Current Scenario of Patent Act: Compulsory Licensing

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ABSTRACT

Process of compulsory licensing glared after the Doha declaration. Doha declaration explored the way for compulsory licensing around the globe and also insisted that TRIPS agreement does not and would not prevent any member from taking measure to protect public health. After Doha Declaration many countries aggressively amended their patent regime for purpose of compulsory licensing. Compulsory license can be issued to a generic company on different grounds to fulfill the patient need and to improve quality of life. Before Doha declaration, big pharmaceutical companies are continuously taking the advantages to earn money by sustaining monopoly because of the rigid patent protection. The higher cost of patented molecules had been a major hindrance, limiting its affordability and accessibility to millions of patients mainly for the developing countries. Compulsory licensing had opened the way for the developing countries to fulfill their health's desires at affordable prices. This review article will provide brief insight into the past and present scenario of compulsory licenses issues related to patent around the globe, with special emphasis on India.

Keywords: Compulsory license, Patent, Innovation, Generic drugs, Intellectual property right.

INTRODUCTION

The aim of bringing together the intellectual property rights on a globe scale was succeeded after the agreement on Trade Related Aspects of Intellectual property rights (TRIPS) which was mainly driven by developed countries and accepted by the World Trade Organization in 1994.[1,2] Patent protection acts under TRIPS provided the exclusive right to the research based pharmaceutical or Innovator to sell their medicine without any restriction on the prices to recoup their cost involved into research. Finally, it become the most serious and controversial matter, on one side research based pharmaceutical company arguing for their rights to sell the product at the price what they want, taking into account the high risk as well as high cost of research and development and on the other hand, developing countries arguing for their rights to purchase medicines at lower prices to fulfil their health desire.[2,3]

A new landmark comes into the field of intellectual property right in 14 November 2001, after the declaration on the TRIPS agreement and public health (the Doha Declaration) which confirmed that TRIPS does not and should not prevent members from taking measures to protect public health and that every members are free to determine the grounds upon which compulsory licences can be issued, which can include public health crisis. This Doha declaration broadens and enlightens the compulsory licensing phenomena and facilitates the launch of generic drugs of the patent pharmaceutical to satisfy the public health desires. Doha declaration put emphasis on compulsory licensing to facilitate the use of patent without any authorization from patent holder.

Compulsory licensing is the key process of granting the license to the third party by the government in order to utilize the patent and other form of intellectual property without the consent of patent holder, which allows regulators to break a patent holder's monopoly in situations where the monopoly is abused to deny access to the

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innovation to a very large number of people specially in case of necessary emergencies.[4,5]

COMPULSORY LICENSE AND PATENT ISSUE

Although all the countries legislation contained the clause of compulsory licensing but dimension of issuing this license varies and depends upon the different factors like health status, disease burden and development status and innovation capacity. India is a developing country with a population of more than 1 billion and having low economic status while high disease burden. So, this phenomenon of compulsory licensing is very important with regard to Indian perspective. There are some brief about the India patent act focussing to the compulsory licensing and about some recent cases.

Indian perspective

The Indian Patent Act 1970, amended first in 1999, the second in 2002 and the third in 2005. This third amended Indian patent act 2005 explored the phenomenon of compulsory licensing and make possible for the grant of compulsory license that are contained in the section 84 to 92 of the Indian Patents Act 1970.

Compulsory license can be granted in India at any time after the expiration of three years from the date of the sealing of a patent, any person interested can make an application to the Controller for grant of compulsory licence on patent on any of the following grounds as per section 84(1):-

- If reasonable requirements of the public have not been satisfied
- If the patent invention is not available to the public at an affordable price
- If the patent invention is not worked in the territory of India

A compulsory license may also be granted for:-

- For exports in certain exceptional circumstances (Section 92 A)
- In case of national emergency, extreme urgency of public non-commercial use by notification of the Central Government in the official gazette [Section 92 A]
- To countries having insufficient or no manufacturing capacity in the pharmaceutical sector to address public health problem [Section 92 A (1)].

The first ever compulsory license application made in India was by Natco Pharma for the manufacturing and exportation of Roche's patented anti-cancer drug Erlotinib to Nepal but was resulted as unsuccessful; Natco Pharma filled second application for compulsory license to the Indian patent office for the manufacturing and export of Sunitinib (Sutent) which was also not granted.

