Compulsory Licensing under Indian Patents Act

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ABSTRACT
Patents in India are granted for encouraging the inventions on a commercial scale. Patent Act by way of inserting the provision of compulsory licensing contemplated that the patents do not obstruct the protection of public health and nutrition. Thus, the compulsory licensing serves in two ways—firstly by giving pleasure to the patentees for their invention by way of royalty and secondly, by making the patented products available to the public at a large at an affordable and cheaper cost.

In the present paper, the author highlighted the process of granting compulsory licenses as per the Patents Act, 1970. Simultaneously, the emphasis has been given on the compulsory licensing in the pharmaceutical products in India along with a few suggestions.

Key Terms: Patent, Patentee, Compulsory Licensing, TRIPS Agreement, Controller

INTRODUCTION
A compulsory license is that license which statutorily allows third parties to use or manufacture that product without the permission of the patent owner (patentee) and in exchange specified royalty is granted to the later i.e. patent owner. Compulsory licensing provision is an outcome of patent rights and it is a remedial measure for it. In other words, it is a grant of Intellectual Property license by the administrative procedures managed by the Government of India without the consent of the owner of the intellectual property for the wide utilization of the protected right.

Historical Background
In 1624, United Kingdom first time recognized compulsory licensing for the prevention of patents for not being worked commercially.

TRIPS Agreement
The Trade-Related Aspects of Intellectual Property Rights that are negotiated by the World Trade Organization (WTO) members are called as the TRIPS agreement. This agreement made mandatory for all member states to put into practice the legislation to protect the intellectual property of the corporate sector in the respective states. TRIPS agreement also provides an effective system for the resolution of Intellectual Property related disputes among members state systematically.

The most controversial aspect of the TRIPS agreement is the protection of pharmaceutical products. Article 27 of the TRIPS agreement relates to the patentable subject matter. To overcome the state health crisis, through DOHA declaration, TRIPS agreement provides a provision for the WTO state members to use the compulsory licensing provision to balance the immediate public health needs of the society and the long term incentives to innovators.

The Doha declaration provisions of compulsory licensing in respect of public health have given the solution to save lives and protect public health. Doha Declaration states:

"The TRIPS Agreement does not prevent member states from taking measures for the protection of public health. While making adherence to the TRIPS Agreement, it is guaranteed that the Agreement should be clear in a manner encouraging of WTO members’ right to protect public health and also to raise access to medicines for the
public at large. Each member state has the right to grant compulsory licenses and the freedom to set the grounds upon which such licenses are granted.

Article 31 of the TRIPS Agreement also provides that in case of “national emergency” or “extreme urgency”, after due process requirements are fulfilled, a “Non-Voluntary” license may be granted to the domestic producers without authorization of its right holder. Similarly, Article 31 restricts the rights for domestic use only i.e. its use on the local level only. Though there is provision for compulsory licensing under Article 31 of the TRIPS agreement, the states which don’t have technical experts cannot address public health emergency related issues.

Paris convention also gives the right to each member state to define what is a national emergency or extreme urgency?

**TRIPS Agreement and India**

In April 1995, India became a party to the TRIPS Agreement. The Patent Act of 1970 was in violation with Article 27 of the TRIPS Agreement. Hence, India needed to make some amendments in its IPR laws compliant with this Agreement.

As India is a member to TRIPS Agreement, it can grant CL under certain circumstances such as health crisis, national emergency, extreme urgency to ensure access to affordable products.

**Abuse of Patent Rights and Grant of Compulsory License?**

Whether it is an invention of a product or a process, Patent is an inventor’s exclusive right and it is granted for the specific/limited period to the inventor.

The abuse of patent rights is very common everywhere throughout the world. It can be seen in the following forms.

- The demand for the patented articles is fulfilled by importing it abroad only and not by manufacturing it at the local level and thus discouraging the new trade or development in the existing trade.
- Licenses are refused to work on the local level.
- Restrictive conditions are imposed on the use, sale or lease of the patented article and therefore, patent monopoly rights are prolonged even after the expiry of the patent.

In patent law, there is a remedy to grant compulsory licenses by the statutory body and also to revoke the patent for non-working of it.

Thus, compulsory licensing is that measure of Patent Act which ensures that patentee will not misuse his/her rights. In simple words, it is a license allotted to a third party for manufacture, use or sale of the product or makes the use of a process which provides the new ideas to do something without the permission of the owner of the patent. This measure is applied for the purpose of public health or national emergency or extreme urgency or health crises only. As the compulsory license works against the patentee i.e. owner of the patent, certain conditions are imposed by the government that is to be fulfilled by the party to whom the compulsory license will be granted.

For example, if patented drug is available at very high cost and it is not affordable to the poor people of the society to buy and use it, then the Government of India can issue a compulsory license to the third party i.e. other pharmaceutical company to make the same drug available to the poor at a low rate. The intent behind this is to make the drug available to the society at large at a cheap price.

