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Compulsory Licensing and Voluntary Licensing of Patents & Covid 19

A.K.BALAJI[1]

ABSTRACT

We are under the second wave of COVID – 19. As the world is hit by the pandemic Novel Coronavirus we are forced to restrict ourselves at home and the access to the public has become very limited. Suddenly everything has become so dark, so vague, so unpredictable yet we need to move on. India being the second largest populous country the current pandemic will be a very big challenge to us. We are facing a biggest lockdown of this century to slow down the spread of the virus. We are in one of the toughest time where slowly every country will face another wave of a great recession, there will be a big hit in the economy of many countries.

Keywords: *Compulsory Licensing and Voluntary Licensing, Pandemic, World, Country, Superpower, Economy.*

I. INTRODUCTION

The world countries are finding it difficult to handle the present situation of COVID – 19. So far India is handling the situation in a better way, however, the biggest challenge is the optimum utilization of the Pharma resources available in India. In a way the present pandemic is a Bio-War where every country is struggling to get a hold of the Pharma stocks for their own utilization on the one hand and the self-sufficient countries are more focused on economically gaining from the export of these pharma products. In this paper an attempt is made to analyze the license most used during emergency or pandemic situation by referring to the provisions and cases related to patent law of India.

The first motive of a democratic country should be in such a way like no matter what ever the situation is but nothing should be a threat against to the welfare of all the citizens regarding the biological safety and financial security of all the citizens. Monopolizing a particular pharma company with alliance to a government for the need of vaccines or other medical products is just exactly equal to inhumane slavery because this clearly exhibits the incapability of the government. The selfish attitude of monopolization of a particular pharma company can be

[1] Author is a Research Scholar at SRM Institute of Science and Technology, India.

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replaced by the legal concept of compulsory licensing of the patented medicines to many other domestic pharma companies and by doing the same the people can achieve a sustainable development all over the country.

The best government must be capable enough to satisfy all the medical needs of the people by not depending on the private pharma companies but still many democratic countries have opened their doors for welcoming the medicines from abroad with a casual excuse by saying that it's the duty of the government to protect its citizens in all possible ways but on the other side the democratic governments failed to realize that the pharma companies from abroad exports tons and tons of medical products for developing their financial strength.

(A) Objectives

1. To study the nature of License used during emergency and the pandemic Situation.
2. To examine the Provisions for grant of compulsory and voluntary license as per the Patents Act of India.
3. To analyse the kind of permission / approval / grant given by the Indian Patent office.
4. To discuss the case laws wherein the license where explored.
5. To suggest a possible solution to evade the above challenges in India.

(B) Research Methodology

In order to achieve the above objectives, I have followed an observation method. The present method involves a study about the economic impact published on a day-to-day basis, which includes news article, research journal publication, books, discussions with the business sectors people and observing the everyday activity of the marketplace. With the continuous study of the above factors I am trying to come out with a possible solution to the existing problem.

II. COMPULSORY LICENSE

Compulsory license is a provision which is explained by Indian Patents Act, 1970, under section 84 & 92. The meaning of Compulsory licensing is generally explained as - when a government allows someone (An individual or Company) to produce a patented product or process (Technology) without the consent of the patent owner or plans to use the patent-protected invention itself.

Under the reasonable requirements the Controller of Patents or High Court grant the permission to utilize the technology.

In simple terms means a Grant of permission for an enterprise seeking to use another Intellectual Property (IP) without the consent of the proprietor. The Basic requirement is the

Government will provide the permission for compulsory licensing when there is no access or limited access to the patented foreign product. This is even ratified under the TRIPS agreement and India is one the leading country to apply this concept.

They are

- Emergency purposes – Extreme emergency or National Emergency
- If it is a lifesaving drug
- Product is not a position to buy an affordable price in the market.
- Patented invention is not worked or manufactured or marketed in India directly.
- Avoid anti-competitive practices in the Market.

Benefits

- Limited period of access to utilize the technology
- Based on revenue sharing basis
- Accessing the technology with the aid of law.
- Exclusive right to Manufacture, use sale and offer for sale without the consent of the original owner.

