PERSPECTIVES

presents emerging issues and ideas that call for action or rethinking by managers, administrators, and policy makers in organizations

Competition and Intellectual Property Policies in the Indian Pharmaceutical Sector

VIKALPA
The Journal for Decision Makers
42(2) 61–79

SAGE Publications
sagepub.in/home.nav
DOI: 10.1177/0256090917704561
http://vik.sagepub.com
SAGE

Shamim S. Mondal and Viswanath Pingali*

The Indian pharmaceuticals market is estimated to be the third largest in the world in terms of volume, and one of the largest in terms of value created (Economics Division, 2017). This industry is also a key player not just within India but also across the globe; the Indian pharmaceutical companies produce bulk drugs that are exported to several countries, including the Organisation for Economic Co-operation and Development (OECD) nations. When compared to the other pharmaceutical sectors in the world such as the mature markets in the OECD countries, the Indian pharmaceutical market is unique due to several reasons: a changing patent regime (from product patents to only process patents and then back to product patents), unique nature of competition (for example, branded generics as against pure generics), etc. Given this exceptional nature of the pharmaceutical market, it is important to understand this sector from a public policy angle.

In this article, we provide a perspective from the point of view of two important aspects of public policy: competition policy and intellectual property. With the enactment of the Indian Competition Act in 2002, India has become one of the newer countries that have a robust competition regime in place. In this context, some pertinent issues emerge: (1) How do various firms (domestic and international) compete in India? (2) What role does the practice of branded generics (more prevalent in India than elsewhere) play, etc. At the same time, the Indian patent regime has also undergone a series of changes. The Patents Act of 1970 allowed for only process patenting; however, with India signing the Trade-Related Intellectual Property (TRIPS) agreement, product patenting had to be implemented from 2005. Given the short time span since its implementation, one could say that the current patent policy followed in India is still nascent. In this context, several questions such as why patents are important, how firms react to various policy changes in this space, etc., become important to understand.

KEY WORDS

Pharmaceutical Policy
Intellectual Property
Competition Law

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, global multinational

*Authors are listed in the alphabetical order of their last name.

manufacturers dominated the Indian pharmaceutical industry. The Patents and Designs Act (1911) enacted in the British era governed the sector and ensured strong product patent protection regime (Center for Trade and Development, 2010). 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. There were very few indigenous manufacturers of consequence during this time, and 8 of the top 10 pharmaceutical firms were subsidiaries of multinational corporations (MNCs; Greene, 2007). Most of the patents originated from foreign countries, a consequence of underdevelopment of India. Thus, while the price of products was very high, access to such products was not guaranteed even if someone was willing to pay such high prices (*Weekly Notes*, 1964). India was severely dependent on the import of pharmaceutical products. Lack of affordability, coupled with lack of domestic competition, had led to a sub-optimal equilibrium.

Concerned about such state of affairs, the Government of India (GOI) formed a one-man committee of Justice N. Rajagopala Ayyangar in 1957 to revise the laws of patents and design. In 1970, GOI adopted the recommendations of the Ayyangar Committee and formulated the Patents Act (1970), which allowed only process patent protection for pharmaceutical products for a period of seven years from the date of patent filing. The Patents Act (1970) can be considered a watershed moment in the evolution of the pharmaceutical industry in India. It led to the development of a domestic pharmaceutical industry, which now specializes in reverse engineering bulk drugs. Moreover, the Foreign Exchange Regulation Act (1973) limited foreign ownership of Indian companies to 40 per cent, except for some exceptional cases, and they were required to produce most of the bulk drugs (active pharmaceutical ingredients) 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. This legal framework created opportunities for the domestic pharmaceutical companies to specialize in manufacturing of generic versions of patented pharmaceutical drugs. The domestic companies were supported by research and development (R&D) activities undertaken by the GOI. Two public sector companies, Hindustan Antibiotics Ltd. (HAL) and Indian Drugs and Pharmaceuticals Ltd. (IDPL), engaged in significant R&D, 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) have been established.

The next phase in the Indian pharmaceutical industry began when India became a signatory to the World Trade Organization (WTO) in 1995. India was required to offer a product patent regime, which extended to the pharmaceutical companies as well. Thus, the Indian Patents Act was amended in 2005 to accommodate WTO regulations. An immediate consequence of this is that the previous strength of the Indian pharmaceutical industry of reverse engineering a patented drug 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 R&D activities in India. While that did not necessarily happen, the domestic industry found another source of growth: a large number of drugs coming off patent protection in the USA that permitted the Indian companies to sell generic drugs in the USA, provided they were able to obtain regulatory approval. The industry continued to grow, mostly fuelled by exports of global generics. For instance, in 2000–2001, Dr. Reddy's Laboratories, one of the leading pharmaceutical companies in India, had roughly equal shares of sales of global generics (50 per cent) and active pharmaceutical ingredients (44 per cent) (Dr. Reddy's Laboratories, 2002). In 2014–2015, the sale of global generics was nearly 4 to 5 times that of Active Pharmaceutical Ingredients (APIs) for Dr. Reddy's Laboratories (Dr. Reddy's Laboratories, 2015). For the same company, the domestic revenue was approximately 13 per cent of its overall sales in 2014–2015, whereas, in 2000–2001, the domestic revenue was 54 per cent of the total sales. For the current market leader, Sun Pharmaceutical Industries Ltd., APIs constituted almost 35 per cent of the revenues earned in 1999–2000

(Sun Pharmaceuticals, 2001–02), whereas in 2014–2015, the APIs constitute less than 4 per cent by revenue (Sun Pharmaceuticals, 2015). By 2009–2010, the Indian pharmaceutical industry became the 3rd largest in the world by volume of production having 10 per cent of the global share and 14th by value having 1.4 per cent of global share (Ministry of Finance).

