INTERNATIONAL JOURNAL FOR LEGAL RESEARCH AND ANALYSIS

Open Access, Refereed Journal Multi Disciplinary
Peer Reviewed

www.ijlra.com

DISCLAIMER

No part of this publication may be reproduced or copied in any form by any means without prior written permission of Managing Editor of IJLRA. The views expressed in this publication are purely personal opinions ofthe authors and do not reflect the views of the Editorial Team of IJLRA.

Though every effort has been made to ensure that the information in Volume II Issue 7 is accurate and appropriately cited/referenced, neither the Editorial Board nor IJLRA shall be held liable or responsible in any manner whatsever for any consequences for any action taken by anyone on the basis of information in the Journal.

Copyright © International Journal for Legal Research & Analysis

EDITORIAL TEAM

EDITORS

Dr. Samrat Datta

Dr. Samrat Datta Seedling School of Law and Governance, Jaipur National University, Jaipur. Dr. Samrat Datta is currently associated with Seedling School of Law and Governance, Jaipur National University, Jaipur. Dr. Datta has completed his graduation i.e., B.A.LL.B. from Law College Dehradun, Hemvati Nandan Bahuguna Garhwal University, Srinagar, Uttarakhand. He is an alumnus of KIIT University, Bhubaneswar where he pursued his post-graduation (LL.M.) in Criminal Law and subsequently completed his Ph.D. in Police Law and Information Technology from the Pacific Academy of Higher Education and Research University, Udaipur in 2020. His area of interest and research is Criminal and Police Law. Dr. Datta has a teaching experience of 7 years in various law schools across North India and has held administrative positions like Academic Coordinator, Centre Superintendent for Examinations, Deputy Controller of Examinations, Member of the Proctorial Board

Dr. Namita Jain

Head & Associate Professor

School of Law, JECRC University, Jaipur Ph.D. (Commercial Law) LL.M., UGC -NET Post Graduation Diploma in Taxation law and Practice, Bachelor of Commerce.

Teaching Experience: 12 years, AWARDS AND RECOGNITION of Dr. Namita Jain are - ICF Global Excellence Award 2020 in the category of educationalist by I Can Foundation, India.India Women Empowerment Award in the category of "Emerging Excellence in Academics by Prime Time & Utkrisht Bharat Foundation, New Delhi.(2020). Conferred in FL Book of Top 21 Record Holders in the category of education by Fashion Lifestyle Magazine, New Delhi. (2020).Certificate of Appreciation for organizing and managing the Professional Development Training Program on IPR in Collaboration with Trade Innovations Services, Jaipur on March 14th, 2019

Mrs.S.Kalpana

Assistant professor of Law

Mrs.S.Kalpana, presently Assistant professor of Law, VelTech Rangarajan Dr. Sagunthala R & D Institute of Science and Technology, Avadi.Formerly Assistant professor of Law,Vels University in the year 2019 to 2020, Worked as Guest Faculty, Chennai Dr.Ambedkar Law College, Pudupakkam. Published one book. Published 8Articles in various reputed Law Journals. Conducted 1Moot court competition and participated in nearly 80 National and International seminars and webinars conducted on various subjects of Law. Did ML in Criminal Law and Criminal Justice Administration.10 paper presentations in various National and International seminars. Attended more than 10 FDP programs. Ph.D. in Law pursuing.

Avinash Kumar

Avinash Kumar has completed his Ph.D. in International Investment Law from the Dept. of Law & Governance, Central University of South Bihar. His research work is on "International Investment Agreement and State's right to regulate Foreign Investment." He qualified UGC-NET and has been selected for the prestigious ICSSR Doctoral Fellowship.He is an alumnus of the Faculty of Law, University of Delhi. Formerly he has been elected as Students Union President of Law Centre-1, University of Delhi.Moreover, he completed his LL.M. from the University of Delhi (2014-16), dissertation on "Cross-border Merger & Acquisition"; LL.B. from the University of Delhi (2011-14), and B.A. (Hons.) from Maharaja Agrasen College, University of Delhi. He has also obtained P.G. Diploma in IPR from the Indian Society of International Law, New Delhi.He has qualified UGC – NET examination and has been awarded ICSSR – Doctoral Fellowship. He has published six-plus articles and presented 9 plus papers in national and international seminars/conferences. He participated in several workshops on research methodology and teaching and learning.

