



## RIGHTS OF PATENTEE: STUDY OF REVOCATION OF PATENT AND COMPULSORY LICENSE \*

### INTRODUCTION

To define a patent, very basically it means a statutory right which confers certain exclusive rights on the grantee for an invention, for a definite period, subject to certain conditions. Such conditions are enumerated under Section 47 of The Patents Act, 1970. This grant of patent gives the patentee the exclusive right to use the patented article or process. He has the monopoly over it and as a result, he can prevent all others from using that patented article or process. Under this statutory right, the patentee also has the right to assign the patent or grant licenses under it or otherwise deal with it in any manner for consideration.

### ABUSE OF PATENT RIGHTS AND REMEDIES:

There is a common legal latin maxim “*Ubi Jus Ibi Remedium*” meaning that “Where there is a right, there is a remedy.” Now where statutory rights are granted for patent protection, it is very clear that in case of abuse of such patent rights, there must be an appropriate remedy. Abuse of such monopoly rights is a common phenomenon in all countries which may occur by various ways like meeting the demand for the patented articles solely from importation and not by producing the goods locally thereby discouraging the local trade and establishment of new trade or industry, or by refusing to grant licenses for working of the patent on a local level, or by imposing unreasonable terms and conditions on the licensees thereby discouraging voluntary licensing, or also by imposing unreasonable conditions on the use, sale or lease of the patented articles so as to enable the patentee to use the patent rights and have monopoly over it even after the patent has expired. The general principles of working of patented invention have been laid down under *Section 83 of The Patents Act, 1970*. The provision clarifies the very purpose of granting patent to a person being encouragement of more inventions and its working in a commercial scale and not merely granting monopoly rights for the same to the patentees. The purpose of granting such patent rights is not in any way to restrain trade practices and also the provision checks that such

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rights are not misused by the patentee causing disadvantage to other producers and the ones who voluntary licensing for such patented articles or processes. However, there are statutory remedies for such abuse of patent rights:

1. Providing a system of compulsory licensing by the controller under certain specified circumstances.
2. Revocation of the patent for non-working.

The paper discusses the two remedies in detail.

## **COMPULSORY LICENSES**

In simple terms, when a government allows someone else to produce the patented product or process without the consent of the patent owner, it is known as compulsory licensing which is one of the flexibilities on patent protection included in the WTO's agreement on intellectual property — the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement.

The Patent Act ensures that the protection of public health and nutrition is not impeded by the patents and that the patent rights are not abused in any manner. The grant of compulsory license therefore balances between the two objectives: First, appreciating patentees for their invention of the patented articles and rewarding them and second, making these patented products available to a larger mass at an affordable price in developing and under developed countries.

The statutory right is conferred from the provision of *Section 84 of the Patents Act* which deals with grant of compulsory license due to “Non-Working /Unaffordable Pprices of Patented Article”.

Under the provision, compulsory licenses are granted by the Controller to an interested person so as to:

- a. Prevent the abuse of the patent as a monopoly granted to the patentee;
- b. Enable an interested person for commercial exploitation of the patented invention ; and
- c. Address the public health concern in India and take measures to improve it.

Section 83 lays down the grounds under which compulsory licenses may be granted. Any person interested or already the holder of the license under the patent can make request to the Controller for grant of Compulsory license on patent after three years from the “date of grant” of that patent on the grounds<sup>1</sup> dealt under Section 83. These are:

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<sup>1</sup> For parallel provisions see S. 37(2) of the U.K Act of 1949, S.22 of the Indian Act of 1911 and S. 27(2) of the U.K Act of 1907.

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

The Controller while granting a license, checks the fulfilment of these two general purposes:

- i. Patented inventions are worked in India on a commercial scale without any undue delay and to the fullest extent that is reasonably practicable.
- ii. The interests of any person for the time being working on inventions in India are not unfairly prejudiced.

The Controller's duty is also of an impartial nature while granting a compulsory license. There are few factors which are to be considered by him while granting license laid down under Section 84(6) of the Patents Act. The Controller has to check the nature of invention as to how complex it is, it has to check the time which has elapsed since the grant of the patent to the patentee. Also, the Controller needs to look into the ability of the applicant to put the invention for the use and advantage of the public. He also needs to see if any measures are already taken by the patentees or any licensee to use the invention that has been granted patent.

### **FIRST COMPULSORY LICENSE OF PATENT GRANTED BY INDIA**

The first compulsory license was granted by the patent office of India on March 9, 2012 to Natco Pharma Ltd. for producing the generic version of Bayer Corporation's patented medicine Nexavar (sorafenib tosylate), which is used for Liver and Kidney cancer's treatment.

#### **Brief background of the case:**

Natco was the first company to get a compulsory licence in India, in 2012 to manufacture and sell the blockbuster drug Nexavar. Though Bayer approached the Intellectual Property Appellate Board against the decision of the Controller General of Patents, but didn't get an order in its favour. The appellate body had said a stay on the patent office's decision saying that it would "jeopardise the interest of the public who need the drug" that Bayer claims improves the quality of life of the persons in need. The High court did not interfere with the decision.

On an ultimate appeal in the Supreme Court, Bayer claimed that the compulsory licensing was violative of its intellectual property and had sought redress in the top court.