Section 84 of Indian Patents Act provides for Compulsory license

In normal course, after the expiration of three years from the date of the grant of a patent, any person interested

Provided that this clause shall not be applicable in case of national emergency or other circumstances of extreme urgency or in case of public non-commercial use or on establishment of ground of any kind of strong anti-competitive practices which was adopted by the patentee,

Reasonable period – 6 months

Section 92 - Special provision for the compulsory licences on notifications by the Central Government[2]

Section 92 A - Compulsory licence for export of patented pharmaceutical products in certain exceptional circumstances

Section 100 - Power of the Central Government to use inventions for the purposes of Government[3]

[2] 4th Edition, P.Narayanan, Patent Law, page no 320, Eastern Law House, 2006
[3] ibid

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III. CASE STUDY IN INDIA WHEREIN COMPULSORY LICENSE WAS GRANTED & REFUSED

(A) Natco Vs Bayer[4]

Bayer's patented drug → Sorafenib tosylate – for advanced stage of kidney and liver cancer – under –brand name – Nexavar

Patent

- Sold in India for Rs. 2,80,428
- Natco – an Indian Pharmaceutical applied for voluntary license to manufacture to manufacture and sell the drug, proposed to sell at the price of Rs. 8,800 for a month's therapy
- Natco – applied for compulsory license to the Patent office, India

Natco requested Bayer to provide the permission to produce the drug, the permission was denied by Bayer, hence the application filed before the Patent office.

Product name : Nexavar

- Patent No: IN215758
- Nature : Anti-cancer drug (Liver Cancer Drug)
- Hydrabad based company filed the application for compulsory licensing to utilize this Patent technology.

Reason:

- Total requirement was 23,000/- bottles per month.
- Per capita income in India – No person can buy.
- Price Rs.8,880/- for per month.
- After Compulsory license the product will be available for Rs.2,120/-

Finally Bayer received via order on 9th March, 2011 by Controller General of Patents and conditionally to share 6% of profit on every quarter sales. Against this order Bayer filed an appeal before Intellectual Property Appellate Board – Appeal was dismissed.

IV. COMPULSORY LICENSE REFUSED CASES

(A) Bdr Pharmaceuaticals Vs Bristol Myers[5]

[4]spicyip.com, https://spicyip.com/wp-content/uploads/2018/02/Natco-v.-Bayer-INTELLECTUAL-PROPERTY-APPELLATE-BOARD-CHENNAI-%E2%80%93-4th-March-2013.pdf, (last visited on 01.11.2021 at 05:35 PM)
[5]spicyip, https://spicyip.com/wpcontent/uploads/2017/07/CLA1of2013.pdf, (last visited on 01.11.2021 at 05:38

In BDR pharmaceuticals the controller rejected the BDR application 4th March 2013 for the Bristol –Mysers Squibb cancer drug SPRYCEL. The controller of patents rejected the Compulsory license (CL) by stating that BDR failed to a make a prima facie case for the grant of the compulsory license (CL). The controller observed that BDR had made no credible attempt to procure a license from the patent holder → also the applicant has also not acquired the ability to work the invention to public advantage.

(B) Astraceneca Vs Lee Pharma[6]

Lee Pharma vs AstraZeneca AB → Lee Pharma a Hyderabad based pharma company → filed application for CL 29 june 2015 for patent covering – AstraZeneca diabetes management drug "SAXAGLIPTIN". The application was rejected by the controller stating the same reason as above. Now in India we are in the Pandemic situation, leading Indian pharmaceuticals pioneers like Reddy Laboratories, Ranbaxy and Cipla are also interested and have filed the Applications and expressed their interest to produce the Covid -19 drugs.

V. HOW TO APPLY FOR COMPULSORY LICENSING IN INDIA[7]

1. An application to be filed before the Indian patent office → with relevant facts & evidence → controller will analyze the prima facie case made by the applicant against the patentee.
2. The application will also be published in the official journal → the patentee or any other person desiring to oppose the applicant → can oppose → 2 months from the date of publication → form 14
3. Controller → will analyze the applicant's ability to work the invention, efforts to obtain the license, reasonable terms → if the efforts were not successful or reasonable within the 6 months period from the date of the application → controller will decided the grant or rejection of the application.
4. Notice of rejection from the controller → the applicant may seek for a personal hearing → decision will be passed based on the hearing.
5. If controller grants the license – terms and conditions will be set by him. The controller also decides on the royalties based on the following:
    - The patentee's investment in the invention

PM)

[6]Office of the Controller General of Patents, Designs and Trade Marks - Department for Promotion of Industry and Internal Trade – Ministry of Commerce and Industry – Government of India, https://ipindia.gov.in/writereaddata/Portal/News/33_1_2-compulsory-license-application-20jan2016.pdf, (last visited on 01.11.2021 at 5:39 PM)

[7] 4th Edition, P.Narayanan, Patent Law, page no 321, Eastern Law House, 2006

- The working - ability of the patentee's invention made by the applicant
- The actual selling price of the patented articles at affordable or reasonable price; and
- The term of the license
- Clarify the provisions applicable for exporting & importing the patent article, non-exclusivity & non-assignment of the license, among others.
- Licensing of related patents → in case if the patented invention is not workable without the help of the related invention.

