MERGERS BETWEEN GENERICS: HOW COMPETITION COMMISSION OF INDIA PROMOTES INNOVATION AND ACCESS THROUGH MERGER CONTROL?

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Indian pharma industry is popularly known as the pharmacy of the world as the industry supplies annually over 10% (in terms of volume) of the worldwide demand for pharma products. This article concentrates on the role of the Competition Commission of India (CCI) in promoting access and innovation in the Indian pharma through its merger control regime. Pursuing an inter-disciplinary approach using insights from competition law, economics and corporate strategy, this article attempts to answer the question whether inorganic growth enhances efficiencies by helping parties leverage their key strengths and seek growth in new relevant product and geographic markets taking into due account the dynamics of the Indian pharma and the core competencies of the merging parties. This article discusses the theory of harm and remedies in all the pharma mergers assessed by the CCI till date.

1. Introduction[1]

India is popularly known as the 'pharmacy of the world' and the country's pharma industry has played a vital role to ensure access to medicines to the less-privileged at highly competitive rates.[2] On the legal front, this has also

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[1] Following Acronyms are used in this article: AAEC: Appreciable Adverse Effect on Competition; AIOCD: All India Organization for Chemists and Druggists; ANDA: Abbreviated New Drug Application; API: Active Pharmaceutical Ingredients; CAGR: Compound Annual Growth Rate; CCI: Competition Commission of India; CGHS: Central Government Employees Health Scheme; cGMP: current Good Manufacturing Practice; IPRs: Intellectual Property Rights; FDA: Food and Drug Administration; FTC: Federal Trade Commission; HHIPL: Hospira Healthcare India Private Limited; NLEM: National List of Essential Medicines; NME: New Molecular Entities; NPPA: National Pharmaceutical Pricing Authority; OCPL: Orchid Chemicals and Pharmaceuticals Limited; PBMs: Pharmacy Benefit Managers; R&D: Research & Development; RoI: return on investment; SEPs: Standard Essential Patents; SCP: Structure Conduct Performance; YoY: Year-on-Year.

[2] For a case study discussion on India, IPRs, trade and access to affordable medicines, Sidonie Descheemaeker, 'India, Pharmacy of the Developing World: IP, Trade and Access to Medicine' *Jura Falconis Jg. 49,* 2012-2013 number 3, pp. 560-569

led to some critically acclaimed decisions from the Indian patent office and the Indian judiciary.[3] The country's pharmaceuticals industry by offering medicines at an affordable rate has played a key role in attaining the sustainable development goal number three that is 'ensuring healthy lives and promote well-being for all at all ages' - not only in India but also across the world.[4] In addition to this static that is price and quantity-led competition, pharmaceuticals industry has another key dimension - that is dynamic innovation-led competition. Interestingly, not only in India, but also across the world, even though the innovation debate has been central to other aspects of law such as ex-post enforcement of competition law (cartels and abuse of dominance) and Intellectual Property Rights (IPRs), scant attention has been paid to the role of merger control in promoting innovation.[5] In that respect, this article seeks to make a unique contribution to the literature on competition policy by assessing the role of Indian merger control in promoting competition and innovation in the pharmaceuticals sector.

This article makes the following three noteworthy contributions to the competition policy literature. First, it offers an exhaustive discussion as regards the practice of the CCI on mergers between generics. The article's concentration on the impact of mergers on competition, innovation and access in generics is a unique contribution to the competition policy literature, as to the best knowledge of the author, it is the only article that systematically and critically addresses the issue in the context of merger control. Second, by

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<https://www.law.kuleuven.be/apps/jura/public/art/49n3/descheemaeker.pdf> accessed 23 Nov 2018.

[3] Sarah Boseley, 'Novartis denied cancer drug patent in landmark Indian case' *The Guardian* (Online 1 April 2013) <https://www.theguardian.com/world/2013/apr/01/novartis-denied-cancer-drug-patent-india> accessed 14 April 2018. The Indian Supreme Court's decision that Novartis's improvements to its drug were an ever-greening strategy and did not merit patent protection. The judgment was welcomed by campaigners including Swiss, Geneva-based NGO Médecins Sans Frontières (Doctors without Borders). For a discussion on the boundaries set by Article 27 TRIPS Agreement and section 3(d) of the Indian Patent Act and the Novartis case, see Henning Grosse Ruse-Khan and Roberto Romandini, 'Patentability of Pharmaceutical Inventions under TRIPS: Domestic Court Practice as a test for International Policy Space', *Max Planck Institute for Innovation and Competition Research Paper No. 16-*02, pp. 23-43 published in *Mercurio Bryan* (Ed.), Contemporary Issues in Pharmaceutical Patent Law, Routledge Research in Intellectual Property (2016).

[4] Kiran Mazumdar Shaw, Leveraging affordable innovation to tackle India's healthcare challenge, *IIM Bangalore Management Review* (16 November 2017) <https://doi.org/10.1016/j.iimb.2017.11.003> accessed 23 Nov 2018.

[5] Rachel Brandenburger, Logan Breed and Falk Schöning, The Role of Innovation in Merger Control – A Hot Topic, *Competition Policy International* July 2016 (1), p. 4.

pursuing an inter-disciplinary methodology using insights from corporate strategy, competition policy and economics, the article instead of pursuing the traditional structure conduct performance (SCP) paradigm of the Harvard school, pursues a more dynamic innovation-led approach, as it first attempts to answer the following fundamental question: looking at the dynamics of the Indian generics industry and the core competencies of the merging parties, is there some merit in inorganic growth[6] that helps parties leverage their core competencies, such as seek growth in new relevant product and geographic markets? Finally, pursuing a case study methodology, it assesses one of the largest conditional clearance decisions by the Indian CCI to date – the three-to-two merger between Sun Pharma and Ranbaxy.[7]

2. Indian Pharmaceuticals Industry

In this section, we first discuss and distinguish between the pharmaceuticals value chain in India and that of the developing world, followed by a

[6] Inorganic growth refers to growth through M&As, joint ventures and other alliances.

[7] Kindly note that even though the merger has been discussed elsewhere in the literature, but to the best knowledge of the author it is for the first time, that the merger has been examined critically and in-depth. Additionally, it is also the first time that a comparative and inter-disciplinary methodology has been employed to study a merger decision in the pharma sector. For a discussion on CCI's conditional clearance decision in Sun Pharma/Ranbaxy, see for instance, Shamim S. Mondal and Vishwanath Pingali, 'Competition and Intellectual Property Policies in the Indian Pharma Sector', *Vikalpa* 42(2) 2017, pp. 61-79; Shamim S. Mondal and Vishwanath Pingali, 'Competition Law and the Pharmaceutical Sector in India', *W.P. No. 2015-11-02* (November 2015)*, Indian Institute of Management Ahmedabad, India, Research and Publications*; Sanchit Srivastava and Shubhashish Chaudhri, 'A Bitter Pill to Swallow – Analyzing Anti-trust Concerns in the Indian Pharmaceutical Sector', RGNUL Student Research Review 1(2) <http://www.rslr.in/uploads/3/2/0/5/32050109/a_bitter_pill_to_swallow.pdf > accessed 7 May 2018; Kalyani Singh, 'The Rising Tide: Competition Law Enforcement in the Indian Pharmaceutical Sector', *Competition Policy International Antitrust Chronicle* November 2014(2), <https://www.competitionpolicyinternational.com/the-rising-tide-competition-law-enforcement-in-the-indian-pharmaceutical-sector/> accessed 7 May 2018; Sunil A Nathani and Gauri Chhabra, The CCI Comes of Age – Orders Divestiture for the First Time in a Merger, *International Committee: ABA Section of Antitrust Law* March 2015 Vol 1, pp. 12-13, <https://www.americanbar.org/content/dam/aba/publications/antitrust_law/at311000_newsletter_201503.authcheckdam.pdf> accessed 7 May 2018; Jyoti Kumari, Role of CCI in Merger Control in Indian Pharma Industry, <https://indianbarassociation.org/wp-content/uploads/2013/02/Role-of-CCI-in-merger-control-in-india-pharma-industry.pdf > accessed 7 May 2018; Swarnim Shrivastava, Taming Pharmaceutical Giants – CCI's role in merger control, Presentation at Indian Bar Association <https://www.indianbarassociation.org/wp-content/uploads/2013/02/Swarnim-Shrivastava.pdf > accessed 7 May 2018.

discussion on the nature of competition between innovators, generics and branded generics.

