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ABOUT US

INTERNATIONAL JOURNAL FOR LEGAL RESEARCH & ANLAYSIS ISSN

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COMPULSORY LICENSING FOR ANTI-CANCER DRUGS

Authored By- Shifa Hakimullah Khan

ABSTRACT:

Nearly 10 million fatalities worldwide are attributed to cancer, which is a primary cause of death. Poorer nations frequently have considerably lower cancer survival rates. Because many new oncology medications are incredibly expensive, access to cancer treatments is a significant issue in low-middle income countries (LMICs). In India specifically, more than two lakh women received a breast cancer diagnosis in 2020. The biggest problems oncology is currently facing are how to give more patients in LMICs access to expensive yet life-saving treatments. According to a recent survey, 69% of Indian household face financial vulnerability and instability, while families earn an average of Rs. 23,000 each month[1].

What constitutes a "fair price" is not defined. It is customary to match the cost of drug consumption to the patients' income levels because patients with complex diseases typically need many prescription. The purpose of a compulsory license is to boost the access of the public to the patented high priced medicines. This article discusses about the need of compulsory licensing for life saving anti-cancer drugs. According to Indian Patent Act,1970, compulsory license can be granted for the patents after expiry of three years of patent. This article highlighted the provision of Section 84 and Section 92 of Indian Patent Act,1970.

Keywords: Compulsory licensing, Cancer drugs, TRIPS, exorbitantly medicines, affordability, Schemes.

[1](2022). Average Income Of Indian Family Is Rs 23,000 Per Month: Survey [Online]. Available at: https://www.india.com/business/average-income-of-indian-family-is-rs-23000-per-month-survey-5725299/ (Accessed: 21 January 2023).

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WHAT IS COMPULSORY LICENSING:

Compulsory licensing is a government's authorization to someone else to produce the patented product or process without the consent of the patent owner. While there has been particular attention to use of compulsory licensing for pharmaceuticals, it can also apply to patents in any field.[2]

A voluntary licence from the patentee must first obtained by the applicant before submitting an application for the compulsory licence, if within the alloted time (6 months) the application is unable to get a licence at reasonable and equitable terms, the applicant may submit a request for compulsory licensing to the controller.

COMPULSORY LICENSING PROVISION IN THE INDIAN PATENTS ACT:

As per Section 84,After expiration of three years from the date of the grant of a patent any person interested may make application to controller for grant of compulsory licence on patent on following grounds such as,

1.Reasonable requirement of the public with respect to the patented invention have not been satisfied or
2.Patent invention is not available to the public at affordable prices or
3.Patent invention is not worked in the territory of India.[3]

As per Section92, 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.[4]

[2]Wto [Online]. Fact Sheet. Available at: https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm (Accessed: 21 January 2023).
[3] The Patents Act,1970 § 84, No. 39, Acts of parliament, 1970,(India).
[4] The Patents Act,1970,§ 92, No. 39, Acts of parliament, 1970, (India).

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The Patent holder enjoys market dominance in the absence of a competing products, setting the price as per his own choice cause 'monopoly' which may increase the possibilities of abuse of patent rights. The high price patented medicine may make them unaffordable and limit the availability of those medicines to people who are in need.

TRIPS AGREEMENT:

The TRIPS Agreement allows compulsory licensing as part of the Agreement's overall balance between promoting access to existing drugs and promoting research and development into new drugs. Article 31 of the Agreement allows compulsory licensing and government use of a patent without the authorization of its owner, under a number of conditions aimed at protecting the legitimate interests of the patent holder. The option to grant a compulsory licence under Article 31 for the purpose of manufacturing or import is available to all members. It can cover all products or technologies needed to treat a disease or to fight a pandemic.

Under the conditions in Article 31, normally, the person or company applying for a licence must have first attempted, unsuccessfully, to obtain a voluntary licence from the right holder on reasonable commercial terms. If a compulsory licence is issued, adequate remuneration must still be paid to the patent holder. But incase of "national emergencies", "other circumstances of extreme urgency" or "public non-commercial use" (or "government use") or anti-competitive practices, there is no need to try for a voluntary licence.[5]

Following the TRIPS Agreement, the WTO adopted the Doha Declaration in 2001, which supported the idea that member states could get patent rights by issuing compulsory licences that would allow them access necessary medicines if these medicines were urgently needed to protect the public's health.

[5]TRIPS Agreement.

