there is no prima facie case and may close the case, or may determine that there is a prima facie case and direct the DG to undertake an investigation. The DG, after a conduct of investigation, recommends whether there is a contravention of the Competition Act. The CCI, upon receipt of the recommendations of DG, invites objections or suggestions from concerned parties. After consideration of all submissions, the CCI may either close the matter and provide its ruling, or choose to conduct further inquiry either with help of the DG, or by itself. If the CCI finds any party in contravention of the Competition Act, it is empowered to discontinue the alleged anti-competitive practice, and impose a penalty that may not exceed more than 10 percent of the average of the turnover for the last three preceding financial years. Three specific areas where the CCI has provisions for anti-competitive conduct are areas prohibiting agreements, abuse of dominant position and combinations, which are effectively mergers and acquisitions. In case of mergers and acquisitions, the CCI is empowered to issue show-cause notices to parties entering into M&A, and it may go ahead with an investigation in case it deems such action necessary after receiving answers from the parties. Upon investigation, the CCI may allow the M&A to go through if it is satisfied of its pro-competitive benefits, or it may disallow

[26] See www.cci.gov.in/about-cci.
[27] The Competition Act, 2002.

the M&A on grounds that it will adversely affect competition, or it may propose changes if it is satisfied that minor changes to the proposed merger will be acceptable. The CCI also has an appellate tribunal that aggrieved parties can approach in case of an adverse ruling by CCI.

So far as we can tell, while the CCI has entertained cases with respect to horizontal agreements in the supply chain and mergers and acquisitions in the pharmaceutical industry, no cases in the areas of abuse of dominance by a pharmaceutical company has been adjudicated by the CCI. We discuss in details our take on the cases adjudicated by the CCI in the following sections.

6. Assessment of Anti-Competitive Conduct – Defining Market and Measuring Market Power

The starting point for any understanding the competitive framework in any sector is through defining appropriate market. Once the market is defined the next issue to be resolved is the extent of market power vested in the hands of the existing firms. One of the most commonly accepted tools to measure market power or market concentration is the *Herfindahl-Hirschman Index* (HHI). Simply defined, HHI is calculated as the sum of the squares of the market shares of various firms in the appropriate market. If the market is a monopoly, then 100% of the market is held by a single firm, and hence, HHI is ten thousand (square of hundred). On the other hand, if the market is closer to competitive levels, there are several firms with negligible market shares, and the HHI is closer to zero. As per the Department of Justice (DoJ) of USA, markets where HHI exceeds 2500 are considered highly concentrated, whereas markets with HHI between 1500 and 2500 are considered moderately concentrated.[28] Mergers that result in an increase in HHI beyond a typical threshold are typically discouraged because they enhance market concentration, and these thresholds depend on the pre-merger concentration in the market.[29] In order to compute HHI, it is essential that we define what the appropriate market is.

While there are several ways in which one can define the market boundary, one of the most rigorous tests economists tend to use for defining the market is *Small but Significant Non-*

[28] http://www.justice.gov/atr/herfindahl-hirschman-index
[29] http://www.justice.gov/atr/horizontal-merger-guidelines-08192010#5c

transitory Increase in Price (SSNIP) test.[30] The test asks a simple question: would a small increment in price result in consumers shifting to a different product? As a typical norm, in practice, a small increment is defined as around 5% increase in the price. If the small increment indeed sends significant fraction of consumers away, and results in reduced profits, then all products to which the consumers move can be considered a part of the relevant market for that product. On the other hand, if the increment in prices does not erode the consumer base, one could conclude that the product enjoys significant market power. As Lemley and McKenna (2012) put it, "So if a bottle of Coke costs $1.60, unless a price increase of eight cents would send so many consumers running to buy Pepsi that Coke would lose money, the two don't compete… By our classic antitrust definition, then, Coke and Pepsi are not in the same market."[31]

When it comes to the market for pharmaceuticals, the definition of appropriate market tends to be even more complicated than the Coke and Pepsi example described above. A straightforward way to define the appropriate market is to define the market at a molecular level. Therefore, all the brands associated with that molecule become part of the relevant market. It is also realistic to assume that for a small increment in the price of a brand for a given molecule, the consumer moves to alternative brands of that molecule. Therefore, HHI is simply the sum of square of market shares of various brands available for that molecule. However, such an approach is likely to define markets very narrowly. This is because of two nuances that are specific to the pharmaceutical market.

The first pertinent issue in the pharmaceutical markets is the competition between the innovators (multi-national corporations (MNCs)) and the generic manufacturers. A pertinent question here is do consumers perceive a molecule manufactured by a generic manufacturer as a perfect substitute for the molecule manufactured by the innovator. Some recent research shows that it is not necessarily the case in India – everything else being equal consumers prefer innovators' brands (multi-national manufacturers) over the domestic brands.[32] There could be several reasons for the consumer perception. Off late there have been several media reports about

[30] Apart from SSNIP, there are some other tests like Elzinga and Hogarty test. However, this test is more applicable in the case of geographical markets.
[31] Lemley and McKenna (2012), Pages: 2056-57.
[32] See Chatterjee, Kubo and Pingali (2015) in the case of oral anti-diabetic market

drugs manufactured in India being of lower quality.[33] Anecdotal evidence apart, even some recent empirical research has highlighted this issue.[34] Given this, it is quite possible that *everything else being equal* consumers treat pharmaceuticals from multinationals different from the equivalent ones produced in India.