ABOUT US

INTERNATIONAL JOURNAL FOR LEGAL RESEARCH & ANLAYSIS ISSN

2582-6433 is an Online Journal is Monthly, Peer Review, Academic Journal, Published online, that seeks to provide an interactive platform for the publication of Short Articles, Long Articles, Book Review, Case Comments, Research Papers, Essay in the field of Law & Multidisciplinary issue. Our aim is to upgrade the level of interaction and discourse about contemporary issues of law. We are eager to become a highly cited academic publication, through quality contributions from students, academics, professionals from the industry, the bar and the bench. INTERNATIONAL JOURNAL FOR LEGAL RESEARCH & ANALYSIS ISSN 2582-6433 welcomes contributions from all legal branches, as long as the work is original, unpublished and is in consonance with the submission guidelines.

BAYER CORP VS NATCO PHARMA THE FIRST AND TILL DATE ONLY COMPULSORY LICENSING OF PATENT IN INDIA

AUTHORED BY - ANISHA MAAN

Abstract:

The current paper talks about the compulsory licensing regime in India. The international provisions which provide for the development of the patent licensing regimes for countries to inculcate into domestic laws and abide by them. The paper sheds light on the very first and till date the only compulsory licensing case Bayer Corp vs Natco Pharma. The contentions put forth by the parties and the reasons for the outcome of the case. The start to the end of the case which has been the hall ways of the controller general then proceeded to the IPAB advancing to the Bombay high court finally resting in the supreme court of India where it founds its destination and final answer. The paper explorers the importance of the voluntary licensing, TRIPS agreement, the Doha Conference. The patents act 1970 which talks about the compulsory licensing under section 84. The conditions for the grant of compulsory licensing primarily depend upon the general availability of the patented invention to the public at large, the affordability and the workability of the patent till date in the country. A compulsory license can be sought only on the expiration of certain conditions: from the lapse of 3 years when the patent was registered, when the voluntary licensing has been exhausted. The law does not manmade for a voluntary license to be sought multiple times, once it fails compulsory licensing is the only option. The concept of royalty is to be followed religiously which is set by the authorities. The compulsory license can be revoked after the expiry of 2 year from the date it was granted.

Introduction

The demand for medicines is ever growing with every new day a new health issue is discovered, along with which many new developments take place in the labs which lead to generation of new medicines some effective some partially, some affordable some only to be used as reference due to the price factor. With so much economic variations in the society worldwide not all can get access to the fancy "pricy" medicines. Here is where the debate arises that are

the Pharma companies only innovative where it needs to be, where it pockets money even after the recovery of the cost of the R&D, production etc. the approach depends on the use of the medicine, by what kind of people and the reach of it.

There has been a difference of opinion between two section of thinkers who believe that medicines eventually are made for the larger masses to consume and not only the ones who can afford them comfortably, while on the other hand this section of people only think to protect the innovation and make profits from it. Both the arguments have their pros and cons which can be weighed against each other and still be on the same level.

It does take financial assistance to dwell deeper to create, research and build something new and to recover and make profit is the cardinal rule of an entity whereas it is made to cater to the society and the people who are in need of it.

The same conflict of interest arose between the bayer corp and Natco ltd, the incident does have a backdrop to it but that has no influence over Marcos actions which were taken, it began with Cipla a company in India who began producing the generic version of sorafenib drug.

Background

Bayer corp is a global company engaged mainly in the agricultural and healthcare life science with a history of 160 yrs. specific to India the companies presence can be traced back to 126yrs from the year 1896. From having its roots in Europe evolving from a dyestuff textile factory to a chemical factory and eventually venturing into other sectors bayer has come a long way creating a dominant position in Pharma and agricultural sectors.

Natco Pharma Limited established in the year 1981 in Hyderabad. Natco is well recognised for its innovation in pharmaceuticals R&D. Providing generic medicines to the masses.

