

A BITTER PILL TO SWALLOW – ANALYZING ANTI-TRUST CONCERNS IN THE INDIAN PHARMACEUTICAL SECTOR

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ABSTRACT

The regulation of innovation and the optimal design of legal institutions in an environment of uncertainty are two of the most important policy challenges of the twenty-first century. Innovation is critical to economic growth. Regulatory decisions and, in particular, competition and intellectual property regimes can have profound consequences for economic growth. However, remarkably little is settled about the relationship between innovation, competition and regulatory policy. The debate between which shall prevail – the legal monopoly of an inventor or creator who has invested his time, labour and capital in coming up with new technology and the competition policy of the State which aims to ensure that monopoly is not used to disrupt market dynamics – takes spotlight in context of the pharmaceutical sector. Public health is an essential cog in the social machinery and it is the duty of the State as parens patriae to ensure proper health care facilities for its citizens. However, the drugs manufactured by pharmaceutical companies are protected under the patent law which grants the companies a right to exclude others from exploiting their invention. So what if the companies themselves exploit their invention in order to maximize monetary gain? The State has countermeasures such as compulsory licensing under TRIPS and the anti-trust regime which prevents an enterprise from abusing its dominant position to the detriment of consumers.

This paper is an attempt to highlight the emerging issues in the ongoing battle between profit-oriented entities and the regulatory authorities in the field of drug manufacture, pricing and procurement. The authors shall try to suggest the reasons why, and methods by which the Competition Commission of India can regulate the

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pharmaceutical sector so as to ensure that the healthcare sector in our nation is not adversely influenced while at the same time there is enough incentive for private companies to invest in the development of new drugs for the patient population.

1. INTRODUCTION – A BIRD’S-EYE VIEW OF THE TUSSELE BETWEEN IPRs AND COMPETITION LAW

Intellectual Property Rights (hereinafter referred to as ‘IPRs’) and Competition Law are like two quibbling siblings – while the former is all about exclusion, the latter is about liberation. IPRs are basically rights that allow the right-holder to exclude others from exploiting an intangible asset. The objective of granting IPRs is twofold – firstly, it is a sign that the law promotes other people to be innovative by offering them new technologies and creations which increase the knowledgebase of the public; and secondly, it also serves to protect the time, labour, skill and capital of the inventor/author from undue exploitation by any member of the public. IPRs also encourage the possibility of various kinds of investments, such as in research and development (R&D).

However, the rights conferred may take the unruly shape of a monopoly and lead to significant market power, especially if there are no or inferior substitutes on either the demand or supply side of the market. In other words, it becomes extremely tough for new players or players who make generic and/or affordable versions of the protected product, to enter the market. Perceived *ex post*, IPRs may operate as barriers to entry for third parties. There is a much controversial trade-off between the incentive to innovation and investment therein, and the liberty of others to use the protected product freely. In this debate, it is often competition in innovation which takes precedence over competition from someone providing the same product in the same way. In this regard, Joseph Schumpeter has argued that the “competition” in question should be the competition incurred from the entry of new products in the market, the new sources of supply, and the new organization – and this competition should work in order to provide for an advantageous change in quality but without adversely affecting the profits and outputs of the pre-existing firms.¹

¹ J.A. Schumpeter, *Capitalism, Socialism and Democracy* 84 (George, Allen and Unwin Ltd, London, 1943); cited by V. Korah, *Competition Law and Intellectual Property Rights*, 129,

There has been a significant change in the approach and objective of competition law over the years. At first there was considerable dispute over the actual function of competition law – whether it served as a benevolent gatekeeper of the market, allowing access to competitors; or whether it worked towards increasing efficiency and consumer welfare. In the last decade, the European Union policy in relation to competition law has undergone a paradigm shift from catering to the competitors, especially small and medium sized enterprises, to protecting consumer welfare.² The United States of America went through similar changes prior to this period and the regulators claim that they are pro-consumer.³ However, the scenario in developing nations such as India is different from the aforementioned developed nations. On the one hand there is the need to promote the small and medium sized firms with better access to indigenous resources to move outside the shadow of multinational firms that are rich enough to invest considerably in R&D, while on the other hand there is a duty to ensure that the public is positively benefited from this competition. With regard to the pharmaceutical sector, there is the additional responsibility upon developing nations of promoting domestic industry since the product market is global and not restricted to national boundaries. In such situations, the domestic industry has to face stiff competition from the multinational firms in terms of market strategies, product qualities and revenue share.

In this regard, the pharmaceutical sector rests tentatively on the fault-lines between these policy objectives – competition, intellectual property, state regulation and social welfare. The pharmaceutical sector has been characterized by the Schumpeterian concept of “creative destruction” – the market revitalizes itself from within by scrapping old and failing businesses and reallocating resources to newer and thriving ones.⁴ The role of competition law in pharmaceutical sector arose since product patents on drugs and pharmaceuticals were allowed under the Indian patent law⁵ and its role is ailing with an insufferable complexity.

131 in Vinod Dhall, *Competition Law Today* (Oxford University Press, New Delhi, 2007).

² *Commission notice, Guidelines on the Application of Article 81 (3) of the Treaty*, OJ 2004, C101/97, available at <http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2004:101:0097:0118:EN:PDF> last seen on 04/11/2014.

³ *Supra* 1.

⁴ Geoffrey A. Maine, Joshua D. Wright, *Competition Policy and Patent Law under Uncertainty: Regulating Innovation*, 3(Cambridge University Press, New York, 2011).

⁵ The Patents (Amendment) Act, 2005.

The debate between incentivizing firms to develop new products by granting them patent protection which aids the inventors/developers in marketing said products(IP) and promoting price competition to reduce health expenditure and maximizing public benefit (anti-trust regulations) acquires limelight in the pharmaceutical industry.

This paper seeks to examine the above discussed conflict by examining the regulatory measures in India, and contrasting them with those in the UK, USA and the European Union, including the UK. The authors will seek to provide an alternative route to the much criticized mode of compulsory licensing by empowering the apex anti-trust authority of India – the Competition Commission of India – to deal with matters relating to pharmaceutical sector.

2. UNDERSTANDING THE DYNAMICS OF PATENT AND COMPETITION LAW IN RELATION TO THE EUROPEAN COMMISSION

2.1. Need for Patent Monopoly for Originators

There are two facets which add importance to this deliberation – one economic and the other legal. The ‘originators’ (innovative pharmaceutical companies that develop new medicines) bring about substantial public health benefits for the population. However, the issue of finance and research is not a sinecure one.

Originators are incentivized to develop new products (whether for a completely novel clinical therapy or as an enhancement to an existing method) by the promise of patent monopoly to exploit the monetary returns thereof. The average cost of developing a new drug and bringing it to the market is estimated, by the European Federation of Pharmaceutical Industries and Associations (EFPIA)⁶, to be over USD 1.3 billion. Such an incredible amount is the resultant of the shift from

⁶ *Submission to the European Commission in relation to the Pharmaceutical Sector Inquiry*, European Federation of Pharmaceutical Industries and Associations (EFPIA), <http://www.efpia.org/content/default.asp?PageID=559&DocID=4892> last seen on 04/11/2014) para 50, citing JA DiMasi and HG Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different*, (2007) 28 Managerial and Decision Economics 469-79.

drugs based on traditional chemical compounds to biotechnologies.⁷ R&D costs occupy a significant fraction of development costs for a new drug – the report for an inquiry conducted by the European Commission in 2008-09 (hereinafter ‘Report’) had found that for the period of 2000-07, originators spent on an average 17% of their global turnover upon R&D.⁸ For biopharmaceutical industries, this percentage went up to 40%.⁹ Therefore, these figures suggest that the superiority granted by patents to these companies is justified.

Furthermore, these products have a gestation period ranging typically between 10-12 years after initial discovery and patenting of a compound before they actually reach the market. There are two major consequences of this – firstly, because so much of the patent-protected time period expires prior to the commercial utilization of the product the scope of recoupment of R&D costs gets substantially reduced; and secondly, due to this delay patent protection may expire before the product acquires an attractive niche in the marketplace which allows generic firms to enter with a relatively low commercial risk (since the initial cost of entry has already been borne by the originators) by legitimately making copies of the patented product available at a cheaper price than it. The authors have provided herewith a table depicting this phenomenon in the Indian market.¹⁰

However, due to the whip of competition law it is often the case that these monopolies have to succumb to the public welfare. Pharmaceutical giant Novartis AG in its comments on this report stated that the Commission had failed to take into account the pricing and reimbursement policies of its member States, as these are the “single biggest obstacle to generic competition”¹¹. It also contended herein that there is no relation between anti-competitive practices and pharmaceutical innovation and that there is no incentive to manufacture medicines which

⁷ Simon Priddis and Simon Constantine, *The Pharmaceutical Sector, Intellectual Property and Competition Law in Europe*, 241-275, 243 in *Intellectual Property and Competition Law: New Frontiers* (Steven Anderman and Ariel Ezrachi, New Delhi, Oxford University Press, 2009).

