

# **Competition Issues in the Indian Pharmaceuticals Sector**

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# Executive Summary

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Most healthcare expenditure in India consists of ‘out of pocket’ spending by patients and their families, and a substantial proportion of this is accounted for by the cost of medicines. Such expenses are directly responsible for households falling into poverty or having to sell assets or incur debts, impairing their standard of living. Inability to afford medications leads to morbidity, lost workdays, and low productivity. The cost and availability of drugs is therefore a key development issue, directly impacted by various government policies that affect the degree of competition.

The market for pharmaceuticals, which is the subject of this study, has several features that require a special kind of economic analysis. Consumer choice is influenced by doctors and pharmacists, who in turn are influenced by the medical representatives and marketing strategies of the producers. This results in the possibility of ‘supplier induced demand’ and market failure. The pharma market is also vulnerable to collusive agreements between producers or along the supply chain, anti-competitive mergers and acquisitions, and abuse of intellectual property rights.

Until 1970, the Indian pharmaceutical market was dependent on imports and dominated by multinational corporations. Drug prices were amongst the highest in the world. The scenario changed dramatically after the Patents Act of 1970 allowed process but not product patents for pharmaceuticals, enabling Indian firms to imitate foreign drugs by making minor modifications to the manufacturing process. In the same year, a new and far more extensive Drug Prices Control Order was promulgated, bringing a swathe of medicines under stringent price controls. The Foreign Exchange Regulation Act of 1973 limited foreign equity ownership to 40% except for products involving high technology. Those firms that were allowed to maintain higher equity stakes were forced to produce bulk drugs in the country rather than rely on imports. Finally, like other industries, domestic pharmaceuticals manufacturing benefited from the highly protectionist trade regime based on high tariffs and stringent import licensing. All these policies were put into reverse gear from the late 1980s. In particular, imports and foreign investment which had been kept at bay were now permitted to increase their penetration of the domestic market, and product patents were reintroduced in 2005 as part of India’s obligations under the WTO TRIPS Agreement.

As a result of these changes, our findings show that imports of pharmaceuticals rose, but exports rose much faster as Indian industry, having reached a certain degree of maturity during its sheltered period, now became a pharmacy to the world. There was a wave of mergers and acquisitions, increasingly involving foreign takeovers of Indian firms. More firms have exited than entered the industry in recent years. Despite these trends, price-cost margins of the industry have been under pressure, and concentration (measured by standard indicators like the concentration ratio and the Hirschman-Herfindahl Index) has fallen, especially after accounting for import competition. However, due to brand-name differentiation and marketing strategies, concentration is high and rising, with widely dispersed prices, at the level of some individual standardized generic drugs. This is quite apart from the exorbitant pricing of patented drugs, especially imports. Price-cost margins in the industry are positively related to firms’ market shares, but negatively to their assets, advertising intensity and research intensity in the same year. The latter two variables, however, positively affect margins with a lag of a few years.

Competition (antitrust) law can address anti-competitive conduct by pharmaceutical producers and distributors. India's erstwhile competition law, the 1969 Monopolies and Restrictive Trade Practices Act was ineffective, but the Competition Act of 2002 has shown more promise since its enforcement began in 2009. In three related recent cases, national and regional associations of wholesale and retail distributors of medicines were found to have been engaging in a range of cartel practices such as limiting the number of stockists in each region; preventing manufacturers from appointing distributors of their choice; refusing to distribute particular products in order to wrest better terms from the manufacturers; and in some cases preventing chemists from giving retail discounts. The Competition Commission of India (CCI) imposed the maximum possible fine of 10% of the associations' turnover. But as this largely comprised their membership fees, it was negligible relative to their members' turnover from selling drugs.

These cases also threw light on the fixation of retail margins by the associations, which they justified by referring to the fixation of retail margins by the government for drugs under price control. This facilitates collusion. It also amounts to resale price maintenance (RPM) with official sanction, although the usual economic arguments in favour of RPM are weak in the case of pharma products. Another possible anti-competitive practice, of manufacturers inducing retailers not to stock rival brands, requires further investigation. Their inducements to doctors to prescribe their brands is really a matter of professional ethics rather than competition law. Requiring greater transparency for drug companies' funding of the medical profession would be a first step.

Sections of the Competition Act that require notification and screening of mergers above specified asset and turnover thresholds were brought into force only in mid-2011, and only six merger applications in the pharma sector have been reviewed since then. All of them have been approved because they did not pose competition concerns. In one case, the CCI forced the parties to modify their non-compete agreement. However, many other mergers in the sector were not reviewed because they fell below the notification thresholds. There is a case for reducing the thresholds for critical sectors like pharmaceuticals, which will be possible only as and when a recently-tabled bill to amend the Competition Act is passed by Parliament.

India has been imposing price controls on bulk drugs and their formulations since the 1960s, although the number of drugs under control has been progressively reduced and the pricing formula made more generous. A major change in the approach has been proposed in the National Pharmaceuticals Pricing Policy (NPPP) 2012. Although it will greatly expand the number of drugs under control, it will cover only formulations. Most importantly, it will shift from the existing cost-based formula for fixing the prices to a market-based approach in which regulated prices will be determined by the average prices of all brands with market shares greater than 1%. There is an ongoing controversy over whether this will raise or lower drug prices and profits, and how manufacturers may evade its impact. There are weaknesses in the arguments of both sides, and many of the problems associated with price controls have not been adequately addressed. However, there is evidence that for many drugs, the range of existing prices and also the putative price under the new control formula are much higher than the competitive price that has been discovered by procurement mechanisms such as that of the Tamil Nadu Medical Supplies Corporation (TNMSC) and the central government's Jan Aushadhi Scheme. The solution therefore lies in unleashing the power of competition rather than in proliferating controls.

Another area of current controversy is the wave of foreign takeovers of Indian pharma companies ('brownfield' foreign direct investment, or FDI), with possibly adverse consequences for competition and research and development. An official committee (Maira Committee) recently reviewed this trend and found no cause for alarm, but recommended that merger proposals be reviewed by the CCI with reduced notification thresholds and greater input of public health expertise. However, the government shortly thereafter decided to route all brownfield merger proposals in the pharma sector through the Foreign Investments Promotion Board, a non-transparent process which the Maira Committee had explicitly advised against.

There is conflicting evidence on whether foreign firms have been acquiring a greater share of the Indian pharmaceuticals market, or whether foreign takeovers have reduced the research and development spending of the acquired firms. However, it does seem that the performance of multinational drug companies is worse than that of their Indian counterparts in regard to investment, R&D and exports.

A further contentious area of debate is the impact of the product patent regime introduced in 2005 to comply with the TRIPS agreement. The evidence suggests that although R&D spending has increased subsequently, the number of patents granted has not. It is therefore not established that strengthened patent protection has stimulated innovation. On the other hand, there are encouraging recent signs of India beginning to use the flexibilities under the TRIPS agreement to attack patent monopolies head-on via compulsory licensing, denial of patents for incremental innovation ('evergreening') or for trying to patent known products, and post-grant opposition suits resulting in revocation of patents that were wrongly granted. Grey areas of the law that are yet to be explored include treatment of patents as essential facilities, which would bring them under the abuse of dominance provisions of the Competition Act, and parallel imports of drugs from other countries where they may be cheaper.

Another encouraging development is the belated revival of manufacturing in public sector units that were sick or closed down. Along with a ramping up of public procurement and distribution, as demonstrated by the TNMSC model and the Jan Aushadhi programme, this could go a long way to alleviating the problem of high costs and poor availability of drugs in India. It would blunt the marketing power of branded generics. Debranding would go even further, but as brands are taken as a signal of reliable quality, this would require much greater enforcement of quality standards under the Drugs and Cosmetics Act to weed out substandard drugs. In the meanwhile, scaling up public procurement along with in-built quality controls mechanisms would address both problems.

On the other hand, a highly anti-competitive and discriminatory policy pursued by the government is its readiness to grant antidumping duties on imports of many essential bulk drugs. Although India's procedures are compliant with the rules of the WTO, these are very weak, especially as regards imports from China for which special rules apply. A recent Supreme Court ruling amounts to ensuring protection of the most inefficient Indian producers. The rules need to be revisited and the interests of consumers taken into account.

In summary, the Indian pharmaceutical sector presents a range of practices that militate against competition. Many of these relate to the behaviour of producers and distributors, but they are in some instances reinforced by government policies. The solutions lie in recognizing the anti-competitive effects of such policies, reforming them so as to minimize the harm to competition

while fulfilling their other objectives, and more actively deploying pro-competition policies in the areas of antitrust enforcement, exploitation of TRIPS flexibilities, and public production, procurement and distribution.

# 1. Introduction

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Healthcare costs in general, and the price and availability of medicines in particular, are deeply implicated in the poor quality of life of millions of Indians. In 2011, according to the latest available data, 69% of total health expenditure in India was financed by private sources, of which “out of pocket” (OOP) expenditure by households comprised 86%.<sup>1</sup> The first figure reflects the low public provisioning of healthcare; the second reflects the low coverage of private health insurance (which funded only about 5% of private health expenditure) and employer-provided medical benefits; both figures are high by even the standards of developing countries. Appropriate adjustment of household consumption expenditure figures compiled by the National Sample Survey (NSS) to take healthcare spending into account would raise the proportion of the population that lies below the poverty line (Gupta 2009). Even for households above the poverty line, spending on healthcare is a major cause of falling below it: as evocatively captured in the title of a recent book, people are only “one illness away” from poverty (Krishna, 2010).<sup>2</sup>

The proportion of OOP health expenditure that is spent on medicines is not reliably estimated. According to a 2004 NSS household survey on health, it accounted for 63 per cent of outpatient expenses and 25 per cent of hospitalization expenses, while the consumer expenditure survey (CES) later the same year reported figures of 82 and 41 per cent, respectively.<sup>3</sup> In the 2009-10 CES, expenditure on drugs accounted for over two-thirds of households’ OOP expenditure, rising to three-fourths for the poorest 20% of households (Selvaraj and Karan 2012, Table 3). A field survey of only poor households in five different locations in India, conducted by a group of researchers in 2005, found that drugs accounted for 49 per cent of OOP healthcare spending, with the rest being distributed between tests, consultations, and hospitalization expenses. Expenditure on drugs was much lower when treatment was obtained from public or charitable providers as compared to private providers. But between 88 and 99 per cent of respondents across locations still reported that they relied on private providers for drugs, and these figures were significantly higher than those reporting that they had accessed private providers for hospitalization or consultations. In other words, patients relied on private providers for drugs even when they used the relatively low-cost providers for the other components of treatment (Dror et al, 2008). All this evidence strongly suggests that drug prices are directly implicated in poverty.

The seriousness of the problem goes beyond poverty as conventionally measured. All these calculations are based on households’ reported spending on healthcare, which could have diverted their purchasing power from other important expenditures, such as nutrition and education, which would impair the future earning ability of their members. If they sell productive assets or go into debt to finance healthcare expenses, this too could have a long-term impact on their spending. To the extent that they could not afford treatment, their earning ability would be compromised by premature mortality as well as avoidable morbidity, resulting in workdays lost and low productivity at work. Drug pricing and availability is therefore important from both the rival perspectives of what constitutes development. From the ‘instrumental’ perspective, it impairs India’s human capital and

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<sup>1</sup> <http://apps.who.int/nha/database>, viewed 25 April 2013.

<sup>2</sup> See also Berman et al (2010).

<sup>3</sup> Ibid, Table 1.

labour productivity, with adverse consequences for output, competitiveness and growth. From the perspective of the ‘capabilities’ approach, it impairs the ability of its people to achieve ‘functionings’ that they value, in particular their ability to lead a long and healthy life.<sup>4</sup>

### *The economics of the market for pharmaceuticals*

The pharmaceutical sector is, perhaps uniquely, an industry in which the normal processes of competition do not work in a textbook manner. On the demand side, apart from standard over-the-counter medicines, we do not have individual consumers exercising their freedom to choose between competing products, based on their features and relative prices. Although the exact chemical composition of medicines is mandatorily printed on the packaging, most consumers are not qualified to understand the pharmacological properties of these ingredients. Drugs cannot therefore be regarded as ‘search goods’, whose relevant characteristics the consumer can assess before purchase. Nor are they ‘experience goods’, whose characteristics the consumer can determine after consumption, given that their effects may not be evident for a long time (e.g. treatments for tuberculosis); may be preventive rather than curative, so their effect cannot be observed (e.g. vaccines and micronutrient supplements); and even if a particular medication is effective it may not work again even for the same illness, as in the case of drug-resistant strains of bacteria.

Rather, drugs fit into the category of ‘credence goods’, for which the consumer relies on medical advice. To a great extent, therefore, demand is driven by the prescribing behaviour of healthcare providers. For them, drugs may indeed be search or experience goods, but they do not have to pay for them and are not necessarily sensitive to price. The providers may themselves be unaware of the potential outcomes of some drugs, especially new ones. Medical representatives of pharma companies are employed to bridge this information gap, but these representatives themselves may be imperfectly knowledgeable and/or have an incentive to promote the sales of the product without adequate regard to its efficacy or safety. Chemists (pharmacists) may also substitute the prescribed drugs with others that may or may not be equivalent, or may themselves prescribe drugs to patients who are unwilling to go to a doctor. So the final consumers are actually many times removed from the producers. In economic terms, there are multiple layers of asymmetric information, with providers, chemists and medical representatives acting as agents on behalf of the patients (principals). There is therefore the possibility of “supplier-induced demand”. At the same time, many of these products are essential for human well-being, even making the difference between life and death. Consumers are therefore not price-sensitive, and are willing to sacrifice other consumption needs in order to incur healthcare expenses.

There are also significant externalities involved in immunization against communicable diseases. Consequently, the socially desirable allocation of essential vaccines is nearly universal coverage, and cannot be left to individuals deciding how to allocate their budgets. Even if there were no problems of information asymmetry, therefore, the cost and availability of drugs would be a matter of public policy. Moving away from the paradigm of consumer welfare based on individual choice and individual perceptions of well-being, at least some drugs can be regarded as ‘merit goods’, which should be available to all as a matter of basic rights as citizens, regardless of willingness and ability to pay.

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<sup>4</sup> The two approaches are contrasted in Sen (1999).

Although these issues are important even in advanced countries, the situation in India is especially serious due to greater lack of awareness, information and education amongst consumers; the limited coverage of health insurance; the relative absence of large, well-informed and cost-conscious institutional purchasers (whether public or private) who can exercise countervailing power against suppliers; and weaknesses in the regulatory framework.

On the supply side, the pharmaceutical industry worldwide is dominated by a handful of firms, with their market dominance reinforced by patent protection (whose scope they continually try to enlarge), mega-mergers, large advertising and marketing budgets directed at the healthcare providers who actually influence consumer 'choice', and a tendency towards collusive behaviour, as demonstrated in multiple high-profile cartel prosecutions of multinational firms, some of whom have been repeat offenders.

Here again, the situation in India is perhaps more serious. The structure of the pharmaceutical sector in India, and the behaviour of market players, suggest that all the major dimensions of competition law need to be brought into play. As pointed out in the pioneering study by Nanda and Khan (2006), there is the possibility of anti-competitive horizontal agreements at the level of producers as well as distributors, vertical agreements between producers and distributors in the supply chain; abuse of dominance arising out of patent protection; and mergers and acquisitions which increasingly involve foreign takeovers of Indian firms. In addition, several other 'flanking' government policies, some unique to the sector, have a significant impact on competition in the pharmaceutical sector. Most obviously, it is perhaps the only sector in which the Indian government still regulates the prices of private producers for a range of products. Significant changes in the scope and methodology of the fixation of drug prices are currently being hotly debated, so it is a major substantive section of our report. Other relevant policies that we cover are those affecting:

- Foreign direct investment
- International trade
- Protection of intellectual property
- Pharmaceutical quality standards
- Public procurement, production and distribution.

The Indian pharmaceutical sector is therefore a very suitable subject for a competition impact assessment exercise of government policy. This project report consists of three inter-related parts. We first describe how the policy environment conditioned the evolution of the Indian pharmaceutical industry over the last half century. This is followed by a statistical analysis of the market structure of the pharmaceutical industry over the last two decades, based on standard measures of concentration, entry and exit, and the relationship between profit margins and concentration. We then try to identify the anti-competitive practices prevailing in the Indian market for pharmaceuticals, and their relationship to government policies, by reviewing (a) the limited literature on the subject, and (b) all pharma-related cases decided by the Competition Commission of India since it began enforcing the Competition Act in 2009. We also undertake a detailed analysis of the flanking policies listed above. Finally, we evaluate these policies on the basis of our findings, using the OECD Competition Assessment Toolkit as adapted by the Consumer Unity and Trust Society (CUTS).



## 2. The Policy Framework and Evolution of the Industry<sup>5</sup>

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Prior to 1970, the Indian pharmaceuticals industry was relatively small in terms of production capacity. At the time of Independence in 1947, India's pharmaceuticals market was dominated by MNCs (multinational corporations) that controlled between 80 to 90 percent of the market primarily through imports. Foreign companies held the patents for almost all pharmaceutical products in India under patent, and the drug prices in India were among the highest in the world (Greene, 2007). The pharmaceuticals market in India remained import-dependent through the 1960s until the government initiated the policies aimed at self-reliance through local production. At that time, 8 out of the 10 top pharmaceutical firms in India (ordered in terms of sales) were subsidiaries of MNCs. To facilitate independent supply of pharmaceutical products in the Indian market, the government funded five state-owned pharmaceutical companies and several national laboratories which developed process technologies that were transferred to domestic private sector drug manufacturers.

Since the industry was largely under the control of MNCs with very few domestic players, huge dependence on imports and very high prices of drugs, the government felt the need to regulate the industry. The structure of the industry has been dynamic and has evolved following the various regulatory changes. To end the dominance of foreign drug companies, the Indian government followed a series of policies to make the country self-sufficient and improve the affordability of drugs. The patent laws were amended, price controls on essential drugs were imposed, there were limits on foreign companies under the Foreign Exchange Regulation Act (FERA), and restrictions on imports. We briefly describe these measures below in order to provide the necessary background for our discussion of market structure. Detailed analysis of more recent developments is undertaken in later sections.

### *Patents Act 1970*

One of the most important regulations in the pharma industry across the world is related to the patent laws. Patents are important for incentivising research and development that is crucial for the pharma industry. However, a patent gives its owners the monopoly rights over the molecule. The Patents Act 1970 formed the centrepiece of a new policy regime that had the explicit purpose of promotion of a self-reliant indigenous drug industry. This may be called the turning point for the industry. Prior to 1970, India recognized both process and product patents. With the Indian Patents Act (IPA) of 1970, the product patents were disregarded and only process patents were recognized for a period of 5 years after the grant of patent or 7 years after the date of filing for patent, whichever was earlier. So now the pharma companies could produce even the patented drugs following a different process. The companies simply reverse engineered the drugs, tinkered with the process slightly and came out with equivalent drugs that were much cheaper than the originals. The

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<sup>5</sup> This section is based on Chaudhuri (2005), Sampath (2005), Greene (2007) and IEG (2010).

companies didn't do much R&D except for reverse engineering. The industry became largely self-sufficient following the 1970 IPA.

There was growing unrest in the developed countries of Europe and US about the weak patent laws in the developing countries and how that led to little or no appropriation for their innovations. They asked for stricter patent regimes to protect their innovations and they were successful in implementing Trade Related Intellectual Property Rights (TRIPS) in all the WTO member countries as part of the Marrakesh Agreement of 1994 which set up the World Trade Organization (WTO). India and other developing countries were given ten years to make various changes in its patent law to bring them in line with TRIPS by January 2005. In India the IPA 1970 has been amended thrice since. The first amendment was in 1999 which introduced mailbox provisions to receive product patent applications; exclusive marketing rights (EMRs) were made retrospective from January 1, 1995. The second amendment in 2002 extended the term of patent to 20 years, imposed the burden of proof on the infringer as opposed to the patent holder, along with changes in the provisions governing compulsory licensing. The last amendment in 2005 finally recognised product patents as well. These changes encouraged significant numbers of foreign pharmaceutical companies to participate in the Indian market and, in 2005 foreign drug producers filed approximately 8,926 patent applications to cover their patented drugs sold as generics in the Indian market.

Opponents of TRIPS believe that the strict patent law regime will again see the dominance of foreign MNCs in India, more consolidation of firms, acquisitions of Indian firms by the foreign players, hence higher prices and lower competition. However many feel that the Indian pharma industry has achieved self sufficiency following the policies led by the government, and therefore India was set to embark on a product patent regime and move up higher in the value chain of innovation and produce new chemical entities. But many still feel that only foreign MNCs and the big Indian pharma companies can undertake innovation while the small and medium firms will be either acquired by the larger ones or will be shut down owing to the stricter patent laws and tough competition from the foreign MNCs. On the other hand, it is argued that as many products are going off patent, fewer drugs are granted patents, and flexibility is provided under TRIPS like compulsory licensing etc, even the small and medium firms can find their way. These issues will be discussed in the section on TRIPS.

### *Price Controls*

Also in 1970, the Drugs Price Control Order (DPCO) was substantially revised. The DPCO is an order issued by the Government, under Section 3 of the Essential Commodities Act, 1955, empowering it to fix and regulate the prices of essential bulk drugs and their formulations. The order incorporates a list of bulk drugs whose prices are to be controlled, the procedure for fixation and revision of prices, the procedure for implementation, the procedure for recovery of dues, the penalties for contravention, and various other guidelines and directions. The order is subject to the guidelines of Drug Policy and supposedly aims to ensure equitable distribution, increased supply, and cheap availability of bulk drugs. It played a vital role in directing the pharmaceutical industry's fortunes. The order was a landmark regulation and has had several implications in shaping the Indian pharmaceuticals industry (Gouri, 2009). The DPCO also impacted the interests of the foreign firms rather badly. While the weak patent law was making it tough for the foreign MNCs to operate in the

Indian market, the drug price controls added to their difficulty by limiting their prices and profits for the drugs that came under DPCO.

The DPCO 1970 was revised in 1979 on the recommendations of the Hathi Committee. The revised DPCO stipulated ceiling prices for 370 bulk drugs and their formulations, covering about 80% of the Indian pharmaceutical market. However, as we shall show in our section on price control, the coverage was steadily reduced in subsequent DPCOs and the principle of price fixation made more favourable to the producers. While the DPCO was being revised, the Patents Act continued to prohibit product patents until 2005. The relaxation of DPCO could have acted as an incentive for the foreign MNCs but the weak patent law regime acted as a major impediment for them. These changes brought major differences in the market structure from being largely dominated by the MNCs to being dominated by the domestic companies.

### *FERA related Restrictions*

The Foreign Exchange Regulation Act, 1973, in conjunction with the New Drugs Policy of 1978, also had a far-reaching impact on the Indian pharmaceuticals sector. Foreign companies producing only formulations or bulk drugs not involving 'high technology' were forced to reduce equity in their Indian subsidiaries to 40% or below. The FERA companies (those with more than 40% equity) were required to supply at least half their output to non-associated formulators, and to produce bulk drugs and formulations in the ratio of 1:5 by value. So, the MNCs were not allowed to market formulations unless they produced bulk drugs in the country. The ratio was reduced to 1:4 in 1986.

The regulation requiring multinationals to produce bulk drugs domestically was abolished in 1994, as was the requirement to supply bulk drugs to non-associated formulators. Foreign equity upto 100% through the automatic route was allowed from 2001. The consequences of these changes will be discussed further below.

### *Trade Policy*

For decades, India was a highly protected economy, with high tariff duties and cumbersome import licensing procedures insulating domestic producers from foreign competition. These barriers have been substantially dismantled since 1991, subjecting Indian industry to global competition. Liberalization actually began somewhat earlier for pharmaceuticals, at least in terms of import licensing. It was one of the very few sectors where the 'import coverage ratio' (share of imports subject to licensing) declined during the 1980s (Das, 2003, p.27). Import licensing was scaled back for most capital and intermediate goods during the 1990s as part of the liberalization initiated in 1991, but retained for consumer goods until India had to abolish the remaining restrictions in 2000-01 after losing dispute settlement cases at the WTO. The pharmaceuticals sector, which straddles both intermediate goods (bulk drugs) and consumer goods (formulations), was again in the forefront, with its import coverage ratio falling to nearly zero even in the 1990s (ibid).

At present, almost all pharmaceutical products (corresponding to ITC(HS) classification code 30) are freely importable, subject to a standard rate of customs duty of 10%, countervailing duty of 16%, special countervailing duty of 4%, and educational cess of 3%. The last three match the duties payable by domestic producers, so they cannot be regarded as discriminatory and anticompetitive.

Under the South Asian Free Trade Agreement (SAFTA), there is a preferential basic rate of 8% for imports from Pakistan and Sri Lanka, and zero from the other SAFTA members (Bangladesh, Bhutan, Maldives and Nepal). However, many antibiotics are on the negative list for Pakistan and Sri Lanka, meaning that they have to pay the standard rate. As the other SAFTA members are unlikely to have manufacturing capacity, this essentially prevents Pakistani and Sri Lankan antibiotics from getting favoured treatment.<sup>6</sup> Also, imports from SAFTA partners are subject to Rules of Origin which require substantial processing in the exporting country<sup>7</sup> to ensure that other countries do not route their exports so as to obtain preferential rates.

There are also some non-tariff barriers in place. All pharma imports are subject to Sanitary and Phytosanitary Standards as laid down in the Drugs and Cosmetics Act, and a few specified drugs require the manufacturing premises of foreign drug manufacturers and the individual drugs to undergo registration and licensing by the Drug Controller General of India prior to import.

The standard customs duty rates are somewhat misleading, because India is the world's most active user of anti-dumping duties (ADD). These are additional duties which are imposed on exporters who have been found to have been engaged in 'dumping'. The issue is directly contradictory to basic competition principles, so it deserves detailed treatment in a separate section below.

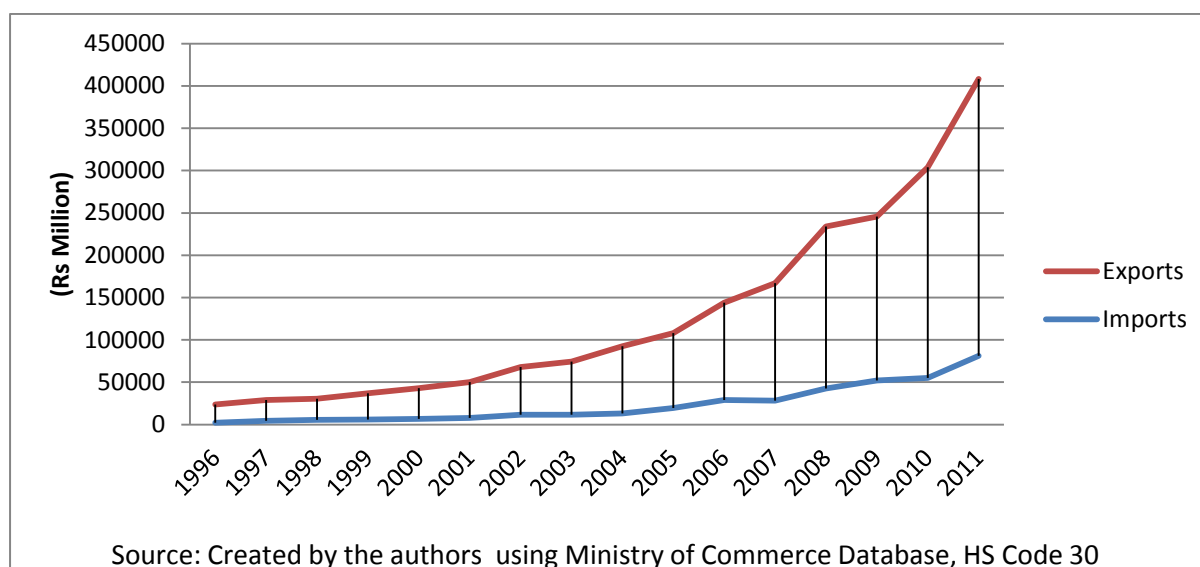
On the export side, the growth of indigenous manufacturing capacity and R&D which was encouraged by a lax patent regime allowed India to become a major pharma exporter, to the extent that the country is sometimes described as a 'pharmacy to the world'. As shown in Fig. 1, exports have continued to grow rapidly in recent years, despite stronger patent protection, as many drugs have gone off-patent in developed-country markets and rising healthcare costs have prompted national health systems to source drugs from India. Although export performance is not the subject of this study, the growing trade surplus in pharma products may have an impact on domestic competition by diverting output away from the domestic market. However, as we shall show with some calculations below, this fear is unfounded.

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<sup>6</sup> <http://compendium.iift.ac.in>, viewed 3 January 2013.

<sup>7</sup> The basic principles are that (a) the exported commodity must have a 4-digit HS code different from those of all the inputs used in its manufacture that do not originate from that country; (b) such inputs must not constitute more than 60% of the FOB value of the exported product; (c) the final stage of processing must be undertaken in the exporting SAFTA country.

FIGURE 1



### *Regulation of Mergers and Acquisitions<sup>8</sup>*

In this section, we discuss developments during era of the MRTP Act, especially the twenty years (1991-2011) in which India did not regulate mergers from the perspective of either concentration or competition. We deal with merger review under the Competition Act in section 3.3 below.

The old Monopolies and Restrictive Trade Practices Act of 1969 required so-called ‘MRTP companies’<sup>9</sup> to obtain prior government approval for mergers, amalgamations and takeovers (as well as for establishment of new undertakings and substantial expansion of old ones). The objective was to control the concentration of economic power rather than to protect competition. But this chapter of the MRTP Act was very patchily and arbitrarily enforced: the list of MRTP companies had substantial omissions,<sup>10</sup> and especially after the first few years, merger applications were decided by the government without referral to the MRTP Commission. Competition assessment did not appear to be the basis for granting or refusing permission. The relevant sections of the Act were deleted by an amendment in 1991, which triggered an upsurge of mergers across sectors, with the activity within each industry being concentrated in a window of two or three years, as is characteristic of merger waves in many countries (see Agarwal and Bhattacharjea, 2006, and other literature cited there).

<sup>8</sup> The distinction between these two terms is largely legalistic: a merger involves at least one participating firm losing its identity, while in an acquisition control of one firm passes to (the owners of) another while the acquired firm continues to exist. From the perspective of competition policy, however, both involve a larger share of an industry’s assets and sales coming under common control, as well as possible efficiency gains, so we use the term ‘merger’ to include both.

<sup>9</sup> These were firms that, along with their interconnected undertakings, had assets or market shares exceeding certain specified thresholds.

<sup>10</sup> Many companies escaped either because product categories were defined broadly for computing market shares, or a company could be connected with others in a business group such that their combined assets exceeded the threshold, but complex patterns of inter-corporate shareholdings made it almost impossible for the government and MRTP Commission to establish interconnection (Oza, 1971; Chandra, 1977).

Compilation of a comprehensive database on mergers in India is a problem that has plagued several researchers, but from three different studies using different datasets we can get a composite picture of acceleration of merger activity in the pharma industry. Both Agarwal (2002) and Kaur (2012), as well as the Prowess data used for our study (see Figure 2 below), show that the industry was relatively late in joining the 1990s merger bandwagon; the frequency of mergers (measured by the number of mergers per year) remained largely unchanged to begin with. For the period 1990-2012, a total of 364 M&A deals took place where the pharma companies were acquirers. Out of these 56% of the deals took place in the Post TRIPS period. A total of 551 deals took place where the pharma companies were the targets. 46% of these deals happened in the Post TRIPS period.