About sorafenib:

Sorafenib is a drug used to treat advanced renal cell carcinoma {late stage kidney cancer}, hepatocellular carcinoma {liver cancer} in cases where surgery has been ruled. It is also used to treate differentiated thyroid cancer which is recurring, or has spread throughout the whole body to other parts.

Sorafenib medels with the growth of cancer cells, which are technically destroyed by the body. Sorafenib is marketed worldwide under the brand name Nexavar.
Sorafenib was developed by bayer pharmaceuticals in 2001, the patent issuing authority being USPTO [united states patent and trademark office]

What is compulsory licensing:

Compulsory licensing is a process by which the government themselves use or allows anyone else to use patented products of someone else without the consent of the patent owner. Compulsory licensing is a kind of flexibility found place in WTO'S agreement on intellectual property, the TRIPS (trade related aspects of intellectual property rights) agreement.

TRIPS - ARTICLE 31:

Compulsory licensing either being acquired by an individual or company has to within a reasonable period of time tried to negotiate a voluntary license with the patent owner, if the said process fils can a compulsory license be granted.

There must be proper financial/ economic remuneration to be paid to the to the patent holder after the issuing of the compulsory licensing. The TRIPS agreement does not define "financial" or "economic" anywhere, the decision lies with the authorities of the concerned country.

The only Time when the step of voluntary licensing can be skipped is during "emergencies" but the remuneration cannot be skipped and is mandatory to pay. they can be a. national emergencies, b. Other circumstances or extreme urgency, c.public non - commercial use", or d. Anti- competitive practices.

Doha ministerial conference 2001:

Doha ministerial conference 2001 has brought a change in the TRIPS agreement adding an additional type of compulsory licensing. It states that cheaper copies produced elsewhere should be made available to countries unable to manufacture pharmaceuticals.

The aim of the said change incorporated is if a country is to obtain a compulsory license for the production of its own affordable pharmaceuticals, overseas producers can step in and supply the needful even if a compulsory license is needed in that country.

SECTION 84 - COMPULSORY LICENSING IN INDIA, THE PATENT ACT OF 1970:

Section 84 of the Patent Act of 1970 talks about compulsory licensing in India. Compulsory licensing is derived in India from article 31 of TRIPS. Compulsory licensing is dealt with in chapter XVI of the act.

Section 84 puts out who can apply for compulsory licensing, an application for grant of compulsory licensing can be made nay time after the expiration of the mandatory time of 3 years from the date of the grant of the patent.

Section 84(1):

As per section 84(1) any interested person to gain a compulsory license may after the expiration of 3 years from the date of the grant of a patent may apply for the same through an application made to the controller for the grant of compulsory licensing on any of the following grounds.

- Requirements of the public have not been satisfied with respect to the patented invention.
- Patented inventions have not been made accessible to the public at a affordable price
- The patented invention has not been worked in the territory of India.

Conditions for the grant of compulsory licensing can be inferred from section 84(1) of the patent act of 1970:

1. When the innovation has not been made available in the public domain in sufficient quality compulsory license can be applied for.
2. Non- affordability: when the invention has been fairly high priced which cannot be utilised by the people, this becomes a ground for the grant off the compulsory licensing.
3. Working of the patent: when the patent has not be worked on in India commercially on a big scale within a reasonable time frame, a compulsory license cab be granted for the benefit if the people to a third party making such arrangements for the workability.

Facts of the case:

Backdrop:

Cipla was the very first Pharma to produce and market the generic version of sorafenib. It was introduced in the year 2008 under the name “soranib” with the description of “sorafenib tablets 200mg”.

A suit of infringement was filed against cipla by bayer before the indian courts.during the tussle between cipla and bayer, Natco Pharma another generic manufacturer in the mean time filed for compulsory licensing against buyers patent on sorafenib before the controller of patents. {check to change}. The compulsory licensing was demanded under section 84 (1) of the indian patent act of 1970, as amended in 2005.

Tussle between bayer corp and natch: the first compulsory licensing case in india till date;

Bayer obtained marketing approval for Sorafenib in 2005 and launched its product worldwide in 2006 under the brand name nexavar. The drug was launched in india in 2008.

Bayers total sales of Sorafenib in 2009 were US$934 million

Bayer charged approxametly US$ 66,813 per patent per year whereas in india US$ 5,500 per month for this drug.