⁸ *Pharmaceutical Sector Inquiry Final Report, European Commission*, available at <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.htm>, last seen 04/11/2014.

⁹ *Ibid*, para 56.

¹⁰ See Appendix, table 1.

¹¹ *Consultation on the preliminary findings of the Pharmaceutical Sector Inquiry*, available at http://ec.europa.eu/competition/consultations/2009_pharma/novartis.pdf last seen 04/11/2014.

are a small but significant enhancement over existing therapies, and that the regulatory practices of member States in favour of the generic companies thwart the purpose of companies such as Novartis AG investing in R&D.¹² Similarly Bayer AG lambasted the contention of the report that the growth of the generics industry has been hampered as a result of anti-competitive practices of the research-based industry ('BigPharma'). It has criticized the nomenclature given by the Report to "legitimate, legal and appropriate activities ranging from filing and enforcement of patents to development and launch of improved products" as a "tool-box" used by originators to hinder the entry of generic players into the market.¹³

2.2. Dynamics of Competition in the Pharmaceutical Sector

The analysis of the interaction between competition law and intellectual property is somewhat inconvenienced by the multiple variants of competition that exists in the pharmaceutical sector. These can be categorized broadly into four different modes:

- i. Originators competing *inter se* through innovation to bring a new product into the market; and for this purpose each originator seeks to develop a unique product i.e. which could not be substituted easily and would be the only drug available to treat a particular condition. [Inter-brand competition]
- ii. Direct 'in market' competition amongst companies that supply the same patented product i.e. parallel trading. Thus, there is a stiff competition faced by distributors of products in developed economies (where the product is priced higher) from their counterparts in the developing/under-developed economies (where the price of the product is cheaper) [Intra-brand competition].
- iii. Direct 'in market' competition between different brand names vis-à-vis the same patented product; in this the parameters are founded on efficacy i.e. therapeutic effect, absence of side-effects and patient convenience, along with price.
- iv. Competition from manufacturers of generic equivalents as the market exclusivity of an originator's product diminishes.

¹² Ibid.

¹³ Ibid 9, 'Bayer' available at http://ec.europa.eu/competition/consultations/2009_pharma/bayer.pdf, last seen on 04/11/2014.

In short, affairs operate in a *virtuous circle* in the pharmaceutical sector. First a firm would develop a new product through research and innovation. Since the new product would bring about a positive change in the competition in the relevant marketplace, the firm would reap substantial profits which are protected by the patent monopoly. The product would also induce competitors of the firm to come up with innovative alternatives to the same product (ideally without encroaching upon the former's patent rights). Following expiry of statutory protection, the product would enter the public domain wherein it would face competition from its generic counterparts manufactured at a lower cost than it. Firms then would compete for a subsequent innovation (better than the previous one) in order to win over the business in the marketplace.

The EU has hit the right note in this debate, inasmuch that if upon enforcement of Article 102 Treaty on the Functioning of European Union (hereinafter referred to as "TFEU") an obligation to supply drugs were imposed upon the originators in lieu of remuneration, it would result in dissuading them from investment and innovation thereby harming consumers.¹⁴ The European Courts have propounded that the exercise of IPRs would only be considered contrary in "exceptional circumstances"; thus making it a factual rather than legal question.¹⁵ In India however, u/s 3 of the Competition Act, 2002 the standard specified for exercise of IPRs is "reasonable". The authors suggest that the distinction between the EU and Indian approach is that while the former operates on a belief that *per se* exercise of IPRs would not necessarily hinder free and fair competition, the latter is based on a *rebuttable presumption* that IPRs do not hinder competition because they are *statutory* rights.

¹⁴ *Guidance on the Commission's Enforcement Priorities in applying Article 82 of the EC Treaty to Abusive Exclusionary Conduct by Dominant Undertakings*, European Commission, [2009] OJ C45/07 para 75, available at <http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2009:045:0007:0020:EN:PDF>, last seen 04/11/2014.

¹⁵ Case T-201/04 *Microsoft v Commission*, [2007] ECR II-3601, para 331.

3. A LOOK AT THE PHARMACEUTICAL INDUSTRY IN INDIA

3.1. Structure

The pharmaceutical sector in India is the fourth largest pharmaceutical industry in terms of volume and thirteenth in value across the world. It contributes 8% to global production and comprises of 2% in terms of market share in pharmaceuticals. The Indian pharmaceutical industry at the end of 2007 was estimated at a staggering USD 18 billion, with the domestic industries contributing USD 10.76 billion. India is one of the top 20 countries that export pharmaceuticals, and also accounts for approximately 21% of patent challenges.¹⁶ Therefore, indubitably the pharmaceutical sector in India is no stranger to development.

The industry in India is a mixed bag – some sub-sectors are dominated by foreign firms and multinational corporations (MNCs) such as Bayer, Novartis, Pfizer etc., whereas Indian firms such as Sun, Lupin, Cipla etc. have the upper hand. The authors have provided with a volume-based comparison depicting transitions in share of MNCs and Indian companies over the years. In Financial Year 2013-14 the domestic pharmaceutical industry accounted for over 70% of the pharmaceutical market.¹⁷

The domestic companies invest very little in basic R&D, since their profitability as compared with the pharmaceutical giants is low and may not increase substantially in the near future. A look at the top 10 Indian companies in terms of investment in R&D has been provided herewith.¹⁸

3.2. Legal Framework

In the 2001 Doha Declaration on TRIPS and Public Health¹⁹, it was clarified that pharmaceutical patents could be granted by the Member countries. This enhancement was put into effect in 2003 and the

¹⁶ *Report of the Task Force on Strategy for Increasing Exports of Pharmaceutical Products*, available at <http://commerce.nic.in/publications/Report%20Tas%20Force%20Pharma%2012th%20Dec%2008.pdf?id=16>, last seen on 04/11/2014.

¹⁷ See Appendix, table 7.

¹⁸ See Appendix, table 3.

¹⁹ *Declaration on the TRIPS Agreement and Public Health*, WTO Ministerial Conference of 2001, Doha, November 9 – November 13, 2001, available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm, last seen on 04/11/2014.

Members decided to make it a permanent amendment to TRIPS in 2005 subject to ratification by two-thirds of the total members.²⁰

The pressure of globalization put India under an obligation to amend its Patent Act in order to conform to the amended TRIPS. According to TRIPS, the developing countries (including India) had time until January 1, 2005, to enact domestic legislation to conform to the amended agreement. Since the Indian patent regime did not previously allow product patents for drugs, it became obligatory to provide for a 'mail box' facility for filing patent claims to protect these products with effect from January 1, 1995. Similarly those 'mail box' patent applications that satisfied certain conditions were entitled to receive exclusive marketing rights for five years. The amendment of the Patents Act came into force on January 1, 2005, incorporating the provisions for granting product patent in all fields of technology including chemicals, food, drugs and agrochemicals. In order to protect the interest of Indian industry, including the pharmaceutical industry, full transition period of ten years available under the TRIPS Agreement was utilized. In the amendment, a provision was made that in respect of applications for drugs and medicines filed before January 1, 2005 the rights of patentee shall accrue only from the date of grant of the patent and not with retrospective effect.

3.3. Scope of Anti-competitive Practices in the Indian Pharmaceutical Industry

There are basically two defined types of anti-competitive structures – horizontal agreements (e.g.: cartels, collusions) and vertical agreements (e.g.: tie-in, exclusive supply and distribution agreements, refusal to deal). A plain look at s 3 (3) of the Competition Act 2002 suggests that it is designed to deal with the horizontal agreements, whereas s 3 (4) primarily concerns itself with the latter type. The abuse by any enterprise of its dominant position in the relevant market is governed under s 4. Ss 5 and 6 give the Competition Commission of India power to examine any combination (mergers, acquisition or amalgamation) for anti-competitive effect.

²⁰ WTO OMC, *Fact Sheet*, TRIPS and Pharmaceutical Patents (September 2006), available at http://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf, last seen on 04/11/2014.

With regard to horizontal and vertical agreements, although there have been very few reported cases of collusion in the Indian pharmaceutical market²¹, it may be suggested here that it is tough to presume the inexistence of tendencies to such an end amongst competing manufacturers. For instance, a very rampant (and unethical) practice that major pharmaceutical companies employ is that of influencing doctors and pharmacists towards prescribing their products by lucrative commissions, free samples and travel and other luxury packages. This expenditure is embedded in the cost of the drugs and is borne by the hapless consumers.²² These activities of doctors along with the companies are essentially collusive behaviour and therefore illegal. The Medical Council of India Guidelines (hereinafter referred to as ‘**MCI Guidelines**’) specifically dictates that doctors should prescribe drugs with generic names, thereby an effort to curb the practice of brand loyalist doctors and pharma companies.²³ The violation of these Guidelines by any medical practitioner, according to Section 20A of the Medical Council Act, 1956, constitutes “professional misconduct” and therefore is binding upon the industry. But the MCI Guidelines have no binding effect on pharmaceutical companies, so in order to bolster this objective even further by an amendment to the Guidelines dated December 10, 2009 a new clause 6.8 was added which specifically regulated the conduct of doctors and their professional association with pharmaceutical companies and allied health sector industry.²⁴

Gratifications in the form of gifts, travel facilities, hospitality arrangements or cash benefits have now been strictly disallowed. However, it is recommended by the authors that since pharmaceutical industries are one of the key players in the healthcare milieu these MCI Guidelines should be made applicable *mutatis mutandis* to them as well, or separate guidelines intended to regulate their conduct should be framed.

