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Compulsory license ensures patent rights & public health: Expert

Nandita Vijay, Bengaluru, **Wednesday, January 18, 2012, 08:00 Hrs [IST]**

Compulsory license, specifically under Section-92A of the Patents (Amendment) Ordinance, 2004 for export of pharmaceutical substances, ensures a balance between patent rights and public health is maintained, according to Bindu Sharma, Patent Attorney, Origiin IP Solutions LLP.

One of the prime objectives of patent grant in India is to ensure that the inventions are developed in the country on a commercial scale and to the fullest extent without any undue delay. If an invention by the patentee ceases to function, or reasonable requirements of the public are not met or the patented product is not available to public at a reasonable price, the compulsory license is available as a remedy against abuse of patent right, stated Sharma while commenting on the export of pharmaceutical compounds and compulsory license.

Under Section 92A, the compulsory licence is available only for manufacture and export of patented pharmaceutical product to any country having insufficient or no manufacturing capacity in the pharmaceutical sector and is a product addressing the public health problems, she added.

Compulsory license could be granted, in a national emergency or non working of the invention for 3 years from the date of grant. The 2005 Act has made certain grounds for compulsory licensing keeping in view the agenda of Doha Declaration and August 30, 2003 WTO decision.

Section-92A enforced on January 1, 2005, provides for grant of compulsory licence by the Controller for export of patented pharmaceutical product in certain exceptional circumstances. It is granted by the country to which the export is intended. This provision was further amended by The Patents (Amendment) Act, 2005, to allow grant of compulsory licence even in cases, where the importing country has by notification or otherwise, allowed importation of patented pharmaceutical products from India. Though India provided a compulsory license provision for exports under section 92A, it has also put burden on importing countries to amend their legislation if they require medicines from India, stated Sharma.

Many patent law systems provide granting of compulsory licenses in various situations. The Paris Convention of 1883 provides that each contracting State may take legislative measures for the grant of compulsory licenses. The agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) also has specific provisions if a compulsory license is issued.

A case law pertaining to compulsory license under Section 92 A was when Africa was in the grip of HIV/AIDS epidemic and the patents for anti-retroviral drug combination (ARV) was the in hands of few pharmaceutical companies like GSK and Merck among others who were exclusively marketing the drugs at prices around $10,000 per patient annually. Cipla, offered a generic version of the drug at about 3 per cent of the price. The African government procured from Cipla, for which they were sued by drug multinationals for violating their patent rights. But they were forced to withdraw the suit due to an outrage by the international community. This incident became an issue in international forums like WHO, UN, UNCAD and WTO ministerial conference at Doha, in November 2001 where the issue of pharmaceutical patent and public interest was taken up and a declaration was made on 'TRIPS Agreement and Public Health'.

"The Doha Declaration became a milestone in the TRIPS Agreement as it ensured a balance between public health and patent rights, besides setting forth a clear preventive standard," stated Sharma.

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