Abstract of the Essay

Merger Control is one of the three pillars of competition law next to prohibition of anti-competitive agreements and prohibition of abuse of dominance. Non-scrutiny of horizontal mergers may lead to unilateral anti-competitive effects on the market. Yet, the Competition Commission of India has rarely taken up detailed investigations into mergers, Ranbaxy-Sun Pharma being the first phase II investigation in India. The essay argues in favour of a stronger merger control regime with interest of the consumer included in the assessment of a combination. It presses for Merger remedy guidelines to be adopted by India for better control on M&A activity.

As far as the pharmaceutical sector is concerned, the inbound mergers have been taking place since the Indian government has allowed 100% Foreign Direct Investment (FDI). This essay also deals with the question that how far may the Competition Commission interfere with the dealings of the other authorities like Foreign Investment Promotion Board (FIPB) which regulate foreign investments in India. Also it presses upon the need to lower the merger thresholds in order to better regulate the pharmaceutical sector.
Introduction – Competition Issues in Pharmaceutical Industry

The pharmaceutical (pharma) sector is surely one of the very few sectors which has troubled almost all the competition regulatory authorities round the globe. Factors such as lower labour cost, resource availability and a large market bring this sector to the limelight of various international pharma giants all across the globe for venturing into business or investments in the Indian domestic market. The growth emergence of the market is also leading to the emergence of certain anti-practices in the market affecting other smaller companies and the public at large. Also, the interface of patents law and competition law has become increasingly important to the pharmaceutical sector affecting areas such as drug patenting, licensing and technology transfer or unilateral business decisions, e.g. on pricing, marketing or whom to supply. In practice the rules involve complicated assessments, e.g. of market power and market effects. Therefore, stake-holders may find the lines between the legal and the illegal practices and life cycle management activities precariously fine.¹ Practices preventing or delaying entry of generic rivals into the pharmaceuticals market, particularly the contents of patent settlement agreements, are currently under the scrutiny of the European Commission as generic-side competition is essential for a proper functioning of the market as well as consumer welfare.²

Mergers between pharmaceutical companies are of a particular concern for multinational companies with a strong market position. It is important to ensure that a new merger neither impedes generic competition, nor limits competition in research and development.³ Pharmaceutical corporations resort to inorganic growth in order to survive in the market. The obvious reasons to merge are to enhance productivity in the research and development

¹ Josef Drexl and Nari Lee, Pharmaceutical innovation, Competition and Patent Law 24 (Edward Elgar Publishing Ltd. 2013)
² In July 2009 the European Commission launched an inquiry into the pharmaceutical sector, the outcome of which is summarised in the European Commission Communication on the final report, available at: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html
³ Hanna Stakkheya, Competition Law v. patent settlement agreements
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activities, prevent exploitation of patents and to reduce stringent competition in the market from other generic drug makers. The increasing trend of consolidation in the pharmaceutical sector raises more competition concerns than any other industry due to its strong linkage with consumer welfare and the life of patients.\textsuperscript{4}

The past decade has witnessed some significant Mergers and Acquisitions (M&A) deals that changed the face of Indian pharma industry. Some of them were the acquisition of Matrix Lab by US-based Mylan Inc in August 2006, Japan’s Daiichi Sankyo acquired Ranbaxy Laboratories in June 2008, France-based Sanofi Aventis took over Shanta Biotech in July 2009 and last year, in May, US-based Abbot Laboratories acquired Piramal Healthcare.\textsuperscript{5}

According to research and statistics, India is in the top 10 pharma sales market in the world.\textsuperscript{6}

\textbf{Why do we need a strong merger control law?}

\textit{A merger leads to a “bad” outcome only if it creates a dominant enterprise that subsequently abuses its dominance.}\textsuperscript{7}

The author believes that a developing competition law jurisdiction like India should enact a powerful merger control law that looks in deeper than just the Appreciable Adverse Effect on Competition (AAEC). A merger activity may harm competition by creating or enhancing the merged firm’s ability or incentives to exercise market power either unilaterally or through coordination with rivals resulting in price increases above competitive levels for a significant period of time, reductions in quality or a slowing of innovation, etc.\textsuperscript{8}

\textsuperscript{4} Prachi Gupta, Competition Issues in the Pharmaceutical Sector, Competition Law Reports, October 2013.
\textsuperscript{5} BS Reporter, “Maira committee favours no change in pharma FDI policy” Business Standard, Sept. 28, 2011.
\textsuperscript{7} S.V.S. Raghavan Committee, Report: High Level Committee on Competition Policy Law, para 4.6.2.
\textsuperscript{8} T. Ramappa, “Competition Law in India: Policy, Issues and developments”, (Oxford University Press, New Delhi 2\textsuperscript{nd} edn., 2009).
A merger leads to a higher concentration in the respective market. This increases the possibility of collusive or unilaterally harmful behaviour in that particular market. Collusion is more likely in industries producing relatively homogeneous products and characterised by small and frequent transactions, the terms of which cannot be kept secret. The merger is likely to be unilaterally harmful when the two merging firms produce similar products in a concentrated differentiated product market.