Second, the difference between *inter-molecular* competition and *intra-molecular* competition needs to be clearly differentiated, especially in the Indian context. This is because, unlike the more mature pharmaceutical markets, India adopts a practice of branded generics. That is, in India, even the generic medicine requires a brand name, unlike in the US, where the generic medicine sells purely on the molecular name. While *intra-molecular* competition refers to competition between various brands of a same molecule, *inter-molecular* competition refers to competition across various molecules. For example, several manufacturers in India produce and sell famotidine, a common antacid, under various brand names: Acredin (Nicholas Piramal India), Topcid (Torrent Pharmaceuticals), Facid (Intas Laboratories), etc. The competition among various brands of famotidine is an example of *intra-molecular* competition. At the same time, famotidine itself competes for a doctor's attention with other H_2-receptor antagonist molecules like ranitidine, cimetidine, etc., and proton pump inhibitors like omeprazole, lansoprazole, etc. This can be termed as *inter-molecular* competition.[35] As this example clearly suggests, there is evidence of substitution not just within various brands within a single molecule, but also among various molecules.

Intra-molecular competition has become more important in the recent times with the emergence of biological drugs like vaccines. Since these drugs are sensitive to manufacturing process, substitution with the innovator drugs is not straightforward.[36] Inter-molecular competition is also pertinent in the Indian context, especially given that most of the population is not insurance covered, and pay for the expenses out of pocket. Consider the following hypothetical situation where the most suitable drug for a patient is A, which is patent protected and hence, expensive. However, suppose drug B is not the most efficacious for the patient, but is genericized, and hence inexpensive. Given the financial condition it is not improbable that the

[33] http://in.reuters.com/article/2014/03/18/usa-india-genericdrugs-idINDEEA2H03120140318 and http://www.forbes.com/sites/theapothecary/2014/09/17/india-must-fix-its-drug-quality-problem/
[34] See Bate et al (2014)
[35] Chatterjee, Kubo and Pingali (2013)
[36] See Wang and Chow (2012)

doctor would prescribe drug B and not drug A. Even in some mature markets like US, there is some evidence of insurance companies insisting on compensating only a substitutable generic molecule, and not the prescribed molecule.[37]

Given these confounding factors, how does one define appropriate market in order to apply SSNIP test? Research in empirical economics has developed several techniques that can be applied in order to estimate this cross-price elasticity. One of the popular econometric tools to measure elasticity of demand is the discrete choice models like multinomial logit and nested logit models. In all these models, consumer's mean utility is estimated as a function of the drug's characteristics, individual's characteristics (to the extent data is available) and substitutable products. From there on, cross price elasticities of various drugs (brands within the same molecule and brads across molecules) are estimated. In the Indian pharmaceutical markets too, several research papers have employed such techniques. For example, see Dutta (2011) in case of drugs across various therapeutic categories, and Chatterjee, Kubo and Pingali (2015) in case of oral anti diabetics market. Another technique that is commonly used to estimate cross-price elasticities is *Almost Ideal Demand System* (AIDS) developed in Deaton and Muellbauer (1980). In the Indian context, Chaudhuri et al (2006) have applied this model to study floroquinolones market.

6.1 Assessment of Merger and Acquisition Activities by the CCI – the Sun – Ranbaxy Merger Case

Some of these issues regarding the market definition and market power have come to the forefront in the recently concluded merger of Sun Pharma and Ranbaxy. The details of the investigation by DG and the decision of the CCI are available on the CCI website., The examination of "Combinations" or Mergers and Acquisitions are undertaken under Section 29 of the Competition Act. The Competition Commission of India had initially raised objections to this merger citing the reason that the merger may hurt competition.[38] The Commission has subsequently cleared the merger with a rider stating that the companies have to divest eight drugs together – Tamlet brand for Sun Pharma and Eligard, Terlibax, Rosuvas, Raciper, Terlibax,

[37] Anthem Insurance suggests equivalent generic medicine for patented molecules prescribed by the doctor: http://ir.antheminc.com/phoenix.zhtml?c=130104&p=irol-newsArticle&ID=736618
[38] http://www.dnaindia.com/money/report-cci-says-sun-s-takeover-of-ranbaxy-may-hurt-competition-2016279