**Principles Applicable To Working of Patented Inventions**

According to Section 83 of Indian Patents act, 1970, the following are general principles such as:

- The patents are granted for encouraging the invention and also to ensure that they are worked in whole India on a commercial basis and is used to its fullest extent.
- That patents are not granted to the patentee merely to enjoy a monopoly for importing the patented article.
- The Patents granted should act for public interest only and it is not granted for impeding public health.
- Patents granted in any way do not prohibit the Government machinery in taking steps/actions to protect public health.
- The patentee would not abuse the patent right.
- Patents are granted to make them available at a reasonable and affordable price to the general public.

**Procedure to apply for Compulsory License in India**

After the completion of the period of three years from the date of grant of a patent, any interested person can apply for a Compulsory License in Indian Patent office. S.84 of Patent Act, 1970 enunciates that any interested person may apply to the controller alleging that,

- The patented invention is not fulfilling the reasonable requirements of the public.
- The patented invention is not available to the public at large, it is not used in the whole territory of India and also not available at the affordable prices.

The following are the aspects that the controller takes into consideration while granting the compulsory license.

- Nature/Type of an invention.
- The time period has elapsed from the grant of the patent.
- To make full use of the invention the measures that patentee or licensee has taken.
- Whether the applicant is having enough capacity to invest money for working of the invention and also whether he can use the patented invention for the use of the public at large. The controller then makes a review of the applications and on the satisfaction that a prima facie case is made out, then the applicant will be directed to fulfill the requirement needed to grant the Compulsory License. A copy of the application will be also be sent to the patentee or other persons having an interest in the patent. Similarly, the application for the compulsory license will be published in the official gazette of the patent office.

The patentee or any other interested person may file a notice of opposition to oppose the application for compulsory license within the period of two months of publication of notice in the official gazette. The notice of opposition must state the reasons for opposition, the terms, and conditions that would be acceptable to the person opposing the application and any important evidence supporting the opposition. A copy of the notice of opposition is also sent to the applicant of the compulsory license. Then hearing of both parties will be conducted. After hearing the controller will make the decision whether the compulsory license is to be granted or not.
After the decision of the controller to grant a compulsory license, the terms and conditions of the CL will be determined.

**Compulsory Licenses and National Emergency**

S. 92 of the Patent Act, 1970 enunciates that the central government may grant CL in the following cases:

- In the case of National emergency including issues of public health.
- In the case of Extreme Urgency
- In the case of public non-commercial use of patent

The Central Government can publish the notice of the grant of CL in the official gazette stating the situation of national emergency, extreme urgency. After the publication of the notice, the CL will be granted by the controller to the person who applied for such a license. The CL once granted under S.92 cannot be challenged by the patentee by opposition or through the court. But, it is mandatory to notify the patentee about the grant of CL by the controller.

**License Revision and Termination**

The licensee of a compulsory license may revise his license by making an application after a period of twelve months of his use of the invention on a commercial scale. The application has to contain evidence and facts supporting the application, relief or remedy sought by the licensee. A hearing may be requested by the license holder. The controller will review the application and after the hearing, the application may be granted or denied. After the grant of the application, the controller will revise the terms and conditions of the compulsory license.

A compulsory license can be terminated by the controller if the terms and conditions under which the license was granted do not exist.

**Case Study on Compulsory License**

Since long, India and its IP policies have been the target of allegations about granting the “Compulsory License”. However, India’s stand has been appearing in a delicate or graceful way. The Natco V. Bayer case is one of the most famous cases in relation to Compulsory Licensing for the grant of the first compulsory license in the world after the TRIPS agreement. The patent office of India on 9th March 2012 granted its first compulsory license to Natco Pharma Ltd for the purpose of producing a generic version (generic drug) of Bayer’s Corporation’s Patented drug “Nexavar” which is useful for the cure of kidney and liver cancer. Bayer Corporation was selling the drug Nexavar at a very high price i.e. 2.80 lakhs for the medicine required for one month. Natco applied for CL and assured that it will sell the same medicine to the public at large only at 3% of the price that is near about Rs. 8400/- of the price charged by Bayer Corporation.

As per the Patents Act, all the three mandatory grounds were taken into consideration by the Controller for deciding the application for issuing CL against the Bayer. These are as follow:

- Unsatisfied Public requirements which are reasonable
- The drug is not made available to the general public at affordable, reasonable price
- The patented invention is not being used in the Indian Territory. In this case, the controller directed Natco Pharma Ltd to pay 6% of the net sale to Bayer as royalty. Simultaneously, Natco Pharma Ltd was also directed to sell the drug within the Indian territory and also to supply the drug-free of cost per year to at least 600 deserving patients.

By the Controller’s decision, Bayer became aggrieved and hence he moved to the Intellectual Property Appellate Board (IPAB) alleging that the grant of CL against him was illegal and not able to be upheld. But this plea of Bayer rejected by the Intellectual Property Appellate Board claiming that it would suppress and jeopardize the interest of the public and patients suffering from the disease. It was also held that it is an honour for the public to get the drug at a cheaper rate.

Chief of Intellectual Property Appellate Board, Prabha Sridavan on 04/03/2013, the given order in an open court and upheld the decision of Controller for grant of CL on Bayer’s patented drug, namely Sorafenib Tosylate 12.