**FIGURE 2**



Source: Own calculations using Prowess data

Both Kaur (2012, p.247), with data from 1990-2005, as well as our compilation of Prowess data over 1990-2010, show a sharp acceleration in the number of mergers per annum after 2000. Agarwal's study, which covers 1973-2000 and uses several other supplementary sources of information, documents more mergers in the period which overlaps with ours and shows that the upturn began in 1997 (Agarwal 2002, p.83). There is no doubt, however, that pharma mergers have become more frequent after the turn of the century. All three sources suggest that the majority of mergers involving pharma firms have involved other pharma firms, i.e. they have been horizontal mergers. Kaur's study also shows that only about 30-35 firms were involved in more than 100 of the 109 mergers that occurred during her sample period. In other words, some firms engaged in multiple mergers.

As shown by Kaur (2012) in her detailed analysis, at least for the period up to 2005, mergers in this sector displayed contradictory and even paradoxical patterns. Bigger, less leveraged and more profitable firms tended to acquire smaller, more leveraged and less profitable firms. But the acquiring firms were not all large firms. They actually exhibited lower productivity (measured by the ratio of sales to net assets) and sales growth as compared to the acquired firms, whose lower

profitability was attributable to their higher interest burden on account of greater indebtedness. Acquiring firms were more profitable and productive than other firms of similar size that did not engage in mergers, and they were less debt-burdened. Acquired firms tended to be more productive and profitable (before interest payments), but more highly indebted, than non-acquired firms of similar size. Higher indebtedness, therefore, explains both the likelihood of being acquired as well as the inability to engage in acquisitions, and mergers in the pharma sector appear to have been driven by a desire to exploit financial synergies.<sup>11</sup> Consequently, most mergers were 'friendly'. These findings are relevant to the revival of merger review under the Competition Act, which we discuss in section 4 below.

### *Regulation and Business Strategies in the Indian Pharmaceutical Industry*

The combined effect of the Indian Patents Act, FERA, the high degree of import protection, and the drug pricing regime was to give a tremendous boost to the Indian pharmaceutical industry.

In the year 1970, the domestic sector was virtually non-existent, with 15% of Indian firms as against 85% foreign firms in the local market. In terms of retail sales value, in 1970, only two firms in the top ten firms were Indian and the rest were subsidiaries of multinational companies. This ratio of 15% Indian firms to 85% foreign firms in 1970 grew to 50% each of Indian and foreign firms by 1982, which further increased to 61% Indian firms versus 39% foreign firms by the year 1999 (OPPI, 2000). Of the top 10 firms in 2001, eight were Indian firms and only two were subsidiaries of multinational companies (Sampath, 2005).

The IPA 1970, DPCO 1970 and FERA 1973 had an important influence on the Indian pharma industry. The interests of the foreign companies were hampered and they were slowly losing interest in the industry. Lanjouw (1997) points out the impact of IPA 1970, "As a result, the number of patents granted per year fell by three-quarters over the following decade, from 3,923 in 1970-71 (of which 629 were to Indian applicants, 3,294 to foreign applicants) down to 1,019 in 1980-81 (349 Indian, 670 foreign). Although all inventors were affected by the weakened patent regime, it is clear that foreigners, in particular, no longer found taking out a patent in India worthwhile." The weak patent regime therefore was a disincentive for the foreign MNCs to operate in India. The impact of the weak patent law was seen in reality also, "when the Order came into force, multinational companies operating in India lost interest in expanding their operations in the Indian market, which included R&D efforts, due to the low profit margins involved (ibid). The local industry on the other hand, was quick to take cue from the flexibilities contained in the Patent Act: they developed extensive skills in chemistry-based reverse engineering which forms the core of their product and process development skills until today." (Sampath 2005).

As the country has embarked on the new patent law regime, with concurrent liberalization of industrial, trade and price control policies, the industry is experiencing major changes. There is consolidation in the industry in the form of mergers, acquisitions, joint ventures, contract research and manufacturing etc. The foreign companies are acquiring the leading Indian companies. Ranbaxy's acquisition by Daichii, Piramal's acquisition by Abbott, and Dabur's acquisition by Fresenius Kabi Oncology Ltd. are just a few examples where the leading Indian pharma companies

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<sup>11</sup> Acquiring firms obtain tax benefits by taking on the debt burden of acquired firms.

have been acquired by the foreign companies. “Many of the world’s leading pharmaceutical companies have subsidiaries or other operations in India. Multinational companies like GlaxoSmithKline (GSK) Baxter, Aventis, Pfizer, Novartis, Wyeth, and Merck have been active in India’s pharmaceutical market mainly through subsidiaries. The reintroduction of product patents precipitated the return of a large number of other MNCs, some of whom left during the process patent era. MNC pharmaceutical companies have also been attracted by tax holidays, the deduction of capital R&D expenditures, and other financial incentives offered by the Indian government” (Greene 2007). These developments have been analysed in more detail below in the sections on combinations and foreign investment. As a prelude, we provide a statistical overview of aggregate trends in the industry over the past decade. India’s total value of production of bulk drugs and formulations with their rate of growth is given in the following table:

Value of Production (Including Exports) of Bulk Drugs and Formulations	Bulk Drugs	Growth (%)	Formulations	Growth (%)2
				(Rupees in Crores)
Year				
2001-02	5439	19.7	21104	15
2002-03	6529	19.3	24185	14.8
2003-04	7779	19.14	27692	14.5
2004-05	9249	18.9	31685	14.4
2005-06	10635	15	38022	20
2006-07	12125	14	45626	20
2007-08	13822	14	54751	20
2008-09	15204	10	66796	22
2009-10	17487	15	83495	25
2010-11	17894*	15.2	98691*	18.1
2011-12	20936*	17	112014*	13.5
Source: IDMA Annual Publication 2012				
* means estimated				

The growth rate of the value of bulk drugs decreased till 2008-09 and picked up later on. Since the figures are in terms of value and not output, we cannot distinguish between increases in quantities or prices. The growth rate of the value of formulations increased till 2009-10 and then fell in the later years. Overall, the value of bulk drugs has been less than that of formulations. It should be kept in mind, however, that these are figures for domestic production only. The actual availability of drugs would be supplemented by imports but reduced by exports, both of which as shown above have been increasing in recent years. We try to account for all these trends in the following section.



### 3. Indicators of Market Structure

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We have closely analysed the market structure of the pharma industry in India, as reflected in the number of firms, their relative sizes, size of the largest firms, the concentration of firms in the industry, price cost margin, barriers to entry, the pattern of entry and exit of the firms, import competition, export intensity, the merger and acquisition activities, amount of foreign inflows in the industry, the composition of players (domestic and foreign), research and development activity, advertising and marketing activities etc.

According to the First Pharmaceutical Manufacturing Census of India, reported in the *Annual Report of the Department of Pharmaceuticals 2010-11*, there were 10,563 pharma manufacturing units in India, comprising 8174 producing formulations and 2389 producing bulk drugs. However, according to the Annual Survey of Industries 2010-11, the number of operating factories under the corresponding industry code 21 ('Basic Pharmaceutical Products and Pharmaceutical Preparations') was only 3957.<sup>12</sup> The ASI covers only units in the 'organized' sector (those employing ten or more workers with power), so this lower figure could mean that a large number of the units covered by the Pharmaceutical Manufacturing Census were either in the unorganized sector (employing less than ten workers) or were not operational. Both figures would, of course, overstate the degree of competition, as (a) a firm (ownership unit) may own or control several manufacturing units; (b) formulations and bulk drugs do not compete in the same market. In fact, within each category, competition is within distinct therapeutic segments and within particular classes of medications that are imperfectly substitutable for each other. We try to take both issues into account in the following analysis.

We deal with the first issue by using firm-wise data for sales and merger activities, using the widely-used CMIE Prowess database. It is important to be clear about the strengths and limitations of this database. It is compiled from the annual audited profit and loss statements and balance sheets from the National Stock Exchange or the Bombay Stock Exchange. Prowess also attempts to cover unlisted companies (public or private) on a best-effort basis. It does not cover private limited companies whose annual reports are not publicly available, or small business enterprises that do not prepare any audited accounts at all. Further, inclusion of a company in the database simply means that it was the first year for which CMIE could obtain data, not that it was formed or began its operations in that year. Similarly, a gap in the series for a company could mean that data were unavailable for that year, not that the company had no sales.

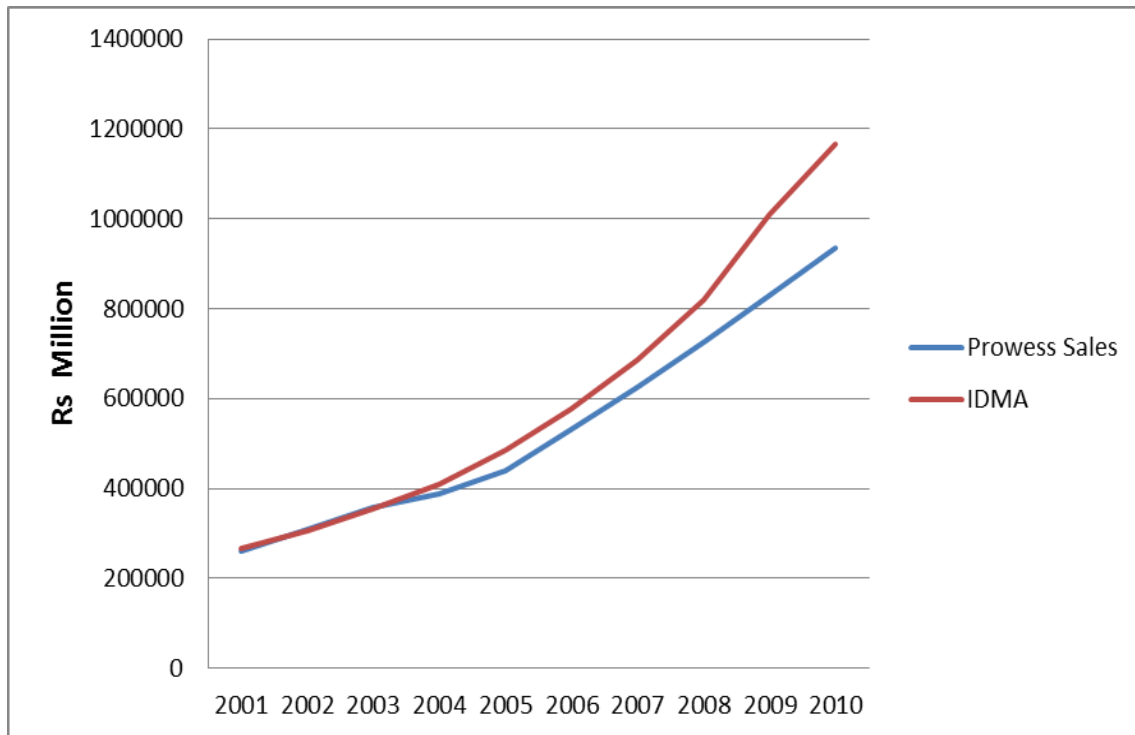
Although Prowess covers only about 600 pharma manufacturers in India, these are the relatively larger firms. Although they contribute a declining share of the industry's sales, their contribution has been over 80% in recent years. We arrive at this figure by comparing the total sales of the Prowess firms with total industry production<sup>13</sup> as reported by the latest (2012) Annual Publication of the Indian Drugs Manufacturers' Association (IDMA). The divergence is illustrated in Fig 3, and we take it into account in the measures of market concentration that we compute below.

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<sup>12</sup> Ministry of Statistics and Programme Implementation, Central Statistics Office, *Annual Survey of Industries 2010-11: Summary Results for Factory Sector*, Statement 5A, p.27.

<sup>13</sup> We are taking production as a proxy for sales. As both figures include exports, the difference would be net changes in inventories, which should wash out over a number of years.

FIGURE 3



There is massive heterogeneity in size even amongst the Prowess firms. The Indian pharmaceutical industry's typical feature is extreme fragmentation with concentration at the top. That is, it comprises a very large number of small firms and a small number of large firms. The market share of even the largest firms is about 9%, calculated at the industry sales level. This might suggest that the industry is fairly competitive, but such a conclusion is flawed. This is because the actual competition takes place at the level of therapeutic segments. In a particular segment, there might actually be high concentration of a few firms. We shall attempt to analyse this phenomenon with the very limited data available at the level of specific drugs. However, we begin our analysis with aggregate data at the industry level.

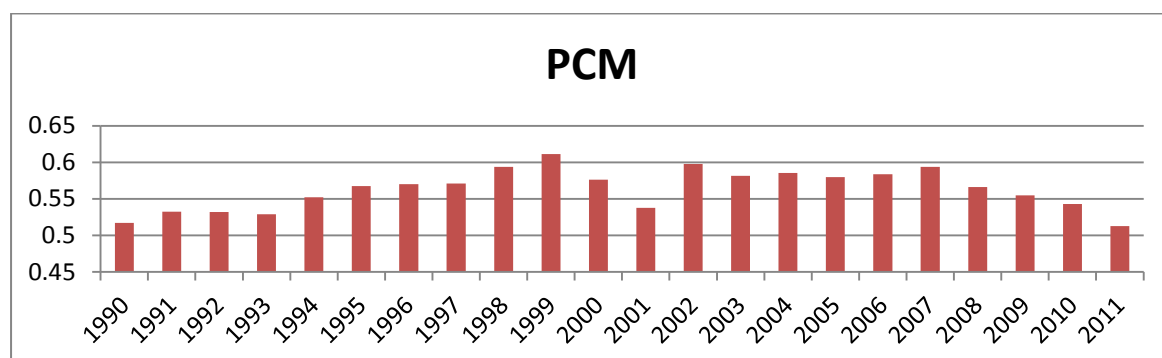
### 1) Price-Cost Margin

Price-cost margin (PCM) is the difference between price and marginal cost as fraction of price. It is usually taken as an indicator of market power because the larger the margin, higher is the market power. It is defined as  $(P-c)/P$ , where  $P$  is the price per unit and  $c$  is the average cost per unit. For calculating it for a firm or for the industry as a whole, it is difficult to compute it in the above fashion because firms produce multiple products. In the literature on PCM, it is computed as follows:

$$\frac{[\text{Value of output} - \{\text{Salary and Wages} + \text{Expenditure on Materials} + \text{Expenditure on Power}\}]}{\text{Value of Output}}$$

As such, PCM is also a measure of profitability. We have calculated PCM at the industry level for the period 1990-2011 for the pharmaceutical firms in the Prowess database. The range of PCM is 0.51 to 0.61 and the average is 0.56. There appears to be a declining trend in recent years, which could be on account of more competition, either from new entrants or from imports, or to a general decline in demand, or regulatory changes. We assess these possibilities below.

**FIGURE 4**



## 2) Concentration

Concentration measures give an insight about the competition in an industry. The higher is the industry concentration, the lower is the level of competition and we expect a small number of firms to control the market. Economists rely on the market shares of the firms to arrive at concentration indices. The most commonly used concentration indices are the Hirschman-Herfindahl Index (HHI) and the four firm concentration ratio (CR4). While the former adds the square of market shares of all the firms in the industry, the latter adds the market share of the top four firms, ranked on the basis of sales or market share. The HHI ranges from close to zero for a highly fragmented industry with many small firms, to 10,000 for a pure monopoly. Similarly, the CR4 ranges from close to zero to 100.

As part of her study on mergers, Kaur (2012, pp.318-24) calculates the HHI for pharmaceuticals using Prowess data and shows that it declined considerably during the 1990s and then rose somewhat during 2000-2004, due to almost no entry and an upsurge in merger activity. She shows that this is mirrored by similar trends in the combined market share of the top four firms in the industry (CR4), but not for the next eight firms. This indicates that the increase in concentration in the more recent period is attributable to the enlargement of market shares of the top four firms. However, she argues that the composition and ranking of the 12 leading firms (in terms of sales) changed considerably over the period, and interprets this as a sign of healthy competition. Using somewhat more recent Prowess data going up to 2007, but only for those pharma firms quoted on the Bombay Stock Exchange, Mody et al (2011) also found a sharp decline in the HHI during the 1990s, followed by an equally sharp increase in the 2000s.

However, domestic competition is also affected by the level of imports in an industry, and by the presence of domestic producers not covered by Prowess. We try to allow for both these important

competitive influences. Import penetration ratio reflects the dependence on imports for domestic consumption of a particular commodity. It is calculated as follows:

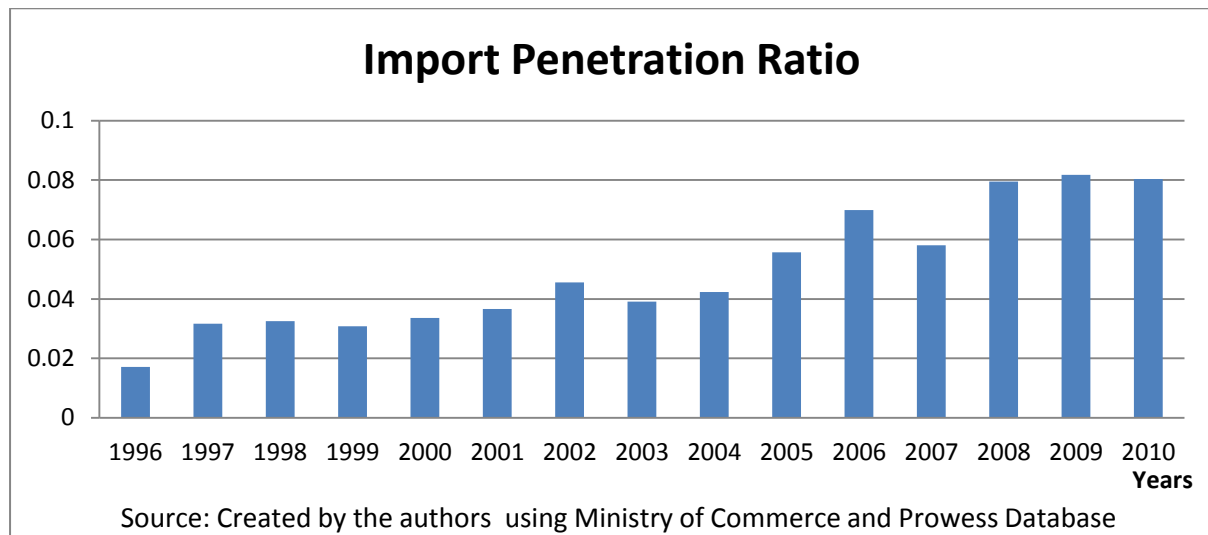
$$\frac{\text{Imports}}{\text{Domestic Consumption}}$$

where

$$\text{Domestic Consumption} = \text{Total Sales} - \text{Exports} + \text{Imports}$$

We have computed the import penetration for the period 1996-2011. Data on imports and exports are available from Ministry of Commerce and Industry, Department of Commerce, GOI for years after 1996. Import penetration has increased significantly from 1% in 1996 to as much as 8% in 2008-2010. The graph below shows the trend of import penetration ratio.<sup>14</sup>

FIGURE 5



The level of both exports and imports of pharmaceuticals are rising in the industry; exports are growing faster than the imports, leading to a trend of increasing net exports as shown in Fig. 1. While exports from India have an impact on the competition in the importing country's market, imports into India increase competition in the Indian market. Since the domestic consumption adds net imports to the total sales, and the net imports are negative for the industry, domestic consumption decreases on account of net imports. Market share of the  $i^{th}$  firm adjusted for trade (imports and exports) is therefore given by:

<sup>14</sup> This is necessarily a rough approximation. In the numerator we have included only imports under HS code 30 (pharmaceutical products). Many bulk drugs are classified under HS 29 (organic chemicals) but cannot be separated out. In the denominator, we have data only on sales of the Prowess firms, as we do not have data on the sales of the non-Prowess firms going back to 1996 when the trade data commences. However, as Figure 3 shows, the discrepancy becomes noticeable only after 2004, so relying on Prowess alone is not too inaccurate for earlier years. While the first approximation would bias the estimated import penetration ratio downward, the second would bias it upward.

$$MS_i^{trade} = \frac{Sales_i - Exports_i}{Total Sales + Total Imports - Total Exports}$$

When we thus adjust for trade, the persistent excess of exports over imports for the pharma sector will reduce the denominator of the market share. But the numerator with trade is also smaller than the one without trade. So the net effect is ambiguous. We try to calculate the effect of adjusting for trade. However, this adjustment can only be done from 1996 onwards, as trade data are available on a consistent classification only thereafter.

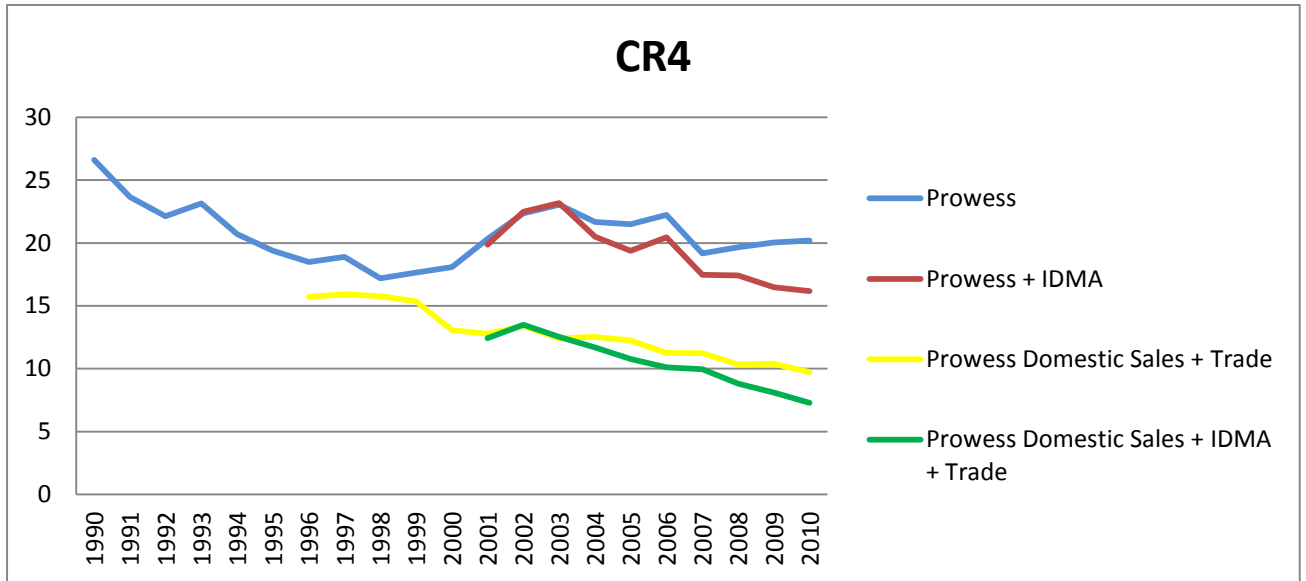
Determining market shares only from Prowess data also misses out on competition from the non-Prowess firms, which as Figure 3 shows have been steadily expanding their market share. Even though they still contribute less than 20% of sales in recent years, and are likely to be relatively small, they would constitute a ‘competitive fringe’ for the larger producers, and should not be ignored. We have tried to incorporate them into the denominator of the CR4 measure by replacing the aggregate sales of the Prowess firms with total industry production as reported by the IDMA Annual Publication. The IDMA does not provide firm-wise data. But as the top firms are listed with Prowess, there are reasons to believe that the top 4 firms in the industry will also be the top 4 firms according to the Prowess database. Therefore we can pick up the top 4 firms from Prowess and divide their sales by the IDMA’s production figures to get a more realistic picture of the market shares, as the market shares based on just Prowess database will be overestimated. So we have calculated CR4 using the Prowess Sales in the numerator and IDMA’s production figures in the denominator. However, IDMA data are available only from 2001 onwards. To summarize the data being used:

- Firm level sales data for 616 firms in the Indian pharmaceutical industry is taken from CMIE’s Prowess database. Data has been taken from 1990-2010.
- Total industry production as reported by IDMA Annual Publication, which has production data for bulk and formulations drugs but doesn’t have the firm level data. It is available for years after 2001.
- Trade data has been taken from the Ministry of Commerce website, for the HS category 30. It is available for years after 1996.

#### *Four-firm concentration ratio*

For comparison, we have depicted the CR4 computed with aggregate sales of the Prowess firms alone as well as with the broader IDMA production total, each one with and without adjustment for net imports. The following graph shows the CR4 with and without adjusting for trade. In two of the four lines the base for calculation for market shares is the Prowess sum of firms’ sales and in the remaining two it is the IDMA production figures.

FIGURE 6



The blue line is the trend of CR4 taking just Prowess' data without any trade. It shows a falling trend after around 2003. The red line uses data from Prowess and IDMA, therefore it is for the years 2001 onwards. It lies below the blue line because the production figures exceed the sales from Prowess figures. It too shows a falling trend after 2003. The yellow and the green lines incorporate the trade data also. The yellow line uses the Prowess data and the trade data, it is therefore for the years after 1996. The green line uses the Prowess data in the numerator and the IDMA data in the denominator and trade data in both the numerator and the denominator. Both show declining trends after 2002. The decline in CR4 is visible in all four measures, but especially in those that account for competition for non-Prowess firms and imports.

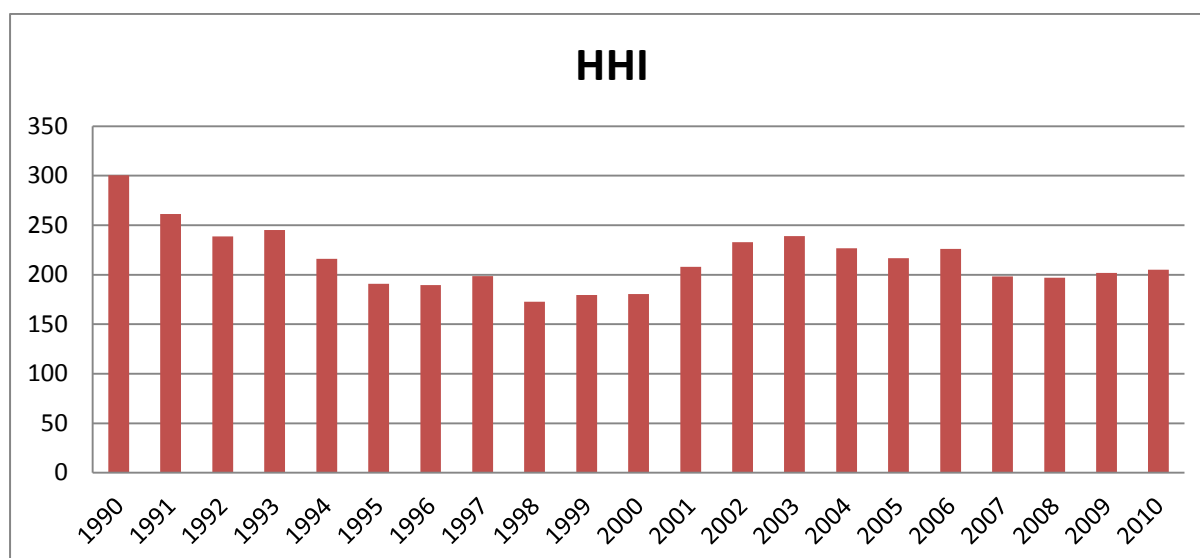
#### Hirschman-Herfindahl Index (HHI)

HHI uses the information about all the firms in the industry. It is calculated as follows:

$$HHI = \sum MS_i^2$$

We cannot make the adjustments using the IDMA production figures or the trade data, because these are not available at the firm level. Therefore, for calculating HHI we can only rely on the Prowess firm level sales data. Even for the Prowess firms, we cannot make the adjustment for trade in the numerator of the  $MS_i$  expression by subtracting the reported export sales from total sales to get domestic sales. It turned out that in many cases, the reported exports exceeded total sales, so we would have obtained meaningless negative figures for  $MS$ . With these caveats, the HHI for the period 1990-2010 for the Prowess firms is presented below. Even the HHI shows a falling trend after 2003 which seems to indicate that competition has increased in the market in the later years.

FIG 7



Whichever figures we use, it appears that both the Herfindahl index and CR4 in the industry are rather low, indicating that the industry is not concentrated. The HHI is well below 300, and would be even lower if we could have accounted for competition from imports and non-Prowess firms. A value greater than 1000 is regarded as indicative of a moderately concentrated industry in the merger guidelines of the United States. The decline in the HHI after 2003 is broadly consistent with the trends shown by all the four CR4 indices in the preceding Figure, despite the very different definition and construction of the indices. All these trends are also consistent with the declining PCMs shown in Figure 4.

However, our concentration measures would underestimate concentration for three reasons. First, concentration ratios should be computed for firms at the same stage of production; if we are interested in competition from the perspective of ultimate consumers, we should use data only on final sales. But as pointed out at the beginning of this section, about a quarter of the manufacturers produce bulk drugs. Even for formulations, many small pharma firms undertake contract manufacturing for larger firms which market the drugs under their own brand names. Although they cannot be identified separately in either the Prowess or IDMA data, these upstream contract manufacturers—which probably belong to the competitive fringe—should not be included in the total sales to consumers, so the concentration measures would be higher than the one we have calculated. Second, we have treated imports as a competitive fringe, whereas we know that increasingly they include very expensive patented drugs, which effectively monopolize their markets. Finally, and related to this, in the pharmaceutical industry actual competition takes place at the level of therapeutic segments which cater to distinct diseases like cardio-vascular, anti-diabetes etc. Even within a therapeutic segment, competition is at the level of a narrower range of drugs for particular conditions. For both reasons, using the total sales and imports of pharmaceuticals provides a very crude measure of competition.

Jha (2007) observed the level of competition for some individual drugs. The following table has been taken from her paper. The first column has the name of the molecules, the second column tells us

the therapeutic segment of the molecule and the third column shows the number of producers of the given molecule. The data has been compiled from the retail formulations data for the month of February 2006 from ORG IMS. All these drugs were sold as off patented drugs since they entered the Indian market before 2005. This is why we see so many producers of the same molecule. Looking at the number of brands we might think that there the market for the molecules is competitive but the last column which gives the four firm concentration ratio is quite high especially for molecules like Ciprofloxacin, quinine, chloroquine and highest for lovastatin. Thus, the markets for drugs are actually concentrated if we look at the four firm concentration ratio at the therapeutic segment.

#### **Extent of Competition in Therapeutic Segments\***

Name of the Drug	Therapeutic Category	No of Brands	Share of Top 4 Brands (Per Cent)
Ciprofloxacin	Quinolones	200	60
Levofloxacin	Quinolones	45	48
Chloroquine	Anti-Malaria	43	93
Quinine	Anti-Malaria	24	85
Rh Adults	Anti-Tuberculosis	63	79
RHEZ FD (Rifampicin +Isoniazid+ Pyrazinamide)	Anti-Tuberculosis	40	70
RHE(Rifampicin +Isoniazid+ Ethambutol)	Anti-Tuberculosis	42	65
Atorvastatin	Statins	75	47
Simvastatin	Statins	25	84
Lovastatin	Statins	15	98

*Note:* \*The drugs categories include all dosages and forms of individual brands.

Source: Jha (2007)

We have attempted a similar exercise with more recent data at the level of specific dosages for individual drugs, while also calculating the Herfindahl index to facilitate comparison with the industry concentration measures above. This solves both the problems of underestimation built into the use of aggregate data which we discussed above: the data is only on final sales, and at the level of individual drugs. We have data on nine formulations which represent one dosage each for the major molecule in their respective therapeutic categories for the years 2005 and 2010 (moving average total upto August). This data has been kindly provided by Shri D.G. Shah of the Indian Pharmaceutical Alliance. We have computed the concentration indices for these nine formulations, clubbing together variants of the same drug produced by the same producer, as they should not be regarded as competing varieties. As these data are compiled from distributors rather than manufacturers, they include imports and the brands of non-Prowess firms, so the adjustments we made to the industry concentration measures are unnecessary.