The expectation that the companies would invest heavily in R&D 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, spending as low as only a percentage of its total sales, perhaps daunted by some high profile failures (Joseph, 2011). Only a handful of Indian companies spend more than 10 per cent of their revenue on R&D; a possible reason could be the uncertainty surrounding the intellectual property regime.

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 per cent of its bulk drug requirements from China (Dey, 2014). Thus, Indian firms now face significant competition from Chinese firms in the bulk drugs segment, which poses a 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…' (Kumar, 2015, Para 3). It recommended providing appropriate infrastructure, creation of manufacturing clusters, revival of public sector units, and providing economic incentives to the players in this field.

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.

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, but this often does not apply to pharmaceutical products. This results in highly inelastic demand for certain life-saving pharmaceutical products, and if 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.

The pharmaceutical industry invests in R&D for development, 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 one is marketed successfully; and the cost of bringing in a successful product to the market is estimated at more than USD 2.5 billion (DiMassi, Grabowski, & Hansen, 2014). In the absence of any protection, an intellectual property once developed is available to all for commercial production. Given the costs and risks involved, 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, the production costs of such drugs are relatively low. Thus, there is scope for static inefficiency, which raises prices of drugs in the short to medium term making them inaccessible to a large number of people in the absence of any mechanism to offer public support (Chaudhuri, Goldberg, & Jia, 2006). But without this patent protection, it is unlikely that the pharmaceutical industry will actually invest in R&D to invent new and better pharmaceutical drugs for future.

This tension between the two concerns is referred to as the dynamic efficiency of the pharmaceutical industry. The regulatory architecture governing the pharmaceutical industry must find a balance between the need to provide cheap access to medicines to the population at large and also incentivizing innovating pharmaceutical companies to continue to invest in

high risk R&D, so that better quality drugs and drugs for treatment of hitherto untreated diseases could be developed. This trade-off between the current and future market conditions is what governs the structure of regulatory policy for the pharmaceutical industry.

Another important aspect that differentiates the pharmaceutical industry from the other industries is that the end users do not 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 maintaining a sales force. We discuss the implications for competition of this particular aspect later.

Pharmaceutical Industry and the Nature of its Market in India

The pharmaceutical industry is one of the most important industries in India, with quite a few Indian firms becoming 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 2013–2014, including exports (Organisation of Pharmaceutical Producers of India, 2014). The Indian market is dominated by generics with 72 per cent market share in terms of revenues. Patented drugs cover only 9 per cent of the overall market, supplied almost entirely by MNCs, whereas OTC market is 19 per cent. India is also the largest exporter of generic drugs in the world, accounting for 20 per cent of the worldwide exports (India Brand Equity Foundation, 2015).

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 a pharmaceutical industry 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 OTCs, drug prices in India are among the cheapest in the world.

***Nature of Price Competition*:** Price competition among generics is an important feature of the 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. 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 consumer 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. The phenomenon of branded generics dilutes price competition. Firms have also traditionally used combination of drugs (drug cocktails) to differentiate themselves from the competition. This product differentiation has the potential to keep the prices high. Almost 50 per cent of the total drugs sold in India are fixed-dose combination drugs. While such combination therapies improve patient compliance, the health outcomes are questionable (Mahr & Siddiqi, 2015). In the recent past, the GOI banned 344 such drugs. However, the Delhi High Court quashed this ban (*The Economic Times*, 2016).

Price competition coexists with price controls. Since 1970, the pharmaceutical prices have been controlled through the DPCOs 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 through DPCO, 1995. However, the DPCO, 2013 brought a large number (348) of domestic generic formulations under the ambit of price regulation covering an estimated 30 per cent 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 National Pharmaceutical Pricing Authority (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*. In implementing this, the NPPA brought 108 formulations under price control in July 2014. Due to opposition from pharmaceutical companies, this order was withdrawn in September 2014; however, the NPPA submitted to Delhi High Court that while this order will not be in effect going forward, the pricing of the formulations brought under control in July will not be changed as the central government's notification applies prospectively and not retrospectively. This implies that all those 108 drugs remain under price control (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. In September 2016, a news article stated that the number of drugs under price control is 467. The article further claimed that there are several other drugs that are classified as essential, and hence are likely to come under price regulation soon (*The Indian Express*, 2016). While some reduction and addition might happen to the final list, it is clear at the time of writing this article that the number of such drugs is still likely to be large.

Perhaps due to such extensive price control measures and threat of use of other TRIPS-allowed tools such as compulsory licensing and parallel imports, a recent study by Duggan, Garthwaite, and Goyal (2016) found that there has been a very modest increase of 3–6 per cent in prices of pharmaceutical drugs receiving patents in India. Another possible reason for this finding could be the limited purchasing power of an average Indian consumer. Since majority of prescriptions are not covered by any form of insurance, the demand for new drugs tends to be highly elastic even for patented products (without much direct competition) for affordability reasons. We discuss the affordability issue later in the article.

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 per cent 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 per cent margin to arrive at retail prices (DPCO, 2013).

Theoretically, price competition can also 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: (1) procure drugs for sale in government hospitals and primary health care centres through centralized tendering (e.g., Tamil Nadu through Tamil Nadu Medical Services Corporation Ltd); or (2) 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 GOI 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.

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 of this industry.

***Cost Advantages*:** One of the primary advantages enjoyed by the Indian producers is low-cost but high quality manufacturing of drugs. According to Greene

(2007), the cost advantages stem from lower labour costs (approximately one-seventh of that in the USA), lower infrastructure costs and fixed costs when compared to the USA and Western Europe. While some bulk drug producers have been able to maintain the cost advantage and thrive with process innovations that usher in greater efficiency (Sharma, 2014), Indian bulk drugs 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 drugs production to formulations, where the pharmaceutical companies enjoy higher profit margins, other bulk drugs producers have targeted regulated markets where the margins are somewhat protected (Dey, 2012; Reddy, 2004). 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 to conduct clinical trials, which would lead to reduction in costs.