The issues before the court were:

- a. Voluntary License
- b. Reasonable **Requirements of Public**
- c. Reasonably Affordable Price

#### d. Not Worked in the Territory of India

Although Bayer tried to argue that there was a substantial question of law involved, the top court dismissed its appeal as it was without any merits in its view. The Health activists said it was an important development as this may be the first case in the developing world wherein a compulsory licence was granted by a quasi-judicial body and not overturned by a top court.

Decision of the patent office had created a furore across multinational drug makers. This decision, according to them, would result in compulsory licensing weakening patents and discourage pharma companies from investing in drug discovery and invention. Another European major, Novartis, faced a setback in India when the Supreme Court rejected the Swiss company's plea to keep patent on its cancer drug Glivec. The order given in the case of the Bayer may raise serious concerns to patent holders, especially of drugs and pharmaceuticals as striking a balance between the rights of the patent holder and the users of the patented product is always difficult and it is all the more difficult in the case of drugs wherein a humanitarian approach prevails over commercial taking. However it may be too early to come to such conclusion since this is the first ever compulsory license and also considering the specific facts of the case.

There also exists a provision for grant of compulsory licenses on notification by Central Government under Section 92 of The Patents Act. It says that in circumstances of national emergency, or of extreme urgency or in the case of public non-commercial use, the grant of compulsory license in respect of any patented invention may become necessary. Under such situation, the Central Government may make a declaration to that effect by notification in the official gazette. The Controller then, on application made by any interested person, grant to the applicant a licence under the patent on terms and conditions that he may think fit for the particular case. The Controller while determining such terms and conditions, must check that the products manufactured under that patent must be available to the public at the lowest prices consistent with the patentee deriving a reasonable advantage from their patent rights.

### **REVOCAION OF PATENT**

Revocation of Patent is another remedy for the misuse of patent. Herein, the Controller can make an order to revoke a patent for non-working or if the reasonable requirements of the public are still not met after the grant of compulsory license. The statutory power is derived from the provision of Section 85 of the Patents Act which says that where, in respect of a patent, a compulsory license has been granted, the Central Government or any person interested may after the expiration of two years from the date of the order granting the first compulsory license, apply to the Controller for an order revoking the patent 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. Also, it is important to note that such an application for revocation of patent should be decided within one year by the Controller.

Now a question might arise as to what is meant by the term “working”. Though the term has not been defined under the Act, however, Section 83 (a), 83 (b) and Section 85 (7) (e) refer to working of patent in India, and are helpful in the interpretation of the term “working”.

The provision of Section 83 provides the general principles in India which are applicable to the working of patented inventions. A parallel can be drawn to this provision by Article 7 and 8 of the TRIPS agreement which are akin to it. Section 83 (a) states that the patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay. Section 83 (b) further, clearly states that the patents are not granted merely to enable the patentees or patent licensees to enjoy the monopoly for importation of the patented article. Section 83 (c) and Section 83 (f) also talk about promotion of technology innovation, technology transfer and prevention of abuse of patent rights to unreasonably restrain international transfer of technology. The interesting point here is that Section 83 of the Act is merely a guiding principle and is not binding. However, this provision is helpful interpretation of local working requirement under the Patent Act of India.

Section 85 (7) (d) on the other hand, states that reasonable requirements of the public are deemed to have not been met when the patented invention is not worked in the territory of India on a commercial scale to an adequate extent as is reasonably practicable. Further, Section 85 (7) (e) states that the reasonable requirement of the public are deemed to have not been met if the working of the patented invention in the territory of India on a commercial scale is being prevented or hindered by the importation of the patented article by the patentee or patent licensees from abroad. The point here that calls for attention is that this provision does not bar importation of patented article as to constitute the working of patent in India, however gives directions for situations where such importation results in preventing or hindering the working of the product within India. In such circumstances, it would be deemed that reasonable requirement of public is not met, which is again a separate ground for grant of compulsory license being another remedy.

The conditions necessary for revocation of patent are following:

- a. A compulsory license has been granted in respect of the patent.
- b. Two years have passed since the date of ordering the first compulsory license.

- c. In spite of the compulsory license or licenses being granted, the patented invention has not been worked in India or that reasonable requirements of public in respect of the patented invention has not been satisfied, or that the patented invention is not available to the public at a reasonably affordable price.

Upon satisfaction of the above conditions by the Central Government or nay other interested person may make an application to the Controller for an order of revocation of the patent in question.

## **CONCLUSION**

It is clear that there have been rights given to persons for invention of articles or processes called Patent Rights. These rights do encourage the general public to come up with more inventions which are for the advancement of the benefit of the general public. Such inventions are also necessary for under developed countries and developing countries because a country cannot develop nor its people, if the developing processes are stagnant and are not seeing any growth in them. However, where rights have been granted and monopoly power has been given to the patentee or a certain period, it is quite obvious that such powers can be misused or abused. However, the good part is that for prevention of such misuse and abuse, there lies remedies which have been granted statutory backing. The two being compulsory license and revocation of patent for non-working. It prevents the patentees from having monopoly over the inventions and the processes for a period extending the usual period granted by the Patent. It gives chances to other interested people if they want to have licenses for such patented articles in lieu of some benefits to the original patentee. As India is a developing country, it is looking forward for more such patents as India is rich in its culture and traditions which are also responsible for traditional medicines and treatments which are yet to be uncovered and unrevealed.

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