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COMPULSORY LICENSING DOES NOT AFFECT DIRECT INVESTMENT INFLOWS IN THE COUNTRY:

However, Countries issuing compulsory licenses may face pressure from industry and trading partners. For example, in 2002 when Egypt issued a compulsory license for sildenafil (a phosphodiesterase type 5 inhibitor used to treat erectile dysfunction), Pfizer announced it would rethink its investment in a modern production facility in the country. Despite this isolated case, the use of compulsory licenses does not appear to lead to an overall reduction in foreign direct investment in countries that adopt the scheme. For example, Brazil and South Africa have benefited from considerable investments despite their issuance of compulsory licenses for HIV medications. In Thailand, even though the Office of the U.S Trade Representative withdrew duty-free, preferred access to the U.S. market for several Thai products in response to the compulsory licenses issued for docetaxel, letrozole, and erlotinib, a net economic benefit was still observed (with savings of $140 million over five years). Moreover, between 2002 and 2008, no relationship could be found between the use of the compulsory licenses and foreign direct investment inflows in the country.[6]

NATCO v. BAYER CASE:

On March 9, 2012, the Patent Office granted Hyderabad based Natco Pharma the first ever Compulsory license in India for the production of a generic version of Bayer's Nexavar, an anti cancer drug (chemically known as Sorafenib tosylate)used to treat liver and kidney cancer.

In the **NATCO v. BAYER** case, it was established that only 2% of cancer patients had easy access to the medicine and Bayer was selling it for an exorbitant amount of ₹ 2,80,000 for a month's treatment. Further, on the ground that Nexavar was being imported within the territory of India, the Indian Patent Office granted Natco pharma a compulsory licence, ensuring that

[6]G. Lopes, (2014). Compulsory Licensing: A Double-Edged Sword in the Fight for Access to Cancer Medications in Low- and Middle-Income Countries [Online]. ASCO Connection. Available at: https://connection.asco.org/blogs/compulsory-licensing-double-edged-sword-fight-access-cancer-medications-low-and-middle-income (Accessed: 19 January 2023).

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the tablets would be sold for ₹8,880 per month. It was agreed that Natco pharma would pay Bayer a royalty of 6% of the drug's net sales.[7]

COMPULSORY LICENSING NOT GRANTED:

In **Lee Pharma Ltd. V. AstraZeneca AB,**[8] On 29th June 2015, an application under Section 84(1) of Indian Patent Act,1970, has been filed, seeking the grant of a licence for manufacturing and selling the compound SAXAGLIPTIN, The grounds for making the application are as follows:

- that the reasonable requirement of the public with respect to the patented invention have not been satisfied, and
- that the patented invention is not available to the public at a reasonably affordable price, and
- that the patented invention is not worked in the territory of India.

SAXAGLIPTIN, as a dipeptidyl peptidase-4 (DPP-4) inhibitor, is a drug prescribed for the treatment of Type-II diabetes mellitus.

In the matter of **'Bayer Corporation V. UOI & Ors'**, the Hon'ble Bombay High Court in its judgement ruled that the reasonable requirement of the public has to be considered by the authorities in the context of number of patients requiring the patented drug. However lee pharma has not shown what is the reasonable requirements of the public with respect SAXAGLIPTIN in India in the context of number of Type-II DM patients requiring SAXAGLIPTIN.

Lee pharma also not shown comparative requirements of SAXAGLIPTIN and other (DPP-4) inhibitors, LINAGLIPTIN, SITAGLIPTIN and VILDAGLIPTIN, which are required for treatment of Type-II DM and are available in the Indian market, so that the reasonable requirement of the public in respect to SAXAGLIPTIN could be arrived. SITAGLIPTIN and

[7]T. Goyal, (2017). Compulsory Licensing [Online]. India. Available at: https://www.mondaq.com/india/patent/617670/compulsory-licensing (Accessed: 20 January 2023).

[8]C.L.A.NO.1 of 2015.

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VILDAGLIPTIN are also listed as essential medicines along with SAXAGLIPTIN for the treatment of Type-II DM.

Lee pharma argued that out of all DPP-4 inhibitors presently available in India, SAXAGLIPTIN is the latest and best option for the treatment of Type-II DM while the others have side effects, however in support of their argument they neither submitted any comparative study nor submitted any authentic evidence from the any statutory authority or the doctor's body to clearly establish that SAXAGLIPTIN is the best option with no or comparative less side effects over the others.

The price of other three DPP-4 inhibitors (LINAGLIPTIN, SITAGLIPTIN and VILDAGLIPTIN) despite such large volume having the same prices/ranges of prices are affordable in India. Lee pharma has failed to prima facie show that the patented invention is not available to the public at a reasonably affordable price.