Product Innovation:[1] Indian firms have historically specialized in process innovation, and not necessarily product innovations. 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 estimated that of 10,000 molecules that receive a product patent, only about one is successfully marketed (DiMassi et al., 2014). 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. DiMasi et al. (2016) estimates that the cost of developing and successfully marketing a new drug in the USA costs $ 2.58 billion in 2013 prices. The largest R&D spent by an Indian firm in 2015 is about USD 300 million by the Sun Pharmaceuticals (that merged with Ranbaxy Laboratories), 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.

Due to the high risk of product development, comparatively low investment in R&D and somewhat uncertain regulatory environment that involves unethical practices, and delays in approval and uncertainty regarding the conduct of clinical trials, it has become challenging to establish India as an innovation hub. Thus, Indian firms have looked at strategies that require them to only take up innovation partially. One clear strategy adopted by the Indian pharmaceutical manufacturers is the 'out-licensing strategy' wherein they develop the chemical compound up to a point and leave the late stage development and marketing of the drug to other firms in exchange for payments and royalty. Some other Indian companies are following a strategy of in-licensing products developed by other companies wherein Indian firms 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 royalty payments at a later stage, 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 centre 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 Food and Drug Administration (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 (*DNA*, 2015). 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—such as 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 registration and approval of clinical trials have resulted in a lot of companies moving clinical trials out of India (Nair, 2015).

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 (Ferranti, 2012).

***Marketing Practices*:** In India and in most parts of the world, most pharmaceutical products (except for the OTC 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 Organisation of Pharmaceutical Producers of India (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 & Bahri, 2011). The final consumer, thus, may not have a choice that he/she can exercise. This itself may dilute price competition. The market failure on account of asymmetric information may have adverse effect on price competition, leading to further market failure which results in greater market power.

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 the 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. 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 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 health care 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 per cent of all expenditure on health in India as of 2011 is out-of-pocket (Bhattacharjea & Sindhwani, 2014), and expenditure on medicine constitutes 72 per cent of the out-of-pocket expenditure, among the highest in the world (Mehta, 2015).

There is some evidence that the doctors do not necessarily prescribe medicine that will be the cheapest for the patient without compromising on quality. A study by Nguyen (2011) finds evidence of higher-priced 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 International in 1995 and 2010 have found evidence of a tendency for irrational prescription involving unnecessary medicines, and that only 20 per cent of patients visiting public hospitals were prescribed medicines that they could obtain from the hospitals 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.

In many states, the government regulations require doctors working in government hospitals to prescribe only the generic name of the drug in their prescriptions and government dispensaries in 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 system in place, such a requirement may not have any impact, and doctors could simply ignore the stipulation. Thirdly, the sales force of companies will shift focus from doctors to pharmacists and 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 leading to price reductions.

In 2015, GOI had asked for voluntary compliance of pharmaceutical companies and physicians with Uniform Code of Pharmaceutical Marketing Practices (UCPMP). In the UCPMP, 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 six months, and if compliance was found to be unsatisfactory, it would be made a statutory law. So far, the government 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 government may look to enforce this legally (Jagdale, 2015).

With the penetration of Internet in India, one would expect that the power a doctor currently possesses in terms of determining the brand of the molecule prescribed would erode. Several websites (for example, www.drugs.com, www.drugsupdate.com, etc.) provide the names of various brands for each molecule and the associated price. Ideally, patients would be able to look up the prescribed medicine and figure out the brand that is cheaper, and if the manufacturer is of good repute. There are also mobile phone applications like Drugs Dictionary which help the patients in comparing brands for a given molecule. Simple economic intuition suggests that such availability of information reduces the incentive for pharmaceutical companies to influence doctors' prescription behaviour. That said, while one would expect this to cease being a concern in the long run, it remains a major issue currently.

***Distribution Channel*:** In India, medicines are distributed through retail pharmacies to patients upon production of a prescription from a doctor (for any medicine other than the OTCs). However, the medicines need to be transported from the place of production (plants and pharmaceutical companies) to the place where they are sold (retail pharmacies). As described in Jeffrey (2007), due to peculiarities in Indian tax system where inter-state sale of goods is taxed by the central government but inter-state movement of goods is not, Indian pharmaceutical companies maintain Carrying (or Clearing) and Forwarding Agents (CFAs) to maintain stocks of their products in every state they intend to sell. This replaced an earlier arrangement prior to mid-1990s, where companies themselves maintained depots and warehouses in each state. The CFA earns a percentage margin of total revenue.

The stockists or wholesalers form the next level in the supply chain procuring medicines 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. As per Jeffrey (2007) estimates on these discounts range from 2 per cent to 10 per cent for CFAs on the turnover, and the margin obtained by wholesalers is close to 8 per cent for price-controlled drugs and around 16 per cent 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 to 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 India Organisation of Chemists and Druggists (AIOCD). AIOCD has state chapters, as well as associations at district levels, which are affiliated to AIOCD. In the recent past, the AIOCD strictly controlled 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 granting 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 any wholesaler can stock them or it is sold by a retailer. They also charged pharmaceutical companies product information services (PIS) charges 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 Indian Drug Manufacturers' Association (IDMA) and Organization of Pharmaceutical Producers of India (OPPI), two associations representing drug manufacturers in India. And in case any pharmaceutical company did not comply with these directives, AIOCD would allegedly boycott those pharmaceutical companies. Thus, AIOCD was (and probably still is) a very powerful association that allegedly restricted trade in a significant way until the CCI repeatedly found its practices unlawful in a series of cases. 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 the CCI in the pharmaceutical sector.

COMPETITION COMMISSION OF INDIA AND THE PHARMACEUTICAL INDUSTRY

In this section, we review the recent regulatory efforts in India 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.