First compulsory license

Almost a decade after the doha declaration, finally on 9 march 2012, India granted its first compulsory license to Natco for Bayer's drug Nexaver, after being convinced that all the factors enumerated under section 84 of the Indian patent act were satisfied i.e. reasonable requirements of the public not being met, patentee failed to work the invention within the India, and drug was not available at affordable prices. Now, Indian generic manufacturer Natco is selling Sorafenib tosylate at Rs. 8,800 per month therapy as compare to Nexaver cost of Rs 2.88 lakh per month-resulting in a 97 percent less than to that of Nexaver. Natco is paying the royalties to Bayer on a quarterly basis at the rate of 6 percent of the net sales of the medicine in accordance with remuneration guidelines set forth by the United Nations Development Programme.[5–9]

Recently on January 2013, health ministry of India recommended three anti-cancer drugs-trastuzumab, ixabepilone and dasatinib for compulsory licenses. This will allow the government to produce generic versions of the patented medicines and sell them at affordable price.[10]

Take a look into these recent directives and initiation by the health ministry, it can be concluded that Indian government is considering the patient need on high priority and ready to issue the compulsory licenses for patented molecule if invention is not able to work in India.

Glivec patent case

In India, patent related issues are running since over the past years. Glivec patent case was one of the recent and historic cases in the history of India which forced the other country to think into their patent regime. This was a protracted battle, which was begun from January, 2006 and come into an end on 1 April 2013 with a historic decision and reflected the strong patent act of India. Supreme Court of India denied Novartis' application to patent an updated version of its cancer drug Glivec (Imatinib), stating that the product fails the tests of invention and patentability requirements of India's patent act as per the section 3(d) and section 3 (b) of Indian Patent act. Although, this newer form of Glivec has been patented in nearly 40 countries including the United States, Russia and China but it is not able to satisfy Indian patent act. These two section of Indian patent act section 3(d) (the mere discovery of any new property of new use for a known substance or of the mere use of a known process, machine or apparatus

unless such known process results in a new product or employs at least one new reactant) and section 3(b) (an invention the primary or intended use of which would be contrary to law or morality or injurious to public health) became the reason for which patent was not granted for Glivec drug in India and also these section of patent act became the hurdle for the other big pharmaceutical or MNCs in this current scenario.[11–13]

GLOBAL PERSPECTIVE

This phenomenon of compulsory licensing experienced different view from different part of globe. Mainly developing countries are giving importance to the compulsory licensing because of unavailability and unaffordability of the medicines and they are continuously granting the more and more compulsory licenses. On the other hand developed countries like US, Europe are opposing the compulsory licensing and are putting pressure on developing countries not to issue compulsory license as it would decline the innovation. Different instances of compulsory licenses took place all around the globe within past 12 years after Doha declaration.

Table 1 - showing the instances of compulsory licensing happened all around the globe and grounds on which licenses were issued.[5,14–22]

Recently in 2012, China also had opened the way for generic drugs in the country by making an amendment to its Intellectual property laws in order to allow the government to issue compulsory licenses for local generics makers to produce drugs which are still under patent period. But there has been no real case of compulsory licensing of patent molecule till date from china.[23,24]

IMPACT OF COMPULSORY LICENSING

These are the some major areas which will be affected by compulsory licensing in the coming future:-

1. **Innovation: -** These emerging instances of compulsory licensing around the globe would decline the innovation because it will hamper the desire