	Concentration at the Drug Level: 2005				
Therapeutic Category	Molecule	No. of Drugs/Packs	No. of Formulator	CR4	HHI
Anti-infectives	Cefixime Oral Sol. 200 mg	55	51	66.60	1557.03
Cardiac	Atorvastatin 10 mg	61	53	47.68	846.43
Gastro Intestinal	Rabeprazole + Domeperidone 20 mg	25	23	57.70	1370.67
Respiratory	Cough Prep. Ethicals 100 ml	618	212	41.32	641.79
Pain / Analgesics	Diclofenac Combination OS 50 mg	231	136	31.50	430.52
Vitamins / Minerals / Nutrients	Calcium Oral Solids 250 IU	208	134	66.35	1471.19
Anti Diabetic	Human Insulins 40 IU	50	8	97.96	4566.20
Gynaec.	Conv.Iron Liquid 200 ml	126	90	57.89	1122.91
Neuro / CNS	Alprazolam OS 0.5 mg	85	69	76.31	1697.31

	Concentration at the Drug Level: 2010				
Therapeutic Category	Molecule	No. of Drugs/Packs	No. of Formulator	CR4	HHI
Anti-infectives	Cefixime Oral Sol. 200 mg	136	76	49.10	854.22
Cardiac	Atorvastatin 10 mg	87	58	41.59	685.27
Gastro Intestinal	Rabeprazole + Domeperidone 20 mg	91	74	33.23	497.40
Respiratory	Cough Prep. Ethicals 100 ml	582	205	34.12	449.77
Pain / Analgesics	Diclofenac Combination OS 50 mg	145	96	55.32	963.04
Vitamins / Minerals / Nutrients	Calcium Oral Solids 250 IU	28	20	95.34	7450.90
Anti Diabetic	Human Insulins 40 IU	36	10	93.35	4771.17
Gynaec.	Conv.Iron Liquid 200 ml	148	96	72.97	2492.88
Neuro / CNS	Alprazolam OS 0.5 mg	78	51	71.76	1642.64

At the level of individual drugs, these concentration measures are indeed much higher than for the industry as a whole, despite the presence of dozens of competitors for standardized products.<sup>15</sup> The HHI exceeds 1000 in four of these nine market-leading drugs. The lowest HHI and CR4 are for cough preparations, which is a heterogeneous category and should probably be ignored. Over the five years between our two data points, concentration has decreased in five molecules: Cefixime, Atorvastatin, Rabeprazol, Alprazolam and Cough Preparations. Concentration has substantially increased for Calcium Oral Solids, from 134 producers in 2005 to only 20 producers in 2010. The CR4 has gone up from 66% to 95%, and a single brand (Shelcal) has a market share of 86%. The market for human insulin is also highly concentrated with only 10 producers and a CR4 of 93% in 2010. For iron liquids, concentration has increased despite the increase in number of packs and producers. The reason for such high concentration cannot be legal or technological barriers to entry: None of these drugs is patent protected, and all are produced by standardized technologies. The answer lies in industry marketing practices that introduce artificial differentiation.

<sup>15</sup> The concentration measures would be overstated to the extent that other drugs (or dosages of the same drugs) are substitutable. For example, two 5 mg tablets would perfectly substitute for a 10 mg tablet of Atorvastatin, and there are also other similar drugs (e.g. the other statins in the preceding table) in the market.

### 3) Branding in order to differentiate identical drugs

As we discuss in our section on drug price control below, several commentators have pointed out that there is huge price dispersion for each narrowly-defined and chemically identical medication, even though there are dozens of competing brands. In such a scenario with homogenous goods, basic economic theory would expect that competitive forces would ensure a uniform price. Any brand charging a higher price would lose its market. No doubt firms have different costs, but with homogenous products, this should be reflected in diverging market shares rather than price dispersion. Selvaraj et al (2012) expect the lowest price brands to have the highest market shares, whereas at least for the drugs whose prices they present, the opposite seems to be the case. Thus, more competition, in the usual sense of more producers, does not seem to be the remedy.

The key to the puzzle is that unlike in most developed countries, in India even generic drugs are branded and thus differentiated from chemically identical substitutes. The price paradox can then be explained in terms of advertising and marketing efforts of the leading brands, which enables them to effectively differentiate their products and maintain high prices as well as market shares. If demand is positively related to advertising, an old established result called the Dorfman-Steiner condition shows mathematically that the price-cost margin is positively related to the ratio of advertising expenditure to sales revenue.

In the case of pharmaceuticals, however, it is not a simple case of consumers exercising their free choice, influenced by advertising. As emphasized in the Introduction, much of the actual demand arises from the prescribing behaviour of doctors, and firms' marketing activities are geared to influencing them not just by advertising and publicity, but also through means that many would regard as unethical, such as paying for their conferences, travel and other expenses. A practising surgeon has recently revealed the forces at work:

The person who presently determines the brand is the doctor who prescribes it. So we need to examine how an average doctor in India, given a wide variety of choices, chooses to prescribe a particular brand. This is a difficult process to unravel and there is only anecdotal evidence. The choice of brand that a doctor chooses could be based on perceived quality, familiarity, marketing, availability, incentive, and perhaps affordability. Often it is a mixture of all of these, making the decision subjective and in a sense arbitrary. Some of these are conscious choices, but others may be subconscious decisions influenced by powerful branding and marketing. Thus, while it is commonsensical to assume that an average doctor will always factor in price and affordability when choosing a brand, especially since healthcare in India is costly and doctors struggle to get patients to complete courses of drugs, this is not necessarily so.... There is something called "brand loyalty" and "brand familiarity", which develops over prescribing the same product for years. This is a subconscious process. Sometimes it could be just plain ignorance about the availability of a cheaper alternative that makes doctors continue to prescribe costlier brands. But one cannot ignore the role of what are euphemistically called marketing "incentives", which basically mean the inappropriate influence pharmaceutical companies exert on doctors. This runs deep. Hospitals choose to stock only certain drugs in their in-house pharmacies and insist that hospitalised patients buy drugs only from the hospital pharmacy. Drug companies sell drugs to hospitals at a price much lower than what the patient is charged, further incentivising the hospital to stock their products. The cheaper brands often get left out in this game (Nagral 2013, pp.13-14).

Doctors may also refer patients to particular chemists who claim that the prescribed brand is unavailable and substitute it with another which they are being induced to sell by pharma

companies. Again, choice is distorted and the consumer ends up buying a possibly more expensive (and perhaps unsafe) drug. Even for over-the-counter medications which do not require doctors' prescriptions, it is evident to anyone who has visited a chemist that not all brands are available, and those that are available tend to be of the large companies. The cheap varieties are just not available. Since the patients do not have effective choice, they end up buying the expensive medicines. This is a key competition issue that we address below. In a pioneering study of the pricing behaviour of 44 new chemical entities launched in the Indian market in recent years, Wattal (2013) found that although intra-molecular (i.e. inter-brand) competition restrained price increases over time, imitative drugs did exhibit increases relative to their launch prices. She provides evidence that the market shares of leading pharma companies is positively related to their advertising and marketing expenditure. Kotwani (2013) tracks the markups at various stages in the supply chain for seven common drugs and finds wide variation in prices, not only of brands produced by different firms, but also between different versions of the same drug produced by the same firm (as earlier found by Selvaraj et al 2012). While branded versions are marketed by the manufacturers' medical representatives to the medical practitioners who prescribe them, the branded-generics are sold via distributors (wholesalers as well as retail chemists) who receive huge margins. Kotwani shows that distributors also benefit from incentives in which they are given some free packs depending on the number they sell (i.e., trade schemes in the nature of "buy ten, get two free"). The free packs are usually sold to consumers at the full Maximum Retail Price (MRP) printed on them, so this amounts to an additional margin for the distributors. (In section 4.1 below, we show that collusive agreements in the supply chain have restrained competition between distributors.)

But why does branding succeed in allowing some manufacturers a price premium for an identical product even in the case of over-the-counter medicines where several brands are available? Apart from chemists being given incentives for pushing the more expensive brands, one reason could be that known brands and even high prices are taken as signals of reliable quality, especially in a context of widespread manufacture of substandard drugs and poor enforcement of the Drugs and Cosmetics Act of 1940, under which the central and state governments are supposed to regulate manufacturing standards. The industry has strongly resisted the proposal for unbranding generics, which would require that they should be sold only under their generic names. The resulting 'head to head' competition between undifferentiated products would certainly cause a precipitous fall in prices. Nagral (2013) strongly recommends that doctors should prescribe only by the generic names. But he recounts the story of a patient who, even after exhausting his life savings on cancer treatment, continued to buy a very expensive branded drug produced by a multinational company despite much cheaper generic brands being available. When asked why, he said a senior specialist had told him "that the cheaper brands are no good.... How can I compromise on quality?" In a recent newspaper article, a prominent pharma entrepreneur has lambasted the proposal for debranding of drugs, predicting that it will lead to the market being flooded with substandard drugs and the industry being starved of funds for research and development, both these consequences being harmful for consumers (Shaw, 2012). But the same article also states that branding generics has enabled the industry to create shareholder value, with pharma stocks outperforming the Sensex and foreign investors paying high valuations for Indian pharma companies. Selvaraj and Farooqui (2012) have shown that profitability in the Indian pharmaceutical industry has been much higher than that of other major industries. So is the opposition to banning branded generics really on behalf of consumers?

#### 4) Entry and Exit of Firms in the Indian Pharmaceutical Industry

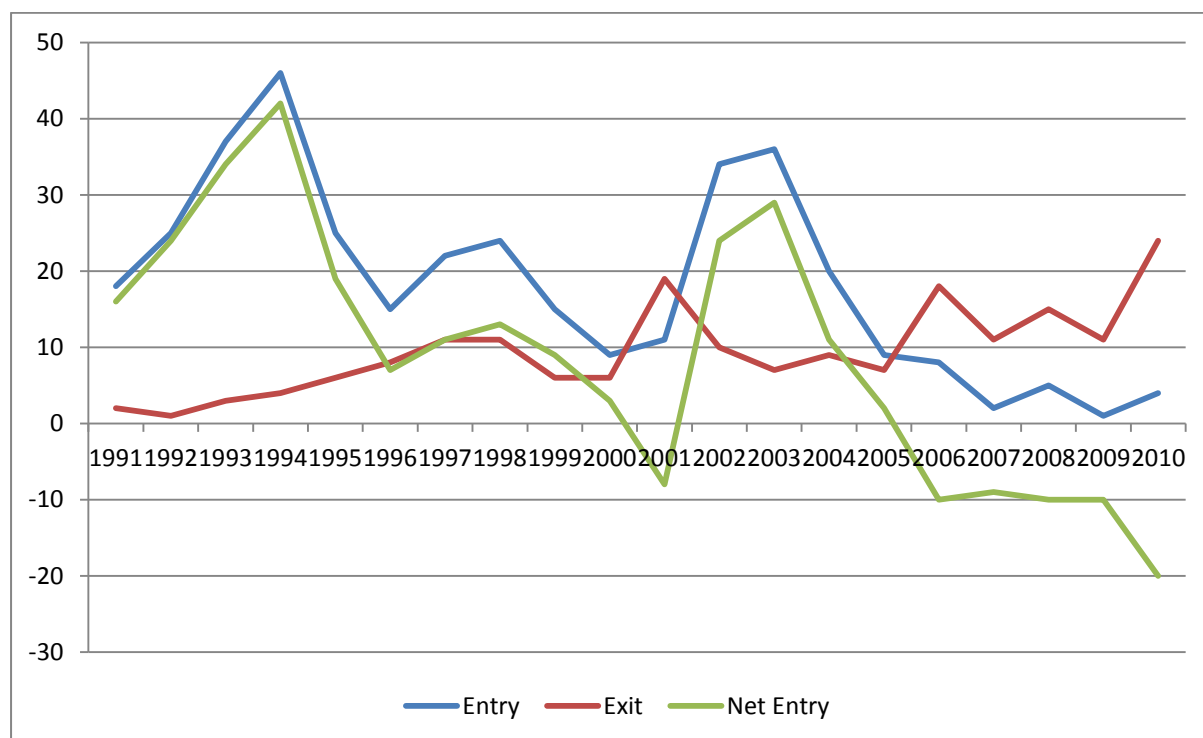
We have tried to look at the dynamics of the entry and exit of firms in the Indian pharma industry. Data has been taken from CMIE's Prowess database. 1990 has been taken as the base year because of availability of data in Prowess. 'Entry' in our analysis refers to firms that have zero sales of goods in 1990 but show a positive sales of goods in any year after 1990. For example, if firm A has zero sales of goods in 1990 but shows positive sales of goods in 1992, firm A is presumed to be making entry in 1992.<sup>16</sup> 'Exit' in our analysis means those firms that had positive sales of goods in any year beginning 1990 but then reported zero sales between a particular year and 2010. For example if firm B had positive sales of goods till 1995 and zero sales of goods between 1996 and 2010, then firm B is presumed to have exited in year 1996.

In 1990, 88 firms were reporting positive sales. Between 1990 and 2010, 366 firms have entered and 189 have exited the industry. In recent years entry has been less than exit, implying net exit. In each year the number of firms entering the industry and those exiting from the industry are recorded. Net entry is calculated as the difference between the number of firms entering and those exiting. The graph below (Fig. 8) shows the trend of entry, exit and net entry. Net entry has fallen continuously after 2003 and has even turned negative since 2006, which means that more firms are exiting than entering the industry. This is clear from the trend of entry and exit. While entry falls sharply from 2004 onwards, exit picks up after 2005. The declining trend in price-cost margin that we detected above (Fig. 7) cannot therefore be attributed to greater entry into the industry. On the contrary, exit of some firms that were making losses or low profits should have pulled up the average profitability (reflected in the PCM) of the survivors. The fact that PCM continued to decline shows that margins were under considerable pressure, probably from imports. Low-priced ('dumped') imports of bulk drugs from China are sometimes blamed for this pressure, and even for driving out Indian producers. But even if this were true, these cheap imported inputs would have increased the margins of formulators, whose branding and promotional tactics would prevent the lower costs from being fully passed on to consumers. Clearly, a more disaggregated analysis is called for. (The issue of dumping is discussed in section 8 below.)

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<sup>16</sup> This definition of 'entry' may not be the same as the year of incorporation.

**FIGURE 8**



Source: Computed by the authors using Prowess data

Firms might exit because they merged with other firms or simply shut down. Since we have data on mergers and acquisitions of firms from CMIE's Prowess database, we have been able to trace the mergers and acquisitions of those firms that have exited from the industry. If the year of exit corresponds with their year of merger or acquisition, then the exit is attributed to merger or acquisition. Exit of 32 firms can be accounted by their merger, acquisition or sale of asset out of the total exit of 189 firms. So it seems that the majority of firms that disappeared actually closed down.

Using only the smaller sample of Prowess firms listed on the BSE, Mody et al (2011) also showed an entry boom in the sector in the first half of the 1990s, but entry remaining negligible thereafter up to 2009. These were presumably the bigger firms in Prowess. In conjunction with the trends depicted in Figure 8, this suggests that many smaller firms overcrowded the sector in the early 2000s and could not survive. Recall that Kaur's analysis of mergers in the 1990s showed that many of the acquired firms were saddled with high debt and were hit by the high interest rate regime that prevailed at the time. Such a scenario might be repeated, with the Reserve Bank of India continuing with its tight monetary policy to fight inflation, while manufacturing has been slowing down. Noting that the rise in exit began in 2005, coinciding with India becoming fully TRIPS-compliant, it is possible that many firms could not survive in a product patent regime. Many units are also reported to have shut down because they were unable to comply with WHO-compatible Good Manufacturing Practice (GMP) norms, although compliance deadlines have been relaxed for the medium and small-scale units.

Going forward, an additional downside is emerging: many small firms which set up manufacturing units in Baddi (Himachal Pradesh) to take advantage of generous excise and income tax concessions

announced in 2003 are facing hard times due to overcapacity and pressure on margins. They are also faced with the expiry of the 10 year duty exemption period over the next few years. Many of them are contract manufacturers who are reported to be looking for potential acquirers (Roy, 2013). This has implications for merger review under the Competition Act, which we discuss in section 4 below.

Other possible reasons for pressures on profitability and consequent exit are common to all export-oriented manufacturing industries. One is the global slump in demand following the 2008 financial crisis and fiscal austerity policies that developed countries imposed in its wake. The other is the real appreciation of the rupee caused by the inflow of foreign portfolio investments, consequent on the slowdown in developed markets combined with liberalization of the capital account in India.

## 5) Determinants of Price Cost Margin: Structure-Conduct-Performance Analysis

Price Cost Margin (PCM) as described above depends on various factors. This relationship has traditionally been modelled in the context of the “Structure-Conduct-Performance” (SCP) paradigm, which uses a standard econometric technique known as regression analysis that seeks to quantify the influence of various factors that might influence the PCMs. In this section, we undertake such an exercise for the Indian pharma sector. But first, we give a simplified introduction to regression analysis. In our regression, PCM is the dependent variable which depends on the explanatory variables which are also called the independent variables, which will be discussed further below. In a simple linear regression the dependent variable  $y$  is regressed on one independent variable  $x$ . A simple linear regression in an equation form is represented below:

$$y = \alpha + \beta x + u$$

$\alpha$  and  $\beta$  are called the parameters of the regression model which are estimated using the available data on  $y$  and  $x$ . The coefficient  $\beta$  shows the relationship between  $y$  and  $x$ . It measures the change in  $y$  due to a given change in  $x$ . There is an error term denoted by  $u$  which represents factors other than  $x$  that affect  $y$ . It captures the variation in  $y$  which is not explained by variation in  $x$ . It is called the error term as it accounts for the unexplained or unobserved variation in  $y$ .

A multiple linear regression, which we are going to perform in this section, has more than one explanatory variable. In reality there will always be more than one variable that affect a given variable. For example the PCM of a firm depends on its market share, its expenditures, its assets etc. So it is important to account for all such variables because if we do not include these, the estimate of the parameters can be biased. A typical example of a multiple linear regression is as follows:

$$y = \alpha + \beta_1 x_1 + \beta_2 x_2 + \dots + \beta_k x_k + u$$

The  $\beta$  coefficient with each of the explanatory variables is the partial regression coefficients. It is partial in the sense that it measures the impact of one explanatory variable on the dependent variable keeping other explanatory variables fixed. The  $\beta$  coefficients that we obtain are not precise, but are estimated subject to statistical errors that are minimized by using appropriate econometric techniques. Other standard techniques are then used to determine whether a particular coefficient is ‘significant’ (i.e., significantly above or below zero), such that it is unlikely to have been the result of chance factors.

A regression analysis can be cross-sectional in nature, it can be a time series or it can be both. A cross section econometric analysis consists of a sample of firms, households, students, cities, states etc at a given point of time. There is no time dimension there. The regression analysis for a cross-sectional data studies the differences in the dependent and the independent variables across the observations and then estimates the relationship between the dependent and independent variables. A time series analysis on the other hand has a single observation unit like a firm, a family, a state or a country, and data is collected for this unit over time.

A panel data analysis incorporates both cross sectional data and time series data. It has data for various cross sectional units running into more than one period. Some variables are the same across the cross section units but change over time like policies affecting the industry which will be same for all the firms in the industry. Some variables are the same over time but vary across units, like certain characteristics of the firms which do not change over time like its ownership etc. Variables can also vary both across time and observations like sales of the firms etc. In our study we have used panel data for 610 pharmaceutical firms over the period 1990-2010.

Price Cost Margin (PCM) as defined in an earlier section depends on various explanatory variables. This has traditionally been modelled in the context of the “Structure-Conduct-Performance” (SCP) paradigm. Stephen Martin in his book *Advanced Industrial Economics* (2002) in the chapter “Early Empirical Studies of Structure-Conduct-Performance Relationships” describes PCM of a firm as dependent on the market share of the firm, four firm concentration ratio of the industry the firm belongs to, assets of the firm and advertising to sales ratio. The latter two variables have traditionally been regarded as creating ‘barriers to entry’ for new firms, thereby maintaining the market shares and profits of the incumbents. Goldar and Kato (2006) have looked at the impact of liberalisation on PCM of firms from various industries. They have related PCMs to market share, square of market share, import penetration ratio (which should depress the PCMs), capital output ratio (which should raise it), and an interaction term between market share and import penetration ratio. They have used panel data techniques for their analysis.

We have based our regression model on these two sources and have made a few modifications. In particular, we note that Athreye and Kapur (2006) found that advertising intensity and the ratio of royalties and technology fees to sales (which they used instead of R&D intensity) was either insignificant or significantly negative in explaining CR4 in the same period for most of the nine industries in their study, which covered the period 1970-99. In other words, these expenses have a concentration-reducing (i.e. competition enhancing) effect in the year in which they are carried out. One of these industries was ‘medicinal preparations’, for which both variables were negative and insignificant. They also gave an explanation for these findings in terms of the transitional dynamics of industrial restructuring, according to which these ‘sunk cost’ variables would have the expected positive effect on concentration only after a lag. We take this into account by including the lagged values of these variables for up to three years prior to the current year.<sup>17</sup> This helps to determine whether the benefits of such expenditures to firms, in terms of reduced competition might only be realized with a lag.

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<sup>17</sup> Athreye and Kapur also referred to the effect of price controls, which were strongly enforced during most of their period. This would neutralize the effects of the usual determinants of concentration. As we shall show below, the coverage of price controls was substantially relaxed after 1995, so we would expect the fundamental determinants to be at work in a less restrained way during our period 1990-2010.



In our study, we have regressed the PCM of all the firms in the Indian pharmaceutical industry on the market share of firms, the square of market shares,<sup>18</sup> R&D intensity of the firm, both current and lagged, the sum of advertising and marketing expenditure intensity, both current and lagged, the export intensity of the firms, log of<sup>19</sup> total assets, export intensity of the firms and time dummies to capture the impact of TRIPS regime on the PCM. In econometrics when a variable is qualitative in nature, that is, it can be classified into categories, then we use a dummy variable for such a variable. A dummy variable is binary, it takes value 0 or 1. For example, if gender is an explanatory variable in a regression, we take a dummy (binary) variable to quantify it. For example if  $x$  is the dummy variable for gender then it takes a value of 1 for females and 0 for males (or vice-versa). In general if there are two categories, like male or female, we take one dummy variable. In our study there are three periods of study, the period before TRIPS (pre 1995), the transitionary period where India was given time to adjust its patent laws in accordance with TRIPS (1995-2004), and post TRIPS period. So we will use two dummy variables here, one each for the second and third periods. The coefficients that are estimated for these variables will tell us about the changes in PCMs in the transition period and the post-TRIPS period respectively, relative to the pre-TRIPS period, controlling for other variables.

Thus, the model is as follows:

$$PCM_{it} = \beta_0 + \beta_1 MS_{it} + \beta_2 MS_{it}^2 + \beta_3 \log(Assets_{it}) + \beta_4 EXI_{it} + \beta_5 Trips_t + \beta_6 PostTrips_t \\ + \beta_7 RDI_{it} + \beta_8 RDI_{it-1} + \beta_9 RDI_{it-2} \\ + \beta_{10} RDI_{it-3} + \beta_{11} AdMkt_{it} + \beta_{12} AdMkt_{it-1} + \beta_{13} AdMkt_{it-2} + \beta_{14} AdMkt_{it-3} \\ + error_{it}$$

Notations:

- **$i$  and  $t$**  denote firm and time respectively.
- **$PCM$**  is the price cost margin.
- **$MS$  and  $MS^2$**  are market share of the firm and square of the market share respectively
- **$RDI$**  is the R&D intensity of the firm calculated as  $\frac{R\&D\ Expenditure}{Sales}$
- **$EXI$**  is the export intensity of the firms calculated as  $\frac{Export}{Sales}$
- **$AdMkt$**  is the intensity of advertising and marketing expenditure calculated as  $\frac{Advertising\ Exp + Marketing\ Exp}{Sales}$
- **$Trips$**  is the dummy variable that takes value 1 for years between 1995-2004 and 0 otherwise

<sup>18</sup> Higher market share is expected to affect the PCM of a firm positively. However, as the market share of a firm increases after a certain level, it may have a weaker impact on PCM, and may even start impacting the profits of a firm negatively. This can be due to managerial inefficiencies that set in as firms become very large. A positive coefficient on the squared market share would suggest this 'inverted-U' shaped relationship.

<sup>19</sup> When we take log of an explanatory variable, the regression coefficient gives us in this case, the absolute change in PCM upon 1% change in the assets of a company.



- ***PostTrips*** is the dummy variable that takes value 1 for years between 2005-2010 and 0 otherwise

#### *Data*

Data for the above variables have been taken from CMIE's Prowess database for the years 1990-2010. There are 610 pharma firms listed in the Prowess database. Time has been divided into 3 periods:

- Before Trips 1990-1994
- Trips 1995-2004
- Post Trips 2005-2010

#### *Regression Results*

We have used a linear regression model, employing panel data techniques. The regression results are tabulated below, but the main results can be intuitively explained as follows:

- The coefficient of Market share is positive and significant at 10% level of significance. So, firms with higher market share earn higher PCM. In other words, market share is important in explaining PCM of firms and higher market share will lead to higher PCM.
- The coefficient of market share squared is negative but insignificant. This suggests (weakly) that as the market shares of firms grow beyond a level, the PCM of the firms tend to decline. This could be because of managerial inefficiencies, diseconomies of scale etc.
- The coefficient of log (assets) is negative and significant. So bigger firms (on the basis of assets) have lower PCM. So, while the assets of the firms are important in explaining their PCM, they have a negative impact.
- Export intensity has a small positive coefficient but it is insignificant. Firms with higher exports will earn higher PCM but this relationship is not important.
- Trips and Post Trips have positive and significant coefficients suggesting that as compared to the pre TRIPS period, PCM of firms have gone up in the following two periods. This might suggest that TRIPS have had a competition reducing affect in the Indian pharmaceutical industry.
- The coefficient of R&D intensity is negative and significant. This might be because when R&D expenditure is done the benefits of it are seen at a later date whereas the expenditure is done today. This is confirmed when we include lagged R&D expenditure. We have included lags till 3 periods. The results show that R&D expenditure of one period before has a negative and significant impact on PCM of the current period, R&D expenditure of 3 periods before has a positive and significant impact on current PCM. So, R&D expenditure does have a positive and significant impact on PCM but the effect is realised with a lag. Firms that do higher R&D earn higher profits in the future.

- Advertising and Marketing Expenditure Intensity is negative and significant. When we include the expenditure of the lagged periods, we see that the coefficients of advertising and marketing expenditure of the past 3 periods are all positive and significant for two and three periods ago. This confirms the hypothesis that advertising and marketing expenditures have strong and positive impact on the PCM of the firms in the pharmaceutical industry and the results of such expenditures are also realised with a lag.
- Together all the variables are significant in explaining variations in PCM as reflected by the significant F statistic.

Most of our results are in line with expectations. However, on the finding that market shares are positively related to PCM, suggesting that exercise of market power raises profit margins, we must note the caveat known as the ‘Demsetz critique’: both higher market shares and lower costs may be a reflection of greater productivity. One novel finding is with regard to the R&D and Advertising variables, where we found (contrary to theoretical expectations) that the contemporaneous effect of these expenditures on PCM is negative, but their lagged effect is positive. A possible explanation is that part of these expenditures is accounted for by wages, salaries and materials used in the firms’ advertising and research divisions,<sup>20</sup> which would reduce the PCM in the current period but raise it in future periods as they pay off in terms of greater brand loyalty, lower costs and better quality.

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<sup>20</sup> This is true of most leading research-intensive Indian firms: see “Pharma R&D: Basic drug research only a part”, *Business Standard*, 22 April 2013. The same article points out that a significant part of reported R&D expenditures is on generic development rather than innovation, and also on regulatory compliance costs.

## Regression Results

Fixed-effects (within) regression	Number of obs	=	6341	
Group variable: cid	Number of groups	=	585	
R-sq: within = 0.5082	Obs per group: min	=	1	
between = 0.3140	avg	=	10.8	
overall = 0.4568	max	=	21	
	F(14,5742)	=	423.79	
corr(u_i, xb) = 0.0199	Prob > F	=	0.0000	
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PCM	Coefficient	Std. Err.	t P> t  [95% Conf. Interval]	
-----+-----				
MS	.9984233	.5897741	1.69 0.091	-.1577565 2.154603
MSSqrd	-.1041018	.0810337	-1.28 0.199	-.2629585 .0547548
LogAssets	-.3756898	.146527	-2.56 0.010	-.662938 -.0884416
EXI	.0011399	.0011555	0.99 0.324	-.0011252 .003405
Trips	.7542762	.3808537	1.98 0.048	.0076592 1.500893
PostTrips	.8492808	.4622887	1.84 0.066	-.0569794 1.755541
RDI	-1.629013	.0299631	-54.37 0.000	-1.687752 -1.570274
lag1RDI	-.0562049	.0299009	-1.88 0.060	-.1148219 .0024121
lag2RDI	.0357552	.0323754	1.10 0.269	-.0277129 .0992232
lag3RDI	.0584297	.032358	1.81 0.071	-.0050043 .1218636
AdMkt	-2.02957	.0403621	-50.28 0.000	-2.108695 -1.950445
lag1Admkt	.0512969	.0382271	1.34 0.180	-.0236425 .1262364
lag2Admkt	.0832811	.0375647	2.22 0.027	.0096401 .156922
lag3Admkt	.1701362	.0373239	4.56 0.000	.0969673 .2433051
cons	1.459252	.6844924	2.13 0.033	.1173889 2.801116
-----+-----				
sigma_u	8.5800683			
sigma_e	8.3140785			
rho	.51574059	(fraction of variance due to u_i)		
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F test that all u_i=0:	F (584, 5742) =	5.01	Prob > F = 0.0000	

## 4. Competition Law

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India's Monopolies and Restrictive Trade Practices Act of 1969 was one of the earliest competition laws in the developing world. But the way it was drafted, amended, interpreted and enforced made it relatively ineffective as a competition law, although it served well as a consumer protection law after it was amended in 1986 to include 'Unfair Trade Practices' and provisions for compensating consumers for their losses. The MRTP Commission was understaffed and underfunded, and could only impose 'cease and desist' orders. Although several international cartels involving pharma products (especially vitamins) were detected by American and European competition agencies during the 1990s, and India was certainly a major importer of some of these products, the MRTP Commission remained a passive spectator. We were unable to find a single cartel case pertaining to pharma producers (domestic or foreign) after 1991. And in any case, the Supreme Court's judgment in the 2002 *Haridas Exports* case held that the MRTP Commission had no jurisdiction over the activities of foreign firms, even if they had an effect in India, unless these activities involved an Indian party.

The more modern Competition Act was enacted in 2002, with a clearer focus on competition, provision for substantial penalties and explicit provision for jurisdiction over foreign conduct having anticompetitive effects in India. However, various legal challenges delayed its implementation.<sup>21</sup> The Competition Commission of India (CCI) was not fully constituted till 2009. Thereafter, the Act came into force in phases. The provisions regulating anticompetitive agreements and abuse of dominance came into effect in May 2009, but the merger control provisions and the accompanying Combination Regulations became effective only in June 2011. We shall discuss the relevance of the Competition Act to the Indian pharma industry under the three broad heads of anti-competitive agreements, abuse of dominance, and combinations (i.e., mergers and acquisitions).