Triolvance and Olanex for Ranbaxy.[39] This is ostensibly being done to ensure that the merger does not lead to an increase in the concentration for the markets of the respective molecules. Based on the publicly available documents it is clear that *intra-molecular* competition was seriously considered when defining the appropriate market. For various reasons described above, defining market at molecular level restricts the market definition to be rather narrow, because it ignores *inter-molecular* competition. That said, perhaps, the CCI is being conservative in defining the appropriate market! After all, if there is no market power concentration at a molecule level, it is difficult to argue that there is market concentration even if the market definition is extended. In fact, if there is market concentration at a molecular level, the market concentration may not be beneficial if there is a significant *inter-molecular* competition. It is possible that some of these molecules act as substitutes in other markets. As to what repercussions the merger would have on other molecular markets needs to be considered as well. It is also worth noting that the analysis is conceptually similar to the one undertaken by US FTC regarding the harm to competition for minocycline tablets in the USA.[40]

Asking Sun and Ranbaxy to divest some molecules before the merger is ostensibly done in order to ensure that the competition at a molecular level is preserved. The implementation of such practices can lead to certain nuances that ought to be seriously considered. (These arguments reflect the practice of divesting the molecules itself, and not in reference to Sun and Ranbaxy.) The sale of molecules common across the two merging parties is likely to be a distress sale and they would like to sell these molecules at the earliest. Next, it is well known in oligopoly theory that *'n firm oligopoly'* is weakly less profitable than *'n-1 firm oligopoly'*. Therefore, both merging parties would have incentive to keep competition low. This implies both of them have an incentive to divest the molecule to competitors who are not that significant – be it in terms of the size, market presence etc. Therefore, as to who the acquirees are and what the terms of sale are need to be verified so that there is no possibility of increased market concentration in the future as well.

[39] http://www.business-standard.com/article/companies/cci-gives-nod-to-sun-ranbaxy-merger-asks-to-divest-7-drug-assets-114120800727_1.html
[40] "In the Matter of Sun Pharmaceutical Industries Ltd., Ranbaxy Laboratories Ltd. and Daiichi Sankyo Co., Ltd." Docket No. C-4506, available from https://www.ftc.gov/system/files/documents/cases/150130sunranbaxycmpt.pdf.

Another thing that needs to be considered in a merger case is the realization of economies of scale and scope. Especially in pharmaceutical markets, where cost of maintaining marketing and operations channels is quite high, and research and development expenses are quite substantial, mergers can sometime result in substantial cost savings. These cost savings can be passed on to the end consumers in the form of reduced prices. For example, the Sun and Ranbaxy merger would enable both pharmaceutical companies access to each other's networks (marketing, warehousing, etc.), thereby reducing setup costs. Therefore, the tradeoff in any merger and acquisition is to look at the potential for reduced costs (and hence reduced prices) with increase in concentration. The bottom line is rigorous empirical exercise needs to be carried on a case by case basis in order to determine the appropriate market, and subsequent consequences of a merger.

6.2 Some Recent Cases on Horizontal Agreements in Supply Chain and Bid-Rigging

In this segment, we examine some of the cases that the CCI has adjudicated with regards to the pharmaceutical sector. The Competition Commission was fully constituted in 2009, so that is the time from which it has been adjudicating on various competition related matters. Examination of the CCI website reveals that there are cases in the "Antitrust" segment, which relates to Sections 26 and 27 of the Competition Act. Here we undertake a review of cases pertaining to the pharmaceutical sector under this head.

Under the Antitrust cases, a large majority of the cases fall under the horizontal agreements among members of the trade association: All India Organization of Chemists and Druggists (AIOCD). All these cases share a common theme: that AIOCD, through its subsidiary state and other regional associations of chemists and druggists (stockists, wholesalers and retail outlets) engaged in restricting competition through a series of anticompetitive acts to the detriment of consumers. These acts include fixation of profit margins for drugs whose prices are not determined by the National Pharmaceutical Pricing Authority (NPPA), restriction on appointment of distributors, issuance of "No Objection Certificates," boycott of pharmaceutical companies that did not comply with their policies and charging of Product Information Service fees on a mandatory basis. The fines imposed by the CCI ranged from Rs. 0.053 million to Rs.

183.85 millions. In each of these cases, the informants were aggrieved retailers that were not part of AIOCD, or public authorities, and in one case it was a *suo moto* case. In a few of these cases, it was mentioned that drug manufacturing associations such as Indian Drug Manufacturers Association (IDMA) and Organization of Pharmaceutical Producers of India (OPPI) had an agreement with the AIOCD with regard to fixation of margins, but the agreement was terminated before 2011. In at least three of these cases, even though all members found instances of anticompetitive behavior, all members of CCI were not in agreement, and dissenting orders were submitted. For instance, the majority opinion of CCI contended in the M/s Sandhya Drug Agency case that OPPI and DMAI are victims of the practices of AIOCD, basically agreeing with the contentions of the drug associations. The majority order also mentioned that the office bearers of AIOCD are not liable for any anticompetitive acts. Other members disagreed that IDMA and OPPI were not culpable, and that other office bearers were also culpable, and also that fixation of margin does not result in price fixing.[41] Another member maintained that the office bearers and the other associations are culpable as well, and also had issues with computation of penalty.[42] Similar disagreements in opinion also were there in M/s Santuka Associates Pvt. Ltd. Vs AIOCD, Varca Druggist and Chemist case and the Vedant Bio Sciences case.

