LexOrbis INTELLECTUAL PROPERTY ATTORNEYS

Indigenously manufactured patented drugs exempted from Drug Price Control!

Written by Manisha Singh and Co-Authored by Swati Gupta
LexOrbis - www.lexorbis.com

The Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) has notified an order amending paragraph 32 of Drugs Prices Control Order 2013, effective from January 3, 2019:

> ***a manufacturer is producing a new drug patented under the Indian Patent Act 1970 (39 of 1970) for a period of five years from the date of commencement of its commercial marketing by the manufacturer in the country.***

As per the amendment, new drugs patented in India are exempted from price control for a period of five years from the date of commencement of their commercial marketing. This amendment was intended to boost the patenting of innovations in India. Most likely, it would encourage foreign pharmaceutical companies to manufacture and commercialise their new patented drugs and medical devices in India.

Under the Essential Commodities Act, 1955, the Government has passed many Drug Price Control Orders (DPCO) from time to time to regulate the price of essential and lifesaving drugs to make notified medicines available at a rate fixed by the Government. In order to encourage the Indian Innovators to innovate new drugs, paragraph 32 of DPCO 2013, has exempted new patented drugs or nep delivery system of indigenous origin from the price control.

After the para 32 amendments in 2019, drugs patented by foreigners in India were also exempted from the price control. This exemption is available to a manufacturer producing a new drug patented under the Indian Patent Act 1970 (39 of 1970) for a period of five years from the date of commencement of its commercial marketing by the manufacturer in the country. Earlier, this exception of price control was available only for the new patented drugs or new drugs involving a new delivery system indigenously developed in India, not for the patented drugs developed outside of India. However, after the DPCO 2019 amendment, the patented drugs developed outside of India would also be exempted from the drug price control. However, the patentee is required to manufacture it in India to avail of this benefit.

The aim of the DPCO, 2013, issued under section 3 of the Essential Commodities Act, 1955, is to ensure that essential drugs are available to all at affordable prices. However, the 2019 amendment would have a detrimental effect on the affordability of drugs under para 32 exception, as the pharmaceutical companies could now keep the prices high for the patented drugs developed outside India. The Delhi High Court has notified a petition by All India Drug Action Network (AIDAN) challenging the amendment of DPCO. The petition highlights the challenges associated with price control of the patented drugs according to the recent amendment:

- *The new exemption has questioned the clarity w.r.t. date of commencement of its commercial marketing by the manufacturer in the country. It is difficult to ascertain whether the commencement of commercial marketing defines the date of manufacture of drugs in India or the date of import of the drug in India or the date of making the drug available to the retailers.*

- *The amendment has increased the list of drugs exempted from the price control since the drugs which are not of indigenous origin are also exempted from the price control.*

- *Also, the amendment has removed the term 'product patent' from para. 32(i) of DPCO 2013 thereby extending the exemption of price control to include any kind of patent including devices, dosages, forms, compositions, and process patents as long as it relates to a new drug.*

- The petition has also questioned the link between Drug Price Control order and The Patent's Act 1970.

Conclusion:

The 2019 amendment of the Drug Price Control Order is a welcome step enabling foreign pharmaceutical companies to manufacture and commercialise their innovative drugs in India without any price control at par with indigenously developed drugs. Further, it would facilitate the introduction of new drugs in India, which were only available for foreign patients, or its availability to Indian patients was very expensive. On the one hand, this amendment would encourage building up manufacturing capacity in India and, on the other, attract FDI in the drug sector. Some activists feel that the 2019 amendment would have a detrimental effect on the affordability of drugs as it gives a free hand to fix the price of the new drug. However, after three years of the grant, the Controller can grant the authorisation of a patented drug to the third party in the form of a Compulsory Licence if the patented drug is not available at an affordable price. The 2019 amendment would boost the manufacturing of pharmaceuticals in India by giving price control exception to the patented drugs for a period of just five years.