Natco pharma filed for a compulsory licence for the patented drug of the bayer corp before the controller of patents on 29 July, 2011. The compulsory licensing was requested under conditions of section 84(1) of the patents acts of india 1970. The controller on 9 march, 2012 granted the compulsory license and awarded royalty at 6% from the net sales to bayer corp and the terms and conditions were drafted by the controller. The price for the drug to be sold at was fixed at Rs. 8800/- (eight thousand eight hundred).

The compulsory license granted to Natco Pharma was conditioned:

A. Non - exclusive,
B. Non - exclusive
C. For the balance term of the patent (the term of a Patent in India is 20 years, compulsory license an be applied for after the expiration of 3 years from the date of grant of the patent)

The controller had granted natco the compulsory licensing on the grounds of bayer corps failure to meet the requirements under section 84 of the patents act 1970. Which were in this case:

1. Was not available to the general public at a reasonable price,
2. Was not satisfying the need for the drug within India and

3. Had not been worked well within India.

The biggest contention of natco Pharma was that they were proposing to sell the soraphenib drug under RS 10,000/- (ten thousand) to a patient each month whereas bayer corp was selling the drug priced at RS 2,80,428/- (two lakhs eighty thousand four hundred twenty eight) the non reasonable pricing was the main factory contributing to the grant of the compulsory licensing.

Voluntary licensing:

Voluntary licensing is an important aspect which shall be complied with before requesting for a compulsory licensing. Voluntary licensing is when the third part desirous of using the patent seeks permission from the patent owner to do so. This is done through writing an application to the patent owner and requesting him for the same, setting out the terms and conditions and royalty negotiations. Once the voluntary licensing way has been failed that's when compulsory licensing comes into the picture.

Natco pharmas request for a voluntary license was rejected on December 27, 2010, natco was seeking license to manufacture and sell the patented drug.

Bayer corp appealed to the Indian Intellectual Property Appellate Board (IPAB) against the decision of the controller:

There were several questions raised infront of the tribunal involving procedural as well as substantial grounds and particularly of pure law.

On 4 march, 2013, the Tribunal after duly hearing both the parties upheld the order of the controller granting compulsory licensing to Natco Pharma. However there was a modification made to the order the royalty awarded was increased from 6% to 7% of the net sales of the patented drug.

The law regarding compulsory licensing was further clarified by the IPAB. It was made clear that the grant of a compulsory license shall depend on a case to case basis, further mentioning the TRIPS agreement which does not give a carte blanche when it comes to matters concerning compulsory licensing. It stated that there shall be an analysis of grant of such compulsory

license on individualises and case to case Basis. The decision of the IPAB was founded on the basis of the benefits that the public shall be getting.

The following pointers were highlighted by the IPAB which were not to be neglected while deciding the appeal:

- The grant of patents shall not impede protection of public health:
- The rights and obligation of the patentee must be balanced with the grant of the patent:
- The benefits of the patented invention shall be made available to the public at a reasonably affordable price by the patentee.

Out of many contention put forth by the appellate bayer corp the most important was that involving a voluntary licensing. According to the bayer corp Natco Pharma did not put forth a proper voluntary licensing request and which was not in compliance with section 84 (6) (iv). The respondents letter seeking voluntary licensing to the appellant (bayer) outlined the inability of the appellant to meet with the requirements laid down in section 84 of the patent act, 1970, and that the respondent wanted to sell the drug for a much lower price at what it was being sold at that point. The letter was viewed as a veiled threat by the appellant owing to the contents which included that the letter for voluntary license was made without prejudice to the respondents right to challenge the patent.

It was noted that if there was a veiled threat were was also a veiled answer. There was an offer made for a voluntary license which was rejected by the appellant, hence there is no provision which stated that there shall be subsequent offers for voluntary licensing. The first failed attempt for voluntary licensing is enough to applying for a compulsory licensing.

The tribunal was not in conformity with the controllers findings regarding section 84 (1) (C), the tribunal did not agree that the working in India in terms of section 84 (1)(c) of the act could only be satisfied if the patented drug was manufactured in India.