We offer some perspective regarding the methodology followed by the DG,[43] and the decision making by the CCI. We feel that analysis of any such case should proceed in a step-wise fashion. First, as discussed in the previous segment, a relevant market needs to be established. In this case, implicitly the DG considered the geographic market to be the local area in which the informant wanted to be a stockiest/retailer, and the relevant product market being the services of the stockiest/retailer obtained by the drug manufacturer. Next, the relevant question to ascertain is whether the defendants (or Opposite Parties) had a dominant position in this market that could be potentially abused. In this instance, given the wide membership and the ability to influence a drug manufacturer's ability to appoint a stockiest/retailer through NOC/LOC, the dominant position/market power is also not in question. For this, the DG relied on submissions by individual drug companies as well as IDMA and OPPI. Third, to ascertain whether this specific

[41] Order by Dr. Geeta Gouri, member, CCI.
[42] Order by Justice (retd.) S. N. Dhingra, member, CCI.
[43] It is important to note here that details of the investigation conducted by DG are not made public by the CCI except through the reports written by the Commission members. Thus, we rely on publicly available information in this case.

conduct has potential to cause harm to the public through limiting supplies, raising prices or in any other way, and whether, in this case it indeed did so. Among the factors that should have been relied upon was extent of collusion between the drug associations and AIOCD leading to consumer harm, or whether there was any non-cooperative bargaining in the agreements between the associations, given that the drug manufacturer associations are also quite economically powerful entities. This analysis calls for the creation of a counterfactual but-for world in which such agreements are absent, and analyze how the market would have changed in such a but-for world. Lastly, assuming that the conduct would lead to consumer harm, it would have been appropriate to first quantify the magnitude of the consumer harm, and in case there was indeed going to be a certain amount of consumer overpayment, apportion the blame on to each of the opposite parties through appropriate analysis. For instance, if margin fixation led to higher prices paid by the consumer, then an appropriate way to compute lost consumer savings would have been to compute what retail prices would have prevailed in the market without margin fixation, and in turn what wholesale prices would have prevailed in the market in the absence of margin fixation. This would not only find the lost savings of the consumer, but will also compute the excess profits earned or profits lost by the drug companies. Such an analysis should be conceptually straightforward provided some information exists on the nature of competition and margins prevalent in a similar market without such margin fixation, and the relevant price elasticities of demand for the products in question, both at the business-to-business (wholesale level) and business-to-consumer (retail level).

Other cases dealing with horizontal agreements relate to bid-rigging in public procurement. One such case was Bio-Med Pvt. Ltd. vs. Union of India and two multinational companies, viz. GlaxoSmithKline and Sanofi for procurement of Quadrivalent Meningococcal Meningitis vaccines (QMMV) for Hajj pilgrims. The fact of this case is that the Govt. of India floats tender for procurement of QMMV each year, and Bio-Med is an indigenous producer competing against the other two companies. Bio-Med alleged that the Indian Govt. arbitrarily changed the qualifying criteria for bidding which resulted in Bio-Med being disqualified from bidding. Bio-Med also alleged that the other two companies have indulged in collusive practices of bid rotations and geographical allocations. While the DG did not find that there was anything wrong in the policies adopted by Central Govt. based on an order by the Delhi High Court, it did

find instances of anticompetitive behavior based on analysis of price bids by the two pharmaceutical companies. Here again, the analysis could have proceeded along the lines we outlined in the previous paragraph.

6.3 Other areas that may benefit from increased scrutiny by the CCI

Our view is that while CCI has focused its energies at looking into horizontal agreements (mergers and acquisitions, collusions under a trade body for margin fixation, collusive practices under bid-rigging in cases of public procurement), it has either not focused its attention on vertical agreements (agreements between trade associations at wholesale and retail levels), or has failed to find any such instances. Our view is that the CCI may want to look into these areas more carefully. In particular, it was somewhat curious that in the various AIOCD related cases, the CCI majority view has held that OPPI and IDMA were victims of anticompetitive conduct by AIOCD and its subsidiaries. It is rather curious that the pharmaceutical bodies, which are quite powerful lobby groups of their own, never brought this to the attention of the CCI or its predecessor during the lengthy period that it had a Memorandum of Agreement, until they were made a party to the proceedings. While some of these have been noted in separate orders by individual CCI members, an appropriate framework to deal with such cases seem somewhat lacking.

