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Patent linkage impermissible in India: Cipla

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New Delhi: The dispute between Indian drug companies and the Big Pharma over “patent linkage” has reached the domain of judiciary.

German drug major Bayer AG’s attempt to introduce the concept of patent linkage into the Indian legislation is “impermissible” as it is not covered by the Trips Agreement to which India is a signatory, according to domestic pharma major Cipla Ltd.

Patent linkage is the term used to refer to the practice of drug quality regulators — the Drugs Controller General of India in India’s case— denying marketing approvals for generic drugs citing existence of patents. The contrarian argument is that drug regulators should have nothing to do with patents, and they should restrict themselves to evaluating the safety and efficacy of drugs.

Opposing Bayer’s plea that the concept of patent linkage is in consonance with effective enforceability of intellectual property rights, including patent rights as mandated by Part III of Trips, Cipla in its reply submitted before the Supreme Court said that patent linkage is a Trips Plus concept. Besides, the linkage is not even contemplated in either the Drugs & Cosmetics Act, 1940, or the Patents Act, 1970, it added.

According to local pharma firm, Trips Plus provisions are contrary to the intent and spirit of the Trips Agreement which in the preamble itself provides that patent rights are private in nature. Besides, various safeguards like compulsory licensing that are allowed to a nation under the Trips Agreement are rendered completely redundant and meaningless in nature by the Trips Plus provision, it said, adding that patent linkage is a policy decision and is required to be taken by the government or Parliament and is outside the jurisdiction of the courts. The reply has come on a petition filed by Bayer seeking protection for its Nexavar even as Cipla’s plea for grant of marketing approval for generic version of its kidney cancer drug, Sorafenib, is pending before the regulatory authorities.