Under Section 84 of the Patents Act, 1970 as on today only one compulsory license has been granted by the Controller of Patents on 9-3-2012 to M/s. NATCO Pharma, Hyderabad for Indian Patent No. 215758 (Carboxyaryl substituted diphenyl ureas). This patent was initially granted to M/s. Bayer Corporation on 03-03-2008 for the drug “Sorafenib Tosylate” for the treatment of kidney and liver cancer. As per the information given by C. R. Chaudhary, the Minister of State Commerce and Industry, in a written reply in the Lok Sabha, there is no specific proposal pending at present before the Government for the grant of a compulsory license.

Since the grant of the first CL, not a single more CL has been granted. Unexpectedly only 3 more claims for issuance of compulsory license have been made in India since the Bayer case as follows 12.

**Claim 1:** In the case of Emcure Pharmaceuticals V. Roche, the first claim was made for Roche’s Drug “Trastuzumab” which was commonly known as Herceptin. The application was made under section 92 of the Patents Act, which allows the government to grant the license in case of a national emergency. However, the Ministry of Health was denied by the Department of Industrial Policy and Promotion for further actions in this application.

**Claim 2:** In the case of BDR Pharma and Bristol Myers Squibb (BMS), BDR Pharma in March 2013 filed an application for a grant of a Compulsory License for the anti-cancer drug of Bristol Myer “Dastanib”. On 29th October 2013, the Controller rejected the application of BDR Pharma on the grounds that no prima facie case is made out by BDR Pharma for the grant of a compulsory license, and also BDR Pharma failed to make efforts to obtain a voluntary license from Bristol Myers Squibb on reasonable terms and conditions.

**Claim 3:** In the case of Lee Pharma V. AstraZeneca, Lee Pharma, a Hyderabad-based Drug manufacturing company, on 29th June 2015, filed a CL application under Section 84(1) of the Indian Patents Act. The CL application was made against the drug “Saxagliptin” which is used for the diabetes treatment. The Patent was granted on 30th April 2007 to Bristol Myers Squibb comp. Which was assigned to AstraZeneca. Lee Pharma alleged in the claim that AstraZeneca is importing the drug “Saxagliptin” at even less than a rupee and charging near about Rs 45 for every tablet, hence it is beyond the reach of most Indian patients. It was also argued that AstraZeneca has not made adequate efforts to make the drug in India which is a breach of patent laws of the country. The Controller held that there is no prima facie case made out u/s 84 of the Patents Act and issued a decision on 12/08/2015 in favor of AstraZeneca 15.
Compulsory License Impedes Patent Innovations: True or False?

There are various arguments that the new patent innovations are getting impeded because of the grant of compulsory licenses. The information stated in the below-mentioned table indicates the number of applications filed in the patent domain of different sectors with respect to the corresponding year.

<table>
<thead>
<tr>
<th>Year</th>
<th>Drug/Pharma Sector</th>
<th>Electrical Sector</th>
<th>Computer or Electronics Sector</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009-2010</td>
<td>3070</td>
<td>2736</td>
<td>7646</td>
</tr>
<tr>
<td>2010-2011</td>
<td>3526</td>
<td>2719</td>
<td>9594</td>
</tr>
<tr>
<td>2011-2012</td>
<td>2726</td>
<td>4160</td>
<td>4225</td>
</tr>
<tr>
<td>2012-2013</td>
<td>2954</td>
<td>3568</td>
<td>4424</td>
</tr>
<tr>
<td>2013-2014</td>
<td>2507</td>
<td>4371</td>
<td>4410</td>
</tr>
</tbody>
</table>

From the above-mentioned table, it can be seen that though the first compulsory license was granted in the year 2012, in the above-stated sectors, there is no major decrease in filings for patents. The filings made in the case of the computer/electronics sector also showed an increase after the grant of the first CL in the year 2012. Thus, the arguments that compulsory license impedes new patent innovations are thus not supported by substantial facts. However, it is important to note that we cannot presume that there is any drop in filings because of fear of CLs.

From the above table, it is also revealed that despite the complicated and often questioned IP policies of India, there is an increase in the filing of patent applications every year and thus indicates that the state of affairs is not as bad as they understood. So also after meeting the limitations such as skilled human resources, infrastructure, we can expect that Indian Patent office will function at par with USPTO (United Nations Patent Office) or EPO (European Patent Office)\(^4\).

**Suggestions**

The government needs to seriously promote and support the country’s pharmaceutical industry so that it has a world-class standard. There should be consistent efforts of the Government to develop the faith and confidence in locally produced generic drugs among the general public, patients, doctors, and medical personnel. This has proved to be successful in many countries, such as Japan and Canada. Also, there should be campaigns for the application of generic drugs as first priority drugs. Drug-price control mechanism should be created at the national level. At the time of granting a compulsory license, there should be a complete study of the need/ requirement of the drug for whom a CL is to be granted. This study should be conducted by the Government medical sector. Private medical practitioners’ and medical representatives’ advice should also be taken into consideration while granting the compulsory license to an individual.

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