The petitioner went on to file a writ of certiorari in the Bombay hight court to quash the impugned order passed by the IPAB which was merged along the controllers order. On 15 July, 2014, the Bombay High court confirmed the findings of the tribunal.

The Bombay high court was in compliance with the terms and conditions on which the compulsory license was granted to natco Pharma as they meet section 90 of the act, the enhancement of the royalty from 6% to 7% of the net sales of the drug sold by natco was taken into note.

A special leave petition was filed by the bayer corp against the decision of the Bombay high court with the supreme court. The SLP was dismissed and upheld the compulsory license. The bayer corp was asked about the cost of developing the drug and why hadn't it submit the details of the R&D expenses involved in developing the drug to the controller. It was discovered that the company had recovered all the money spent on developing the drug in the first year itself which was based on the records produced before the drug controller.

According to natco Pharma, in india at least 100,00 people suffer from different types of renal cell carcinoma and hepatic cell carcinoma. Further every year 30,000 new patients are diagnosed with both these diseases and nearly 24,000 patients die.

Knowledge at Wharton article had made some observations:

According to the Wharton article natco was awarded the compulsory license on three grounds:

I. The price at which the drug was sold by bayer was not "reasonable enough" which was accessible by only 2% of India's patient population, and was not manufactured in the country.
II. Natco's version of the drug Sorafenib is priced at 97% less than the German brand bayer corp
III. The Natco ruling could result in more demands being raised for compulsory licenses, at present in India about 90% of the patent- protected drugs of pharmaceuticals multinationals are imported and priced very high.

Factors taken into account for the grant of a compulsory license:

(i) The measures taken by a patentee to use the invention to its fullest since the time it has been selling, the nature of the patent
(ii) The applicants capacity and ability to work the invention to the public advantage:
(iii) Were the applicant granted the compulsory license there shall be capability of the applicant to undertake the risk in providing capital and working the invention:

(iv) There has been a voluntary licensing initiation which has failed within a reasonable time. In the case of national emergency or other circumstances of extreme urgency or in case of public non-commercial use or on establishment of a ground of anti-competitive practices adopted by the patentee, this factor need not be considered.

Recent dispute over regorafenib:

Delhi high court has refused to grant interim injunction in favour of bayer healthcare in patent dispute over regorafenib. Bayer healthcare LLC was refused an interim injunction in a patent litigation against Natco Pharma and MSN Laboratories in which the former has sought interim injunction against the two Indian companies from infringing the patent rights of its anti-cancer drug regorafenib, branded in India as Nublexa and Resihance.

The court as due consideration over the facts and arguments put forth, held the public interest as paramount and noted the price difference between the patented product and the products from the indian generic firms, along with a genus patent technically covering the compound has already expired patent protection in the country, while rejecting the application for interim injunction.

Justice navin Chawla observed in an ordered dated July 5 ,2023 that such injunction may be refused in public interest as there was a starc disparity between the price of the product offered by the plaintiff (bayer) and the defendant (Natco and MSN Labs) for a diseases which is life threatening.

In the present case, bayer is selling their product at the range of Rs. 36,995/- (thirty six thousand nine hundred ninety five) by importing the same into India, on the other hand the defendants selling price is Rs. 9000/- (nine thousand) which is manufactured within India.

The defendants were given directs to maintain complete accounts of manufacture and sale of the products with the subject patent and file statement of accounts, on affidavits on a half yearly basis before the court this is to be done to maintain balance of convenience.

REFERENCES

- https://www.mayoclinic.org/drugs-supplements/sorafenib-oral-route/side-effects/drg-20068145?p=1#:~:text=Sorafenib%20is%20used%20to%20treat,an%20antineoplastic%20(cancer)%20agent. - mayo clinic
- 2. https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm
- https://knowledge.wharton.upenn.edu/article/sparring-over-sorafenib-how-will-%20natcos-move-against-bayer-affect-pharma-licensing/
- https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/nexavar-licence-case-sc-dismisses-bayers-appeal-against-hc-decision/articleshow/45500051.cms?from=mdr
- https://www.pharmabiz.com/NewsDetails.aspx?aid=160210&sid=
- 1 Law relating to intellectual property rights - V.K. AHUJA

IJLRA