



MAR GREGORIOS COLLEGE OF LAW

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THE CENTRE FOR INTELLECTUAL PROPERTY RIGHTS | WEEKLY STUDENT BULLETIN

## In re Exorbitant Pricing of Life Saving Patented Medicines (X v. Union of India)

Neha S

10th Semester, BBA, LL.B

The Kerala High Court is currently seized of a case relating to affordability of life saving drugs and the potential use of compulsory licensing mechanism available under the Indian Patent Act, 1970 in such cases. The now deceased petitioner in the case was a retired woman diagnosed with common sub type of breast cancer. Her prescribed medications were Ribociclib (Rs. 58,140 per month), Letrozole (Rs. 1027.75 per month), and Zoledronic Acid (Rs. 4,313 per month). Novartis holds the patent over Ribociclib and it has so far not been licensed for manufacture by generic drug companies, hence the high price of the drug. The petitioner's total household income (including the pension of her husband) was only Rs. 74,400/-,

hence she filed a petition in the Kerala High Court in June 2022 seeking government assistance for the affordable production of the medicine.

Pursuant to her death in September, 2022, the writ petition became a suo motto case of the court titled "In re Exorbitant Pricing of Life Saving Patented Medicines." The case impleaded a number of other respondents other than the State, including pharmaceutical giants such as Eli Lilly and Novartis. In one of its later orders, the Kerala High Court requested the Centre to submit data on the number of persons who have breast cancer in India and if there are alternative schemes for supplying breast cancer medicines. Breast cancer has ranked number one cancer among Indian females with age adjusted rate as high as 25.8 per 100,000 women and mortality 12.7 per 100,000 women.



## COMPULSORY LICENCING – THE PATENT ACT, 1970

Compulsory licences may be sought from the Controller of Patents three years after the grant of a patent if:

- the reasonable requirements of the public were not met with respect to the patented invention;
- the patented invention is not available to the public at an affordable price; or
- the patented invention is not worked in India.

Compulsory licences may also be granted based on notification by the Central Government in situations of national emergency, circumstances of extreme urgency or cases of public non-commercial use (Section 92).

## COMPULSORY LICENCES – PRECEDENT

The only precedent as far as grant of compulsory licence is concerned is *Bayer v. Union of India* (2014, Bom). This case challenges the decision of the Intellectual Property Appellate Board (IPAB) relating to the grant of compulsory licensing in respect of a drug Sorafenib Tosylate, sold under the brand name Nexavar by Bayer Corporation and used to treat kidney and liver cancer.

NATCO, a generic drug manufacturer sought a license to manufacture and sell the drug in India at a price of less than less than Rs.10,000/- per month as against Bayer's price of Rs.2,80,428/- per month. The Controller of Patent granted the compulsory license to NATCO, drafted the license agreement for the parties and stipulated royalty of 6% to be paid by NATCO to Bayer from the sale of the drug. Neither the IPAB nor the Bombay High Court interfered with the findings of the Controller except for increasing the royalty amount from 6% to 7%.

The Bombay High Court while examining the matter reiterated 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.' In the case of Nexavar, the court observed that in total 8842 patients required the drug in 2011. However, Bayer had only sold 593 boxes of the drug which amounted to supply of the drug to 2011 patients only.

## **CAN COMPULSORY LICENSING BRIDGE THE HEALTHCARE GAP?**

**In the current case, the complication arises from the fact that in order for granting of compulsory licensing, there has to be an applicant who should be a pharmaceutical company. Since no company has come forward yet seeking compulsory licensing of Ribociclib, who should be granted the license is an important question at hand. Even when these issues regarding the granting of compulsory license is dealt with, there still exist a valid concern regarding the gap in technical know-how when it comes to compulsory licensing. Licensees may lack the expertise to fully utilize patented technology, potentially limiting its societal benefits. Compliance with technical standards may be problematic, raising concerns about performance and safety. Licensees may become overly reliant on the patent holder for technical support, impacting long-term sustainability and innovation.**

**The Kerala High Court has sought information from the Centre on the relevant policies regarding the availability and affordability of life saving drugs. Overall, one may be compelled to arrive at a conclusion that compulsory licensing may not be the appropriate remedy for this issue.**

### **SOURCES:**

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