Further, lee pharma has failed to show exact quantitative requirement of SAXAGLIPTIN in terms of number of patients requiring it or whether it is in shortage.

Lee Pharma has failed to provide evidence and failed to satisfy controller regarding any of the ground as specified in Section 84(1) of the Indian Patents Act.

COMPULSORY LICENSING FOR LIFE SAVING ANTI-CANCER DRUGS:

Even though science and technology have advanced significantly, there are still significant gaps in access to healthcare. Therefore, despite the fact that medical science attempts to extend life expectancy, millions of people still lack access to existing medications. Pharmaceutical patents are another major obstacle to accessing new medications, particularly in low and middle income nations where the health financing systems are already subpar.

According to GLOBOCAN data 2020, in India, Breast Cancer accounted for 13.5% of all cancer cases and 10.6% of all deaths. The estimated number of incident cases of cancer in India for the year 2022 was found to be 14,61,427 (crude rate 100.4 per 100,000). The incidence of

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cancer cases is estimated to increase by 12.8 percent in 2025 as compared to 2020. In India, the burden of cancer incidence is still rising. Breast cancer was discovered to be the most prevalent of the top five cancers that affect women.[9]

139th COMMITTEE REPORT:

The 'Cancer Care Plan and Management' report was released by the Rajya Sabha standing committee on health. The committee found that, due to the high cost of cancer treatment, almost 40% of cancer hospitalisation cases are financed mostly through loans, assets sales, and contributions from friends and family. The high cost of medical care has significantly lower survival rates in developing countries. The five year survival rates for breast cancer are estimated to be 65% and 45% in India and South Africa, respectively compared to approximately 90% in high income countries. As per the WHO report on the pricing of cancer medicine and its impacts, The cost of course of standard treatment for early stage HER2(human epidermal growth factor receptor) positive breast cancer would be equivalent to about 10 years of average annual wages in India and South Africa and 1.7 years in the United States.[10]

On December 22, 2022, Dr. Lorho S. Pfoze, a Lok Sabha member and joint convenor of the IMPF(Indian Medical Parliamentarian's Forum), wrote to Prime Minister Modi requesting that the government appoint an expert panel to look into the issue of the high cost of cancer treatment. It requested that the panel determine whether the government use provisions (Section 100) of the Indian Patent Act can be used to treat breast cancer. **Additionally, it claimed that three breast cancer drugs, Palbociclib, Ribociclib and Abemaciclib cost between ₹48,000 to ₹95,000 for a month's dose and required urgent government intervention.** Despite the fact that numerous government and state funded health insurance programmes aim to increase access to cancer care for particular population groups, no single programme has been designed to fully cover the expense of cancer diagnosis and treatment for all beneficiaries stated by IMPF. "Further, the plans are very fragmented, and the type of

[9]A. W. Group, Cancer incidence estimates for 2022 & projection for 2025: Result from National Cancer Registry Programme, India [Online]. PubMed. Available at: https://pubmed.ncbi.nlm.nih.gov/36510887/ (Accessed: 20 January 2023).
[10]P. B. Jayakumar, (2023). Medical Parliamentarians seek universal free cancer care in India [Online]. Fortune India. Available at: https://www.fortuneindia.com/macro/medical-parliamentarians-seek-universal-free-cancer-care-in-india/111010 (Accessed: 17 January 2023).

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treatment that is offered varies significantly across the country. The letter to the PM added that the various public insurance plans are confined only to inpatient treatment and high level tertiary care, including expensive drugs are not covered.[11]

Trastuzumb brands currently cost between ₹58,000 and ₹63,000 per 440 mg vial in India. Patients with early breast cancer and HER2 positive require about 18 cycles of trastuzumab based therapy, which now costs more than 10 lakh rupees in India.

Due to the unpredictability and local variation of the approval, clinical acceptance and inclusion of expensive new medicines, it become difficult for insurance companies to appropriately calculate policy rates. To keep up with the expense of care, insurance premiums must be significantly increased.

RIBOCICLIB CASE:

Following the tragic death of the petitioner who had earlier pleaded with the government to utilise the patent Act levers to restrain the increasing costs of a life-saving drug, the Kerala High Court recently took suo moto cognizance of a drug's unaffordability. The medication in question is Ribociclib, which is used to treat a few types of breast cancer and is sold under the brand names KISQALI (in the USA) and KRYXANA (in India).