### 4.1 Anticompetitive Agreements

Potentially anticompetitive agreements can be of two types: horizontal (between firms producing the same or similar goods) and vertical (between firms at different stages in the supply chain). Under Section 3 of India's Competition Act, such agreements are illegal if they have an appreciable adverse effect on competition (AAEC). Like the competition laws of most countries, India's Act singles out so-called 'hard core' horizontal agreements (cartels) for special treatment. These are agreements between competitors to fix prices, restrict quantities, rig bids or allocate markets. Such agreements (subject to a specific exemption for joint ventures) are *presumed* to have an AAEC, although this presumption can be rebutted with reference to certain potential benefits enumerated in Section 19(3).

So far, no case involving pharmaceutical manufacturers' cartels has been decided by the CCI. Nor have there been any cases in which pharma manufacturers have been investigated for forming joint

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<sup>21</sup> See Bhattacharjea (2010 and 2012) for an assessment of the MRTP era, the impact of the *Haridas Exports* judgment, the strengths and weaknesses of the Competition Act, the reasons for its delayed implementation, and an analysis of some of the early cases.

ventures, or agreements to enforce intellectual property rights, both of which are activities especially relevant to this industry and are dealt with in specific subsections of Section 3 of the Competition Act.

#### *Collusion along the pharma distribution chain*

In three significant cases, however, brazen collusion has been found amongst chemists (pharmacies).<sup>22</sup> These cases expose a raft of common anticompetitive practices affecting the pharma distribution chain all over the country for over 30 years, involving producers as well as distributors, with government policy playing a facilitating role. The Orders by different Members of the Commission in this case are also instructive, because they show that there can be differences in the interpretation of the same body of apparently conclusive evidence.

The first two cases, against the regional chemists' associations of Goa and Baroda, were originally filed before the Monopolies and Restrictive Practices Commission in 2009, shortly before it was wound up and the MRTP Act was repealed. Under section 66(6) of the Competition Act, investigations initiated by the MRTP Commission were transferred to the CCI, to be disposed of as the CCI thought fit. As per its practice, the CCI ordered reinvestigation in the two cases and assessed them under the relevant provisions of the Competition Act. The third case was filed directly before the CCI under the Competition Act in 2011, naming the All India Organization of Chemists and Druggists (AIOCD), as well as the two major national pharma manufacturers' associations, Organization of Pharmaceutical Producers of India (OPPI) and the Indian Drugs Manufacturers' Association (IDMA) as 'opposite parties' (the term given to respondents in the Competition Act). The informants and evidence in each case were broadly similar, as the regional associations had been implementing the guidelines of their national body, the AIOCD, in terms of the latter's memorandum of agreement signed with OPPI and IDMA as far back as 1982. The informants' evidence in each case was broadly confirmed, with more practices being brought to light, by further investigations that the CCI ordered its Director General (DG) to undertake. In particular, following the AIOCD guidelines, the regional affiliates had imposed limits on the number of stockists (wholesalers) in each territory, and prevented pharma companies from appointing stockists without a no-objection certificate from the local chemists' association. The pharma companies could appoint stockists/retailers only from among the members of the associations.

The DG also found evidence that AIOCD and the regional associations had fixed trade margins of wholesalers and retailers at 10% and 20% respectively. The associations also made distribution of drugs contingent on the manufacturers obtaining approval under the Public Information System (PIS), for which a fee was charged by the associations to disseminate information about drugs. No drugs could be distributed without PIS approval, which was often withheld or delayed to extract better terms from the manufacturers. The Goa association went further and prohibited retailers from giving discounts to consumers and restricted wholesalers from giving discounts of more than 2% to retailers. Further, the stockists were not allowed to pass on the benefits of schemes

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<sup>22</sup> *Varca Chemist and Druggist and others vs Chemists and Druggists Association, Goa*, decided 11 June 2012; *Vedant Bio Sciences vs Chemists & Druggists Association of Baroda*, decided 5 September 2012; *M/s Santuka Associates Pvt. Ltd. vs All India Organization of Chemists and Druggists and Ors.*, decided 19 February 2013. It should be kept in mind that the CCI orders can be appealed to the Competition Appellate Tribunal and then to the Supreme Court.

introduced by the pharma companies, and bids for government tenders had to be routed only through authorized stockists. Finally, the associations in some cases had imposed fines on stockists and retailers and ordered boycotts of the drugs supplied by pharma companies who violated these conditions.<sup>23</sup> Unusually for a cartel case, in which firms usually collude without leaving any documentary evidence, in these cases there was ample evidence in the form of Memorandum of Association, annual reports, guidelines, letters, and minutes of meetings of the associations, as well as depositions by their members and of the pharma company representatives.

After disposing of arguments of the chemists' associations, the majority order of the Commission found these activities to be violations of Sections 3(3)(a) and 3(3)(b) of the Competition Act, which deal respectively with horizontal agreements that fix prices and restrict quantities. Such agreements are presumed to be anti-competitive. The Commission directed that these activities should cease, and imposed fines of 10% of the average annual turnover of the respective pharmacy associations for two years—the maximum penalty permissible under the Act. Action against office bearers of the associations was deferred. In the AIOCD case, where OPPI and IDMA had been named as opposite parties, the majority held that the two manufacturers' associations could not be held liable. As they were not operating at the same level of trade as the distributors, section 3(3), which concerns horizontal anticompetitive agreements, could not be applied. And as AIOCD, IDMA and OPPI were not 'enterprises', their vertical agreement did not come under section 3(4). In fact, the majority opined that the manufacturers' associations were victims of the exploitative tactics of AIOCD.

Three members of the Commission gave separate orders. While agreeing that the chemists' associations had engaged in anticompetitive practices, they each disagreed with the majority on particular points. All three members concurred with the majority on the anticompetitive effects of the limitation on the number of stockists, the requirement that manufacturers should obtain an NOC from the associations before appointing a new stockist, and the boycotting of firms who did not comply with the MOU. They also concurred that prohibition of discounts at the retail level in Goa was anticompetitive. However, all three members felt that the amount charged for PIS approval was too insignificant to affect competition. One of them opined that manufacturers might actually regard PIS as the most cost-effective way of disseminating information about drugs, which they are legally obliged to do. Its efficiencies would then outweigh any restrictive effect. While one member held that the office bearers of the associations could not be held liable, another held that IDMA and OPPI, as well as their office-bearers, would also be liable. Another opined that basing the fine only on the associations' own turnover would allow cartel members to escape the penalty by forming associations. He calculated much bigger fines based on rough estimates of the turnover of the chemists constituting the association.

As the focus of our report is on the role of government policies in restricting competition, the dissenting views of two of these members on the issue of fixation of trade margins in the Goa case assumes significance. They observed that the government's National Pharmaceutical Pricing Authority (NPPA) itself fixes the margins for 'scheduled' drugs (those under price control), at 8% for wholesalers and 16% for retailers. The margins of 10% and 20% respectively fixed by CDAG and other regional associations for non-scheduled drugs (those which are not under price control) were

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<sup>23</sup> Nanda and Khan (2006, p.197) summarized three MRTP cases from 1982, 1984 and 1996 in which pharmacists' associations, including AIOCD, had been told to cease and desist from these practices. The recent cases decided by the CCI show how ineffective these strictures were.

slightly higher. These margins were fixed as a percentage of the Maximum Retail Price (MRP), which is set by the manufacturers, not the distributors. In all three cases, in the opinion of these two members, fixing the margins did not amount to fixing the prices. At least in the Goa case, they felt that as the margins were in line with those prescribed by the NPPA for scheduled drugs, they were not unreasonable.

While appreciating the separate orders that unpacked the omnibus allegations against CDAG, we are unable to agree with the view that margin fixation is not necessarily anticompetitive. Profit-maximizing firms will reduce their output and increase their price to allow for a distribution margin applied to the final price. The fact that distributors were restrained from giving discounts indicates that the margins were above the competitive level, which would keep the price paid by consumers above what it could have been. The fact that the margins fixed by the industry for non-scheduled drugs are only slightly higher than those fixed by the NPPA for scheduled drugs does not make them reasonable. In any case, reasonableness or fairness of prices should not be relevant in a cartel inquiry. If anything, as we shall discuss in our section of price control below, the fixation of prices by the NPPA can itself serve as a collusion-facilitating practice. But we agree with the views of one dissenting member that fixing the penalty on the basis of the turnover of the associations (which would consist mainly of membership fees etc) would severely diminish its deterrent effect. However, the CCI would then have to investigate the accounts of hundreds of retailers to determine their individual turnovers.

#### *Other anticompetitive agreements*

While on the subject of anticompetitive agreements, we can briefly touch upon some other industry practices. First, the fixation of margins by the NPPA, which was treated as sacrosanct by the CCI in the chemists' case, amounts to a legal mandate for resale price maintenance (RPM). The modern treatment of RPM, which has evolved over several decades in light of Chicago School criticism, does not regard it as harmful per se. Its anticompetitive effect has to be balanced against possible benefits, inasmuch as it encourages retailers to provide point-of-sales services (e.g. local advertising; facilities and trained staff for explaining or demonstrating the product) that benefit consumers. Without RPM, retailers would have no incentive to do so, as consumers could avail of their services and then make the actual purchase from rival retailers who do not incur the costs of providing such services and can therefore offer discounts. Prohibiting discounts through imposition of RPM would prevent this kind of free riding and encourage retailers to invest in such services. However, in the case of retail sale of medicines, this argument seems very weak. Unlike electronics or cars, consumers do not need the product to be explained or demonstrated at the point of sale. The minimal requirement that each outlet should have a qualified pharmacist can be enforced by law, regardless of the prices being charged by rivals.

Second, as pointed out in the preceding section, there is suspicion that doctors are induced to prescribe particular brands and/or refer patients to particular chemists. Would this constitute 'tying' and be dealt with under the Competition Act as an anticompetitive vertical agreement under Section 3(4), which specifically includes "tie-in arrangements"? This would seem infeasible in light of a recent decision of the CCI in a case in which providers of direct-to-home satellite television services were forcing subscribers to buy set-top boxes from them. The CCI held that that Section 3(4) applies to agreements between persons or enterprises "at different stages or levels of the production chain

in different markets”. It would not apply to an agreement with consumers, who must necessarily be in the same market.<sup>24</sup> Presumably, the same principle would apply to an ‘agreement’ between doctors and patients. As long as all consumers in a locality were not being forced to go to the same chemist, it would also be difficult to establish that this practice would have an appreciable adverse effect on competition in the relevant market, as required by Section 3(4).

However, another practice of the pharma companies would certainly come under Section 3(4). As we observed in our review of market structure, very often the chemically identical but cheaper varieties of a drug are just not available in chemists’ stores, enabling higher-priced brands to maintain high market shares. This may be because of “exclusive supply agreements”, defined in Section 3(4) as “any agreement restricting in any manner the purchaser in the course of his trade from acquiring or otherwise dealing in any goods other than those of the seller or any other person”. Such agreements, better known as exclusive dealing agreements, are classic vertical restraints with possible AAEC. Unlike the tying of consumer choice, these agreements are between firms at different stages of the supply chain, and would fall squarely under Section 3(4). As with RPM, the efficiency defence of exclusive dealing is on weak ground here. The usual claim is that such agreements encourage manufacturers to invest in training retailers’ staff, providing display units, etc, because otherwise these investments could be used to promote the products of rival producers, who would thus get a ‘free ride’. This argument seems hollow in the case of chemists. Evidence is needed as to the prevalence of such practices.

Finally, there is the uncharted territory of anticompetitive clauses built into patent licensing agreements. Even before enforcement of the Competition Act began, two Canadian scholars Ghosh and Ross (2008) had warned that its treatment of intellectual property rights was deficient. They pointed out that Section 3(5) contains a blanket exemption for all agreements whereby a right holder imposes “reasonable conditions” to protect his rights. This leaves unclear the status of particular kinds of anticompetitive agreements that are routinely scrutinized in other countries. The Competition Act in its entirety is silent on remedies specific to abuse of IPRs such as parallel imports and compulsory licensing. We shall review the recent attempts to impose such remedies under the Patents Act below.

## *4.2 Abuse of Dominance*

No case concerning abuse of a dominant position (which would be a violation of Section 4 of the Competition Act) in the pharma industry has yet been decided, although with the strengthening of patent protection after the Patents Act was amended in 2005, many firms have acquired legal monopolies of particular drugs and thus attained dominance. This raises the intriguing question of whether patents can be regarded as ‘essential facilities’ which have to be made available to competitors on fair, reasonable and non-discriminatory (FRAND) terms. So far, the essential facilities doctrine has been applied to intellectual property in the form of standards and copyrights in other jurisdictions. But the phrasing of section 4(1)(c), which includes “practices resulting in denial of market access in any manner” under abuse of a dominant position, seems open to denial of access to patented technology, although any such analysis would be premature at present.

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<sup>24</sup> *Consumer Online Foundation v. Tata Sky Ltd.*



We can, however, revisit the issue of doctors restricting competition by prescribing particular drugs when cheaper ones are available. Even if it cannot be addressed as an anticompetitive agreement under section 3(4), could this practice be treated as an abuse of dominance under Section 4(1)(c)?<sup>25</sup> However, it would be difficult to argue that doctors hold a dominant position except perhaps in rural areas where there are no alternative providers. As the CCI has held in several cases (see Bhattacharjea 2012), even if a party enters into an agreement that restricts his or her choice, it would not be regarded as a breach of Section 4 as long as there was sufficient ex ante choice of suppliers (in this case doctors). Here again, the practice that might be vulnerable (if established by enquiry) is the possibility that some manufacturers are maintaining the dominance of their brands by forcing chemists not to stock rival brands.

This issue of doctors prescribing particular brands for non-medical reasons is really a matter of professional ethics rather than competition policy. It is unlikely that the Medical Council of India would be prepared to treat this as professional misconduct that would allow it to deregister the practitioner under section 24 of the Medical Council Act, 1956. It really requires a code of ethics and enforcement by the Indian Medical Association, the MCI and the pharmaceutical industry. Transparency in the relationship between producers and medical professionals may help. A recent directive of the Australian Competition and Consumer Commission has authorized a revised Code of Conduct by the industry association Medicine Australia, which requires member companies to report the aggregate spending on payments to healthcare professionals for advisory board and consultancy arrangements; sponsorships to attend medical conferences and educational events; speaking at educational events; and also sponsorships of all individual organizations. This is intended to be a transitional measure, pending development of a revised Code that requires reporting of individual payments.<sup>26</sup>

#### *4.3: Combinations<sup>27</sup> under the Competition Act*

Since the sections of the Competition Act dealing with combinations came into effect in June 2011, the CCI has passed orders in six M&A deals in the pharma sector. All six of them got approved. A brief summary of these deals is as follows, with the operative portion of the Commission's orders given in italics:

**1) Firms Involved:** Reckitt Benckiser Investments India Private Limited (RBIPL), Paras Pharmaceuticals Limited (PPL) and Halite Personal Care India Private Limited (HPCIL)

**Date of Application:** 23<sup>rd</sup> February 2012 **Date of Order:** 8<sup>th</sup> May 2012

**Section of the Act:** 5 (c)

The proposed combination related to **merger** of RBIPL with PPL as the first step and de-merger of personal care division of PPL into and with HPCIL as the second step.

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<sup>25</sup> Although Section 4 prohibits "an enterprise or group" from abusing its dominant position, 'enterprise' is defined in Section 2(h) to include any person who provides services.

<sup>26</sup> <http://www.pharmatimes.com/Article/12-12-24/>

Australian\_pharma\_accepts\_watchdog\_decision\_on\_doctor\_payments.aspx, viewed 9 January 2013.

<sup>27</sup> The term 'combinations' is used in the relevant sections of the Competition Act, 2002, to cover both mergers and acquisitions.

*The ultimate holding company of RB Singapore, RBIPL, PPL and HPCIL is Reckitt Benckiser Group Plc. (RB Group). The ultimate control over the activities carried on by the parties to the combination before and after the combination would remain with RB Group. Therefore, the proposed combination is not likely to have any adverse competition concerns.*

**2) Firms Involved:** Orchid Research Laboratories Limited (ORLL) **and** Orchid Chemicals and Pharmaceuticals Limited (OCPL)

**Date of Application:** 3<sup>rd</sup> February 2012 **Date of Order:** 29<sup>th</sup> February 2012

**Section of the Act:** 5 (c)

The combination was a **merger** of ORLL into OCPL pursuant to a scheme of amalgamation under the Companies Act, 1956.

*While OPCL is engaged in the production of API and formulations, ORLL is engaged only in the area of drug discovery and development of new chemical entities. Further, the ultimate control over the activities carried out by OPCL and ORLL, before and after the combination, remains with OPCL. The proposed combination is therefore not likely to have any adverse competition effects and it got approved by the Commission.*

**3) Firms Involved:** Mitsui & Co. Limited (Mitsui) **and** Arch Pharma Labs Limited (Arch)

**Date of Application:** 9<sup>th</sup> August 2012 **Date of Order:** 19<sup>th</sup> September 2012

**Section of the Act:** 5 (a)

The proposed combination relates to **acquisition** of 26.71% equity shares of Arch by Mitsui. Mitsui already holds 5.25% of the equity share capital of Arch.

*Mitsui through its subsidiary MicroBiopharm is engaged in the business of manufacture and sale of APIs, intermediates, contract manufacturing and contract research services globally but not in India. Further, Mitsui does not have any direct or indirect control in any other enterprise in India which is engaged in the business similar to that of Arch in India. Also, there are a lot of companies globally that in the business of manufacture and sale of APIs, intermediates, contract manufacturing and contract research which are much larger in size as compared to Arch and Mitsui. Also, both are not engaged in similar businesses and any vertical relation is not significant. Therefore, the proposed combination is not likely to have any adverse competitive effects.*

**4) Firms Involved:** G&K Baby Care Private Limited (G&K), Danone Asia Pacific Holdings Pte Limited (Danone Asia Pacific), Wockhardt Limited (Workhardt) and Carol Info Services Limited (Carol) **and** Wockhardt EU Operations (Swiss) AG (Workhardt EU)

**Date of Application:** 24<sup>th</sup> August 2011 **Date of Order:** 15<sup>th</sup> September 2011

**Section of the Act:** 5(a)

The combination related to **acquisition** by G&K Baby Care Private Limited and Danone Asia Pacific Holdings Pte Limited (acquirers) of certain assets of Wockhardt Limited and Carol Info Services Limited and Wockhardt EU Operations (Swiss) AG (collectively referred to as Workhardt Group). The combination comprises the following acquisitions:

- a) G&K acquired the nutrition business of Wockhardt
- b) G&K will acquire the contract manufacturing business of Carol
- c) Danone Asia Pacific acquired certain intellectual properties of Workhardt EU

*The proposed combination relates to nutraceutical sector. This sector is in its infancy stage and is less than 1% of the global nutraceutical sector. In India, this sector has been growing at a much faster rate than the global nutraceutical sector. The combination relates to baby food and medical nutrition business which are regulated by Food Safety and Standards Authority in India. The activities of the Danone Group in India relates to bottled water and fresh dairy product and it is not present in any activity in which the acquired businesses. Further given the small market share of Workhardt group in baby food business (7%) and medical nutrition business (less than 10%) and significant presence of other players in the baby food and medical nutrition business, the proposed combination is not likely to have any adverse competitive affects in India. The Commission therefore approved the combination.*

5) **Firms Involved:** Orchid Chemicals and Pharmaceutical Limited (OCPL) **and** Hospira Healthcare India Private Limited (HHIPL)

**Date of Application:** 27<sup>th</sup> September 2012 **Date of Order:** 21<sup>st</sup> December 2012

**Section of the Act:** 5 (a)

The combination related to **acquisition** of the some businesses which will be called as Transferred Business by HHIPL from OCPL, as per the terms of the Business Transfer Agreement (BTA).

**OCPL** a listed public company, is a 100% export oriented unit and is engaged in the manufacture of Active Pharmaceutical Ingredients (APIs) and oral formulations and Non-Penicillin and Non-Penem Non-Cephalosporin (NPNC) verticals in the pharma sector. It is also engaged in New Drug Discovery (NDD), Novel Drug Delivery System (NDDS) and Contract Research and Manufacturing Services (CRAMS). It exports to more than 75 countries including the highly regulated markets of US, Europe and Japan. It used to earlier manufacture the injectable formulations in Cephalosporin, Penem and Penicillin segments; however these segments were transferred by the OCPL to HHIPL in 2009 pursuant to an earlier BTA.

**HHIPL** is a 100% indirect subsidiary of Hospira, Inc. USA. It is engaged in the manufacture and export of various inject-able formulations in Cephalosporin, Penem and Penicillin verticals in the pharmaceutical sector. It pre-dominantly conducts its business for the regulated markets of Canada, USA, Europe and certain Asia-Pacific and Middle-East countries.

This was the only one of the six cases in which possible competition issues arose. Although there was only negligible horizontal overlap between the formulations offered by the two companies, there was an existing vertical linkage: HHIPL was procuring active pharmaceutical ingredients called

Penems from OCPL which it converted into formulations. In 2011-12, 89% of the Penems produced by OCPL were purchased by HHIPL, so this acquisition would amount to vertical integration. But as OCPL had a negligible share of the market for Penems in India, the Commission held that this would not be likely to result in the foreclosure of the domestic markets.

However, the BTA contains a non-compete clause which stipulates that OCPL and its promoter, can not undertake certain business activities pertaining to the transferred business for a period of 8 years and 5 years respectively. It restricts research and development and testing of Penems and Penicillin for the APIs for inject-able formulations. The parties have submitted that this is a standard industry practice as it allows the acquirer to obtain full value from the acquired assets. It is further stated that HHIPL considers these restrictions as necessary as an essential safeguard since OCPL possesses the experience, know-how, capacity and capability to establish an independent business that could overlap with the transferred business.

The parties were asked to provide the justifications for the non-compete clause. In response, the parties submitted the following changes: a) limit the duration of non-compete obligation to 4 years in relation to domestic market in India b) OCPL shall be allowed to conduct research, development and testing on such new molecules that would result in the development of new Penem and Penicillin APIs for injectable formulations which are currently non-existent in the world.

After these changes are incorporated into the BTA, it is believed that the proposed combination is not likely to have any adverse competition concerns and therefore approved.

Non-compete clauses as part of a BTA are widely used, and despite their obvious anticompetitive effect, they are usually upheld as long as they are reasonable and of limited duration. Without them, a seller would find it hard to get full value for his business. In fact, as long ago as 1711, the historic first common-law competition decision in the UK (*Mitchel vs Reynolds*) upheld such a non-compete agreement. The division of businesses amongst the Ambani brothers also involved such an agreement. The CCI did well to limit the anticompetitive effect in the Orchid-Hospira case, especially in regard to future research and development by OPCL. This is an important issue concerning foreign investment in the Indian pharma industry, as we shall discuss in our section on FDI below.

**6) Firms Involved:** PHL Holdings Private Limited (PHPL) and Piramal Enterprises Limited (PEL)

**Date of Application:** 3<sup>rd</sup> December 2012 **Date of Order:** 27<sup>th</sup> December 2012

**Section of the Act:** 5 (c)

The combination related to **amalgamation** of PHPL into PEL.

*It is observed that the proposed combination is an arrangement between the enterprises of the same group and that the control over the activities of PEL before and after the combination would remain unchanged. Therefore the proposed combination is not likely to have any adverse competitive concerns in India and therefore got approved.*

Thus, these cases were brought under the CCI's scanner and the deals got approved, because

- they involved restructuring among group affiliates with no change in control (cases 1, 2 and 6), or

- they had no significant effect on competition due to (a) absence of horizontal or vertical relationships between the parties and (b) presence of many other players (3 and 4), or
- suitable modifications were made so as to minimize adverse effects on competition (5).

However, threshold asset and turnover levels for reviewable mergers are quite high, so that many deals escape from CCI's purview when they actually could have anticompetitive effects. In March 2011, shortly before the merger provisions were brought into force in June, the government issued a notification enhancing the thresholds specified in the 2002 Act by 50% to account for inflation, and separately exempting Combinations (for five years) where the target enterprise, including its divisions, units, and subsidiaries has either:

- assets not exceeding Rs. 250 crores (USD 50 million) in India; or
- turnover not exceeding Rs. 750 crores (USD 150 million) in India.

We have looked at those deals that took place after June 2011, when merger control provisions and the accompanying Combination Regulations became effective, upto December 2012. We have tried to identify those deals in this subset that did not come under CCI's scanner because of the above mentioned notification.

### Merger Deals

In the following 3 deals of mergers in the pharma industry the combined assets of the two firms are greater than the CCI's threshold of Rs 1500 crore, but these deals were exempted from CCI's scanner because the assets and the turnover of the acquired company were less than Rs 250 crore and Rs 750 crore. Had this added constraint not been in existence, these deals would have been screened by the CCI. However, because two of these involved acquisition of subsidiaries, according to the CCI Combinations Regulations they may still have been approved because they had no appreciable effect on competition.

Date	Acquirer	T	A	Target	T-Target	A-Target	Combined T	Combined A
		Rs. Million	Rs. Million		Rs. Million	Rs. Million	Rs Crore	Rs Crore
26-Jul-12	Biocon Ltd.	13656	28308	Biocon Biopharmaceuticals Pvt. Ltd.	101.9	2395.3	1375.79	3070.33
02-Aug-12	Elder Pharmaceuticals Ltd.	9924.9	17276.7	Elder Health Care Ltd.	486.3	751	1041.12	1802.77
17-Sep-11	Ipca Laboratories Ltd.	18787	19185.9	Tonira Pharma Ltd. [Merged]	303.2	580	1909.02	1976.59
Source	CMIE Prowess and Authors' Calculations							
T and A	Turnover and Assets							
	These are all exempted from the CCI's scanner because their assets and/or turnover are less than 250 and 750 crore							
	The combined assets and/or turnover are above the threshold set by CCI							

### Sale of Assets

In the following two deals involving sale of assets, the combined assets/turnover was above the threshold set by CCI but these deals were exempted because of the above mentioned notification.

Date	Target	T	A	Acquirer	T-Acquirer	A-Acquirer	Combined T	Combined A
<b>Sale of Assets</b>		Rs. Million	Rs. Million		Rs. Million	Rs. Million	Rs. Crore	Rs. Crore
22-Jul-11	J B Chemicals & Pharmaceuticals Ltd.	7276.1	10118.2	Dr. Reddy'S Laboratories Ltd.	50311	102673	5758.71	11279.12
16-Oct-12	S M S Pharmaceuticals Ltd.	2446.1	4730.9	Mylan Laboratories Ltd.	35785.2	50787.5	3823.13	5551.84
Source	CMIE Prowess and Authors' Calculations							
T and A	Turnover and Assets							
	These are all exempted from the CCI's scanner because their assets and/or turnover are less than 250 and 750 crore							
	The combined assets/turnover are above the threshold set by CCI							

## Remarks

The above deals did not come under the CCI's scanner because of the added exemption in terms of the assets turnover that came in through a Notification issued in March 2011. Also, the above mentioned deals are not exhaustive of all such deals. For these deals we have data on assets and turnover of the acquired and acquirer companies. There could well be more deals than just the five highlighted above, but because of lack of data on the assets and turnover of the combining firms, we cannot identify them. There have been several proposals to lower the thresholds for the pharma sector so that more M&A deals, especially those involving foreign firms are scrutinised. The government has recently tabled in an official bill in Parliament to amend the Competition Act so as to enable thresholds to be lowered. We shall discuss this issue in more detail in our section on Foreign Direct Investment.

In another respect, however, there may be a case to be generous towards mergers. In section 3 above, we drew attention towards increasing exit among pharma companies since around 2004, and we gave some possible reasons for this phenomenon. In this scenario, now that merger review has commenced under the Competition Act, the CCI may have to pay serious attention to the possibility that merger will be the only way to keep a distressed firm in operation, even if control passes to a rival and therefore lessens competition in the relevant market. If instead it were to close down, the impact on competition may be even worse, with its output and capacity being lost. This 'failing firm defence' (Section 20(4)(k) of the Competition Act) is one of the factors that the CCI is directed to have 'due regard to' while inquiring into the possible adverse effect of a combination on competition. Although competition law does not explicitly take other objectives into account, saving the jobs of at least some of the employees of the failing firm could also be considered, as well as preventing default on payments to vendors, creditors and the government in the form of tax revenues. India has a particularly poor record in allowing firms to close down while efficiently settling their dues to various stakeholders, so the merger route may be the best alternative.

## 5. Drug Price Control<sup>28</sup>

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As briefly mentioned in our survey of policies in section 2 above, successive Drug Price Control Orders (DPCOs) progressively relaxed the rigours of control, both in terms of the number of drugs covered and the principle of price fixation. The number of bulk drugs covered by controls fell from 347 in 1979, to 142 in 1987, to 76 in 1995 (of which two were later deleted). As of March 2013, 74 bulk drugs and about 1550 formulations that use them as ingredients were subject to control by the National Pharmaceutical Pricing Authority (NPPA) under the 1995 DPCO. A new 2013 DPCO vastly increased the span of control, but it came into force after our study was completed. The following analysis therefore discusses the older system, with an assessment of the justifications for changing to the new one, as set out in the National Pharmaceuticals Pricing Policy, 2012 (NPPP-2012) which underlies the 2013 DPCO.

Prices of bulk drugs were hitherto fixed so as to guarantee a minimum rate of return on net worth or capital employed. This rate of return was revised upward in successive DPCOs. Prices of formulations, however, were fixed on the basis of a cost-plus formula:

$RP = (MC + CC + PM + PC) \times (1 + MAPE/100) + ED$ , where

RP = retail price

MC = materials cost

CC = conversion cost

PM = packing material cost of formulation

PC = packing cost of shipment

MAPE = maximum allowable post-manufacturing expenses.

ED = excise duties

While MC can be based on the controlled price of the bulk ingredients, the other costs were based on industry norms determined by site visits to major manufacturers by NPPA inspectors. MAPE is given as a markup over costs. Along with shrinking the span of control, this markup too has been progressively raised, from 40% in the 1979 DPCO, to 75% in 1987, to a flat 100% of costs of production in the 1995 DPCO. Imported formulations are allowed MAPE of 50% over landed costs.<sup>29</sup> Price control applies only to firms above certain turnover and market share thresholds. The government can consider a request from manufacturers to revise the controlled price. Prices of formulations not listed in the DPCO (non-scheduled drugs) which satisfy a different set of turnover and market share criteria were monitored. Increases of over 10% annually in prices of such drugs can

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<sup>28</sup> The descriptive material in this section is based on Gouri (2009), Chaudhuri (2005, ch.8) and Selvaraj et al (2012).

<sup>29</sup> In 2011, the NPPA issued a notification reducing this markup to 35% for imported insulin products, but the Department of Pharmaceuticals recently directed it to review its order. About 86% of the Indian insulin market is provided by imports. ("Imported Insulin to Cost More", *Business Standard*, 12 March 2013).



only be permitted by the NPPA, which can also revise any prices in the public interest and recover excess revenue that firms might earn by charging prices above the controlled level.

