Bayer Corporation v. Union of India– A Fight between Necessity and Cupidity

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Introduction

Granting of Compulsory Licence of Patent in Pharmaceutical field has been in controversy interminably in India. The clash between profit making industries and social welfare oriented associations is not a new controversy[1]. India being a third world country has already faced major issues in claiming Traditional knowledge which the western world has capitalized by exploiting centuries old practices and making the same old discoveries and invention which are already known to indigenous public[2].

Now with the growth of Inventions and discoveries, the medical field has also progressed by developing vaccines and making business out of it. Usually when a vaccine or medicine is made, the company Patents the products and manufacturing process so that they receive protection from exploitation. Once a Patent is registered, the Patentee gets complete monopoly right over the patented product[3].

India, became a signatory to TRIPS agreement, an international agreement to provide more extensive protection of intellectual property. Consequently, India passed the Patents Amendment Act, 2005[4].

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[1] Mansi Sood, *Natco Pharma Ltd. v. Bayer Corporation And The Compulsory Licensing Regime In India*, NUJS LAW REVIEW (Jan. 13, 2021, 9:10 P.M), nujslawreview.org/wp-content/uploads/2016/12/mansi.pdf.
[2] Nijar, Gurdial Singh, *TRIPs and Biodiversity: The Threat and Responses: a Third World View*, United States: Third World Network (1996).
[3] Arunima Singh, *Towards The TRIPS Agreement*, LAWCTOPUS (Jan. 13, 2021, 9:10 p.m.), www.lawctopus.com/academike/trips-agreement.
[4] *WTO's Intellectual property: protection and enforcement*, World Trade Organisation (Jan. 13, 2021 9:10 p.m.), www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm.

This case became the first case where a Compulsory license was issued after India becoming a signatory to TRIPS (Trade Related Aspects of Intellectual Property Rights) and also to the Doha Declaration in 2001.

Background Facts of the Case

This Case Commentary revolves around the history of how "Nexavar" – a patented drug for curing Kidney cancer came to India in the form of "Compulsory License" to Natco Pharmaceuticals Ltd.

Bayer Corporation, a US based Corporation which developed Sorafenib Tosylate[5] sold under the trademark "Nexavar" to be used in treatment of Kidney Cancer. The drug performs the function of relieving the pain as well as slows down the spread of cancer.

On 3rd Mar, 2008, Bayer Corporation applied and was granted a Patent in India for "Nexavar"

On 6th Dec, 2010, Natco Pharmaceuticals Ltd approached Bayer Corporation for grant of voluntary license for monopoly of the patented drug.

The controversy arose when greed took over necessity. Bayer Corporation was selling the drugs at Rs. 2,80,428/- (Two Lakhs Eighty Thousand and Four Hundred and Twenty Eight Rupees) per month worth of tablets which is so expensive that not even the middle class could afford such a price for 30 tablets. The need of this drug was felt by Natco and hence during the approach of voluntary license of the patented drug, Natco proposed to sell the same drug at Rs. 10,000/- (Ten Thousand Rupees) per month. This was unacceptable for Bayer Corporation as it would lead to huge loss.

On 27th Dec, 2010, Bayer Corporation rejected Natco's offer for voluntary license and gave Natco Pharmaceuticals a 14 days period if Natco had anything to add further. The greed of money was clearly understood by Natco Pharmaceuticals. Conflict of right or wrong was put in front of Natco and it had a chance to become a multi-millionaire company. All they had to do was to sell the drugs at Bayer Corporation's price and they could have become one of the top pharmaceuticals of all time in India.

[5] Sorafenib Tosylate, PUBCHEM (Jan. 13, 2021 9:10 p.m.), pubchem.ncbi.nlm.nih.gov/compound/Sorafenib-tosylate.

But the Intention of Bayer Corporation was not to become big but to serve the needy. Leaving behind the lifetime opportunity to become something big, Natco, after a few months, took a brave step to change the Pharmaceutical face of India.

On the other hand CIPLA, another Indian Pharmaceutical, was already selling the drugs as "Soranib" at Rs 30,000/-(Thirty thousand Rupees) for a month later it sold at Rs. 5,400/- . CIPLA did not take prior permission or licence from Bayer Corporation and hence was undergoing litigation in Delhi High Court for infringement of Bayer Corporation's Patent[6].