Even if no potential entrants are immediately visible, a large enough price increase (or high enough profitability) could encourage entry. So, it needs to be established, how high the expected price increase is likely to be. Following this, it is important to consider, whether entry is really likely, how quick it will be and whether it will be sufficient enough to make up for the reduced competition resulting from the merger.\(^9\)

The case can be made that even mergers that lead to an uncompetitive outcome could result in certain “efficiencies” that more than make up for the welfare loss resulting from this. The Russian law has such a provision. The US law has generally been balanced in favour of competition. However, the “failing firm” defence has, at times, been accepted by courts. If a firm is, indeed failing and likely to go out of business, it is not clear what social welfare loss would occur, if this firm’s assets were taken over by another firm.\(^10\)

**Brownfield is CCI’s field.**

The Reserve bank of India (RBI) released a clarificatory circular dated April 1, 2014 regarding FDI in pharma sector.\(^11\) It allows 100% FDI for Greenfield investments via automatic route. However the Brownfield investments require FIPB approval. Three years back on 28\(^{th}\) of September, 2011, the Planning Commission came out with a high-level

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\(^9\) SVS Raghavan Committee Report: High Level Committee on Competition Policy Law para 4.6.3.

\(^{10}\) id., para 4.6.4.

committee report, headed by Arun Maira, for the regulation of pharmaceutical M&As. The committee report stated that government will use the Competition Commission of India (CCI) and the Foreign Investment Promotion Board (FIPB) to keep a watch on acquisitions in the pharma sector to stave off the possibility of cartelization and dominance by multinational companies. The report thrived for more stringent merger control thresholds, bringing in more pharma M&A within the ambit of CCI. Based on this report, a circular was released by the ministry of commerce & Industry, Government of India. It stated that in case of brownfield investments in the pharma sector, FDI will be allowed through the FIPB approval route for a period of up to six months. During this period, necessary enabling regulations will be put in place by the CCI for effective oversight on mergers and acquisitions to ensure that there is a balance between public health concerns and attracting FDI in the pharma sector. Thereafter, the requisite oversight will be done by the CCI entirely in accordance with the competition laws of the country.\textsuperscript{12} Arun Maira stated that M&A deals in the crucial health sector should not be left only to the Foreign Investment Promotion Board (FIPB), since it does not follow a "not a transparent" process.\textsuperscript{13} He advocated for CCI’s control over pharma consolidations stating, "We need a filter definitely. Because we want to be sure that drug prices don't go out of control as a result of any monopolistic market".\textsuperscript{14} Another problem highlighted by Maira was that the FIPB is an inter-ministerial body of senior officials where once a proposal is cleared, "it cannot go further".\textsuperscript{15} On the other hand, CCI is a "transparent and pretty sophisticated instrument" in a sense that there is a review procedure prescribed under the Competition Act, 2002, where any decision by the CCI can be challenged. Thus, CCI has the onus of regulating the M&A activity of the pharma sector.

\textsuperscript{13} PTI, “Let all pharma M&As be cleared by CCI: Plan Panel” Business Standard, Sept. 27, 2014.
\textsuperscript{14} Id.
\textsuperscript{15} Id.
CCI’s Suspensory Regime – so far so good?

