CPI COMPETITION POLICY INTERNATIONAL

CPI Antitrust Chronicle
Nov 2014 (2)

The Rising Tide: Competition Law Enforcement in the Indian Pharmaceutical Sector

Kalyani Singh
Luthra and Luthra Law Offices

The Rising Tide: Competition Law Enforcement in the Indian Pharmaceutical Sector

Kalyani Singh [1]

I. INTRODUCTION

Given the sensitivity and direct impact on consumers, it is of little surprise that the pharmaceutical industry—if not an absolute—ranks as one of the most controversial and actively pursued sectors by antitrust authorities across the world. India is no exception to this rule.

On September 4, 2014, the Competition Commission of India ("CCI") issued a notice seeking public comments subsequent to initiating its first Phase II investigation in the *Sun/Ranbaxy* merger case.[2] Not only is this case a watershed development in merger enforcement, it is also a strong indication towards increasing competition law enforcement in the Indian pharmaceutical sector. This article highlights the recent developments and future trends in this industry in India.

II. INDIAN PHARMACEUTICAL INDUSTRY

In order to fully comprehend the specific importance of this sector, it's imperative to first understand some peculiarities of the Indian pharmaceutical industry.

In India, unlike most countries, the burden of healthcare expenditure is primarily borne by private individuals. In such a scenario, price becomes one of the most pertinent issues in relation to pharmaceutical products. This is evident from the fact that, in India, there are numerous policies and regulations controlling the prices of various pharmaceutical products.[3] This is perhaps one of the primary explanations for the proliferation of generic manufacturers in India.

Predictably, government authorities in India have been even more attuned to the burden on consumers in this sector. The first compulsory license granted by the Indian Patents Office, for the manufacture and sale of Bayer's patented drug Nexavar,[4] is an excellent manifestation of this. In such a situation, it is only natural to expect rigorous competition law enforcement in this sector.

III. CURRENT ENFORCEMENT IN THE PHARMA SECTOR

To date, enforcement in this sector has been limited to cases related to anticompetitive agreements and mergers.

---

[1] Associate at Luthra and Luthra Law Offices, currently on secondment in Brussels. The views expressed in this article are personal and are exclusively those of the author.

[2] C-2014/05/170, *available at* http://cci.gov.in/May2011/PressRelease/C-2014-05-170-Press-Release.pdf.

[3] For instance, *see* Drug Policy 1986 *available at* http://www.nppaindia.nic.in/index1.html.

[4] *Natco Pharma Limited v. Bayer Corporation,* Compulsory License Application No 1/2011.

A. Anticompetitive Agreements—The Muddled Distribution Chain

Competition law across the world is replete with cases relating to the pharmaceutical sector. Typically these cases pertain to concerted practices between pharmaceutical manufacturers—recent transatlantic proliferation of pay-for-delay agreements has made this industry rather infamous.

Surprisingly, the CCI has taken a somewhat unconventional approach in cases relating to anticompetitive agreements. Notably, in India, it is the distribution chain that has been in the limelight for anticompetitive practices. The CCI, in as many as eight cases,[5] has penalized various trade associations of chemists and druggists for imposing certain conditions on their members to be in contravention of Section 3(3) of the Competition Act, 2002 (Competition Act). Section 3(3) of the Competition Act is the equivalent of the colloquial *per se* anticompetitive agreements; it provides for certain types of conducts that are deemed *per se* anticompetitive.[6] The CCI, in these eight cases, held the imposition of such conditions by the associations to directly or indirectly result in controlling the prices and supply of drugs through concerted and restrictive practices, thereby violating Section 3(3).