Even though the basic principles – in terms of industry structure and competition policy remain the same, significant differences in "patent regimes, regulatory policies, health insurances" [8] and innovator, branded generics or generic-led competition, means that the competitive dynamics across countries may be very different. This in turn implies that some of the challenges that one may encounter in India and other developing economies are substantially different from those encountered in the more mature economies where the citizens enjoy an extensive health insurance coverage and the healthcare industry is highly regulated and well-monitored.

A good starting point to highlight these differences is the pharmaceuticals value chain in the EU and the US[9] on the one hand and in India, which may closely resemble those of other developing economies, on the other. Figure 1.1 and figure 1.2 highlight the flow of product, information and money in the pharma value chain in India and in developed economies respectively. In the developed economies (figure 1.2), the industry is highly regulated and well-organized, with the regulators ensuring the quality of the product. In India (figure 1.1), the doctors prescribe the medication, the pharmacies sell it and the consumers pay for it.[10] Doctors, who are the prescribers of the medication are largely insensitive to the price of the medication. In addition, there is also rampant corruption in the sector, with pharma companies often bribing doctors to prescribe their products in return for various cash and non-cash benefits that may include international conferences and exotic holiday locations.[11] Prices are regulated by the National Regulator, the National

[8] Patricia M. Danzon, Competition and Antitrust Issues in the Pharmaceutical Industry (Final Report July 2014) *The Wharton School, University of Pennsylvania*, p. 46.

[9] Hence, otherwise specially referred, the expression developed economies is used to refer to the EU and US.

[10] Kindly note an important exception to this value chain is the public sector employees. The Central Government Employees for instance enjoy the Central Government Employees Health Scheme (CGHS). The CGHS offers benefits and advantages that are similar in scope to those available in the developed economies.

[11] Shamim S. Mondal and Vishwanath Pingali, Competition and Intellectual Property Policies in the Indian Pharma Sector, *Vikalpa 42 (2)* April-June 2017, pp. 67-68. The authors refer to the study by CUTS International, that identified other irrational practices including evidence that doctors tended to irrationally prescribe medication when not necessarily required and prescription of generics with brand names that were available at nearby pharmacies. See also the discussion on Uniform Code of Pharmaceutical Marketing Practices (UCPMP), introduced by the Indian Government in 2015 that recommends a set of voluntary conduct to

Pharmaceutical Pricing Authority (NPPA). Absence of sufficient regulatory control over quality means that in India, brand and pricing are considered as key indicators of quality. In the developed world, like in India, the doctors prescribe the medication, the pharmacies dispense it and the end consumer uses it. However, presence of insurers in the EU and the US and the presence of the pharmacy benefit managers (PBMs) in addition in the US ensures that the prices remain under control. In fact, this has been cited by the industry as one of the rationales for extremely competitive prices of generics and also a significant factor that has generated series of waves of consolidation in the US generics industry. Individual consumers tend to suffer from the classic tragedy of commons[12] and cannot negotiate for the best prices. Insurers and PBMs resolve this collective action problem and ensure that the prices of the products remain competitive.[13]

be adopted by healthcare professionals and pharmaceutical companies, though the code has so far failed to show any positive impact in the sector, at p. 68. See generally CUTS (2014) Competition Concerns in Marketing and the Distribution Segments of the Indian Pharmaceutical Industry, *OECD*.

[12] Garrett Hardin, The Tragedy of the Commons, *Science* 162 (13 December 1968), pp 1243-1248. The tragedy of commons refers to a collective action problem where the different agents are unable to come together and collectively negotiate a solution that may otherwise be beneficial collectively for the group. The tragedy arises on account of the fact that whereas the negotiating agent bears the cost, the benefits of the resulting advantage are collectively enjoyed by the society.

[13] Even though, I limit this observation here to the case of generics, it applies with equal vigour to the new drug launches.

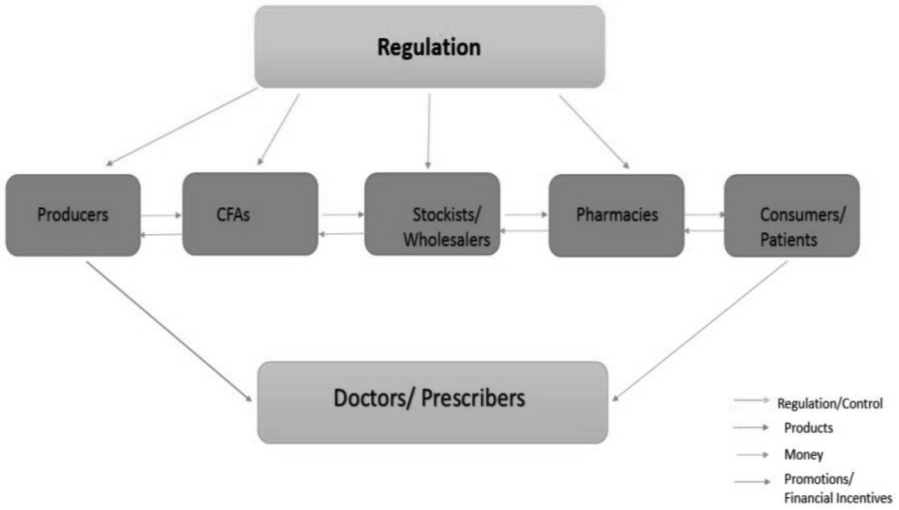

Figure 1.1 Value Chain of the Indian Pharma Industry: Flow of Goods, Regulation, Promotion and Money[14]

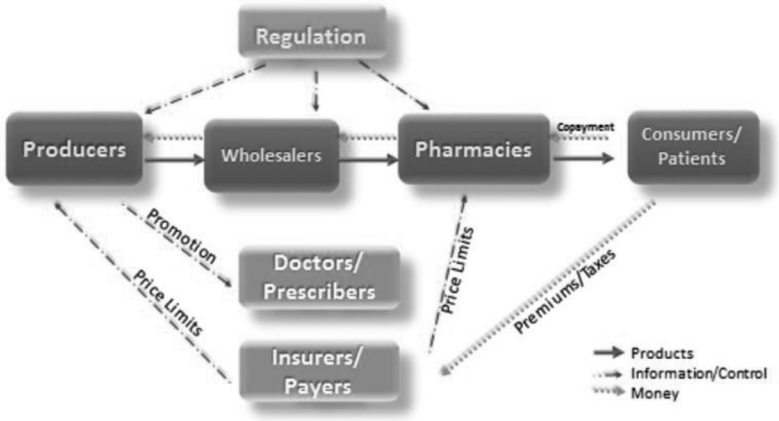

Figure 1.2 Pharmaceutical Value Chain: Flow of Goods, Information and Money (in the US and the EU)[15]

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[14] This figure borrows from the description of the structure of the Indian pharmaceuticals industry by Shamim S. Mondal and Vishwanath Pingali, *Competition Law and the Pharmaceutical Sector in India, W.P. No. 2015-11-02* (November 2015), Indian Institute of Management Ahmedabad, India, Research and Publications, pp. 18-21. CFA refers to the Carrying (or Clearing) and Forward Agents. CFAs play an important role in the value chain on account of the tax structure in India and how taxation is divided between the State and the Center. With the coming of General Sales Tax (GST) in force, it is possible that CFA may play a less significant role in the future.

[15] Source: Patricia M. Danzon, Competition and Antitrust Issues in the Pharmaceutical Industry (Final Report July 2014) The Wharton School, University of Pennsylvania, p. 5.