More importantly, the matter of relationship between the physicians and pharmaceutical companies that subvert competition to the detriment of consumers has not been adequately addressed by the CCI (or any other regulatory body, for that matter). (Bhattacharjea & Sindhwani, 2014) look at this issue in depth and conclude that this particular matter can come in for consideration either under Section 3(4)(a) of the Competition Act that deals with "tie-in" agreements, or Section 4(1)(c) which relates to abuse of a dominant position by a person (i.e., the physician in this case). But such agreements can also focus on the pharmaceutical company rather than the physician. The allegation is that physicians, upon inducement from the pharmaceutical companies, write prescriptions which do not lead to the cheapest possible available medicine to the patient, which we view as an exclusionary conduct.[44] Under Section

[44] We also recognize that this is potentially an anti-steering behavior engaged in by pharmaceutical companies and the physician, where steering at the point of sale (pharmacy) to a cheaper option is pro-competitive. However, it appears to be a moot point because the pharmacists are unable to dispense anything other than the brand prescribed by the physicians because of Section 65(11-A) of the DCA in part VI. This matter may be looked further into from a medium term policy perspective, in addition to

3(4)(b) and 3(4)(c) of the Competition Act, "exclusive supply agreements" and "exclusive distribution agreements" are both found to be anticompetitive, and we believe these could be invoked to look into the agreements (formal or informal, as the Competition Act does not specify formal agreements) for possible anticompetitive behavior. (Bhattacharjea & Sindhwani, 2014) also contend that a doctor is not really in a position to abuse dominance unless he or she is the sole supplier in a geographic area, so Section 4 of Competition Act cannot be invoked and consider this as a matter of ethics and not of competition. We agree this is the case if we are considering arbitrary increases in consultation fees by the doctor, for which the demand curve is likely to be quite elastic. However, the issue at hand is prescribing behavior by the physician. In markets with imperfect and severely asymmetric information, which characterizes the physician-patient relationship, especially related to knowledge of availability of medicines and the physician-pharmaceutical company relationship (unknown to patient, built more on commercial interests), the demand for a physician is likely to be insensitive to prescribing behavior by the physician, and thus the physician can indeed abuse this information advantage. And they are more likely to do so if they are not answerable (Nguyen T. A., 2011). Moreover, in many cases, doctors run their own private nursing homes with an internal pharmacy, and the conflict of interest here could be substantial, as well as the dominance. In any case, if the current laws are inadequate to deal with this, then revisions to the Competition Act can be undertaken to bring such exclusionary behavior under the ambit of the Act after suitable consultations with all stakeholders.

In certain cases involving compulsory licensing and parallel importing (abuses of Intellectual Property Rights), issues that affect competition, the Competition Act is silent (Ghosh & Ross, 2008). This might explain why no parties have approached CCI with prayer for remedies from such acts, and directly approached the justice system in India under the Patent Act. For instance, in the Nexavar (a cancer drug) case of compulsory licensing involving Bayer (the originator and patent holder for Nexavar) and Natco Pharma (the generic company which approached Bayer for a license but was denied), the latter approached the Controller of Patents Court for a compulsory license, which granted the compulsory license. The issues considered by the Controller under the Sections 84(1)(a), (b) and (c) of Patent Act was firstly, whether

incentivizing the pharmacist to dispense the cheapest product through means such as reference pricing under health insurance schemes.

"reasonable requirements of the public" were met by the patentee; secondly, whether the patented innovation is available to the public at a "reasonably affordable price" and thirdly, whether patented innovation has "not worked in the territory of India?"[45] It is worth noting here that an issue that should be debated is of consequences on competition and resultant effect on consumers, both for the short as well as the long term. A patent sets aside competition laws for incentivizing the originator company, and so when revoking a patent, issues pertaining to competition must be considered. Especially while considering pricing, reasoning related to economic aspects of such decisions are important. Cases of this kind are great opportunities for the CCI to bring competition issues into the ambit of discussion, so that it can do justice to its Advocacy role, as envisioned in its constitution.

We also envision a world where pharmaceutical pricing in India will be determined more and more by market forces, especially if public provisioning of healthcare and insurance coverage in the country increases which will reduce out-of-pocket expenses on pharmaceutical drugs by Indians. Moreover, regulatory supervision of manufacturing units to ensure strict manufacturing and medicine quality standards, if implemented strictly, will result in more price competition by generics and elimination of the phenomenon of branded generics. Pricing is a competitive strategy in most market forms, and encouraging intense price competition rather than price regulation to bring down prices should be the goal of any competition authority. Thus, it may be imperative for CCI to work in close cooperation with NPPA and other pricing authorities such that competition issues related to pricing may be brought into consideration in those cases.

Some commentators have lamented that post-2005, India has not seen much R&D investments from pharmaceutical companies, especially multinational companies that are worldwide leaders in innovation (Chaudhury, 2014). From our discussion, it is perhaps somewhat obvious why this is the case. There are many gray areas where competition laws overlap with other laws, and our understanding is that the Competition Act (or CCI, through advocacy) has not clarified positions on aspects of competition in these issues. This creates an uncertain environment where innovator companies would be wary of making the kind of investments that may be required to bring innovative drugs to the market. We see this as an

[45] The Patents Act, 1970, India.

opportunity for the CCI to take a leading role in bringing clarity regarding areas where competitive concerns are paramount.