The novelty of these cases however, is not so much in the substantive assessment of the conduct but the unprecedented enforcement by the CCI. The CCI in all these cases imposed a fine of 10 percent of the aggregate turnover of these associations—the maximum penalty leviable for anticompetitive practices.[7] Not only did the CCI impose maximum penalties in these cases, some of them happened to be the few where the CCI has also prosecuted individual officers for infringement under Section 48 of the Competition Act.[8] Further, the CCI—again for the first time—also issued a notice in public interest, specifically highlighting the anticompetitive practices of the trade associations.[9]

---

[5] *Varca Druggist & Chemist & Ors. v. Chemists and Druggists Association, Goa*, MRTP C-127/2009/DGIR4/28; *Vedant Bio Sciences v. Chemists & Druggists Association of Baroda*, Case No. C-87/2009/DGIR; *M/s Santuka Associates Pvt. Ltd. v. All India Organization of Chemists and Druggists and Ors.*, Case No. 20/2011; *M/s Sandhya Drug Agency v. Assam Drug Dealers Association and Ors.*, Case No. 41/2011; *M/s Peeveear Medical Agencies, Kerala v. All India Organization of Chemists and Druggists and Ors.*, Case No. 30/2011; *M/s Arora Medical Hall, Ferozepur vs Chemists & Druggists Association, Ferozepur & Ors.*, Case No. 60/2012; *In Re: Bengal Chemist and Druggist Association*, *Suo moto* Case No. 02 of 2012 and Ref. Case No. 01 of 2013; and *Collective boycott/refusal to deal by the Chemists & Druggists Association, Goa (CDAG), M/s Glenmark Company and, M/s Wockhardt Ltd.*, *Suo moto* Case No. 05/2013.

[6] This means that once it is established that a conduct falls under Section 3(3), the burden then shifts to the defendant to rebut this presumption. *See, Reliance Big Entertainment Private Limited v. Tamil Nadu Film Exhibitors Association*, Case No. 78/2011.

[7] Section 27 of the Competition Act.

[8] *See,* Chemists & Druggists Association, Ferozepur, *supra* n. 5; and In Re: Bengal Chemist, *supra* n. 5. Section 48 of the Competition Act empowers the CCI to hold individual officers personally liable for the anticompetitive conduct of the defendant company. As per orders passed until November 19, 2014, cases where action under Section 48 has been taken, all except one, have been in relation to chemists and druggists.

[9] Public Notice dated 31 January 2014, *available at* http://cci.gov.in/May2011/OrderOfCommission/PublicNotice/PublicNotice-DrugsAndMedicines.pdf

B. Merger Enforcement—The Abbreviated Assessment

Mergers and acquisitions are collectively referred to as combinations under the Competition Act.[10] Section 6 of the Competition Act prohibits those combinations that cause, or are likely to cause, an appreciable adverse effect on competition ("AAEC") in India and requires that such combinations are treated as void. Importantly, the regime is suspensory, which means that transactions subject to merger control review by the CCI cannot be concluded until merger clearance in India has been obtained or a review period of 210 calendar days has passed, whichever comes first.[11]

As per the provisions of the Competition Act, on receipt of a notification, the CCI is required to form a *prima facie* opinion on whether the combination causes, or is likely to cause, an AAEC in the relevant market in India within a period of 30 days,[12] more commonly known as the Phase I review process. At the end of the Phase I review period, in case the CCI forms a *prima facie* opinion that a combination causes, or is likely to cause, an AAEC, a detailed investigation will follow and the standstill obligation will continue until a final decision is reached by the CCI or a review period of 210 calendar days has passed.[13] This is Phase II review of the investigation process.

Merger enforcement in India has generally been non-controversial. Until as recently as 2014, the CCI cleared all cases within Phase I review, including cases relating to the pharma sector. In fact, their assessment seemed to indicate that pharma was a more or less competitive sector, primarily looking outbound, with insignificant impact in India.[14] At most, the only issues in this sector were in relation to non-compete clauses. Following the EU ancillary restraints doctrine, the CCI has permitted non-compete clauses that are "necessary" and "reasonable" to the transaction. Additionally, in line with the benchmark provided in the EU ancillary restraint guidelines, such clauses spanning across a period of more than four years were found to be excessive.[15]

Notably, contrary to the practice followed in other jurisdictions, the CCI refrained from arriving at a definitive market definition when assessing these cases, despite some of them being horizontal mergers.[16] The primary reason for this approach seemed to be the insignificant impact of the transactions in India as most of these cases related to entities that primarily exported.[17]

---

[10] Section 5 of the Competition Act.

[11] Section 31 of the Competition Act.

[12] Section 29 of the Competition Act read with Regulation 19(1), Competition Commission of India (Procedure in regard to the transaction of Business relating to Combinations) Regulations, 2011 (Combination Regulations). Combination Regulations further supplement provisions relating to merger control under the Competition Act.