Assessment of Anti-competitive Conduct-defining Market and Measuring Market Power

To understand the nature of competition in any market, it is important to identify what the relevant market is. While in some cases market definition tends to be straightforward, in some other cases it is more nuanced. When it comes to the market for pharmaceuticals, the definition of appropriate market tends to be more complicated. An obvious 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. 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 is the competition between the innovators (MNCs) and the generic manufacturers. 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 (multinational manufacturers) over the domestic brands (Chatterjee, Kubo, & Pingali, 2015). There could be several reasons for this consumer perception such as media reports about drugs manufactured in India being of lower quality (Clarke & Berkrot, 2014). Anecdotal evidence apart, even some recent empirical research has highlighted this issue (Bate, Jin, Mathur, & Attaran, 2014). 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 USA, 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 such as Ranitidine, Cimetidine, etc., and proton pump inhibitors (PPI) such as Omeprazole, Lansoprazole, etc. This can be termed as *inter-molecular* competition. 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 (Wang & Chow, 2012). *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 doctor would prescribe drug B and not drug A. Even in some mature markets like USA, there is some evidence of insurance companies insisting on compensating only a substitutable generic molecule, and not the prescribed molecule. Probably, technological interventions via the Internet, discussed previously, can provide some solution here, but it is still a pertinent issue currently.

Given these confounding factors, how does one define appropriate market in order to apply small but significant non-transitory increase in price (SSNIP) test?[2] 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 such as 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 brands across molecules) are estimated. In the Indian pharmaceutical markets too, several research papers have employed such techniques; for example, Dutta (2011) in case of drugs across various therapeutic categories, and Chatterjee et al. (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.

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 Pharmaceuticals and Ranbaxy. The details of the investigation by director general 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 CCI had initially raised objections to this merger citing the reason that the merger may hurt competition (*DNA*, 2014). The Commission subsequently cleared the merger with a rider stating that the companies have to divest eight drugs altogether: Tamlet (Sun Pharma) and Eligard, Terlibax, Rosuvas, Raciper, Terlibax, Triolvance, and Olanex for Ranbaxy (Mishra & Patel, 2014). 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, even if there is

market concentration at a molecular level, the market concentration may not be exploitable by the manufacturer 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 need to be considered as well. It is also worth noting that the analysis is conceptually similar to the one undertaken by US Federal Trade Commission (FTC), regarding the harm to competition for Minocycline tablets in the USA.[3]

Asking Sun Pharmaceuticals and Ranbaxy Laboratories 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 Pharmaceuticals and Ranbaxy Laboratories.) 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 an incentive to keep competition low. This implies that 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 acquires these molecules, 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.[4,5]

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 R&D 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 Pharmaceuticals and Ranbaxy Laboratories merger would enable both pharmaceutical companies access to each other's networks (marketing, warehousing, etc.), thereby reducing set-up costs. Therefore, the trade-off 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 that 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.

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. A large majority of these cases fall under the horizontal agreements among members of the trade association: 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 anti-competitive acts to the detriment of consumers. These acts include fixation of profit margins for drugs whose prices are not determined by the NPPA, restriction on appointment of distributors, issuance of NOC, 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 USD 800 to USD 3 million. 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 is mentioned that drug manufacturing associations such as IDMA and 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 such cases, even though all members of CCI found instances of anti-competitive behaviour, all of them were not in agreement, and dissenting orders were submitted. For instance, the majority opinion of CCI contended that in the M/s Sandhya Drug Agency case (2011) OPPI and IDMA 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 anti-competitive acts. However, few CCI members disagreed with IDMA and OPPI being viewed as victims and felt that they were culpable for actions as well. A segment of CCI members also felt that fixing the margins does not result in price fixing itself (as per the order by Geeta Gouri, member CCI). Similar disagreements in opinion also were seen in

M/s Santuka Associates Pvt. Ltd. v. AIOCD (2013), the Varca Druggist and Chemist case (2009), and the Vedant Bio Sciences case (2012). The most recent case that we could find was of M/s Maruti & Company, Bangalore v. Karnataka Chemist & Druggist Association and Lupin Ltd., where the CCI members unanimously held the defendants guilty of misconduct in August 2016. Significantly, Lupin Ltd. was also found guilty of suppressing competition, and was fined around USD 11.25, the first time a pharmaceutical company has been held guilty for refusing to supply drugs to a retailer in the absence of a NOC. In addition, employees of Lupin Ltd. were also found guilty and fined.

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, namely GlaxoSmithKline (GSK) and Sanofi for procurement of Quadrivalent Meningococcal Meningitis vaccines (QMMV) for Hajj pilgrims (2013). The Government of India floats a tender for procurement of QMMV each year. In this instance, Bio-Med is an indigenous producer competing against GSK and Sanofi. Bio-Med alleged that the GOI arbitrarily changed the qualifying criteria for bidding, which resulted in Bio-Med being disqualified from bidding. Bio-Med also alleged that GSK and Sanofi indulged in collusive practices of bid rotations and geographical allocations. The director general did not find anything wrong in the policies adopted by the GOI, based on an order by the Delhi High Court. However, it did find instances of anti-competitive behaviour based on analysis of price bids by the two pharmaceutical companies.

INTELLECTUAL PROPERTY AND THE PHARMACEUTICAL SECTOR

Wikipedia defines patent 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. (Patent, n.d, para 1)

While R&D 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 the innovator to obtain a reasonable profit; once the patent has expired, competition is free to enter, with gains in consumer surplus. As pointed out earlier, subsequent to signing the TRIPS agreement with the WTO in 1995, India had to adopt more liberal intellectual property laws. These laws became effective 10 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. 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 R&D, which improves the probability of discovering new drugs, with the same cycle 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. 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 (Rockett, 2007).