On 29th July, 2011, Natco applied to the controller of Patents for grant of Compulsory License under Section 84(1)(3) of Patent Act, 2005[7].

Legal History

Proceeding Before Controller

Natco had satisfied all the conditions of the Patents Act, 1970[8]. It also proposed that it will sell the patented drug at Rs 8800/- (Eight Thousand Eight Hundred Rupees) for 30 days of therapy.

On 9th Mar, 2012 the Controller General of Patent issued an order granting compulsory license to Natco Pharmaceuticals to manufacture and sell the patented drug "Nexavar" and reimburse with a royalty at 6% of its net sales to Bayer Corporation till the term of the Patent. According to this order, NATCO could sell the drug only in India and had to supply the drug to as a minimum of 600 needy patients free of cost each year.

The reasoning behind the order was that the price charged by Bayer Corporation was not an affordable price when compared to purchasing power of the public or to meet the requirements in the

[6] *BAYER Vs CIPLA & UOI*, WP (C) No. 7833/2008.
[7] Apoorva Mandhani, *Bayer Corporation v. Union of India*, INDIALAW (Jan. 13, 2021, 9:10 p.m.).
[8] Patents Act,1970 § 84(1).

market and hence Bayer Corporation contravened the Patent Act and Natco Pharmaceuticals was issued with Compulsory License.

Proceeding Before Intellectual Property Appellate Board (IPAB)

Bayer Corporation, not satisfied with the Controller's order, appealed in IPAB contending that the Compulsory License issued to Natco depict redundancy as the drug was already available at a lower price (CIPLA selling the same at Rs. 5,400/- per month) than the price specified by the Controller General.

Bayer Corporation also alleged that if the Sorafenib Tosylate drug was already available in the market at affordable prices, then section 84(1)(b) of the Patents Act,1970 cannot be one of the issues.

However, the IPAB rejected this contention stating it was not the Patentee (Bayer Corporation) who was supplying the Patented drug at even-handed price also the Patentee had a case against CIPLA for the same drug before Delhi High Court.

This judgement furthermore gave explanation to the word "Patented Invention" used under section 84, which refers to the invention must be:

– made available to public by the Patentee;

– Reasonable requirements of the public must be satisfied;

– worked in the territory of India.

Bayer Corporation argued, with respect to the requirement of getting the drug worked in India, the word "work" would include importing of the patented product and not just local production. IPAB commented that the conjecture would depend on a case to case basis and the phrase has an open ended meaning.

The IPAB passed the judgement against Bayer Corporation with the reasoning that granting an injunction in favour of Natco Pharmaceutical would jeopardize the public interest.

Proceeding Before High Court

Aggrieved from the order passed by IPAB, The Bayer Corporation appealed to Bombay High Court. The Appellant raised an issue that whether the supplies by Natco & CIPLA of the disputed drug have to be taken into account to determine the satisfaction of reasonable requirement test?

The High Court judgement relied on the fact that even after taking Cipla's supplies into consideration, still the public prerequisite would not be met and commitment to meet the reasonable requirement of the public must be of the patent holder alone, either by patentee himself or through his licensees.

The High court, with respect to the requirement of getting the drug worked in the territory of India, it was held that when a patent holder is being drawn against with an application for Compulsory Licence, it is upon the patent holder to show that the patented invention is working in the territory of India by production or otherwise. Although, the patent holder needs to satisfy the authorities under the Patent Act (such as Controller General) as to why the patented design was not being manufactured in India keeping view Section 83 of the Patent Act. In such cases, the phrase "worked in India", according to the Court, could not mean merely manufacture in India.

Bayer Corporation had theorized a dual pricing system under the Patient Assistance Program (PAP). Under this Program, when a patient bought three dosages of the patented drug, he was provided with the remaining tablets for the whole month, free of cost[9]. Although, this concept was unaccepted as a defence for Section 84 (1) (b) of the Patent Act, which insists on that the patented drug should be made available to the public at a reasonably affordable price i.e. to any portion of the public tendering the price.