[13] Section 29 and 31 of the Competition Act.

[14] For instance *see*, *Notice given by Meiji Seika Pharma Co., Ltd.*, C-2014/07/189; *Notice given by Mylan Inc.*, C-2013/04/116; and *Notice for Acquisition filed by Orchid Chemicals & Pharmaceuticals Limited and Hospira Healthcare India Private Limited*, C-2012/09/79.

[15] Mylan Inc., *Id;* Orchid Chemicals, *Id.*

[16] *Id.*

[17] *Supra* n. 14.

It was only in the *Elder/Torrent*[18] case where the CCI undertook a more detailed analysis and, for the first time, defined the relevant market based on the therapeutic category of the products. Nevertheless, save for the non-compete clauses, no competition issues were observed here either.

Interestingly, in 2014 the CCI initiated its first phase II investigation in the Sun/Ranbaxy[19] merger. This case relates to a proposed merger between Sun Pharmaceuticals and Ranbaxy Laboratories. If approved, the merger is believed to create the fifth largest generics manufacturer in the world and the largest in India. The CCI formed a *prima facie* opinion that the deal is likely to cause an AAEC and consequently commenced an in-depth investigation.[20] Moreover, the CCI also sought public comments—yet again a first for merger enforcement in India.

Presumably, the CCI—as in the *Elder/Torrent* case—took a narrower approach to market definition when arriving at this conclusion. The assessment of the CCI seems to be based on the premise that proposed combination would result in Sun Pharma having a market share of more than 40 percent for at least 25 drugs. Out of these, for nine drugs its market share could be more than 65 percent.[21] Had the CCI taken its earlier approach, the transaction would have posed minimal concerns since the aggregate market share, post-transaction, seems to amounts to 9.2 percent[22] in the pharmaceutical sector.

IV. FUTURE TRENDS

Given these recent developments in Indian competition jurisprudence, enforcement trends in the coming future are likely to have exponential bearings on the pharmaceutical sector.

A. Merger Enforcement—A Meticulous Assessment

With gradual maturity, it is only natural that merger enforcement would be more nuanced in the coming future. The *Sun/Ranbaxy* case is clearly illustrative of such a trend. Importantly, this case is indicative of an increased scrutiny as opposed to the earlier somewhat ambivalent disposition in pharma cases.

Predictably this trend is most reflected in the CCI's approach to market definition. As mentioned above, recent decisional practice illustrates a more microscopic market definition as typically observed in more mature jurisdictions. The concept of defining a pharmaceutical market on the basis of therapeutic categorization—if not at a narrower level—seems to be the new basis. In fact, if required, the CCI could also adopt a narrower categorization.[23] A direct consequence of this approach is a more detailed assessment at the *prima facie* stage.

---

[18] Notice for acquisition given by Torrent Pharmaceuticals Limited and Elder Pharmaceuticals Limited, C-2014/01/148, ¶ 9.

[19] *Supra* n. 2.

[20] Section 29 of the Competition Act provides for the procedure to be followed where the CCI takes a *prima facie* opinion that the proposed combination is likely to cause an AAEC.

[21] http://articles.economictimes.indiatimes.com/2014-10-18/news/55172874_1_competition-watchdog-sun-ranbaxy-competition-law.

[22] *See,* http://cci.gov.in/May2011/Home/C-2014-05-170-Form-IV.pdf.

[23] *See,* for instance, Elder/Torrent case, *supra* n. 18, where the CCI also considered the possibility of defining the market a molecular level, ¶ 9.

Here it is important to note that even during a Phase I review, the CCI is empowered to make additional inquiries if it feels that the information provided by the parties is insufficient.[24] The CCI in such situations typically issues a defect notice seeking further information, which, in turn, stops the clock till the requisite information is provided.[25] This often results in a merger assessment spanning across a period which is longer than the exact 30 days provided for a Phase I review, or the ultimate 210 days limit within which the CCI is mandated to complete its review.[26] With respect to pharma cases, the CCI, even with its abbreviated assessment, often has taken longer than actual 30 calendar days to arrive at a *prima facie* opinion.[27] Predictably, a detailed scrutiny is more than likely to translate into a longer review period.