Indian pharma industry is characterised by two kinds of players: First, the multinationals who largely play on their well-recognized brand name and innovative products. They control over 30% of the market (figure 2.3). Secondly, it is the domestic pharma that controls about 70% of the market and comprises amongst others, the following lead players: Sun, Lupin, Cipla, Dr Reddy's etc.[16] Branded generics control about 80% of the market (revenue-wise) (figure 2.1). [17] Not only in India, but at a global level as well, the Indian pharma industry has established itself as the largest provider of generic drugs, contributing annually over 3.6 per cent (in terms of value) and over 10% (in terms of volume) of the market.[18]

Indian pharma exports to over 200 countries across the world, with US as the key market - for the year 2016-2017: 40.6% of exports were to the American continent; 19.7% to Europe, 19.1% to Africa and 18.8% to Asia.[19] In the US generics market too, Indian pharma sector is a major player, where it controls over 30% of the market (in terms of volume) and 10% of the US$ 70-80 billion market in terms of value.[20] The US generics market is better represented through figure 2.2, considering price and not branding is the key driver of competition. Today, over 88% of the prescriptions in the US are for generics, as compared to only 19% in 1984.[21] This is a very interesting observation, somewhat contrary to what one may otherwise anticipate - that even in a developed economy like the US, generics play such a key role.

Even though generics play an important role in both India and the US, it is interesting to observe that there is one key difference between the two countries. Indian market is very special as branded generics play a key role in this generics-driven market. Firms sell drugs that have the same molecular composition but different brand names. Leaving consumer perception and brand differentiation aside, these different brands have the same chemical

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[16] Sanchit Srivastava and Shubhashish Chaudhri, A Bitter Pill to Swallow – Analyzing Anti-trust Concerns in the Indian Pharmaceutical Sector, pp. 32-33.
[17] India Brand Equity Foundation, Report on Indian Pharmaceutical Industry, prepared by Aranca, <https://www.ibef.org/industry/pharmaceutical-india.aspx> accessed 23 Nov 2018.
[18] *Ibid.*
[19] *Ibid.*
[20] *Ibid.*, p. 15.
[21] Joanna Shepherd, Consolidation and Innovation in the Pharmaceuticals Industry: Role of Innovation in the Current Innovation Ecosystem, 20 *Journal of Healthcare Law and Policy* (2017), p. 5.

properties and therapeutic effects as they are based on the same molecule and therefore, can be considered as substitutes for one another. The All India Organization for Chemists and Druggists (AIOCD) accordingly classifies the pharmaceutical products on the basis of the therapeutic area, super, group and at the molecular level. In the US, however, the generics competition is completely price-driven and in that respect the battle for prices is a race to the bottom. Thus, using branding and influencing customer perception, the generics in India have tried to differentiate and distinctly position their brands (figure 2.1), based on the fundamental 4Ps of Marketing[22] – product, price, place and promotion. Unlike in the developed world, following patent expiration where there is 'no protection against the switch to generics'[23], in the Indian generics-led pharma sector – branding is a key strategy to differentiate from other drugs that are essentially based on the same molecular formulation. In addition, it may be useful to add that branding in the pharma sector, may take place at two levels – at the product level or the company level.

In India, branding at both these levels may be observed – at the product-level, prominent examples include 'Digene', a commonly used anta-acid for indigestion, stomach upset and heartburn and at the company-level, 'Himalaya' is a well-recognised brand name that offers Ayurvedic[24] products created from years of R&D efforts. At the company level, prior to the FDA investigation and the acquisition of Ranbaxy by Sun, Ranbaxy, India's oldest generic company, was the most well-recognized and respected pharma brand in the country.[25] Roche and Novartis are some prominent examples that have established themselves as company-level brand names in specific therapeutic

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[22] Philip Kotler and Gary Armstrong, *Principles of Marketing* (Prentice Hall, 8th ed, 1999) at p. 44.

[23] Janice MacLennan, *Brand Planning for the Pharmaceutical Industry* (Gower Publishing, 1st ed, 2004), p. 3.

[24] Ayurveda is an old traditional system of Indian medication. Unlike the present-day pharmaceuticals industry where drug approvals are based on clinical trials and regulatory approvals, 'Ayurveda' is based on the principles mentioned in *Sushruta Samhita* that were taught by *Bhagwan Dhanvantari,* the Hindu god of Ayurveda to a group of physicians, including Sushruta, the author of *Sushruta Samhita.* See generally WHO Traditional Medicine Strategy 2014-2023; Ayurveda, Oxford University Press; Michael Alexander Populorum, Trends und Bechäftigungsfelder im Gesundheits- und Wellness-Tourismus: Berufsentwicklung, Kompetenzprofile und Qualifizierungsbedarf in wellness-bezogenen Freizeit- und Gesundheitsberufen, *LIT Verlag Münster* (2008).

[25] Arpita Mehrotra and Arun Aditya Sahay, Sun Pharma acquires Ranbaxy: The Postmerger Blues, *Conference Paper* (December 2016) <https://www.researchgate.net/publication/311544172> p. 11.

areas (figure 2.3). In addition to sales & marketing, concentrated R&D efforts and M&A have been strategically employed to concentrate on specific therapeutic areas. Table 1 (below) highlights the price premium paid (in the Indian currency Rupees, ₹) by an average Indian consumer for purchasing generic and its branded equivalent.

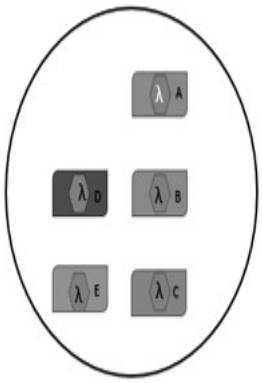

Figure 2.1 Relevant Product Market for **Branded Generics** (with same molecular formulation)

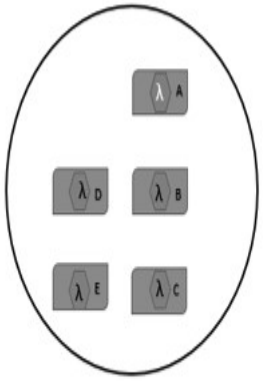

Figure 2.2 Relevant Product Market for **Generics** (with same molecular formulation)

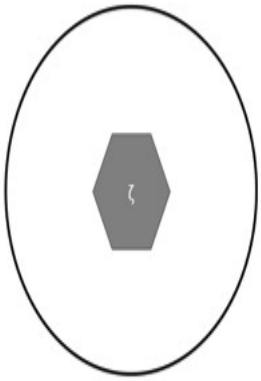

Figure 2.3 Relevant Product Market for **Originator**

(as on December, 2010)

Used as	Generic drug	Price	Branded Drug	Price
Painkiller	Paracetamol	Rs 2.45	Crocin	Rs 11.00
			Calpol	Rs 10.70
	Paracetamol syrup	Rs 9.00	Crocin (syrup)	Rs 15.00
			Febrex	Rs 20.50
	Diclofenac sodium + paracetamol	Rs 4.40	Diclogesic	Rs 19.40
Antibiotic	Amoxycilin	Rs 13.20	LMX	Rs 40.00
			Remox	Rs 38.70
	Azithromycin	Rs 41.80	Azee	Rs 107.00
			Azithral	Rs 128.55
Anti-TB	Ethambutol	Rs 14.80	Myambutol	Rs 15.30
Vitamins	Folic acid	Rs 2.80	Folivite	Rs 11.80
	B-complex	Rs 1.80	Becosul	Rs 11.00
Cardiovascular (Blood Pressure) drug	Atenolol	Rs 7.00	Aten	Rs 23.80

Table 1: Price Difference between Branded Generics and the Generic Drug in India[26]

[26] Department Related Parliamentary Standing Committee on Commerce, One Hundred and Tenth Report on FDI in Pharmaceutical Sector, *Parliament of India Rajya Sabha* (August 2013), p. 3.