7. Intellectual Property and Competition Law

Patent can be termed as a 'set of exclusive rights granted by a sovereign state to an inventor or assignee for a limited period of time in exchange for detailed disclosure of an invention. An invention is a solution to a specific technological problem, and is a product or a process.'[46] While research and development is a risky activity involving a lot of sunk expenditure, mimicking the innovation can be a relatively costless exercise. Entry of competition forces the price to go down, making the recovery of sunk expenses difficult. This also implies that there is no 'monetary reward' for innovation. Therefore, a patent is granted in the short run in order to enable innovator to obtain a reasonable profit; once the patent is expired, competition is free to enter, with gains in consumer surplus. As pointed out earlier, subsequent to signing the Trade Related Intellectual Property Rights (TRIPS) agreement with the World Trade Organization (WTO) in 1995, India had to adopt more liberal intellectual property laws. These laws became effective ten years later – since 2005, when product patents (and not just the process patents) were also allowed. However, there are several claims that the Indian patent laws are not as stringent as those of the West.

In the context of pharmaceutical markets too, the above concerns are valid. Innovation in pharmaceuticals is an expensive and risky investment, whereas replication need not be.[47] The trade-off between the twin objectives of improving innovation and increasing consumer surplus is characterized in Hughes, Moore and Snyder (2002). Their argument is better understood through a hypothetical scenario. Imagine in Period 1, a drug is invented, and subsequently enjoys patent status for that period. The firm employs monopoly pricing and makes profits in that period. In Period 2 the patent expires and competition enters, thereby reducing the price closer to marginal cost. As a result of this, consumer surplus and total welfare increase. The profits earned in the first period provide sufficient incentive for the innovator to invest in research and development, which improves the probability of discovering new drugs, with the same cycle

[46] https://en.wikipedia.org/wiki/Patent
[47] See Grabowski (2007) and http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014..pdf for details on pharmaceutical research and development expenditure.

repeating itself. If, on the other hand, Period 1 is characterized with lax patent laws, then price is closer to marginal cost in Period 1 itself. This improves consumer surplus in Period 1 itself. However, since there is no incentive for R&D, firms refuse to invest in R&D. This leads to no new drug entering the market from Period 2 onwards, thereby harming future consumer surplus, and perhaps overall long term surplus as well.[48]

How true is this conjecture in the real world? Filson (2012) provides an answer. Using a dynamic equilibrium model which endogenizes the firms' R&D expenditure he argues that had the US followed price control mechanisms that exist elsewhere, the innovation in pharmaceutical industry would have reduced by more than 40%. Research also shows that lack of innovative medicine could result in adverse health outcomes. For example, Lichtenberg (2005) argues that new drugs add up to one week in terms of increased life expectancy, suggesting that improved welfare in the short run does indeed lead to loss in consumer surplus in the long run. The loss in consumer surplus is not limited to reduced innovation alone – even refusal to launch (or delay in launching) in the markets with lesser protection to intellectual property by the innovators is well documented in the literature.[49] More specifically, some industry players in the pharmaceutical markets have echoed the similar sentiments when they said that, 'not respecting IP norms' has led to India losing several lucrative investment deals in the pharmaceutical space.[50]

7.1 Way Forward: The Indian Patent Scenario

With becoming a signatory of TRIPS agreement, India has formally recognized the validity of patents through the new Patent Act. However, a few pertinent issues remain, both at in the law and at the level of practice. In a recent court judgment, the Supreme Court of India has disallowed Glenmark Pharmaceuticals from selling copies of Merck Sharp and Dohme's (MSD) drug, Januvia (sitagliptin phosphate).[51] However, the judgment also stipulates that Glenmark is allowed to sell the existing stocks that have already been manufactured. Even if, at a later stage,

[48] For a comprehensive review of theoretical connection between innovation and intellectual property protection, see Rockett (2010).
[49] For example, Berndt and Cockburn (2014) show that out of 184 molecules approved by the FDA only ninety have been marketed in India. For detailed review of literature pertaining to delayed/refusal to launch, please see Pingali and Chatterjee (2015).
[50] http://articles.economictimes.indiatimes.com/2015-03-31/news/60682269_1_sofosbuvir-swine-flu-drug-kidney-cancer-drug-sorafenib

[51] http://in.reuters.com/article/2015/05/15/glenmark-phrm-merck-co-lawsuit-idINKBN0O011I20150515

MSD's patent for sitagliptin phosphate is upheld, it is not clear as to what penalties would be imposed on Glenmark for the breach of patent in the first place. At the same time, if the patent is indeed invalidated, it is not clear as to what penalties would be imposed on MSD for false patenting. In a more mature market, the mechanism of damage claims by the innovator, or damage claims by the consumer (in case of false patenting) are well established. This incident also highlights another regulatory disconnect: the body that approves new drugs in India (DCGI) and the patent office. For any patent law to be effective, these loose ends have to be tied up.

