



Impact of Competition Law on Pharma Industry

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The Indian pharmaceutical industry is one of the leading sectors contributing towards country's economic growth. The practices followed in the pharma industry have wide impact both from the consumer and the market perspective, being a sensitive sector. The primary concerns of the industry revolve around protection of its research and development ("R & D") and innovative products developed, which to a large extent are protected by virtue of the intellectual property ("IP") legislations ensuring flow of innovative drugs. The crucial aspect to be tested is whether the protection vested amounts to pharma companies assuming a monopoly situation in the market, leading to huge price margins and substantial market power. The growth of pharmaceutical industry though protected under several IP laws, raises competition law issues.

The regulatory framework in the pharma industry operates at two levels: licensing and pricing. The need to provide protection to pharmaceutical companies for their innovation is well recognized under the Competition Act, 2002 ("Act") however the same is restricted by providing specific inclusions under Section 3(5) of the Act. Horizontal agreements in the pharma sector would involve agreements entered at same level between pharmaceutical companies to restrict supply/fix prices similar to situations including "payment of delay" as prevalent in United States whereas vertical agreements are entered between players at different levels in the supply chain being

pharmaceutical companies and pharmacists/hospitals in the form of tie-in arrangements.

The provisions of Section 3(3) and 3(4) of the Act pertain to agreements entered between enterprises restricting purchase/sale prices, curtailing supply/production of goods and services as well as entering exclusive supply/distribution arrangements, creating tie-in arrangements with the intention of adversely affecting the market. The pharmaceutical companies holding valid patents could enter into agreements with hospitals/pharmacists restricting prices if unregulated by the Drug Price Control Order ("DPCO") and entry in the absence of generic drug manufacturers, as well as inter-se between pharmaceutical companies may lead to possible violations under the Act.

Cartels by industry associations have been widespread across jurisdictions to set standard prices for both stockists and retailers but the same has often led to restricting prices. Although the provisions of the Act recognize protection granted under IP legislations, yet associations formed to exchange data and information serving purposes other than protection of the right holders could invite possible competition law violations.

Mergers and Takeovers in the pharmaceutical sectors have also grown considerably in the past few years. Section 5 of the Act prescribes the thresholds under which combinations shall be examined

whereas Section 6 states that any combination which causes or is likely to cause an appreciable adverse effect on competition within the relevant market in India shall be void. The regulatory authorities should be extremely mindful prior to sanctioning such deals considering the possible impact it may have on the market and ultimate end consumers, especially as it involves public health.

Intellectual property legislations and competition law have different objectives, the former protecting private rights and the latter adopting a pro-consumer approach prevents innovation and efficiency from hindering the market. The growth of the pharma industry depends on the proper functioning and integration of both laws harmoniously to achieve the desired result.

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