Background-The patent number for the Ribociclib is 283133 and is available under the title "pyrroloppyrimidine Compounds And Their Uses". The patent is registered under Novartis name and is valid till 2027.The drug's monthly dosage cost ₹58,140. The petitioner earlier claimed that if the medicine is made in India, the price will drop substantially. Presently, Switzerland is where the medicine is imported from. Since Ribociclib currently has a patent monopoly, preventing it for manufactures to produce the drug without the patent holder's consent. The petitioner refers to Section 92 of the patent Act,1970 which provides for

[11]P. B. Jayakumar, (2023). Medical Parliamentarians seek universal free cancer care in India [Online]. Fortune India. Available at: https://www.fortuneindia.com/macro/medical-parliamentarians-seek-universal-free-cancer-care-in-india/111010 (Accessed: 17 January 2023).

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compulsory license and Section 100 which empowers the Government to requisition life saving medicines in cases of extreme necesssity.[12]

Section 92, empowers the Central government to issue compulsory licenses subject to three conditions: (a) there must be a national emergency; (b) the requirement must be extremely urgent; (c) it must be for public non-commercial use.

According to data, an alarming high percentage of people die from breast cancer because they cannot afford the expensive medication and treatment. The right to life guaranteed under the Constitution, coupled with the state's duty to improve public health, call for emergent and effective action in the matter.

Considering that breast cancer is one of the most prevalent types of cancer in India and is responsible for the highest number of cancer related deaths among women in India, the likelihood of the granting of a compulsory licence appears beneficial in the current situation where the high cost of the drug Ribociclib is seriously limiting access to the medication used in the treatment of the disease.

PRAJA AROGYA VEDIKA URGES UNION GOVERNMENT TO MAKE BREAST CANCER DRUGS AFFORDABLE:

PAV general secretary T. Kameswara Rao and president M.V. Ramanaiah wrote to the Union Minister for Chemicals and Fertilizers Mansukh Mandviya pointing out that the Indian Council of Medical Research reported that 100.5 out of every 100,000 women were being diagnosed with breast cancer. This indicates that one in every 22 women has breast cancer. By 2030, the number is predicted to increase from the current 1,82,000 cases to 2,50,000.

[12]P. Gour, (2022). State's Inaction, Petitioner's Death Makes Kerala High Court to Take Suo Moto Cognizance of Ribociclib Unaffordability [Online]. SpicyIP. Available at: https://spicyip.com/2022/09/states-inaction-petitioners-death-makes-kerala-high-court-to-take-suo-moto-cognizance-of-ribociclibs-unaffordability.html (Accessed: 17 January 2023).

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Form 27 of the Patent Act relates to the statement regarding the working of a patented invention on a commercial scale. The analysis of Form 27 of patent no. 283133 infers the following:

- In 2018, 8299 units of Ribocicilib (200 mg) were imported and valued at INR 12,70,09,834. (Public requirement met adequately, not fully extent)
- In 2019, 24,857 units of Ribocicilib (200 mg) were imported and valued at INR 37,18,38,664.[13](Public requirement met adequately, not fully extent)

Due to the fact that they are patented medicines, Ribociclib, Palbociclib, and Abemaciclib are prohibitively expensive and difficult to obtain for a reasonable price. They requested the introduction of Ribociclib, Palbociclib, and Abemaciclib as a component of the free treatment programme under the National Cancer Control programme, and that the Central Government invoke compulsory licences under Sections 84, 92, and Section 100 of the Indian Patent Act to enable free and affordable access to these three cancer medications through the generic manufacturing.[14]

As enshrined in Section 83 "General principles applicable to working of patented inventions" of the Indian Patents Act, 1970, "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". It is further enshrined that patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public.

EFFICACY OF RIBOCICLIB, PALBOCICLIB AND ABEMACICLIB:

Women who received letrozole (Femara) and the CDK 4/6 inhibitor Ribociclib (Kisqali) as their initial treatment for advance breast cancer overall lived about 1 year longer than those

[13]D. M. Dewan, (2022). The Ribociclib review [Online]. Lexology. Available at: https://www.lexology.com/library/detail.aspx?g=92dc0728-7242-4ca7-a8e7-cd538d938051 (Accessed: 17 January 2023).

[14] T. H. Bureau, (2023). Make breast cancer drugs affordable, Praja Arogya Vedika urges Union government [Online]. The Hindu . Available at: https://www.thehindu.com/news/cities/Visakhapatnam/make-breast-cancer-drugs-affordable-praja-arogya-vedika-urges-union-government/article66424945.ece (Accessed: 27 January 2023).

