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INVITED ARTICLE

COMPULSORY LICENSE IN LIGHT OF INDIAN PATENT PERSPECTIVE

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Abstract

The compulsory license is defined as an involuntary license between a willing licensee and an unwilling licensor, imposed and enforced by the controller of patents. Compulsory license is a very effective legal tool which can allow the third parties to produce and manufacture the intellectually protected product or process at reasonable cheaper price. Till date, healthcare or pharmaceutical sector is the only sector of interest for the compulsory. Very recently India has also joined the list of such countries after the grant of first compulsory license to M/s Natco for producing Nexavar® (Sorafenib Tosylate) which is patented by M/s Bayer. The very main purpose of the compulsory license is to prevent the patentee from abusing intellectual right and to rectify the unfair trade practice and to consider the easy availability of the basic health need of the society at reasonable affordable price. Department of Industrial Policy and Promotion (DIPP) initiated the thought process of issuing compulsory licenses for Herceptin® (Trastuzumab) which is used in the treatment of breast cancer, Ixempora® (Ixabepilone) which is used in treatment of chemotherapy and Sprycel® (Dasatinib) which is used in treatment of leukemia. The present review gives an overview about the compulsory licensing aspects pertaining to India.

Keywords: *Compulsory license, Indian Patent Act, Natco vs. Bayer*

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Introduction

Compulsory license is a self-explaining word meaning a license agreement under any compulsion and not by willingness. The compulsory license can be better defined as an involuntary license between a willing licensee and an unwilling licensor, imposed and enforced by the controller of patents. Compulsory license is a very effective legal tool which can allow the third parties to produce and manufacture the intellectually protected product or process at reasonable cheaper price and at a constant sufficient quantity through license so that the society does not remain deprived from any product or have to pay very high amount for the same.

The compulsory license were introduced and implemented by many international arrangements like WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) and World Intellectual Property Organization (WIPO) [1].

Compulsory license and Pharma sector

Till date, healthcare or pharmaceutical sector is the only sector of interest for the compulsory license or in other words, it is the only sector which has the requirement of compulsory licensing.

As per the survey, during 2001 to 2007, nearly 52 developing and least developing countries have allowed compulsory license for anti-cancer and anti-HIV drugs which are otherwise priced very high by the innovator due to patent protection [2]. Very recently India has also joined the list of such countries after the grant of first compulsory license to Natco for producing Nexavar® (Sorafenib Tosylate) which is patented by Bayer [3].

When we talk about pharmaceutical industry, we cannot forget India as India is one of the largest supplier of pharmaceutical products all over the globe and majority of Indian pharmaceutical organizations are involved in the generic drugs and Indian Patent Act which includes the statutory provision of compulsory license.

Compulsory license provisions in Indian Patent Act

As per Indian Patent Act, compulsory license related provisions are covered under section 84 to section 94.3 [4].

Section 84(1) says at any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory license on patent on any of the following grounds, namely:

(a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or

(b) that the patented invention is not available to the public at a reasonably affordable price, or

(c) that the patented invention is not worked in the territory of India.

It is crystal clear from above clause that a very first requirement is expiration of three years after the grant of patent. The reason

behind it may be to give respect to the invention and exclusive right to patentee to get benefit from the exclusive right till three years from the grant of patent.

Secondly, the third party seeking for compulsory license can apply for a compulsory license showing fulfillment of any of the above three criteria along with the proper justification and proof to support the argument. However while considering any application for compulsory license, the controller will look in to many other factors too, like the ability and capacity of the applicant to work for the invention in public benefit at reasonable price and also whether the applicant has made an efforts to obtain a license from the patentee on reasonable terms and conditions and such efforts have not been successful within a reasonable period of at least as six months.

As per section 92, if the Central Government is satisfied, in respect of any patent in force in circumstances of national emergency or in circumstances of extreme urgency or in case of public non-commercial use, it gives notification in the official gazette and subsequently on receipt of the application, compulsory license is granted as per the terms and conditions as the controller thinks fit.