3. Competition and Innovation

Market for generics is volume-driven as distinguished from new molecular entities (NMEs) that are value driven. The different competitive dynamics are on account of different cost structures for originators and generics. Whereas it costs an average $2.6 billion to successfully launch an NME, following patent expiry, launch of a generic's equivalent costs only $1 to 2 million.[27] In addition, there is an average time lag from discovery to successful launch of an NME.[28] Comparative time lag for generics is much shorter, on average between one to three years. Whereas the originators usually concentrate on product innovation – through introduction of innovative products or substantially improve the quality of existing products; generics focus on cost-reducing innovation.[29]

Indian pharma industry's focus on cost-reducing innovation in that respect is a direct result of the policy objective and the pre-2005 Patents Act that allowed only process patents. One of the key reasons to offer patent protection is that the innovators successfully introduce their innovation and following patent expiry the results of the innovation are available at affordable rates. Viewed from that perspective, dynamic competition too in the long rung promotes price and quantity-led competition.[30] Competition amongst generics ensures that benefits of the innovation, once they are off-patent or reverse-engineered (as was the case with the erstwhile patent regime), are effectively delivered to the end consumer at affordable rates. In the context of merger control, preserving a certain number of competitors, therefore, plays a key role in promoting price-led and quantity-led competition. Manufacturers that are in advanced stage of developing a generic equivalent and have received the relevant regulatory approval are actual potential competitors, as distinguished from perceived potential competitors. In case of mergers between generics, both the Indian CCI and the US FTC have attached great

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[27] These are the average prices for the US. In India, considering the less onerous regulatory approval, launch of a generic cost a fraction of the value in the US. Figures taken from Joanna Shepherd, Consolidation and Innovation in the Pharmaceuticals Industry: Role of Innovation in the Current Innovation Ecosystem, 20 *Journal of Healthcare Law and Policy* (2017) p. 5.
[28] Patricia M. Danzon, Competition and Antitrust Issues in the Pharmaceutical Industry (Final Report July 2014) *The Wharton School, University of Pennsylvania*, p. 4.
[29] Giulio Federico, Gregor Langus and Tommaso Valletti, Horizontal Mergers and Product Innovation (February 18), *European Commission*, p. 2.
[30] Payal Malik, Competition Law in India: Developing Efficient Markets for Greater Good, *Vikalpa* 42(2) (April-June 2016), pp. 175- 181.

value to these actual potential competitors and cleared mergers following submission of remedies that ensured successful entry of these players who enjoyed an 'entry advantage' over the other players in the industry.[31]

4. Pharma mergers

In merger control, the first question that competition authorities need ask themselves is the reason that makes the two companies take a decision to come together. Just as it is important for businesses to understand the principles of competition law and policy to make better strategic decisions; an understanding of the rationale for particular business decisions by the business community better equips the competition authorities to take decisions that foster competition in innovation. In case of a merger, relevant questions touching upon the strategy of an enterprise include - are there potential efficiencies that can in turn lower the costs and hence, increase static and dynamic efficiencies or do the parties compete closely in a given competition space (localized competition space) and thus, the merger will lessen the competitive constraint in the relevant market. Based on this proposed approach, in this section we first discuss the strategic rationale for the merger between Sun Pharma and Ranbaxy (section 4.1), followed by a discussion on CCI's (section 4.2) and FTC's (section 4.3) assessment of the relevant markets and the theories of harm.

4.1 Strategic Rationale for Sun Pharma/Ranbaxy Merger

2014/2015 was a peak year for M&A activity in the pharma industry – both for the big pharma as well as for the generic manufacturers.[32] Patent cliff and a weak R&D product pipeline prompted the big pharma to consolidate and seek alternative avenues of growth.[33] The generics market – both in the US and in India, is highly competitive with many significant market players. In the US, there are over 100 generic players that constantly fight for the market share in the world's largest pharma market, that accounts for half of global

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[31] Joseph F. Brodley, Potential Competition Mergers: A Structural Synthesis, *87 Yale Law Journal 1* (1977), pp. 11-12; Joseph F. Brodley, Potential Competition Doctrine, *71 California Law Review 2* (1983), pp. 372, 378.

[32] Marc-André Gagnon and Karena D. Volesky, *Globalization and Health (2017) 13: 62* <https://globalizationandhealth.biomedcentral.com/articles/10.1186/s12992-017-0285-x> accessed 23 Nov 2018.

[33] Patricia Danzon, Mergers and Acquisitions in the Pharmaceutical and Biotech Industries, *28 Managerial and Decision Economics*.

sales.[34] In the US, between 2017 and 2019 alone, drugs worth US$ 55 billion are expected to go off patent.[35] Despite these opportunities, the US generics market remains highly competitive, as the manufacturers have to negotiate prices with the wholesalers, retailers and insurers. Substantial bargaining power of these three groups implies that there is an overall downward pressure on the prices of the generics. This has in turn led to significant consolidation in the US generics market and it is expected that from some 100+ generics today, there may finally emerge 10-20 generics companies by 2020.[36]

In addition to this strategic rationale, other commonly identified reasons why generic firms engage in M&A include: 1. substantial economies of scale on account of administrative and capital cost savings; 2. patent cliff in the pharma sector - this offers generics increased opportunities to enter new product markets; 3. vertical integration as a strategy to buy parts of the supply chain and 4. the emergence of biosimilars.[37] In addition, M&As have also been used to 'corner niche segments' in the generics market and substantially increase prices of certain drugs.[38] Examples include, substantial price increase in the market for generics like dextroamphetamine used for treatment of attention deficit disorder and nitroprusside used for treatment of high blood pressure in the US.[39] In India, following Piramal Healthcare's acquisition by Abbott Laboratories, the prices of Gardenal 60 mg tablets[40] increased from ₹

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[34] Robert Wessman, CEO and founder Alvogen, Alvogen Founder: Generic Drug Prices will Drive Consolidation, (Online, 7 December 2017) *World Finance* <https://www.worldfinance.com/videos/alvogen-founder-generic-drug-price-wars-will-drive-consolidation> accessed 23 Nov 2018.

[35] India Brand Equity Foundation, Report on Indian Pharmaceutical Industry, prepared by Aranca <https://www.ibef.org/industry/pharmaceutical-india.aspx> accessed 7 May 2018.

[36] Robert Wessman, CEO and founder Alvogen, Alvogen Founder: Generic Drug Prices will Drive Consolidation, (Online 7 December 2017) *World Finance* <https://www.worldfinance.com/videos/alvogen-founder-generic-drug-price-wars-will-drive-consolidation> accessed 7 May 2018; Jennifer Barrett, Generic Drug Companies Seek Consolidation Amid Pricing Pressures, *Pharmacy Times* (Online, 19 January 2017) <http://www.pharmacytimes.com/publications/issue/2017/january2017/generic-drug-companies-seek-consolidation-amid-pricing-pressures> accessed 23 Nov 2018.
Marc-André Gagnon and Karena D. Volesky, *Globalization and Health (2017) 13: 62* <https://globalizationandhealth.biomedcentral.com/articles/10.1186/s12992-017-0285-x> accessed 23 Nov 2018.

[38] *Ibid.*

[39] *Ibid.*; JA Greene, G Anderson and JM Sharstein, *Role of the FDA in affordability of off patent pharmaceuticals*; JD Alpern, WM Stauffer and AS Kesselheim, High Cost Generic Drugs: Implications for Patients and Policymakers (2014)

[40] Gardenal 60 mg is used for the treatment of Epilepsy.

16 in May 2009 to about ₹ 35.36 in May 2011, indicating a post-merger 121% increase in prices. Likewise, the Haemaccel Injection 300 ml increased from ₹ 99.02 to ₹ 215 that is a 117% price increase during the same time period.[41]

Indian generics supply over 40% of the generics and over the counter medicines in the US. Even at the time the US Food and Drug Administration (FDA) banned imports from Ranbaxy's four production facilities in India[42] on account of the company's failure to meet the current Good Manufacturing Practice (cGMP) requirements, Ranbaxy sold generics worth US $ 1 billion in that year alone in the US.[43]

In 2014, Sun Pharma purchased Ranbaxy from its parent company Japan's Daiichi Sankyo for $4 billion, making it India's top and world's top 10 pharma M&A deal for the year 2014.[44] Sun's decision to buy Ranbaxy from its owners Daiichi Sankyo was considered a major surprise by many industry analysts. With this deal, Sun expected to get a foothold in the Japanese market. Second, considering Ranbaxy's brand equity in the Indian market and its strong foothold in the US market, where it owned a very large portfolio of ANDAs and first-to-file opportunities were identified as important sources of shareholder value creation by Dilip Shanghvi, the founder and Chief Executive Officer (CEO) of Sun.