6. **Termination of license**
   - On application made by the patentee or any other person deriving title or interest in the patent → application needs to be served to the person holding the compulsory license ← he may file his objection if any → hearing will be held → decision of the controller
7. Normally request for grant of Compulsory License is published and Patentee and other interested persons are afforded reasonable opportunity to defend the grant. But in case of national emergency and any other urgent condition in the interest of the public, the Controller of Patents may first grant the License and then notify the Patentee and the other interested persons.

   Under some special circumstances like medical emergency supported by notification by any other foreign country in this regard, the controller of patents may even grant compulsory license to meet the medical emergency in that country.

- **Patents Act** – compulsory license can be granted only after the expiry of three years after the grant of the patent under the following grounds

1. That the fundamental requirements of the public with respect to the patented invention have not been satisfied; or
2. That the patented invention is not at all available to the public at a affordable price; or
3. That the patented invention failed to work in the territory of India.

- Natco → was granted compulsory license for the balance term of the patent (after the lapse of 4 years of grant), subject to the payment of the royalty of 6% of the net sales of the drug to Bayer.

NEXAVAR → Life enhancing and not lifesaving drug

VI. COVID – 19 - COMPULSORY LICENSING & VOLUNTARY LICENSING

(A) Glenmark Pharmaceuticals

Brand Name – FabiFlu

Developed – Active Pharmaceutical Ingredient (API) & the formulation for the drug in-house, applied for – obtained – regulatory approval for assess to the drug in Phase III trials for mild to moderate Covid-19

Treatment - cases of mild to moderate Covid-19

Approval - The Drug Controller General of India (DCGI)[8]

Under the Drug and Cosmetics Act, it is mentioned that the regulation of manufacture, sale and distribution of Drugs is primarily under the concern of the state authorities while the Central Authorities are responsible for the approval of New variety of Drugs, Clinical Trials in the country, laying down the basic standards for Drugs, Control over the quality of imported Drugs, coordination of the activities of State Drug Control Organisations and also providing an wise expert's advice with a view of bring about the uniformity in the enforcement of the Drugs and Cosmetics Act.

The Drug Controller General of India (DCGI) is actually responsible for the approval of licenses of specified categories of Drugs such as blood and blood products, I.V.Fluids, Vaccine and Sera. The Central Drugs Standard Control Organization Head quarter is located at FDA Bhawan, Kotla Road, New Delhi 110002 and it functions under the Directorate General of Health Services.

Permission granted for - manufacture and market favipiravir for "restricted emergency use" in mild to moderate cases

Favipiravir - Drug background → 200 mg -- 1800 mg (twice a day) acts against RNA polymerase (enzyme) i.e it inhibits RNA polymerase (which is responsible for viral multiplication). So when the viral multiplication is reduced the viral load will not go up and patient will get better clinical attention.

VII. RESEARCH AT PRESENT CONDUCTED → IN INDIA, JAPAN, CHINA AND RUSSIA[9]

In India in March 2020 conducted study / trial with 150 patient to test the efficacy of the

[8] Indian Council of Medical Research, https://www.icmr.gov.in/pdf/press_realease_files/HFW_DCGI_energency_use_authorisation_03012021_2.pdf, (last visited on 01.11.2021 at 5:47 PM)

[9] FDA – U.S. Food & Drug Administration, https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-drug-combination-treatment-covid-19, (last visited on 01.11.2021 at 5:48 PM)

medication by 4days the patients showed improvement (clinical trials)

In China study conducted wherein one trial included 80 showed the same results

Usage → "The best thing is that it is an oral drug, while Remdesiver is an intravenous drug."

This drug has been approved actually in Japan since 2014 for the treatment of the novel or re-emergency influenza virus infections – has shown clinical improvement of up to **88%** in mild to moderate Covid-19 cases

Drug included under the category of – **"INVESTIGATIONAL THERAPY" only for restricted emergency use →** energetic phosphorylated form (favipiravir-RTP) in cells and is identified as a substrate by viral RNA polymerase, so actually inhibiting the activity of RNA polymerase

It claims that → "The antiviral provides broad-spectrum RNA disease coverage with clinical rehabilitation seen in the 20 to 90 age group. Favipiravir can be used in COVID-19 patients with co-morbid conditions like diabetes and cardiomyopathy with mild COVID 19 to moderate indications". It offers a rapid contraction in viral load in 4 days and provides faster emblematic and radiological progression

Reasoning given by Glenmark - according to the company, Favipiravir demonstrated promising clinical evidence, with positive results in mild to moderate Covid-19 cases. Clinical improvement was observed in age groups of 20 to >90 years.