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 USA followed price control mechanisms that exist elsewhere, the innovation in pharmaceutical industry would have reduced by more than 40 per cent. 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.[6] 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 (Rajagopal, 2015).

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 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) (Reuters, 2015). However, the judgment also stipulates that Glenmark Pharmaceuticals is allowed to sell the existing stocks that have already been manufactured. Even if, at a later stage, MSD's patent for Sitagliptin Phosphate is upheld, it is not clear as to what penalties would be imposed on Glenmark Pharmaceuticals 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 (in case of patent infringement), 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 (Drug Controller General of India, [DCGI]) and the patent office are not working together. That is, approval for launching a drug is provided without ascertaining whether or not a valid patent exists for the product. 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 such as encouraging pooled R&D across various firms so that the risk is sufficiently diversified and strengthening public research initiatives (e.g., Council of Scientific & Industrial Research [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 (Danzon & Towse, 2003), 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 (Pingali & Chatterjee, 2015).

Competition Policy and Intellectual Property

Another issue that is important to take note of is how intellectual property is related to competition. 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 the final product, then its dominance is extended to the 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. (Refer to Rey and Salant [2012] for theoretical modelling of this issue.)

In the pharmaceutical context too, there is a scope for violation of competition laws through exploiting intellectual property. For instance, the innovator could collude with a generic and stop the generic from entering the market by *sufficiently* compensating the generics manufacturer. Popularly, this kind of behaviour is known as *pay for delay*, or reverse payment patent

settlement. Obviously, such practices lead to violation of competition law.[7] In the USA, the Supreme Court passed a landmark judgment in the Actavis case in 2013, where it held that Solvay Pharmaceuticals' agreements with Actavis Inc., Paddock Inc., and Par Pharmaceuticals Cos. could be challenged by FTC. Here, Solvay Pharmaceuticals, the producer of AndroGel, entered into an agreement with the three aforementioned companies to delay the entry of their FDA-approved generic substitute for a specified number of years in exchange for monetary payments (*Federal Trade Commission vs. Actavis, Inc.*, 2013). 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 PPI markets through misrepresentations to various patent offices in the EU (Eccles, 2013).

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 USA, 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. 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'. (Such entry is referred to as an entry through a Paragraph IV challenge.) 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). 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. Bulow (2004) discusses the economics of Paragraph IV challenges in his research.

Empirical evidence suggests that 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 fostering competition—generics have an incentive to challenge the patent, if patents are filed on non-standard grounds. For example, line extensions (e.g., new route of administration, extended releases, and alternative dosage strengths of existing molecules) of the existing medicines that have been patented seem to be the main targets of Paragraph IV challenges (Hemphill & Sampath, 2010). 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 Patents Act (2005) is created in order to curb some such anti-competitive practices like filing patents for frivolous benefits. The section rules that a *mere discovery of a new form of a known* substance which does not result in the enhancement of the known efficacy of that substance or the *mere discovery of any new property or new use for a known substance* or of the *mere use of a known process, machine, or apparatus unless such known process results in a new product or employs at least one new reactant* is not qualified as an invention, and thus is not patentable. As an explanation, the act further states that

> for the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

The purpose of this section is to ensure that the life of existing patents is not artificially extended due to some frivolous reasons (a practice commonly referred to as evergreening). However, since what constitutes as *differ significantly* is not fully articulated, the section has attracted significant debate. In the recent times, Section 3(d) has come into focus because of the case involving a blood cancer drug by the Swiss pharmaceutical giant, Novartis called Glivec® (Imatinib Mesylate). While Novartis filed a patent for Imatinib Mesylate, the Supreme Court ruled that Glivec could not be patented because the cancer-curing properties of Imatinib were widely known before the introduction of Glivec itself, citing Section 3(d). The argument was that the novelty of Glivec lies in making Imatinib more absorbable by the human body to fight cancer. (While Imatinib is not absorbable, Imatinib Mesylate is more absorbable, and hence more effective.)

In sum, it is clear that the intellectual property and competition are completely intertwined with

each other. Therefore, as we move to a more robust competition regime, the CCI ought to be more vigilant in the intellectual property domain as well; as the Bulow (2004) study shows, the chances of harming competition via possession of intellectual property are high. The concerns raised therein are very much valid even today!

CONCLUSION

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. We conclude by discussing some important questions that need to be addressed in this market both from research and public policy point of view, with a developing countries' perspective (more specifically, India).

The first issue that needs to be resolved is the trade-off between availability of medicine at cheaper price and 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 R&D and manufacturing within India for indigenous consumption could be another way in which prices for innovative medicines can be lowered.[8] For such initiatives to succeed, a more robust intellectual property regime is important. In India currently, it is not clear as to what the damages would be, if a patent violation is found. In fact, it is not even clear if patent status is taken into consideration when a drug is approved!

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 control. Therefore, whether the answer to this debate is universal, or 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. A related area where the policy needs to focus on is advertising.[9] While informative advertisement can be useful, persuasive advertising can be modelled as prisoners' dilemma. Moreover, 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. But can India afford to move from branded generics to pure generics market (as is the case in the USA, for example)? Given that there are significant quality differences across brands, the answer is not straightforward.

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. One could, for example, consider negotiated pricing for government hospitals across various geographies. For such differential pricing to work, markets have to be plugged so that arbitrage opportunities that arise from difference in pricing are not prevalent. In such cases, government listed price controls (like the DPCO 2013 list discussed earlier) sounds like an attractive proposition. However, this might lead to several unintended consequences. For example, the price control might provide an artificial coordination point for firms to tacitly collude. Moreover, firms have an incentive to withdraw cheaper drugs from the market and reintroduce them in a different form closer to the price control. Therefore, a regulatory authority like CCI ought to be vigilant about these laws that could harm competition.

