

Govt use of compulsory licence - Sovereign immunity

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The US Patent Law 35 U.S.C while being silent on Compulsory Licence (CL) has a separate code for granting of CL outside the provisions of the US Patent Law. This code called 28 U.S.C. § 1498 explicitly states that the Government is free to invoke this provision when the invention covered by a patent is “used or manufactured by or for” the Government.

The Indian Patent Law under Indian Patents Act, 1970, explicitly provides for grant of CL to third party (not being for government use) starting from Section 83 to Section 94. Recently, on 9th March, 2012, CL was granted under Section 84 for Sorefenib (Nexavar®) to Natco by the Controller General (CG) of Patents. The order is accessible online on the website of the Indian Patent Office.

Currently, the order of the CG granting CL to Natco under Section 84 has been appealed by the patentee, Bayer to Intellectual Property Appellate Board (IPAB). While the order of the Controller is dated March 2012, the appeal is dated May 2012.

The important Sections for the grant of CL to third party available under the Patents Act, 1970 are Section 83, Section 84, Section 92 and Section 92-A.

Section 83 relates to general principles applicable to working of patented inventions, for example, Section 83(b) states that patent are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article. Similarly, while, Section 83(g) states that patents are granted to make benefit of the patented invention available at reasonably affordable prices to the public, Section 83(d) states that patent should not impede protection of public health and nutrition and should act as instrument to promote public interest.

Section 84 states that a CL application to the Controller can be made after three years from the date of grant of the patent, if,

- (a) reasonable requirements of the public with respect to the patented invention have not been satisfied or
- (b) patented invention is not available to the public at a reasonably affordable price or
- (c) patented invention is not worked in the territory of India.

Section 92 provides for special provision for compulsory licences on notifications by Central government. The said provision deals with the grant of CL in conditions of national emergency or extreme urgency or public non-commercial use.

There is a general perception that Section 92 cannot be invoked unless there is national emergency, since, the conditions are not similar to Section 84, wherein any of the three grounds can be invoked (all of which have been referred to and invoked in the order granting the CL). The conditions for the grant of CL under Section 92 is ‘or’ basis, wherein the third condition is ‘or’ public non-commercial use.

However, while Section 92 can be only invoked for public health crises relating to Acquired Immuno Deficiency Syndrome, human immunodeficiency virus, tuberculosis, malaria or other epidemics, Section 84 can be invoked for inventions relating to any field of technology.

Section 92A of the Patents Act, 1970 can be invoked for making an application for CL for manufacture and export of patented pharmaceutical products to countries having insufficient or no manufacturing capacity in the pharmaceutical sector. However, the proviso states that CL has to be granted by such country by notification or otherwise and must allow importation of the patented pharmaceutical products from India.

All such CL applications under Section 84, Section 92 and Section 92A have to be made to the Controller. The office of the controller general is a subordinate office under the Department of Industrial Policy and Promotion (DIPP) and DIPP in turn comes under Ministry of Commerce and Industry.

CL for government use

Provisions for application of CL for the purposes of Government are dealt with under Section 99 to Section 101.

Section 99 clarifies and defines the ‘use of invention for purposes of government’. It states that an invention is said to be used for the purposes of government if it is made, used, exercised or vended for the purposes of the Central government, a State government or a government undertaking.

This provision in India is similar to the CL provision in 28 U.S.C. 1498 of USA. There are case laws both in India and USA wherein CL provision has been used for Government use of patented invention. The Indian case law relates to Garware Wall Ropes Ltd. vs. A. I. Chopra, Engineers & Contractors and Konkan Railway Corporation wherein patent Nos. 196240 and 201177 for ‘GSR and Spiral Lock Systems’ were subject of the suit. It was held that under Section 99 and Section 100 even a third person i.e. contractor can be allowed to use the patent for the purposes of government or government undertakings, however, subject to agreement or licence given by the patentee or payment of royalty, etc.

The US case law relates to ciprofloxacin (anthrax), Tamiflu (avian flu), Blackberry services and Zoltek Corp (F-22 fighter jets). In the ciprofloxacin case in 2001, 28 USC 1498 was threatened to be used by DHHS Secretary Tommy Thompson to authorize importation of generic ciprofloxacin for building up stock against possible anthrax attacks. In 2005, the US Government persuaded US manufacturers to increase production of Oseltamivir (Tamiflu®) against potential avian flu epidemic to enable easy access of medicines by US Government. In 2007, in the Zoltek Corp case relating to process for making material used in F-22 fighter jets, the US Government justified the act of importation from a unlicensed manufacturer without payment of royalty to the patentee under 28 USC 1498.

Section 101 details the right of third parties in respect of use of invention for purposes of government. It states that any licence, assignment or agreement granted or made between the patentee and any person other than the Central government shall have no effect if the agreement provides restriction on government use.

In a recent inter-ministerial meeting addressing the pharma industry which was attended by pharma industry associations, it has been reportedly stated by the Commerce Minister that when

there is genuine cases where life-saving medicines are not accessible at affordable price, any interested person may approach Central government, Ministry of Commerce and Industry to invoke Sections 99 to 101 for grant of CL for Government use. This is justified under Section 99 which defines use of invention for purposes of government if it is made, used, exercised or vended for the purposes of the Central government, a State government or a government undertaking.

The implication of the statement of the Commerce Minister appears to be that in case of genuine need for CL for making available life-saving medicines through government or government authorised channels, the grant of the CL may be simpler and smoother without any technical and legal hassles and long drawn out procedural disputes, compared to the long-drawn out procedures at the office of the Controller of Patents.

It appears from the statement of the Commerce Minister that there is scope to put to test the provisions from Sections 99 to 101, provided the CL applicant makes out a fit and suitable case, to the government.

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