In Indian patent act, there is one more special provision under Section 92-A, which is meant for the compulsory license for export of patented pharmaceutical products in certain exceptional circumstances. In this case the compulsory license can be granted to manufacture any patented product and process in India with condition that such products is to be exported to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problem provided compulsory license has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India.

The very main purpose of the compulsory license is to prevent the patentee from abusing intellectual right and to rectify the unfair trade practice and to consider the easy availability of the basic health need of the society at reasonable affordable price.

Indian patent act has inserted certain check point to prevent abuse of this provision by the third party by way of possibility of revision of terms and condition of license and revocation of license. The controller can revise the terms and condition after receipt of an application by any party after one year of grant of license based on reevaluation of the factors considered at the time of granting compulsory license. The controller can also revoke granted compulsory license on receipt of an application any time after two years from the grant of license by patentee on the ground that the patented invention has not been worked in the territory of India or that reasonable requirements of the public with respect to the patented invention has not been satisfied or that the patented invention is not available to the public at a reasonably affordable price.

First compulsory license of Indian patent scenario since 1970: M/s Natco Vs M/s Bayer: M/s Bayer is patentee holding compound patent IN215758 which covers the Sorafenib Tosylate which is marketed as Nexavar® for the treatment of hepatocellular carcinoma and renal cell carcinoma. M/s. Natco applied for compulsory license of IN215758. Natco has argued that a) drug was not easily available to the public based on the Form-27 filed by M/s Bayer in year 2009 and 2010 b) M/s Bayer was selling Nexavar® at a price of INR 2,80,000 per month in India.

After reviewing the application for compulsory license from M/s Natco in light of the evidence provided and justifications, the controller has finally granted the first compulsory license of Indian patent history in March 2012 based on terms and condition from which few are listed here [5].

- The price of the licensee shall not exceed Rs.8880 for a pack of 120 tablets.
- The licensee shall manufacture the drug at his own manufacturing facility and shall not outsource the production.
- The license is non-exclusive and non-assignable.
- The licensee shall pay royalty at the rate of 6% (Later revised to for 7% by IPAB) of the net sales of the drug on a quarterly basis.
- The licensee shall supply the drug covered by the Patent to at least 600 needy and deserving patients per year free of cost.
- The licensee is solely and exclusively responsible for its product and for all associated product liability.

The decision of granting the compulsory license was welcomed by Indian generic pharmaceutical industry as one of the approach to cope up the patent related hurdles but they have to move over with caution and as per statutory requirement laid down in legislation. If not, the road will end with dead end.

Earlier in January 2013, Department of Industrial Policy and Promotion (DIPP) has initiated the thought process of issuing compulsory licenses for Herceptin® (Trastuzumab) which is used in the treatment of breast cancer, Ixempora® (Ixabepilone) which is used in treatment of chemotherapy and Sprycel® (Dasatinib) which is used in treatment of leukaemia [6]. However as per the recent development in this matter, the approval was given only to Sprycel® (Dasatinib) and remaining two drugs are either under discussion or rejected for time being form the consideration of compulsory license.

Interestingly M/s BDR Pharma, a Mumbai based pharmaceutical company had applied for compulsory license for Sprycel® (Dasatinib) in March 2013 before the thought process of DIPP. More interestingly the compulsory license application of M/s BDR Pharma has been

rejected by the Controller General and provided the statement that M/s BDR Pharma was not successful to establish the "prima facie" case in support of their application for compulsory license [7]. As discussed above regarding provision of compulsory license, the controller also considers the reasonable efforts made by the applicant to obtain voluntary license from the patentee and in case of M/s BDR Pharma, the failure to establish this, was one of the ground reasons for rejection.

Future prospective

Either failure or success, it is a good move by Indian generic pharmaceutical companies approaching for compulsory license and contributing towards the corporate social responsibility in one or other way. The effective use of the provision of compulsory license can reduce the cost of healthcare products protected by patent up to affordability of the public at large for developing and least developed countries. Compulsory license application filed by M/s BDR Pharma is a good example for big Indian generic companies to think in this direction and target all anti-cancer and anti-HIV drugs which are available at a very high cost by patentee.

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