Section 84(7) of the Patent Act provides a reckoning fiction which deems that necessity of the public is not satisfied, if the demand is not met to an "adequate extent". The High Court held that so far as drugs are concerned, the sufficient extent test has to be 100% i.e., to the fullest extent. The court also observed that the drug has to be made available to every patient and cannot be deprived at the altar of the rights of the patent holder. Thus the High Court Dismissed Bayer Corporation's petition

[9] Jash Vaidya, *Compulsory Licensing of Patents in India*, Jash for a Just World (Jan. 13, 2021 9:10 p.m.), jashvaidya.wordpress.com/2015/11/27/compulsory-licensing-of-patents-in-india/.

Proceeding in Supreme Court

Bayer Corporation, by Special Leave Petition, filed before the Supreme Court. The Apex Court noted that they are not inclined to interfere as they found no fault with the order of the Controller adjourning the application for compulsory license to Natco Pharmaceutical under section 84 of the Patent Act. Accordingly, the petition challenging the order of the High Court was dismissed with a raise in royalty from 6% to 7% of the net sale of Natco as reimbursement for the compulsory license keeping in mind that Bayer Corporation had led no evidence to show the expenses incurred by it to invent the patented drug[10]

Comments

This was the first ever case where compulsory licence was brought in front of the Controller General. This decision is important not just for potential compulsory license applicants but also for forthcoming patent seekers. This judgement not only raises important questions about how exactly 'reasonable affordability' is to be defined from a public perspective but also the usage of an ambiguous standard like this which could increase the scope for subjectivity. However, even without precise definitions, the emphasis on the public perspective looks promising. It demonstrates the focus of Indian pharmaceutical patent law, which pushes towards affordable access to the larger public and that the Court's primary concern is that of public interest. The IPAB, through this case, has straightened out that it will not allow Pharmaceutical companies to squirm out of compulsory licenses without actually working their patent for the benefit of the general public.

Even though this case looks promising for an easier Compulsory License, it indirectly affects the investors of research and development, marketing, etc and also could create lack of motivation for the upcoming researchers but when questions of necessity and service to mankind come into picture, making money out of it seems immoral.

[10] Supra note 6.

COVID-19 and Patent

With the Vaccines hitting the market, Developing countries such as Africa and India are pushing the WTO for short-term suspension of Intellectual property rights (IPRs) for patent of Covid-19 vaccines and other new technologies so that they are accessible for needy countries. This is also to ensure that not only the richest countries could afford and have access to the vaccines, medicines and other things to contain the pandemic. The developed countries including UK, USA, Canada and EU and Pharmaceutical Industries oppose this move stating Intellectual Property system is necessary to encourage novel inventions of vaccines, diagnostics, and cures, which might dry up in its absence[11].

Thomas Cueni, Director General of The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), commented that wearing down patent protections has far-reaching outcomes and waiver of patents this time would risk causing harm to the whole medical infrastructure that allowed Covid vaccines to be developed in record time. While the poor and developing countries, which have higher populations to serve, need the vaccine at cheap cost which can be done only by compulsory license or removal of IPRs protection from that particular invention[12]. With the government bearing the cost would just result in an increase in world debts and a few groups of people getting rich while the whole world suffers.

Imagine getting a vaccine during a pandemic becomes more of a luxury than necessity. In my personal opinion, vaccine made should be available open and the Government should pay gratitude in form of one-time payment or in mode of Royalty which can be done by compulsory license which the Bayer's case clearly stipulates.

[11] Ann Danaiya Usher, *South Africa and India push for COVID-19 patents ban*, The Lancet, (Jan. 13, 2021 9:10 p.m.), www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32581-2/.

[12] Hugo Miller, Susan Decker, *Covid-19 vaccines: India's proposed WTO patent waiver faces stiff opposition from US, EU, MINT*, Bloomberg (Jan. 13, 2021 9:10 p.m.), www.livemint.com/science/health/covid-19-vaccines-india-s-proposed-wto-patent-waiver-faces-stiff-opposition-from-us-eu-11608117804521.html.

Conclusion

This case reflects not only in the perspective of necessity but also points out how desperate are those who invent medicines and vaccines and yet struggle to make a living out of it. The problem lies with inventing a cure to necessity with a motive of making money which should be curtailed right from the beginning. Bayer Corporation v Union of India case not only showed the reality of how pharmaceutical industries perform but also showed the conflict between right and wrong, between personal nourishment and societal development and the only solution our legislative body could produce is of paying royalty to reimburse the patentee for the hard work and a lifetime achievement of few scientists.