M&A activities are ex-ante, non-adversarial role of a Competition regulator. India follows a suspensory regime for merger control. The filing of merger notice has to be done within 30 days of consummation of the merger deal. In order to determine whether a combination would have the effect of or is likely to have an appreciable adverse effect on competition in the relevant market, CCI shall have due regard to all or any of the following factors as mentioned in Section 20(4) of the Competition Act, 2002. Section 6 states that no person or enterprise shall enter into a combination which causes or is likely to cause an appreciable adverse effect on competition within relevant market in India.\(^{16}\) The threshold for assessment of merger in the European Union is whether merger may substantially impede effective competition, while in the UK emphasis is on the ability of merger to substantially lessen the competition.\(^{17}\)

In India, Transactions must be notified to the Competition Commission of India (CCI) within 30 days of the execution of any agreement or ‘other document’ for the acquisition or acquiring of control. The Recommended Practices for Merger Notification Procedures by the International competition Network (ICN) is of the view that suspensory jurisdictions should not impose a deadline for pre-merger notifications.\(^{18}\)

Modification as a merger remedy

Modifications to a proposed transaction, with a view to eliminate possible competition concerns identified by a competition authority are known as remedies. In most jurisdictions including the European Union (‘EU’), it is the responsibility of the competition authority to

\(^{16}\) Section 6, Competition Act, 2002.


show that a proposed transaction would significantly impede competition. Once the competition authority identifies the likely competition concerns, it communicates its apprehension to the concerned parties and gives them an opportunity to formulate appropriate and corresponding remedial proposals. Section 31 of the Indian Competition Act, 2002 allows Commission to propose a modification to the merger.

In United States, Baxter International agreed to settle antitrust concerns stemming from its proposed acquisition of Immuno International AG. According to complaint issued in the consent order, the acquisition would create world’s largest manufacturer of human plasma products used to treat haemophilia and to control bleeding in surgical applications. The consent order requires Baxter to divest its Autoplex blood plasma product and to license Immunio’s fibrin sealant to Commission approved buyers.¹⁹

CCI approved the proposed acquisition of the active pharmaceutical ingredients (‘API’) business of Orchid Chemicals and Pharmaceuticals Limited (‘Orchid’) by the Indian subsidiary of Hospira Inc. USA (‘Hospira’).²⁰ This was for the first time that a merger control enforcement in India that CCI has approved a proposed transaction subject to certain modifications to the terms of the business transfer agreement (‘BTA’) entered into between the parties. In this case, these modifications were offered by the Orchid and Hospira when CCI sought justification from them regarding certain terms of the BTA, including the duration of the non-compete obligation of Orchid and the restriction on the Orchid to carry out research and development of certain types of API. In a latter decision, CCI approved the acquisition of 65.12% of the equity share capital of GGCL by GDNL subject to a broad

²⁰ Combination Case No. C-2012/09/79.
undertaking by GDNL that it will ensure that GGCL’s contracts with its customers comply with the provisions of the Act.\(^{21}\)

Interestingly, CCI’s decisions in both these cases are silent on the specific competition concerns that prompted it to seek modifications to the transaction between Orchid and Hospira, or require GDNL to give an undertaking ensuring compliance with the provisions of the Act. Equally, CCI’s orders clearing both the transactions do not shed any light on how the perceived competition concerns would be addressed, by requiring the concerned parties to modify certain aspects of the transaction or give an undertaking to address any potential competition concerns. CCI’s reluctance to highlight the possible competition concerns in the transactions between Orchid-Hospira and GGCL-GDNL, coupled with the absence of any indication on how the modifications or undertakings offered by the respective parties would allay the competition concerns brings to fore the issue of ‘remedies’ in merger review. Further, in the absence of any clear guidelines to this effect under the Act, the larger question that looms is how will CCI clarify to companies involved in merger cases how best to address competition concerns and ensure that competition concerns are dealt with more effectively.

The author suggests the need for adopting modification guidelines in India similar to the developed jurisdictions. The EU Merger Remedy Notice indicates that divestiture commitments are the best way to eliminate competition concerns resulting from both horizontal overlaps and vertical or conglomerate mergers.\(^{22}\) On the other hand, in the EU, behavioral remedies i.e. commitments relating to the future behavior of the merged entity are acceptable only in very specific and exceptional circumstances. This may not only make the merger review process more transparent, but also reduce the time lost in exploring possible remedies mid-way through the merger review process.

\(^{21}\) Combination Case No. C-2012/11/88.

Lower the Merger Thresholds, Please!

Merger scrutiny by CCI for the pharma companies becomes limited to those companies meeting the merger threshold requirements. Under the existing law, only combinations that involve target companies with a turnover of above Rs 750 Crores and assets worth more than 250 Crores need to be assessed by the Commission. 23 According to the Health Ministry, the turnover of most of the pharma companies is below the prescribed threshold that is 750 Crore and hence pharma companies will escape CCI scrutiny.24

Ranbaxy-Sun Pharma Merger –CCI Enters Phase II

Ranbaxy received a direction vide letter dated August 27, 2014 under Section 29(2) of the Competition Act, 2002 from the Competition Commission of India directing the company to publish the details of the proposed combination in the prescribed format within 10 working days from the date of the said letter.25 The CCI has used its power to take public comments and expert opinion regarding the largest pharma merger in the country.

