

## Provisions For Compulsory Licensing Under Section 84 Of Indian Patent Act,1970 : An Analysis And Consequences

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### **Abstract-**

Provisions for Compulsory Licensing in India can be said to have been derived from Article 31 of the TRIPS. Chapter XVI of the Patents Act, 1970, deals with the provisions and procedures related to the granting of Compulsory Licenses in India. Section 84 of the Patents Act, 1970 mentions who can apply for a Compulsory License, according to which any interested person including an existing licensee can make an application for the grant to the controller. According to the section 84, the application for the grant of a Compulsory License can be made any time after the expiration of three years from the date of grant of patent, Following conditions shall be fulfilled- (a) The reasonable requirements of the public with respect to the patent invention have not been satisfied(b)The patented invention is not available to the public at a reasonably affordable price(c)The patented invention has not been operational in the territory of India.

Under section 92(1) of Indian Patent Act,1970, 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, that it is necessary that compulsory licenses should be granted at any time after the sealing thereof to work the invention, it may make a declaration to that effect, by notification in the official gazette.

**Keywords:** Compulsory license , National emergency, Article 31 of TRIPS, Indian patent Act,1970

### **1. Introduction-**

Patents are not granted merely to enable patentees to enjoy monopoly rights. Patents granted do not in any way prohibits central government in taking measures to protect public health.

There are several provisions that remedy misuse of patents rights and provide legal framework to the Office of the Controller General of Patents, Designs and Trade Marks generally known as the “Indian Patent Office” to grant a compulsory license to a third party. Under Indian Patent Laws, a compulsory licensing can be granted after 3 years of getting a patent. Moreover, the Indian Patent Office might grant a compulsory license only if the use of the patented product is not satisfying public requirements or the patented product is not accessible to the public at a reasonable price, or the patentee has not worked the patented product in India. In other words, compulsory licenses will only be imposed when an innovation which could be greatly beneficial to the public interest is not being used – or at least not sufficiently – by the patent owner.

The TRIPS Agreement and the national patent legislations around the world which are framed in the light of TRIPS have, therefore laid down obligations along with limitations on the rights of the patentee, if discharged dutifully will balance the conflicting interests involved in the patent system. The monopoly right of the patentee is limited through revocation and compulsory licensing of patent. It is therefore evident that the whole system of patent is grounded on the balance between public benefit and patent monopoly.

**2.Objectives** (i)To critically examine the section 84 of compulsory licensing as enumerated in the Patents Act, 1970.

(ii) To study how far those provisions have succeeded in ensuring reasonable access

to common people in national emergencies or urgencies.

(iii) To critically examine significance of compulsory licensing for India.

### **3.Literature Review**

i) Cícero Gontijo, “Changing The Patent System from the Paris Convention to the TRIPS Agreement:The Position of Brazil” Global Issue Paper No. 26(Dec, 2005), Translated by Andrea CarinaCeschi;UNCTAD-ICTSD, Resource Book on TRIPS and Development 462 (Cambridge, New York, 2005).

The 1883 Paris Convention first accepted CL on the grounds of failure to work.

ii) Hamid Beladi and Kwan Choi (eds.), *Frontiers of Economics and Globalization* 440-441 (Elsevier, Netherland, 2007).

The TRIPS Agreement takes into account the need to protect public health over patent owners' private interests.

iii) Justin Malbon and Charles Lawson (eds.), *Interpreting and Implementing the TRIPS Agreement Is it Fair?* 97-132 (Edward Elgar, Cheltenham 2008); Susan K. Sell, *Private Power, Public Law The Globalization of Intellectual Property Rights*, 7-28 (Cambridge, UK, 2003).

In 1994, the WTO adopted the TRIPS Agreement, which determined how the protection of intellectual property should be governed.

iv) WIPO, *Intellectual Property Handbook: Policy, Law and Use*, 35 (WIPO, Geneva, 2001)

Nevertheless, the grounds for granting CL has not been stated in the TRIPS Agreement.

v) Article 7, TRIPS Agreement reads as: "The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."

vi) Article 8, TRIPS Agreement reads as: "Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement; Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be need to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology."

vii) Article 6, TRIPS Agreement reads as: "For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights." Certain relevant TRIPS provision in Article 6 for the proper implementation of public health-related policies.

viii)Shubhra Khanna, "TRIPS, Pharmaceutical Patents and Health Care for the Poor in India", *ILI L Rev.*71(2016); A. Bagchi, "Compulsory Licensing and the Duty of Good Faith in TRIPS" *55 SLR* 1529 (2003).