Further relaxation of the control regime was proposed in the National Pharmaceutical Policy of 2002, under which the number of bulk drugs under price control was to be reduced to less than 35, the turnover and market share thresholds were to be raised, all drugs whose unit price did not exceed Rs 2 were to be excluded, and drugs developed through indigenous R&D were to be exempt. The implementation of this policy was, however, blocked in 2003 by an interim Supreme Court order in response to a Public Interest Litigation. This order remains in force while the government has tried to comply with the Court's directive to review the policy. Under pressure from the Supreme Court, the government set up various committees and two empowered groups of ministers to re-examine the drug pricing issue, and also revised the 1996 National List of Essential Medicines (NLEM) in 2003 and again in 2011 to cover 348 bulk drugs and 652 formulations based upon them, constituting about 60% of the domestic market. Finally, the government came out with the Draft National Pharmaceuticals Pricing Policy, 2011, which triggered a furious controversy. Very recently (7 December 2012), the government brought out the NPPP-2012, which addresses some, but by no means all of the critics' concerns. We shall try to analyze the issues dispassionately, emphasizing the competition dimension, while also pointing out some significant changes in the NPPP-2012 as compared to the Draft NPPP-2011.<sup>30</sup>

The Draft NPPP-2011 proposed to replace the turnover and market share criteria for coverage with the criterion of essentiality. It would expand the coverage of price control to all 348 drugs on the NLEM, all combinations of drugs in the NLEM, as well as combinations of NLEM with non-NLEM drugs. According to Nayak (2011), this would have extended the span of control from 60% to 75% of the pharmaceutical market. However, in the revised NPPP-2012, the detailed guidelines and formulae laid down in the Draft for fixing the prices of combination drugs has disappeared, and only a provision for manufacturers to seek pre-launch price approval from the government for such drugs has been included. It remains to be seen on what basis approval is given or refused.

The proposal to expand the span of price control to all NLEM drugs has been widely welcomed, but not the related proposal to move from regulating both bulk drugs and their formulations to regulating formulations only. The justification given for this change (in both the 2011 Draft and the NPPP-2012) is that a bulk drug can be used to produce many different formulations, not all of which are essential. Conversely, price control has led to the cessation of production of as many as 27 out of 74 bulk drugs currently covered by the 1995 DPCO, adversely affecting production of formulations that may be regarded as essential. It was also argued that the existing system is unnecessarily cumbersome and does not control the prices of the drugs actually prescribed by doctors, who are often decisive in patients' choice of medications due to asymmetric information. Finally, in a speculative attempt at competition analysis, the NPPP argues that fixing the prices of bulk drugs made it likely that manufacturers would prefer existing buyers (formulators) over potential new entrants, preventing the emergence of new firms and formulations. The argument is presumably that if bulk drug prices were decontrolled, then more efficient entrants could bid away supplies from

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<sup>30</sup> We note, however, that implementation of the new NPPP requires a new DPCO, which had not been released when this report was finalized. This DPCO may involve further modifications. Also, the Supreme Court, while hearing the PIL challenging the 2002 NPPP, has expressed its opposition to abandoning cost-based price fixation, although its final judgment is still awaited.



existing buyers, but the theoretical basis for this is not spelt out. It is equally possible that downstream producers, being able to overprice their non-essential formulations with savvy marketing, could bid away supplies of bulk drugs from those producing essential formulations.

Critics of the formulations-only approach (Selvaraj et al 2012, Srinivasan and Phadke 2013) have pointed out that it would allow firms to produce inessential formulations using bulk drugs in the NLEM, by combining them with non-NLEM drugs. They point out that India already has a huge variety of fixed-dose combinations, many of which are therapeutically inessential or irrational. As mentioned above, the NPPP-2012 actually does away with the principles governing price control for such combination drugs and replaces it with discretionary authorization, which would be a return to the days of the licence-permit raj. Even earlier, Chaudhuri (2005, ch.8) had documented various ways in which firms evaded price controls, such as:

- Changing the composition of formulations by adding or substituting a non-controlled ingredient.
- Shifting production to nominally independent small-scale units exempted from price control.
- Charging higher prices while legally challenging the controlled price. Even if manufacturers lose the case and the NPPA recovers the excess, the consumers who have been overcharged do not get compensation.<sup>31</sup>

Perhaps the most controversial proposal in the NPPP is the changeover from cost-based to market-based pricing for formulations. The NPPP points out that annual fixation of prices based on this formula requires manufacturers to provide extremely detailed cost information, resulting in delays and scope for manipulation. As the prices for formulations of a particular drug are fixed in a narrow band, it discourages fresh entry at an uncovered price point. This is again unconvincing. If prices are fixed as ceilings, there is nothing to prevent a more efficient entrant from entering with a lower price.

The NPPP next argues that detailed cost-based pricing is “anomalous” in an increasingly market-based economy. Interestingly, the revised NPPP-2012 omits a few sentences in the Draft NPPP-2011 which mentioned this anomaly in the context of subjecting 60% of a 48,000 crore industry to detailed administrative pricing. Possibly, the Ministry was stung by critics like Selvaraj et al (2012), who cited this passage to accuse it of being more concerned about the industry than of the millions of Indians who are impoverished by high drug prices. Finally, the NPPP (both draft and final) points out that when input prices (now including those of bulk drugs) are not controlled, cost-based fixation of prices for formulations will lead to distortions and possible movement of production from controlled to non-controlled formulations, as has already happened in case of some bulk drugs. This will adversely impact availability of NLEM drugs and also the industry’s ability to invest and take advantage of drugs going off-patent in developed countries.

Industry representatives<sup>32</sup> argue, with considerable justification, that ‘normative’ costing by the NPPA unrealistically tries to establish norms across efficient units and inefficient units with widely

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<sup>31</sup> As per the 2011-12 Annual Report of the Department of Pharmaceuticals, demand notices for recovery of 2318.54 crores had been issued since inception of NPPA till December, 2011, but only Rs. 217.42 crores had been recovered.

varying technologies and management practices. The cost norms make no allowance for research and development or export market development expenses. We might add that there is no allowance for upgradation of manufacturing standards to comply with WHO Good Manufacturing Practices (GMP) norms, which has been made mandatory by the government under Schedule M of the Drugs and Cosmetics Act.<sup>33</sup> A uniform MAPE discourages firms that actually incur such expenses and gives a higher profit margin to those who do not. It is alleged by the industry that the fear of widening scope of price control has inhibited investment in the sector in the last two years.

The industry also finds it unfair that domestic firms are subject to cost inspections while foreign producers are not.<sup>34</sup> Perhaps the MAPE of 50% of landed costs for imports allows a higher ceiling price as compared to the cost-based price fixed for domestic manufacturers for the same formulation. This can be guaranteed by suitable overinvoicing of imports, for which Chaudhuri (2005, ch.8) reviews compelling evidence from the 1960s and 1970s. But a higher price is compatible with higher sales only if the brand is promoted by other means.

Moving decisively away from cost-based pricing, the proposed new market-based formula in the Draft NPPP-2011 originally fixed prices at the average prices of the top three selling drugs within each category. These prices would be revised annually based on increases in the Wholesale Price Index (WPI) for manufactured goods, and would be the same for domestic and imported drugs. The Draft NPPP-2011 document claimed that for more than half the NLEM drugs, this formula would result in reduction of the price of the highest price brand by up to 5%, and by more than 20% for nearly a third of the brands. (The NPPP-2012 offers no such calculations.) Opponents, however, protested that the formula would escalate the ceiling price far above the current levels fixed by the cost-based regime to the level of the most expensive brands. The formula was then revised to the weighted average (later re-revised in the NPPP-2012 to the simple average) of prices of all brands with a market share of more than 1%. However, critics (Selvaraj et al 2012; Selvaraj and Farooqui 2012; Srinivasan and Phadke 2013) are still opposed to the new formula on various grounds:

- Pointing to many instances where the market leaders are amongst the most highly priced, they predict that market-based pricing will escalate the ceiling prices. For drugs that are currently under price control, they show that the market-based price will be much higher than the cost-based price.
- They show that moving from average prices of the top three brands to the average of all those with more than 1% market share makes little difference. (Their calculations were based on the weighted average, as proposed by the Draft NPPP-2011, but some media reports suggest that a simple average would make little difference.)

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<sup>32</sup> These arguments are based on a note submitted to the authors by Shri D.G. Shah of the Indian Pharmaceutical Alliance.

<sup>33</sup> The Ministry of Micro, Small and Medium Enterprises has a Credit Linked Capital Subsidy Scheme (CLCSS) for Technology Up-gradation which has been extended to pharma MSMEs for 179 items of machinery and equipment required, mainly for GMP compliance. However, this subsidizes only the fixed investment costs, not the costs of operation and maintenance, which would also include higher remuneration for better qualified technicians. A higher profit margin would be required to meet such recurring costs.

<sup>34</sup> Coming from a completely different perspective, Chaudhuri (2012, p.49) reports a case in which a foreign firm obtained a court order to block the NPPA's attempt to ascertain its costs. He calls for the DPCO to be revised so as to authorize the NPPA to get foreign cost data. This would be impractical and also subject to the many valid objections to cost-based price control that we discuss below.

- They also criticize the proposal to exempt all drugs whose unit price is less than Rs 3, arguing that prices will then move up to Rs 3. (This proposal has been dropped in the NPPP-2012.)
- They point out that the prices of the market leaders, and even the prices of the cheapest varieties, are a large multiple of the prices of the same drugs procured by the Tamil Nadu Medical Supplies Corporation (TNMSC), which is widely acknowledged to have the best programme in the country for procuring generic drugs and distributing them through public health facilities. This indicates the large margins accruing to manufacturers and distributors. They also give evidence that the pharma sector has been far more profitable than other sectors.
- They predict that manufacturers will simply change the dosages specified in the NLEM and also modify the composition to make new fixed dose combinations to escape price controls, as they have done even under the cost-based regime. It is not clear how the NPPP-2012 proposes to deal with this. In fact, it explicitly limits (in paras 4(iii) and (v)) the span of control to dosages and strengths listed in NLEM, and it omits the detailed guidelines given in the Draft NPPP-2011 (para 4(9)) for fixation of prices of new non-NLEM dosages and strengths. Instead, it gives a very confusingly-written paragraph (4(viii)) which suggests that the reduction in price of the same molecule in other dosages and strengths, or of other medicines in the same therapeutic category, will be applied. But this will cover existing non-standard formulations; how will the prices of new ones be fixed?
- They also predict that manufacturers will migrate to therapeutically similar ‘me-too’ drugs that are not in the NLEM, and give numerous examples of such drugs. The effective span of control will be reduced by this and the preceding escape route.
- Srinivasan and Phadke (2013) question the reliability of the private IMS database which the NPPP proposes to use for identifying the market shares and prices of drugs on the basis of which the prices will be fixed.

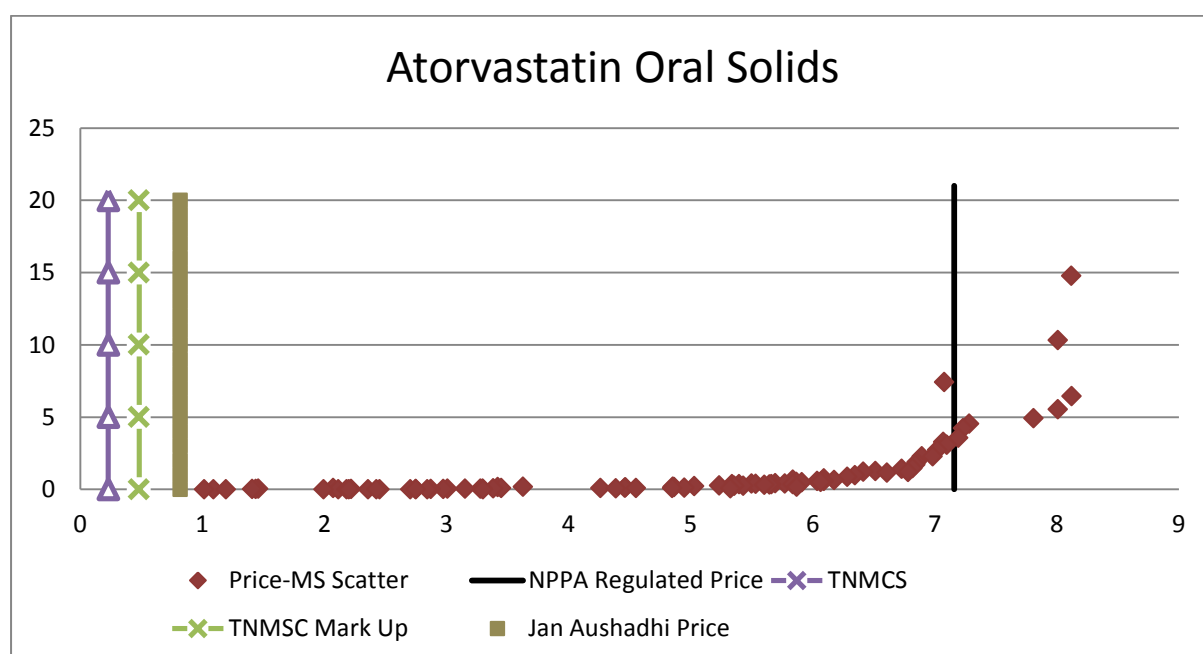
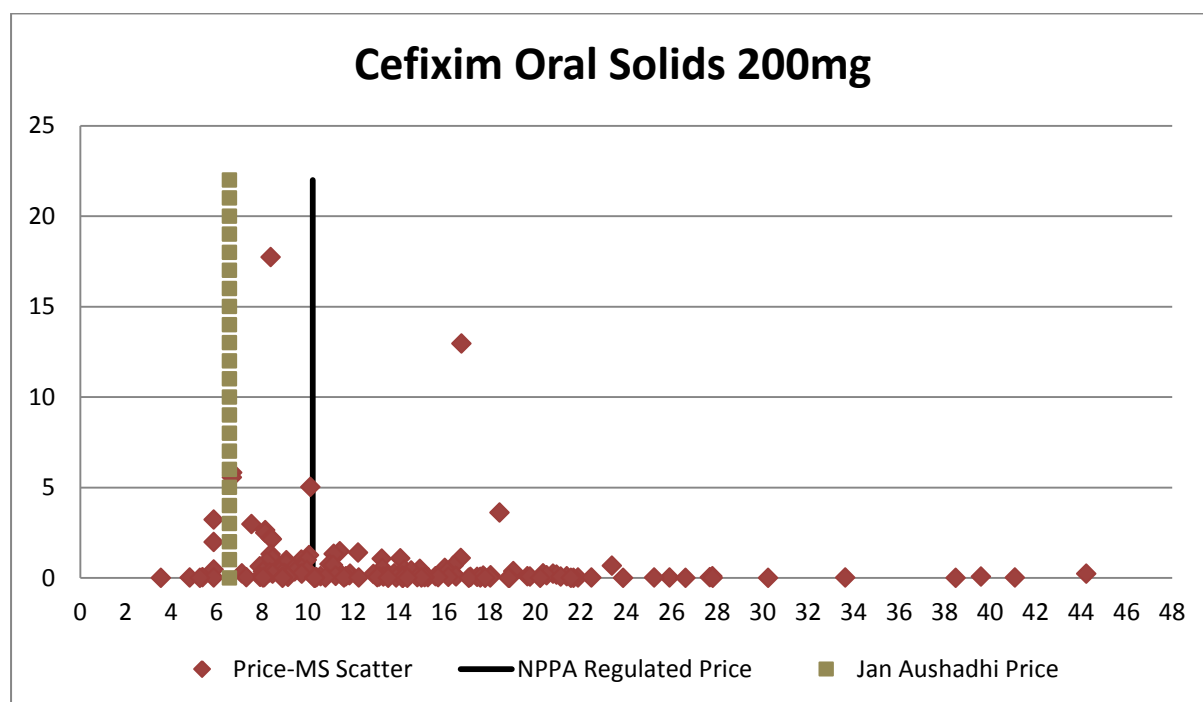
While these critics see the NPPP as being in the interest of the pharma industry, industry associations have protested that the new formula will slash the prices of many leading brands and halve industry profit on domestic sales.<sup>35</sup> Mr D.G. Shah of the Indian Pharmaceutical Alliance has forcefully argued that the market leaders are not the price leaders, and provided us with price and market share data for all brands for the highest-selling drug in each of eight therapeutic categories (moving average totals for 2010 up to August). On the basis of this data we have plotted the scatter of price and market share (based on value).<sup>36</sup> For the five drugs in the NLEM, we have also computed what the controlled price would have been under the formula given in NPPP-2012. We have also depicted the prices at which these drugs were procured by the Tamil Nadu Medical Supplies Corporation, and the prices charged by the government’s Jan Aushadhi network (both for 2010). The

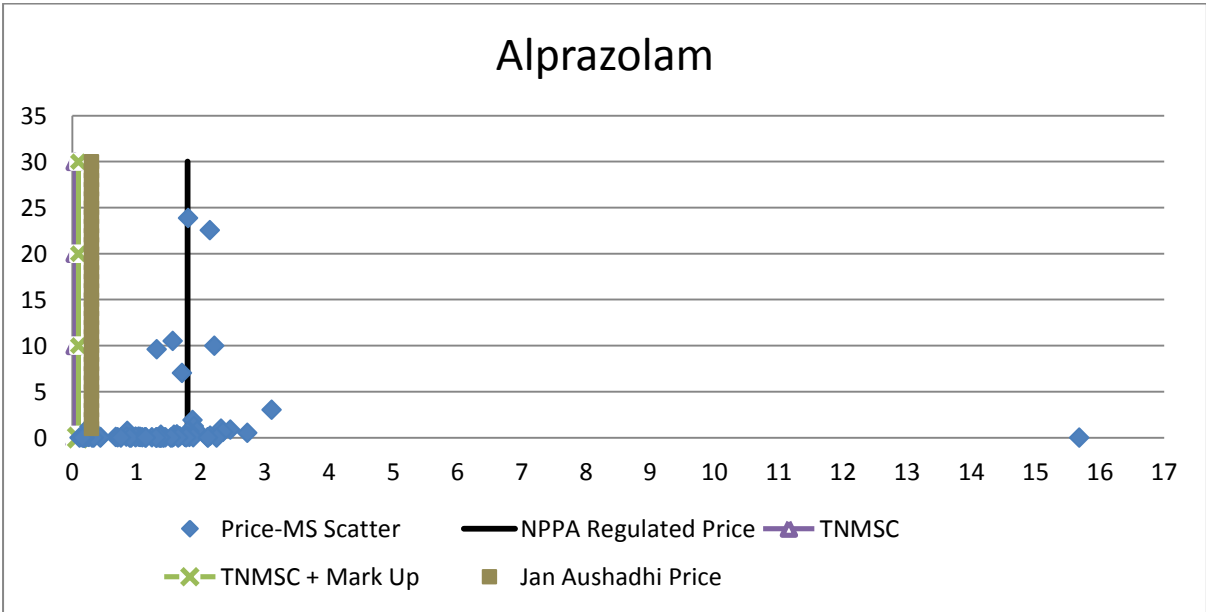
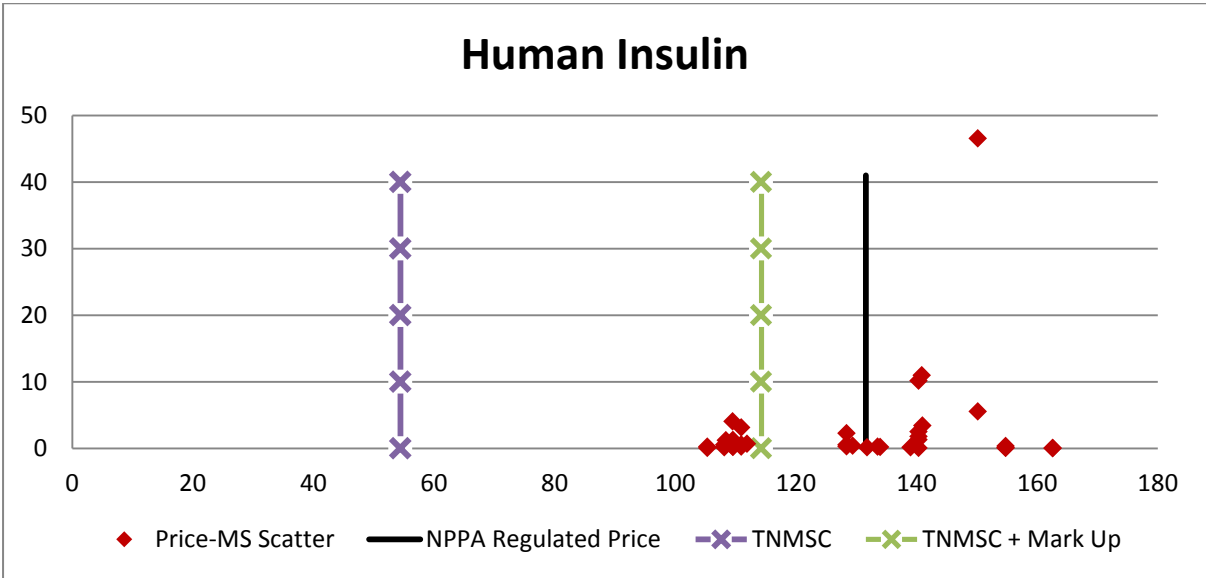
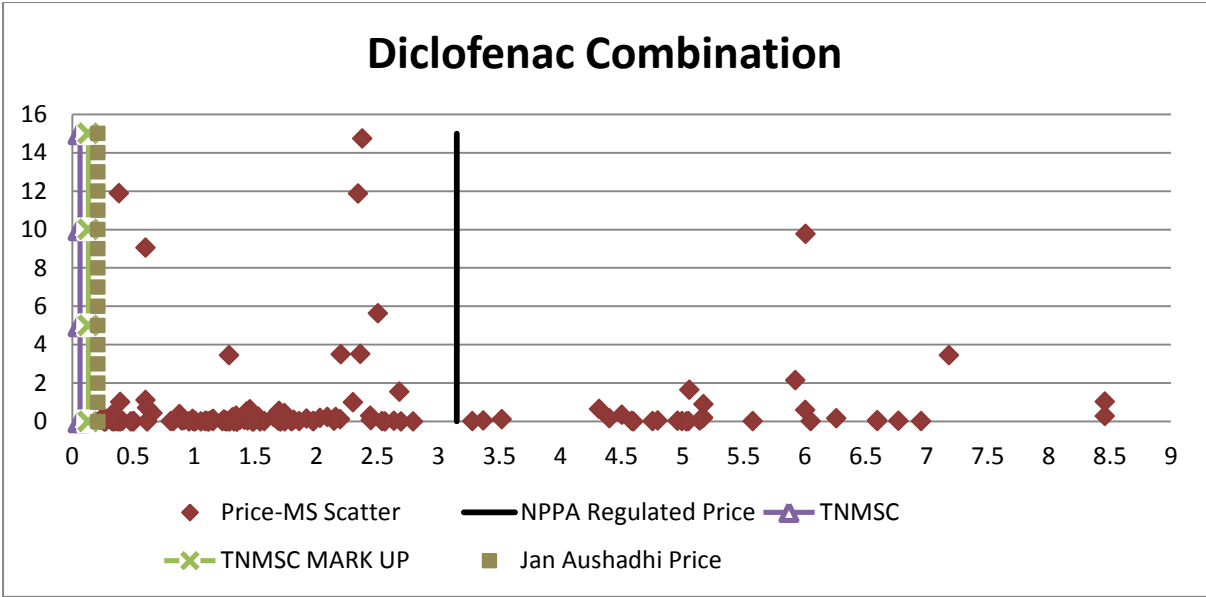
<sup>35</sup> “New Drug Policy Will Hurt Investments in the Sector”, *Business Standard* 26 November 2012.

<sup>36</sup> Details of the specific dosage of each drug are as in the table in section 2.2 above. We have not used market share based on units sold because they are not much different from that based on value. Also, in fixing the prices of essential goods, it is proposed that prices will be based on the average prices of brands whose market shares (based on value) are more than 1%. So we have also used market shares based on values for our calculations. List of NLEM drugs and the Jan Aushadhi prices are from the website of the Department of Pharmaceuticals.

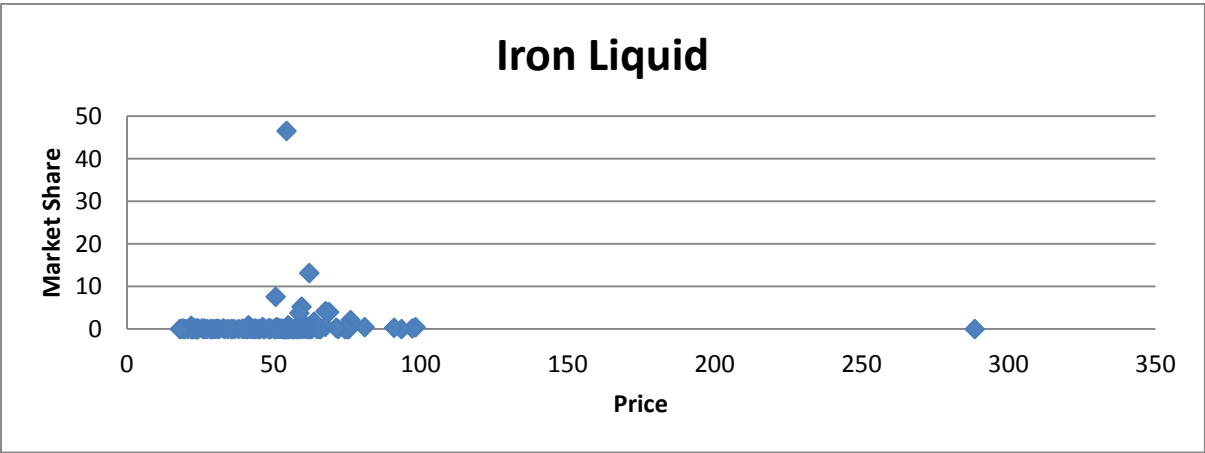
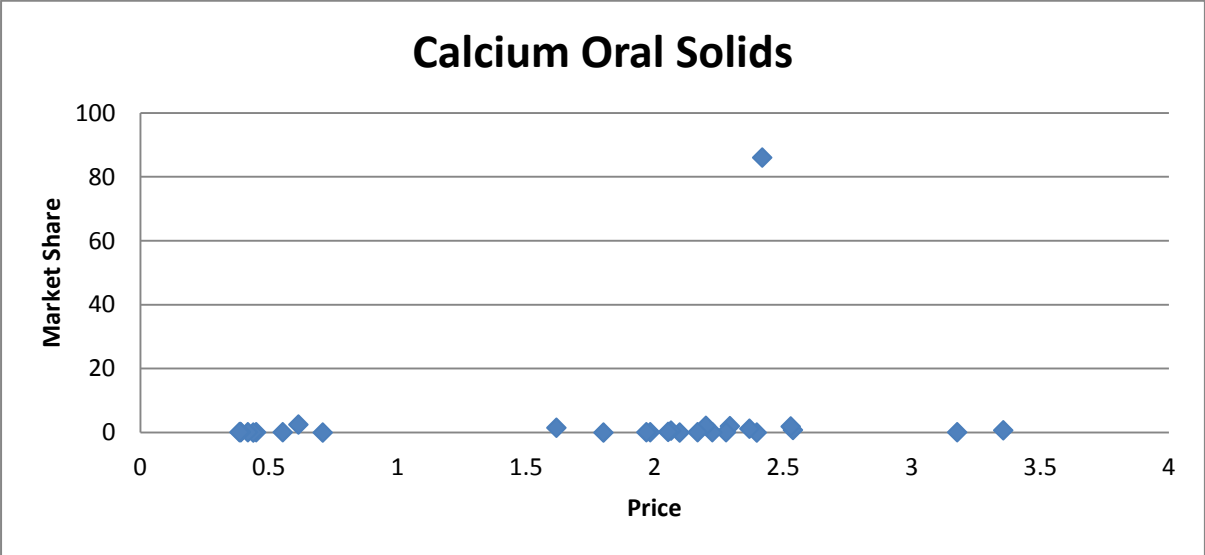
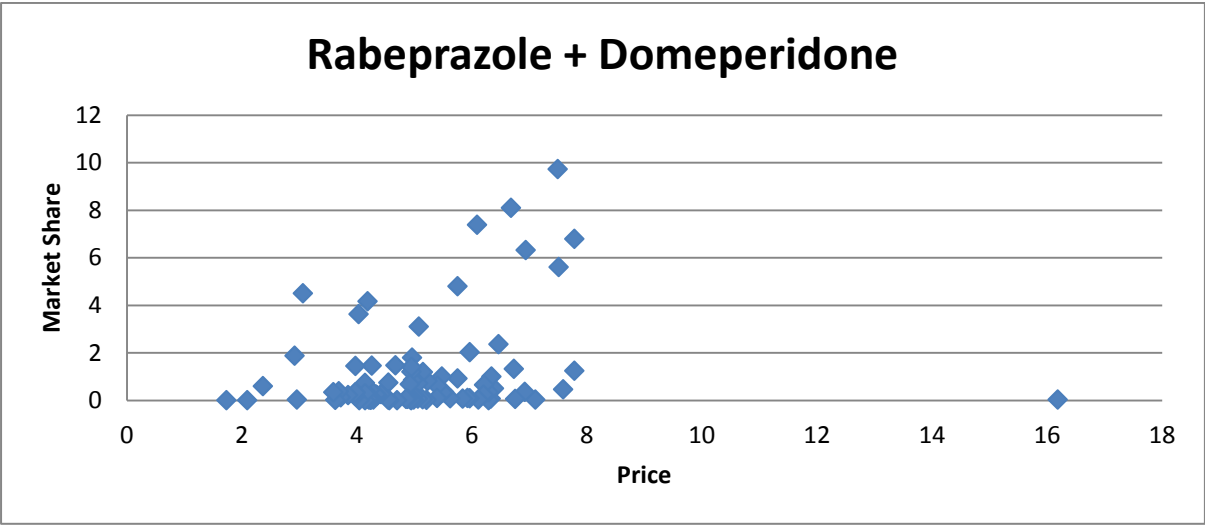
TNMSC prices, based on the lowest bid prices by vendors, represent what a 'competitive' price might be, without branding and marketing, so we have added a markup of 110% to allow for additional expenditures through commercial distribution channels. Jan Aushadhi prices already include a markup to cover transport and distribution costs and a modest profit margin for cooperative societies, NGOs and charitable organizations who take on the task of running a Jan Aushadhi store.

## NLEM DRUGS





NON-NLEM DRUGS



Except for Atorvastatin, these charts seem to support Mr Shah's argument that market leaders are not price leaders, so the prices of many of the more expensive brands with higher prices will have to be reduced under the new price control formula.<sup>37</sup> However, the data are for only one dosage for each of the eight drugs for which data was provided, and even for many of these, the brands above the NPPP price have very low market shares, so the price reduction will benefit very few consumers. And the controlled price may simultaneously serve as a focal point for raising the prices of the lower-priced brands which also command a high market share towards the ceiling level. However, this tendency will be moderated by the NPPA's declared intention to limit annual price rises to ten per cent.

It is also apparent from the diagrams that except for Cefexim, the imputed NPPP market-based controlled price is much higher than the price that would be possible even with a 110% markup over the procurement prices of the TNMSC or the selling prices of Jan Aushadhi. This shows the huge profit margins of the manufacturers, and not just those producing the leading brands.

Of course, these charts are drawn for only the eight drugs for which we had data, of which only five are on the NLEM which will bring them under price control. Clearly, both sides of this debate can find many drugs that will 'prove' their point. It is not possible to undertake a comprehensive assessment across all the 348 NLEM drugs proposed to be brought under price control, each of which has several producers, dosages and pack sizes. However, a few critical remarks can be made, impartially directed at both sides.