The merger also offered Sun Pharma, a more global footprint - additional operations in 65 countries, 47 manufacturing facilities across 5 continents - including access to emerging markets like Russia, Romania, Brazil, Malaysia and South Africa on one hand, and the ownership of Ranbaxy B.V.,

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[41] Latha Jishnu, Curing the ills of Pharma FDI (Online 15 August 2012) *Down to Earth* <http://www.downtoearth.org.in/news/curing-the-ills-of-pharma-fdi-38787> accessed 23 Nov 2018.

[42] These included Ranbaxy's plants at Toansa, Paonta Sahib, Dewas and Mohali in India.

[43] Jennifer Thompson and Andrew Ward, Ranbaxy shares sink on US FDA product ban, *Financial Times* (Online 24 January 2014) <https://www.ft.com/content/bb89aa0e-84c5-11e3-a793-00144feab7de> accessed 7 May 2018; U.S. Food & Drug Administration, Questions and Answers on Drugs Manufactured at the Dewas and Paonta Sahib Facilities of Ranbaxy Laboratories Ltd. <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/ucm118442.htm> accessed 23 Nov 2018.

[44] EJ Lane, Ranbaxy-Sun U.S. approval hinges on selling antibacterial drug as FTC notes reach of Indian generic unit *Fierce Pharma* (Online 2015) < https://www.fiercepharma.com/sales-and-marketing/ranbaxy-sun-u-s-approval-hinges-on-selling-antibacterial-drug-as-ftc-notes> accessed 23 Nov 2018.

Netherlands, the Dutch subsidiary of Ranbaxy on the other.[45] Moreover, the merger was an all-stock deal, wherein the Ranbaxy shareholders received eight shares of Sun pharma for every 10 shares of Ranbaxy that they held.[46] Daiichi also indemnified Sun of any further FDA investigation relating to the above mentioned sites. Ranbaxy had earlier settled for US$500 million the FDA investigation on these sites. Overall, this implied that Daiichi continued to share the risks (or benefits) of a successful post-merger integration. Sun Pharma/ Ranbaxy was reviewed and conditionally cleared by both the Indian CCI and the US FTC as we discuss next.

4.2 Competition Commission of India on Sun Pharma/Ranbaxy

In Sun Pharma/ Ranbaxy**, t**he CCI defined the relevant product market at the molecular level that is medicines/ formulations that were based on the same API were identified as distinct relevant product markets.[47] The CCI assessed forty-nine relevant markets for generics and two relevant markets for formulations.[48] Out of these forty-nine markets, the CCI did not identify any competition concerns in 38 relevant markets (78% of the relevant product markets studied by the CCI) and another four molecules (8% of the relevant product market studied) were covered in the National List of Essential Medicines (NLEM) and were thus, subject to price control by the NPPA.[49] Competition concerns were identified in the remaining seven that is 14% of the markets studied (Graph 1).

It may be useful to highlight the important reasons that led to CCI's assessment that 38 markets (that is over 78% of the markets) did not lead to any competition concerns. In many of these markets, even though the merged entity's market shares were between 40-55%, presence of three, four and in

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[45] Arpita Mehrotra and Arun Aditya Sahay, Sun Pharma acquires Ranbaxy: The Postmerger Blues, *Conference Paper* (December 2016) <https://www.researchgate.net/publication/311544172> pp. 7, 9; Jyoti Kumari, Role of CCI in Merger Control in Indian Pharma Industry, <https://indianbarassociation.org/wp-content/uploads/2013/02/Role-of-CCI-in-merger-control-in-india-pharma-industry.pdf > accessed 23 Nov 2018, pp. 1-2.

[46] Knowledge Wharton, India's Sun Pharma Takes over a beleaguered Ranbaxy Labs (11 April 2014) *Wharton Business* <http://knowledge.wharton.upenn.edu/article/indias-sun-pharma-takes-beleaguered-ranbaxy-labs/> accessed 23 Nov 2018.

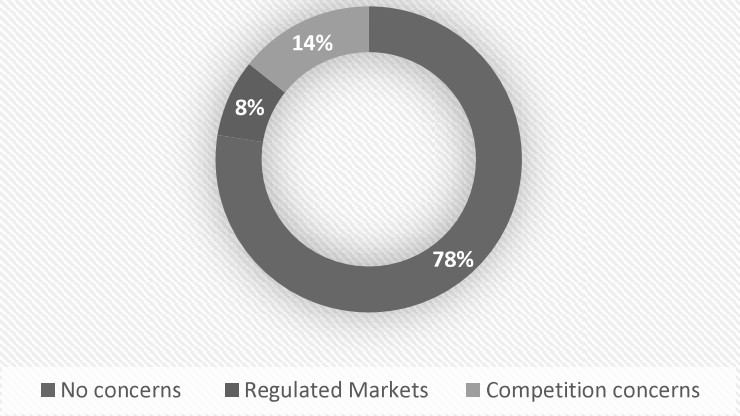
[47] Combination Registration No. C-2014/05/170 *Sun Pharmaceuticals Industries Limited/ Ranbaxy Laboratories Limited*, Order under Section 31(7) of the Competition Act, 2002, paras 13-15.

[48] *Ibid.*, paras 19-20.

[49] *Ibid.*, paras 23-24.

some cases even five other significant players, meant that these other generics' manufacturers would continue to exercise an important competitive constraint on the merged entity. Moreover, in none of these markets - either Sun Pharma or Ranbaxy was a lead player.[50]

Graph 1. CCI's assessment of Relevant Markets in Sun Pharma/ Ranbaxy



The Commission also assessed the impact of the merger on potential competition. Ranbaxy at the time had two pipeline products with the formulation Sitagliptin, classified under the therapeutic category 'Oral Anti-diabetics'. Sun pharma already sold formulations containing Sitagliptin under the brand name 'Istavel' and 'Istamet' that it licensed from the patent owner MSD. Apart from these two, Glenmark was the only other active player in this product market. The Commission assessed the impact of the merger on the incentives of Ranbaxy to launch the pipeline product.[51] The patent was licensed by MSD was under judicial review, the CCI expected that in case the courts found that the patent was invalid, there may be significant market entry by other players to launch a generic version of the molecule.[52]

The Commission's decision though lamentably did not discuss the counter-factual that is what would happen in case the patent was found valid and the courts allowed MSD's request for injunction against the infringing parties. In such a scenario, Glenmark and the merged entity would have been left as the only two active manufacturers in the relevant product market. This in turn

[50] *Ibid.*, para 24.
[51] *Ibid.*, paras 25.
[52] *Ibid.*, paras 26.

might have led to identification of competition concerns in this market as well and possibly, it would have also required a remedy to alleviate the resulting anti-competitive effects.

Merger was likely to result in appreciable adverse effect on competition (AAEC) in the seven relevant product markets identified in Table 2. As discussed in section 2 above, the competition in generics in India is based on different brands available for the same molecule. The CCI accordingly identified the brands offered by Sun Pharma and Ranbaxy for each one of these molecules.

