BioSpect
the business of Bi
24 years of leveraging the business of Bio
www.biospectrumindia.co

Why India must push for relaxation of Canadian fixed drug price policy

24 August 2023 | News | By Bhagwati Prasad

India is keen on expanding the scope of waivers to diagnostics and therapeutics



Experts have recommended the Indian government should emphasise the need to broaden the scope of pharmaceutical equivalence among other intellectual property (IP) related subjects to Canada considering India's strength as a generic provider.

For a generic drug to be considered equivalent to the patented drug in Canada, the generic drug must contain an 'identical amount of identical medicinal ingredients' as the patented drug. Legislative changes have been proposed to widen the scope of such equivalence, but these are yet to be codified into law.

Canada does not grant any exclusivity period for marketing generic drugs. However, Canada does have a provision which rewards the generic drugs company for the expense and risk of challenging patents. Therefore, the Indian government may also emphasise the need for such exclusivity to incentivise the generic industry.

Canadian law provides for expedited drug review processes in exceptional cases such as reviews of drugs for life-threatening diseases. However, the criteria applied to trigger expedited review are not clear. The Indian government may also discuss the possibility of extending the scope of coverage of expedited approvals to other categories of drugs and may seek greater clarity on the criteria and processes involved.

In the USA, the first maker of any generic drug that challenges an existing patent is entitled to a 180-day period of exclusivity during which no other generic for the same patented drug can be marketed. A Drug Establishment License is required for any company that fabricates, packages, labels, distributes, imports, wholesales, and/or tests drugs.

Sumanta Choudhury, Advisor, Pharmaceuticals Export Promotion Council of India (Pharmexcil) explains, "Canada accords 'innovative drugs' with market exclusivity for 8 years. As mentioned previously, there is no exclusivity for the first generic manufacturer. As a part of the Canada-European Union Comprehensive Economic and Trade Agreement, new pharmaceutical products are granted additional exclusivity through the protection of an eligible patent. As a result, the actual exclusivity period for products from the European Union would increase from 8 to 10 years through the operation of a 'patent linkage system'. These provisions form part of Canada's free trade agreement obligations, so it is unlikely that these would be altered in the near future".

"However, India may still flag the issue as causing inordinate delays in generic drug approvals. There is a lack of a formal patent opposition framework in Canada. India has established formal procedures for pre- and post-grant opposition. During negotiations, India should not make any commitment relating to altering its patent opposition system," adds Choudhary.

"The Canadian Supreme Court has interpreted Canadian patents to have extraterritorial application, namely the Saccharin Doctrine which broadly states that if a drug is produced with a patented intermediate, such drug would infringe the patent for the intermediate when the final product is imported and sold in Canada. The Doctrine includes both products and processes. The Indian government should strongly put forth the position that patent protection should be limited to Canadian territory during negotiations," Choudhury further explains.

India and Canada have a similar stance on compulsory licensing, especially on life-saving medicine such as the COVID-19 vaccines. However, India is keen on expanding the scope of such waivers to diagnostics and therapeutics and may liaise with the Canadian government on its position regarding such waivers.

Bhagwati Prasad