To begin with the critics of the NPPP, they have not adequately addressed the issues concerning the problems of cost-based pricing. Manipulation of cost data by regulated firms is a well-recognized problem in economics. Selvaraj and Farooqui (2012) believe that this is no longer a serious problem, because manufacturers are expected to file returns for excise and value added taxes which require reporting of cost data, while imported inputs must have a price declared for customs valuation. Srinivasan and Phadke (2013) propose that controlled prices should be fixed on the basis of a markup over such verified input prices alone. However, this would not allow producers to pass on increases in labour, energy and packaging costs. It also unrealistically assumes a high level of competence and integrity on the part of officials in reconciling data from different firms and different agencies. Misinvoicing of imports is a common practice; it is facilitated if a multinational with a branch in India imports inputs from its own overseas affiliate (intra-firm trade). Moreover, the critics do not confront the possibility that suppression of prices may induce cessation of production of essential drugs, reduction of investment and research and development, and possible diversion to export markets where prices are higher. It gives no incentive to the manufacturer to increase efficiency, because any reduction in materials costs can be penalized by a reduction in the cost-based ceiling price after a period of 'regulatory lag'.

These are all standard criticisms of price controls. The solutions, within the control paradigm, would be even more controls. These would include price ceilings for all existing combinations as well as new ones as they are created, or alternatively prohibition of such combinations unless they have a clear therapeutic advantage. The problem of manufacturers ceasing to produce unprofitable drugs is

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<sup>37</sup> This is also the case with some of the drugs listed by Selvaraj et al (2012), Selvaraj and Farooqui (2012) and Srinivasan and Phadke (2013), who compare the average prices to the prices of only the highest and lowest market prices and the TNMSC prices of the drugs in their sample.

actually recognized by the NPPP-2012, but it gives a completely vacuous ‘solution’ that is rightly criticized by Srinivasan and Phadke: “The production levels, availability and accessibility to the NLEM drugs and formulations should not fall after price control is introduced and the Department of Pharmaceuticals will ensure that production levels are maintained by an appropriate mechanism” (NPPP-2012, para 4(xviii)). There is no practical way of implementing such quantity-forcing controls. It is sometimes used in the regulation of natural monopolies with one product (such as power), where a regulated firm is subject to a ‘common carrier’ mandate to meet all demand at the controlled price. But enforcing this for all 348 NLEM drugs, each produced by dozens, if not hundreds of firms, would be impossible.

On the other hand, the industry critics of price control and the authors of the NPPP are on weak ground (apart from the flaws in their arguments that we pointed out above) in insisting that price control is anachronistic in a liberalized market economy. Canada and Australia, both indubitably successful market economies, exercise price supervision and control over drug prices, although on a much more limited scale than India. It is hardly coincidental that these countries rank near the top of the UNDP Human Development Index, which includes life expectancy as well as conventional per capita income.

Another problem with the NPPP-2012 is that it prescribes that the new controlled prices should be revised annually on the basis of increases in the wholesale price index (WPI), not the WPI for manufactured goods as proposed in the Draft NPPP-2011. The rationale and implications of this change are unclear. But whatever price index is used, this proposal is inconsistent with the standard practice in other countries where price-cap regulation is used (e.g. USA for telephones, UK for power, gas and telephones). There, the regulated price is adjusted for the rate of inflation (usually given by the retail price index) *minus* X%, where the ‘X-factor’ compels the firms to increase their efficiency over time. The regulator must commit to maintain this formula for several years in order to assure the firms that cost reductions are not penalized by subsequent reductions of the regulated price. Again, other countries implement this scheme only for regulated public utilities, where the number of firms and products is manageable.

We have some further criticisms of price controls, whether cost-based or market based, which both sides of the controversy need to consider. Empirical evidence for other countries and industries suggests that ceiling prices can serve as a focal point for oligopolistic coordination or tacit collusion (see Knittel and Stango, 2003, and earlier literature cited there). Price transparency at the initiative of the industry is regarded as a ‘facilitating practice’ for collusion, both in economic theory as well as by antitrust regulators. Does it make a difference if the government itself sets and publicizes the prices? In widely-publicized case, in June-July 2011 the CCI imposed fines totaling nearly Rs 7,000 crores on twelve major cement manufacturers and the Cement Manufacturers’ Association (CMA) for coordinating prices and limiting production and supply of cement.<sup>38</sup> No direct evidence of a collusive agreement was found, but there was evidence of parallel movements in prices, production and dispatch of cement within each region, as well as evidence that the firms had been collecting and sharing information on their wholesale and retail prices. Together with other indirect evidence of factors consistent with collusion, the CCI held that the firms had engaged in cartel behaviour. It

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<sup>38</sup> Case No. 29/2010, [Builders’ Association of India vs Cement Manufacturers’ Association & Ors.](#), order dated 20 June 2012, and RTPE-52/2006, *In re: Alleged Cartelization by Cement Manufacturers*, order dated 30 July 2012. See Bhattacharjea and De (2012) for discussion of these and similar cartel cases decided by the CCI.



did not exonerate the firms on the grounds that the Department of Industrial Policy and Promotion (DIPP) under the Ministry of Commerce and Industry had directed the CMA to collect and submit wholesale and retail price, production and capacity data from across the country. In the case of drugs, the focal price is set and publicized by the NPPA.<sup>39</sup> Can the firms be blamed for coordinating their pricing accordingly? As discussed above in our section on collusion in the supply chain, similar issues arise with regard to the fixation of retail margins.

Finally, critics have pointed out that the NLEM still excludes patented drugs; anti-AIDS medications; biopharmaceuticals; remedies and nutritional supplements based on the traditional Ayurveda, Unani, and Siddha systems of medicine which are increasingly being commercialized by large firms; chemical reagents used for diagnostic testing; ‘me-too’ drugs that are similar to those in the NLEM; and even those in the NLEM but not in the specified dosages (Selvaraj and Farooqui, 2012; Selvaraj et al, 2012; and personal communication from N. Lalitha). In fact, NPPP-2012 notes that separate committee to look into pricing of patented drugs was constituted in February 2007. This committee only very recently submitted its report after six years. We have not had the opportunity to go through it, but according to news reports it recommends that prices be negotiated with the companies and will apply only to patented drugs sold to the public procurement system or reimbursable through health insurance, which usually does not cover out-patient treatment. It will therefore cover only a tiny minority of patients.

Our general conclusion is that price controls, whether cost-based or market-based, will give rise to a multiplicity of problems if they are implemented on such a large number of drugs. From a competition perspective, it would be better to unleash the forces of competition by cracking down on anti-competitive practices and the marketing techniques of the pharma companies based on branding. There is a genuine concern that debranding will lead to an increase in spurious and substandard drugs. But the incentive to produce such drugs will also be reduced by erosion of the high premiums on leading brands. Nonetheless, increasing the efficiency of the enforcement mechanism under the Drugs and Cosmetics Act will help. Probably the most effective intervention would be to ramp up the system of public procurement and distribution of generics, where branding is irrelevant and quality control can be exercised by the procurement agency. We discuss this in section 9 below.

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<sup>39</sup> There is a broader issue that goes far beyond drugs or price controls. For decades, the government has required manufacturers of all packaged products to print the Maximum Retail Price (MRP) on the package itself. The latest such regulation is the Legal Metrology (Packaged Commodities) Rules, 2011. Although this is a well-intentioned measure to prevent consumers from being overcharged by retailers, it also mandates price transparency that can be a facilitating practice for collusion by manufacturers, retailers or both.

## 6. Foreign Direct Investment (FDI)

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As noted in the Introduction, there has been growing concern over the influx of foreign pharmaceutical firms into the Indian market, primarily in the form of mergers and acquisitions of Indian firms ('brownfield' FDI). While 'greenfield' FDI (setting up of a new unit) potentially increases competition, acquisition of an existing firm reduces actual or potential competition, depending on whether the target firm was an actual or potential competitor. Even if it was not, so that domestic consumer welfare is not harmed, such a merger can be questioned on a total welfare standard because it results in an outflow of profits. Whether brownfield or greenfield, it is feared that multinational corporations (MNCs), with their deep pockets and marketing techniques will distort competition in the Indian market, adversely affecting pharmaceutical prices. In the case of acquisitions, they may terminate the production of cheaper drugs produced by the Indian firms that they take over, and perhaps also scale back their research and development activities so as to prevent potential competition for their brands. Responding to some of these concerns, in June 2011 the Government of India set up a High Level Committee under the Chairmanship of Shri Arun Maira, Member (Industry) in the Planning Commission. The members were Secretaries of the Ministry of Health and Family Welfare and the Departments of Industrial Policy and Promotion, Pharmaceuticals, and Biotechnology; the Director General of the Council of Scientific and Industrial Research, the Drug Controller of India, and the Chief Economic Adviser of the Ministry of Finance. Its lengthy terms of reference were compactly summarized in the Committee's report<sup>40</sup> (p.4) as follows:

- What is the most effective way in which the Indian government can 'control' and regulate the influx of foreign companies into the Indian pharmaceutical market to ensure that there is no detrimental effect of these acquisitions on prices and availability of medicines in India?
- What are the principal actions necessary, in addition to the above, to ensure that medicines are affordable and accessible to all, especially the poor?
- What policies are required to grow a vibrant, competitive, and innovative pharma sector?

In just three months, the Committee met representatives of the major pharma manufacturers' associations, the CCI, and other experts, and submitted a comprehensive and well-balanced report. It recognized that foreign pharma companies were facing rising costs, regulatory burdens and pressures to moderate healthcare expenses in their home markets, and so were looking to invest in developing countries with lower production costs and more rapidly expanding markets.

The Committee received data from various industry associations on the link between FDI and rising prices and reduced availability of drugs. However, it found that the evidence was "both insufficient and contradictory" (p.3 of the report). It gave more credence to a study by the Department of Pharmaceuticals, which analysed price and quantity data over 2008-11 for three categories of large pharma companies: the seven top domestic companies, the seven top multinationals, and seven major Indian companies acquired by MNCs. It found no significant difference between the categories in respect of the proportion of packs that had shown price increases. As regards

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<sup>40</sup> *Affordable, Accessible, Acceptable Medicines for All: Issues regarding FDI policy in pharma sector* (hereafter referred to as the Maira Committee Report).

availability, it found that there had been a year on year increase in the total number of medicine packs available in the domestic market, as well as an increase in the number of new drugs/formulations introduced by all the three categories of firms. The Department's study concluded that it could not be inferred that acquisitions of Indian firms had resulted in higher prices or lower availability. The study also presented data that showed that pharma exports had slowed down, probably on account of recession in the major Western markets. It could not be concluded that exports had diverted production for the domestic market: both had grown, and as the report rightly pointed out, the two markets were not in a zero sum situation.

While this analysis was reasonable in the limited time given to the Committee to submit its report, a few critical comments are in order. First, while endorsing the conclusions regarding the insignificant impact of foreign acquisitions on drug prices and availability, the Committee itself noted that "the acquisitions are recent and more definitive trends will become evident over time". Second, the study looked at the aggregate number of packs in the market. This does not tell us anything about whether production of individual drugs was downscaled. Third, an increase in the number of formulations does not tell us anything about their importance for the kind of diseases that pose public health problems. And it is doubtful that more varieties of multivitamins or cough syrup, for example, represent innovative dynamism, whether by Indian or foreign firms. Also it is not clear whether the roughly 2300 'new' formulations mentioned by the study were new in the market, or whether each one was new (that is, being produced for the first time) for a particular company. Finally, the report did not address the issue of whether foreign takeovers would result in reduction or reorientation of Indian firms' R&D or a change in their strategy away from contesting foreign patents or seeking compulsory licences.

Be that as it may, the major part of the Maira Committee Report did try to address the contentious question of how to deal with foreign takeovers. The Ministry of Health strongly opined that the CCI did not have the capability to address a range of public health and industrial policy issues, nor could the Ministry appear before it to represent the interests of consumers. The Ministry therefore argued that foreign acquisitions of more than 51 per cent of the equity of Indian firms should require approval by the Foreign Investments Promotion Board (FIPB), while greenfield FDI would continue to come under the 100 per cent automatic approval route. While noting the lack of unanimity on this issue (and annexing a note of dissent from the Ministry), the Maira Committee expressed its reluctance to return to a system of non-transparent discretionary approvals by the FIPB, reminiscent of the era of the 'license raj'. It pointed out that the Competition Act provides a framework of legal transparency and requires evidence-based, time-bound decision making, with well-defined rights for the parties, including the right of appeal. The Act also empowers the CCI to address all the relevant concerns about the impact of acquisitions on price, availability, innovation, competition, and intellectual property rights, and to order structural or behavioural remedies to deal with any adverse effects. It also provides for consultations with outside bodies and individuals with relevant expertise. In this respect, the CCI might actually be better placed than the FIPB.

The Committee's praise for the Competition Act and the CCI was not, however, unqualified. It expressed concern that the asset and turnover thresholds above which combinations are subject to review by the CCI were too high. It pointed out that the turnover of most of the Indian pharma companies that are targets of foreign firms is below the new threshold for the minimum size of the target firm alone, announced by government notification in 2011, just before merger review powers

were brought into force. As for the thresholds for the combined size of the acquirer and target, the Committee pointed out (without giving any specific examples) that many acquisitions by multinationals are made by subsidiaries or special purpose vehicles created for the purpose. As these entities would have negligible assets and turnover, the global assets or turnover of their parent companies would have to be taken into account—but these would come under the much higher thresholds for ‘groups’. Annexure 4 of the Report tabulates the size of the world’s pharma giants, and points out that only the top 18 would exceed the turnover threshold. However, this calculation could be misleading, as the threshold is applied to the *combined* turnover of the post-merger entity, so the turnover of the target firm would have to be added. A more accurate and relevant calculation in the same Annexure is that only the top 10-12 Indian companies would exceed the turnover threshold for target firms. Takeover of smaller firms would not require notification or approval. However, the report called for reducing both these thresholds for the pharma industry specifically. In particular, it opined (again without providing evidence) that abolishing the target-specific threshold “would bring over two-thirds of the relevant proposals under the purview of the Commission” (Report, p.6). We have tried to assess these claims in our merger section (4.3) above, but due to lack of data we could identify only a handful of merger cases that escaped scrutiny.

We now briefly summarize some of the Committee’s other recommendations, which we find unexceptionable. Addressing the concern of the Ministry of Health that the CCI would not have the expertise to deal with the specific public health issues involved in foreign acquisition of Indian pharma companies, the Committee recommended setting up a Standing Advisory Committee with representation from all relevant government departments and agencies to assist the CCI. On other pharma-related policy matters, the Committee boldly stated that India should resist pressures to allow patent holders to extend patent protection by exploiting ‘data exclusivity’ or ‘evergreening’ (discussed in section 7 below). It also strongly reaffirmed the need for India to retain the right to award compulsory licences. It also called for government to step up its funding drug of development, through the public sector as well as public private partnerships, and for selective price controls and free supply of essential drugs through the public health system. The Committee’s suggestions for increasing greenfield FDI were in very general terms, and it deferred to the government’s new Manufacturing Policy and Draft Twelfth Plan documents for details. The Committee also observed that both Indian and foreign pharma companies were complicit in anti-competitive practices, and ownership (Indian or foreign) could not be blamed for unnecessarily high prices. In a clear endorsement of maintaining competitive neutrality, the Committee opined that “the solutions must be structural and apply to all companies in the industry” (p.11).

The government’s response to the Maira Committee’s recommendations amounted to a snub. In October 2011, within a month of the report being submitted, approval for all brownfield FDI in pharma was consigned to the FIPB, despite the Committee’s majority view being against it. Shortly thereafter, another High Level Expert Group on Universal Health Coverage submitted its report, with a brief recommendation on FDI which seemingly endorsed the government’s decision retrospectively:

we also need to urgently revisit India’s FDI regulations to amend the present rules of an automatic route of 100% share of foreign players in the Indian industry to less than 49%, so as to retain predominance of Indian pharmaceutical companies and preserve our self-sufficiency in drug production. Another option is to move the drug industry from an

automatic route to the Foreign Investment Promotion Board (FIPB) route, which would ensure that all proposals of foreign mergers and acquisitions of Indian drug companies are scrutinised thoroughly. (p.132, Recommendation 3(c))

This recommendation was not based on even the limited kind of empirical evidence offered by the Maira Committee in coming to a diametrically opposite conclusion, nor did it weigh the limitations of the FIPB approval process. It did not even mention the Competition Act or the CCI; in fact the only time the word 'competition' occurs in the report are in its chapters reviewing foreign healthcare systems and health insurance, and a solitary reference to how India's pre-TRIPS IPR regime permitted Indian companies to provide competition for patented foreign drugs (p.130). The Expert Group took it for granted that predominance of Indian companies and self-sufficiency in drug production were desirable objectives in themselves.

However, as the Maira Committee report had indicated, the FIPB did not have guidelines to address the public health issues that the Ministry of Health had flagged, and investment proposals worth thousands of crores of rupees were allegedly held up. An inter-ministerial group was set up to draft suitable guidelines, and Rs 3000 crore worth of pending proposals were cleared in November 2012. But differences remained, with the Finance Ministry wanting brownfield FDI resulting in acquisition of less than 49% of the Indian firm's equity to revert to the automatic route, and the Ministries of Health and Commerce and Industry wanting approval of all brownfield FDI to stay with the FIPB. The Prime Minister apparently had to step in to resolve the differences, and in December 2012, despite pushing a number of measures to liberalize FDI in other sectors, so as to give the impression that the government was serious about restarting the stalled process of economic reforms, the Union cabinet decided to continue with the FIPB channel for brownfield FDI in pharmaceuticals.<sup>41</sup>

It is believed that this is a temporary measure until the CCI is empowered to deal with the issues raised by foreign takeovers in the pharmaceutical sector. On 10 December 2012, a long-awaited bill was introduced in the Lok Sabha to amend the Competition Act so as to (among other changes) allow the government, in consultation with the Commission, to notify different asset and turnover thresholds "for any class of enterprises" (not just those in the pharma sector), and to make consultations with other regulatory agencies mandatory rather than voluntary as at present. At the time of writing, it remains to be seen whether the bill is passed by Parliament, and if so how far the thresholds are relaxed. However, it has recently been reported that after a lull that followed the high-profile foreign acquisitions of 2008-2010, multinationals have again started showing interest in acquiring mid-sized Indian pharma firms with established portfolios of generics that are poised to enter the US market as several drugs go off-patent. Indian firms are reportedly willing to sell as they fear erosion of their profit margins in the Indian market because of rising power costs and policy uncertainty, especially with regard to the extension of price controls. At the same time, unlike the large Indian companies, they do not have distribution channels to penetrate foreign markets. Selling

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<sup>41</sup> This paragraph is based on a news report, "FIPB to approve foreign investments in pharma sector", *Economic Times*, 4 December 2012 (<http://economictimes.indiatimes.com/news/news-by-industry/healthcare/biotech/pharmaceuticals/fipb-to-approve-foreign-investments-in-pharma-sector/articleshow/17468096.cms>)

to MNCs therefore makes sense.<sup>42</sup> It is imperative, therefore, that the policy with respect to foreign acquisitions should be straightened out as soon as possible.

### *Assessment*

We now assess the arguments for and against FDI (greenfield or brownfield) in the Indian pharma industry. As outlined in section 2.1 above, foreign firms have always played a role. In the pre-TRIPS regime their interests were harmed because of the weak patent law under which their products could be reverse-engineered and produced using a different process. It is believed that in the post-TRIPS regime the foreign firms will be able to achieve higher market shares because the patented products will not be produced by anyone except the innovator.

Various studies have looked at the impact of TRIPS on the market shares of the Indian and foreign firms. In a report: “Effects of New Patents Regime on Consumers and Producers of Drugs/Medicines in India” conducted by the Institute of Economic Growth submitted to the UNCTAD, they found that the market share of foreign companies has declined during 2004-08 in eight of the eleven segments analysed in this study. The three segments in which the market share of foreign firms has increased are Antacid Antiflatulents, Muscle Relaxant and Statins. The increase they say is not because of the product patent regime but because of the brand name of the products sold by the leading foreign companies in this segment. “The main reason why the new patent regime has not seen an increase in the market share of foreign companies is that the existing foreign companies have mostly been operating in the generic segments only where the domestic companies dominate”.<sup>43</sup> The report found that none of the major foreign companies had launched their patented products in India even after 21 months of the start of product patent regime, though they have been introducing them in other parts of the world. The foreign companies feel that generic manufacturers are provided with marketing approval of the patented product by the Drug Controller General of India and therefore they are apprehensive in marketing their patented products in India. On the other hand, the foreign firms have launched original brands of the already existing Indian generics.

The report found that the market share of the Indian firms has gone up during the period 2004-08. They attribute this to three reasons: Firstly, the Indian companies have increased penetration in small towns and villages where foreign companies are not active. Also, some Indian firms have tied up with large foreign companies to produce in-license drugs. This has led to increased sales by the domestic firms. For instance, Dr Reddy’s has a license from Merck & Co. to sell simvastatin as an authorized generic drug. Secondly, significant foreign investment is taking place in the Indian pharma industry in the form of contract research and contract manufacturing, which has led to increased competitiveness and hence sales in the process. Thirdly, a number of patented drugs have gone off-patent in the recent years and their generic versions are produced by the Indian companies. The IEG report covered the period upto 2008. A recent news brief shows that Indian firms maintained and slightly increased their market shares from about 81.3% to 83.4% between 2007-2012.<sup>44</sup>

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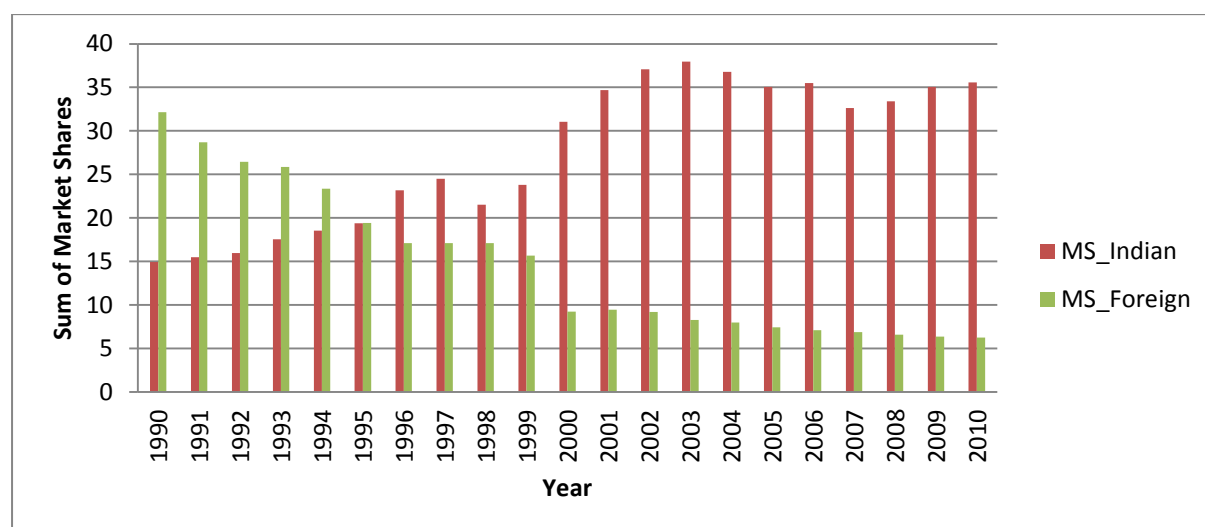
<sup>42</sup> “M&A Fever Returns to Pharma”, *Business Standard*, 18 March 2013.

<sup>43</sup> Effects of New Patents Regime on Consumers and Producers of Drugs/Medicines in India accessed at <http://wtocentre.iift.ac.in/UNCTAD/09.pdf>

<sup>44</sup> “Statsguru: Indian pharma is high on profit, low on R&D”, *Business Standard* 5 April 2013.

Chaudhuri (2012) claims that the market share of the foreign firms has instead gone up. “In March 2008, there was only one MNC (GSK) among the top 10 companies in India. By December 2010 the number of MNCs in the top 10 went up to three (GSK, Ranbaxy and the Abbott group). The Abbott group comprising Abbott, Piramal Healthcare and Solvay Pharma is now the largest company in India with a market share of 6.2% ahead of the second largest Cipla (5.7%). Abbott was the 30th largest company in the domestic formulations market in March 2008 with a market share of only 1.1%. Thus, the declining trend in the aggregate market share of the MNCs which started in the 1970s has been reversed. The MNCs are recovering lost ground. The post-TRIPS environment and the strategy being adopted by the MNCs suggest that they are on the way to dominating the industry again” (Chaudhuri 2012).

To check the validity of this claim we have compared the market shares of the domestic vis-a-vis the foreign firms for the periods before and after the TRIPS. Based on data availability, we can only use total sales of the firms to derive at market shares. We have looked at the sum of market shares of the top<sup>45</sup> ten foreign firms and the top ten domestic firms for this comparison. In 1990, there was a huge positive difference between the sum of market shares of foreign and domestic firms. Over time the difference declined and in 1995 their sum was equal. Since then, the sum of market shares of Indian firms has dominated that of foreign firms. While the sum of market shares of the top ten Indian firms has been increasing, that of the foreign firms has been going down, as shown in the following graph.



(Source: Computed by the authors from Prowess data)

The claim that the industry will be dominated by the foreign firms is not supported by the data. If anything, the share of the Indian firms has only gone up after 1995 which marks as the starting point of the era of TRIPS. However, as emphasised earlier, actual competition takes place at the therapeutic segment level and these figures are at a very broad level. Data at the level of therapeutic level may be more appropriate to see the dominance of foreign firms if any. Also, these data are only for sales of companies registered in India, and would underestimate the foreign share to the extent it is supplied through imports.

<sup>45</sup> The top firms have been selected on the basis of their ranking based on their sales of goods in the year 2010.



Apart from the issue of market shares of Indian and foreign firms, the debate also concerns the behaviour of foreign firms. Chaudhuri (2005, 2012) has provided detailed evidence that foreign firms, whatever their mode of entry, have not delivered the expected benefits and are associated with very high prices. He shows that investment in plant and machinery has been virtually stagnant for the nine pharma MNCs for which Prowess data is available since 1994, while it has risen almost twenty-fold for the top ten Indian companies over the same period. Instead, the MNCs are increasingly exporting formulations (both patented and generic) to India, either through their domestic affiliates or through Indian pharma companies who act as their authorized agents. He argues that the MNCs are not only interested in the markets for patented drugs but are growing in the generics segments as well. "The MNCS are also expanding vigorously in the generic segments and are trying to grow not only organically but through mergers & acquisitions and strategic alliance with Indian generic companies." The patents on many blockbuster molecules are expiring now and the developed country markets are facing constraints on their future growth. Therefore, the foreign companies have shifted focus towards the generic segments in the developing countries. They monopolize many new drugs marketed in India after 1995, including non-patented drugs for which there is no legal barrier to competition. This indicates that complex manufacturing processes may discourage competitors from entering the market. Chaudhuri lists several of these drugs which have prices exceeding Rs 10,000 per dose, which means that a full course of treatment could cost several lakh rupees.

#### *Effects on Foreign Trade*

Jha (2007) asserted that even after India has become a net exporter of pharmaceuticals, India's dependence on imported active pharmaceutical ingredients has increased over the period of her analysis 1997-2007. The Indian affiliates of the multinationals are more interested in investing in financial securities in India rather than investing in their pharma businesses. She also points out that the strategic alliances between Indian and foreign firms in the form of contract research and manufacturing has resulted in biases in the choice of therapeutic areas towards life-style related products. She has compared the pattern of production of bulk drugs and formulations by the domestic and the foreign firms. Indian firms' share in bulk drugs has increased from 41% in 1995 to 62% in 2004 and India is the highest recipient of the of US FDA approvals of bulk drugs outside the US.

In terms of bulk drugs and formulations also, Jha (2007) sees a similar bias. "Multinational companies import either bulk drugs or some life saving, new generation, under patent formulations from their parent companies, to India. The share of bulk drugs and finished goods in total imports is consistently increasing for MNCs. Since 1994 when the ratio requirement for bulk drugs-formulations was abolished, many foreign companies closed down their bulk drugs manufacturing plants in India. GSK closed its manufacturing unit for Ranitidine in Surat which was a base for providing the drug not only in India but also to its subsidiaries. The MNCs are engaging in simply importing rather than undertaking investment or subcontracting the production of bulk drugs in the country" (Jha, 2007).

Chaudhuri (2012) also shows that the MNC's exports from India are growing much more slowly than that of the top ten Indian companies; their export to sales ratio is stagnant at around 5% since 1994,



while that of the Indian companies has risen from 28% to nearly 50% in the same period. The net foreign exchange earnings of the MNCs are negative while that of the Indian companies is positive.

To re-examine these issues with more recent data, we have looked at the major exporters of pharma products within the pharma industry for the year 2010-11. The gross sales of the firms are inclusive of export sales. Therefore, we have calculated the share of exports in their total sales of the top 20 firms (ranked on export value) in the Indian pharma industry. The data has been taken from CMIE's Prowess database. Out of these 20 companies, there is only one foreign company which is Mylan Laboratories Ltd. The rest are all Indian companies.

Company Name	Total Sales	Exports	Export/Sales
	Rs Million	Rs Million	(%)
Ranbaxy Laboratories Ltd.	66946.7	54114.8	80.8326624
Dr. Reddy'S Laboratories Ltd.	66443	48405	72.85191819
Cipla Ltd.	60785.2	36920.3	60.73896277
Mylan Laboratories Ltd.	35785.2	34171.1	95.4894761
Lupin Ltd.	52162.8	30329.2	58.1433512
Aurobindo Pharma Ltd.	42144.4	29239.9	69.38027354
Divi'S Laboratories Ltd.	18473.5	16091.9	87.1080196
Sun Pharmaceutical Inds. Ltd.	24631	14628.2	59.38938736
Jubilant Life Sciences Ltd.	27088.9	13576	50.11646837
Cadila Healthcare Ltd.	24565	13569	55.23712599
Ipca Laboratories Ltd.	23185	13533.6	58.37222342
Wockhardt Ltd.	23786.6	12094.4	50.84543398
Orchid Chemicals & Pharmaceuticals Ltd.	16264.4	8466.6	52.0560242
Torrent Pharmaceuticals Ltd.	19673.9	7585.4	38.55564987
Biocon Ltd.	13656	6661	48.77709432
Nectar Lifesciences Ltd.	12656.4	6548.4	51.73983123
Piramal Enterprises Ltd.	9388.8	6515.3	69.3943848
Ind-Swift Laboratories Ltd.	13255.8	5800	43.75443202
Glenmark Pharmaceuticals Ltd.	15473.1	5405.8	34.93676122
Strides Arcolab Ltd.	4901.3	5404.6	110.2687042
Source: CMIE Prowess			

A similar exercise was done for major importers of pharmaceutical finished products and raw materials used in pharmaceutical products. The top 20 importers of pharmaceutical products are listed below:

Company Name	Sales of goods (Rs Million)	Import of finished goods (Rs Million)	Imports Finished/Sales (%)
Sanofi India Ltd.	11732.9	1902.8	16.2176444
Jubilant Life Sciences Ltd.	27088.9	1729.3	6.383795577
Novartis India Ltd.	447.7	1312.8	293.2320751
Wyeth Ltd.	6009.7	1245.3	20.72150024
Glaxosmithkline Pharmaceuticals Ltd.	19306.5	1088.7	5.639033486
Merck Ltd.	4416.1	757.2	17.14635085
Cadila Healthcare Ltd.	24565	690	2.808874415
D S M Anti Infectives India Ltd.	5769.5	485.7	8.418407141
Abbott India Ltd.	7993.3	482.6	6.037556454
Unimark Remedies Ltd.	6601.5	463.5	7.021131561
Pfizer Ltd.	9248.5	453.4	4.902416608
Lupin Ltd.	52162.8	280.2	0.537164416
Piramal Enterprises Ltd.	9388.8	278.9	2.970560668
Zydus Animal Health Ltd.	761.6	131.7	17.29254202
Ipca Laboratories Ltd.	23185	88.2	0.380418374
Claris Lifesciences Ltd.	6589.2	81.2	1.232319553
Jagsonpal Pharmaceuticals Ltd.	1638.9	72.8	4.442003783
Morepen Laboratories Ltd.	1986.5	63.7	3.206644853
Elder Health Care Ltd.	486.3	45	9.253547193
Span Diagnostics Ltd.	585.2	25.7	4.391660971
Source: CMIE Prowess			

Among the top 11 importers of pharmaceutical products, as many as 7 are foreign firms whereas there is only one exporter of foreign origin in the top 20 exporters of pharmaceutical products from India. When we look at the import of raw materials in India of the top 20 companies, the data looks like:

Company Name	Sales of goods (Rs Million)	Import of raw materials (Rs Million)	Import Raw Material/Sales (%)
Aurobindo Pharma Ltd.	42144.4	13845.1	32.85157696
Cipla Ltd.	60785.2	9543.4	15.70020334
Mylan Laboratories Ltd.	35785.2	9018.1	25.20064161
Ranbaxy Laboratories Ltd.	66946.7	7592.7	11.34141041
Dr. Reddy'S Laboratories Ltd.	66443	6914	10.40591183
Lupin Ltd.	52162.8	6233.1	11.94932021
Jubilant Life Sciences Ltd.	27088.9	4761.5	17.57731026
Orchid Chemicals & Pharmaceuticals Ltc	16264.4	4594.5	28.24881336
Ind-Swift Laboratories Ltd.	13255.8	4460	33.64564945
D S M Anti Infectives India Ltd.	5769.5	4134.3	71.65785597
Biocon Ltd.	13656	4026	29.48154657
Ipca Laboratories Ltd.	23185	3753.8	16.1906405
Divi'S Laboratories Ltd.	18473.5	3503.6	18.96554524
Arch Pharmalabs Ltd.	13214.2	3471.3	26.26946769
Sun Pharmaceutical Inds. Ltd.	24631	2895.2	11.75429337
Nectar Lifesciences Ltd.	12656.4	2735.7	21.61515123
Surya Pharmaceutical Ltd.	16477.4	2699.5	16.38304587
Wockhardt Ltd.	23786.6	2314.9	9.731949921
Piramal Enterprises Ltd.	9388.8	2285	24.33750852
Panacea Biotec Ltd.	6303.2	2184	34.64906714
Source: CMIE Prowess			

The data confirms that while Indian firms are importing raw materials for manufacturing pharma products, the foreign firms are importing finished products. There is only one foreign firm in the top 20 that is importing raw materials. This means that while Indian firms are enabling manufacturing capabilities in India, the foreign firms are not interested in producing in India; they are present in India, but importing finished products and selling them in India.