The biggest hurdle to the merger clearance of Sun-Ranbaxy is the concentration post merger. CCI, in general, uses the Herfindahl-Hirschman index (HHI) to assess the concentration in the market in order to determine AAEC.

While evaluating horizontal mergers, the OFT is likely to regard any market with a post-merger HHI in excess of 1800 as highly concentrated, and any market with a post merger HHI of 1000 as concentrated. In a highly concentrated market, a merger with delta in excess of 50 may give rise to potential competition concerns. In a concentrated market, a merger

23 Section 5, Competition Act, 2002.
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with a delta in excess of 100 may give rise to potential competition concerns.26 The Competition Commission however, notes that it will consider HHI thresholds ‘only as one factor in its wider assessment of competition.’27

In Air Tours/First Choice28 the Commission held that the concentration would lead to the creation or strengthening of a collective dominant position on the UK-short haul foreign package holiday market. The dominant position would be held by Air/Tours (32 percent) and Thomson 27 percent and Thomas Cook (20 percent). The concept of non-coordinated effects were identified. The Commission held that it is not essential to show that parties would adopt a common policy on the market. The ability to engage in tacit collusion is not essential. It was sufficient that each individual undertaking operating on the oligopolistic market had sufficient market power on the market to act independently.29

The new ECMR granted the Commission the right to extend its Phase II proceedings in agreement with the parties for up to 20 days30; this has furnished the Commission with more time to collect evidence and to discuss any necessary commitments with the parties. According to Berg, this is the price that must be paid for the improvement of scrutiny and avoidance of low-quality decisions which have been compromised by time constraints.31 Sun pharma-Ranbaxy merger has opened up phase II investigations in India but a judicious use of this provision is required.

26 Mergers: Substantive Assessment Guidance, May 2003, para 4.3.
28 Airtours/First Choice Case (2000 O.J. L93/1)
29 Id. at para 54.
30 EC Regulation 139/2004, Article 10(3).
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CCI’s merger control – way to go

The Sun-Ranbaxy merger scrutiny is a promising move by CCI showing the world that the commission is evolving as a regulator. However, certain orders in the past could have been scrutinised upto the level CCI has reached today. One of them is the Jet-Etihad order.\(^{32}\) Before giving it clearance, CCI should have entered phase II since more scrutiny was required. The ex-official of Air India, Mr. Jeetendra Bhargava, did raise a question on the appreciable adverse effect on competition arising from the merger but the case ended up in deciding the *locus standi* for an appeal before competition authorities. The author feels that the fate of the merger could have been better decided by CCI.

Comparing the Indian merger control regime with that with the US merger control regime would be a little unfair as the two regimes are considerably distinctive in their approaches. However, a better practice could be adopted by CCI from the developed American law. The Federal Trade Commission (FTC) released the amendments to HSR pre-notification rules on November 6, 2013. These amendments were created in order to clarify situations in which transfers of pharmaceutical patents are notified under the Hart-Scott-Rodino Antitrust Improvements Act 1976 (HSR Act). The notified rule was that all transfers of exclusive pharmaceutical patent rights are potentially notifiable, even when the patent owner retains some of the production rights or any other co-exclusive exploitation rights (for instance, the right to co-develop or co-commercialise the final product). In short, every transfer where significant commercial patent rights are transmitted will now be notifiable.

The CCI could think on these lines as a merger between pharma companies includes the transfer of intellectual property rights, in this case drug patents. This would be a prospective move in terms of avoiding future litigation involving patent ownerships.

\(^{32}\) Combination Case no. C-2013/05/122.
Conclusion

It may be helpful if CCI were to bring in guidelines on merger remedies on similar lines as its counterparts in European Union and the United States. Merger remedy guidelines may help the parties to a transaction gauge, in advance, the type of concern that CCI may raise, and what possible remedial measures may work to address the concerns.

CCI can be a better regulator by ensuring special attention to the pharma sector. The competition regulator can bring a positive impact on the distribution of medicines in India as well as prices charged to the customers. Reduction of merger threshold, for at least pharmaceutical companies should be enforced to reaffirm the government’s belief of CCI being a better regulator for investment in pharma sector. With this be done, one can hope that the Indian pharmaceutical market can be regulated in a systematic and organized manner.