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who received letrozole alone, according to the MONALEESA-2 clinical trial. In a related earlier clinical trial, letrozole alone was not as effective as Ribocicilib with letrozole adding a full year to overall survival. Doctors often use both Ribociclib and Palbociclib interchangeably because of their similar mechanisms of action. Some doctors present at the meeting stated that as a result of these trials, they are more inclined to suggest Ribocicilib or Abemaciclib in the future. When patients' cancers start to get worse during initial treatment, they will often get chemotherapy as part of their next line of treatment. But in the MONALEESA-2 trial, Dr. Hortobagyi reported, patients in the Ribociclib group were able to avoid taking chemotherapy for up to a year or longer than those in the letrozole-only group. Overall survival data from large clinical trials of Palbociclib and Abemaciclib as a first-line treatment in postmenopausal women with HR-positive, HER2-negative advanced breast cancer (called PALOMA-2 and MONARCH 3, respectively) are expected to be available soon, Dr. McShane said, and she expects that they will also show an improved overall survival with the CDK4/6 inhibitor.[15]

Ribociclib is currently the only CDK4/6 inhibitor with a proven benefit on overall survival across all three Phase III trials of the MONALEESA clinical program with different endocrine therapy partners, regardless of menopausal status or line of therapy.

FINANCIAL AID THROGH SCHEMES COVER CANCER PATIENTS DWELLING

IN BELOW POVERTY LINE:

1. **Central Goverentment Scheme (Health Minister's Cancer Patients Fund):** Regional Cancer Center administer this programme, which typically offers financial assistance to cancer patients up to Rs. 2 lakhs and Rs. 5 lakhs in cases of emergency. Individual cases that require more than two lakhs in financial support are forwarded to the ministry for handling. All 27 regional cancer centres have contributed to the revolving funds. The fund often offers financial assistance to cancer patients who live in areas where the poverty level is below.

[15]E. Winstead, (2022). Ribociclib Improves Survival in Advanced Breast Cancer [Online]. Available at: https://www.cancer.gov/news-events/cancer-currents-blog/2021/ribociclib-improves-metastatic-breast-cancer-survival (Accessed: 17 January 2023).

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Only inside the 27 regional cancer centres is financial assistance permitted for cancer treatment..

2. **Pradhan Mantri Jan Arogya Yojana Scheme or Ayushman Bharat Yojana:** It is referred to be the Government of India's flagship National Health Protection Scheme. The Ayushman Bharat Yojana will assist underprivileged families in accessing the best healthcare services, with insurance coverage of up to INR 5 lakh for each family per year for secondary and tertiary hospitalisation costs, including diagnostic costs, medical treatment costs, hospitalisation, pre-existing illnesses, and several critical illnesses. The individuals belonging to schedule caste and schedule tribe families are eligible to gain the benefits of this scheme, The households with no male members fall under the age group of 16-59, The familes are dwelling in one room with Kuccha Kuccha walls and roof, The household without a healthy adult member and one disabled member, Manual scavenger families and manual labour as the primary source of family income involving landless household earning.[16]

CONCLUSION:

An innovation can only be made, sold or used by the person who has the patent, who also has the exclusive right to do so because they generate new, improved ways of doing things or new products that give them a competitive advantage on the market, inventions enable many businesses to succeed. Generally, an inventor is granted a monopoly over his creation for a period of time, allowing him to commercially use and exploit it in the market to the exclusion of others.

The primary goal of a compulsory licence is to increase public access to expensive, patented medicines. Compulsory licensing was viewed as an essential elements by the TRIPS and Doha Declaration in order to give health benefits to all people equally. For health emergencies like epidemics and the unavailability of essential medicines at a fair price, compulsory licensing should be reserved. Ribociclib, Palbociclib and Abemaciclib is prohibitively expensive because it is not produced in India. Earlier goverentment had issued compulsory licence in the case of

[16] S. Murugan, (2022). Financial Support for Cancer Treatment By Indian Government [Online]. ZenOnco.io. Available at: https://zenonco.io/cancer/government-schemes-for-cancer-patients-in-india/ (Accessed: 27 January 2023).

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Kidney Cancer Drug (Nexavar). As a result the drug which was earlier available at a very high price of Rs. 2,80,000 was reduced to Rs. 8,800 by Natco pharma. Similar steps need to be taken in case of the drugs for treatment of breast cancer, so that the cost of treatment is reduced considerabely, thereby bringing the medicines within the reach of the common people.