The drug is actually said to provide a rapid decrease in the viral load within 4 days, along with quicker symptomatic and radiological improvement. Favipiravir was demonstrated up to 88% of the clinical improvement in patients with mild to moderate Covid-19.

Glenmark said that from mild to moderate category of Covid-19 patients with co-morbid conditions such as diabetes and heart disease can also use the drug.

Other Drug companies

Hetero and Cipla

Drug – Remdesivir

Approval given on – 20-06-2020

Usage – for restricted emergency use, for patients in moderate stage of the disease i.e on oxygen

Background – **Cipla & Hetero →** entered into non-exclusive licensing agreement with US Pharma giant **Gilead Sciences** since it is the patent holder for the drug Remdesivir

Gilead Science

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They have applied to Indian Drug Regulatory Agency, Central Drug Control standard organization (CDCSO) → for import and marketing of Remdesivir on 29th May → approval granted on 1st June 2020.

Gilead Licensing[10]

- ✓ Signed and non-exclusive → voluntary licensing of patent agreements with 5 generic pharma
- ✓ to manufacture and also to distribute the Remdesivir, a potential antiviral therapy for Covid-19
    - Cipla,
    - Jubilant Life Sciences,
    - Hetero,
    - BRD and
    - Mylan
- Following the above Jubilant Life Sciences, Dr Reddy's Labs approached India's drug regulator to make and sell remdesivir in the country and are still awaiting permission
- These applications are being processed by the CDSCO in accordance with the laid down procedures [It has said that being an injectable formulation, testing for assay, identity, impurities, bacterial endotoxin test and also the sterility have become very critical for the patient's safety and this data needs to be provided by the companies]
- The Serum Institute, which is known for the world's largest manufacturer of vaccines by volume, is working on several candidates for coronavirus—including potentially mass-producing the AstraZeneca and Oxford university one—as well as developing its own
- The companies are actually at various intermediate stages of inspection of the manufacturing facilities, verification of data, stability testing, emergency laboratory testing as per protocol etc, the health ministry had earlier said.
- Being a typical injectable formulation, testing for assay, impurities, identity, sterility and bacterial endotoxin test have become very critical for patient safety and this data need to be provided by the companies, the ministry had said

Cipla and Hetero Labs have already entered into non-exclusive patent licensing agreements with the US pharma giant Gilead Sciences, which is the patent holder of the drug remdesivir.

[10]The New Indian Express, https://www.newindianexpress.com/business/2020/may/14/four-indian-firms-ink-licensing-pact-with-gilead-for-covid-19-drug-remdesivir-2143054.html, (last visited on 01.11.2021 at 5:54 PM)

Remdesiver

Trips

- Under TRIPS – patent rights are not absolute – but are subject to limitations
- The TRIPS agreement also actually allows the limited exceptions to be made by the members – that such exceptions does not unreasonably conflict with the normal exploitation of the patent & Do not unreasonably prejudice the interest of the patent holder, taking into account the legitimate interest of the third parties
- The WTO Panel in Canada – The Patent protection for the pharmaceutical products have decided that this provision, allowing limited exceptions, covered a provision of Canadian law which permits the use by generic producers of patented products, without authorization and prior expiry of the patent term, for the purpose of seeking regulatory approval from public health authorities for the marketing of their generic version as soon as the patent expires ← this provision is sometimes referred to as "regulatory exceptions" or "Bolar Provision" ← the panel report was adopted by WTO Dispute Settlement Body on 7th April 2000 ← this agreement also allows member to authorize use by third parties (compulsory licenses)

VIII. CONCLUSION

- An effort must be first made to obtain a voluntary license on reasonable commercial terms and conditions
- That the remuneration which was paid to the correct holder shall be adequate in the circumstances of each case, taking into account the economic value of the license.
- This TRIPS aims – recognize the members to take measures consistent with anti-competitive practices & provides more flexible conditions for the grant of compulsory licenses
- However, during this present pandemic not only Indian Pharmaceuticals but the Pharma companies around the world had opted for voluntary licensing rather than the compulsory licensing.

The present pandemic has proved that at times of emergencies it is important to be ethical and provide service to the society.

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