It usually depends on market conditions and how CL is combined with other considerations in domestic legislation. In fact, CL has a significant impact on human security and the right to health services.

ix)Aaditya Mattoo and Robert M. Stern (eds.), *India and The WTO* 367(Oxford, Washington, 2003);Amanpreet Kaur and Rekha Chaturvedi, *Supra* note 8; Amrita Narlikar, *The World Trade Organization: A Very Short Introduction* 22-41(Oxford, New York, 2005)

India is one of the signatories to the TRIPS Agreement.

x)S Srinivasan, "The Compulsory Licence forNexavar A Landmark Order" *27(14) EPW* 10-13(2012)

Interpretations by judicial authorities like in Natco –Bayer case and Lee Pharma case.

#### **4.Discussions and Conclusion.**

The welfare of people or the public is the paramount law. Through the systematic analysis of patent law and practice relating to intellectual property rights it can well be established that the concept of compulsory licensing revolves around the societal obligations associated to any intellectual property rights.

As per patent Act,1970,compulsory licensing under section 84,any interested person may make an application to the controller for grant of compulsory license for patented product or process by using Form-17 of the Act. Moreover, there is also provision of termination of compulsory License.

Governments have devised several limitations and exceptions including compulsory licenses to restrict intellectual property rights in national interest and general public interest or in case of misuse or abuse of rights. The Indian Patents and Design Act 1911 provided for product patent resulting in high cost of innovative technologies and unaffordable for Indian population and obstruction to reverse engineering. After independence and based on the recommendation of several committees Indian enacted its own patent law in 1970 which recognized only process patents for pharmaceuticals, foods and chemicals removing the hurdles for reverse engineering and helped to cater basic needs of Indian populace. Taking benefit of this provision India developed its industrial base. India achieved considerable development only

within few decades of its independence due to its development policies including limitations to IP rights.

Even the Berne Convention was not liberal towards the developing economies and provided only little flexibility in the nature of foreign vessel exemption and compulsory working requirements. Further it imposed too many restrictions for using these limitations and almost restricted the grant of patents for non-working by providing that importation would amount to working. It was only in 1925 that provision of compulsory licenses for non working domestically was included through amendment. Thus, the Berne Convention also ignored the legitimate needs of the developing countries. But as it lacked any effective sanction and was silent as to few points. Thus, according enough discretion to Members of Union to formulate their domestic IP legislations. Similarly, the Berne Convention was drafted, created and established by developed countries. without taking into notice the needs and situations of the developing nations. Due to this the Convention lacked voice of developing countries and their specific concerns. It was only in 1967, that the Berne Convention was revised after a long struggle to incorporate the demands of developing nations. Paris Convention and Universal Copyright Convention also recognized compulsory licenses respectively for patents and copyright with sufficient liberty to developing nations. Almost things were manageable till the last decade of 20th Century in internationally and in India. India witnessed multiple changes in its economic and trade policies in last decade of 20th Century. In 1991 India was struggling internally due to huge economic crisis and externally to secure interests of developing nations in GATT negotiations.

India's first ever compulsory license was granted by the patent office on March 9, 2012, to Hyderabad based Natco pharma to produce a generic version of Bayer's nexavar, an anti cancer agent used in the treatment of liver and kidney cancer.

Even as per the international obligation by India under the TRIPS Agreement, compulsory licenses are authorized as seen from Article 31 of this Treaty.

There is need of more mindful and social use of patents. It is not trade related issue but it is a constitutional, jurisprudential and policy based concern for all developing countries. There is need that government shall ensure a research friendly environment through funding and subsidies for compulsory licensing. Protection of monetary interest of patentee can be addressed by fixing a consolidated amount to be paid and payment as per case to case.

#### **5.Suggestions(Way Forward)**

a) India should demand for amendment of provisions providing equal protection for all categories of inventions. As every invention

does not have same shelf life so why to grant them equal protection. Thus, equal patent protection should be ended.

b) Criteria of affordability as per income strata, adherence to social responsibility by patentee for viability and affordability of product, incentivizing mechanism by government will lead to better use of patent licensing provisions.

c) Any act of licensing and refusal to license shall not be at cost of oversighting public interest and paramount fundamental Rights to health.

d) A transparent policy on expenditure made on research and development in order to bring out new medications should be implemented by the Indian government, so that the requirements for setting a reasonable price may be met.

e) Prior to signing free trade agreements, the Indian government must go through the democratic process, publish the document public, and include representatives from all sections of society in the negotiation process.

f) Judicial activism is the key to give life to the law and therefore impact of judicial interest, interference, initiatives shall result in to effective implementation of licensing provisions.

g) In order to keep track of the growing number of TRIPS-Plus agreements The World Trade Organization (WTO) must consider establishing a body to provide a report on a system to verify agreements that are in conflict with the social welfare requirements of TRIPS and the mission of the Doha Declaration.

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