S. No	Relevant Market	Brand owned/ in-licensed/ distributed by Sun Pharma	Brand owned/ in-licensed/ distributed by Ranbaxy
1	Tamsulosin + Tolterodine	Tamlet	Roliflo
2	Rosuvastatin + Ezetimibe	Razavel EZ	Rosuvas EZ
3	Leuprorelin	Lupride	Eligard
4	Terlipressin	Terlyz	Terlibax
5	Olanzapine + Fluoxetine	Oleanz Plus	Olanex F
6	Levosulpiride + Esomeprazole	Sompraz L	Raciper L
7	Olmersartan + Amlodipine + Hydroclorthiazide	Triolmezest	Triolvance

Table 2: Relevant Markets with competition concerns and brand names[53]

4.3 FTC on Sun Pharma/ Ranbaxy

In the US, the FTC was of the opinion that the merger would violate section 7 of the Clayton Act and section 5 of the FTC Act as the merger led to increase in concentration in the relevant market for "development, license, manufacture, marketing, distribution, and sale of generic minocycline

[53] CCI decision in Sun Pharma/ Ranbaxy, p. 29.

hydrochloride 50 mg, 75 mg, and 100 mg tablets" (minocycline tablets[54]) in the United States.[55] In the US, at the time of the merger, there were only three manufacturers of minocycline – Ranbaxy, Dr Reddy's Laboratories and Par Pharmaceuticals.[56] Sun was one of the potential competitors as it had a product under development and an ANDA application under review.[57] Considering that entry in the generics market, was subject to the development of a bioequivalent drug and ANDA approval by the FDA, the FTC was of the opinion, that entry with the meaning of paragraph 6 and 7 of the US Horizontal Merger Guidelines 2010 was unlikely to be 'timely, likely or sufficient' to counteract the anti-competitive effects of the transactions. The merger thus, led to 'elimination of future competition'.[58]

5. Design of remedies

5.1 CCI in Sun/Ranbaxy Merger

To alleviate the likely AAEC, the CCI proposed to the parties, divestment of the brands highlighted in yellow in Table 3 below.[59]

S. No	Relevant Market	Brand owned/ in-licensed/ distributed by Sun Pharma	Brand owned/ in-licensed/ distributed by Ranbaxy
1	Tamsulosin + Tolterodine	Tamlet	Roliflo
2	Rosuvastatin + Ezetimibe	Razavel EZ	Rosuvas EZ
3	Leuprorelin	Lupride	Eligard
4	Terlipressin	Terlyz	Terlibax
5	Olanzapine + Fluoxetine	Oleanz Plus	Olanex F

[54] Minocycline tablets are used for the treatment of bacterial infection, including pneumonia, respiratory, genital and urinary tract infections, acne and other skin infections.
[55] In the Matter of Sun Pharmaceuticals, Ranbaxy Laboratories and Daiichi Sankyo Ltd., Complaint, Docket No. C-4506, pp. 1-3.
[56] *Ibid.*, p. 3.
[57] *Ibid.*
[58] *Ibid.*
[59] Combination Registration No. C-2014/05/170 *Sun Pharmaceuticals Industries Limited/ Ranbaxy Laboratories Limited*, Order under Section 31(7) of the Competition Act, 2002, paras 32-33.

6	Levosulpiride + Esomeprazole	Sompraz L	Raciper L
7	Olmersartan + Amlodipine + Hydroclorthiazide	Triolmezest	Triolvance

In response to CCI's proposed divestiture, the parties requested that as regards the relevant market for Leuprorelin, the Commission may instead consider the divestiture of Ranbaxy's Eligard instead of Sun Pharma's Lupride.[60] This was accepted by the CCI as this divestiture was relatively easier as well as effective to eliminate the likely AAEC considering that Ranbaxy had only distribution rights from another pharma market as regards Eligard.[61] In addition, in case the parties failed to divest the distribution rights within the first divestiture period, they offered to divest Sun Pharma's Lupride brand.[62] (*see* Table 4 below)

S. No	Relevant Market	Brand owned/ in-licensed/ distributed by Sun Pharma	Brand owned/ in-licensed/ distributed by Ranbaxy
1	Tamsulosin + Tolterodine	Tamlet	Roliflo
2	Rosuvastatin + Ezetimibe	Razavel EZ	Rosuvas EZ
3	Leuprorelin	Lupride	Eligard
4	Terlipressin	Terlyz	Terlibax
5	Olanzapine + Fluoxetine	Oleanz Plus	Olanex F
6	Levosulpiride + Esomeprazole	Sompraz L	Raciper L
7	Olmersartan + Amlodipine + Hydroclorthiazide	Triolmezest	Triolvance

Table 4: Divestiture commitments by Sun Pharma/ Ranbaxy
(the parties proposed the divestiture of brands highlighted in yellow this table. Brand Lupride highlighted in green was a proposed crown jewel divestment.)

[60] *Ibid.*, para 34.
[61] *Ibid.*, para 35.
[62] *Ibid.*, para 35.

The divestiture was to be executed as an asset sale transaction and completed within the first divestiture period that was six months following the Commission's approval.[63] To ensure the "economic viability, marketability and competitiveness of the Divestment Products"[64], the parties were required to use their best efforts to preserve the viability of the business. This included appointment of a senior management level employee (a Hold Separate Manager) who was to work in close relationship and report on a periodic basis to the Monitoring Agency.[65] The parties were expected to offer sufficient information to the potential purchaser to help them undertake reasonable due diligence as regards the divested products.[66] The final sale and purchase agreement (SPA) and the purchaser were both subject to the approval of the CCI.[67]

Purchaser was expected to be independent of the Parties; have "financial resources, proven expertise, manufacturing capability or ability to outsource manufacturing and incentives to maintain and develop" the product; active in the sales and marketing of pharma products in India; able to obtain the required regulatory approvals from relevant regulatory authorities and not create any additional competition concerns.[68] The parties were to appoint a Monitoring Agency that would oversee the on-going management of the Divestment Business, review and assess potential purchasers and submit to the Commission on a periodic basis a written report about the operation and management and the progress of sale of the Divestment business.[69] This was expected to help the Agency effectively perform the responsibilities delegated to it by the CCI under the Agency Mandate. In case the Parties failed to divest the proposed assets within a period of six months, the Commission was to appoint a Divestiture Agency to effect the sale of Alternate Divestment Product during the second divestiture period (a period of four months) at no minimum price to a Commission approved purchaser.[70] Though 'not' specifically mentioned in the CCI's decision, the latter provision may be seen as the equivalent of a crown jewel provision. A crown jewel provision is an

[63] *Ibid.*, para 44.
[64] *Ibid.*, para 48.
[65] *Ibid.*, paras 49-51.
[66] *Ibid.*, para 52.
[67] *Ibid.*, paras 55-56.
[68] *Ibid.*, para 55.
[69] *Ibid.*, para 63.
[70] *Ibid.*, paras 69-72.

alternative divestiture proposal that the merging parties offer to divest in case they fail to divest the initially identified assets within the first divestiture period.[71]

5.2 FTC in Sun Pharma/Ranbaxy

To alleviate FTC's competition concerns in Sun Pharma/Ranbaxy, the parties offered to divest within ten days of consummation of the acquisition, all the Minocycline product assets and licenses (that included ANDA applications) to Torrent Pharma.[72] If for some unforeseen reason this divestiture was not approved by the FTC, the parties offered to divest 'in good faith and at no minimum price' to a Commission approved-buyer all the Minocycline product assets and licenses within 180 days of the merger.[73] To protect the confidentiality of the Business Information, the employees that have had responsibilities relating to the Monocycline Products, were to enter into a 'confidentiality agreement' that required continued confidentiality and non-disclosure of the business information to the personnel of the merged entity.[74] In addition, the merged entity undertook an 'Employee Non-Solicitation Clause' according to which Minocycline core product employees that were to be retained or hired by the Acquirer of the Divested Business could not be solicited by the merged entity. The employees were however, not subject to any conditions and thus, they could apply to the merged entity for employment.[75]

The merged entity also offered to undertake all reasonable efforts to 'preserve the marketability, viability and competitiveness of the Minocycline Products'.[76] Unlike, the CCI decision, however, the FTC did not appoint a monitoring trustee. Instead, the FTC reserved the right to appoint a monitor (Interim Monitor), whose selection was subject to the 'consent of Respondents'.[77] In addition, another noteworthy difference between the CCI's and the FTC's decision was that the latter also insulated the Acquirer from

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[71] Federal Trade Commission, Frequently Asked Questions about Merger Consent Order Provisions, 24, 25 <https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/mergers/merger-faq> accessed 23 Nov 2018.
[72] In the Matter of Sun Pharmaceuticals, Ranbaxy Laboratories and Daiichi Sankyo Ltd., Decision and Order, Docket No. C-4506, p. 19.
[73] *Ibid*.
[74] *Ibid.*, pp. 23-24.
[75] *Ibid.*, pp. 24-25.
[76] *Ibid.*, p. 25.
[77] *Ibid.*, p.28.

patent-related disputes as regards the acquired products that could adversely impact the R&D efforts or sale, import, export or distribution of Minocycline Products in the US.[78]

6. Other Pharma mergers

This section discusses Orchid/Hospira, Mylan/Agila and Torrent/Elder – three conditional clearance decisions of the CCI subject to non-structural remedies. Orchid/Hospira, was a merger between Orchid Chemicals and Pharmaceuticals Limited (OCPL) and Hospira Healthcare India Private Limited (HHIPL), a 100% subsidiary of Hospira Inc, USA. It was a case of vertical transaction, as the OCPL's business transferred comprising of its Betalactum (Penems including Carbapenems and Penicillins) API business and associated R&D facilities was an important input for HHIPL's injectable formulations.[79] The business under consideration were largely concentrated on exports with negligible presence in the domestic markets. To receive the CCI's clearance, the parties offered the following commitments – first, the non-compete clause in the business transfer agreement (BTA) as regards the Indian domestic market was reduced to four years and second, the BTA was amended to allow R&D in new Penem (including Carbapenem) and Penicilin APIs for injectable formulations.