#### *Effects on Research and Development*

Another argument often made against increasing foreign takeovers of Indian firms is that they will reduce domestic R&D. We have tried to look at the impact of foreign acquisition of the Indian firms on their R&D expenditure. Foreign acquisition can lead to increased R&D for the Indian (acquired) firms owing to the technological capabilities of the advanced foreign firms. However, there can be a strategic motive as well that can lead to reduced R&D of the acquired firms to limit competition in innovation. Therefore, we have looked at the R&D expenditure of the acquired firms before and after the acquisition. From the database that we have used, Prowess, for the time period 1990-2011, there have been 93 substantial acquisitions (above 15% stake) of the Indian firms. Out of these 93 firms, only 53 firms have data for R&D expenditure and out of these 53 firms 24 firms were acquired by the foreign companies. We have analysed the R&D expenditure of these 24 companies. The analysis shows that:

- For 4 companies we can say that R&D has declined or stopped after acquisition
- For 6 companies we can say that R&D has increased after acquisition
- For 2 companies we can say that there has been no effect of acquisition on R&D
- For 5 companies there is no pattern before or after the acquisition
- For one company (Ranbaxy Laboratories) R&D is sustained throughout
- For 6 companies there is either too little data or it is too early to say anything

Therefore, our analysis is rather inconclusive in claiming anything about the impact of acquisition on R&D expenditure of the firms. We are also unable to find any evidence to support the widely-held belief that foreign firms undertake innovation mainly geared to treatment of 'lifestyle' diseases of the affluent, while indigenous firms are better at innovations for diseases that affect the masses.

## 7. TRIPS and Patent Protection

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Protection of intellectual property rights is an especially crucial issue for the pharmaceutical industry, because of the huge costs and length of time involved in developing, testing, and obtaining regulatory approval for a new drug; the high risk of failure at each stage; and the greater possibility of imitation of a chemical product (once its composition is made public in the patent application) as compared to other manufactured items. Not surprisingly, the global pharmaceutical giants were at the forefront of pushing for the TRIPS Agreement and using their governments to overcome the opposition of developing countries. As discussed in various sections above, the resulting amendments of the Indian Patents Act, which had allowed a domestic pharmaceutical sector to flourish, have brought about a sea change in the scenario. We discuss the consequences for research and development in India, and the recent measures taken to exploit flexibilities in the TRIPS Agreement.

### **TRIPS and the Indian Pharmaceutical Industry**

The Indian pharmaceutical industry has followed different stages of technological innovation, and the evolution of technological capability in the industry may be attributed to the institutional and regulatory frameworks that have existed from time to time. Kale and Little (2007) have described the evolution of the R&D capabilities and learning processes in the Indian pharmaceutical industry as follows: “the industry has followed a trajectory that started with duplicative imitation followed by creative imitation, rising up the value chain of pharmaceutical R&D and finally as a result of change in patent law industry achieving the learning required to develop capabilities in innovative research and development (R&D). The analysis reveals that the strengthening of patent laws as a result of the ‘Agreement on Trade-Related Aspects of Intellectual Property Rights’ (TRIPS) had a positive impact on large Indian pharmaceutical firms and catalysed their movement from imitators to innovators. It played an important role in creating a ‘crisis for their existence’ that triggered their movement towards innovative R&D competencies.”<sup>46</sup>

In this section we examine the innovative activity in the Indian pharmaceutical industry in the pre and post TRIPS era at the industry and at the firm level, using two indicators of innovation, input indicator and output indicator. Patents serve as an output indicator while R&D expenditure of the firms serves as an input indicator. On the other hand, patents confer monopoly rights to the owner of the patent, which is especially costly for consumers in the case of drugs. So we also examine the flexibilities that TRIPS allows for to prevent excessive pricing, and the limited extent to which they have been implemented in India.

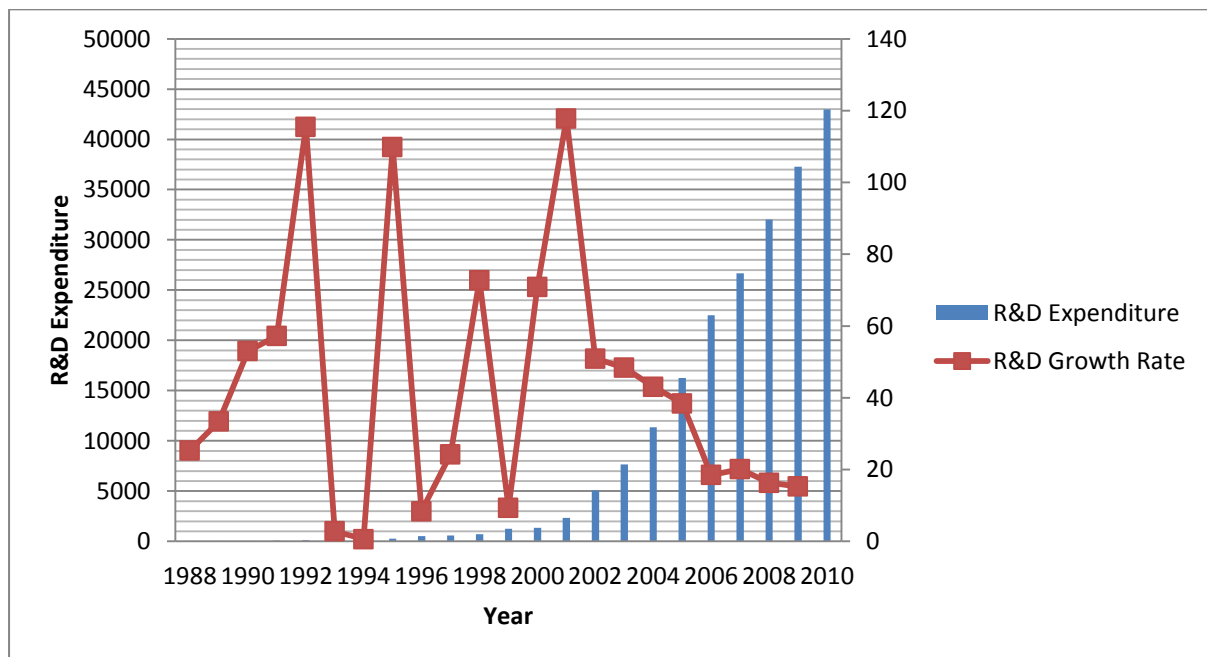
### *R&D Expenditure*

We have looked at the R&D expenditure of the firms in the industry, noting that a substantial part of what is accounted for under R&D expenditure in India is actually devoted to generic development, legal fees and regulatory costs (see n. 17 above). The database we have used is the CMIE’s Prowess database. There are 613 pharma companies in this database. Out of these only 236 firms have data

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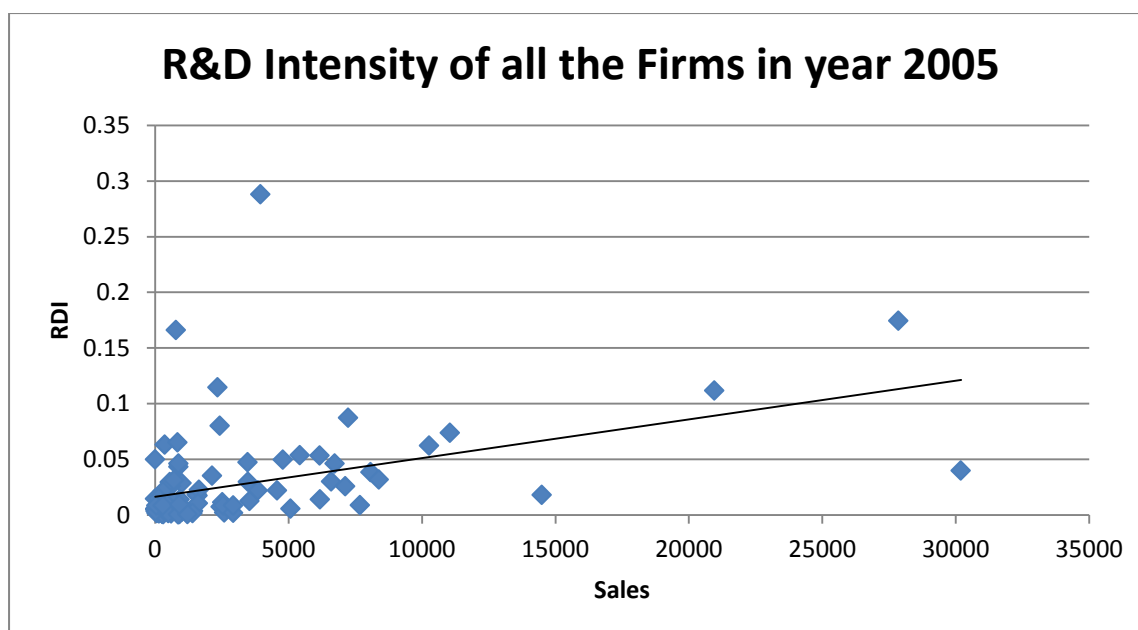
<sup>46</sup> Kale and Little (2007), p 590.

on R&D expenditure in at least one year in the period 1988-2010. The following figure shows the R&D expenditure in the pharma industry in the period 1998-2010. While R&D expenditure has increased consistently in all the years, its growth rate has consistently fallen after 2001.



(Source: Computed by the authors from Prowess data)

Comparing just the R&D expenditure across firms is a very crude measure as it does not capture the firm size effect which is captured by the sales revenue. It is observed from the data that the larger firms do greater R&D expenditure. What remains to see is the R&D intensity of the firms in relation to the firm size. R&D intensity is the ratio of firms' R&D expenditure to their sales. We have plotted below the scatter of R&D intensity and sales of the firms for all the firms in the industry in year 2005. There is a positive relationship between R&D intensity and firm size. So bigger firms not just spend more in R&D compared to the smaller firms but their intensity of expenditure in R&D is also more.



(Source: Computed by the authors from Prowess data)

### R&D Intensity of Indian and Foreign firms

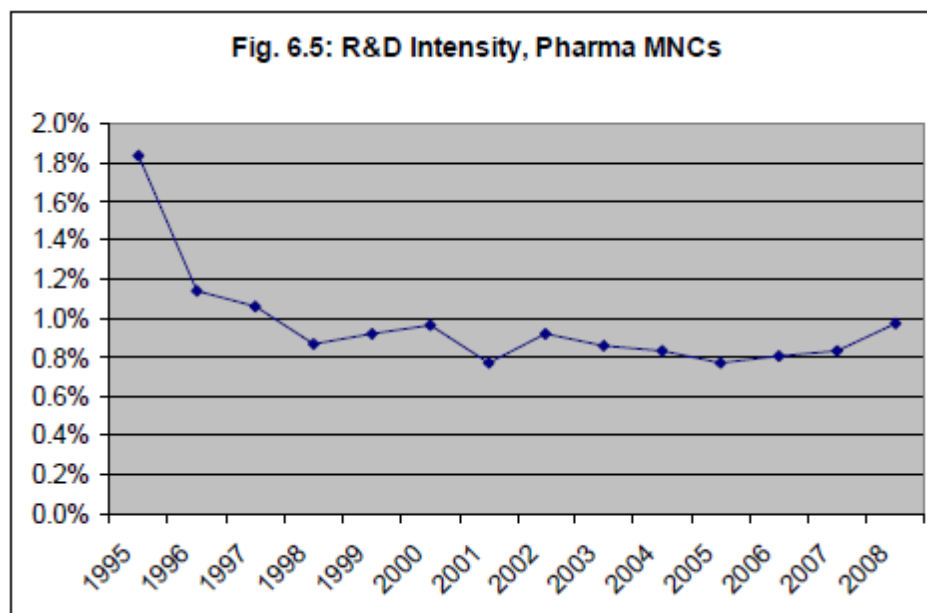
The IEG (2010) report has divided the firms in the Indian pharma industry across 5 categories and has shown R&D intensity across these 5 categories. The categories are:

- I. Indian Bulk drugs and Formulations – Large
- II. Indian Bulk drugs and Formulations - Medium and Small
- III. Indian Bulk Drugs
- IV. Indian Formulators
- V. Multinational Corporations

The findings of the report were summarized as follows:

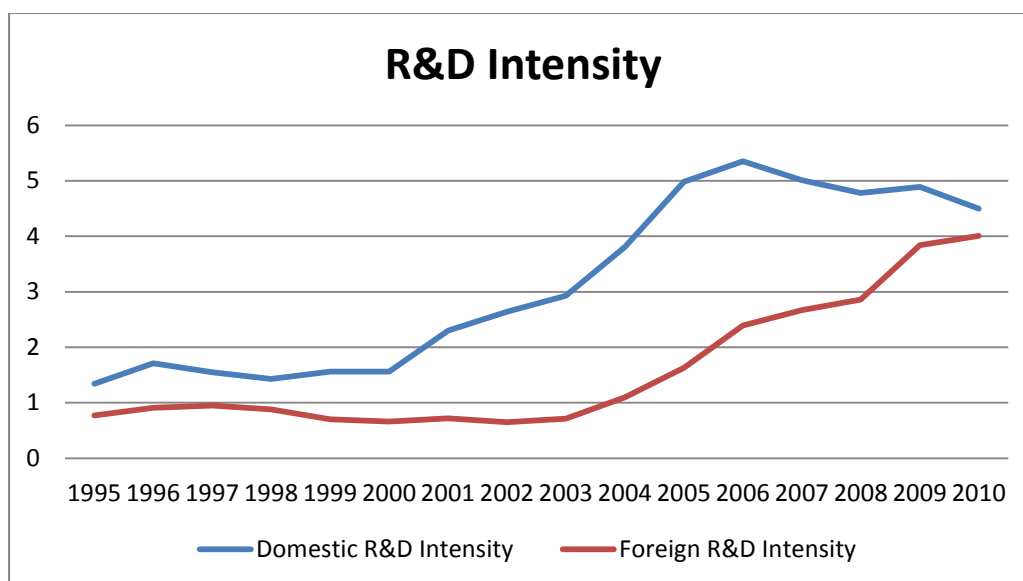
“In the period since 1995, there was a significant upward trend in R&D intensity among medium/small bulk drugs and formulations manufacturers, large firms engaged in manufacture of bulk drugs and formulations, and bulk drug manufacturers. R&D intensity among medium/small bulk drugs and formulations manufacturers, for instance, increased from about 1% in 1999-00 to about 8% in 2008-09. There were similar large increases in the R&D intensity of large bulk drug and formulations manufacturers, and bulk drug manufacturers. The large bulk drug and formulations manufacturers have been investing in R&D from an earlier period as they cater to international markets in a big way and are therefore influenced by the patent systems in those countries in which they are diversifying. The formulators have not shown any marked upward trend in this regard as their activity does not require any major technological up gradation. The subsidiaries of multinational firms also do not show any tendency to enhance their investment in R&D; in fact there is a downward trend in their R&D intensity. The product patents are welcomed by the MNCs but it seems they prefer to import their patented drugs than undertake research activities in the country.

At least at this point, this seems to be the trend in India” (IEG, 2010, p. 121). We reproduce Fig. 6.5 from the report:



*(Source: “Effects of New Patents Regime on Consumers and Producers of Drugs/Medicines in India”, Report submitted by the Institute of Economic Growth, DU to the UNCTAD, August 2010 p. 122)*

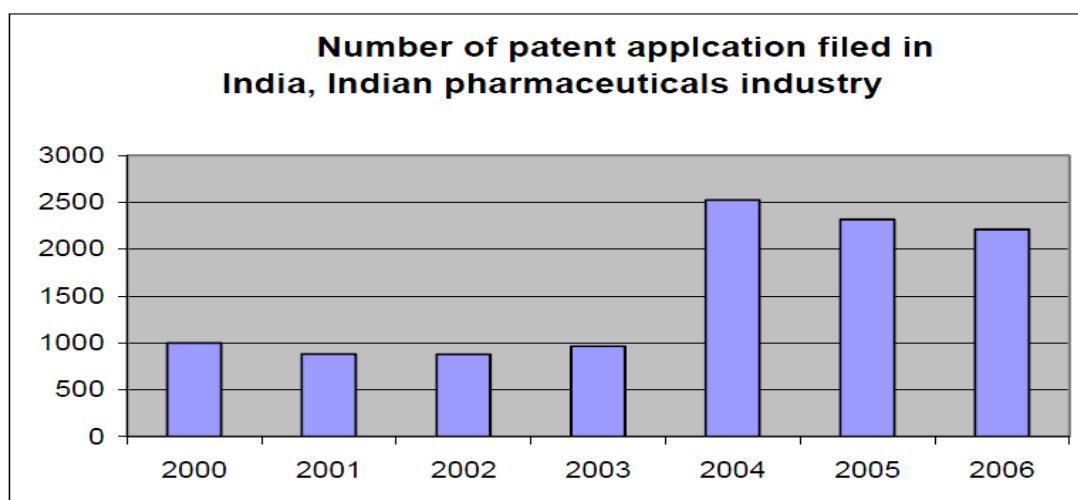
The R&D intensity of the foreign MNCs shows a sharp decline in the period 1995-1998 and remained stable for ten years after that. However, as the following Figure shows, it seems to have picked up more recently, while that of Indian firms has declined. But before attributing these developments to the product patent regime since 2005, we should note that the simultaneous increase in R&D intensity of foreign firms and decline in that of Indian firms could be partly due to the foreign takeover of research-intensive Indian firms like Ranbaxy, which would result in reclassification from domestic to foreign. It is also possible that TRIPS has encouraged MNCs to increase R&D in their home countries rather than in countries like India, and to serve the foreign markets through exports. This seems to be the pattern identified by Jha (2007), Chaudhuri (2012), and our own review of recent trade data in our section on FDI. Even if R&D intensity of Indian firms remains higher than MNCs, the total R&D spending of even the biggest Indian firms is minuscule as compared to MNC giants (Department of Pharmaceuticals 2012, p.19).



Source: Computed by the authors from data in Department of Pharmaceuticals (2012, p.19)

### Patents

The IEG (2010) report emphasises the increase in R&D efforts of the Indian pharmaceutical industry. They have shown an increase in the patent applications filed in the period 2000-2006. The following graph has been taken from their report

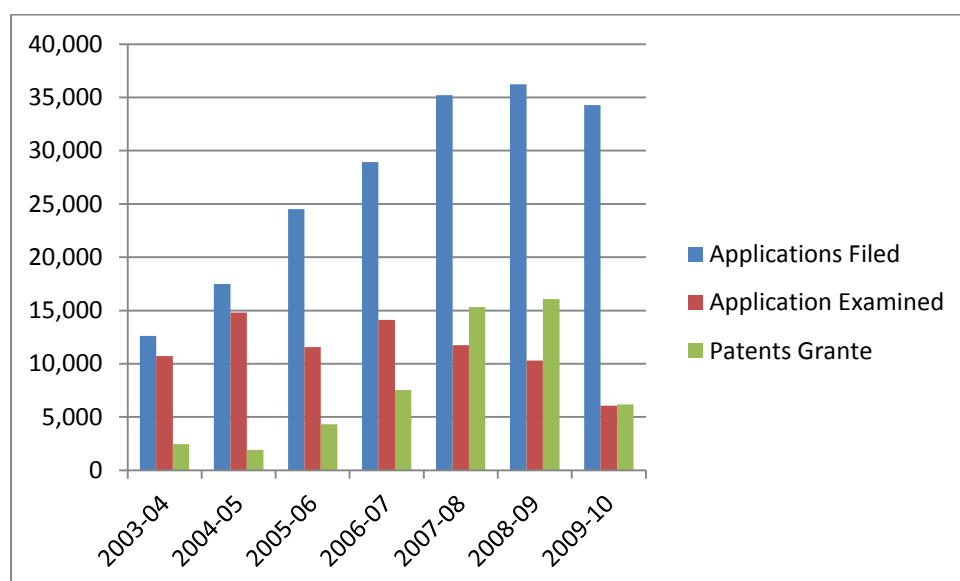


(Source: "Effects of New Patents Regime on Consumers and Producers of Drugs/Medicines in India", Report submitted by the Institute of Economic Growth, DU to the UNCTAD, August 2010)

Lalitha (2013) has provided evidence on the status of patent applications in India for the period 2003-10, on the basis of which we have drawn the following graph. It shows that the number of patent applications for pharma patents has gone up considerably in the period 2003-04 to 2009-10. While the number of patents granted has gone up consistently till 2008-09, there was a huge decline in the year 2009-10. This is because only 18% cases were examined in this year. While 6168 patents



were granted in this year, many patents applications must have been from the previous years. This is why patents granted in a given year are more than the number of applications examined in that year. Lalitha attributes the low number of application examined and granted to the shortage of examiners.



(Computed by the authors using data from Lalitha (2013))

### Firm-wise Patenting

Data on patents filed in India includes both Indian and foreign applicants. But we are more interested in the impact of TRIPS on innovation by Indian firms. Haley and Haley (2011) have compared the patenting activity of the firms in the Indian pharmaceutical industry in the pre and post TRIPS period. 2001-2004 is the pre TRIPS period in their study and for the post TRIPS period they have data for the years 2005-2008. While the former is the process patent regime, the latter is the product patent regime. "Significant growth in patents occurred from 2001 to 2004, despite a substantial decline in patents from the Government's primary research labs, the Council for Scientific and Industrial Research (CSIR), from 2003 to 2004. Ranbaxy's patent productivity over the same two-year period helped to offset CSIR's decline. Despite ranking among India's five largest pharmaceutical companies, Cipla had the lowest percentage of sales invested in R&D, indicating its reliance on process patents through backward engineering" (Haley and Haley 2012). They have also showed the post TRIPS patenting by the select firms. "The new patent regime aimed to foster innovation and to increase patents; yet, the number of patents issued in each year fluctuated wildly. Patents for 2006 fell to 315 from 468 in 2005, skyrocketed up to 750 in 2007, but then plummeted back down to 484 in 2008 (ibid)." The following tables have been taken from their work which shows the patenting activity in the pre and post TRIPS period.

Pharmaceutical patents in India's process-patent regime, 2001–2004.  
Source: Indian Patent Office; Independent research.

Organization	Number of patents			
	2001	2002	2003	2004
<i>All Pharma</i>	295			784
Ranbaxy		66	121	
CSIR	124	69		
Cipla*				32
Jubilant Organosys				16
Vaman Technologis				12
Matrix Labs				12
Hetero				10
Wockhardt**				10

\* Cipla invested <5% of sales on R&D, the lowest among India's top 5.

\*\* Especially significant because of its Biotech operations.

The italics merely differentiate between statistics for the industry as a whole and statistics for individual companies.

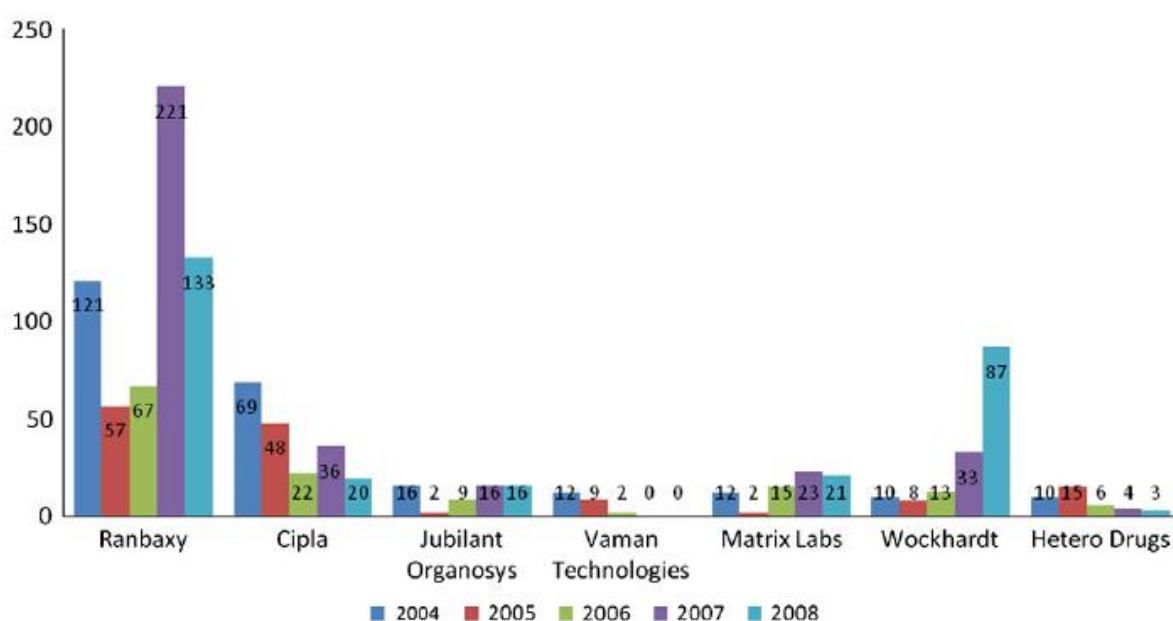
(Source: Haley and Haley 2012)

Pharmaceutical patents in India's product-patent regime, 2005–2008.  
Source: India Big Patent Database; Independent research.

Company	2005	2006	2007	2008
Alembic	9	12	27	8
Aurobindo	6	20	54	28
Biocon	2	11	21	4
Cadila	41	32	61	35
Cipla	44	22	36	20
Dr. Reddy's	107	8	100	51
Hetero Drugs	15	6	4	3
Jubilant Organosys	2	9	16	16
Lupin	18	27	35	16
Matrix Labs	2	15	23	21
Natco	29	18	34	14
Nicholas Piramal	4	5	8	5
Orchid	7	2	31	10
Ranbaxy	57	67	221	133
Reliance Life Sci.	10	12	12	13
Sun Pharma	84	14	25	6
Themis	3	6	2	3
Torrent	20	16	7	11
Wockhardt	8	13	33	87
Total	468	315	750	484

(Source: Haley and Haley 2012)

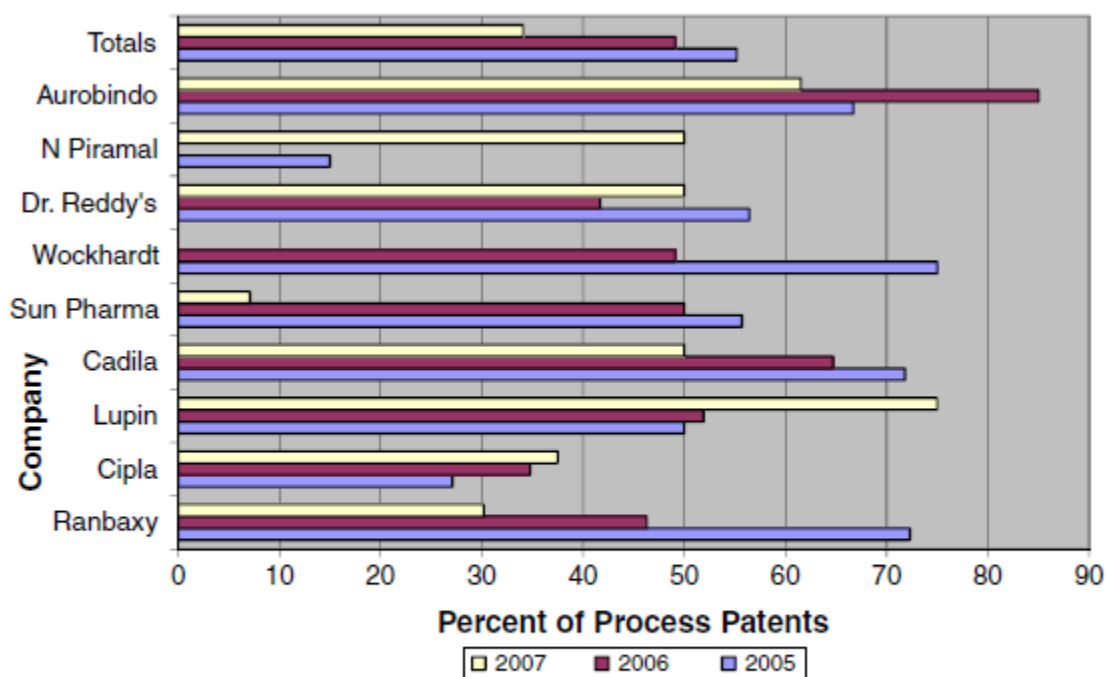
Haley and Haley (2012) also show that the patenting activity in the post TRIPS period has dropped. “The number of patents per year for five of the seven companies, as well as the overall total number of patents per year across all companies, dropped. After a significant drop between 2004 and 2005, Ranbaxy's patents held constant in 2006, spiked in 2007, only to plummet in 2008. India's second-largest pharmaceutical company, Cipla, dropped in number of patents in each of the five years. Matrix Labs and Wockhardt bucked this downward trend by following differing routes to success. Wockhardt moved strongly into bio-genetics and product patents, through both acquisition and research, increasing its patents every year. Conversely, Matrix emphasized generics and process research, to plateau in 2008, at a higher level than in 2004. These results indicate that product patent regimes may not promote greater rates of innovation and process-patent regimes may not stunt innovation” (Haley and Haley 2012).



