



## Emerging Antitrust Issues: Implications on India's Pharma Industry

Economic Laws Practice and Vinson & Elkins hosted a webinar on the above subject on 18 July 2019. The following salient points were analyzed during this event.

### A. Sectoral regulation in the pharma industry

- The pharma sector in India is heavily regulated, with laws and statutory authorities overseeing various facets of the industry, from manufacturing of drugs to advertisement and promotion and sale.
- In India, the primary statute that regulates the pharmaceutical industry is the Drugs and Cosmetics Act, 1940 along with the Drug (Price Control) Order, 2013. In addition, the National Pharmaceutical Pricing Authority regulates the pricing of drugs.
- In the US, the US Food and Drug Administration is responsible for reviewing, approving and regulating medical products, including pharmaceutical drugs and medical devices.
- The Competition Commission of India (**CCI**) regulates competition in markets including pharmaceutical sector pursuant to its mandate under the Competition Act, 2002 (**Act**).

### B. CCI's experience with pharma sector so far

- So far, a vast majority of cases before the CCI have involved issues of appointment of stockists by pharmaceutical companies based on "no-objection certificate" from chemists and druggist association and mandatory collection of product information services charges by such associations for advertisement of new products in the market.
- CCI has repeatedly found these practices to be anti-competitive and penalized both the trade associations and pharmaceutical companies. In few recent orders, the CCI has also called upon the pharmaceutical companies to set up in-house competition compliance programs.
- While assessing combinations, the CCI recognized certain sector specific qualities of the pharma industry, especially when assessing ancillary restraints. These specific considerations pertain to product market definition and non-compete clauses.
- In recent years, the CCI has also initiated investigation on allegations of price cartelization through co-marketing agreements, denial of market access, differential pricing and "pay for delay" arrangements.

### C. Compensation rights in light of anti-competitive conduct by pharma companies

- In India, any person may make an application to the competition appellate authority i.e. National Company Law Appellate Tribunal (**NCLAT**) seeking compensation for any loss or damage *shown* to have been suffered by the claimant on account of contravention of the Act by an enterprise.
- Such applications can be filed either after the CCI passes a final order or once the NCLAT upholds CCI's order. Per practice, in case a matter has been appealed before the Supreme Court of India (*the last appellate body for the purposes of the Act*) and an interim stay has been granted, the NCLAT keeps the compensation application in abeyance awaiting a final decision of the Supreme Court.

- In US, under federal law, private plaintiffs may recover treble damages plus costs for violations of antitrust laws. In doing so, it is relevant for the claimant to provide that the defendant violated the antitrust laws, and that the illegal conduct caused the plaintiff economic injury.

#### D. Assessment of mergers in the pharma industry

- Under the Act, any acquisition of shares or voting rights or assets or control; or a merger or amalgamation needs to be mandatorily modified to the CCI, provided the jurisdictional thresholds are satisfied and the transaction does not benefit from any exemption.
- The CCI has held commercialization rights including IPRs and goodwill to be asset for computation of the monetary thresholds.
- While assessing a transaction, should the CCI form an opinion that the transaction has or is likely to have an appreciable adverse effect on competition (**AAEC**), but such adverse effect can be eliminated by suitable modifications, it may propose appropriate modification to the transaction.
- Modifications may be either behavioral or structural or both. In *Sun/Ranbaxy*, the CCI, after conducting a detailed investigation (phase 2), concluded that the high combined market shares for certain overlapping molecules would likely result in AAEC. Accordingly, it directed the divestment of seven brands to an approved purchaser.
- Similarly, in the US, while assessing *Teva/Allegran*, the FTC noted that in line of the parties' market position and absent a remedy, the transaction would substantially reduce competition in the generic market and ordered divestiture of 79 products to other manufacturers.

#### E. Settlement of patent disputes and antitrust concerns

- Agreements between actual or potential competitors including manufacturing agreements, if causing or likely to cause AAEC are prohibited under the Act.
- When the patent holding company enters into private agreements with generic manufactures to delay entry of generics for a consideration, it may raise concerns under the Act.
- While the patent holder may have entered into such a settlement in view of the exclusive rights granted to it under the Indian Patents Act, 1970, it is up to the CCI to consider and assess if the pay for delay arrangement can be seen as a reasonable and necessary condition for protecting its rights under Section 3(5) of the Act. It may also be seen as a way to restrict the entry of a potential competitor in the market based on specific facts of a given case.
- In the US, the lower courts continue to grapple with how to apply the decision given by SCOTUS in *FTC v. Actavis*. In this landmark decision, the Court had held that reverse payment agreements are to be scrutinized under the rule of reason test, even if within the scope of the patent.

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