Increased use of technology may provide solutions to some of these issues; however, some others require careful planning involving all relevant stakeholders. Moreover, 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 such as China, Russia, Brazil, etc. The Competition Commission of India, the Indian Patent Office, the Department of Health, and the Department of Pharmaceuticals should work on addressing these questions and provide a roadmap for these issues.

ACKNOWLEDGEMENTS

We thank Payal Malik and Aditya Bhattacharjea for comments on the earlier drafts of the article. A part of the manuscript was developed when Viswanath Pingali was a George C. Lamb Fellow at the Kenan Institute for Ethics at Duke University, Durham, NC, USA. Viswanath thanks the hospitality of Duke University in preparation of this manuscript.

NOTES

1. This segment borrows heavily from Joseph (2011).
2. small but significant and non-transitory increase in price (SSNIP) test is widely used in the antitrust literature to identify relevant market. Imagine X is a manufacturer of a molecule A. Suppose X increases the price of molecule A by (say) 5 per cent. All those molecules whose demand is affected as a result of this non-transitory price change, comprise the relevant market for A.
3. 'In the Matter of Sun Pharmaceutical Industries Ltd., Ranbaxy Laboratories Ltd., and Daiichi Sankyo Co., Ltd.' (Docket No. C-4506). Retrieved from https://www.ftc.gov/system/files/documents/cases/150130sunranbaxy-cmpt.pdf
4. To our knowledge, Sun Pharmaceuticals and Ranbaxy Laboratories merger was the most prominent merger in the pharmaceutical market where such detailed divestiture measures were ordered. Divestitures in other mergers may not have been followed so stringently because either: (a) the merging parties are small; or (b) have no molecules in common.
5. It should also be noted that brown field investments (Indian firms acquired by foreign firms) first come under the purview of Foreign Investment Promotion Board (FIPB) of India before they come under CCI's lenses. The recent acquisition of India operations of Kemwell by Recipharm and China's Shanghai Fosun Pharmaceuticals' acquisition of majority stake in Gland Pharmaceuticals are some such examples. While the former was approved by all fronts as of 2 January 2017, the latter is, to our knowledge, still pending subject to approval at FIPB, and then CCI.
6. For example, Berndt and Cockburn (2014) show that out of 184 molecules approved by the FDA, only 90 have been marketed in India. For a detailed review of literature pertaining to delayed/refusal to launch, please see Pingali and Chatterjee (2015). A recent paper by Cockburn, Lanjouw, and Schankerman (2016) has also argued that innovator companies delay the introduction of new drugs to countries which do not offer strong patent protection.
7. The FTC of the USA maintains a website where recent cases involving pay for delay are listed (retrieved from https://www.ftc.gov/news-events/media-resources/mergers-competition/pay-delay). For the economic arguments behind this practice and some of the earlier incidences of pay for delay, see Bulow (2004).
8. 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 FDA- (of the US government) approved manufacturing units outside the USA (retrieved from http://www.business-standard.com/article/companies/drug-makers-should-learn-to-appreciate-fda-needs-better-say-experts-114112000926_1.html).
9. In India, pharmaceutical companies are not allowed to advertise prescription drugs directly to the consumers. Therefore, pharmaceutical companies stick to advertising only to the doctors. In the pharmaceutical jargon, such practice is referred to as detailing. For expositional clarity, we stick to advertising.

REFERENCES

Bate, R., Jin, G. Z., Mathur, A., & Attaran, A. (2014). *Poor quality drugs and global trade: A pilot study* (Working Paper No. 20469). National Bureau of Economic Research. Retrieved 12 October 2015, from http://www.nber.org/papers/w20469.pdf

Berndt, E., & Cockburn, I. A. (2014). The hidden cost of low prices: Limited access to new drugs in India. *Health Affairs*, *33*(9), 1567–1575.

Bhattacharjea, A., & Sindhwani, F. (2014). *Competition issues in the Indian pharmaceuticals sector*. New Delhi: Center for Development Economics, Delhi School of Economics and CUTS-CIRC.

Bulow, J. (2004). The gaming of pharmaceutical patents. *Innovation Policy and the Economy*, *4*, 145–187.

Business Standard (BS Reporter). (2014, September 17). Sun Pharma, Merck & Co enter agreement for Tildrakizumab. Retrieved 9 November 2015, from: http://www.business-standard.com/article/companies/sun-pharma-merck-co-enter-agreement-for-tildrakizumab-114091701073_1.html

Business Standard. (2015, July 17). NPPA adds 39 more drugs to the controlled list. Retrieved 9 November 2015, from http://www.business-standard.com/article/economy-policy/nppa-adds-39-more-drugs-to-the-controlled-list-115071700029_1.html

Chatterjee, C., Kubo, K., & Pingali, V. (2015). The consumer welfare implications of patent protection, pricing, and licensing in the Indian oral anti-diabetic drug market. *Journal of Health Economics*, *44*, 255–273.

Chaudhuri, S. (2014). *Intellectual property rights and innovation: MNCs in pharmaceutical industry in India after TRIPS*. New Delhi: Institute for Studies in Industrial Development.

Chaudhuri, S., Goldberg, P., & Jia, P. (2006). Estimating the effects of global patent protection in pharmaceuticals: A case study of Quinolones in India. *American Economic Review*, *96*(5), 1477–1514.

Clarke, T., & Berkrot, B. (2014, March 18). Unease grows among the US doctors over Indian drug quality. Retrieved 18 March 2017, from http://www.reuters.com/article/us-usa-india-genericdrugs-insight-idUSBREA2H06Y20140318

Cockburn, I. M., Lanjouw, J. O., & Schankerman, M. (2016). Patents and the global diffusion of new drugs. *American Economic Review*, *106*(1), 136–164.

Center for Trade and Development. (2010). Competition Law and Indian Pharmaceutical Industry. Retrieved on 16 March 2017, from www.cci.gov.in/sites/default/files/PharmInd230611_0.pdf

Danzon, P., & Towse, A. (2003). Differential pricing for pharmaceuticals: Reconciling access, R&D and patents. *International Journal of Health Care Finance and Economics*, *3*(3), 183–205.