²¹ See *In re: Bengal Chemists and Druggists Association and Dr. Chintamani Ghosh*, [2014] 121 CLA 196 (CCI)

²² Khomba Singh, *Free samples to doctors to be now considered part of taxable income*, The Economic Times (07/08/2012), available at http://articles.economicstimes.indiatimes.com/2012-08-07/news/33083546_1_drug-makers-pharmaceutical-companies-free-samples, last seen on 04 October 2014.

²³ Regulations 1.6 and 1.7, Medical Council of India (Professional Conduct, Etiquette and Ethics) Regulations, 2002, available at <http://www.medindia.net/education/mci-guidelines.asp>, last seen on 04/11/2014.

²⁴ *Id.*

Secondly, in the context of anti competitive combinations, it is submitted by the authors that this situation was presumed as highly unlikely given the variegated structure of the Indian pharmaceutical industry which on the contrary ensures free and fair competition, until first major combination has only occurred recently between Sun Pharma and Ranbaxy. The authors shall discuss this in more detail in the following section. However, an analogy can be drawn from other sectors wherein foreign players entering our market with the sole intent of maximizing profit and the pressure of drug prices makes them resort to mergers and amalgamations with Indian companies so as to unite portfolios, achieve a decrease in the cost of development and an increase in market reach. These deals can pose a threat to the indigenous industries, and as a corollary to competition; which is the reason why the Competition Act provides for a stringent mechanism for regulation of combinations and there potential effects on the market.

The issue of abuse of dominant position is the focal point of discussion in this debate. Since the pharmaceutical industry is largely based on know-how and now the Patent Act allows product patents for pharmaceuticals, companies acquire a near-monopoly status as a result of patent grants, which is often abused to the detriment of consumers. This is because albeit the focus of competition law lies in substitutability/interchangeability of goods on demand side, there have been instances where life-saving drugs were priced as exorbitantly as over INR 3 lakhs for a month's dosage; and such drugs may not always have viable substitutes available in the market. Pharmaceutical manufacturers consistently demand a liberal anti-trust regime as according to them competition and not price regulation increases innovation which would lead to availability of better drugs. However abuse of the patent protection in favour of recoupment of their investments by companies impedes development which results in the end consumer bearing the brunt of the blast. Ensuring essential healthcare facilities is one of the primary requirements to be fulfilled by any government in the world, especially in a developing country such as India.

4. COMPULSORY LICENSING IN INDIA – THE NEXAVAR CONTROVERSY

“Between our trade and our health, we have chosen to look after our health.”

- Luiz Inacio Lula da Silva (President of Brazil); on compulsory licensing of AIDS drugs

A compulsory license is basically an involuntary contract entered between a party willing to contract and a party which is not willing and it is imposed and enforced by the state. Compulsory licensing is a form of state intervention with the rights of the patentee, granted on grounds such as exorbitant prices of essential facilities or commodities; or patents being not allowed in the country; or when the person exercises his IPR right is such a way so as to be violating the public interest at large. In a nutshell the entire concept of compulsory licensing is that the rights-holder is compelled by court or competent authority to license his rights to other parties in public interest, and he or she gets royalty which is provided and sanctioned by said court or other competent authority.

Compulsory licensing has been mandated by several international conventions/ agreements like World Intellectual Property Organization (WIPO), Paris Convention for the Protection of Industrial Property²⁵ and WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).²⁶ These international agreements have given several grounds to their contracting states to like promotion of public health and nutrition or to promote the public sectors of vital importance to their socio economic and technological importance.

In India the law on compulsory licensing is provided for under Ss 84-90 of the Indian Patents Act 1970. S 84 (1) is the substantive law on the issue, listing the criteria on which an application for compulsory license may be allowed by the Controller of Patents (“Controller”):

- i. the reasonable requirements of the public insofar the patented invention are not satisfied with the *status quo*; or
- ii. the patented invention is not available to the public at an affordable price; or
- iii. the patented invention is not *worked* within the territory of India.

²⁵ Article 5(a) TRIPS.

²⁶ Id, Art. 8, 31 and 40.

A compulsory license is encumbered with certain qualifications which emphasize the fact that the law in order to elevate public interest does not completely subvert the interests of the inventor, and that these are modes to secure such interest. Firstly, the application for grant of a compulsory license may be filed only by *any person interested* i.e. holding either a technical or financial interest in the working of the patent (albeit a compulsory license is generally motivated by financial concerns); but the Controller has to keep in mind the attempts made by the applicant to obtain a voluntary license from the patentee²⁷, and the ability of the applicant to work the invention to the benefit of the masses²⁸; and a compulsory license may be revoked on ground of non-working by the applicant.²⁹ Therefore, there is a risk involved once an applicant is granted the compulsory license for any patented invention. Secondly this license is non-exclusive, non-assignable and for a fixed term (usually the remainder of the term of the patent, but it can be for a shorter period if the public interest is sufficiently satisfied therein), and is deemed to operate as an agreement between the patentee and the applicant.³⁰ Furthermore a reasonable sum in the form of royalty has to be paid to the patentee by the applicant-licensee in pursuance of this order, which is fixed by the Controller.³¹

Compulsory licensing has been a contentious issue in India since our country recently joined the bandwagon after the Controller awarded a compulsory license for a cancer drug Nexavar patented by Bayer AG to generic drug maker NATCO Pharma³² wherein it was observed and written by the Controller Mr. P.H. Kurien, while awarding that:

“...a right cannot be absolute. Whenever conferred upon a patentee, the right also carries accompanying obligations towards the public at large. These rights and obligations, if religiously enjoyed and discharged, will balance out each other. A slight imbalance may fetch highly undesirable results. It is this fine balance of rights and obligations that is in question in this case.”³³

Prior to licensing of this drug, it was observed by the Controller that the statistics of supply of this drug in India did not justify reasonable

²⁷ Section 84 (6) (iv), The Patents Act 1970.

²⁸ Id, Section 84(6) (ii).

²⁹ Id, Section 85 (1).

³⁰ Id, Section 93.

³¹ Id, Section 90 (1) (i).

³² C.L.A. No. 1 of 2011, Order pronounced on March 9, 2012.

³³ Id, para 1.

requirements of the public and “depicted the neglectful conduct of the patentee as far as India is concerned”. The patentee did not take any steps to start the working of the invention on a commercial scale to an adequate extent, which is denoted by the import figures of 2008-10³⁴ as below.

It would be interesting to note that Bayer tried to escape liability by citing infringing copies of Nexavar being sold by Cipla in India at INR 30,000 which reduced the profit margin of Bayer while at the same time made available the drug to the public at a lower price. However, this contention was rejected by the Controller holding that Cipla’s sales are irrelevant due to the fact that it is an infringer facing injunction, and the demands for a life-saving drug cannot be left to the contingent outcome of the injunction suit. Bayer also contended that the applicant had only satisfied the first requirement under s 84 (1) and not the other two requirements namely (b) and (c) (i.e. invention not available at an affordable price and not worked in the territory of India), which was dismissed by the Controller as “an objection of a hyper-technical nature”³⁵. Therefore, the Controller’s order was primarily founded on the “reasonable requirement of the public” criterion under s 84 (1).

In appeal to the Intellectual Property Appellate Board (IPAB)³⁶, the IPAB while upholding the order of the Controller further added that the term “reasonably affordable price” should be construed from the point of view of different classes and sections of the public and not from the convenience of the innovator.³⁷ Therefore, the IPAB clearly emphasized upon the importance of social welfare rather than the profitability of the manufacturer/inventor. It also held that the conditions prescribed under s 84 (1) are mutually exclusive i.e. even if one of these conditions is satisfied the Controller can grant a compulsory license in favour of the applicant.³⁸ In this case the excessively expensive price of the drug was the tipping factor as it affected its affordability to the patients.

As for the issue of “working” of the patented invention in the territory of India, it was held by the IPAB that this was a question of fact and would be determined on a case-to-case basis. In some cases it could be only restricted to local manufacture, whereas in others it could extend to

³⁴ See Appendix, table 9.

³⁵ Id, para 8 (a).

³⁶ Bayer AG v. UOI, Controller of Patents and NATCO Pharma, MIPR 2013 (2) 97.

³⁷ Id, para 32.

