

Instances of Compulsory Licenses in India

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Introduction

India is a sovereign country and there is no doubt about it as such. It's the duty of the legislature, executive and judiciary to protect the interests of its people. But at the same time the international commitments made by India shall not be forgotten. One of such international commitments is the protection of intellectual property rights in the country according to the TRIPs agreement of WTO. India being a signatory country to the TRIPs had a mandate to incorporate some provisions in Indian Patent regime, and India has successfully amended its patent law. Compulsory License is one such provision that's been incorporated in the Indian Patents Act from the TRIPs agreement. International business community felt that even after being a signatory to TRIPs long back and having provisions providing about compulsory license, it was not in compliance with international standards and regulations for the protection of intellectual property since only one compulsory license has been issues till now.

Recently India has a very tough situation as it has vast disparity in the economic conditions of its citizens, and that makes it hard for the government to strike a balance between ensuring strict compliance with international standards of patent protection and properly safeguarding public health. India should worry about the realistic situation of the availability of drugs which are produces as a final result after years of

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research which are required for the large population. Further for the development of multinational companies to set-up production units in India, necessary environment is essentially required and must be created.

Indian Scenario

Compulsory license shall be considered as a last option, applicant is required to make reasonable efforts for the voluntary license from the patent holder first and only on the denial from the holder such application shall be made. Well with this let's look in to Indian scenario with regard to compulsory license. India's first and only compulsory license till today was granted in 2012, to the Natco Pharma. The Bayer v. Natco pharma was the first Indian case where the compulsory license was granted. The case opened ample of questions with regard to Indian paten Policies. The case was decided in less than 6 months that made clear that the interest of public at large is paramount, instead of having very strict IP Laws.

The fact of the case is that the Natco pharma is an Indian company who applied for the license of the generic production of Bayer Corporation's Nexavar. Nexavar is a drug which is used for the treatment of Liver and Kidney cancer. The three grounds provided by section 84 were all met, i.e. Bayer's drug couldn't meet the reasonable requirement of the public, it was not available at reasonably affordable price to the public, and the invention was not worked in India. Bayer offered the drug at the cost of Rs. 2.8 lakh for a month's therapy whereas Natco pharma offered to sell the drug at the cost of Rs. 8,800 only. The Compulsory license was granted to the Natco pharma on the ground that the interest of public at large is more important.

Encouraged by this decision, one another Mumbai based, Indian company BDR pharmaceuticals filed an application for a compulsory license of one anti-cancer drug Sprycel. It's a patented drug in India. BMS, a Multinational Pharma company holds the patent of it. BDR sent a letter to BMS, asking for the voluntary license of the mentioned drug to which Bristol responded by raising certain queries to be answered by BDR. But BDR instead of replying to the queries raised, filed an application for grant of compulsory license for the drug to the patent office. BDR used the above mentioned queries as their bone contention and contended that BMS used these queries as a delayed tactics.

It was held by the Controller General that BDR pharmaceutical failed to make a prima facie case for a compulsory license. The Controller General said that before going to the merits of the case the threshold requirement of establishing a prima facie case must be satisfied. According to the Controller General BDR couldn't make the reasonable attempt to get the compulsory license and hence doesn't satisfy the statutory requirement that the supplicant must negotiate in good faith for the period of 6 months. As per section 87 of Indian Patent Act, 1970, on receiving the application, the controller should consider the evidence therein to determine whether a prima facie case is made out on the basis of the facts disclosed in the application.¹

India has made several amendments to the existing patent act to make its laws as per the mandate of TRIPs. India follows the approach in compliance with its international commitments. India follows a

¹ *Patents Act 1970, section 87(1)*

consistent practice. The ground upon which compulsory license was granted in Bayer's case hold good even for BMS case. The grant of compulsory license is not inconsistent with the incentive provided to the patentees. The reason for it is that compulsory license can be obtained only after expiration of 3 years of grant of patent. One of the basic jurisprudence governing the subject of IPRs lies in balancing the conflicting interest of patentee's exclusive rights and benefitting public from the invention.

Conclusion

Compulsory license plays a vital role where there are certain patented inventions that are important in health and well being of the community. The license is granted only when certain conditions are satisfied, which is provided under the Indian patent Act. The Act also provides about the revocation of the compulsory license when the subjected invention is not worked in a proper manner within sufficient time period. In such cases the granted compulsory license can be revoked. Compulsory licenses can be used to decrease the burden of cost of the production, and reduce the barriers to innovation, and ultimately providing greater access to these tools for public at large.

Compulsory license in India is still an emerging concept and it exists in the Indian patent laws. Compulsory licenses of patented invention grants exclusive rights to the applicant but such rights are granted only in certain situations. The concept is still growing and till now only one compulsory license is being granted by the India. With the development some changes always occurs and hence let's hope that the compulsory

license always works in a positive manner in India and thereby the IP remains protected.