In Mylan/ Agila, Mylan, a generics company incorporated in Pennsylvania, USA acquired Agila, a wholly owned subsidiary (WOS) of Strides Acrolab Ltd.[80] Both the target enterprise and the acquirer had limited domestic presence in India.[81] The Commission was concerned with the Restrictive Covenant Agreement (RCA) that prohibited the promoters of acquired company from engaging in or economically investing in injectable, parenteral, ophthalmic or oncology pharma products at any level along the value chain, anywhere in the world. To receive CCI's conditional approval, the parties offered the following commitments – first, limiting the duration of the NCAs as regards Indian market to only four years; second, restricting the scope of NCAs to only the products manufactured or pipeline products and

[78] *Ibid.*, pp. 26-27.
[79] Competition Commission of India, Orchid/Hospira, dt. 21 December 2012, paras 1,5,8.
[80] Combination Registration No. C-2013/04/116 dt 20 June 2013, paras 1-10.
[81] *Ibid.*, para 14.

third, allowing the promoters of Agila to engage in R&D for developing new injectable formulations that were at the time non-existent.[82]

In Torrent/Elder, Torrent acquired Elder's certain branded domestic formulations business in India and Nepal.[83] In addition, the parties also entered into a Manufacturing and Supply Agreement (MSA) according to which Elder offered to manufacture for a period of three years certain products exclusively for Torrent.[84] Parties' rationale for the transaction was that it allowed Torrent to strengthen and expand its product portfolio in its core therapeutic areas, as well as enter into new therapeutic categories.[85] The merger led to horizontal overlap in over sixteen therapeutic categories, out of which the combined market share of the parties exceeded 10 per cent in the following four product markets – Calcium + Vitamin D3; Calcium + Calcitriol; Platelet Aggregation Inhibitors and Combination of Two Diuretics.[86]

However, the concentration did not lead to any AAEC on account of horizontal concerns – first, as the merger specific increase in concentration was only nominal – meaning that increase in market share was on account of only one of the parties' market share, wherein the other had an insignificant contribution and second, price of the medicines under consideration were subject to the regulation of NPPA.[87] Competition concerns were identified on account of 'non-compete agreement' (NCA) between the parties.[88] To alleviate CCI's competition concerns, the parties deleted over 11 therapeutic areas in the Promoter NCA and the Semit NCA; created a 'carve-out' of 36 existing products of Elder from the scope of NCAs – this allowed Elder to continue manufacturing, market, distribute and sell these products. Second, the acquirer reduced the duration of NCAs for Primary Therapeutic Areas from five to four years in the Promoter NCA and Semit NCA. Finally, certain provisions of the Promoter NCA and Semit NCA that were likely to adversely impact competition were deleted.[89]

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[82] *Ibid.*, para 21.
[83] Torrent/Elder, C-2014/01/148, para 6.
[84] *Ibid.*
[85] *Ibid.*, para 7.
[86] *Ibid.*, paras 9-10.
[87] Torrent/Elder, C-2014/01/148, para 11-13.
[88] Torrent/Elder, C-2014/01/148, para 15-16.
[89] Torrent/Elder, C-2014/01/148, para 17.

6. Summary and Conclusions

Following opening of the Indian pharma sector to 100 % Foreign Direct Investment (FDIs) through automatic route starting 2011 on one hand, and worldwide a largely number of blockbusters going off-patent on the other, pharma has experienced significant consolidation in the last few years. (*See* Figure 3) In India, some important mergers amongst these were also subject to the review of the CCI.

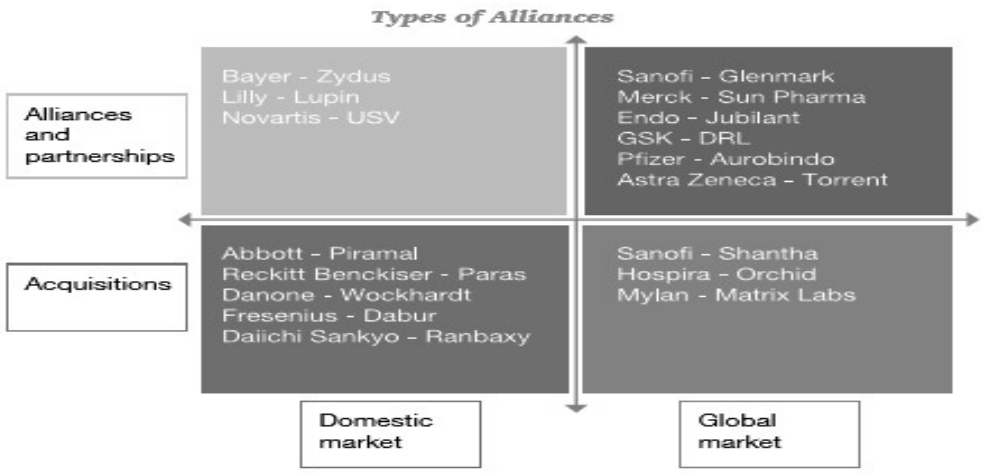

Figure 3 Alliances and Partnerships in the Indian Pharma[90]

It may be useful to observe here that even though Sun Pharma/ Ranbaxy is widely recognized as the first clearance decision that was subject to structural commitments; use of the expression 'carve-out' in the Torrent/Elder decision (*see* section 6) raises some doubt as to whether the latter may actually be the first structural clearance decision of the CCI.

The remedies in Sun Pharma/ Ranbaxy are well in line with internationally accepted practice of design of remedies in merger control. It may be useful to highlight some useful similarities and differences though. The 'principle of proportionality' is a very important principle in design of remedies. As the objective of merger control law is to preserve pre-merger conditions of competition - the merger control framework and remedies, if any, must respect this principle. In the EU, for instance, Recital 30 of the 2004 Merger

[90] Confederation of Indian Industry and Price Waterhouse Coopers, Indian Pharma Inc.: Enhancing value through Alliances and Partnerships, *Pharma Summit* (2011), p. 9.

Control Regulation states that the commitments proposed should be proportional to the competition concerns identified and must eliminate those concerns in entirety.[91] This self-limit on the exercise of discretion by the competition authority is a result of the 'principle of legitimate expectations'.[92] In Sun Pharma/ Ranbaxy, the CCI made it sufficiently clear that the objective of the modification to the proposed combination was to "maintain the existing level of competition in the relevant markets in India".[93]

On the issue of divergences, it may be useful to mention the following noteworthy aspects. First, the CCI clearly specified to the parties the nature of modifications and the assets that it expected them to divest.[94] The CCI was also open to subsequent changes by the Parties, taking into due account the nature of the business.[95] It is a well-established practice that the commitments are proposed by the parties, the competition authority can only accept or reject those commitments.[96] Whereas from a perusal of the CCI's decisions in Mylan/Agila, Orchid/Hospira and Torrent/Elder, it emerges that the parties proposed the remedies; Sun Pharma/ Ranbaxy indicates that it was the Commission that first suggested the remedies. Clarity as regards proposal, design and nature of remedies accepted by the CCI may be useful to remove this confusion. The CCI can for instance issue guidelines on merger remedies that can be an important guide for businesses seeking inorganic growth through M&As.