³⁸ Id, para 38.

cover importation as well. In this case, the patentee failed to adduce evidence in order to establish that the patent would be worked effectively merely by importation and that it could not be manufactured locally to the same effect.³⁹

The cancer drug Nexavar is now available at INR 8900 instead of the previous price of INR 2.8 lakh per month. At its original price it was available to only 2% of total patients of liver and kidney cancer. The license means that the same drug after compulsory licensing is available at just 3% of its earlier price to a larger section of patients. Bayer was sanctioned 6% of profits from sale of Nexavar by NATCO Pharma.⁴⁰

However there is a caveat to compulsory licensing of patented pharmaceuticals inasmuch it should only be implemented in dire cases to rectify the unfair trade practice by a patentee. It should be treated as an option of the last resort by the State, lest apprehensions of compulsory licensing may cause companies to not to venture into Indian jurisdiction for want of profitability. Extraordinary cases involving IPRs over life-saving drugs and essential services may be licensed if all the prerequisites of compulsory licensing are proved against a patentee. Multinational companies use a lot of their money, resources and technology in devising efficient life-saving drugs for the public so compulsorily licensing would add as a benefit and fair and free competition will get a boost, but it may also bring about a feeling of mistrust amongst the companies.

5. A CASE STUDY OF THE LEGAL SETUP IN THE USA

It has been observed by statistical figures that the benefits to consumers in the USA has been phenomenal, which sets a perfect example for balance between intellectual property and competition law. A report from the Congressional Budget Office analyzing the impact of generic drugs on competition in the pharmaceutical market has estimated that since 1994 consumers save up to USD 8-10 billion annually on

³⁹ Ibid, para 51.

⁴⁰ *India's First Ever Compulsory License Granted*, Pharma Times, available at http://www.pharmatimes.com/article/12-03-12/India_s_firstever_compulsory_license_-_a_game-changing_move.aspx, last seen on 04/10/ 2014.

prescription drugs due to the advent of generic drugs in the market.⁴¹ Apart from the Federal Trade Commission's sustained efforts to restrict the surging cost of prescription drugs and healthcare in the States, one of the most beneficial statutes in this regard has been the Hatch – Waxman Act⁴², enacted in 1984. The objective of this Act was to accomplish a balance of intellectual property and competition policies while at the same time ensuring there was enough incentive for originators to indulge in new drug development.⁴³

5.1. The Hatch – Waxman Act – Mechanism and Impact

Hatch-Waxman Act also amended the Federal Food, Drug, and Cosmetic Act s 505(j) (21 U.S.C. 355(j)) which sets forth the process by which would-be marketers of generic drugs can file Abbreviated New Drug Applications (ANDAs) to seek Food and Drug Administration (FDA) approval of the generic version. When an ANDA is filed, the application must contain a certification with respect to the patents listed in the Orange Book.⁴⁴

There are four certification options i.e. Paragraph I certifies that there are no patents listed, Paragraph II certifies that the patent had expired; Paragraph III certifies that the patent will expire and Paragraph IV certifies that the patent is invalid or will not be infringed by the generic drug. Section 505 (j) (5) (B) (iv), the so called Paragraph IV, allows 180-day exclusivity to companies that are the First-To-File (FTF) an ANDA against patents listed in the Orange Book.⁴⁵

⁴¹ Congressional Budget Office, *How increased competition from generic drugs has affected prices and returns in the pharmaceutical industry* (July 1998), 31, available at <http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/6xx/doc655/pharm.pdf>, last seen 04/11/2014.

⁴² The Drug Price Competition and Patent Term Restoration Act, 1984.

⁴³ *H R Rep No. 98-857(I), 14-15 (1984) reprinted in 1984 USCCAN 2647*, available at [http://www.cadc.uscourts.gov/internet/opinions.nsf/83C7394DFFEB2AC485256F12006E8166/\\$file/97-5188a.txt](http://www.cadc.uscourts.gov/internet/opinions.nsf/83C7394DFFEB2AC485256F12006E8166/$file/97-5188a.txt), last seen on 04/11/2014.

⁴⁴ The “*Orange Book*” is an annual publication of the FDA, which contains a list of: (1) approved prescription drugs; (2) approved over the counter (OTC) drugs (3) biologics; and (4) products that were approved but were revoked, available at <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/UCM071436.pdf>, last seen on 04/11/2014.

⁴⁵ Y. Srihari, S. Padmaja and G. Srinivasa Rao, *Implications of Drug Price Competition and Patent Term Restoration Act (DPCPTR) on Indian Pharma Industry*, 14(6) *Journal of Intellectual Property Rights* 501.

The Hatch-Waxman Act provides for an exclusivity period of 180 days from filing for the first-filing generic drug companies which can be triggered by a court decision of invalidity or non-infringement or by one of the first-filing generics entering the market. The FDA does not grant a generic company the right to manufacture the drug for which it has filed a Paragraph IV certification after the first filer until either one of these events occur. The court's decision need not be in a dispute directly contested by any of the first-filing generics.

The impact of introduction of Hatch-Waxman has been immensely positive for the pharmaceutical industry in the USA. Besides a significant reduction in expenditure on prescription drugs, anti-competitive practices such as collusive agreements between originators and generic manufacturers whereby the latter kept the generic version of a drug patented by the former off the market for a massive sum of money were curbed by the Federal Trade Commission (FTC) on a number of occasions.⁴⁶ The measures taken by FTC against delay-to-file agreements have encouraged the entry of generic drugs in the market after expiry of patent term, showing as much as a 50% drop in drug prices.⁴⁷ A table has been provided by which exhibits the sales in USA of top drugs which lost their patent protection during 2004-08.⁴⁸

However if the generic manufacturer files a Paragraph IV certification on grounds that the patented invention would not be infringed by its generic copy, the applicant is sued by the originator. The Act provided that in case any lawsuit is filed against an ANDA applicant the FDA cannot grant approval before the expiry of 30 months from the date of filing or final court decision, whichever is earlier.⁴⁹ Herein if the parties settle out of court and the originator somehow convinces the generic manufacturer to keep its product off the market for the balance period of the patent in lieu of compensation paid by the originator, this settlement would defeat the purpose of the Act.

⁴⁶ See *Abbott v Geneva*, C-3945 (26/05/2000), available at <http://www.ftc.gov/os/2000/03>, last seen on 04/11/2014; *FTC v Mylan Laboratories Inc.*, FTC File No. X990015 (29/11/2000), available at <http://www.ftc.gov/opa/2000/11/mylanfin.htm>, last seen on 04/11/2014; *Hoecsht Marion Roussel v Carderm Capital LP and Andrx Corp*, FTC File No. 9810368, available at <http://www.ftc.gov/enforcement/cases-proceedings/9810368/hoecsht-marion-roussel-inc-carderm-capital-lp-andrx>, last seen on 04/11/2014.

⁴⁷ *Supra* 45, 504.

⁴⁸ See Appendix, table 4

⁴⁹ *Supra* 45, 502.

Indian generic pharma companies have also derived advantage from this Act. Out of the first-time generic approvals for ANDAs by the FDA in 2004-08, 83 were filed by Indian companies. Ranbaxy led the table with 19 approvals followed by Dr. Reddy with 13 ANDA approvals, illustrated by a graph.⁵⁰

The first Indian company to file ANDA and receive a 180-day exclusive marketing period for a generic drug was Dr Reddy's with the launch of Fluoxetine 40 mg capsules on August 3, 2001. Fluoxetine sales of USD 68.5 million contributed 21% of the total turnover in 2001-02.⁵¹ Indian companies are the first to file ANDAs with Paragraph IV for 4 products out of 15 products by sales.⁵²⁵³

Therefore even though Indian companies entered into the US generics market as late as 1997, since then the number of companies as well as the number of ANDAs by Indian companies have increased exponentially. Indian companies have been empowered to compete with companies from other nations as well as *inter se* to launch a product sooner than the other after the expiry of a product patent. Most of the top Indian companies now have a major contribution in their annual turnover from the US market.

6. UGANDA AND BRAZIL – PERSPECTIVES OF UNDER-DEVELOPED COUNTRIES

Uganda showed an example of balancing public necessity with patent protection and at the same time controlling the competition when it successfully combated the HIV/AIDS crisis during 2000-02. Generic competition, use of the public health exceptions in TRIPS and State funding for health service are some key steps that were taken by the Ugandan policymakers in order to provide free drugs to the patient populace.⁵⁴

⁵⁰ See Appendix, table 5.

⁵¹ *Supra* 45, at 508.

⁵² *Ibid.*

⁵³ *Supra* 54.

⁵⁴ C. Wendo, *Uganda Begins Distributing Free Antiretrovirals*, 363 THE LANCET 2062 (19/06/2004), available at <http://download.thelancet.com/pdfs/journals/lancet/PIIS0140673604164959.pdf?id=haaMfi0Nh268cLlzOEJu>, last seen on 04/11/2014 (the article can be accessed after a free subscription to the website).