B. Anticompetitive Agreements—Casting a Wider Net

As discussed above, with respect to anticompetitive agreements, only the distribution chain has been subject to CCI's scrutiny so far. However, the CCI is expected to broaden its assessment and focus on pharmaceutical manufacturers. In fact, taking its cue from the United States and EU, the CCI is believed to have already started looking at usual suspects and is investigating alleged pay-for-delay agreements entered into by pharmaceutical companies.[28]

Here it is important to note that India has borrowed heavily from EU jurisprudence.[29] Resultantly, such agreements if established, in all probability, will be deemed *per se* anticompetitive under Section 3(3) of the Competition Act.

C. The Trickle-Down Effect—Collaboration Agreements

The focus on manufacturers is likely to trickle down to an assessment of other forms of agreements. The pharmaceutical sector happens to be one of the few sectors where cooperation agreements between various manufacturers are commonplace. Such agreements are typically co-marketing or co-branding agreements between various manufacturers. While such agreements between competitors are traditionally frowned upon, in this industry they are generally believed to be efficiency enhancing and therefore permissible.

India is no exception to such agreements.[30] However, to date none of these agreements has been scrutinized under the Competition Act. Nevertheless, the probability of such

---

[24] Regulations 14(3) and 19(2), Combination Regulations.

[25] Proviso to Regulation 19(2) of the Combination Regulations.

[26] *Supra* n. 13.

[27] For instance in Mylan Inc., *supra* n. 14, notification was made on April 1, 2013 while an order was passed on June 22, 2013. Similarly in Elder case, *supra* n. 18, notification was made on January 13, 2014 while an order was passed on March 26, 2014.

[28] *See* http://www.livemint.com/Companies/RVVDhRh7oTfpqlIphkb6jM/CCI-to-scan-drug-patent-settlements.html.

[29] *In Automobiles Dealers Association, Hathras, UP v. Global Automobiles & Others, Case No. 33/2011,* the CCI relied on the EU guidelines on vertical restraints when assessing a vertical agreement under the Competition Act. Similarly, the COMPAT in *M/s Excel Corps and Others v. Competition Commission and others, Appeal No. 79 of 2012; 80 of 2012; and 81 of 2012 (against In Re: Aluminium Phosphide Tablets Manufacturers, Suo-moto case No. 2/2011),* relied on guidelines in the EU and Office of Fair Trading, U.K. to propound the definition of relevant turnover.

[30] For instance *see* http://www.emcure.co.in/business_marketing.asp; http://economictimes.indiatimes.com/glaxosmithkline-pharmaceuticals-ltd/infocompanyhistory/companyid-

agreements also being reviewed is imminent. The assessment of these agreements is likely to be rather contentious. Given the emulation of EU jurisprudence, one would expect the CCI to follow a similar approach and generally adopt an effects-based analysis in these cases. However, unlike in the European Union, the Competition Act draws a clear distinction between horizontal, vertical, and all other forms of agreements.[31] Consequently, such agreements are likely to be assessed within the purview of Section 3(3) of the Competition Act.

Since these cases represent uncharted territory, it is difficult to predict what approach the CCI is likely to take. Typically an effects-based assessment has been reserved only for agreements other than horizontal agreements. Nevertheless, given the general efficiency-enhancing nature of such agreements, it is highly probable that the CCI will also assess these agreements under the rule of reason approach.

D. Abuse of Dominance—An India Specific Enforcement

As already mentioned, Indian literature is rather sparse regarding abuse of dominance cases relating to the pharma sector. Nevertheless, given the importance and nature of this sector, it is reasonable to expect cases relating to this category as well.

While probable trends seem to be ostensibly similar to the ones present in other jurisdictions, enforcement of competition law in India will, in all probability, cause significant divergence.