Another consideration is innovation for medicines pertaining to India specific diseases or orphan indications that only affect small fraction of people. Given the lower demand (in terms of volume or affordability or both) associated with such medicines it may take longer to recover the sunk R&D expenses. Therefore, it may require additional incentives – in terms of subsidizing R&D, extending patent protection, etc. – for firms to invest in such medicines. Further, measures like encouraging pooled R&D across various firms so that the risk is sufficiently diversified, strengthening public research initiatives (for example, CSIR) might be the other ways through which innovation can be fostered while keeping drug prices relatively low. Recent research has also discussed differential pricing[52] (where prices are different in India when compared to the developed economies) and local licensing (where marketing of drug is licensed to local pharmaceutical manufacturers in order to take advantage of superior outreach) as some of the ways in which developing countries can balance encouraging innovation and promoting access.[53]

7.2 Competition Policy and Intellectual Property

Another issue that is important take note of, especially in the context of this chapter, is how intellectual property is related to competitiveness. Benefits of innovations notwithstanding, the nature of exclusivity associated with patents implies that it is a barrier to entry. Further, without appropriate competition law in place, it is possible that such exclusivity can easily be extended to other markets, especially in production processes involving several layers. For example, if a firm holds a patent for an upstream product, it has exclusivity in the upstream market. If the firm refuses permission to other firms (or charges exorbitant prices to the other firms) to make use of the upstream product in order to manufacture final product, then its dominance is extended to the

[52] See Danzon and Towse (2003)
[53] See Pingali and Chatterjee (2015)

downstream market as well. Without appropriate restrictions in place, the upstream firm has every incentive to impose such restrictions, and such practice can result in lower consumer surplus as well.[54]

In the pharmaceutical context too, there is a scope for violation of competition laws through exploiting intellectual property. One way in which this could be achieved is that the innovator could collude with a generic and stop the generic from entering the market by *sufficiently* compensating the generics manufacturer. Obviously, such practices lead to violation of competition law.[55] Another way in which the competition laws are violated is through misrepresenting of patents, thereby artificially extending the life of the patent. For example, in 2012, the Court of Justice of the European Union (CJEU) has ruled that, among other charges, AstraZeneca has abused its dominant position in the proton pump inhibitors (PPI) markets through misrepresentations to various patent offices in the EU.[56]

A main theme that emerges in this context is that the intellectual property and competition in the market are interrelated entities. Major jurisdictions all over the world have adopted several ways to curb entry barriers arising out of intellectual property. For example, in the US, the drug price competition and patent term restoration act – popularly known as the Hatch Waxman Act of 1984 – lays down the rules in which pharmaceutical firms compete. It suggests that the generic manufacturers need not conduct clinical trials (a practice prior to 1984) for entering the market. Upon patent expiry, it is sufficient for them to establish that their medicine is bio-equivalent to that of the innovator's. For five years since the launch of the drug, the innovators need not share their safety and efficacy data with the generics (called the data exclusivity period), but subsequently the data becomes available. This removes a big barrier to entry in terms of upfront fixed costs, and enables generic firms to price their drugs lot lower, while ensuring that sufficient incentive is provided to the innovator. Second, the law also mandates that the prescriptions by the doctors be written based on the generic name of the medicine, and not on the brand name. If available, the pharmacist can disburse the generic medicine to the patient. In fact, most prescription insurances cover only for generic medicines. This reduces the entry barrier that arises because of advertising and enables generic firms to sell

[54] See Rey and Salant (2012) for theoretical modelling of this issue.
[55] Bulow (2004) discusses several cases in the US, where the Federal Trade Commission (FTC) has ruled that the innovator has allegedly paid the generic(s) from entering the market in the first place.
[56] http://www.twobirds.com/en/news/articles/2012/court-of-justice-upholds-astrazeneca-abuse-dominance-decision0113

their medicine.[57] Finally, there is a provision within the act to discourage false patenting. If a generic believes that the patent is invalid, it can launch the drug 'at risk'. If the courts find the patent to be valid, the generic firm will have to pay three times the damages incurred by the innovator (called treble damages).[58] For taking the risk, the generics are rewarded through an exclusivity period of six months, where no other generic is allowed to enter the market.

Empirical evidence does suggest the generics are challenging the patents of the innovators more frequently, and reasonably early in the product life cycle. Research also shows that this act has been successful in avoiding competition through evergreening of patents. For example, line-extensions of the existing medicines that have been patented seem to be the main targets of paragraph IV challenges.[59] Therefore, it is clear that this law has tried to balance encouraging innovation while ensuring fair competition, and serves as an example of how competition can be fostered through market based solutions itself. Ostensibly, Section 3(d) of the Indian Patent Act (2005) is created to counter such evergreening practices. However, as the recent debates suggest further clarity is required on its interpretation so that innovation is not unduly hampered, while protecting consumer interests.