AIDS is an incurable disease and can only be mitigated by the used of anti-retroviral drugs (ARVs). As such, access to ARVs is pivotal to the survival and life quality of the infected population. Research showed that due to entry of generic ARVs in the Ugandan market, prices of branded drugs fell significantly. The largest decrease was in the prices of D4T, from USD 173 for a monthly dosage of 40 mg to USD 118 in December 2000, to USD 23 in February 2001 and then eventually at a paltry USD 6 in April 2002.⁵⁵ Such significant price reductions ensured that the public received the best standard of pharmaceuticals at a very affordable price.⁵⁶ Seven ARVs are patented in Uganda, and five of these have generic variants which are flown from India.⁵⁷

In Brazil, a similar situation arose which was efficiently rectified by the Brazilian Government by adopting a decree which laid down rules for grant of compulsory licenses in case of “national emergency” and “public interest”. The definition provided to these concepts is vast enough to cover almost all aspects of social welfare such as public health, nutrition, environmental protection – thus ensuring the fulfilment of most basic needs.⁵⁸

These cases are nearer to the heart of the Indian economy. India can emulate the steps taken by Uganda or Brazil in order to combat deadly diseases such as AIDS, tuberculosis, malaria, dengue – except for AIDS all other diseases are curable but a large section of rural population is afflicted by these till date due to inaccessible prices of the branded drugs available in the market. In fact, some towns in India have already made the shift from branded to generic – most of these movements have been spearheaded by public spirited individuals. In 2012 Maharashtra was the first state to officially establish generic pharmacies – wherein only drugs

⁵⁵ M.K. Smith, *Generic Competition, Price, and Access To Medicines: The Case of Antiretrovirals in Uganda*, Oxfam Briefing Paper Series, Briefing Paper No. 26, Oxfam GB, Oxford (2002), available at <http://oxfamilibrary.openrepository.com/oxfam/bitstream/10546/114502/bp26-generic-competition-price-access-medicines-100702-en.pdf>.
txt, last seen on 04/11/2014.

⁵⁶ Anon, *Closing the Access Gap: The Equitable Access License*, available at <http://uaem.org/cms/assets/uploads/2013/03/EAL-primer.pdf>, last seen on 04/11/2014.

⁵⁷ Ibid.

⁵⁸ International Centre for Trade and Sustainable Development, *WTO Disputes rise again: Bananas, patents & aircrafts*, ICTSD BRIDGES Weekly News Digest, 5 (20/02/2001), available at <http://www.ictsd.org/html/weekly/story5.20-02-01.htm>, last seen on 04/11/2014.

with generic names were made available at affordable prices to the consumers.⁵⁹

7. EXAMINING THE CAPACITY OF THE COMPETITION COMMISSION OF INDIA (“CCI”/ “COMMISSION”) IN REGULATION OF PHARMACEUTICAL SECTOR IN INDIA

Under the Monopolies and Restrictive Trade Practices Act 1969 (“MRTP Act”) monopoly itself was considered to be bad. But the enactment of The Competition Act 2002 marked a change in policy of the Indian Government; inasmuch the Act does not prohibit monopoly *per se* but only its abuse to the detriment of competitors to the extent that the offending enterprise has a dominant position with respect to the relevant market. The object of the Act is clear from the Preamble which states that it is:

“An Act to provide, keeping in view of the economic development of the country, for the establishment of a Commission to prevent practices having adverse effect on competition, to promote and sustain competition in markets, to protect the interests of consumers and to ensure freedom of trade carried on by other participants in markets, in India, and for matters connected therewith or incidental thereto”

Therefore, consumer welfare was considered as one of the objectives of this Act by the legislators. Nonetheless, the Raghavan Committee Report (which suggested that this Act be enacted to replace the erstwhile Act) did not want the CCI to excessively interfere with the market. However, the report did acknowledge the presence of anti-competitive tendencies extant in the pharmaceutical sector.⁶⁰ On the issue of standards and quality, the Committee observed that if there are certain firms in a particular sector which are in a better economic position than their competitors they may use their dominance to create arbitrary standards and norms to prevent competition from flourishing. Such practices which prevent market access should attract the relevant provisions dealing with abuse of dominant position.⁶¹

⁵⁹ Anon, *Satyamev Jayate: Maharashtra flags off Generic Medicine Stores across the State*, ZeeNews Bureau(16 June 2012), available at http://zeenews.india.com/entertainment/idiotbox/satyamev-jayate-maharashtra-flags-off-generic-medicine-stores-across-the-state_113515.html, last seen on 04/11/2014.

⁶⁰ The Raghavan Committee Report (1991), para 2.4-2.

⁶¹ *Ibid*, para 4.3.

The Act does not expressly arm the CCI with the power to regulate pharmaceutical companies. However, the provisions regarding abuse of dominant position/predatory pricing⁶² and regulation of combinations⁶³ would nevertheless apply to any potentially anti-competitive activities by these companies. Section 3 and 4 was brought in force vide notification in 2009, seven years after the enactment of the main Act. S 3(3)⁶⁴ can prove helpful in dealing with agreements which manipulate the supply chain. Mass boycott of products and doctors agreeing to prescribe or not to prescribe a particular brand are within the purview of s 3(3) prohibitions. Some agreements under Section 3(3) are presumed to be illegal if they are in the nature of quintessential cartels. The section can also be enforced to restrain collusive practices in drug procurement.

By virtue of Section 4 (1), the Commission can take note of unfair prices in case of pharmaceuticals as well if the actor in question has a dominant position. Nothing in the Act precludes the CCI from intervening in price regulation of drugs or granting compulsory licenses. As may be evinced from Section 84 (1) of the Patents Act, the compulsory licensing criteria provided therein is motivated by public interest concerns and therefore are not based on stricter competition analysis. Currently there is no settled position upon whether the CCI can grant orders partaking the nature of compulsory licenses, nevertheless an analysis of the provisions in Section 27 and Section 28 of the Act confer a great deal of power on the CCI to grant access which may include compulsory licenses. Section 27(g) of the Act provides for the orders by the Commission after inquiry into agreements or abuse of dominant position.

The Controller in *Bayer v. Natco* had granted a compulsory license to Natco for the drug Nexavar owing to the fact that it was not available to the public at a reasonably affordable price. In doing so, the term “reasonably affordable price” was construed in reference to the price to the public and not Bayer’s R&D costs. Therefore, it is not entirely inconceivable that a similar order could be granted by the Commission under Section 27 (g) if a complaint were filed against a dominant pharmaceutical company, alleging that the price charged for a drug is unfair as it is unaffordable to the general public or that the same drug could be accessed by the public more easily if it were manufactured by some other

⁶² Supra 23.

⁶³ Sections. 5 & 6, The Competition Act, 2002.

⁶⁴ Supra 22.

firm. Such a complaint could be tenable under Section 4 (2) (a) (ii) of the 2002 Act.

Similarly, a refusal to license IP held exclusively by an enterprise could be interpreted as limiting the “production of goods or provision of services or market”, or restrict the “technical or scientific development relating to goods or services to the prejudice of consumers”, or result in denial of market access; all three of which amount to abuse of dominant position under Ss 4 (2) (b) (i), 4 (2) (b) (ii) and 4 (2) (c) of the 2002 Act.⁶⁵

Therefore, a purposive interpretation of this blanket provision can confer upon the CCI the power to grant a compulsory license of IPRs in case the exclusivity conferred by the rights is used by the right-holder to gain unfair advantage in the relevant market. The Commission may also pass an order for transfer of property rights (both tangible and intangible i.e. intellectual property) under s 28 (2) (a).⁶⁶ It is the opinion of the authors that the Competition Act exhibits strong inclination towards the interests of the “common man” than on competitors or competitive approach, thereby giving rise to an argument that even the CCI can grant compulsory license of pharmaceutical patents under consumer welfare and socialist considerations.

8. INSTANCES OF ACTION TAKEN BY CCI VIS-À-VIS PHARMACEUTICAL INDUSTRIES IN INDIA

8.1. Curbing Abuse of Dominance by Pharmaceutical Associations

In the recent past, the CCI has played an active part in restraining abuse of dominance and cartelizing tendencies by the associations of chemists, druggists, stockists, whole-sellers and manufacturers which could have had a potential adverse impact over public health. In a press release dated 03 February 2014⁶⁷ the CCI identified and emphasized upon

⁶⁵ N.S. Chopra, D. Muthappa, *The Curious Case of Compulsory Licensing in India*, Competition Law International 8(2) (August 2012), available at <http://awa2013.concurrences.com/business-articles-awards/article/the-curious-case-of-compulsory>, last seen on 08/01/2015.

⁶⁶ Supra 63, Section. 28 (2)

⁶⁷ Press Information Bureau, Release, *CCI Draws Attention of Associations of Chemists, Druggists, Stockists, Wholesellers and Manufacturers to the Anti-Competitive practices in the Pharmaceutical Industry* (03/02/2014), MANU/PIBU/0109/2014.

certain activities which are anti-competitive and have been held so by the CCI in the past:

1. Issuance of No Objection Certificate or letter of consent by such associations for opening chemist shop/being appointed stockists/ distributor/ whole-seller.
2. Compulsory payment of PIS charges by pharmaceutical firms/ manufacturers to associations for release of new drug/new formulation.
3. Fixation of trade margins at different levels of sale of drugs/ medicines.
4. Issuance of instructions to chemists/ druggists/ shops/ stockists/ whole-sellers/ manufacturers restricting discounts on sale of drugs in retail or wholesale.
5. Issuance of boycott calls by the associations to their members against any enterprise for not following the instructions of associations.