Davis, P. (2015, May 29). *Second circuit finds 'product hopping' by a pharmaceutical company to violate antitrust law*. Retrieved 10 November 2015, from http://www.davispolk.com/sites/default/files/2015–05-29_2nd_Circuit_Finds%20_Product_Hopping_%20to_Violate_Antitrust_Laws.pdf

Deaton, A., & Muellbauer, J. (1980). An almost ideal demand system. *American Economic Review*, *70*(3), 312–326.

Dey, S. (2012, August 27). *API market loses out to formulations*. Retrieved 6 October 2015, from www.business-standard.com/article/printerfriendlyversion?article_id=112082700053_1

_____. (2012). Over-dependence on China for drug ingredients worries NSA. *The Times of India.* Retrieved 24 May 2017, from http://timesofindia.indiatimes.com/india/Overdependence-on-China-for-drug-ingredients-worries-NSA/articleshow/45278715.cms

DiMassi, J., Grabowski, H., & Hansen, R. (2014). *Cost of developing a new drug*. Tufts Center for Drug Development. Retrieved 16 March 2017, from http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014..pdf

DiMasi, J. A., Grabowski, H. G., and Hansen, R. W. (2016). Innovation in the pharmaceutical industry: New estimates of R&D costs. *Journal of Health Economics, 47*, 20–33.

DNA. (2014, September 5). CCI Says Sun's takeover of Ranbaxy may hurt competition. Retrieved 24 May 2017, from http://www.dnaindia.com/money/report-cci-says-sun-s-takeover-of-ranbaxy-may-hurt-competition-2016279

DNA News. (2015, February 2). CRAMS players set for $85 billion US drug bounty. Retrieved 24 May 2017, from http://www.dnaindia.com/money/report-crams-players-set-for-85-billion-us-drug-bounty-2057348

Dr. Reddy's Laboratories. (2002). *2001–2002 annual report*. Hyderabad: Author.

Dr. Reddy's Laboratories. (2015). *2014–2015 annual report*. Hyderabad: Author.

Duggan, M., Garthwaite, C., & Goyal, A. (2016). The market impacts of pharmaceutical product patents in developing countries: Evidence from India. *American Economic Review*, *106*(1), 99–135.

Dutta, A. (2011). From free entry to patent protection: Welfare implications of the Indian pharmaceutical industry. *Review of Economics and Statistics*, *93*(1), 160–178.

Eccles, R. (2013). *Court of justice upholds AstraZeneca abuse of dominance decision*. Retrieved 12 March 2017, from https://www.twobirds.com/en/news/articles/2012/court-of-justice-upholds-astrazeneca-abuse-dominance-decision0113

Economics Division. (2017). New Delhi: Ministry of External Affairs, Government of India. Retrieved 12 March 2017, from http://indiainbusiness.nic.in/newdesign/index.php?param=industryservices_landing/347/1

Federal Trade Commission vs. Actavis, Inc., et al., 2012, 12–416 (Supreme Court of the United States, 17 June 2013).

Ferranti. (2012, August 29). India: A powerhouse of innovation for neglected diseases? *Huffington Post*. Retrieved 24 May 2017, from http://www.huffingtonpost.com/david-de-ferranti/india-health-research_b_1834709.html

Filson, D. (2012). A Markov-perfect equilibrium model of price controls on the performance of the pharmaceutical industry. *RAND Journal of Economics*, *43*(1), 110–138.

Greene, W. (2007). *The emergence of India's pharmaceutical industry and implications for the U.S. generic drug market*. Washington, DC: US International Trade Commission.

Hemphill, C. S., & Sampat, B. N. (2011). When do generics challenge drug patents? *Journal of Empirical Legal Studies*, *8*(4), 613–649.

Hughes, W. H., Moore, M. J., & Snyder, E. A. (2002). *Napsterizing pharmaceuticals: Access, innovation, and consumer welfare* (Working paper No. 9229). Cambridge, MA: National Bureau of Economic Research

India Brand Equity Foundation (IBEF). (2015). *Pharmaceuticals*. Retrieved 6 November 2015, from http://www.ibef.org/download/Pharmaceuticals-March-2015.pdf

Jagdale. (2015, June 9). UCPMP: Code word for pharma industry. *Financial Express*. Retrieved 24 May 2017, from http://www.deccanchronicle.com/151011/nation-current-affairs/article/mega-parks-promote-pharma-sector

Jeffrey, R. (2007). *Pharmaceuticals distribution system in India*. Edinburgh: The Center for International Public Health Policy.

Joseph, R. K. (2011). *The R&D scenario in Indian pharmaceutical industry*. New Delhi: RIS.

Kumar, S.P. (2015, October 11). Mega parks to promote pharma sector. *Deccan Chronicle*. Retrieved 24 May 2017, from http://www.deccanchronicle.com/151011/nation-current-affairs/article/mega-parks-promote-pharma -sector

Lichtenberg, F. R. (2005). The impact of new drug launches on longevity: Evidence from longitudinal, disease-level data from 52 countries, 1982–2001. *International Journal of Health Care Finance and Economics*, *5*(1), 47–73.

Mahr, K., & Siddiqi, Z. (2015). As combination drugs engulf India, an American pharmaceutical giant profits. Reuters. Retrieved on 16 March 2017, from http://www.reuters.com/investigates/special-report/india-medicine-abbott/

Mehta. (2015, January 6). A bitter pill for doctors, pharma companies. *Asian Age*.

Ministry of Finance (2010). *Economic survey of India, 2009–10*. New Delhi: Government of India.