Total patents for seven Indian pharmaceutical companies, 2004–2008.  
Source: India Big Patent Database; Independent research.

(Source: Haley and Haley 2012)

Haley and Haley (2012) have also shown that in the major pharma companies, process patents granted have gone down in the period 2005–2007. “The Indian pharmaceutical industry appears to be engaging in less process innovation, although some individual companies are not. Specifically there is a downward trend in the percent of process oriented patents filed by the largest Indian pharmaceutical companies, and especially by the two companies at the forefront of Indian pharmaceutical research, Ranbaxy and Wockhardt. Sun Pharma's and Cadila's process patents, as well as the overall total percent, have also fallen. The Indian pharmaceutical industry's innovation appears in transition from a process to a product orientation.” (Haley and Haley 2012).



Percent of process patents in India's pharmaceutical industry, 2005–2007.  
Source: India Big Patents Database; Independent research.

(Source: Haley and Haley 2012)

### *Using TRIPS flexibilities*

We now turn to the other side of the TRIPS coin: the flexibilities it provides for preventing excessive increases in prices as a result of strengthened patent protection. We have already reviewed the debate on price control, which is not prohibited by TRIPS. We now look at India's very recent experience with some other measures that are explicitly provided in the TRIPS Agreement.

#### *Compulsory Licensing*

The TRIPS Agreement attempted to strike a balance between promoting access to existing drugs and promoting R&D in new drugs by allowing for compulsory licensing, described in Article 31 as "Other use without authorization of the right holder". If generic companies are given the licences to produce a patented drug on payment of royalty, then competition among generic manufacturers will bring down the prices. At the same time, the royalty payment paid by the generic producers to the innovators should provide them with funds and incentives to innovate. Many countries like UK, Canada, US, Brazil have issued compulsory licences as an important competition enhancing instrument to curb the very high prices of patented drugs.

Chapter XVI of India's Patents Act provides elaborate guidelines for granting a compulsory licence. The first such licence was granted in 2012, seven years after the implementation of the product patent regime. "India's first compulsory licence was awarded in February and given to Hyderabad-based Natco Pharma Ltd to make and sell a copy of cancer drug Nexavar, patented by German drug

maker Bayer HealthCare AG, a subsidiary of Bayer AG.”<sup>47</sup> According to a report<sup>48</sup> prepared by KPMG in 2012, “The drug, patented by Bayer in India in 2008, is used in the treatment of liver and kidney cancer, and costs INR 2.8 lakh for a month’s dosage. After Bayer rejected Natco’s request for a commercial licence to manufacture Nexavar, Natco in September applied for a compulsory licence to make a generic version of the drug. The patent office stipulated that Natco price the drug at Rs 8,880 for a pack of 120 tablets (a month’s dosage) and pay 6 percent of net sales as royalty to Bayer. The ruling clarified that the decision was made based on the facts that:

- Bayer was able to supply its drugs to only 2 percent of the country's patient population and did not meet the 'reasonable public criteria' requirement.
- Its price was not ‘reasonably affordable’
- It was imported and not manufactured in the country.”

The grant of a compulsory licence for Nexavar was subsequently upheld by the Intellectual Property Appellate Board, which however increased the royalty payable to Bayer from 6% to 7% of sales revenue.<sup>49</sup> This decision can still be appealed, first to the Bombay High Court and then to the Supreme Court, so the ultimate outcome remains unclear. Meanwhile, even without a licence, Cipla had already started manufacturing Soranib (a generic version of Nexavar). Bayer had pointed out that Cipla’s entry undermined Natco’s argument regarding limited availability of the drug in India. This was not accepted by the Patents Controller, who observed that Bayer had challenged Cipla in a patent infringement suit in the Delhi High Court, so continued availability was uncertain.

More recently, it was announced that the government was actively considering authorization of compulsory licences for three more cancer drugs: “[Trastuzumab](#) (or Herceptin, used for treating breast cancer), [Ixabepilone](#) (used for chemotherapy in breast cancer treatment) and [Dasatinib](#) (or Sprycel, for leukaemia). These cost an average of \$3,000-4,500 (Rs 1.64-2.45 lakh) for a month's treatment.”<sup>50</sup>

### *Denial of patents for incremental innovation*

The amendment Act of 2005 provided an important qualification in section 3(d) of the Patents Act. Salts, esters, polymorphs, particle size, combinations and other derivatives of known substances cannot be patented ‘unless they differ significantly in properties with regard to efficacy’. In other words secondary patents are not granted unless there are significant therapeutic advantages. This is to deter patent-holders’ attempts to prolong the life of their patent by ‘evergreening’, i.e. obtaining a fresh patent for minor innovations that essentially modify the existing product without significantly enhancing its usefulness. In 1998, during the TRIPS transition period, the drug MNC Novartis filed a mailbox application for the beta crystalline form of its anti-cancer drug, imatinib mesylate (marketed as Glivec). After the new TRIPS-compliant patent approval process was instituted in 2005, the

<sup>47</sup> Taken from: <http://www.livemint.com/Companies/fWcUdihmEP66hZZoXgxctO/Big-pharma-firms-may-learn-to-live-with-compulsory-licensing.html>

<sup>48</sup> KBuzz Sector Insights, Issue 17, May 2012 accessed at <http://www.kpmg.com/IN/en/IssuesAndInsights/ArticlesPublications/kbuzz/Documents/Kbuzz-Issue-17.pdf>

<sup>49</sup> “Bayer pleas dismissed, Natco allowed to sell patent cancer drug”, *Business Standard*, 5 March 2013.

<sup>50</sup> *Business Standard* (16 January 2013), <http://www.business-standard.com/india/news/drug-pricing-govt-decides-to-bypass-three-patents/498851/>

application was rejected by the Patent Controller in 2006 on the basis of section 3(d). Novartis challenged the constitutionality of section 3(d) before the Madras High Court on the grounds that 'efficacy' has not been defined in the Patents Act. This was not accepted by the High Court. In 2009, Novartis also lost its case against the rejection of its patent application for Glivec before the Intellectual Property Appellate Board (IPAB). And on 1 April 2013, the Supreme Court dismissed Novartis' appeal against the IPAB order, holding that "We firmly reject Novartis' case that Imatinib Mesylate is a new product and the outcome of an invention... We hold and find that Imatinib Mesylate is a known substance. Imatinib Mesylate does not qualify the test of 'invention' as laid down in Section 2(1)(j) and Section 2(1)(ja) of the Patents Act." Further, the Court held that the beta crystalline form did not satisfy Section 3(d) because it did not enhance therapeutic efficacy.<sup>51</sup>

The IPAB recently also upheld the Patent Controller's refusal, on grounds of "known prior art", of a patent for Astra Zeneca's anti lung cancer drug Gefitinib (brand name Iressa), which was challenged in a pre-grant opposition suit by Natco, which manufactures its own Gefitinat.<sup>52</sup>

### *Revocation of pharmaceutical patents*

Section 64 of the Patents Act provides for a patent to be revoked on various grounds even after it is granted, and these provisions are also being used more aggressively. The IPAB recently overturned the Patent Controller's rejection of the Sankal Rehabilitation Trust's post-grant opposition to the patent granted for Roche's Hepatitis C drug Pegasys in 2006—the first product patent granted after India became fully TRIPS-compliant in 2005. The IPAB accepted the petitioner's plea that in light of prior art, Pegasys failed the test of being non-obvious.<sup>53</sup> Similarly, on a post-grant opposition claim filed by Cipla, the patent office revoked a patent already granted in 2007 to Pfizer for its anti kidney cancer drug Sutent (sunitinib), on the grounds that it did not involve an inventive step.<sup>54</sup>

### *Parallel imports*

Another TRIPS-compatible remedy for high prices of patented drugs is to import them from countries where they are cheaper. Section 107A(b), which was inserted into the Patents Act by the amendment of 2002 and further amended in 2005, states that "importation of patented products by any person from a person who is duly authorized under the law to produce and sell or distribute the product" is not an infringement. In an interpretation based on the legislative history of the amendments, Basheer and Kochupillai (2009) believe that this section clearly implies that India follows a system of 'international exhaustion' of patent rights, so once the patented product is marketed in one country, the patentee cannot prevent its import into India. However, they acknowledge that there are some ambiguities in the wording of the section, and suggest some amendments that would unambiguously allow parallel imports. Building on a hypothetical scenario in their article, it might be worth exploring the possibility of an Indian firm setting up facilities in Bangladesh to produce a drug that is patented in India, and shipping some of the output to India. (As

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<sup>51</sup> This discussion is based on the excellent article by Chaudhuri (2013), who however warns that the Novartis judgment does not prohibit all new forms of drugs, and does not define what would constitute a 'significant' difference in therapeutic efficacy.

<sup>52</sup> "Astra Zeneca Drug Appeal Dismissed", *Business Standard*, 29 November 2012.

<sup>53</sup> "IPAB Sets Aside Indian Patent for Roche's Hepatitis C Drug", *Business Standard*, 5 November 2012.

<sup>54</sup> "Cipla Wins Patent Opposition Against Pfizer's Cancer Drug", *Business Standard*, 4 October 2012.

a 'least-developed' country, Bangladesh does not have to introduce product patents until 2016.). This would get the benefit of the duty free access given to Bangladesh under SAFTA. Even better, recalling that Bangladesh does not allow for branding of generics, competition would result in lower prices if several independent firms could be induced to produce in Bangladesh a generic version of a drug patented in India. A test case involving a combination of Indian entrepreneurship, economic diplomacy, and legal footwork is called for.

## *Conclusions*

Our analysis of the TRIPS Agreement and its impact on the Indian pharmaceutical industry suggests that R&D expenditure of the firms has gone up consistently in the period 1990-2010, however, the growth rate of R&D has declined in the recent years. Looking at the R&D intensity of the firms, larger firms have higher R&D intensity, and the intensity of both foreign and Indian firms has been rising in the post-TRIPS period. In terms of innovation, many economists argue that very little innovation is done for the diseases of the poor countries. While the number of patent applications has gone up, the patents granted have not increased that much, perhaps because of bottlenecks in the approval process. Patenting at the firm level shows that patents granted to most of the top firms have dropped in the period 2004-2008. Process patents granted to the firms have also gone down considerably in the period 2005-2007. So TRIPS regime has not led to greater patenting activity in the industry. However, this could be because the period under study is not very long and it may be too early to say anything conclusively.

Meanwhile, India is starting to use the flexibilities provided in the TRIPS agreement. While compulsory licences and denial of patents for minor innovations may act as a disincentive for the foreign pharma companies to launch their products in India, it is important to realise that they are crucial for a country like India, which still has majority of its population undertaking out of pocket expenditure for health care. India has started to use the flexibilities provided under TRIPS like compulsory licensing, use of section 3(d) in denying patents for incremental innovation, and revocation of patents that were granted wrongly. From the competition perspective, these steps will prove to be pro-competitive in the short run, and the scope for parallel imports can also be explored. Representatives of MNC pharma companies argue that such measures will discourage R&D, with adverse effects on drug availability in future. Civil society representatives, however, point out that much of the basic research for many of the patented drugs was funded by grants from public institutions. Interestingly, the Maira Committee on FDI policy (discussed above), despite having a more pro-multinational tilt than the official policy, also strongly recommends retaining and using these flexibilities. However, these measures are being very sparingly used in the case of extremely high-cost patented drugs, and some of them are still under appeal. Besides, as Nagral (2013) warns, even if much cheaper generics are made available through such interventions, the branding and marketing power of large companies may still determine doctors' prescriptions. The problem of cost and availability of essential medicines, and of lack of innovation in drugs for more prevalent diseases, remains to be addressed.



## 8. Antidumping

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The WTO Antidumping Agreement permits countries to impose antidumping duties (ADD) to counter ‘dumping’ of exports. Unlike basic or even preferential customs duties, ADD can be imposed on particular firms in particular countries, and are often targeted at the most competitive suppliers. The Agreement defines dumping as exporting goods at a price below normal value, which is normally the price charged by the exporter for ‘like products’ in the exporting country. The WTO Agreement, however, permits other methods of determining normal value in particular cases. It also requires a demonstration of ‘material injury’ being caused to the domestic industry as a result of dumping. But the very general criteria for determining injury and the causal linkage between dumping and injury are easy to prove. Undercutting of domestic prices by imports, or reduction of the domestic producers’ prices, market shares or profitability—all normal effects of competition—are usually sufficient to establish injury even when the ‘injured’ domestic industry is expanding output, employment and capacity. ADD can be imposed initially for five years, but can be renewed for further five-year periods if evidence of continuing dumping and injury can be provided in the so-called ‘sunset review’. Although the interests of domestic users can be taken into account, these are routinely dealt with superficially and do not affect the outcome.

Having gone through these procedures, the Directorate General of Antidumping and Allied Duties (DGAAD) in India’s Commerce Ministry imposes an ADD that is adequate to ensure a ‘non-injurious price’ (NIP) to the domestic industry. Unfortunately, a 2006 Supreme Court judgment, which laid down that the NIP should be determined for the industry as a whole,<sup>55</sup> made this situation worse, because it implies that even the least efficient producers in an industry are guaranteed protection from the most competitively-supplied imports. The Court also made the common mistake of conflating anti-dumping with predatory pricing when it observed that the purpose of the anti-dumping mechanism

was that our industries which had been built up after independence with great difficulties must not be allowed to be destroyed by unfair competition of some foreign companies. Dumping is a well-known method of unfair competition which is adopted by the foreign companies. This is done by selling goods at a very low price for some time so that the domestic industries cannot compete and are thereby destroyed, and after such destruction has taken place, prices are again raised.<sup>56</sup>

This is actually a definition of predatory pricing, which is a competition law issue. But it would be much more difficult for the domestic industry to obtain relief under section 4 of the Indian Competition Act. A case of predatory pricing can only be made out if it can be established that the alleged predator is dominant in the relevant market in India. It would also require a comparison between the foreign firm’s export price and its actual cost of production (not constructed ‘normal value’), and that its price is low enough to “reduce competition or to eliminate the competitors”, not merely to inflict injury.<sup>57</sup> No wonder, then, that Indian industries faced with the challenge of low-

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<sup>55</sup> *Reliance Industries Ltd vs Designated Authority and Others*, (2006) 10 SCC 368, paras 26-35.

<sup>56</sup> *Ibid*, para 10. The same position is articulated in para 12, stating that lower prices benefit consumers only in the short term.

<sup>57</sup> Competition Act, section 4(2)(a)(ii) read with Explanation (b). In the United States and Canada, it would also require a demonstration that the elimination of the domestic industry would enable the foreign predator to



cost imports have resorted to antidumping petitions, rather than predatory pricing cases under the Competition Act. Internationally, too, ADD have been a convenient way for countries to protect selected industries from import competition even as they have liberalized their trade policies. India is no exception, with 663 investigations being initiated between 1995 and mid-2012. The United States and the European Union were far behind in second and third place, with 465 and 444 initiations, respectively.<sup>58</sup>

China has been a frequent target for all major ADD users, thanks to its ability to export at low prices. Imposition of ADD on Chinese exports has been facilitated by special rules drawn up at the time of China's accession to the WTO, under Section 15(a) of its Protocol of Accession. These rules allow other WTO members to treat China as a 'non-market economy', for which authorities in the importing country allowed to impute normal value on the basis of cost of production of the same products in another comparable developing country with a market economy.<sup>59</sup> But if the Chinese exporters or the Indian petitioner are unable to identify an appropriate third country, then India is treated as the surrogate country, and the DGAAD takes into account the international price of raw materials and the consumption norms, conversion and selling and general administration costs as provided by the Indian petitioners who are seeking protection. They have an obvious incentive to inflate the normal value and make it easy to prove that Chinese products are being dumped, while the rules for fixing NIP allow the DGAAD to impose a generous ADD.

The following are some currently imposed ADD on imports of very widely used bulk drugs imported from China. In each of these cases, the petitions went through this process of determining dumping based on 'constructed' normal value, injury and fixation of an ADD based on NIP.<sup>60</sup>

- Ceftriaxone Sodium Sterile (also known as Ceftriaxone Disodium Hemiheptahydrate-Sterile), 2008.
- Metronidazole, 2000, renewed 2006 and 2012. (The order acknowledges that the injury caused to the domestic industry is partly due to the controlled price enforced by the government.)
- Paracetamol, 2002, renewed 2007 and 2013.

It should be kept in mind that, as noted in our discussion of import competition in section 3 above, 'dumped' imports of bulk drugs may well have hurt the domestic producers, but they would have benefited firms producing formulations and—to the extent they may have passed on lower costs in the form of lower prices of the formulations—also consumers. A more holistic assessment of dumping is required.

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recoup the profits that it sacrificed by charging a supposedly predatory price. This is an almost impossible standard to meet, which is why there have been no successful predatory pricing cases in those countries in recent decades.

<sup>58</sup> Figures are from [http://www.wto.org/english/tratop\\_e/adp\\_e/adp\\_e.htm](http://www.wto.org/english/tratop_e/adp_e/adp_e.htm), viewed 23 February 2013. One product from one country counts as a separate initiation.

<sup>59</sup> The Chinese exporters can still individually claim that they work under 'market economy conditions' by showing that their costs and prices are determined by the market rather than state controls or subsidies, but in many cases they do not respond to the corresponding questionnaire from the DGAAD, and even when they do, their claims are seldom accepted.

<sup>60</sup> [http://www.commerce.nic.in/traderemedies/ad\\_casesinindia.asp?id=2](http://www.commerce.nic.in/traderemedies/ad_casesinindia.asp?id=2), last viewed 5 April 2013.

## 9. Public Procurement and Distribution

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Given the acute market failures endemic to the pharma sector, the problems inherent in price control, and the limited potential for exploiting TRIPS flexibilities, we finally turn to very different forms of government intervention: production of drugs in the public sector, and bulk procurement and public distribution.

### *Public sector production*

The public sector was supposed to occupy the ‘commanding heights’ of the pre-reform Indian industrial landscape, and it was extended to the pharmaceutical sector. The state owned units (Hindustan Antibiotics Limited, set up in 1954, and Indian Drugs and Pharmaceuticals Ltd, set up in 1961) had a promising beginning and played a major role in production as well as development of new technologies. However, they became chronically sick during the 1990s as they could not compete with liberalized imports and the marketing strategies of private firms (Chaudhuri 2005). A revival package for HAL and a few other minor PSUs is being implemented, while for IDPL it is under consideration (Department of Pharmaceuticals 2012). Three other public sector units (Central Research Institute at Kasauli, Pasteur Institute at Conoor, and BCG Vaccine Laboratory at Guindy) were closed down by the government in 2008 on the grounds that they did not comply with norms of Good Manufacturing Process (GMP). They had been supplying vaccines for the government’s universal immunization programme (UIP), which then had to rely entirely on private producers. The elimination of competition allowed private manufacturers to increase their prices substantially. Nayak (2011) terms this discrimination against the public sector as ‘reverse competitive neutrality’. (The blacklisting of exports from leading Indian firms by the US Food and Drugs Administration suggests that private sector firms were not subjected to the same degree of scrutiny by Indian regulators, although the argument has been made that Indian standards are different.)

Following public outcry and criticism from the Parliamentary Standing Committee, the three public sector units were reopened in 2010. However, their production has still not picked up and is far short of their earlier levels. As of early 2013, the Guindy unit, which used to supply the UIP’s entire requirement of BCG vaccine, was yet to commence production, while the other two units supply only a small proportion of its requirement of DPT and TT vaccines. The cost of all these vaccines had more than doubled in 2012-13 as compared to 2006-07. Some other public sector units producing measles and polio vaccines were not closed down but still produce insignificant quantities, with the result that the government is sourcing its requirements entirely from large private players (Nagarajan 2013).

Despite their very different views on drug price control, the Planning Commission’s High Level Expert Group, the Maira Committee and the NPPP-2012 all recommend revival of the public sector units to stabilize drug prices. The NPPP-2012 recommends that they should be given preferential allocation for procurement of drugs by the public health system. A margin of price preference, which used to be available for PSUs but would violate competitive neutrality, does not seem to be on the agenda.

## *Public Procurement and Distribution*

The NPPP-2012 and also the official committees call for streamlining the public procurement system so as to keep prices in check. There are several complaints about the way in which the system functions. Nayak (2011) has documented High Court judgments that have held that some state government rules for prequalification as medicine suppliers are arbitrary and designed to limit the number of suppliers. On the other hand, in several cases outside the pharma sector, the CCI has dismissed similar complaints against various PSUs and state certification agencies. Informants had argued that the concerned government entity was dominant, either as a standard-setting body or as a major buyer, and had rigged the specification of goods, certification requirements, or other rules for qualifying as bidders, so as to favour certain suppliers and deny market access to others. Every such complaint was dismissed, with the Commission holding in some cases that the dominance of the government entity was not established, and in every case that the rules were reasonable and non-discriminatory; other suppliers could enter the market by complying with them.<sup>61</sup>

The basic problem in the pharma sector is poor quality control under the Drugs and Cosmetics Act, 1940. If quality certification by state agencies were reliable, there would be no need to impose additional conditions on bidders. Stricter procurement rules to ensure quality supplies can severely restrict the number of eligible bidders and increase the scope for collusion, while relaxing the rules will increase competition at the risk of allowing substandard, spurious or hazardous drugs into the public healthcare system. Poor quality regulation is also the argument given by the large pharma firms for insisting on producing branded generics, where their brand is supposed to be a signal of quality for doctors and patients. As noted in our sections on market structure and price control, this allows for tremendous price variation and high margins for generic drugs, while the industry has resisted moves to force it to market drugs under generic names.

Drug certification is thus an important flanking policy for competition in pharmaceuticals. It is therefore important to improve the enforcement of the Drugs and Cosmetics Act, 1940. However, this is the responsibility of the Central Drug Standard Control Organization (CDSCO) and Drug Controllers in the states, who are often understaffed and allegedly corrupt. A Parliamentary Standing Committee found many cases in which drugs were approved without clinical trials, some merely on the basis of personal recommendations of doctors (Mehta et al, 2013). In at least one case, the recommendations by doctors in different hospitals thousands of miles away from each other were identical, and possibly written by the drug company itself. As of now, centralized procurement and distribution, with quality verification by the procurement agency, seems to be the way forward. The agency would get a better deal by exercising its buyer power. As long as private buyers are not excluded, this would not be a breach of competition law. As shown by some of the studies surveyed in our section on price control, the Tamil Nadu Medical Supplies Corporation procures generics at a fraction of the prices set by manufacturers for commercial distribution. Our own limited data exercise in section 4 showed that the prices are competitive even after allowing a

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<sup>61</sup> [Tata Metaliks Ltd., Kolkata v. The Electro Steel Casting Ltd. & Others](#); [Quoprro Global Services v. Consular Passport & Visa Division, M.E.A.](#); [CSR Nanjing Puzhen Co. Ltd. v. Kolkata Metro Rail Co. Ltd. & Others](#); [Informant v Chief Secretary, Govt. of Haryana & Others](#), [Shri Ravindra Badgaiyan v. M/s Bureau of Indian Standards \(BIS\)](#); [M/s. Kanazia Digital Systems v. The Airport Authority of India](#); [Jupiter Gaming Solutions Private Limited v. Government of Goa & Others](#).

generous markup to cover marketing and distribution expenses. Some other states including Kerala and Odisha have started such schemes on a more limited scale, with varying degrees of success, but with even lower prices than TNMSC's for many drugs (Singh et al 2012). The Union Health Ministry's scheme to procure unbranded generics from PSUs and GMP-certified private producers and distribute them through an expanded network of pharmacies under the Jan Aushadhi Programme would enable this approach to be rolled out on a much bigger scale. As in so many areas of public procurement, suppliers may engage in bid-rigging, but as several recent cases decided by the CCI have shown, PSU managers are ready to file complaints and the CCI has penalized the offenders even without hard evidence of a collusive agreement (Bhattacharjea and De, 2012).

# 10. Conclusions: A Competition Assessment Checklist

We summarize the findings and recommendations of this report by applying the OECD Checklist, as modified by Nayak (2011) for CUTS.

Principle	Identified Issues	Prescriptions
P1: Fostering Competitive Neutrality	Closure of 3 PSU's on grounds of GMP → Reverse Discrimination	Revival package with management overhaul, but subject to competitive neutrality principles
P2: Procedures should be rule bound, transparent, fair and non-discriminatory	<ol style="list-style-type: none"> <li>1. GMP eligibility conditions rejected by High Courts in drug procurement</li> <li>2. Antidumping duties on imports</li> <li>3. Tariff preferences extended to (some) SAFTA members</li> <li>4. Acquisitions of Indian firms by the non-transparent FIPB route</li> </ol>	<ol style="list-style-type: none"> <li>1. Apply GMPs on non-discriminatory basis, but provide concessional credit to MSMEs</li> <li>2. Support tightening of antidumping rules in WTO; take objections by user industries more seriously</li> <li>3. Probably not serious enough to justify changes</li> <li>4. Reroute through CCI with lower notification thresholds and inputs of public health expertise</li> </ol>
P3: Third party access to essential facilities on reasonable fair terms will ensure effective competition and therefore, should be provided in law	Abuse of dominance created by patents (assuming that patents can be treated as essential facilities)	Use TRIPS flexibilities for compulsory licensing and parallel imports more aggressively. Resist pressures to impose 'TRIPS-plus' conditions
P4: Ensure free and fair market process	Huge variation in the prices of the same molecule sold under different names due to branding and marketing expenditures of the big pharma companies	Move towards de-branding after ensuring alternative quality control mechanisms; scale up public procurement and distribution; expose pharma companies' unethical attempts to influence prescribing behaviour; regulate medical practitioners' professional ethics.

Principle	Identified Issues	Prescriptions
P5: Effective Control of anticompetitive conduct through competition rules	<ol style="list-style-type: none"> <li>1. Anticompetitive practices by chemists' associations</li> <li>2. Exclusive dealing agreements between manufacturers and chemists</li> <li>3. Resale price maintenance in drug price control</li> <li>4. Possible anti-competitive mergers that escape scrutiny.</li> </ol>	<ol style="list-style-type: none"> <li>1 and 2. More suo moto inquiries by CCI; impose penalties based on chemists' turnover, not associations'.</li> <li>3. Avoid fixation of trade margins in price control</li> <li>4. Reduce notification and review thresholds for pharma mergers.</li> </ol>
P6: Notification and public justification of deviations from principles of competition policy	<ol style="list-style-type: none"> <li>1. Antidumping and SPSS</li> <li>2. Review of foreign acquisition proposals through FIPB route</li> <li>3. GMP enforcement and exemptions for public procurement</li> </ol>	<p>Give clear public justification for such deviations from competition principles; reroute acquisition proposals through CCI.</p>

# Postscript (January 2014)

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This report was completed and submitted in April 2013. A few recent developments are flagged below to bring it up to date:

**Price Control:** The new Drugs Prices Control Order 2013 has come into force and seems to have reduced the prices of a wide range of drugs covered by the National List of Essential Medicines. However, two problems have arisen:

- Many wholesalers and distributors found their earnings severely eroded at the lower prices and distributor margins, and stopped distributing some of the drugs
- As predicted, firms have started to introduce new variants (such as ‘controlled-release’) which they claim as new drugs which are not subject to the price cap.

**Anticompetitive Agreements:** In December 2013, the CCI decided two more cases against the All India Organization of Chemists and Druggists (AIOCD) and its regional affiliates. The first one was filed by M/s. Peeveear Agencies, alleging that the AIOCD, All Kerala Chemists & Druggists Association (AKCD), Organization of Pharmaceutical Producers of India (OPPI), Indian Drug Manufacturers Association (IDMA) and Janssen-Cilag Pharmaceuticals are limiting and restricting the supply of pharmaceutical drugs. The second one was filed by M/s Sandhya Drug Agency of Barpeta against Assam Drug Dealers Association (ADDA), Barpeta Drug Dealers Association, (BDDA), All India Organization of Chemist and Druggists (AIOCD) and Alkem Laboratories Ltd, alleging stoppage of the supplies of products of Alkem which was done by ADDA and BDDA in collusion with AIOCD.

The other allegations were similar to those in the Varca Druggists and Chemists Association case discussed in section 4.1 above: requiring an NOC/LOC by the stockists, obtaining Product Information System (PIS) from the regional association upon payment of the prescribed fees, fixing the trade margins, and boycotting of products of pharmaceutical companies that do not abide by the agreements. AIOCD had signed MoUs and agreements with organizations like IDMA, OPPI in terms of which a drug manufacturing company can appoint stockists only in consultation with the concerned State/District Chemists & Druggists Association.

As in the earlier cases, the Commission held that the boycott by AIOCD, AKCDA, ADDA and BDDA limits supply of drugs and numbers of players in the market, and the practice of fixed trade margins ultimately results in fixing the prices of the pharmaceutical products. The Commission held that the said conduct of AIOCD and its affiliates namely AKCDA, ADDA & BDDA are in violation of provisions of Section 3(3)(a) and 3(3)(b) of the Act. The Commission also held that OPPI, IDMA and its members appear to be victims of the exploitative tactics of AIOCD and their conduct of entering into MOU with AIOCD should not be treated at par with the conduct of the AIOCD. Therefore, IDMA and OPPI cannot be held liable for violation of the provisions of the Act. With regard to the conduct of Janssen and Alkem, Commission held that the grievance of the informants mainly arises out of the practices of AIOCD and AKCDA for which the Commission has held them liable and there seems no need to pass any specific order against Janssen and Alkem in the matter.

The Commission noted that the violations are the same as in the earlier case of Varca Druggists and Chemists Association and cover a period much prior to the Commission’s order in that case, so it did

not impose any further monetary penalty upon AIOCD. It imposed penalty of 10% of the average of the receipts for financial years 2008-09, 2009-10 & 2010-11 on ADDA. The AKCDA and BDDA had not submitted their financial statements and the Commission has initiated separate proceedings in this regard, and will decide on penalties subsequently. The Commission also passed orders that AIOCD, AKCD, ADDA and BDDA should cease and desist from indulging in grant of NOC for appointment of stockists, fixation of trade margins, collection of PIS charges and boycott of products of pharmaceutical companies. AIOCD will also inform organizations like OPPI, IDMA and their members that there is no requirement of obtaining an NOC for appointment of stockists and the pharmaceutical companies, stockists, and wholesalers are at liberty to give discounts to the customers. PIS charges are not mandatory and PIS services could be availed by manufacturers / pharmaceuticals firms on voluntary basis.

**Mergers and Acquisitions:** In June 2013, the CCI approved two more combinations in the pharma sector, both involving sale of assets by Indian companies (a manufacturing facility of Unichem and a subsidiary of Strides Arcolab) to the multinational Mylan. As both the acquired entities were predominantly export-oriented and did not compete with the acquirer for the same range of drugs, the CCI found no AAEC. However, in the Strides case, it approved only after the acquirer agreed to limit the scope and duration of the non-compete agreement, along the same lines as the Orchid/Hospira case discussed in section 4.3 above.

**Drug Certification:** In August 2013, a Bill to amend the Drugs and Cosmetics Act, 1940, was introduced in the Rajya Sabha. Apart from regulation of clinical trials and medical devices, it provides for centralized licensing of manufacture and sale of 17 categories of critical drugs and setting up of an empowered Central Drugs Authority. It remains to be seen as to whether it is passed in the remaining term of the present Lok Sabha, failing which it will lapse, and whether the new Authority will function any better than the Central Drug Standard Control Organization (CDSCO) which it will replace.



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