The CCI has been instrumental in controlling the abovementioned activities which were normally prevalent among associations comprised of key players in the pharmaceutical industry. The authors have herewith provided a brief summary of the cases in chronological order which served as precursors to each of the above directive. However the fourth point i.e. restriction on discounts to consumers was the central issue in *Re: Bengal Chemists and Druggists Association and Dr. Chintamani Ghosh*⁶⁸, which was decided in March 2014.

*Varca Druggist and Chemist and Ors v. Chemists and Druggists Association Goa ("CDAG")*⁶⁹

The Informant filed a complaint against the guidelines framed by the CDAG for regulation of its members, alleging them as abuse of dominance and unfair and restrictive trade practices. The guidelines were following:

- i. All pharmaceutical companies setting up industry in Goa were to appoint their stockists and wholesalers only from those individuals and firms, who are members of the CDAG. Thus, no person or firm who was not a member of the CDAG is eligible

⁶⁸ (2014) CompLR 221(CCI).

⁶⁹ (2012) CompLR 838 (CCI).

- for being appointed as the stockiest or wholesaler of such a company even if the said person or firm possessed all necessary qualifications.
- ii. A No Objection Certificate (NOC) was required to be obtained from the CDAG prior to appointment of such stockists or wholesalers.
 - iii. A company had to seek prior Public Information System (PIS) approval for introducing any new pharmaceutical product in the territory of Goa. Further, under the system of PIS approvals, the CDAG took an amount of Rs. 500 per drug per category from drug manufacturing companies for introduction/marketing of drugs in Goa.
 - iv. For appointment of more than two stockists, the CDAG had imposed restrictions related to volume of sales achieved by previous stockists of the company. In any case, the total number of stockists appointed by a company could not exceed five. Furthermore, even if the company felt its need, it could not appoint another stockist until one year past the appointment of the previous one.
 - v. If a new entrant (stockist, distributor or retailer of any pharmaceutical product) wished to carry on business without obtaining the membership of CDAG, the CDAG issued directions to all its members debarring them from dealing with such entrant in any manner whatsoever.
 - vi. No credit was given to any retailer, which was contrary to industrial practice of allowing 20 days' credit to retailers.

The Commission held that the cumulative effect of above practices like compulsory membership of the Association for anyone entering into the drug market, obtaining NOC and giving fees for introduction of any new product by any pharmaceutical company and appointment of new stockist and further imposing penalties on violation of guidelines was evidentiary of the fact that the CDAG was engaged in the practice of eventually restricting the number of players in the market and in turn also limiting or controlling supply and availability of drugs. Doing away with the practice of NOC would result in free supply of drugs in the market and consequently more availability of the drugs to the consumers. The guidelines mandating issuance of NOC for appointment of a new or an additional stockist in a particular territory eventually restricted the number of players in the market and in turn also limits or controlled

supply of drugs.⁷⁰ The imposition of mandatory PIS approval followed by imposition of penalties on firms which did not follow this diktat established that the practices and conduct of CDAG were limiting and controlling the supply of drugs in the state of Goain violation of provisions of Section 3(3) (b) of the Act. It is to be noted here that the requirement of PIS approvals *per se* does not have any appreciable adverse effect on competition. Additionally, the regulation and fixation of price margins by CDAG had the inevitable consequence of determining the sale prices of the drugs and thus was held in contravention of Section 3 (3) (a) of the Act. In such circumstances, accessibility of potentially life-saving drugs to the common man at reasonable prices was restricted by the CDAG guidelines.⁷¹

*M/s Peeveear Medical Agencies v. All India Organization of Chemists and Druggists ("AIOCD") and Janssen Cilag Pharmaceuticals Ltd. (A division of M/s Johnson & Johnson Ltd.)*⁷²

The Informant alleged that under the guise of protecting interests of its members, the AIOCD was engaging in abuse of its dominance and entering into anti-competitive agreements with other parties such as the Indian Drugs Manufacturers Association (IDMA) and The Pharmaceuticals & Allied Manufacturers & Distributors Association Ltd. (OPPI) which result in limiting and controlling the supply and markets, and directly influencing the sale and purchase price of the drugs and pharmaceutical products in India. The AIOCD had been controlling the trading policies of different manufacturing companies, regulating profit margins, inspecting the stockists/distributor agreement of manufacturing companies, recommending desired profit margins to all its members and stockists all over the country, and collecting Rs. 2,000/- per drug per category from every manufacturer in each state under the name of PIS approval before permitting them to launch their new medicines. If a manufacturer did not abide by the instructions of AIOCD, its products were boycotted everywhere in the country. The Informant also insinuated that Jansen Cilag Pharma were colluding with the AIOCD and supporting such activities with the ulterior motive of securing unseemly profits and favours of the AIOCD.

⁷⁰ Supra 73, para 26.27.

⁷¹ Supra 73, para 26.44.

⁷² (2014) CompLR 10 (CCI).

The Commission held that mandatory requirement of NOC/LOC from AIOCD (through respective State and District Associations) although evolved to prevent entry of spurious or inferior quality drugs purchased from unauthorized persons; its effect resulted into problems to consumers and limits or controls supply in market thus was deemed to be anti-competitive.

Further on PIS approvals the Commission in light of its previous decisions on this issue⁷³, was of view that payment for PIS approval as advertisement charges, at time of product launch or any change in product brand, dosage, form, strength etc. in respective PIS bulletins ensures certain compliances, which also bolsters advertisement and circulation of product information to all retailers at a very nominal cost and thereby cannot be presumed to be anti-competitive. Nonetheless if the launch of a product in market is made contingent upon PIS approval it would result in restraint of trade and denial of market access.⁷⁴ Moreover, it was observed that any attempt on part of members of AIOCD and or its affiliates to delay or withhold any PIS approval on whatever ground could not be justified. This ultimately deprived consumers of the benefits of such drugs.

On trade margins, after examination of evidence given by DG, the Commission observed that practice of fixed trade margins resulted from MOUs between AIOCD, OPPI and IDMA. Commission also noted that as result of this practice, trade margins were not being determined on competitive basis nor were allowed to fall below agreed percentages. Further the Commission noticed that while margin for retailer was fixed for scheduled (controlled) drugs, for non-scheduled drugs there was no obligation to pay any specified margins either to retailers or to wholesalers. Therefore, an agreement to give fixed trade margins to wholesalers and retailers directly or indirectly affected the purchase prices of the drugs in the open market⁷⁵.

*In re: Bengal Chemist and Druggist Association ("BCDA") and Dr. Chintamani Ghosh*⁷⁶

⁷³ Varca Druggist & Chemist v. CDAG; Santuka Associates Pvt. Ltd. v. AIOCD and Ors. (2013) CompLR 223.

⁷⁴ Id, para 30.

⁷⁵ Id, para 13.12.12.7.

⁷⁶ Supra 72.

This was a *suo moto* inquiry initiated by the CCI after receiving an email alleging anti-competitive practices on part of the BCDA. It was alleged by the Informant that the BCDA's executive committee directed its retailer member not to give discount on the Maximum Retail Price (MRP) in the sale of medicines to consumers. Further, the Informant alleged that in order to ensure strict compliance of its directives, BCDA carried out "vigilance drives" to identify the retailers defying the directions issued by it, and even forced the defiant members to shut their shops as a punishment measure.

The Commission in its well reasoned judgment noted that *the MRP is only a ceiling limit on the price of the product, i.e. it cannot be sold at a higher price. It does not preclude sale of the product(s) below MRP.*⁷⁷ It was evident from the facts of the case that there were a large number of retailers who were willing to offer discounts on MRP to customers. However, the concerted and collusive activities of BCDA members were impedimental to price competition between retailers. This resulted in the fixation of sale prices, since drug prices were not allowed to be influenced by independent market forces. Such conduct of BCDA contravened provisions of Section 3(3)(a) read with Section 3(1) of Act.⁷⁸ When sale of drugs was determined to take place only at MRP, on account of agreement entered into amongst members of the BCDA, then such a trade practice caused or was likely to cause an appreciable adverse effect on competition, especially when almost all retailers and wholesalers were members of BCDA.⁷⁹ It was also a matter of record that BCDA and its affiliated District/Zonal Committees had taken concerted action against retailers offering discounts, by launching organizational movements, threatening them with dire consequences, picketing their shops, collecting fines from them, forcing them to shut their shops, directing their wholesale members not to make supplies and not to cooperate with such retailers. Such a conduct had resulted or was likely to result in controlling and or limiting supply of medicines and market of provision of drugs, which contravened provisions of Section 3(3)(b) of Act. These activities had also adversely affected consumers in addition to retailers concerned. Furthermore it was observed by the Commission that this practice of not offering discounts on drugs was palpably anti-competitive as it would directly the profits made by most of the

⁷⁷ Id, para 61.