Mishra, D., & Patel, D. (2014, December 9). CCI gives nod to Sun–Ranbaxy merger, asks to divest 7 drug assets. *Business Standard*. Retrieved 18 March 2017, from http://www.business-standard.com/article/companies/cci-gives-nod-to-sun-ranbaxy-merger-asks-to-divest-7-drug-assets-114120800727_1.html

Moneycontrol. (2014, October 15). NPPA clarifies stand; says July price control order valid. Retrieved 9 November 2015, from http://www.moneycontrol.com/news/business/nppa-clarifies-stand-says-july-price-control-order-valid_1204395.html

Nair, A. (2015). Clinical research: Regulatory uncertainty hits drug trials in India. *The Pharmaceutical Journal*. Retrieved 18 March 2017, from http://www.pharmaceutical-journal.com/news-and-analysis/features/clinical-research-regulatory-uncertainty-hits-drug-trials-in-india/20068063.article

Nguyen, H. (2011). The principal-agent problems in health care: Evidence from prescribing patterns of private providers in Vietnam. *Health Policy and Planning*, 26(1), i53–i62.

Organisation of Pharmaceutical Producers of India (OPPI). (2014). *2013–2014 annual report*. Mumbai: Author.

Patents. (n.d.). *Wikipedia*. Retrieved May 24, 2017 from https://en.wikipedia.org/wiki/Patent

Pingali, V., & Chatterjee, C. (2015). Balancing affordability and availability in a drug patent regime. *Economic and Political Weekly*, *50*(41), 20–23.

Press Trust of India. (2015, February 25). Govt to implement Katoch committee recommendations. Retrieved 6 November 2015, from http://www.business-standard.com/article/pti-stories/govt-to-implement-katoch-committee-recommendations-115022500808_1.html

Rajagopal, D. (2015, March 31). Compulsory licensing hit India's image: Hetero pharma. *The Economic Times*. Retrieved 24 May 2017, from http://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/compulsory-licensing-hit-indias-image-hetero-pharma/articleshow/46751947.cms

Reddy, V. (2004, January 19). From bulk drugs to formulations. *The Hindu*. Retrieved 24 May 2017, from http://www.thehindu.com/biz/2004/01/19/stories/2004011900261500.htm

Reuters. (2015, May 15). Supreme court bars Glenmark from selling Merck drug copies. Retrieved 24 May 2017, from http://www.reuters.com/article/us-glenmark-phrm-merck-co-lawsuit-idUSKBN0O011S20150515

Rey, P., & Salant, D. (2012). Abuse of dominance and licensing of intellectual property. *International Journal of Industrial Organization*, *30*(6), 518–527.

Rockett, K. (2010). Property rights and invention. In B. Hall and N. Rosenberg *Handbook of the economics of innovation* (Vol. 1, pp. 315–380).

Sharma, E. K. (2014, September 18). Some Indian drug makes are becoming world leaders in niche areas. *Business Today*. Retrieved 24 May 2017, from http://www.business-today.in/magazine/features/indian-bulk-drug-makers-becoming-world-leaders-niche-areas/story/210082.html

Sun Pharmaceuticals. (2002). *2001–2002 annual report*. Mumbai: Author.

Sun Pharmaceuticals. (2015). *2014–2015 annual report*. Mumbai: Author.

The Economic Times. (2016, December 1). Delhi High Court quashes government ban on over 300 medicines like Corex, Saridon. Retrieved 24 May 2017, from http://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/delhi-high-court-quashes-centres-notification-to-ban-344-fixed-dose-combination-drugs/articleshow/55720701.cms

The Indian Express. (2016, Septemner 16). Drug price regulator, NPPA brings 18 drugs under price control, taking the total to 467. Retrieved 24 May 2017, from http://indianexpress.com/article/india/india-news-india/drug-price-regulator-nppa-brings-18-drugs-under-price-control-taking-the-total-to-467-3034649/

Udeshi, A., & Bahri, M. (2011). *The evolution of sales model in the Indian pharma industry.* Mumbai: IMS Consulting Group.

Varca Druggist and Chemist case. (2009). Varca Druggist & Chemist and others vs Chemist and Druggist Association, Goa (MRTP Case No. C-127/20091DG1R4/28).

Vedant Bio Sciences case. (2012). Vedant Bio Science vs Chemist and Druggist Association of Baroda.

Wang, J., & Chow, S.-C. (2012). On the regulatory approval pathway of biosimilar products. *Pharmaceuticals*, *5*(4), 353–368.

Weekly Notes. (1964). Unused patents. *Economic and Political Weekly*, *16*(21), 42.

Yes Bank–ASSOCHAM. (2015). The Indian Pharmaceutical Industry: Changing Dynamics & the Road Ahead. Yes Bank and ASSOCHAM. Retrieved 25 May 2017, from https://www.yesbank.in/pdf/the_indian_pharmaceutical_industry_changing_dynamics.pdf

Shamim S. Mondal is a Faculty Member of SVKM'S NMIMS (deemed to be University). Prior to that, he worked at Alliance University, Bangalore as a Faculty Member and at Analysis Group, Inc. as an Associate Consultant after finishing his doctoral studies from University of Rochester, New York. He is an Applied Economist who works in areas of corporate governance, financial markets, economics of regulations, labour market, and pharmaceutical markets. His current research interest centres around aspects of social capital and social network, and their influences on decision-making by individuals.

e-mail: shamimsm@gmail.com

Viswanath Pingali is an Associate Professor in the Economics area at IIM Ahmedabad. His research interests include industrial organization, public policy, and behavioural economics. The sectors he focuses in are pharmaceuticals and electricity. He has a Masters degree in Quantitative Economics from Indian Statistical Institute, Calcutta and a PhD in Economics with specialization in industrial economics from Northwestern University, Evanston, IL, USA. Before joining academics, he had an experience of working as an Antitrust Economist and in the pharmaceutical industry.

e-mail: viswanath@iima.ac.in