Section 4 of the Competition Act proscribes abuse of dominance by an enterprise. It is in these cases where the CCI has significantly diverged from international jurisdictions and taken an India-specific approach in enforcement.[32] Arguably, the main reason for this prevailing position can be attributed to its consumer-centric priorities. The approach taken by the CCI seems to concentrate on directly protecting consumer interests; as opposed to it being a necessary corollary of unbridled competition in the market. As a result, these priorities have yielded to the traditionally formalistic approach, particularly in abuse of dominance cases. For instance, under the current regime, both exclusionary and exploitative practices are considered to be an abuse.[33] In fact, exploitative conducts like excessive pricing and unfair conditions on consumers have taken a center stage in abuse of dominance cases in India.[34] Additionally, "special responsibility" has been accorded to a dominant enterprise under the Competition Act.[35]

13715.cms; http://www.livemint.com/Companies/l1UJr9if0JCTeKm8VEWFGJ/Cipla-to-partner-with-MSD-Pharma-to-sell-HIV-drug-in-India.html.

[31] *Mr. Ramakant Kini v. Dr. L.H. Hiranandani Hospital, Powai, Mumbai,* Case No. 39/2012, ¶ 9.

[32] *MCX Stock Exchange Ltd. v. National Stock Exchange of India Limited,* Case No. 13/2009, ¶ 10.80.

[33] *Belaire Owners' Association v. DLF Limited, HUDA & Others*, Case No. 19/2010, the CCI held that monopolization by the developer—by imposing unfair terms and conditions on the consumers—was illegal under Section 4. The conduct considered anticompetitive in this case was an exploitative conduct. On the other hand, in the NSE case, *id.,* the CCI was of the view that the conduct price predation by the dominant firm—to the exclusion of its competitors—amounted to abuse of dominance. This offense was also upheld by the COMPAT in National Stock Exchange of India Ltd., *id*.

[34] *Shri Shamsher Kataria v. Honda Siel Cars India Ltd. & Ors.*, Case No. 03/2011.

[35] *National Stock Exchange of India Ltd. v. Competition Commission of India & Ors.,* Appeal No. 15 of 2011, ¶ 69.

While this approach is reflected in all cases, it is likely to be even more conspicuous in the pharma sector.

It is important to remember that, in India, it is the end-consumers that bear the primary burden of healthcare expenditure. In such a scenario, it is only expected for competition policy in India to give credence to the generic sector and take a circumspect approach regarding innovator/originator companies. In light of this landscape, abuse of dominance cases are more than likely to be focused on strategies adopted by originator companies.

As mentioned, dominant undertakings have been accorded a special responsibility; in essence implying a higher level of scrutiny in the conduct of such entities. Predictably, this responsibility would be even greater in cases relating to innovator/originator companies—typically perceived as companies already armed with multiple intellectual property rights ("IPR") protections giving them monopoly rights. Any conduct of such companies that either results in an increase in price or delay of generic competitors will draw heavy scrutiny—necessitating an approach similar to Caesar's wife, i.e. to remain above all suspicion.

With respect to possible conducts likely to be the subject matter of review, impact on consumers is bound to be the most important factor, which implies pricing will be one of the most contentious issues. Thus, questionable conduct would typically comprise of strategies that relate to originator companies' pricing their own products and, more importantly, strategies adopted to delay the entry of generics into the market.

Finally, no discussion of enforcement in the pharma sector is close to being complete without talking about the imminent interface between intellectual property law and competition law. Patent strategies, adopted by innovator companies, to delay entry of generics are perhaps the quintessence of abusive conduct specific to this sector. Naturally, such strategies would also be subject to detailed assessment under the Competition Act.

V. CONCLUSION

The CCI has on numerous occasions stressed the need to ensure competitive neutrality across sectors in the economy. Its commitment to ensure competition across sectors can be seen in the advocacy initiatives undertaken by the CCI.[36] In this vein, the CCI has typically focused on particular industries that it believes have a direct impact on the economy and consumers.

What is perhaps interesting to note is that while these priorities seem to be suggestive of a robust enforcement in an industry such as the pharma sector, the CCI has surprisingly taken a rather deferred approach to date. This is perhaps more demonstrative of the yet nascent state of Indian competition law rather than it being a low priority for the CCI. As is typical of a developing jurisdiction, it is only natural to expect a shift in focus from the so-called "smokestack industries" to sectors that deal with more complex and intricate issues like the pharmaceutical industry.

[36] Per its Newsletter, Volume 5: April-June 2013, *available at* http://cci.gov.in/Newsletter/newsletterjuly2013.pdf.