⁷⁸ Id.

⁷⁹ Id.

members of the BCDA if competitive forces were allowed to operate in the market.⁸⁰

8.2 Regulating Combinations in the Pharmaceutical Industry in light of the Sun-Ranbaxy Deal

The most recent development in pharmaceutical combinations has been the merger of Sun Pharmaceuticals and Ranbaxy Laboratories, which received the official nod on 05 December 2014 by the CCI.⁸¹ This merger has been touted as the most important transaction between two Indian pharmaceutical companies since the enactment of the Competition Act, and it was valued at approximately USD 4 billion by industry experts.⁸² The merged entity would operate in 65 countries across the globe with 47 manufacturing facilities across 5 continents, along with a global portfolio of specialty and generic products. This was also the first case which the CCI subjected to public scrutiny process, since it had found the deal to be *prima facie* anti-competitive.

In its order under Section 31 (7) of the Act, the CCI approved this combination subject to certain conditions. CCI directed Sun Pharma to divest all products containing the compounds tamsulosin and tolterodine which were marketed and supplied under the “Tamlet” brand name. Similarly Ranbaxy was ordered by the regulatory authority to divest all products containing leuprorelin which were marketed and supplied under the “Eligard” brand name. Ranbaxy would also have to divest products such as Terlibax, Rosuvas EZ, Olanex F, Raciper L and Triolvance. The Commission was of the view that unless these brands were divested to third parties the combined entity would hold a monopoly status thereon in terms of market share which would negate the entry of new players. According to the Order:

“The modification to the proposed combination aims to maintain the existing level of competition in the relevant markets through:

a. the creation of a viable, effective, independent and long term competitor in the relevant markets pertaining to the Divestment Product(s);

⁸⁰ Supra 72, para 64.

⁸¹ Combination Registration No. C-2014/05/170.

⁸² *CCI clears \$4-bn Sun Pharmaceutical, Ranbaxy Laboratories merger deal, but adds riders*, The Financial Express (08/12/2014), available at <http://www.financialexpress.com/article/industry/companies/cci-clears-4-bn-sun-pharmaceutical-ranbaxy-laboratories-merger-deal-but-adds-riders/16972>, last seen on 01/01/2015.

*b. ensuring that the Approved Purchaser of Divestment Product(s) has the necessary components, including transitional support arrangements to compete effectively with the Merged Entity in the relevant markets in India.*⁸³

The parties have six months to divest or procure the divestiture of the aforementioned products. This divestiture shall not be effective unless CCI ratifies the terms and conditions of final and binding sale and purchase agreements and the third-party purchasers that have been proposed by the parties.⁸⁴ The two firms are to give full information regarding divestment products to potential purchasers so as to enable them to undertake reasonable due diligence. CCI would appoint an agency to monitor the due diligence process, including the preparation of data room documentation, in accordance with the monitoring agency agreement.⁸⁵ As per the Order, the divestiture shall not concern any intellectual property rights held by the parties which do not contribute to the current operation.⁸⁶

The divestment brands constitute less than one percent of the total revenue of the combined entity in India. This deal, however, would produce India's largest and the world's fifth largest drug manufacturing entity in terms of revenue.⁸⁷ However industry analysts predict that this deal would not result in a lot of revenue loss to the parties involved, as both companies combined hold rights over 300-400 brands thus divestiture of seven would seem insignificant.⁸⁸ This deal would have appreciable effect on consumers as the combined entity would rise in the global market of generic pharmaceuticals, thus ensuring better accessibility to generic variants instead of branded drugs.⁸⁹

⁸³ Supra 16, at para 39.

⁸⁴ Id, para 57.

⁸⁵ Id, para 52.

⁸⁶ Id, para 47.

⁸⁷ *CCI clears Sun-Ranbaxy merger deal with riders, asks two companies to divest some products*, The Economic Times (08/12/2014), available at http://articles.economictimes.indiatimes.com/2014-12-08/news/56839367_1_cci-chairman-ashok-chawla-fair-trade-watchdog-cci-ranbaxy, last seen on 01/01/2015.

⁸⁸ Digbijay Mishra and Deepak Patel, *CCI gives nod to Sun-Ranbaxy Merger, asks to divest 7 drug assets*, The Business Standard (09/12/2014), available at http://www.business-standard.com/article/companies/cci-gives-nod-to-sun-ranbaxy-merger-asks-to-divest-7-drug-assets-114120800727_1.html, last seen on 01/01/2015.

⁸⁹ See Appendix, table 8.

9. CONCLUSION – PAVING A SMOOTHER MIDDLE GROUND

There is a need for better advocacy in the pharmaceutical sector by the CCI. The Centre for Trade and Development (hereinafter referred to as “CENTAD”) in its report on the impact of competition law in the pharmaceutical sector⁹⁰ states that since the Act itself is new and not many government authorities and functionaries are aware of the competition elements while framing policies for the pharmaceutical sector. The pharmaceutical sector is regulated and governed by a myriad of authorities, thereby bolstering the need to sensitize all such authorities about the prevalent competitive elements therein. The industry heavily relies on patents thus expanding the possibility of abuse. Legal rights are granted with intent to improve market conditions, but its abuse adds salt to injury. Incidences of pharmaceutical companies abusing patents and dominant position have been observed globally over the years. This is also confirmed by the recently concluded EU Pharmaceutical Sector Inquiry Report.⁹¹ Therefore, it is the prerogative of the CCI to create awareness about competition in this sector.

Mergers, acquisitions and alliances in the industry need to be regulated vigilantly and examined for potential abuse. The CCI could frame specific guidelines for combinations in pharmaceutical sector which prohibit those combinations which would have a direct or indirect effect of stifling the production of generic drugs. The guidelines relating to intellectual property and competition in comparative jurisdictions should be codified by the CCI so as to render them binding upon all enterprises. Pricing practices of originators may be challenged under s 4 of the Act instead of directly seeking a compulsory license under the Patents Act, as the criteria for abuse of dominance are more objective in nature than those for the grant of a compulsory license. The Commission may also contemplate the application of the essential facilities doctrine in case of accessing patented knowledge. The Supreme Court has imposed certain obligations similar to this doctrine in *Binny Ltd and Anr. v. V Sadasivan*⁹² and it is also provided for in certain statutes.⁹³

⁹⁰ CENTAD, *Competition Law and the Indian Pharmaceutical Industry* (23/06/2011), 179, available at <http://www.cci.gov.in/images/media/completed/PharmInd230611.pdf>, last seen on 04/11/2014.

⁹¹ *Supra* 7.

⁹² AIR 2005 SC 3202.

⁹³ See The Petroleum and Natural Gas Regulatory Board Act 2006, s 2 (m); The Electricity Act 2003, “open access regime”.

In conclusion, it would be hoove to examine a radical opinion expressed by some critics of disallowing patentability of life-saving drugs altogether on the ground that there is no actual evidence that patent protection awarded to originators facilitates research as such; but results in millions of patients to “buy their lives” from these companies.⁹⁴ In this regard, the authors would like to submit that private players in the pharmaceutical sector have technology and the skilled labour force that the State does not have. India is a mixed economy; therefore the State should work hand-in-hand with these companies and allow them to flourish in order to ensure development. Intellectual property is a tool for incentivizing innovation and therefore maximum utilization in favour of these corporations would ensure new drug development. Nonetheless, States have the option to exercise the public health exceptions under the TRIPS in order to grant compulsory licenses for the benefit of the public or regulate the impact of such pharmaceutical corporations upon the relevant product and geographical market in order to ensure free and fair competition. Besides, the internal mechanisms of private entities do not suffer from the evil (some would call it a necessary evil) of bureaucratic power-play and red-tapism. Therefore a proposal to nationalise the entire pharmaceutical research and development sector would do more harm than good, inasmuch it would dissuade the multinational companies from employing their superior know-how for the betterment of the community thus bringing about a situation of stagnancy. The CENTAD report however suggests a cure for this problem – the patentability threshold of life-saving drugs could be increased in order to ensure that the anticompetitive nature of patents does not adversely affect the economy.⁹⁵

Thus it can be concluded that even though the pharmaceutical industry is heavily regulated and the prices of drugs in our country are comparatively lower than their global counterparts, asymmetry in possession of information and exercise of passive market power may often lead to anticompetitive outcomes. It is expected that as per the current framework the CCI may actively play a role in ensuring healthy and competitive markets from a health care perspective which will go a long

⁹⁴ Akansha Mehta, *Patenting of life-saving drugs has created a global health crisis where human life has become a commercial commodity* LSE Impact on Social Sciences Blog, available at <http://blogs.lse.ac.uk/impactofsocialsciences/2014/08/06/the-morality-of-patenting-life-saving-drugs>, last seen on 04/11/2014.

⁹⁵ *Supra* 68, at 201.

way in fulfilment of the objectives laid down in the Competition Act and thereby let the *virtuous circle*⁹⁶ operate smoothly and unhindered.