Table 1: Compulsory Licensing Instances around the Globe

Country	Year	Key Highlights of Compulsory Licensing	Income Group as per GNI Per capita* (Development status)
Zimbabwe	2003	Issue compulsory license to a local generic company- Varichem Pharmaceutical Co. to produce seven generic versions of first line Anti Retroviral Drugs (ARVs).	Low Income
Malaysia	2004	Issue compulsory license to import generic version of Anti Retroviral Drugs (ARVs) from Cipla (India) for 2 years.	Upper middle Income
Indonesia	2004	Indonesia first issued a presidential decree to use compulsory license for two ARVs – lamivudine and nevirapine.	Lower middle Income
	2012	Indonesia issues compulsory licenses against seven HIVs, Hepatitis drug include efavirenz, abacavir, tenofovir, lopinavir/ritonavir, didanosine, and fixed-dose combinations tenofovir/emtricitabine and tenofovir/emtricitabine/efavirenz citing urgent need to improve patient access.	
Mozambique	2004	Issue compulsory license to Pharco Mozambique Ltd. for HIV/AIDS drugs.	Low Income
Zambia	2004	Issue compulsory license to Pharco Ltd., a local producer, production of triple fixed-dose combination for Anti Retroviral Drugs (ARVs) drug.	Lower middle Income
Ghana	2005	Issue compulsory license for import of generic Anti Retroviral Drugs (ARVs).	Lower middle Income
Eritrea	2005	Issue compulsory license to import generic HIV-AIDS medicine from India.	Low Income
Thailand	2006	Issue compulsory license to import generic and locally produce Efavirenz from India.	Lower middle Income
	2007	Issue compulsory license to the heart disease drug Plavix (Clopidogrel bisulphate) and for AIDS drug Kaletra. (LPV+RTV).	
Brazil	2007	Issue compulsory license to import generic efavirenz from India rather than buy Stocrin – the brand name for patented efavirenz – from its US-based manufacturer Merck & Co.	Upper middle Income
Rwanda	2007	In 2007, Rwanda issued a compulsory license for TriAvir (a combination of Zidovudine, Lamivudine and Nevirapine used to treat HIV/AIDS) that it could not produce locally and applied for assistance from Canada.	Low Income
Ecuador	2009	Compulsory licenses were issued by the national Ecuadorian Institute of Intellectual Property (IEPI), and the term of application of the license for ritonavir/lopinavir.	Upper middle Income
	2012	Issue compulsory license for abacavir/lamivudine.	
India	2012	Issue compulsory license to Natco for Bayer's drug Nexaver.	Lower middle Income

of the pharmaceutical companies of the developing countries to go into the research and they may become dependent on the generic medicines as they can easily get it with a marginal cost of investment as compare to research and development cost. Furthermore, research based pharmaceutical companies will not be launch patent molecule in the developing countries as there is always risk of losing the patent and also they will not be able to recoup the cost of research from the market.

2. **Competition and Cost: -** Compulsory licensing ultimately will lead to increases in the competition because more and more generic companies come into the role to capture the high market share. This will help to bring down the prices and ensure easy access for every patient and also it will force the innovator companies to introduce a differential pricing of their patent molecule so that they can stand into the market.
3. **Patients: -** This phenomenon of compulsory licensing extensively helpful for the financially challenged patients of developing countries for easy access to the medicines and into the utilization of innovation at lower prices for maintaining good health perspective. Big pharmaceuticals are providing the free medicine to the financially challenged patient by running different programme like free access-to-medicine mainly in the developing countries to protect their patent.

DISCUSSION AND CONCLUSION

More than a decade after the Doha declaration, compulsory licensing instances continuously increasing around the globe and these instances are reflecting that government of developing countries favouring the compulsory licensing phenomena while government of developed countries are putting pressure on developing countries in order to limiting the compulsory licenses.

Due to the continuous increase in the compulsory licensing instances some expert from giant pharmaceuticals asserts that compulsory licensing would affect the innovation. Innovator will not be able to recoups their amount invested, as innovation required lot of investment and time and there is always a risk of failure. While on the other hand NGO's and other not profitable organization appreciated the compulsory licensing phenomena by stating that this would help to maintain a good health perspective.

Compulsory licensing moving around the patient versus patent issue from the past and after get through from these different compulsory licensing instances which are constantly increasing all around the globe, what we are expecting from all the Government of different countries either developing or developed, a mid way has to be following so that neither the innovation and nor the patient's desire affects. Research based pharmaceutical companies should take necessary steps to fix the cost of their patented molecule according to the economics status of the respective countries if they want to protect their innovation from compulsory licensing. This cutting cost of the patent molecule will assist the innovator company to protect their patents as well as their will be easy accessibility for the developing countries for the utilization of the Innovation. As we know that loss of life would be worse as compare to bearing the incurred losses due to patent lost by the innovator.

So, it can be concluded that compulsory licensing now became the new hope for the financially challenged patients while challenge for the innovators and at last we can say that it turns into the most concerned Intellectual property matter around the globe at this present scenario.

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