In sum, it is clear that the intellectual property and competition are completely intertwined with each other. If one examines the recent court cases in India involving intellectual property in pharmaceutical industry, this relationship is particularly clear. For example, in the *Nexavar* (sorafenib) case, the Supreme Court has said the existing drug is very expensive, and allowed a local manufacturer (Natco) to enter the market in spite of the patent being valid. At the same time, in the case of *Glivec* (imatinib) and *Tarceva* (erlotinib), the Supreme Court has ruled that the patents are not valid anymore. In all these cases, some key questions pertaining to competition law: appropriate market definition, competitive price, etc. need to be addressed. Unfortunately, however, the involvement of Competition Commission of India (CCI) in these cases is minimal. Therefore, for an effective intellectual property regime, it is imperative that the patent office, the judicial authorities and the competition authorities work together.

8. Conclusion

[57] For repercussions to India because of mandating generic based prescriptions, see Chatterjee, Kubo and Pingali (2013).
[58] For exact details on Hatch-Waxman act, see Bulow (2004).
[59] Hemphill and Sampat (2010)

The Indian pharmaceutical industry is one of the major pharmaceutical industries in the world, both in terms of volume of consumption and value of production. Further, given its critical importance, this industry has attracted significant policy attention. Given the ever changing policy environment, it is only appropriate to assume that the firms also adapt their strategies as per the policy environment, thereby altering the industry dynamics itself. For example, the Indian Patent Act in the 1970s that had stipulated that there could only be process patenting as against product patenting, has led to the emergence of the generic pharmaceutical industry, which became a key player not just within India, but also around the world. Lots of research on pharmaceutical markets was published; however, most of it is developed world centric. In spite of India being a huge market for pharmaceuticals with the complete potential not being fully realized, precious little research work that characterizes the dynamics of this market has been undertaken as of now. We conclude this chapter by discussing some of the important questions that need to be addressed in this market both from research and public policy point of view, taking developing countries' perspective (more specifically, India).

First issue that needs to be resolved is the trade-off between availability of medicine at cheaper price with availability of innovative modern medicine. Differential pricing or negotiated pricing between the innovator and the government might be the way forward. Further, incentivizing pharmaceutical companies to produce drugs that are meant for India specific problems (through patent extensions, subsidizing R&D, etc.) might be a way forward. Further, encouraging innovators to invest in research and development, and manufacturing within India for indigenous consumption could be another way in which prices for innovative medicines can be lowered.[60] Such initiatives might work with the current government's schemes like *Make in India* and *Atal Innovation Mission*.

Another issue that needs to be addressed is the price-quality paradox. Ensuring highest quality requires huge investments, which is often reflected in the price. Given that majority of India does not have prescription insurance, this high price drastically reduces affordability. On the other hand, lack of quality medicines involves other side effects from spurious medicines, which could be difficult to comprehend. Therefore, is the answer to this debate universal, or is it

[60] An interesting point to note is that India has several high quality manufacturing units within the country. In fact, India has the largest number of Food and Drug Administration (FDA of the US Government) approved manufacturing units outside the US.`(http://www.business-standard.com/article/companies/drug-makers-should-learn-to-appreciate-fda-needs-better-say-experts-114112000926_1.html)

therapeutic area specific, becomes a relevant question to be answered. This question becomes even more pertinent with regards to expensive and complicated medicines like biological drugs.

The other area where the policy needs to focus on is advertising. Pharmaceutical advertising can be of two kinds: informative and persuasive. While informative advertising informs the physician of the new advances, persuasive advertising, as the name suggests is intended at persuading the doctor to prescribe a particular brand. While informative advertisement can be useful, persuasive advertising can be modelled as prisoners' dilemma. All pharmaceutical companies invest in it, and as a result no one gains substantially. However, these expenses are recovered through higher drug prices, thereby harming total welfare. As long as branded generics exist, persuasive advertising is likely to continue as various pharmaceutical companies vie for doctors' attention.[61] It also generates other externalities. But can India afford to move from branded generics to pure generics market (as is the case in the US, for example)? And under what conditions is such move even possible? One of the offshoots of advertising is that it can act as a significant barrier to entry. At the same time, lack of promotion can be counterproductive to health outcomes, especially where quality is not uniformly regulated.These are some of the questions that need to be addressed globally.

There is a substantial difference in affordability of medicines in India across geographies, income classes etc. A major question that arises in this case is, whether or not innovative pricing mechanisms can be used as a means through which this gap can be addressed. A more pertinent question is whether or not differential pricing (between urban and rural, for example) is indeed sustainable in a country like India. One could, for example, consider negotiated pricing for government hospitals across various geographies. For such differential pricing to work seepages across markets have to be plugged so that arbitrage opportunities that arise of difference in pricing are not prevalent.

These questions are not just important from the Indian standpoint alone; any developing country that aims at a robust pharmaceutical industry that aims at fostering competition, innovation and welfare needs to contemplate on these issues. Therefore, the policies adopted by the Indian authorities are being keenly watched in the international arena; this may provide India with an opportunity to exhibit thought leadership to countries like China, Russia, Brazil, etc.

[61] If prescriptions are written purely with generic name on it (as in the US and other advanced countries), then advertising can be counter-productive because it can encourage free-riding.

Competition Commission of India, the Indian Patent Office, Department of Health and Department of Chemicals should work in addressing these questions and provide a roadmap for these issues.

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