APPENDIX

Table 1:⁹⁷

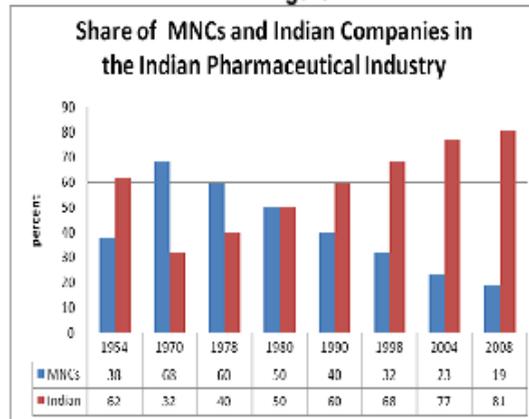
Drug Name	Year of Global Introduction	Year of Indian Marketing Approval or Introduction in India	Introduction Lag (Years)	Year of European Patent Expiry
Cefuroxime sodium	1978	1988	10	1994
Cefaclor	1979	1991	12	1994
Netimicin	1980	1988	8	1994
Aciclovir	1981	1988	7	1995
Ranitidine	1981	1985	4	1997
Captopril	1980	1985	5	1997
Norfloxacin	1984	1988	4	1998
Ketoconazole	1981	1988	7	1998
Famotidine	1984	1989	5	1999
Ceflazidime	1983	1988	5	2000
Ciprofloxacin	1986	1989	3	2001
Ofloxacin		1990		2001
Roxithromycin		1992		2001

Table 2:⁹⁸

⁹⁶ Supra. 13.

⁹⁷ O. Lanjouw, *'The Introduction of Pharmaceutical Product Patents in India: Heartless Exploitation of the Poor and Suffering?'* NBER Working Paper Series, Working Paper No. 6366, National Bureau of Economic Research, Massachusetts (1998).

⁹⁸ S. Chaudhuri, *'R&D for Development of New Drugs for Neglected Diseases: How can India contribute? A study prepared for WHO Commission on IPR, Innovation and Public Health'* available at <http://www.who.int/intellectualproperty/studies/S.%20Chaudhuri.pdf>, last seen on 04/11/2014.

Table 3:⁹⁹

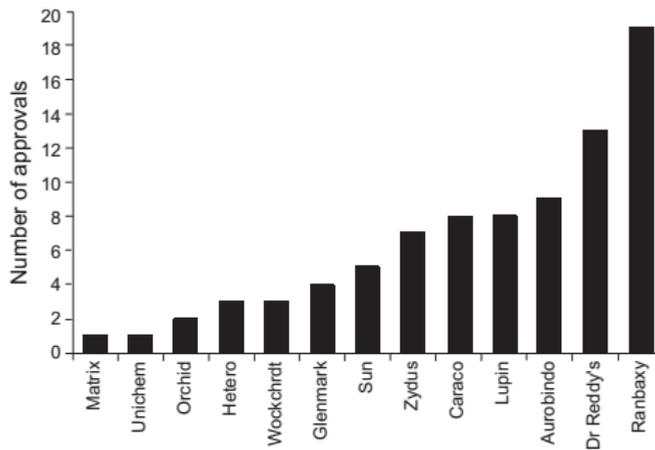
Sl. No.	Company Name	Sales	Research & development expenses	Investment in R & D as % of Sales
1	Ranbaxy Laboratories Ltd.	3,656.2	460.5	12.6
2	Dr. Reddy's Laboratories Ltd.	4,146.2	292.8	7.1
3	Sun Pharmaceutical Inds. Ltd.	1,722.1	188.3	10.9
4	Cipla Ltd.	3,658.0	175.7	4.8
5	Cadila Healthcare Ltd.	1,758.5	161.8	9.2
6	Lupin Ltd.	2,051.7	142.1	6.9
7	Wockhardt Ltd.	1,189.0	126.7	10.7
8	Torrent Pharmaceuticals Ltd.	895.2	112.1	12.5
9	Panacea Biotec Ltd.	843.0	107.2	12.7
10	Aurobindo Pharma Ltd.	1,991.0	96.7	4.9

Table 4:¹⁰⁰

⁹⁹ Ministry of Commerce and Industry, Government of India, *Report of the Task Force on Strategy for Increasing Exports of Pharmaceutical Products*, 20, available at <http://commerce.nic.in/publications/Report%20Tas%20Force%20Pharma%2012th%20Dec%2008.pdf?id=16>, last seen on 04/11/2014.

¹⁰⁰ Available at <https://prod1.newportdata.com/hg/login.asp?ref=/hg/Default.asp?>, last seen on 25/12/2014. Cited in Y. Srihari et al, note50, 504.

Generic drug name	Patent expiry	US retail sales before the patent expiry MAT (\$ million)	US retail sales post patent expiry MAT March 2009 (\$ million)
Pravastatin sodium	2006	1,567	159
Sertraline	2006	3,096	299
Simvastatin	2006	5,786	2,194
Amlodipine besylate	2007	2,790	2,283
Carvedilol	2007	1,606	120
Cetirizine	2007	1,425	104
Zolpidem tartrate	2007	2,491	171
Alendronate sodium	2008	2,183	606
Divalproex sodium	2008	1,751	1,406
Risperidone	2008	2,723	1,752
Venlafaxine	2008	2,941	2,987
Metoprolol succinate	2008	1,666	1,003

Table 5¹⁰¹:Table 6:¹⁰²

¹⁰¹ Available at <http://www.accessdata.fda.gov/scripts/cder/ob/docs/queryai.cfm>, last seen on 04/11/2014. Cited in Y. Srihari et al, note 50, 507.

¹⁰² Cited in Y Srihari et al, note 50, 508.

Table 6— Top 15 US pharmaceutical products by sales

Drug name	2008 sales in \$ billion ⁴¹	FTF generic company	180-day exclusivity possibility
Lipitor	7.8	Ranbaxy	Yes
Nexium	5.9	Ranbaxy	Yes
Plavix	4.9	Apotex	-
Advair diskus	4.4	No Para IV	-
Seroquel	3.9	Teva	No
Singulair	3.5	Teva	No
Enbrel	3.4	No Para IV	-
Neulasta	3.1	No Para IV	-
Actos	3.1	Ranbaxy, Mylan	Yes
Epogen	3.1	No Para IV	-
Prevacid	3.1	Teva	No
Abilify	3.1	Barr, Synthron, Sandoz, Sun	No
Remicade	3.1	No Para IV	-
Effexor XR	3.0	Teva	Yes
Lexapro	2.7	Teva	Yes

Table 7: A bar graph depicting top ten Indian pharmaceutical companies in terms of revenue of last twelve months.

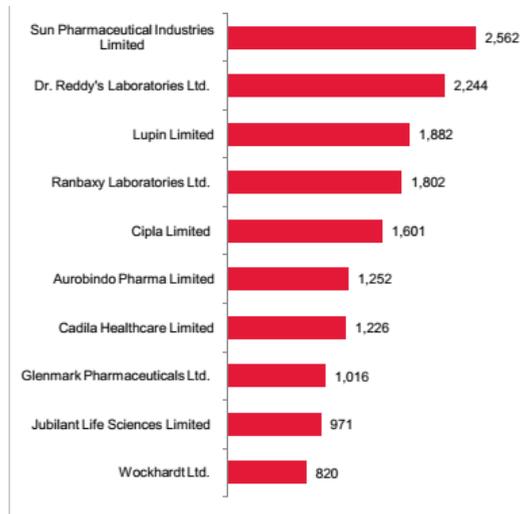


Table 8: Top 10 global generic companies by estimated annual sales post the Sun-Ranbaxy Merger.

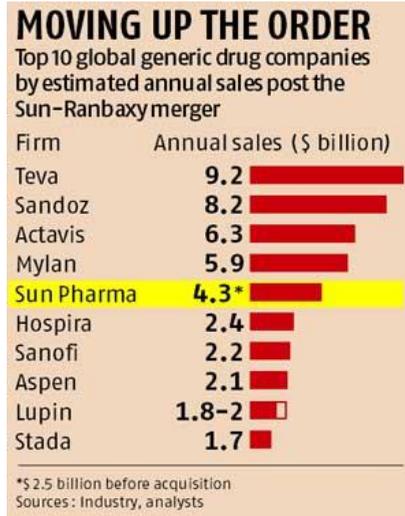


Table 9^{103, 104}

	Total Patients	Demand for 80% of patients	Bottles per month (required)	Bottles Imported in 2008	Bottles Imported in 2009	Bottles Imported in 2010
Liver Cancer	~ 20,000	~ 16,000	~ 16,000	-Nil-	~ 200 bottles	Unknown
Kidney Cancer	~ 8,900	~ 7,120	~ 7,120			

¹⁰³ Supra 32, para 10 (a).

¹⁰⁴ Ibid, para 10 (c).

Sales figures of the drug:

	2006	2007	2008	2009	2010
Sales per year (Worldwide)	\$165m	\$371.7m	\$677.8m	\$843.5m	\$934m
Sales in India	Nil	nil	Nil	16 crores	unknown