As regards the impact of the merger on innovation, it is only three years since Sun Pharma acquired Ranbaxy and in the pharma industry, with large sunk costs and substantial time periods in R&D, it may be a short time frame to assess with confidence the impact of the merger on dynamic competition. It may however be very useful to observe, that by the year 2017, Sun Pharma

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[91] Commission notice on remedies acceptable under Council Regulation (EC) No 139/2004 and under Commission Regulation (EC) No 802/2004 [2008] OJ C 267/01, recital 30.
[92] Ioannis Lianos, 'Competition Law Remedies in Europe Which Limits for Remedial Discretion?' (January 2013) CLES Research Paper Series no. 2/2013, p. 52 <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2235817> accessed 23 Nov 2018.
[93] Combination Registration No. C-2014/05/170 *Sun Pharmaceuticals Industries Limited/ Ranbaxy Laboratories Limited*, Order under Section 31(7) of the Competition Act, 2002, para 39.
[94] *Ibid.*, paras 32, 33.
[95] *Ibid.*, paras 34-36.
[96] Commission notice on remedies acceptable under Council Regulation(EC) No 139/2004 and under Commission Regulation(EC) No 802/2004 [2008] OJ C 267/01.

emerged as the highest spender on R&D in the Indian pharma sector.[97] Following the merger, Sun Pharma's globally dispersed and expanded R&D team offered it enhanced capabilities to concentrate on 'complex products across multiple dosage forms' and invest in speciality pipeline.[98] Post-merger, Sun enjoyed a 16% year on year (YoY) net profit in 2015 and 13% in 2016.[99] This growth was despite the fact that integration of Ranbaxy's 'product portfolio, manufacturing and supply chain' with Sun were identified as some of the key challenges by industry analysts.

From the financial year 2011 to FY 2017, Sun Pharma enjoyed a Compound Annual Growth Rate (CAGR) of 38.3% and invested over 7.6 per cent of its sales totalling US $ 361 million in R&D for the FY 2017 (Graph 2 *below*). It is true that this may be an insignificant amount when compared to the R&D investments by big pharma, but the investment and the annual increase in it, is nonetheless remarkable considering the focus of the generics sector. Moreover, considering there exists substantial cost differences between bringing a new molecular entity to market ($ 2.6 billion) as distinguished from launching a generic version of an off-patent drug ($ 1 to 2 million)[100], even limited R&D investments by the generics may under certain circumstances offer higher return on investment (ROI).

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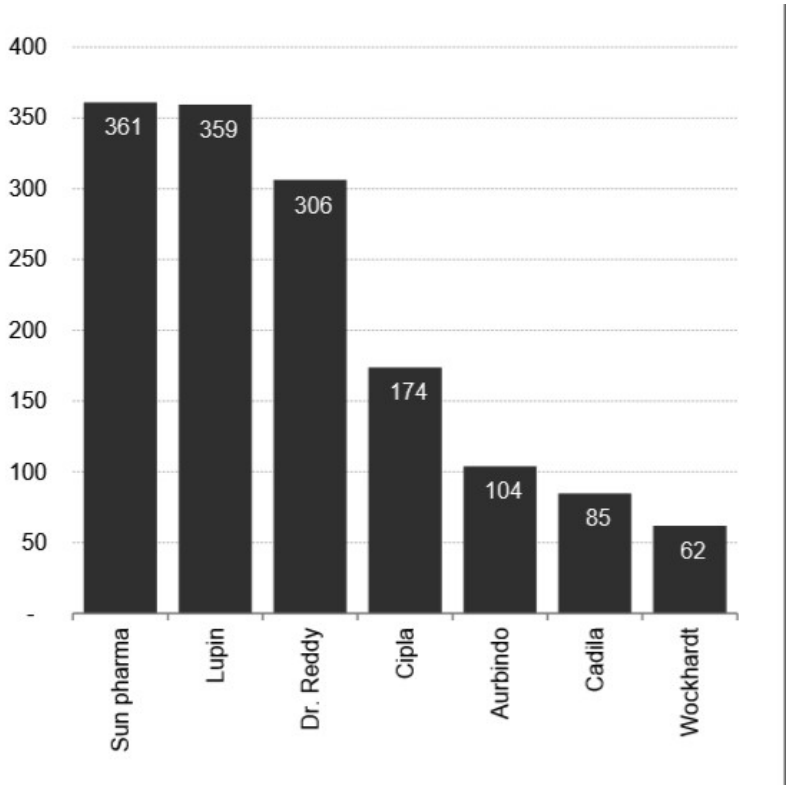
[97] India Brand Equity Foundation, Report on Indian Pharmaceutical Industry, prepared by Aranca, p. 16 <https://www.ibef.org/industry/pharmaceutical-india.aspx> accessed 23 Nov 2018.

[98] *Ibid.*

[99] Arpita Mehrotra and Arun Aditya Sahay, Sun Pharma acquires Ranbaxy: The Postmerger Blues, *Conference Paper* (December 2016) < https://www.researchgate.net/publication/311544172> pp. 10-11.

[100] Joanna Shepherd, Consolidation and Innovation in the Pharmaceuticals Industry: Role of Innovation in the Current Innovation Ecosystem, 20 *Journal of Healthcare Law and Policy* (2017) p. 6.



Graph 2 R&D Spending by top six Indian Pharma companies in FY 2017 (US $ million)

The impact of Sun Pharma/ Ranbaxy on innovation though stands in contrast to the impact of Piramal Healthcare/Abbott. In Piramal Healthcare/Abbott, the founders of Piramal Healthcare entered into a non-compete clause and offered not to manufacture and market generics in India or other emerging economies for a period of eight years following the transaction.[101] Piramal sold its generics-drugs unit to Abbott. One of the reasons for Abbott's acquisition of Primal was that the merger offered Abbott a foothold in the Indian generics market, where over 70% of the market is self-pay.[102] Following the merger, Piramal Healthcare received about $ 2.12 billion upfront plus $400 million for the next four years (total approximating about $ 3.72 billion in total), out of which it channelled over $277 million to restructure the debts of Piramal Life Science and the parent company proposed to invest further in R&D to concentrate on drug discovery and

[101] Peter Loftus and Rumman Ahmed, Abott Labs to buy Indian Business, *Wall Street Journal* (Online 26 May 2010) <https://www.wsj.com/articles/SB10001424052748704852004575257614197847830> accessed 23 Nov 2018.
[102] *Ibid*.

research.[103] It is over seven years since the merger happened, and Piramal does not appear in the list of top seven R&D spenders in the country. It may be useful to mention two factors that distinguish Piramal Healthcare/ Abbott from Sun pharma/ Ranbaxy – first, the merger led to the exit of an important market player in the Indian generics industry and second, the merger was not reviewed by the CCI. It is quite likely that like in the case of Sun Pharma/ Ranbaxy, Piramal/Abbott may have also received Commission's conditional approval only.

As regards the regulation of the Indian pharma industry, even though the NPPC has played a key role in regulating the prices, a better policy objective may be to ensure that the generics meet the 'bioequivalence standard'.[104] This will shoot two birds with one arrow. First, the commonly encountered challenge of consumer perception that Indian generics are usually of inferior quality.[105] Second, and related to the first, it will eliminate the rationale for brand-led competition in India.[106] This in turn will prompt a race to bottom for the prices, as is the case in the other mature markets like the EU and the US. Moreover, considering that the Indian market has some 1000+ players, a price-led market may emerge as one of the most competitive in the world. It is also possible that this in turn may promote dynamic competition. As branding will no longer be a differentiating factor, the Indian pharma, like the big pharma may be motivated to differentiate itself on the basis of R&D, new product launches and innovation capabilities.

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[103] *Ibid*.

[104] Patricia M. Danzon, Competition and Antitrust Issues in the Pharmaceutical Industry (Final Report July 2014) *The Wharton School, University of Pennsylvania*, p. 16.

[105] R Bate, GZ Jin, A Mathur and Attaran, Poor Quality Drugs and Global Trade: A Pilot Study. *National Bureau of Economic Research, Working Paper no.* 20469.

[106] Aditya Bhattacharjea and Fiyanshu Sindhwani, Competition Issues in the Indian Pharmaceuticals Sector, *Centre for Development Economics Delhi School of Economics Project Sponsored by CUTS-CIRC* (January 2014), pp 56, 81-83.